Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Adherium Ltd	Evidence review R	000	021	A UK study published in 2000 has shown that patients who experienced an asthma exacerbation incurred healthcare costs of £381(6); it can be assumed 20 years later this cost is even greater. A smartinhaler has been assumed to cost £100/annum in the cost effectiveness analysis, this would suggest that using a smartinhaler would be more cost effective than the cost incurred from a hospital admission.	Thank you for your comment. The clinical review found smart inhalers to be inferior to usual care in terms of hospital admission and severe asthma exacerbations. Although strong benefits were found in terms of adherence, it is unclear where this always translate into better clinical outcomes for patients. Therefore, the cost-effectiveness of smart inhaler remains doubtful in the general population with asthma. A research recommendation has been written to hopefully generate more evidence in this area.
Adherium Ltd	Evidence review R	000	023	We agree that smart inhalers should be considered for patients with poor adherence and poor control but poor adherence cannot always be determined by medication records. The INCASUN study is a good example of how digital inhalers can help determine those with severe asthma vs difficult asthma. We would therefore suggest that smart inhalers are considered for all patients who have uncontrolled asthma experiencing at least 1 exacerbation.	Thank you for your comment The committee did not recommend routine use of these inhalers for the reasons set out in the guideline and evidence review. They agree that there are circumstances in which they could be useful, but in non-severe asthma this needs to be determined on an individual basis. The committee noted that using digital inhalers prior to prescribing biologics could be beneficial, but this is part of the management of severe

Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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				This would also be cheaper than biologics - A recent publication by Bender et al (2022) found that 63% (n=403) of patients initiated on biologic therapy had suboptimal adherence to ICS prior to starting biologic therapy. Suboptimal adherence to ICS has also been found in patients prescribed mepolizumab biologic therapy for asthma, which has resulted in poorer outcomes when compared to patients who are adherent to their ICS (D'ancona et al, 2020).	asthma which is out of the scope of this guideline. A research recommendation has been written to hopefully generate more evidence in this area.
Adherium Ltd	Evidence review R	013	000	Similarly, 4 patients in the Digitial System group has a hospitalisation (3 in standard care group) – but this cannot be attributed to the Smart Inhaler but potentially the change in medication.	Thank you for your comment.
Adherium Ltd	Evidence review R	015	000	Adverse events – it was reported that 14 (6%) of participants using the Digihaler System had ≥1 treatment-related AE versus none in the standard of care group. The Digital System group changed their treatment, so this observation may be reflection of patient device preference or a treatment-related AE. It is not directly linked to the smartinhaler as the	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

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				Standard of care group had no changes made to their treatment	
Adherium Ltd	Evidence review R	General	General	New evidence shows that Smart inhalers helped patients who were being considered for biological therapy attain disease control. Statistically significant improvements were found in ACQ-6 and FeNO measurements. This study has not been included as published in February 2024. Sykes, Dominic L et al. "Digitally Monitored Inhaled Therapy: A 'Smart' Way to Manage Severe Asthma?" *Journal of asthma.* (2024): 1–6.	Thank you for your comment Biologic therapy is outside our scope.
Adherium Ltd	Evidence review R	General	General	We agree with the limited evidence correlating a direct relationship between smart inhalers, adherence and clinical outcomes but would like to add that there is evidence that poor adherence is detrimental to asthma outcomes. Most the studies included have low participant numbers and therefore have not been powered to show improvements in outcome measures such as asthma control, asthma quality of life, exacerbations and hospitalisations. However, there is strong evidence demonstrating the impact of improving adherence on clinical outcomes already published.	Thank you for your comment The committee agree that good adherence is important, but there needs to be evidence that shows that digital inhalers improve adherence by a margin sufficient to also improve the clinical outcomes that you mention. A research recommendation has been written to hopefully generate more evidence in this area.

Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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Allergy UK	Guideline	021	019	Agree with self management – need to ensure that the guideline / HCps can signpost to appropriate information resources to support patient to make decision about their care and treatment to aid this	Thank you for your comment A link to a suitable template for action plans has been added.
Allergy UK	Guideline	023	1.16.2	Think about telehealthcare as an option for supporting self-management. 13 [BTS/SIGN 2019] ensure patient has devices to support self management eg peak flow for out of hours or remote consultation as additional tool to help guide management and need for access to treatment.	Thank you for your comment The role of PEF in action plans is covered in 1.14.1.
Allergy UK	Guideline	037	018	Agree with recommendation not to prescribe SABA on its own without preventer inhaler	Thank you for your comment
Aneurin Bevan University Health Board	General	General	General	Would it be challenging to implement of any of the draft recommendations? Please say why and for whom. Please include any suggestions that could help users overcome these challenges (for example, existing practical resources or national initiatives. Yes, recommendation 1.2.1, because access to FeNO is not widely available in primary care.	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned.

Asthma: diagnosis, monitoring and chronic asthma management

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Aneurin Bevan University Health Board	Guideline	005	022	Rec 1.2.1 - Access to FeNO is not widely available in primary care. Additionally, we feel that for clarity this point should reiterate that asthma diagnosis should not be solely based on raised FeNO (should be Raised FeNO and supporting clinical history).	Thank you for your comment. The committee agrees that access to FeNO is limited in many places, hence the inclusion of alternative tests. Recommendation 1.2.1 already states that the person undergoing the FeNO test has a history suggestive of asthma.
Aneurin Bevan University Health Board	Guideline	005	026	Given the current issues with spirometry in general practice it's odd SERIALPEAK FLOW readings are not mentioned, Peak Flow meters are easily accessible and can (agree not always) help to diagnose asthma. The fear is if not mentioned some patients will be left undiagnosed if access to Feno / Spirometry is not available in a timely manner. This should be retained until funding becomes available for Feno / Spirometry.	Thank you for your comment. PEF variability has now been added to the diagnosis section.
Aneurin Bevan University Health Board	Guideline	006	016	Why is EOS cut-off >0.5 for children but > than lab reference range for adults?	Thank you for your comment Not only is there laboratory variation, but in childhood the normal eosinophil count changes with age. This would have been very difficult for

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
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					users and the committee therefore recommended a single cut-off.
Aneurin Bevan University Health Board	Guideline	008	018	Rec 1.5.1- We feel that in addition to enquiring about smoking, clinicians should enquire about vaping and environmental issues (pollution, damp, mould, workplace exposures etc).	Thank you for your comment On reconsidering this, the reference to smoking has been removed from 1.5.1. The recommendation is about indices of control, and smoking was therefore out of place there (and it is covered in other recommendations). For the same reason, pollution, moulds etc have not been added.
Aneurin Bevan University Health Board	Guideline	008	019	We welcome the addition of using a validated questionnaire to assess control rather than RCP 3 questions but perhaps this should be 'Use' rather than consider as access is freely available and would support a more thorough assessment.	Thank you for your comment The committee sympathises with your point, but in the evidence review the benefit of using standard questionnaires was not as strong as might have been expected. In this circumstance NICE policy is to use the word "Consider" in its recommendations, therefore this terminology is used in this BTS/NICE/SIGN guidance.

Asthma: diagnosis, monitoring and chronic asthma management

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Aneurin Bevan University Health Board	Guideline	008	022	Rec 1.5.3 - We are surprised by the recommendation that PEFR should not be used to routinely assess control as we feel this is a simple and useful test which promotes patient self-management. Additionally if peak flow is never routinely assessed it is difficult to know what a patient best (or baseline) peak flow is when they are unwell. We would like this recommendation to be reviewed.	Thank you for your comment The evidence (please see Evidence Review M) did not show any benefit of regular PEF monitoring.
Aneurin Bevan University Health Board	Guideline	010	008	Agree, this update is welcomed, nice 'do not do's' support reducing inappropriate prescribing/ behaviours	Thank-you for your comment
Aneurin Bevan University Health Board	Guideline	011	001 – 004	Recommendation 1.6.5 + 1.6.6: Here there is recommendations on giving information about inhaler treatments and correct technique. We wonder if it wouldn't be better to assess the patient's inhaler ability first, even if this is just an observation of forceful and deep (for a DPi) and slow and steady (for an MDi). While the push for a DPi first is in a separate document, should it also be in the main body of the text?	Thank you for your comment. Ensuring that a person can use their inhaler is part of both recommendations 1.6.4 and 1.6.5.
Aneurin Bevan University Health Board	Guideline	011	015	Recommendation 1.6.7: This update is welcomed and crucial for inhaler technique consistency but there is recommendation about prescribing the same device for preventer and inhaler but no recommendation about a	Thank you for your comment. This recommendation is taken from the Inhaler section of the BTS/SIGN guideline. There is no recommendation to prefer combination inhalers

Asthma: diagnosis, monitoring and chronic asthma management

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				preference for combination inhalers over separate inhalers (where possible). Combination inhalers for reliever and treatment preference?	in that section and this was not an area included in the guideline update scope. However, the treatment recommendations in the update recommend combination inhalers at several points.
Aneurin Bevan University Health Board	Guideline	012	004	This update is welcomed and supports Welsh prescribing guidelines where this strategy has already been adopted.	Thank you for your comment
Aneurin Bevan University Health Board	Guideline	013	019	Whilst we appreciate we need to limit high dose ICS, with long waits for secondary care services there is potential for a delay to stepping up from moderate dose which could improve patient control. It would be good if the committee amended the wording here to refer and consider a trial of high dose ICS whilst awaiting a response.	Thank you for your comment The increase from moderate to high dose ICS is where adverse effects of ICS become much more likely, and the committee do not wish to recommend this for all people. It might be appropriate for those with an elevated FeNO level, but most practices do not have access to this as yet. However, please note that recommendations 1.7.6 and 1.7.7 have been amended in response to stakeholder comments, and the possibility of an earlier referral is now included.

Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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Aneurin Bevan University Health Board	Guideline	014	004	Using the word 'consider' conflicts with the DO NOT give SABA alone mentioned on page 10 line 008. This should be changed to 'OFFER'	Thank you for your comment The word "consider" in NICE guidelines refers to situation where the evidence is not watertight and therefore the same applies to this collaborative guideline.
Aneurin Bevan University Health Board	Guideline	015	001	1.7.12: should this read "on high dose ICS/ LABA" not just high dose ICS?	Thank you for your comment This was intended to cover people on high dose ICS plus any other asthma medicines. This has now been spelled out in the recommendation.
Aneurin Bevan University Health Board	Guideline	023	002	This updated is welcomed and would help to prioritise those more in need of a review when capacity issues in general practice arise	Thank you for your comment
Aneurin Bevan University Health Board	Table 1b	069	000	Removing the reference to exercise induced asthma as an expression of poorly controlled asthma is not helpful and has the potential to encourage SABA overuse for this indication	Thank you for your comment Part of the definition of poor control relates to the amount of SABA required. People who use a lot of SABA because of exercise induced symptoms will therefore be identified as readily as people who do so for any other reason and their treatment should be adjusted accordingly.

Asthma: diagnosis, monitoring and chronic asthma management

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ASH Scotland	General/ Recommendation for Research	General	General	Data from the ASH (England) youth (11-17-year-olds) survey found that e-cigarette use has significantly increased among young people during the last few years. Before 2021, 1.5% of young people vaped regularly and in 2024 this increased to 4.5%. A further 3.1% reported occasional vaping, up from 2% in 2021. If e-cigarette causes or worsens asthma symptoms, this will become more apparent in clinics due to the increase in e-cigarette use prevalence among young people. There remains a gap in evidence on the respiratory impact of vaping/heated tobacco products use in young people and clinicians are at the forefront of observing respiratory effects that have yet to be captured in research. It would be valuable if clinicians could capture data that could be used to inform national policies.	Thank you for your comment. The committee agrees.
ASH Scotland	Guideline	**008**	**018**	**1.5.1. Monitoring asthma control: As vaping/e-cigarette use should now be considered in the diagnosis and monitoring of asthma according to the guidelines, we recommend that vaping is also monitored at every review. This is especially important among young people, who are at higher risk**	Thank you for your comment. On reconsidering this, the reference to smoking has been removed from 1.5.1. The recommendation is about indices of control, and

Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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				of taking up smoking or vaping. Heated tobacco product use should also be monitored.	smoking was therefore out of place there (and it is covered in other recommendations).
ASH Scotland	Guideline	017	016	1.9.2 Medicines for management in children under 5: In addition to checking for smoking or second-hand smoke, exposure to second-hand e-cigarette/heated tobacco products emissions should also be checked. Ambient e-cigarette vapour can be triggering for some people with asthma. https://pubmed.ncbi.nlm.nih.gov/28944531/ https://doi.org.10.1016/j.chest.2018.10.005 https://thorax.bmj.com/content/77/7/663 https://www.icoprevencio.cat/uct/wp-content/uploads/sites/10/2022/02/20221130_JATC2_WP8_protocolSAFE_-PDF-1.pdf	Thank you for your comment. The list in brackets offers examples; it is not meant to be exhaustive
ASH Scotland	Guideline	**020**	**024**	**1.13.2 Asthma in adolescents: Exposure to second-hand smoke should be asked about and exposure to second-hand e-cigarette vapour and heated tobacco product emissions should also be checked. Second-hand e-cigarette vapour can be triggering for some people with asthma** **https://pubmed.ncbi.nlm.nih.gov/28944531/** **https://doi.org.10.1016/j.chest.2018.10.005** **https://thorax.bmj.com/content/77/7/663**	Thank you for your comment Second hand exposure is not included because the main point of the recommendation is to help the adolescent who smokes or vapes to try quitting.

Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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				There is conclusive evidence that it contains ultra fine particulates. https://onlinelibrary.wiley.com/doi/full/10.5694/mja2.51890	
ASH Scotland	Guideline	**020**	**024**	**1.13.2 This recommendation advises people to be signposted for smoking cessation services. In Scotland vaping cessation support through NHS cessation services is currently not available in all regional NHS Boards and local Health and Social Care Partnerships. Expert support provided by smoking cessation support services increase the chances of a successful quit smoking attempt by 3-4 times. It is important that patients who smoke or vape are referred to services that can help them. NHS services should be encouraged to adhere to best practice. https://www.who.int/news/item/02-07-2024-who-releases-first-ever-clinical-treatment-guideline-for-tobacco-cessation-in-adults**	Thank you for your comment. Your point is correct and recommendation 1.13.2 has been amended.
ASH Scotland	Guideline	**021**	**000**	**1.14 Self-management: Where smoking/heated tobacco use and vaping have been assessed as not being an issue for a patient, informing people that smoking/heated tobacco products use and**	Thank you for your comment The guideline is already covering a lot of issues. Important though it is, advising people not to

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				vaping can trigger asthma symptoms and exacerbations would be useful, particularly for young people. Alternatively, this could be included in 1.13 Asthma in adolescents.	start smoking is outside our scope and is covered by other pieces of guidance. The recommendation includes a cross-reference to NICE's guideline on tobacco.
ASH Scotland	Recommendation for Research	General	General	More research on the effect of second-hand aerosol/vapour on asthma in children is needed.	Thank you for your comment Research recommendations in a NICE guideline are only made on topics for which an evidence search was conducted but inadequate evidence found, therefore the same is true for this collaborative guideline. They do not express the committee's opinion on research needs beyond this. The effect of environmental triggers on children with asthma was not reviewed for this update and therefore this research cannot be recommended in the guideline, worthy though it is.
ASH Scotland	Recommendation for Research	General	General	Research is urgently needed on the effect of vaping on asthma in young people – including the impact across different ages, different e-cigarette types and ingredients, vaping frequency, and duration (length of time young people have vaped). Research on heated	Thank you for your comment NICE research recommendations are only made on topics for which an evidence search was conducted but inadequate evidence found, therefore the same is true for this collaborative

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				tobacco products use should also be considered.	guideline. They do not express the committee's opinion on research needs beyond this. The effect of environmental triggers on children with asthma was not reviewed for this update and therefore this research cannot be recommended in the guideline, worthy though it is.
Association for Respiratory Technology & Physiology	Guideline	005	022	This recommendation will be challenging given the variable access to FeNO testing in primary care.	Thank you for your comment. The committee agrees that access to FeNO is limited in many places, hence the inclusion of alternative tests
Association for Respiratory Technology & Physiology	Guideline	005	022	We would support the use of fixed cut off point for FeNO in adults and young people to aid diagnostic simplicity.	Thank you for your comment.
Association for Respiratory Technology & Physiology	Guideline	005	026	This recommendation will be challenging given the variable access to quality assured diagnostic spirometry in primary care.	Thank you for your comment. The committee agrees that enhanced accessibility to quality assured spirometry would be extremely valuable.
Association for Respiratory	Guideline	005	026	Whilst technically accurate, this recommendation may potentially cause some confusion in its interpretation. Suggest:	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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Technology & Physiology				'*Diagnose asthma if reversibility is greater than 200 ml and greater than 12% from baseline (or greater than 10% of predicted normal)'.*	The wording has been amended.
Association for Respiratory Technology & Physiology	Guideline	006	001	Rec 1.2.3: this recommendation may potentially increase the workload for respiratory physicians and diagnostic lung function in secondary care as BCT is not routinely available in Primary Care. It may be available in England via Community Diagnostic Centres, but these are not fully established within the 4-nations of UK.	Thank you for your comment. The committee acknowledges this. It is however the best single test for asthma and it would be remiss not to include it, albeit at the end of the testing sequence.
Association for Respiratory Technology & Physiology	Guideline	006	005	We would support the use of fixed cut off point for FeNO in children aged 5 -16 to aid diagnostic simplicity.	Thank you for your comment
Association for Respiratory Technology & Physiology	Guideline	006	010	Rec 1.2.6: the recommendation for skin prick testing (SPT) will potentially increase the workload in secondary care as SPT is not routinely available in Primary Care. It may be available in England via Community Diagnostic Centres, but these are not fully established within the 4-nations of UK.	Thank you for your comment You are correct, but skin prick testing is just one option at this step in the diagnostic process.
Association for Respiratory Technology & Physiology	IND187	General	General	The rationale of the indicator appears sound and is in line with the source guidance.	Thank-you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

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Association for Respiratory Technology & Physiology	IND187	General	General	We are concerned that this recommendation will increase the number of patients requiring quality assured diagnostic spirometry (QADS). This in itself is not an issue, but ARTP is aware of huge backlogs in Primary Care for spirometry and that in many areas, the Community Diagnostic Centres are not yet in a position to manage a further increase in numbers of patients requiring QADS.	Thank you for highlighting this.
Association for Respiratory Technology & Physiology	IND187	General	General	We are concerned that this recommendation will increase the number of patients requiring fractional exhaled nitric oxide (FeNO) measurements. Access to FeNO is Primary Care is inconsistent and patchy and may introduce a 'postcode lottery' as to which areas can deliver this recommendation.	Thank you for highlighting this. Your comments will be considered by NICE where relevant support activity is being planned.
Association for Respiratory Technology & Physiology	IND187	General	General	Implementation of any of the draft recommendations will potentially have the following cost implications to meet increased service demand: - Training and registration of appropriately skilled spirometry practitioners. - Procurement and ongoing maintenance of spirometers. - Procurement and ongoing maintenance of FeNO devices	Thank you for highlighting this. **The draft RIA tools pick up these costs for local assessment.**

Asthma: diagnosis, monitoring and chronic asthma management

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				Cost per test of FeNO (many devices have set 'lifespan' for device and analysis cells.	
Association for Respiratory Technology & Physiology	Rationale and impact	034	018	We agree with the statement about the impact of the recommendation for BCT, the likely capacity issues and the need for significant investment to support this. This should be flagged at the earliest opportunity to reduce bottlenecks in the pathway and optimise the potential savings achieved by the early and accurate diagnosis of asthma.	Thank you for highlighting this. Your comments will be considered by NICE where relevant support activity is being planned.
Association for Respiratory Technology & Physiology	Rationale and impact	037	008	We agree with the statement about use of FeNO and access in primary care. Whilst increased cost is mentioned, the need for ongoing investment to support this appears understated. Unlike spirometers, which are often a 'one-off' cost with a long 'life', FeNO devices often have a finite life. This is either due to expiration of the device or the analysis cell becoming 'exhausted'; delivery of this recommendation will require the appropriate recurring investment to support it.	Thank you for highlighting this. The cost of equipment is included in the draft RIA tools for local assessment.
Association of Paediatric Chartered Physiotherapists	Evidence statement update	005	024	Why are there no mention of Non-pharmacological management not covered in this guideline?	Thank you for your comment Non-pharmacological therapy is not in the scope of this collaborative guideline. Some sections of the previous BTS/SIGN guidance

Asthma: diagnosis, monitoring and chronic asthma management

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					which are not in the NICE scope will be continued by BTS & SIGN.
Association of Paediatric Chartered Physiotherapists	Evidence statement update	006-027	No line	Table 1 section A-R : QOL outcomes, there are other options for children now. PedsQol general with Asthma PedsQol module. These should be considered. In paediatrics. PedsQL TM (Pediatric Quality of Life Inventory TM)	Thank you for your comment. The committee have to limit the number of outcomes they consider and cannot look at all QoL measures.
Association of Paediatric Chartered Physiotherapists	Evidence statement update	041	013	Table 5: asthma QOL outcomes, there are other options for children now. PedsQol general with Asthma PedsQol module. These should be considered or be added as alternate options. In paediatrics for different services layout in clearer and preferred by some parents and patients.. PedsQL TM (Pediatric Quality of Life Inventory TM)	Thank you for your comment. The committee have to limit the number of outcomes they consider and cannot look at all QoL measures.
Association of Paediatric Chartered Physiotherapists	Overall	General	General	There is no mention or multidisciplinary assessment and treatment. (physiotherapy, psychology) both professional are vital in the assessment of differential diagnosis and co morbidities and treatment.	Thank you for your comment Multidisciplinary teams are important in the management of severe asthma, but severe asthma is not within the scope of this guideline update.

Asthma: diagnosis, monitoring and chronic asthma management

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Association of Paediatric Chartered Physiotherapists	Overall	General	General	There is no mention of differential diagnosis (anxiety, hypersensitive cough, ILO, EILO, breathing pattern disorder)	Thank you for your comment The possibility that other conditions may present with similar symptoms is referred to at several points in the guideline, but it focuses on asthma not these differential diagnoses.
Association of Paediatric Chartered Physiotherapists	Overall	General	General	Physiotherapy can be very helpful in supporting asthma, they help with adherence, reliever use reduction, exercise, symptoms recognition, airway clearance, irritable cough, assessing and treating differential diagnosis and comorbidities. I appreciate there isn't a huge amount of evidence but a mention would be very helpful as it has been a lost profession in asthma. I would be happy to be contacted to discuss further (clare.chadwick2@nhs.net)	Thank-you for your comment. Physiotherapists can certainly contribute to the management of asthma, but the guideline deals with what should be done, not who does it.
Association of Paediatric Emergency Medicine	Guideline	General	General	Please can you clarify if the recommendations on diagnosis and pharmacological management refer to urgent and emergency care settings as well as primary care and specialist centres? Many children and young people are discharged directly from emergency care settings and as such, changes to diagnostic testing and starting MART would require access to blood tests and	Thank you for your comment Management of acute asthma is outside the scope of this guideline, but the committee is aware that some people with asthma will attend emergency settings with non-acute problems. In those cases, assuming that the clinician feels

Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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				rapid results, specialist input and education packages.	competent to do so, the recommendations in the guideline could be applied.
Association of Paediatric Emergency Medicine	Guideline	General	General	We welcome new initiatives for making asthma care greener	Thank-you for your comment.
Association of Respiratory Nurses	General	General	General	First of all, we would like to congratulate the team on this guideline which has the potential to transform the way we diagnose and treat asthma.	Thank you
Association of Respiratory Nurses	General	General	General	Instead of GPs and practice nurses use health care professionals in general practice (this includes other health care professionals such as paramedics who may work with people with asthma)	Thank you for your comment. This has been changed.
Association of Respiratory Nurses	General	General	General	Instead of pharmacists use pharmacy professionals (to include pharmacy technicians)	Thank you for your comment. Where pharmacists are mentioned in a recommendation the appropriate term has been used.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Association of Respiratory Nurses	Guideline	1.16.9	000	Link to the Primary Care Respiratory Society Fit to Care Document should be added to guide clinicians re training. Also elearning for healthcare modules on FeNO.	Thank you for your comment NICE recommendations do not incorporate training standards and therefore this BTS/NICE/SIGN guideline is the same.
Association of Respiratory Nurses	Guideline	1.2.3	003	Bronchial responsiveness tests would be impractical if indicated in high numbers of patients	Thank you for your comment This is true at current resource levels.
Association of Respiratory Nurses	Guideline	1.2.4	000	FeNO cut off points may vary with different machines	Thank you for your comment This is true, but the differences are small in most studies, The devices do not include normal ranges for FeNO in their output so the recommendations in the guideline cannot refer to levels above this range as they do for eosinophils.
Association of Respiratory Nurses	Guideline	1.2.6	000	Skin prick testing is not widely available or easily accessible – why only house dust mite?	Thank you for your comment It is not readily available in many settings at present. House dust mite is relevant to asthma in a greater proportion of children than any other single allergen, and there is evidence for its use in diagnosing asthma (evidence review D)

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Association of Respiratory Nurses	Guideline	1.5.1	000	Templates in general practice may need updating to include extra information and these may need to link to QOF	Thank you for your comment
Association of Respiratory Nurses	Guideline	1.5.3	000	Downgrading of peak flow testing here may confuse when it comes to writing up action plans – needs clarification re the role of peak flow	Thank you for your comment The wording of 1.5.3 has been changed
Association of Respiratory Nurses	Guideline	1.5.4	000	Access to FeNO and the cost of provision of this test in general practice is a major issue. National access through collaboration with manufacturers should be made available. There will be issues re using this for diagnosis because of low availability due to cost – asking staff to use it as a monitoring tool too requires funding support to avoid a postcode lottery of access, which will undoubtedly affect deprived areas more than more affluent areas. This is a health inequality issue.	Thank you for your comment There are good reasons for using FeNO as described in the relevant sections on diagnosis and monitoring. The committee agree that access to FeNO devices is limited in some areas and hope that this will improve.
Association of Respiratory Nurses	Guideline	1.6.12	000	There are medicolegal implications to recommending off licence use of drugs. Where does the responsibility lie when a national guideline is recommending this for (potentially) large numbers of children? MHRA advises against off-label use.	Thank you for your comment Ultimately the responsibility lies with a prescriber who must decide whether guideline recommendations should be applied to each individual patient they see. However, NICE will not include an off-licence recommendation unless there is evidence to support it and

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					therefore this collaborative guideline will be the same.
Association of Respiratory Nurses	Guideline	1.6.3	000	8-12 weeks should be acceptable for a final review of the impact of treatment but an interim assessment would be preferable to ensure patient adherence and understanding	Thank you for your comment If there are concerns about adherence or understanding, an earlier review is certainly reasonable. However, reviewing too quickly can be counter-productive because asthma is a variable disease, and the effects of a treatment change may be misjudged if assessed over too short a period.
Association of Respiratory Nurses	Guideline	1.6.4	000	Ability to use the inhaler should be mentioned specifically	Thank you for your comment If assessed as having correct technique, what extra information is needed re ability to use?
Association of Respiratory Nurses	Guideline	1.6.8	000	More returns systems are needed	Thank you for your comment
Association of Respiratory Nurses	Guideline	1.7.1	000	In line with evidence, variable inhaled corticosteroid potency and the lack of dose equivalence, this should clearly indicate budesonide/formoterol rather than ICS/formoterol.	Thank you for your comment This has been changed

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Association of Respiratory Nurses	Guideline	1.7.5	000	MHRA warning re LTRAs should be highlighted. Three months is too long – these drugs work quickly if they are going to. Same applies for 1.8.4 and 1.9.5	Thank you for your comment A link to the MHRA DSU has been included. The review advice has been changed to 8-12 weeks to be compatible with 1.6.3. Reviewing too quickly can be counter-productive because asthma is a variable disease and the effects of a treatment change may be misjudged if assessed over too short a period.
Association of Respiratory Nurses	Guideline	1.7.6	000	This section should come before the one on LTRAs and advise that triple therapy in one inhaler is available vs being able to use MART plus a LAMA.	Thank you for your comment There are published data comparing LAMA to LTRA and neither was clearly superior to the other.
Association of Respiratory Nurses	Guideline	1.7.7	000	The term 'specialist' should be defined – this should be a referral into secondary care with a view to referring on to a severe asthma centre (SAC). A link to the national severe asthma working group referral algorithm would work well here as it highlights the role of primary and secondary care, plus the SACs.	Thank you for your comment Specialist has been included in the Terms Used section
Association of Respiratory Nurses	Guideline	1.7.9	000	Use 'recommend' rather than 'consider' - same for 1.7.10	Thank you for your comment NICE uses the word "consider" for weaker recommendations, in this case because there is

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					no direct supporting evidence on switching from these treatments, and therefore this collaborative guideline follows the same methodology.
Association of Respiratory Nurses	Guideline	1.8.2	000	MART is not licensed here (see previous comments) but combinations are – add a recommendation re fixed dose combinations here – p16 lines 1-4 should come before the discussion of MART	Thank you for your comment There are MART and non-MART pathways for children aged 5-11 and no definitive reason to put one before the other.
Association of Respiratory Nurses	Guideline	1.8.6	000	LAMA not mentioned here – licensed from age 6	Thank you for your comment There were no papers to allow us to position a LAMA in the treatment sequencing.
Association of Respiratory Nurses	Guideline	1.9.1	000	Should the number of episodes be mentioned?	Thank you for your comment This would not really help. "severe" is also not defined as it is difficult to in this age group, particularly when the episodes may not have been observed by a healthcare professional, and if we cannot define "severe" then we cannot stipulate the number of severe episodes.
Association of Respiratory Nurses	Guideline	5	19	General comment regarding objective testing: has oscillometry been considered as a diagnostic test in children? (AGL)	Thank you for your comment It was not included in the scope following the scoping process. It will be suggested to NICE's

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					surveillance team for possible inclusion in future updates.
Asthma + Lung UK	Evidence review A	017	037 – 041	The committee's emphasis on the importance of spirometry as a test for assessing other causes of breathlessness including COPD suggests that use of eosinophil testing or FeNO as the first course of objective testing is insufficient and that without spirometry, people may be misdiagnosed as having asthma.	Thank-you for your comment Evidence review A considers spirometry, not other tests. Evidence on eosinophils and FeNO is presented in other reviews. The diagnostic pathway in the guideline is based on people in whom the history suggests asthma. If other conditions are suspected other tests will be required (the rationale to the diagnosis section in the guideline states this) and in line with this, if COPD is suspected spirometry should be obtained.
Asthma + Lung UK	Evidence review A	017	042 - 051	The committee's recommendation that children being tested with spirometry could be referred to secondary care until diagnostic hubs are more widely available risks increasing demand upon secondary care diagnostics significantly.	Thank-you for your comment The committee acknowledges this. However, misdiagnosis in children and adults can result in later referrals after a period of time in which unnecessary treatment has been given to some and no, or incorrect, treatment to others. It is better to get it right at the onset.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Asthma + Lung UK	Evidence review A	General	General	Evidence review A includes no mention of costs including training or accreditation, both of which are significant barriers to correct, widespread implementation.[i] While these are beyond the scope of this guideline, they must be acknowledged as practical barriers to implementing the guidance's diagnostic pathway. If NICE feel that spirometry in children is a suitable diagnostic test, even if this were to only be within a secondary care setting, this recommendation should be overt and greater availability of spirometry should be advocated.	Thank-you for your comment The guideline recommends spirometry as part of BDR testing, not on its own. By doing so it does in effect recommend greater access to spirometry. We agree that training and accreditation costs represent a practical barrier to implementation.
Asthma + Lung UK	Evidence review C	005	013 - 016	PEF's role as a useful measure of airway calibre variability highlights its utility as an objective test for diagnosing asthma, suggesting that it should be included within the draft guidance's suggested diagnostic pathway.	Thank-you for your comment PEF variability is an insensitive test and the analysis of various testing strategies (see evidence review K) showed that the best test sequences did not include it. However, numerous stakeholders have supported its use and it is now included in the diagnostic section.
Asthma + Lung UK	Evidence review C	014	025 - 032	The factors discussed in section 1.2.5 of Evidence review C outline a strong case for	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				including PEF within the draft guidance's suggested diagnostic pathway.	PEF variability is an insensitive test and the analysis of various testing strategies (see evidence review K) showed that the best test sequences did not include it. However, numerous stakeholders have supported its use and it is now included in the diagnostic section.
Asthma + Lung UK	Evidence review E	General	General	The quality of evidence presented in Evidence Review E was low. In both pieces of evidence, there is imprecision within the estimates of specificity. Section 1.2.5 includes "IgE is also raised in other common childhood conditions and the committee emphasised that it should only be used as a test for asthma when there is also a good history to support the diagnosis." This raises further concerns about test accuracy when using IgE as an objective test for diagnosing asthma. This is also evidenced by the fact that the committee were not able to specify which IgE cut-off point should be used to support an asthma diagnosis because the normal range for IgE levels varies considerably over childhood years.	Thank you for your comment IgE is not the first test in the sequence and the guideline does not recommend it as the only test. The guideline states that all tests, not just IgE, should be combined with a history suggestive of asthma.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Asthma + Lung UK	Evidence review F	032	Table 8	Table 8 states that FeNO was the most cost effective test compared to other tests, further evidencing its suitability for both the adult and 5-16 year old diagnosis pathways.	Thank you for your comment
Asthma + Lung UK	Evidence review F	037	036 - 040	It is essential that the guidance reflect the evidence that FeNO is not "an appropriate test for ruling out an asthma diagnosis in adults that smoke". Smoking, as well as smoking cessation, is not heavily featured within the draft guidance. The impact of smoking status on the utility of FeNO testing must be clearly highlighted to clinicians in order to ensure that the diagnostic pathway (and diagnostic resources) are correctly used and to ensure that patients can benefit from an accurate diagnosis.	Thank you for your comment The guideline does not use FeNO as a rule out test. It suggests that a positive diagnosis can be made if FeNO is high. Since smoking lowers FeNO level the advice is more robust still in smokers.
Asthma + Lung UK	Evidence review F	038	006 - 010	Asthma + Lung UK is concerned about the use of lower qualities studies' findings to overrule or impugn the findings of higher quality studies. The maximum specificity of 0.94 at 40ppb or below suggests a well-evidenced reason for using a lower threshold in FeNO tests when diagnosing asthma.	Thank you for your comment The committee weighed up several factors in setting a FeNO threshold. In particular, because it may be the first and only objective test, they set the threshold for diagnosis at a high level so that fewer people will get a false positive diagnosis on the basis of a single test.
Asthma + Lung UK	Evidence review F	039	021 - 025	The committee's agreement that, at sufficient specificity, FeNO can be a cost-effective	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				alternative to a blood test in diagnosing asthma. The evidence review should also consider that, where this is the case, the utility of FeNO is increased as it is a faster testing process than blood eosinophil testing due to the lack of need for a follow-up appointment. This speed must be counted as a positive factor, promoting higher patient safety and a better patient experience, ensuring quicker diagnosis (if positive) or progression along the diagnostic pathway (if negative). NICE should also take into account the need for further tests/follow-up due to tests having a higher threshold. It seems counter-intuitive for the benchmark for good quality care to be based on the cheapest available test.	The committee agrees that obtaining an immediate result can be a benefit of FeNO (although it depends on the presence of someone able to interpret the result in a clinical context if feedback is to be given there and then). The committee acknowledges that a higher threshold may mean that some people get further tests that might have been avoided, but this is more cost-effective and clinically more desirable than other people starting on asthma treatment with an incorrect diagnosis.
Asthma + Lung UK	Evidence review F	039	032 - 033	Section 1.2.5 highlights that ideal diagnosis of asthma should include measure of inflammation and pulmonary function. This contradicts elements of the diagnostic pathway that would confirm a positive diagnosis upon positive results of a single objective test.	Thank you for your comment The key word is "ideal". If all tests were quickly available this would be recommended, but the committee have to balance this with practical considerations.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Asthma + Lung UK	Evidence review F	039	043 - 045	The guidance given on FeNO thresholds draws from contrasting examples within the evidence review and the conclusion of suggested cut-offs of 50 ppb in adults and 35 ppb in children also vary from the figures given within NICE's diagnosis guidance in April 2014.[ii]	Thank you for your comment The evidence has been updated since 2014.
Asthma + Lung UK	Evidence review F	General	General	By including FeNO within regular asthma reviews, these reviews would have to be conducted face-to-face. In-person reviews provide a more comprehensive review of the patient's condition[iii] and would pair well with more regular inhaler technique checks.	Thank you for your comment. The committee agrees.
Asthma + Lung UK	Evidence review F	General	General	Evidence included within the evidence review showed that implementing routine FeNO monitoring would likely reduce the risk of exacerbations in adults and children, and reduce the average ICS dose in adults. This should increase the quality of life of people with asthma and reduce healthcare spending associated with asthma exacerbations and ICS prescribing. Lower ICS doses could also have other positive impacts, for instance, to the environment. These are significant reasons for increasing the use of FeNO in asthma care and suggest that phrasing	Thank you for your comment The committee agrees. However, NICE currently uses the word "consider" to indicate the certainty of the evidence base behind a recommendation and it is the correct word to apply in this instance. Please note also that following representation from other stakeholders and a review of the evidence, the recommendation for FeNO monitoring in children has been removed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				in the draft guidance allowing clinicians to "consider" using FeNO should be strengthened.	
Asthma + Lung UK	Evidence review F	General	General	The committee's agreement that FeNO has a potential place as an education tool to better inform patients of their condition and of treatment's effectiveness highlights further benefit of FeNO. This is a key reason for increasing use of FeNO.	Thank you for your comment The committee agrees.
Asthma + Lung UK	Evidence review G	016	022 - 024	The evidence review explains that blood eosinophil tests are of use when performed alongside other objective testing. This contradicts the draft guidance's diagnostic pathway wherein blood eosinophil testing is used in isolation.	Thank you for your comment Well spotted. Some of the studies in that review attempted to find a compromise value with the best combination of sensitivity and specificity and reported cut-off values below the upper limit of the normal range. The 2 studies which used higher cut-offs both showed good specificity. The sentence you quote should have stated that the studies overall did not suggest that eosinophil count alone could be diagnostic. It has been amended.
Asthma + Lung UK	Evidence review G	016	024 - 026	The evidence review explains that there is variation between the normal ranges used by different laboratories. The use of varying	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				laboratories' upper limits as the threshold for a positive asthma diagnosis builds inconsistency within the diagnostic pathway and introduces a geographic disparity which will impact patients directly and will also potentially reduce the utility of national data.	The recommendation has to cope with the fact that there is slight variation between laboratories in normal ranges for adults. If one of the upper limits was chosen this would compromise the use of eosinophil level far more, since it would be incorrect for people whose samples go to one of the other labs.
Asthma + Lung UK	Evidence review G	016	039	The evidence review highlights that caution is needed when interpreting results from eosinophil tests. This highlights that eosinophil testing requires skilled, trained clinicians in order to ensure effective use of testing. Without specifying this within the draft guidance, clinicians will potentially be unaware of this, risking over-diagnosis.	Thank you for your comment All NICE guidance assumes, and this BTS/NICE/SIGN guidance is similar, that it will be applied by healthcare professionals who are appropriately trained.
Asthma + Lung UK	Evidence review G	016	039 - 045	The evidence review explores the variability of eosinophil levels and the mitigation/discretion needed to be used by trained clinicians when assessing test results. This reduces the specificity of eosinophil tests and will require significant education or the clinicians making asthma diagnoses.	Thank you for your comment All NICE guidance assumes, and this BTS/NICE/SIGN guidance is similar, that it will be applied by healthcare professionals who are appropriately trained.
Asthma + Lung UK	Evidence review H	017	045 - 047	The evidence review notes that availability of bronchial challenge testing may vary nationally and that, as a result, clinicians should reserve	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				referrals to ensure capacity for those with a complex clinician history and uncertain diagnosis. However, the "rule-in" approach of the diagnosis pathway and the poor availability of other objective tests presents the possibility of very high demand for bronchial challenge testing capacity regardless. Evidence review K highlights that around 30% of children with suspected asthma will need referral to secondary care for a bronchial challenge test.[iv]	The committee agrees. It is regrettable that the single best test for asthma is not more readily available. The figure of 30% of children potentially needing a bronchial challenge test is based on the health-economic model, and as the diagnostic algorithm has not been formally tested as yet, it may not be correct. Moreover, the figure of 30% is for referral to a paediatrician for assessment and possible bronchial challenge test rather than straight to a challenge test, and it was derived before measuring PEF variability was added to the diagnostic sequence.
Asthma + Lung UK	Evidence review H	018	029 – 031	The evidence review also notes that bronchial challenge testing will requirerepeated spirometry measurements. With spirometry access slow to recover post-Covid, this further limits access to bronchial challenge testing.	Thank you for your comment. The repeated spirometry measurements are all done within a single bronchial challenge test on the same day, so access to spirometry alone is a separate issue
Asthma + Lung UK	Evidence review K			Evidence review K uses contrasting data to attempt to make comparative assessments between various diagnosis pathways: in the section exploring FeNO alone, the evidence cites up to date costs (lower than in the studies evaluated). In the section on using combinations	Thank you for your comment. This area was prioritised for an original economic analysis by NICE as the committee were interested in finding the most cost-effective diagnostic algorithm for asthma in

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				of tests, it appears that combinations of tests including FeNO used the study costs and not current costs. This significantly reduces the utility of any results from this comparison and may have massively skewed the results of this section away from using combinations of tests. In any case the use of economic modelling around the use of tests deviates from any focus on the patient and the disease ie: a variable condition with elements of inflammation and obstruction. This section seems overly focussed on economic analysis. The evidence review highlights the robust nature of the Harnan paper and highlights that FeNO+BDR was the most cost-economic option in their paper but the committee felt it to be of limited value due to the fact they were not evaluating a sequential diagnostic pathway. The committee evaluated the evidence for using spirometry and FeNO together with the study using thresholds of FEV1 88.4% and FeNO 19.6ppb. This FeNO level is significantly lower than most levels used by clinicians and	adults and children. A robust economic analysis is required to support strong recommendations particularly in areas of potentially large impact. The cost of FeNO used in the model was estimated using up-to-date information obtained from manufacturers and expert opinion from the committee. Harnan paper was included in the review but, as highlighted in the comment, used old estimations for cost and thresholds for spirometry and FeNO that are not commonly used in the NHS. This prompted us to develop an original analysis that looked at two different thresholds for FeNO. Review F included a detailed estimation of the cost of FeNO used in the economic analysis. A combination of BDR and FeNO was included in several of the diagnostic strategies assessed in adults: 6, 7, 8 and 9. Two different thresholds of FeNO were included, 40ppb and 50ppb, both used by clinicians. The full economic report is

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				suggested by NICE elsewhere in the guideline. It may have been appropriate for NICE to adjust this data to account for this inconsistency and improve sensitivity of combined testing.	published alongside the guideline for public review.
Asthma + Lung UK	Evidence review K	005	006 - 008	The review's introduction correctly acknowledges that no single test can accurately diagnose asthma (owing to the need for testing of pulmonary function and inflammation). This contradicts the draft guidance's diagnosis pathway.	Thank you for your comment. Unfortunately, combinations of tests are also not 100% accurate because of the variable nature of asthma. The guidance is attempting to reconcile the desirability of obtaining some supportive objective evidence with the simplicity of relying on clinical history alone. The committee decided that in people with a good clinical history and a single test result showing strong evidence of eosinophilic inflammation, this would suffice. Other people require further tests.
Asthma + Lung UK	Evidence review K	031	002 - 005	The evidence review discusses the poor and inconsistent availability of FeNO as a barrier to CYP diagnosis. However, the review doesn't highlight that spirometry for CYP is also far from universally available and that this will also have a knock on impact on CYP diagnosis of asthma. Some consideration should be given to strengthening the language around FeNO's	Thank you for your comment. The guideline recommends FeNO as the first line test in children and one of two options as first line test in adults. This should help in making FeNO more widely available.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				inclusion in the adult diagnostic pathway in order to bolster the argument for greater availability of FeNO nationally. The evidence review highlights that around 30% of children with suspected asthma will need referral to secondary care for a bronchial challenge test. This presents a significant number of referrals and a potential strain upon test capacity.	Access to bronchial challenge (for adults and children) is a major problem. The committee recognises this and discussions did touch on whether it should be included, but it is the single best test for asthma and therefore appears at the end of the diagnostic pathway for use when other tests have not helped.
Asthma + Lung UK	Evidence review Q	125	032 - 046	Evidence review Q's exploration of treatment escalation is detailed and covers points that should be explicitly covered in the draft guideline. The role of DPIs and their potential limitation for people suffering a severe exacerbation is vital information when prescribing inhaled therapies, and the role of SABA is also discussed in more detail in this review – clarity is needed in the draft guideline on the use of SABA during exacerbations.	Thank you for your comment. Treatment of exacerbations is not in the scope of this guideline. Complementary guidance on acute asthma will be produced by BTS/SIGN.
Asthma + Lung UK	Evidence review Q	General	General	The draft guidance should highlight that patients with montelukast (LTRA) as part of their maintenance therapy should have all potential side effects explained to them by their clinicians.	Thank you for your comment. This is a general principle which applies to any medicine.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Asthma + Lung UK	Guideline			**1.2.5** FeNO is a key diagnostic tool that forms an essential part of the 5-16-year-old diagnostic pathway outlined in this guidance. It is also a key inclusion in the adult pathway and must be offered as a truly accessible alternative to blood eosinophil testing as the latter may not be acceptable to some patients. On both counts, it is imperative that FeNO is universally available. As such, Asthma + Lung UK recommends that the phrase "or if FeNO is not available" has no place in this guidance and must be removed. Guidance should suggest a standard of care.	Thank you for your comment. The committee are very sympathetic to your comment but are aware that FeNO availability is currently limited (as numerous other Stakeholders have emphasised). They believe that an alternative should be included.
Asthma + Lung UK	Guideline	004	004 - 012	**1.1.1** Asthma + Lung UK recommends the addition of a suggestion that healthcare professionals consider asthma and other respiratory conditions whenever a person presents with any respiratory symptoms including cough, wheeze, breathlessness, chest tightness, chest infection, and sputum production.	Thank you for your comment Some of the symptoms you list are already in 1.1.1. The committee does not wish to add "chest infections"; if these were recurrent (and therefore possibly indicative of asthma) they would cause some of the symptoms already listed. Sputum production without any of the other symptoms is more likely to represent an alternative condition.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Clinicians may be guided by the NHS England breathlessness pathway support tool in diagnosing alternative (non-asthma-related) causes of respiratory symptoms and should be aware of red flags for acute breathlessness.	The committee agrees that the NHS England document is a useful tool.
Asthma + Lung UK	Guideline	004	004 - 012	**1.1.1** Asthma + Lung UK recommends that healthcare professionals review a patient's clinical record for previous episodes which can suggest recurrent respiratory symptoms indicative of asthma. These include a previous respiratory diagnosis, suspected respiratory diagnosis and prescriptions for inhalers, oral corticosteroids and antibiotics, professional-recorded wheeze, or previous testing suggestive of an attempt to make a respiratory diagnosis such as peak flows as these can often provide important clues regarding potential diagnosis.	Thank you for your comment. The features you list are unlikely in someone presenting for the first time.
Asthma + Lung UK	Guideline	004	004 - 012	**1.1.1** This guideline places considerable of emphasis on clinical history and examination ahead of objective testing. The lack of an algorithm within the updated guideline is concerning as these provide helpful guidance for healthcare	Thank you for your comment There is no algorithm covering a structured clinical history because there was no evidence review on signs and symptoms for this update,

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				professionals. It is crucial that the guideline explicitly states that history and examination need to be carried out by someone with the appropriate training and skills needed to identify asthma and the wide range of differential diagnoses and co-morbidities that cause the same symptoms. Appropriate detailed history and further testing/referral should be considered where there are risk factors or factors suggesting an alternative or co-existing condition (cancer, PE, cardiac, COPD, IPF, gastro-oesophageal reflux, ENT causes/post nasal drip, mental health conditions, breathing pattern disorders can all present similarly to asthma).	and no algorithm in the last version of either NICE or BTS/SIGN guidelines. All NICE guidance assumes that the recommendations will be carried out by people with appropriate training, and this BTS/NICE/SIGN guidance is the same. The rationale for the diagnosis recommendations notes that other diagnoses might need to be considered, but guidance on investigating other conditions is outside the scope of this asthma guideline.
Asthma + Lung UK	Guideline	004	009	**1.1.1** Asthma + Lung UK suggests the addition of "potential occupation triggers" within 1.1.1's specified check list. This would prompt clinicians to consult section 1.4 of the guidance if relevant.	Thank you for your comment. There are numerous potential triggers. Whilst occupational asthma is important, in 1.1.1 the aim is to make a diagnosis of asthma irrespective of the cause. Occupational asthma is highlighted separately in section 1.4.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Asthma + Lung UK	Guideline	004	013 - 014	**1.1.2** Asthma + Lung UK suggests adding a read code of "suspected asthma" until a supporting objective test result is available. Patient records should be updated to provide supporting detail and to outline the basis for suspicion. This will help the clinician and/or wider team understand the rationale for considering asthma as a diagnosis. This read code will also enable healthcare providers to monitor people who may have asthma but are not formally diagnosed. This is important due to the variable nature of asthma (diagnosis may take a long time), for people who are not routinely followed up or choose not to be followed up, and where there is a delay in accessing objective testing. This guideline places considerable of emphasis on clinical history and examination ahead of objective testing. It is crucial that the guideline explicitly states that history and examination need to be carried out by someone with the appropriate training and skills needed to identify asthma and the wide range of differential diagnoses and co-morbidities that cause the	Thank you for your comment. The advice that suspected asthma should be coded has been added to 1.1.2.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				same symptoms. Appropriate detailed history and further testing/referral should be considered where there are risk factors or factors suggesting an alternative or co-existing condition (cancer, PE, cardiac, COPD, IPF, gastro-oesophageal reflux, ENT causes/post nasal drip, mental health conditions, breathing pattern disorders can all present similarly to asthma).	
Asthma + Lung UK	Guideline	005	007 - 011	**1.1.5** This section needs greater clarity about treating someone who is acutely unwell as this may be putting patients at risk of not getting appropriate acute management, increasing their risk of death.[v] Asthma + Lung UK recommends specifying that if a patient is suspected of potentially having asthma then they need assessing and treating as if they were already diagnosed. This may include oral steroids at the correct dose for asthma and/or inhalers as appropriate. Acute assessment should presume a diagnosis of asthma and include peak flow, heart rate, respiratory rate, oxygen saturations and chest examination.	Thank you for your comment. Please note also that acute management of asthma is outside the scope, but BTS and SIGN will be producing guidance on this. However, the possible need for oral steroids has been added to 1.1.5.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Chest examination is important as asthma symptoms can overlap with many other conditions including pulmonary embolism, pneumothorax, chest infection/pneumonia. This face-to-face contact also provides an opportunity to demonstrate any inhaler devices and observe inhaler technique where these are being prescribed. Multiple patient surveys conducted by Asthma + Lung UK highlight the positive correlation between in-person appointments and improved access to proper treatment and basic asthma care.[vi]	
Asthma + Lung UK	Guideline	005	009 - 010	**1.1.5** Greater clarity is needed within lines 9 and 10: "spirometry or peak flow with bronchodilator reversibility [BDR]) if the equipment is available". Currently, this suggests that peak flow readings can be used to demonstrate BDR. This would be an important and practical step to improving diagnosis but is at odds with the proposed diagnostic process. Given that peak flow is an essential part of assessing acute asthma symptoms (or suspected asthma) this approach should be	Thank you for your comment. This recommendation deals with the less frequent situation where a person presents with acute symptoms requiring immediate treatment. Whilst the committee would not advise measuring change in PEF in other circumstances, here it is more likely to be possible to measure PEF than FEV1, and the acute response could provide valuable diagnostic information. It does not apply to situations where the person is not acutely unwell, lung function is less likely to be highly

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				highlighted. BDR could be demonstrated by peak flow before and after bronchodilator medication, as part of a peak flow diary while starting preventer medication or before and after a course of oral steroids. The importance of peak flow assessment in acute asthma is highlighted in Scenario: Acute exacerbation of asthma | Management | Asthma | CKS | NICE The guideline should provide clarity on what percentage of reversibility and variability would support a diagnosis of asthma. The guideline must also emphasise that FeNO, eosinophil, and spirometry testing do not demonstrate variability unless the patient is symptomatic at the time of testing, whereas use of PEF can demonstrate variability.	abnormal, and there is time for better standardised testing,
Asthma + Lung UK	Guideline	005	009 – 010	**1.1.5** The draft guideline should include prescriptive guidance for bronchodilator reversibility.	Thank you for your comment. Recommendation 1.1.5 is not part of the current update. It deals with opportunistic measurement of reversibility when a person presents with an acute attack. The regular use of BDR is dealt with in recommendations 1.2.2 and 1.2.5.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Asthma + Lung UK	Guideline	005	012 - 016	**1.1.6** Asthma + Lung UK recommends that the guideline should clarify that acute presentations where asthma is suspected must be followed up routinely within an appropriate timescale, with clear instruction to the patient about when follow up will happen and when to seek help in the meantime. This should be in line with NICE QS Quality statement 4: Follow-up by general practice after emergency care | Asthma | Quality standards | NICE	Thank you for your comment. This recommendation is not part of the current update. Management of acute attacks, and follow-up after these, will be covered in separate guidance by BTS & SIGN.
Asthma + Lung UK	Guideline	005	012 - 016	**1.1.6** Asthma + Lung UK recommends that patients be given information about their suspected diagnosis in order that they understand the condition that they are being investigated for, are safety-netted in terms of worsening symptoms, understand how to use any inhalers they have been prescribed, triggers to avoid, smoking cessation services. Potential guidance could include Asthma + Lung UK's patient-focused resources on diagnosing asthma: Diagnosing asthma | Asthma + Lung UK (asthmaandlung.org.uk)	Thank you for your comment. This is a legacy recommendation, not part of the current update.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Asthma + Lung UK	Guideline	005	017 - 018	**1.1.7** Asthma + Lung UK recommends that the guidance should specify that normal test results do not necessarily exclude asthma. Asthma is a variable condition that may present at some points and not present at others.	Thank you for your comment. This is true, but also obvious from the diagnostic sequence recommended in this guideline in which investigation continues despite normal test results.
Asthma + Lung UK	Guideline	005	022 - 025	**1.2.1** This section needs to be more specific regarding eosinophil counts and laboratory reference ranges. The draft guideline suggests that it should be based on local reference ranges; this creates a postcode lottery and inconsistencies in diagnosis. National standards should be set by this guidance and laboratories must report according to those standards. By increasing the eosinophil level required for a positive result, the test's specificity is increased, leading to fewer false positive diagnoses. However, this increases the likelihood of false negative results, meaning that people with asthma are missed, leading to them facing further objective tests in pursuit of a positive result, all the while going without appropriate,	Thank you for your comment. It would be helpful if every laboratory used exactly the same techniques and reported exactly the same normal range, but at present this is not the case. The health economic analysis took into account all costs related with the diagnostic algorithm, including the cost of each test and the consequences of misdiagnoses. Blood eosinophils was found to be cost-effective as a first test, due to its high specificity and low cost. It is important that the first test of the sequence is highly specific, or there is a risk of overdiagnosis and overtreating asthma. False negative results are expected to be corrected, in large part, by further tests whose costs and

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				informed care, and with the cost of diagnosis likely increasing as further tests are carried out. It is not clear whether the sequence of testing evaluated in this guideline includes the costs of all tests done in the sequence. Eosinophil levels between 0.15 and 0.3 are commonly used and should be specified within the guidance as affording sufficient test specificity and accuracy of diagnosis.[vii] The guideline should also explain the expected proportion of suspected asthma patients will need each test. Elements of this are discussed throughout various evidence reviews (evidence review K explains that around 30% of children will need to be referred to secondary care for bronchial challenge testing) but this should be consistent.	implications are accounted for in the analysis described in the economic report.
Asthma + Lung UK	Guideline	005	022 - 025	**1.2.1** Asthma + Lung UK recommends that 1.2.1 explain that there are other causes of raised eosinophil levels and that these must be differentiated from asthma in order to avoid giving false-positive diagnoses based on eosinophil levels alone. Other potential causes	Thank you for your comment. The committee agrees that other conditions may cause the eosinophil count to be raised, but there are potential confounding factors with most diagnostic tests. Other causes of

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				of high eosinophils include sinusitis, nasal polyps, ABPA, and EGPA which can also cause chest symptoms that mimic asthma. Similarly, smoking can also significantly decrease blood eosinophil levels.	eosinophilia have been noted in the Terms Used section.
Asthma + Lung UK	Guideline	005	022 - 025	**1.2.1** Blood tests might not be acceptable to people with suspected asthma due to a dislike of blood tests/needles, and confusion around the use of blood tests as a diagnostic tool for asthma. This could serve as a barrier to diagnosis. FeNO testing must be made universally available in order to meet the needs of the diagnosis pathway outlined for those aged 5-16, but must also be available in order to diagnose adult patients for whom a blood test is not an acceptable or preferred test. Ensuring informed patient choice is central to providing a quality service within the NHS, and must a key consideration when providing diagnostic tests for asthma.	Thank you for your comment. The committee agrees that some people are not willing to have blood tests, and recommendation 1.2.1 gives FeNO as an alternative.
Asthma + Lung UK	Guideline	005	022 - 025	**1.2.1**	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Asthma + Lung UK recognise the importance of a patient's detailed clinical history which relies on sufficient training and experience to be correctly utilised in a patient's diagnosis and treatment There are different types of asthma that may present with inflammation and/or airway obstruction, diagnosis should be made using both a measure of inflammation and a measure of airway obstruction. NICE's April 2014 diagnostic guidance on the use of FeNO highlights its utility but suggests that it shouldn't be used in isolation from other objective testing.[viii]	This is an update of NICE's earlier guideline. It contains new evidence and need not be expected to come to exactly the same conclusions as its predecessor.
Asthma + Lung UK	Guideline	005	022 - 025	**1.2.1** Diagnosing asthma using patient clinical history and eosinophil count alone is likely to miss other causes of respiratory symptoms such as COPD. COPD can mimic asthma and can co-exist with asthma.[ix] Although initial management would be similar (use of ICS, smoking cessation), the failure to diagnose and read code COPD could inhibit access to appropriate education and self-management and access to specific treatments	Thank you for your comment. The rationale for recommendation 1.2.1 acknowledges that when a person first presents with symptoms compatible with asthma there may well be other conditions which should be considered in the differential diagnosis.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				such as pulmonary rehabilitation. Asthma + Lung UK recommends that the draft guideline inform clinicians of the potential to misdiagnose COPD in this way.	
Asthma + Lung UK	Guideline	005	022 - 025	**1.2.1** Evidence of airway obstruction through peak flow testing can be useful for monitoring disease stability and is essential as part of the assessment of asthma exacerbations.[x] Peak flow should be employed as part of the diagnostic process in conjunction with testing for airway inflammation.	Thank you for your comment. Recommendation 1.2.1 is about diagnosis, not monitoring nor assessment of exacerbations. PEF variability is now included in the diagnosis sections.
Asthma + Lung UK	Guideline	005	022 - 025	**1.2.1** Asthma + Lung UK recommends that the guidance specify that non-T2 asthma will show negative eosinophil and FeNO test results and that the use of objective testing must account for all types of asthma. By not identifying non-T2 asthma (ie negative eosinophils / FeNO testing), a greater number of people with suspected asthma will remain off medication or need a referral to already-stretched secondary care services.	Thank you for your comment. The diagnostic test sequence accounts for all types of asthma. The FeNO or eosinophil count is used as a rule-in test, not to rule out the diagnosis. If negative, the person will proceed to the next test (reversibility measurement).

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Asthma + Lung UK	Guideline	005	024	**1.2.1** A FeNO threshold of 50ppb or more differs from previous NICE guidance which suggested 40ppb. Similarly, 50ppb also differs from the ranges discussed in NICE's April 2014 diagnostic guidance for FeNO.[xi] By increasing the threshold required for a positive result, the test's specificity is increased, leading to fewer false positive diagnoses. However, this increases the likelihood of false negative results, meaning that people with asthma are missed, leading to them facing further objective tests in pursuit of a positive result, all the while going without appropriate, informed care, and with the cost of diagnosis likely increasing as further tests are carried out. It is not clear whether the sequence of testing evaluated in this guideline includes the costs of all tests done in the sequence. Incorrect and delayed diagnosis prevents people from accessing appropriate care and treatment and puts patients at risk. Asthma + Lung UK recommends that FeNO thresholds be re-	Thank you for your comment. Any cut-off value chosen would be a compromise between perfect sensitivity and perfect specificity. The level was set at a slightly high value since this may be the only test people get and the committee therefore wished to err on the side of specificity. This will mean extra tests for some, but getting the diagnosis correct at the start will reduce future problems. Also note that in the last version of the NICE guideline multiple tests were more likely; the current recommendations are more straightforward for patients and healthcare professionals.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				evaluated in order to better balance test specificity with a threshold low enough to prevent patients from unnecessarily slipping through the net and escalating along the diagnosis pathway. Evidence review F explains that thresholds as low as 37ppb can produce specificity values of 0.96; compared to the 0.99 of a far higher ppb.[xii]	
Asthma + Lung UK	Guideline	005	026 - 029	**1.2.2** Asthma may be hard to confirm with eosinophil count, FeNO, or BDR if the person is already on treatment. Asthma + Lung UK recommends that the guideline should clarify the necessary adjustments to diagnosis for patients that are already on medication: should patients continue with objective tests; should they be guided to reduce/stop treatment before being tested? These points must be clarified within the guidance, and guidance on timeframes should be included as a decision aid for clinicians. If FeNO was readily available in primary care then FeNO could be used as a point-of care test	Thank you for your comment. It is true that treatment is likely to normalise most of the available tests. The guideline is aimed at people at first presentation with symptoms. Recommendations on re-assessing the diagnosis in people on treatment were not part of the scope and no evidence search has been done. We will suggest this to NICE's surveillance team to consider for the next iteration of this guideline. The committee agree that diagnosis would be facilitated if point of care tests were available.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				rather than waiting for a blood test or spirometry. Alternatively, if diagnosis relies upon a blood test then the patient would need another appointment for results and starting medication. Universal access to FeNO can be encouraged within this guidance by recommending it outright where appropriate, rather than as an alternative to blood eosinophil tests. We know that if FeNO were made available to all GPs across England, for example, its use could save almost £100m by optimising asthma treatment.[xiii]	
Asthma + Lung UK	Guideline	005	026 - 029	**1.2.2** Spirometry is not recommended 4-6 weeks post infection/acute exacerbation.[xiv] Diagnostic pathways need to consider this when arranging follow-up testing for people with suspected asthma. Asthma + Lung UK recommends an inclusion of this guidance, with signposting to PCRS's position statement if possible, within 1.2.2 in order to fully inform clinicians.	Thank you for your comment. Spirometry should only be performed by trained personnel, and they will be aware of this restriction.
Asthma + Lung UK	Guideline	005 - 007		**1.2** Inclusion of a chart or flow diagram to clearly show the stepwise diagnostic pathway for both adults and children should be included to aid	Thank you for your comment. There is a diagnostic flowchart.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				clinician comprehension and to allow easy explanation of diagnosis to people with suspected asthma. The NHS England breathlessness pathway support tool may be used as a good example.	
Asthma + Lung UK	Guideline	005 - 007	022 - 019	**1.2** Consistency across the diagnosis pathways for adults and those aged 5-16 would simplify this guideline and the provision of asthma diagnosis in primary care. People aged 5-16 and under are recommended FeNO as first line tests; this should be the case for adults, too. This guideline recommends FeNO for routine monitoring as well as before and after changing treatment. If FeNO is readily available in primary care for these purposes then it would make sense to standardise its use in adult and child diagnosis. FeNO would enable a point-of-care diagnosis and immediate start of medication. Alternatively, if diagnosis relies upon a blood test then the patient would need another appointment for results and starting medication. The inclusion of FeNO as a rapid uptake product under the Accelerated Access Collaborative has	Thank you for your comment. The committee do not agree that the process of diagnosis should be exactly the same in children as in adults. The evidence is not identical and there are other considerations to take into account e.g. ability to perform tests.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				seen an increase in access to FeNO, with 53% of PCNs in England now estimated to have access to testing.[xv] Increased uptake of FeNO between April 2021 and March 2023 resulted in an estimated 58,000 people being newly diagnosed with asthma, further highlighting the test's utility.[xvi] We know from Asthma + Lung UK's 'Saving Your Breath' report that if FeNO were made available to all GPs across England, for example, its use could save almost £100m by optimising asthma treatment.[xvii] Table 8 [Evidence review F] states that FeNO was the most cost effective test compared to other tests, further evidencing its suitability for both the adult and 5-16 year old diagnosis pathways.	
Asthma + Lung UK	Guideline	006	001 - 003	**1.2.3** This element needs to clarify whether the patient is symptom-free and/or on medication prescribed to alleviate asthma symptoms at a previous presentation. If a patient is symptom-free and/or has tested negative in objective testing, this could be due to the variable nature of asthma,[xviii] or due to medication. Including a link to NICE's CKS on	Thank you for your comment. It is not clear which part of the guideline this comment refers to. Recommendation 1.2.3 in the draft for consultation relates to measuring bronchial responsiveness. At this stage the person with suspected asthma will have been

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				when to suspect asthma would be helpful to clinicians. This may require another step to explain what to do if tests are negative for either reason: guiding clinicians to consider other conditions, the potential for intermittent symptom presentation, and any current prescriptions and whether tests could be negative due to medication (ie reduce/stop then repeat testing). The inclusion of a chart or flow diagram to clearly show the stepwise diagnostic pathway for both adults and children should be included to aid clinician comprehension and to allow easy explanation of diagnosis to people with suspected asthma. The NHS England breathlessness pathway support tool may be used as a good example.	referred to a specialist which is the appropriate action if the correct diagnosis is elusive. There is a diagnostic flowchart.
Asthma + Lung UK	Guideline	006	001 – 003	**1.2.3** This element must also specify that clinicians must refer to secondary care to measure bronchial responsiveness as this test is not available in primary care.	Thank you for your comment. This is correct at present and has been added to 1.2.4.
Asthma + Lung UK	Guideline	006	005 - 006	**1.2.4**	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Consistency across the diagnosis pathways for adults and those aged 5-16 would simplify this guideline and the provision of asthma diagnosis in primary care. People aged 5-16 and under are recommended FeNO as first line tests; this should be the case for adults, too. This guideline recommends FeNO for routine monitoring as well as before and after changing treatment. If FeNO is readily available in primary care for these purposes then it would make sense to standardise its use in adult and child diagnosis. FeNO would enable a point-of-care diagnosis and immediate start of medication. Alternatively, if diagnosis relies upon a blood test then the patient would need another appointment for results and starting medication. Table 8 [Evidence review F] states that FeNO was the most cost effective test compared to other tests, further evidencing its suitability for both the adult and 5-16 year old diagnosis pathways. FeNO testing must be made universally available in order to meet the needs of the diagnosis pathway outlined for those aged 5-16.	The committee do not agree that the process of diagnosis should be exactly the same in children as in adults. The evidence is not identical and there are other considerations to take into account e.g. ability to perform tests.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Asthma + Lung UK	Guideline	006	007 - 009	**1.2.5** Consistency across the diagnosis pathways for adults and those aged 5-16 would simplify this guideline and the provision of asthma diagnosis in primary care. People aged 5-16 and under are recommended FeNO as first line tests; this should be the case for adults, too. This guideline recommends FeNO for routine monitoring as well as before and after changing treatment. If FeNO is readily available in primary care for these purposes then it would make sense to standardise its use in adult and child diagnosis. FeNO would enable a point-of-care diagnosis and immediate start of medication. Alternatively, if diagnosis relies upon a blood test then the patient would need another appointment for results and starting medication. Table 8 [Evidence review F] states that FeNO was the most cost effective test compared to other tests, further evidencing its suitability for both the adult and 5-16 year old diagnosis pathways.	Thank you for your comment. Recommendation 1.2.5 in the draft guideline relates to bronchodilator reversibility, not FeNO. The committee do not agree that the recommendations should be the same in children as in adults. The evidence is not identical and there are practical considerations such as the greater difficulty in taking blood from children.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				FeNO testing must be made universally available in order to meet the needs of the diagnosis pathway outlined for those aged 5-16.	
Asthma + Lung UK	Guideline	006	010 - 016	**1.2.6** A Skin prick testing is widely acknowledged to be impractical within primary care due to the required training and facilities needed, and is often referred to secondary care as a result.[xix]	Thank you for your comment. Skin prick testing is only one option in recommendation 1.2.6. and the committee feel it is important to include it as a means of avoiding a blood test in a child who is reluctant to have this.
Asthma + Lung UK	Guideline	006	010 - 016	**1.2.6** Blood tests are not always accepted by children which may prevent the use of test for IgE or eosinophil levels.	Thank you for your comment This may be a problem and is why the committee included skin prick testing as a possible alternative.
Asthma + Lung UK	Guideline	006	010 - 016	**1.2.6** The guidance should include additional, common environmental allergens. When conducting skin prick testing to house dust mite, the guidance should also include further triggers such as pollens and moulds. GINA 2023 includes skin prick evaluation for pest rodents as an asthma trigger.[xx]	Thank you for your comment The purpose of this recommendation is not to identify triggers, but to help make a diagnosis. In this respect it is house dust mite sensitivity which is most likely to be useful.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Asthma + Lung UK	Guideline	007	001 - 015	**1.3** Asthma + Lung UK recommends that trial of treatment be specified within section 1.3 in order to ensure the guidance is pragmatic, reflects clinicians' real-world experience, and meets the needs of the age group in question.	Thank you for your comment Recommendation 1.3.1 directs the reader to section 1.9 which deals with a trial of treatment in detail. The committee do not think it appropriate to repeat all this information in 1.3 as well.
Asthma + Lung UK	Guideline	007	004	**1.3.1** Asthma + Lung UK recommends that the use of the term "clinical judgement" should be revised; this guideline should help support clinical judgement, not defer to it as it can vary and may be skewed by knowledge and experience.	Thank you for your comment This recommendation has been amended.
Asthma + Lung UK	Guideline	007	004 - 009	**1.3.1** Asthma + Lung UK recommends that the guideline needs to clarify whether to read code "asthma" or "suspected asthma" in this age group. Adding a read code is essential for arranging follow-up in primary care. It is important that this age group is followed up regularly and confirmatory tests performed once old enough.	Thank you for your comment Coding is covered (for all age groups) in 1.1.2 and 1.1.3.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Asthma + Lung UK	Guideline	007	004-009	**1.3.1** Asthma + Lung UK recommends that 1.3.1 must be more specific about the symptoms and signs to look out for in this age group.	Thank you for your comment Signs and symptoms are covered in the earlier section.
Asthma + Lung UK	Guideline	007	010 - 015	**1.3.2** Asthma + Lung UK recommends that 1.3.2 should specify whether trials away from treatment should be attempted.	Thank you for your comment Recommendation 1.3.1 directs the reader to section 1.9 which deals with a trial of treatment in detail, including trials off treatment. The committee do not think it appropriate to repeat all this information in section 1.3 as well.
Asthma + Lung UK	Guideline	008	010 - 011	**1.4.2** Asthma + Lung UK recommends amending 1.4.2 to specify that patients with suspected or confirmed occupational asthma should have any occupational sensitisers identified and removed as soon as possible in order to limit risk to the patient.[xxi]	Thank you for your comment. The guideline is not attempting to lead people through the process of diagnosing occupational asthma, but to indicate when it should be suspected and onward referral made.
Asthma + Lung UK	Guideline	008	010 - 011	**1.4.2**	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Asthma + Lung UK recommends that 1.4.2 specify whether to commence treatment while awaiting specialist referral for suspected occupational asthma.	Recommendation 1.4.2 is not an updated recommendation and comment on it was not invited. Please note that section 1.4 is about people with a diagnosis of asthma in whom an occupational cause is suspected. Since there is already a diagnosis of asthma, treatment will have been commenced in accordance with sections 1.6 and 1.7.
Asthma + Lung UK	Guideline	008	013 - 014	**1.5.1** Asthma + Lung UK recommends amending the wording of 1.5.1 to also specify that a clinician who has undertaken post-graduate training in asthma should check asthma control whenever the person presents with respiratory symptoms. Asthma + Lung UK also recommends that 1.5.1 include a time frame within the review structure to guide clinicians. To read: "Monitor asthma control at every review and at any presentation by a patient with respiratory symptoms. Review for confirmed asthma should be within 12 months of previous review. In addition to asking about symptoms, check:"	Thank you for your comment The timing of review and the point about an appropriate reviewer are covered in 1.16.1.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Asthma + Lung UK	Guideline	008	013 – 018	**1.5.1** Asthma + Lung UK recommends that this element be more precise in its instruction to clinicians, advising them to check the amount of reliever inhaler used and check prescribing records for reliever inhalers issued.	Thank you for your comment. These items have been added to 1.5.1.
Asthma + Lung UK	Guideline	008	017	**1.5.1** Asthma + Lung UK recommends that a time frame be included to guide accurate review of the number of courses of oral corticosteroids a patient has been prescribed in order to allow overuse indicative of poor condition management to be addressed.[xxii]	Thank you for your comment The committee do not think this is helpful. Any exacerbation requiring oral corticosteroid is a cause for concern and this should be explored at the review.
Asthma + Lung UK	Guideline	008	019 - 021	**1.5.2** Asthma + Lung UK recommends that 1.5.2 be amended to include the Childrens Asthma Control Test (cACT) for monitoring asthma control in 4-11 year olds.[xxiii]	Thank you for your comment Children's questionnaire has been added to the examples.
Asthma + Lung UK	Guideline	008	025 - 027	**1.5.4** FeNO is a key diagnostic tool that forms an essential part of the 5-16-year-old diagnostic pathway outlined in this guidance. It is also a	Thank you for your comment. It is standard practice in NICE guidance to use the word "Consider" for recommendations

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				key inclusion in the adult pathway and must be offered as a truly accessible alternative to blood eosinophil testing as the latter may not be acceptable to some patients. On both counts, it is imperative that FeNO is universally available. As such, Asthma + Lung UK recommends that vague phrasing such as "consider FeNO monitoring" has no place in this guidance and must be replaced with instruction to use FeNO.	where the supporting evidence is positive but not unequivocally so and therefore this terminology will remain in the BTS/NICE/SIGN guidance.
Asthma + Lung UK	Guideline	009	001 - 008	**1.5.5** Asthma + Lung UK recommends including guidance to review a patient's diagnosis when control is suboptimal and assess whether it is likely to be correct.	Thank you for your comment. After further consideration the committee have agreed that there was a lot of overlap between 1.5.5 and 1.6.1 in the draft guideline. 1.5.5 has now been shortened markedly and the points are covered in 1.6.1.
Asthma + Lung UK	Guideline	009	001 - 008	**1.5.5** Include within 1.5.5's bullet points: "assess whether current symptoms are consistent with asthma or another cause"	Thank you for your comment. After further consideration the committee have agreed that there was a lot of overlap between 1.5.5 and 1.6.1 in the draft guideline. 1.5.5 has

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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					now been shortened markedly and the points are covered in 1.6.1.
Asthma + Lung UK	Guideline	009	001 - 008	**1.5.5** Include within 1.5.5's bullet points guidance instructing clinicians to ask about changes in lifestyle, medication, air quality, occupation, housing, health, mental health to identify potential reasons for poor control.	Thank you for your comment. After further consideration the committee have agreed that there was a lot of overlap between 1.5.5 and 1.6.1 in the draft guideline. 1.5.5 has now been shortened markedly and the points are covered in 1.6.1.
Asthma + Lung UK	Guideline	009	001 - 008	**1.5.5** Include within 1.5.5's bullet points guidance to see review of patient's diagnosis using objective tests to assess whether poor control is truly due to asthma.	Thank you for your comment. The revision to recommendation 1.5.5 of the draft guideline (detail now included in 1.6.1) does not specify that objective tests must be done. Exactly how to reconsider the diagnosis will depend on which tests were done initially, when they were done, and the likelihood and nature of any alternative or additional diagnoses.
Asthma + Lung UK	Guideline	009	010 - 015	**1.6**	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				1.6's inclusion of off-license medication, though helpful, may need further exploration in implementation as some prescribers may feel unhappy or unwilling to prescribe in this way, especially with a completely novel way of approaching asthma management with AIR/MART. Similarly, non-prescribing asthma clinicians such as nurses, and pharmacists may rely on other prescribers for their medication choices. A significant communication strategy with education and training will be needed to ensure that a lack of understanding of different inhaler choices, and NICE's information on off-license prescribing does not impact patient access to guideline-level care.	The committee agrees that AIR is relatively new (MART is less so) and that clinician education will be needed.
Asthma + Lung UK	Guideline	009	019	**1.6.1** Asthma + Lung UK recommends extending the list of example additional diagnoses given on line 19. Consider including deconditioning, COPD, gastro-oesophageal reflux, rhinosinusitis, mental health, breathing pattern disorder.	Thank you for your comment. Several stakeholders have suggested additions which might be made to this bullet point, and on reflection the committee have agreed that no examples are necessary, the meaning of the recommendation being clear without them.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Asthma + Lung UK	Guideline	009 - 101	016 - 007	**1.6.1** Asthma + Lung UK recommends using objective measures such as FeNO or peak flow to demonstrate whether symptoms are due to asthma and to establish a baseline ahead of a change in therapy.	Thank you for your comment. A recommendation to monitor FeNO is made in 1.5.4. The significance of an elevated FeNO has now been added to section 1.6.
Asthma + Lung UK	Guideline	010	008 - 010	**1.6.2** Asthma + Lung UK are strongly supportive of the inclusion of guidance to limit SABA-only therapy for treating asthma symptoms. We recommend augmenting 1.6.2 by adding "using MART or AIR in patients 12 or above where possible." AIR's efficacy is well-proven and has been evidenced by reduction in FeNO by multiple studies.[xxiv] MART's inclusion as the preferred controller in Step 3 of GINA's treatment pathway should be mirrored and MART should be prescribed when a patient's symptoms are present most days or wake them once per week or more.[xxv]	Thank you for your comment. The committee understands why you suggest this, but if the initial treatment steps for those aged 12 and over are added to this recommendation then the same would have to be done for those aged 5-11 and the recommendation would be unwieldy and repetitive.
Asthma + Lung UK	Guideline	010	011 - 013	**1.6.3** Asthma + Lung UK recommend the 1.6.3 explicitly advise the use of Asthma Control Tests	Thank you for your comment. 1.6.3 refers the reader to the preceding section on monitoring control. There are several things

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				for adolescents and adults and the use of the Children's Asthma Control Test for those aged 4-11. Asthma + Lung UK agrees that PEF will not be helpful within a normal asthma review, but FeNO or peak flow should be tested prior to a change or treatment and at review and this should be stated within 1.6.3.	which should be done when reviewing whether a treatment change has been beneficial (those you mention as well as checking inhaler technique); these are covered in other recommendations and it is inappropriate to repeat them all here.
Asthma + Lung UK	Guideline	010	011 - 013	**1.6.3** Asthma + Lung UK recommends that patients be given information about their change of treatment in order to better inform them of what to expect from the next step of their care and when/how to seek help if their symptoms worsen or if their new treatment is unsuitable or ineffective. Potential guidance could include Asthma + Lung UK's patient-focused resources on changing asthma treatment: Changing asthma medicines | Asthma + Lung UK (asthmaandlung.org.uk)	Thank you for your comment. Giving information when a new medication is offered (whether first treatment or change in treatment) is a basic principle which applies across all branches of medicine, and this should not need to be stated.
Asthma + Lung UK	Guideline	010	015 - 021	**1.6.4**	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Asthma + Lung UK recommends including "appropriate drug(s) and dose" within 1.6.4's bullet points.	The recommendation is about the type of device, not about the medicine it contains.
Asthma + Lung UK	Guideline	010	015 - 021	**1.6.4** Asthma + Lung UK recommends including "previous medications and intolerances" within 1.6.4's bullet points.	Thank you for your comment. The recommendation is about the type of device, not about the medicine it contains, and reference to previous medications and intolerances is therefore not appropriate.
Asthma + Lung UK	Guideline	011		**1.6.5** Asthma + Lung UK recommends inhalers only being prescribed by their brand name to prevent patients from accidentally being given an alternative device. Pharmacists should, however, be able to maintain suitable autonomy to prescribe available medicines that meet the person's prescription where necessary.	Thank you for your comment. The committee agrees that brand name prescribing is advisable, and this has been recommended by others. However, putting this in the guideline will not prevent "accidentally being given an alternative device" and as you point out, pharmacists may occasionally have no option but to offer an alternative.
Asthma + Lung UK	Guideline	011	001 - 004	**1.6.5** Asthma + Lung UK recommend that the guidance include a link to the Asthma + Lung	Thank you for your comment. Asthma + Lung UK is listed as one of the patient organisations with a link to your website.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				UK website and its resources, or that the guidance include a suggestion to clinicians to make this information available to patients: Changing asthma medicines | Asthma + Lung UK (asthmaandlung.org.uk)	
Asthma + Lung UK	Guideline	011	001 - 004	**1.6.5** Asthma + Lung UK recommends that the guidance include information about how long inhalers last and how people can tell when they are empty. We know from patient survey data that only 36% of people with asthma strongly agree that they can self-manage their condition.[xxvi] Patients deserve guidance that helps them improve their ability to self-manage their condition.	Thank you for your comment. A bullet point has been added recommending that devices with dose counters should be preferred
Asthma + Lung UK	Guideline	011	001 - 004	**1.6.5** Asthma + Lung UK recommends that the guidance include direct reference to the role played by a personalised asthma action plan (PAAP) in informing patients, guiding their care and reflecting changes in the treatment regime. PAAPs are a key element of basic asthma care but our 2024 survey of over 12,000 people	Thank you for your comment. PAAP's are recommended further on in the guideline (section 1.14).

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				found that only 50% across the UK were provided with one as part of their asthma care and that only 86% of those with a PAAP have a say in its content and, thus, their asthma care.[xxvii] If a child has a personalised asthma action plan they are four times less likely to have an asthma attack that requires emergency hospital treatment.[xxviii]	
Asthma + Lung UK	Guideline	011	001 - 004	**1.6.5** Asthma + Lung UK recommends that in addition to the information given to patients on their inhalers, steps should be taken to ensure that patients are prescribed enough medication to ensure that they can take it as instructed up to the date of their follow-up appointment without running out.	Thank you for your comment. This is important but applies to treatment for any condition, and the committee feels that it goes beyond their remit to advise prescribers on the amount of medication to supply.
Asthma + Lung UK	Guideline	011	001 - 004	**1.6.5** Asthma + Lung UK recommends that all medicines be prescribed with adequate instructions and guidance for safe, effective use. This includes ensuring that all prescriptions for inhaler asthma therapies are paired with in-person guidance of inhaler technique on the same type of inhaler, with the patient's	Thank you for your comment. The points you make are all covered by the guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				technique monitored (and, if necessary, corrected) by a clinician who has undertaken post-graduate training in asthma. Asthma + Lung UK's 2024 Life With a Lung Condition survey found that only 50% of people with asthma across the UK had their inhaler technique reviewed in the last year, and that only 4% of those had it done remotely, emphasising the need for in-person reviews.	
Asthma + Lung UK	Guideline	011	005 - 014	**1.6.6** Asthma + Lung UK recommends including links to the Asthma + Lung UK website in order to provide patient-facing guidance on how to correctly use each type of inhaler. How to use your inhaler | Asthma + Lung UK (asthmaandlung.org.uk) Though comprehensive, this guidance should only be used to supplement correct inhaler technique guidance provided in primary care, including ensuring a clinician who has undertaken post-graduate training in asthma sees the patient demonstrate use of their inhaler.	Thank you for your comment. Asthma + Lung UK is listed as one of the patient organisations with a link to your website. The committee agrees that all its recommendations should be carried out by appropriately trained people.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Asthma + Lung UK	Guideline	011	005 - 014	**1.6.6** Asthma + Lung UK recommends including guidance within 1.6.6 that Community Pharmacy optimise adherence and inhaler technique at every opportunity. Community Pharmacy is well placed to support general practice and funding should be optimised to allow this.	Thank you for your comment. 1.6.6 already covers the role of community pharmacists. The recommendation does not specify who should carry it out and therefore if someone is seeing a pharmacist on an asthma-related issue 1.6.6 is applicable.
Asthma + Lung UK	Guideline	011	011	**1.6.6** Asthma + Lung UK recommends removing the reference to "generic device" to ensure that patients receive the same inhaler with each prescription. This is to ensure consistency in people's prescriptions, preventing change of inhaler that may limit a person's ability to correctly use their treatments.	Thank you for your comment. This was not intended as a recommendation for generic devices but was offered as an example because generic switching can sometimes occur without the original prescriber's knowledge, is potentially hazardous, and the committee wished to remind people of this. Since its purpose seems to have caused confusion, the reference to generics has been removed.
Asthma + Lung UK	Guideline	011	015 - 017	**1.6.7** Include "where possible, such as where a LAMA is added."	Thank you for your comment. The words "if possible" have been added.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Asthma + Lung UK	Guideline	011	018 - 019	**1.6.8** Asthma + Lung UK recommends explaining the importance of returning inhalers and reinforcing messaging that they are not to be disposed of in general domestic waste or domestic recycling. Patients should also be clearly informed that correct adherence and technique are essential to reducing unnecessary greenhouse gas emissions: the 'greenest' asthma treatment is that which provides optimum symptom control.[xxix]	Thank you for your comment. The wording has been changed
Asthma + Lung UK	Guideline	012	004 - 011	**1.7.1** Asthma + Lung UK recommends that guidance be explicit to ensure unavoidable clarity to novice clinician: suggest including the wording "Offer a low-dose ICS/formoterol combination inhaler to be taken as needed for symptom relief to people aged 12 and over with newly diagnosed asthma. This is a SABA-free approach so no salbutamol inhaler is required."	Thank you for your comment SABA inhalers are not required for AIR or MART, and this has been added to the descriptions in the Terms Used section. Instruction regarding the amount of medication to prescribe is beyond the remit of the guideline.
Asthma + Lung UK	Guideline	012	004 - 011	**1.7.1**	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Asthma + Lung UK recommends providing information to patients on why and how AIR works in order to ensure patients feel in greater control of their condition and its treatment. AIR (anti-inflammatory reliever) | Asthma + Lung UK (asthmaandlung.org.uk)	We agree, and a link to your website should be included in the Asthma Pathway.
Asthma + Lung UK	Guideline	012	004 - 011	**1.7.1** Asthma + Lung UK recommends including guidance that personalised asthma action plans specifically designed for patients using an AIR inhaler should be given to patients prescribed AIR. Download AIR asthma action plan | Asthma + Lung UK (asthmaandlung.org.uk)	Thank you for your comment The committee agrees that personalised action plans should be offered to all people with asthma (section 1.14). Since these are personalised by definition, for those on AIR they should be designed for AIR.
Asthma + Lung UK	Guideline	012	004 - 011	**1.7.1** Asthma + Lung UK recommends that instructions be made and explained clearly to ensure that patients fully understand how to use their inhaler.	Thank you for your comment This is covered earlier in the guideline (recommendations 1.6.4 to 1.6.8)
Asthma + Lung UK	Guideline	012	004 - 011	**1.7.1** Asthma + Lung UK recommends that prescribing be set up as to allow patients to be	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				able take their inhaler as often as needed within both MART and AIR treatment regimes.	The committee agrees, but instruction on how to organise prescription services is beyond its remit.
Asthma + Lung UK	Guideline	012	004 - 011	**1.7.1** Asthma + Lung UK recommends that inhaler overuse be monitored and that this be tailored to the patient's treatment regime and reviewed regularly at asthma reviews.	Thank you for your comment Inhaler usage should be monitored and this is referred to in recommendations 1.5.1 and 1.15.1.
Asthma + Lung UK	Guideline	012	004 - 011	**1.7.1** Asthma + Lung UK recommends that guidance specifies that patients must know how to manage an asthma attack using an AIR inhaler if prescribed.	Thank you for your comment This should be part of the personalised asthma action plan as referred to in your previous comment (ID681)
Asthma + Lung UK	Guideline	012	004 - 011	**1.7.1** Asthma + Lung UK recommends that the guidance provide a definition of what good asthma control looks like for patients on AIR.	Thank you for your comment Asthma control (and a description of poor control) is described in the Terms Used section. This is the same for people on AIR as it is for those on other regimens.
Asthma + Lung UK	Guideline	012	012 - 017	**1.7.2**	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Asthma + Lung UK recommends providing information to patients on why and how MART works in order to ensure patients feel in greater control of their condition and its treatment. Maintenance and Reliever Therapy (MART) | Asthma + Lung UK (asthmaandlung.org.uk)	A link to your website will be included in the Asthma Pathway
Asthma + Lung UK	Guideline	012	012 - 017	**1.7.2** Asthma + Lung UK recommends including guidance that personalised asthma action plans specifically designed for patients using an AIR inhaler should be given to patients prescribed MART. Download MART asthma action plan | Asthma + Lung UK (asthmaandlung.org.uk)	Thank you for your comment The committee agrees that personalised action plans should be offered to all people with asthma (section 1.14). Since these are personalised by definition, for those on MART (we assume you mean MART rather than AIR) they should be designed for MART.
Asthma + Lung UK	Guideline	012	012 - 017	**1.7.2** Asthma + Lung UK recommends that instructions be made and explained clearly to ensure that patients fully understand how to use their inhaler.	Thank you for your comment This is covered earlier in the guideline (recommendations 1.6.4 to 1.6.8)

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Asthma + Lung UK	Guideline	012	012 - 017	**1.7.2** Asthma + Lung UK recommends that prescribing be set up as to allow patients to be able take their inhaler as often as needed within both MART and AIR treatment regimes.	Thank you for your comment The committee agrees, but instruction on how to organise prescription services is beyond its remit.
Asthma + Lung UK	Guideline	012	012 - 017	**1.7.2** Asthma + Lung UK recommends that guidance specifies that patients must know how to manage an asthma attack using a MART inhaler if prescribed.	Thank you for your comment This should be part of the personalised asthma action plan which all people with asthma should have (recommendation 1.14.1)
Asthma + Lung UK	Guideline	012	012 - 017	**1.7.2** Asthma + Lung UK recommends that the guideline must provide clear guidance to clinicians as to when a patient can move from MART to AIR, and what good control on MART looks like.	Thank you for your comment Decreasing therapy is covered in section 1.10
Asthma + Lung UK	Guideline	012	Lines acros s multip	**1.7** The draft guideline doesn't include an alternate treatment pathway for patients that are unable to be treated with formoterol. GINA 2023 outlines	Thank you for your comment The committee believes that the evidence in adults strongly favours the AIR then MART

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			le pages	an alternate pathway using SABA as the reliever.[xxx] While efforts to reduce SABA prescribing are laudable and in line with Asthma + Lung UK's preferences for asthma care, care must patient-centric and allow for variation in treatment to meet patient need.	strategy over the traditional treatment pathway and have therefore recommended this. The remit of NICE and therefore of this BTS/NICE/SIGN guideline is to offer guidance on the most cost-effective management strategy.
Asthma + Lung UK	Guideline	013	008 - 012	**1.7.5** Asthma + Lung UK recommends that the guidance mandate that clinicians counsel the person on the potential rare side effects on LTRA. Share information about the medication Montelukast | Asthma + Lung UK (asthmaandlung.org.uk)	Thank you for your comment. A link to the MHRA DSU has been added.
Asthma + Lung UK	Guideline	013	016 - 018	**1.7.6** Asthma + Lung UK recommends that the guidance give explicit advice to clinicians on giving the LAMA as a separate inhaler to ensure that the patient is on MART plus LAMA rather than a closed triple therapy (ICS/LABA/LAMA) which is not appropriate for MART.	Thank you for your comment 1.7.6 suggests a trial of the addition of a LAMA, so it would seem easier to add in a LAMA-only inhaler to the current MART rather than changing inhalers completely for what might be a relatively short period of time. However, there is no evidence to prefer this to the option of changing to a triple maintenance inhaler as you

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					describe, and so the recommendation leaves this open.
Asthma + Lung UK	Guideline	013	019 - 021	**1.7.7** Asthma + Lung UK recommends that this guidance must align with the Severe Asthma pathway AAC-Pathway-Overview_v.1.pdf (healthinnovationoxford.org) so that the same criteria are used to ensure a timely referral. The guideline also needs to stipulate not just whether a person is on a specific medication, but whether they have had trials of medicines.	Thank you for your comment This recommendation is compatible with the AAC pathway. In addition, it is worded so as to allow that the person has either had a trial of the listed medication or is still on them.
Asthma + Lung UK	Guideline	013	019 - 021	**1.7.7** Asthma + Lung UK recommends that patients' inhaler technique be reviewed at every possible contact and that the inhaler choice should also be reviewed before making a referral.	Thank you for your comment Recommendation 1.6.6 covers this (it doesn't specifically mention referral, but it does mention poor control which would be the reason for referral in the context of 1.7.7)
Asthma + Lung UK	Guideline	013	019 - 021	**1.7.7** Asthma + Lung UK recommends that all changes from one treatment pathway to another should be made in consultation with the patient	This is an overarching principle and not confined to asthma management. The committee does not think it needs to be stated here.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and that appropriate information and support should be given throughout to inform the patient of this process, about why the change is important, and providing information and the new treatment pathway.	
Asthma + Lung UK	Guideline	013	019 - 021	**1.7.7** Asthma + Lung UK recommends that the guidance should explicitly state that it is not appropriate to switch a patient's treatment without consultation with the patient.	Thank you for your comment This is an overarching principle and not confined to asthma management. The committee does not think it needs to be stated here.
Asthma + Lung UK	Guideline	013	019 - 021	**1.7.7** Asthma + Lung UK recommends that clinicians be advised to document all factors that are suggestive of poor control and the potential reasons for this, as well as any objective evidence to support this including ACT, cACT, FeNO, Peak Flow).	Thank you for your comment Adequate documentation is a core part of good medical practice in any branch of medicine, and the committee does not think it needs to be stated here.
Asthma + Lung UK	Guideline	013	019 - 021	**1.7.7** Asthma + Lung UK recommends clinicians be advised to initiate follow-up appointments with patients be arrange to assess control and satisfaction with new any treatment and that this	Thank you for your comment Recommendation 1.6.3 states that there should be follow up after any treatment change.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				should be documented along with any objective evidence to support this.	
Asthma + Lung UK	Guideline	014	004 - 006	**1.7.8** Asthma + Lung UK recommends that the guidance include the consideration that it may be difficult for patients to understand a significant change in approach by moving to MART or AIR and that this can be alleviated by providing information from Asthma + Lung UK and an appropriate asthma action plan.	Thank you for your comment. A link to the Asthma + Lung UK website will be included in the Asthma Pathway
Asthma + Lung UK	Guideline	014	007 - 014	**1.7.9** Asthma + Lung UK recommends that the guidance include the consideration that it may be difficult for patients to understand a significant change in approach by moving to MART or AIR and that this can be alleviated by providing information from Asthma + Lung UK and an appropriate asthma	Thank you for your comment. Information giving is important. Designing information for patients was not part of the committee's remit. A link to the Asthma + Lung UK website will be included in the Asthma Pathway.
Asthma + Lung UK	Guideline	014	015 - 024	**1.7.10** Asthma + Lung UK recommends that the guidance include the consideration that it may be difficult for patients to understand a significant change in approach by moving to	Thank you for your comment. All people with asthma should have a personalised action plan (recommendation 1.14.1)

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				MART or AIR and that this can be alleviated by providing information from Asthma + Lung UK and an appropriate asthma action plan.	
Asthma + Lung UK	Guideline	015	001 - 002	**1.7.12** Asthma + Lung UK recommends that this guidance must align with the Severe Asthma pathway AAC-Pathway-Overview_v.1.pdf (healthinnovationoxford.org) so that the same criteria are used to ensure a timely referral. The guideline also needs to stipulate not just whether a person is on a specific medication, but whether they have had trials of medicines.	Thank you for your comment 1.7.12 refers to one specific situation where a referral is indicated. It is compatible with the AAC pathway document.
Asthma + Lung UK	Guideline	015	003	**1.8** Asthma + Lung UK recommends suggesting that an MDI and spacer should be the first choice of inhaler for children aged 5-11.[xxxi]	Thank you for your comment Choosing the appropriate inhaler device is covered in section 1.6.
Asthma + Lung UK	Guideline	015	003	**1.8** Asthma + Lung UK recommends that the guidance should advise clinicians to provide information about the medicines prescribed and their effect upon patients' conditions. Asthma	Thank you for your comment. Asthma + Lung UK is listed as one of the patient organisations with a link to your website.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and your child | Asthma + Lung UK (asthmaandlung.org.uk)	
Asthma + Lung UK	Guideline	015	003	**1.8** Asthma + Lung UK recommends that the guidance mandate that patients be provided with an appropriate asthma action plan that provides adequate information on their condition, care, and what to do in the event of an asthma attack.	Thank you for your comment Provision of Asthma Action Plans is covered in section 1.14
Asthma + Lung UK	Guideline	015	003	**1.8** Asthma + Lung UK recommends that the guidance mandate that clinicians ensure children are prescribed with adequate inhalers so that the child has access at all times in multiple settings including at school, with carers, etc.	Thank you for your comment This is very reasonable but advice about numbers of inhalers to provide is not in the scope for this guideline update and there are no equivalent recommendations in the current versions of NICE or BTS/SIGN guidelines.
Asthma + Lung UK	Guideline	015	003	**1.8** Asthma + Lung UK recommends that the guidance advise that clinicians should provide information to support parents/carers' liaison with schools and nurseries. Asthma at school and nursery | Asthma + Lung UK (asthmaandlung.org.uk) and Asthma friendly	Thank you for your comment. Asthma + Lung UK is listed as one of the patient organisations with a link to your website.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				schools - Transformation Partners in Health and Care	
Asthma + Lung UK	Guideline	015	010 - 013	**1.8.2** Asthma + Lung UK recommends that the guidance advises clinicians to provide clear information and instructions about MART for parents, carers, and teachers so that all know how to use the inhalers both routinely and in emergency.	Thank you for your comment. Asthma + Lung UK is listed as one of the patient organisations with a link to your website.
Asthma + Lung UK	Guideline	015	010 - 013	**1.8.2** 1.8.2's inclusion of off-license medication, though helpful, may need further exploration in implementation as some prescribers may feel unhappy or unwilling to prescribe in this way, especially with a completely novel way of approaching asthma management with MART for children. Similarly, non-prescribing asthma clinicians such as nurses, and pharmacists may rely on other prescribers for their medication choices. A significant communication strategy with education and training will be needed to ensure that a lack of understanding of different inhaler choices, and NICE's information on off-	Thank you for your comment The guideline recognises that not all prescribers will be willing to use MART in children and has therefore included an alternative pathway.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				license prescribing does not impact patient access to guideline-level care.	
Asthma + Lung UK	Guideline	016	018 - 021	**1.8.7** Asthma + Lung UK recommends that the guidance be amended to advise that children should also be referred to an asthma specialist if their diagnosis is uncertain.	Thank you for your comment 1.8.7 is about one specific reason for referring. It isn't intended as a list of all the possible reasons for referral.
Asthma + Lung UK	Guideline	018 - 019	023 - 007	**1.10.2** Asthma + Lung UK recommends that clinicians be advised to document all factors that are suggestive of poor control and the potential reasons for this, as well as any objective evidence to support this including ACT, cACT, FeNO, Peak Flow).	Thank you for your comment Good documentation is a core principle of medical practice and should not need a recommendation here.
Asthma + Lung UK	Guideline	018 - 019	023 - 007	**1.10.2** B Provide clear instructions on what to do if control is lost. Arrange follow up to assess control and satisfaction with new treatment and	Thank you for your comment This is covered in 1.10.3.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				document along with any objective evidence to support this)	
Asthma + Lung UK	Guideline	019	008 - 011	**1.10.3** Asthma + Lung UK recommends including the use ACT, cACT, Peak flow within 1.10.3.	Thank you for your comment As this recommendation says that the method of monitoring the reduction should be agreed with the patient, it would be contradictory to specify how this should be done.
Asthma + Lung UK	Guideline	019	012 - 013	**1.10.4** Asthma + Lung UK recommends that the guidance include links to Asthma + Lung UK's Asthma Action Plans and that the appropriate plan (matching the patient's course of treatment) be provided and explained to patients.	Thank you for your comment Apart from the fact that one particular plan is not mentioned, this is what 1.10.4 says.
Asthma + Lung UK	Guideline	019	019 - 022	**1.12** Asthma + Lung UK recommends that additional guidance be provided to patients during their pregnancy explaining how asthma is affected by pregnancy. This should include providing tailored information Asthma and pregnancy | Asthma + Lung UK (asthmaandlung.org.uk)	Thank you for your comment. The recommendations in section 1.12 have been transferred from SIGN158, but the topic area was not reviewed as part of this update. The supporting text remains available in SIGN158.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Asthma + Lung UK	Guideline	020	027 - 028	**1.13.3** Asthma + Lung UK recommends that 1.13.3 should be expanded to include further detail and examples of why and how some adolescents struggle with their inhalers. This must include tailored information. Asthma and young people | Asthma + Lung UK (asthmaandlung.org.uk)	Thank you for your comment NICE recommendations focus on the action to be performed and not on the reasoning behind this. The committee agree that tailored information is important.
Asthma + Lung UK	Guideline	021	002 - 018	1.14.1 Asthma + Lung UK recommends that 1.14.1 include links to Asthma + Lung UK's asthma action plans. These are available for adults and children, for AIR, MART, Preventer & reliever treatment plans, in a number of languages and in a number of formats. The provision of these should be tailored to suit the patient.	Thank you for your comment. A link to the Asthma + Lung UK website will be included in the Asthma Pathway
Asthma + Lung UK	Guideline	021	002 – 018	**1.14** In order to aid patient self-management, Asthma + Lung UK recommends the guideline advise the use of airways diagrams and models to explain airway Iinflammation in asthma and how inhalers work. Explain that SABA alone does not treat the underlying airway inflammation	Thank you for your comment Section 1.14 recommends self-management education programmes but details about what these should cover is outside our scope.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				which causes symptoms and risks flare-ups, and that overuse of SABA is associated with increased risk of asthma attacks. We know from patient surveys that only 36% of people strongly feel they can self-manage their condition.[xxxii] Measures like this could improve patients' abilities to confidently perform self-management.	
Asthma + Lung UK	Guideline	021	002 – 018	**1.14.1** The guideline recommends education but doesn't specify what kind and how this should be delivered to clinicians. Asthma + Lung UK recommends that the guideline address this and provide clarity, and include signposting to Asthma and Lung UK resources as an addition to any education provided.	Thank you for your comment Section 1.14 recommends self-management education programmes but details about what these should cover is outside our scope.
Asthma + Lung UK	Guideline	021	002 – 018	**1.14.1** Asthma + Lung UK recommends that 1.14.1. should include other triggers too as these may have a greater impact on certain patients. Guidance should also be provided on understanding asthma triggers. More information	Thank you for your comment. This is a legacy recommendation from the 2017 guidance. No new evidence review was undertaken, and we cannot make substantial additions to it. However, the recommendation

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				is available at Asthma triggers | Asthma + Lung UK (asthmaandlung.org.uk)	has been changed slightly to indicate that other triggers should be considered.
Asthma + Lung UK	Guideline	021	002 – 018	**1.14.1** Asthma + Lung UK recommends that 1.14.1 should also include guidance to clinicians to prompt asthma patients to have relevant vaccinations; this ask should be tailored to the patient and consider their eligibility for suggested vaccinations.	Thank you for your comment Vaccination advice is not regarded as part of self-management plans.
Asthma + Lung UK	Guideline	021	002 – 018	**1.14.1** Asthma + Lung UK recommends that weight management be included within 1.14.1 and the guideline should include weight reduction in the treatment plan for obese patients with asthma.[xxxiii]	Thank you for your comment Weight reduction is very important, but it this is about management of a comorbidity rather than asthma itself. There is guidance elsewhere on weight reduction and it is inappropriate to include it in general advice about self-management.
Asthma + Lung UK	Guideline	021	002 – 018	**1.14.1** Asthma + Lung UK recommends that exercise be included within 1.14.1 and aerobic and strength exercises be included in tailored	Thank you for your comment Exercise is important, but this point is not specific to asthma, nor just to people with

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				treatment plans for obese patients. Asthma + Lung UK's physical activity resources are patient-focused and should be included within the draft guidance.	asthma who are living with obesity. There is guidance elsewhere on exercise and the committee do not think it is necessary to include it in general advice about self-management.
Asthma + Lung UK	Guideline	021	002 – 018	**1.14.1** Asthma + Lung UK recommends that 1.14.1 should specifically explain what patients need to do to stay well, what to do when they get symptoms and what to do during an asthma attacks. This guidance should be tailored and included in their asthma action plan.	Thank you for your comment What to do when symptoms arise and what to do during an asthma attack are both part and parcel of standard action plans. The committee do not think this needs stating.
Asthma + Lung UK	Guideline	021	002 – 018	**1.14.1** Asthma + Lung UK recommends that the guidance should advise clinicians to specifically explain how the person should access more medication and when/how to access NHS services. This should be explained in a way that ensures clarity for the patient and tailored if necessary to meet individuals' access needs.	Thank you for your comment 1.14.1 offers generalisable advice about action plans and education. How to access medication and access NHS services is (a) subject to local or individual variation (b) not just about asthma.
Asthma + Lung UK	Guideline	021	019 - 023	**1.14.2** Amend phrasing: change "check inhaler technique" to "observe inhaler technique".	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Inhaler technique must be demonstrated by the patient and approved or corrected by a clinician who has undertaken post-graduate training in asthma.	The advice to check inhaler technique in these circumstances is already given earlier in the guideline (section1.6). The wording of 1.14.2 has been changed accordingly.
Asthma + Lung UK	Guideline	022	012 - 021	**1.14.6** Amend phrasing: change "Structured protocols for asthma reviews" to read "Structured protocols and templates for asthma reviews".	Thank you for your comment This recommendation is taken from the BTS/SIGN guidance. There has not been an evidence review for this update and the recommendation has therefore not been amended.
Asthma + Lung UK	Guideline	022	012 - 021	**1.14.6** Asthma + Lung UK recommends including the use of apps within the guidance.	Thank you for your comment This recommendation is taken from the BTS/SIGN guidance. There has not been an evidence review for this update and the recommendation has therefore not been amended.
Asthma + Lung UK	Guideline	022	012 - 021	**1.14.6**	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Asthma + Lung UK recommends including Asthma + Lung UK Breathe Easy groups and online support groups.	This recommendation is taken from the BTS/SIGN guidance. There has not been an evidence review for this update and the recommendation has therefore not been amended.
Asthma + Lung UK	Guideline	022	012 – 021	**1.14.6** Asthma + Lung UK recommends that the guideline specify here that asthma reviews must be conducted in person to ensure they are of the highest possible quality and comprehensively cover the patients' condition and management.	Thank you for your comment The committee agrees, but 1.14.6 is more about novel ideas that should aid implementation of reviews rather than emphasising a long-established principle (albeit one which is not always carried out).
Asthma + Lung UK	Guideline	022	016	**1.14.6** Asthma + Lung UK recommends that line 16 be amended to provide specific detail and clarity as to what pharmacists' roles are and how they can best support patients.	Thank you for your comment 1.14.6 is about strategies to aid in implementing self-management, not about details of the roles of healthcare professionals.
Asthma + Lung UK	Guideline	023	002 - 006	**1.15.1** Asthma + Lung UK recommends that a single episode of unscheduled care for asthma should	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				trigger action as per NICE Quality Statement and BTS Care Bundle. Poor follow-up care after unplanned or emergency admissions increases patients' risk of mortality.[xxxiv]	The committee supports the NICE Quality statements and the BTS Care Bundle for asthma attacks, but neither of these refers to entering people on a risk stratification system, which is the purpose of 1.15.1.
Asthma + Lung UK	Guideline	023	002 - 006	**1.15.1** Asthma + Lung UK recommends that 1.15.1 should include "number of oral corticosteroid doses in last 12 months" within its risk factors.	Thank you for your comment This has been added
Asthma + Lung UK	Guideline	023	008 - 011	**1.16.1** Asthma + Lung UK recommends including "observe inhaler technique" within all contacts. Inhaler technique must be demonstrated by the patient and approved or corrected by a clinician who has undertaken post-graduate training in asthma.	Thank you for your comment Inhaler use has been covered in section 1.6 of the guideline
Asthma + Lung UK	Guideline	023	012 - 013	**1.16.2** Asthma + Lung UK recommends including the use of apps within the guidance.	Thank you for your comment This is a rather vague request. The guideline cannot recommend apps non-specifically. Apps did feature in the evidence for some questions (e.g. digital inhalers) but the committee did not

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					feel that any particular app should be recommended in those instances.
Asthma + Lung UK	Guideline	General	General	This draft guidance has a focus on diagnosis and routine management of asthma. Asthma + Lung UK would have liked to have seen updated guidance to include acute asthma and severe asthma in order to produce a single set of guidelines for all asthma patients. Correct treatment of severe asthma relies upon proactive identification of patients with poor asthma control and an ability to optimise their treatment.[xxxv] This, in turn, relies upon a detailed understanding of the condition within primary care; given this guidance's focus on clinicians using patients' clinical history to inform diagnosis in conjunction with objective testing, we would have hoped to see a similar pathway outlined within this guidance for diagnosis and treating severe asthma.	Thank you for your comment Management of acute asthma is outside the scope of this guideline. BTS & SIGN will be producing updated guidance on this.
Asthma + Lung UK	Guideline	General	General	Inclusions of smoking cessation advice targeted at pregnant women (1.12.2) are vital to include, but this should be taken further by emphasising the importance of smoking cessation throughout	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				the guidance as an essential part of good asthma care. Smoking cessation could be included where smoking is mentioned in 1.5 and should be explored in 1.14. Asthma + Lung UK recommend the draft guidance advise clinicians to undertake very brief advice (VPA) at any appropriate appointment and/or review in primary care, and that comprehensive smoking cessation support be recommended for people with asthma when in secondary care. Further detail should be included within the draft guideline from the NICE smoking cessation guideline.	Smoking is referred to at several points in the guideline, including those you mention. The dangers of smoking are well documented and there are useful resources available from other sources about preventing or quitting smoking. The committee has tried to balance the number of references to this, paying it due regard but not turning an asthma guideline into a smoking cessation guideline.
Asthma + Lung UK	Guideline	General	General	There is concern that trial of treatment is not featured within the draft guideline. This does not reflect pragmatic use of trial of treatment in real world asthma care and should be addressed; trial of treatment dovetails well with guidance to treat people immediately if they are acutely unwell at presentation (1.1.5) and can provide relief for asthma symptoms quickly.	Thank you for your comment NICE's CKS on newly diagnosed asthma advocates a trial of an LTRA, and then other agents if this does not achieve control, in people who are already diagnosed with asthma and are receiving an inhaled steroid. This is in keeping with the previous version of NICE's asthma guideline. The management recommendations

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				NICE's December 2023 Clinical Knowledge Summary for newly diagnosed asthma recommends trial of treatment for add-on therapies if low-dose ICS doesn't allow adequate asthma control[xxxvi] – this contrasts with the guidance's omission of trial of treatment.	have now been changed and the CKS will change accordingly when this guideline update is published.
Asthma + Lung UK	Question 1	General	General	Would it be challenging to implement of any of the draft recommendations? Please say why and for whom. Please include any suggestions that could help users overcome these challenges (for example, existing practical resources or national initiatives. The draft guideline would see significant changes made to the diagnosis and treatment of asthma; the use of a diagnostic algorithm is replaced with a stepwise 'rule-in' method, the use of SABA inhalers is set to be significantly reduced and supplanted in their role as the primary reliever prescribed for newly-diagnosed patients, and the role of clinical history within the asthma diagnostic pathway has been increased. These changes, and others, require a detailed implementation plan and appropriate clinician education in order to be fully realised and to ensure they afford optimum benefit to patients.	Thank you for highlighting these implementation issues. Your comments will be considered by NICE where relevant support activity is being planned.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Asthma + Lung UK knows from qualitative research with clinicians that the use of a diagnostic algorithm aids novice clinicians and who have limited experience in diagnosing asthma. In order to ensure the stepwise diagnostic pathway works, the new guideline must be paired with clear, accessible resources that clarify (much as a flowchart would) how to progress a person's diagnosis. The prospective changes being made to the role of SABA are welcome but must be correctly implemented: clinicians that have routinely prescribed SABA for their whole career must be supported with appropriate resources that highlight the shortcomings of SABA use (and especially of its overuse), and explain the benefits of MART and AIR treatment regimes. Asthma + Lung UK is well placed to help in this, having detailed resources aimed at both clinicians and patients that explain newer inhaled therapies for asthma. The role of SABA must also be carefully dealt with because of patients' potential concerns about being moved away from a treatment they trust. We know that	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				a factor contributing to SABA overuse is the relationship between SABA use and near-immediate relief in many people. SABA inhalers may be requested by patients as 'rescue inhalers' or to offer peace of mind. This must be correctly managed by clinicians and must not negatively impact a person's use of MART or AIR. Again, in this, Asthma + Lung UK's patient-facing resources would be helpful in addressing this and we have recommended that these be included in the draft guidance. The role of a person's clinical history and its impact on their diagnostic journey has also changed within this draft guidance, presenting a further potential obstacle to their implementation. The use of a detailed clinical history in guiding diagnosis relies on clinicians having sufficient training and experience with asthma and respiratory health in general. This training must be widespread to ensure equitable access to healthcare and universal adherence to the draft guideline and must be accessible to clinicians, with protected training time and sufficient funding.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				In addition to these issue-specific concerns, the draft guidance will rely on sufficient primary and secondary care capacity for good implementation. Primary care's capacity for diagnostic testing is of particular concern for FeNO and spirometry, neither of which are universally available despite their inclusion in the draft guideline and FeNO's key role in the children's diagnostic pathway. Secondary care's capacity is also of concern: Evidence Review K states that 30% of children in the children's diagnostic pathway are expected to be referred to secondary care for bronchial challenge testing, placing an increased strain on already limited resources. Similarly, the lack of severe asthma's inclusion within this guidance risks people going without sufficient care due to referral delays, potentially leading to care only being delivered in response to emergency admissions.	
Asthma + Lung UK	Question 2	General	General	**Would implementation of any of the draft recommendations have significant cost implications**?	Thank you for highlighting this.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				While there are costs attached to the successful implementation of the draft guideline, these are outweighed significantly by the cost of inaction or failed implementation. Asthma + Lung UK's 'Saving Your Breath' report shows the scale of savings that can be made by funding and providing better care earlier through an increased focus on proper implementation of diagnostic pathways and correct prescribing. We know that if FeNO were made available to all GPs across England, for example, its use could save almost £100m by optimising asthma treatment.[xxxvii] The same paper recommended that spirometry also be fully funded across the country, an essential element to ensuring the success of the draft guideline given the role of spirometry and FeNO in the diagnostic pathway. Appropriate funding must be given to ensure that clinicians are trained to provide good quality asthma care. This would include standardising training standards and educating clinicians on the key changes being made within the draft guideline (SABA-free prescribing, changes to the diagnostic pathway, guiding patient self-management) and providing good quality,	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				accessible patient-facing resources that can aid clinicians in explaining asthma and its treatment to people. Standardised training is also essential to ensure clinicians are able to correctly diagnose and treat asthma in children. Throughout the submission below Asthma + Lung UK's resources have been highlighted where appropriate. The inconsistent and disparate funding of objective tests such as FeNO and spirometry must also be amended in order for this guideline to be successfully implemented. Such service readiness work is essential given that FeNO is only estimated to be accessible in 53% of PCNs across the country,[xxxviii] though this is an improvement upon FeNO accessibility pre-AAC. ICBs have been slow to resume pre-pandemic levels of spirometry (itself insufficient)[xxxix] and significant improvement must be made nationally to ensure spirometry is accessible for use in diagnosing asthma as the guideline dictates. Asthma + Lung UK have called for ICBs to recognise all costs involved in providing spirometry, including training and accreditation, and for ICBs to develop local payment	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				mechanisms to ensure no one is disadvantaged when setting up a service to meet local need. Similarly, Asthma + Lung UK has called for NHS England to incentivise spirometry within the GP contract and to provide specific funding to improve spirometry training within primary care.[xl]	
AstraZeneca UK	Additional questions – implementation and indicators included at the start of this document	General	General	**Cost of implementation:** Changing clinical practice given pre-existing variability in asthma management in the UK will require investment. By eliminating the use of SABA monotherapy and adopting an ICS/formoterol single track approach to pharmacological intervention, patients and the NHS can expect to see health and economic benefits through reduced exacerbations, hospital admissions and healthcare resource utilisation. We welcome the acknowledgement of the following in the draft guideline, '*the prescription of SABA alone has been commonplace, although this is becoming less so because of the publicity around asthma deaths. The*	Thank you for highlighting this.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				recommendation will reduce its use further. The replacement therapies in adults and children are more expensive, but they should produce clinical benefits and cost-savings through a reduction in exacerbations.' Ultimately, by adopting the approach laid out in this guideline and focussing on improving patient outcomes, NICE, British Thoracic Society (BTS) and Scottish Intercollegiate Guidelines Network (SIGN) are ensuring the greatest benefits to patients and the healthcare system.	
AstraZeneca UK	Additional questions – implementation and indicators included at the start of this document	General	General	**Implementation:** As the guideline committee has already highlighted, the treatment pathway recommended represents a significant change in practice, but this is a much-needed change. We highlight three potential considerations for implementation: i. Integrated Care Boards (ICBs) and regional clinical networks should be encouraged to adopt the one-track pathway recommended in the draft	Thank you for highlighting this

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				guideline. There are currently >60 sub-national guidelines for asthma across the UK, resulting in significant and unnecessary variation in practice and outcomes. Encouraging ICS and regional networks to adopt the one-track pathway (i.e., not having an alternative/traditional pathway) should significantly reduce the variation in practice and allow for faster adoption of national initiatives for implementation as suggested below. ii. Indicators and incentives should be in place to facilitate and accelerate adoption, as they play an important role in supporting the NHS to deliver high quality care and to improve patient outcomes, with a considerable body of evidence demonstrating that incentives are effective in changing clinical practice. NICE	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				should update their indicators for asthma, with two for pharmacological intervention (suggested below). These indicators should then be carried through into the Quality and Outcomes Framework (QOF), to support change in prescribing behaviour, in line with the updated guideline. SABA monotherapy reduction incentives as part of the national Investment and Impact Fund (IIF) have contributed to the observed reduction in prescribing over the past couple of years. Since the IIF incentives have been switched off, ICBs such as Bedfordshire, Luton and Milton Keynes (BLMK) have instated local level SABA reduction incentives, demonstrating the need for incentives to assist with implementation.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				▪ **RESP NEW:** Percentage of patients on the QOF Asthma Register who received six or more SABA inhaler prescriptions* over the previous 12 months OR Percentage of patients on the QOF Asthma Register who received 0 SABA inhaler prescriptions over the previous 12 months. ▪ **RESP NEW:** Percentage of patients on the QOF Asthma Register who are on ICS/formoterol inhaler as AIR or MART. iii. Tools, educational resources, and quality improvement programmes should be introduced to help clinicians with implementation of the guideline, in particular adoption of AIR/MART. ▪ PCRS have developed significant networks within	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				primary care and have a track record of delivering high quality educational initiatives [4]. Given their expertise and experience they would be well positioned to support driving the guideline adoption. ▪ Asthma and Lung UK are well positioned to support patient adoption (post clinical recommendation and prescription) and have resources that are particularly helpful to support education on the recommended treatment pathway e.g., AIR and MART asthma action plans [5] Finally, SENTINEL [6] is an evidence-based quality improvement programme which has been co-developed by commissioners, clinicians, and patients to support the adoption of guideline-based care, specifically MART and AIR focused	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				guidelines. In the pilot PCN where SENTINEL was implemented, in patients who had an asthma review, MART adoption increased, the number of patients prescribed 3 or more SABA inhalers was reduced, and the number of patients with 1 or more exacerbations was decreased post- implementation vs pre-implementation. To date, over 300 PCNs across the UK have adopted SENTINEL [7].	
AstraZeneca UK	Algorithm (Treatment)	003	000	We have explained elsewhere in the response why it is important to specify that only budesonide can be used in combination with formoterol (i.e., budesonide/formoterol) for as-needed use as (AIR therapy. This is also included below* Given this, we suggest changes are made to the blue box in the treatment schematic to change ICS/formoterol to 'budesonide/formoterol' and an additional box/footnote is included stating that only budesonide/formoterol inhalers are licenced for as needed use as AIR therapy. This would also align with the approach taken in the PCRS treatment guide [14] (image attached	Thank-you for your comment Budesonide in the only steroid currently licensed for AIR therapy and this is now indicated in the guideline. However, it is possible that an alternative ICS/formoterol inhaler will obtain a licence in the lifetime of this version of the guideline, and therefore budesonide has not been specified within recommendation 1.7.1

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				below for reference) and provide clarity for busy clinicians who might primarily reference the treatment schematic. * All evidence of ICS/formoterol combination inhalers use as needed, as AIR therapy, exists only with budesonide/formoterol. There is no evidence for non-budesonide/formoterol combination inhalers for use as needed and, to our knowledge, no on-going studies. This is reflected in the committee's robust evidence review (Evidence review: P, Table 2) whereby all evidence informing the recommendation for as-needed AIR therapy includes budesonide/formoterol studies only. In addition, it is well established that there could be intra-class differences in the efficacy and safety profile of ICS. This relates, in particular, to combinations with high-potency steroids like fluticasone [11, 12] (i.e., fluticasone/formoterol combination inhalers) and could pose a patient safety risk should they be used as MART therapy.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Clinicians have also expressed that it is important to specify "budesonide" in the ICS/formoterol combination to avoid potential patient safety risks due to unintended off-label use. This could happen, for example, with beclomethasone/formoterol. For this combination, only the lower strength 100/6 is indicated for use as reliever as part of MART therapy (and not the higher 200/6 dose). In contrast, 200/6 budesonide/formoterol is the approved dose as both AIR and MART. Therefore, by not clarifying that "ICS/formoterol" refers to "budesonide/formoterol", there is a risk of unintentionally prescribing 200/6 beclomethasone/formoterol and using a medication off-licence with very little supportive evidence.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				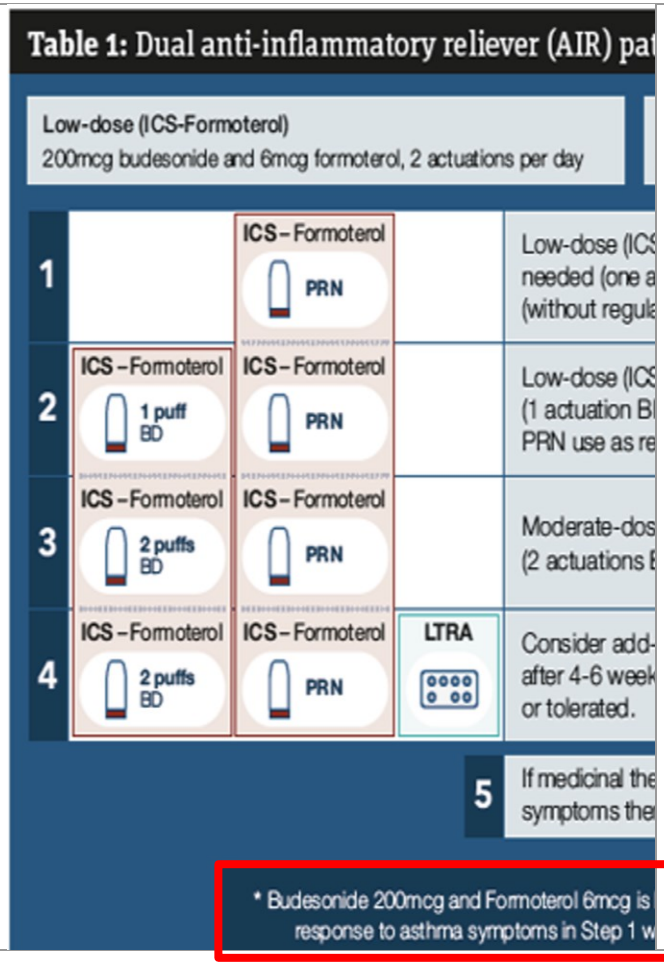	

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Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Source: https://www.pcrs-uk.org/sites/default/files/resource/PCRU_Asthma_Infographic.pdf	
AstraZeneca UK	Algorithm (Treatment)	003	000	Aligned to our comment for recommendation 1.7.1 in the draft guideline (see below for reference)* We suggest 'symptom relief' is replaced with 'anti-inflammatory reliever therapy (AIR therapy) *ICS/formoterol taken as needed for 'symptom relief' does not fully represent the clinical effect of the approach nor does it differentiate from SABA monotherapy reliever, given ICS/formoterol's effect on exacerbations vs SABA monotherapy.	Thank-you for your comment This therapy is symptom driven whatever other benefits it brings. The term AIR therapy has been included.
AstraZeneca UK	Algorithm (Treatment)	003	General	To support clarity, achieve the desired clinical benefits and ensure patient safety, we suggest an amendment to the schematic that states clearly that only ICS/formoterol combination inhalers can be used as part of a MART regimen".	Thank-you for your comment The Figures have been amended and the abbreviation for MART includes clarification that this is using ICS/formoterol.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

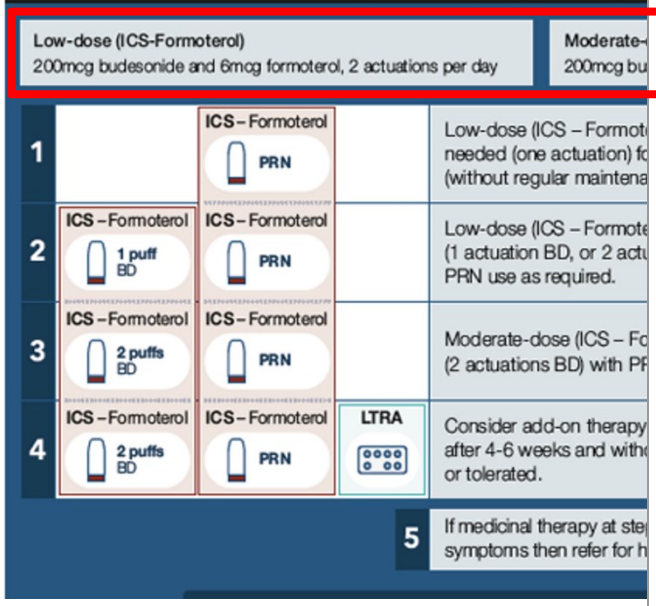
Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Suggested wording: 'ICS/formoterol maintenance and reliever (MART)'	
AstraZeneca UK	Algorithm (Treatment)	General	General	The schematics in the algorithms use the term 'moderate dose'. We suggest amendment of this term to 'medium dose' to improve clarity of guidance and to more closely align with commonly used nomenclature. In addition, we suggest formally defining the terms 'low dose' and 'moderate/medium dose' within the draft guideline but particularly in the treatment algorithms to act as decision-aids for busy clinicians. An example of this highlighted in the red box below from the PCRS update on national guidelines [14]. The definition of dosage is clearly listed alongside the active ingredients to prevent accidental or off-label prescribing. We suggest addition similar to PCRS wording in the draft algorithms.	Thank-you for your comment Moderate is the word chosen by NICE in its existing guideline and the committee agreed to continue this. The cut-offs for low, moderate and high ICS doses are given in the table "Inhaled corticosteroid doses for the BTS, NICE and SIGN asthma guideline" to which links are given in the guideline. The cut-off points are not straightforward because they differ between devices, and by particle size for MDI's, so it is not possible to summarize within an already busy algorithm.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Table 1: Dual anti-inflammatory reliever (AIR) pathway  Source: https://www.pcrsuk.org/sites/default/files/resource/PCRU_Asthma_Infographic.pdf	
AstraZeneca UK	Algorithm (Treatment)	General	General	With reference to the algorithms for people 12 years and older, AstraZeneca suggests that the	Thank-you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				grey box on the right referring to people with uncontrolled asthma who are on the treatment pathway recommended by previous NICE and BTS/SIGN guidelines is headlined '**existing patients on previous treatment combinations'** to improve readability and provide clarity to busy clinicians. In the same way, the new one-track treatment pathway can be clearly labelled **'new patients'** which should improve clarity of guidance and facilitate implementation.	The Figures have been amended
AstraZeneca UK	Algorithm (treatment) & Guideline	General	General	We, along with many clinicians and professional societies, strongly support the treatment pathway and algorithm that is recommended in the draft guideline. The one-track pathway, recommending ICS/formoterol as needed and MART, provides clarity on the optimal approach to asthma management reflecting both clinical end economic considerations and avoids any tendency to continue with current practice and 'business as usual'. This approach has the potential to genuinely transform asthma outcomes in the UK (currently one of the worst in Europe [1]) and address the significant variation of care if implemented systematically.	Thank-you for your comment In general, NICE guidelines defer to the BNF for advice on licensing, cautions etc. rather than detailing all the information whenever a medicine is mentioned. Information is sometimes included within a guideline if there is a particular need, and this has been done for AIR therapy since this is a relatively new concept and unfamiliar to many healthcare professionals. MART has been available for far longer and it should not be necessary to include

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Explicitly explaining which inhalers can be used as MART, and how MART is used, would provide further clarity to users, particularly those who are new to or less experienced in asthma management to reduce the risk of (both from a efficacy and safety perspective) prescribing a ICS/LABA inhaler that cannot be used as MART or providing instructions which do not promote optimal MART use by the patient. Such clarity is key to optimise the guideline for implementation. We propose that a special call out box is included in the guideline and the treatment algorithm that clearly explains that only certain ICS/formoterol inhalers have clinical efficacy and safety evidence supporting their use, and therefore a licence, for MART. We note the definition used in the most recent GINA guideline, p.56 (https://ginasthma.org/wp-content/uploads/2023/07/GINA-2023-Full-report-23_07_06-WMS.pdf) as below and suggest similar wording:	the extra detail (although it is defined in the Terms Used section).

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				'*Maintenance and reliever therapy (MART) – treatment regimen in which the patient uses an ICS-formoterol inhaler every day (maintenance dose), and also uses the same medication as needed for relief of asthma symptoms (reliever doses). MART can be used only with combination ICS-formoterol inhalers such as budesonide/formoterol and beclomethasone/formoterol. Other ICS-formoterol can also potentially be used, but combinations of ICS with non-formoterol LABAs, or ICS-SABA, cannot be used for MART*.' An amendment to the definition of MART on p.25 of draft guidance as well as clear signposting elsewhere in the draft guideline stating "ICS/formoterol maintenance and reliever (MART)" where MART is mentioned is required to support clarity of guidance, achieving the desired clinical benefit with licenced therapies, and to ensure patient safety.	
AstraZeneca UK	Evidence Review: P	005	020	We note that Table 1: PICO characteristics of review question (p. 5-6) in Evidence Review: P (intervention row) specifies that ICS combination inhalers used **as needed (prn)** will be compared	Thank-you for your comment and for highlighting this. For additional clarity, all analyses presenting data on use of ICS combination inhalers has been relabelled as

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				as an intervention to other interventions included in the table. The information specified in the PICO table for the evidence review is then not clearly reflected in the evidence tables included in the remainder of the document. For example, in section 1.1.6 (p. 21) which lists the summary of the 'effectiveness evidence in young people/adults ≥12 year', the distinction between ICS/formoterol used **as needed** as opposed to maintenance is not clear from the section title 1.1.6.2 'SABA compared to ICS/LABA Combination Inhaler'. Similarly, in section 1.1.6.2, the table headings ('Clinical evidence summary: SABA vs ICS/LABA Combination Inhaler in young people and adults ≥12 years' on page 21 and 'Clinical evidence summary: ICS+SABA vs ICS/LABA Combination Inhaler in adults' on p.23 do not make clear that ICS/formoterol prn is being studied. We suggest that these headings as well as the text within the tables accurately reflect that the relevant comparator is the ICS/formoterol	'ICS combination inhaler as needed' in Evidence Review P.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				combination inhaler **prn**, to align with the relevant research question, specified in the guideline PICO table (Table 1) and to improve readability/clarity in the results.	
AstraZeneca UK	Guideline	010	015	**Recommendation 1.6.4** The current draft guideline is the first national guidance that sets out a clear path for clinicians to transition existing patients with uncontrolled asthma on various combinations to the new ICS/formoterol MART regimen. This is a welcome addition to support implementation and provide clarity to clinicians. We fully support the criteria listed for choice of inhaler in recommendation 1.6.4 as it reflects that adherence and technique (strongly linked to device preference) are critical for optimal patient outcomes. The criteria recognise that the ability for a patient to use an appropriate ICS/formoterol inhaler (choice and technique) are the most important factors to support successful implementation of the new treatment pathway. AstraZeneca is in full agreement with NICE/BTS/SIGN that uptake of the pathway will	Thank-you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				ultimately realise the maximum benefit to patients, health system, and the environment. We note that the criteria in recommendation 1.6.4 are based on a thorough review of a large body of evidence and accounts for economic considerations while keeping patient outcomes at the forefront. We strongly believe that maintaining the current outcomes-focused recommendations in the final guideline will give patients and physicians the ability to choose the optimal treatment and as a result maximise patient outcomes and benefits to the health care system. As highlighted in the draft guidance, adopting these recommendations represents a good use of NHS resources and as a result they should be the primary driver of inhaler choice as opposed to focusing predominantly on inhaler acquisition cost. Improving patient outcomes is key to reducing the overall carbon footprint of asthma care and needs to be considered alongside the carbon footprint of devices (given the carbon footprint of care associated with asthma exacerbations). Ultimately, a well-controlled patient is also a low	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				carbon impact patient - this is in line with the BTS Position Statement on Sustainability and the Environment [8] and evidenced by SABINA CARBON [9] and SENTINEL [6]. PCRS also concludes that the least cost-effective inhaler is the one that patients cannot use [10]	
AstraZeneca UK	Guideline	010	015	**Recommendation 1.6.4** While we are in agreement with the criteria included in recommendation 1.6.4, we note that only certain inhalers have demonstrated clinical efficacy and safety as anti-inflammatory reliever or as MART therapy and have regulatory approval/ have licenced indications to be used as such. This is recognised in section 1.6 (page 9) of the draft guideline that states *'licensed indications for asthma inhalers vary between different medicines, different doses and different devices. Not all asthma inhalers are licensed for use in line with the recommendations in this guideline'*. Clinical efficacy and safety evidence should be the primary consideration when it comes to inhaler choice, as such, we suggest that the text	Thank you for your comment. The committee does not believe that this wording would be a useful addition to the bullet points in 1.6.4. This recommendation is about the device only, not the medicine it contains, and all devices should be safe unless misused.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				'Based on available clinical efficacy and safety evidence' should be added as the first bullet in the criteria listed for recommendation 1.6.4.	
AstraZeneca UK	Guideline	011	010	**Recommendation 1.6.6:** We note that the PCRS 2023 guideline [3] and SIGN 158 [13] support prescribing inhalers by brand name and device to account for patient preference and to avoid accidental prescribing of an alternative device. Changing inhaler devices necessitates training the patient on correct inhaler technique to ensure a safe transition, which is associated with additional healthcare resource implications to implement a successful inhaler switch [17] Furthermore, allowing patients and physicians the ability to choose the optimal treatment accounting for patient preference of inhaler device and type will improve patient adherence to treatment, thereby paving the way for improved clinical outcomes and benefits to the health care system.	Thank you for your comment. The committee agrees that brand name prescribing is advisable, and this has been recommended by others. However, pharmacists may occasionally have no option but to offer an alternative.
AstraZeneca UK	Guideline	012	004	**Recommendation 1.7.1:**	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The committee clearly recognises intra-class differences within the long-acting bronchodilator (LABA) class and makes an evidence-based recommendation specifying that formoterol is the only LABA that can be used in combination with an ICS as part of AIR therapy. Therefore, the guidelines should also specify that only budesonide can be used in combination with formoterol (i.e., budesonide/formoterol) for as-needed use as AIR. All evidence generated for ICS/formoterol combination inhalers used as needed, as AIR therapy, exists only for budesonide/formoterol. There is no evidence for non-budesonide/formoterol combination inhalers for use as needed and, to our knowledge, no on-going studies. This is reflected in the committee's robust evidence review (Evidence review: P, Table 2) whereby all evidence informing the recommendation for as-needed AIR therapy includes budesonide/formoterol studies only.	At present the evidence base for AIR therapy is based on budesonide containing products, and the UK licensing reflects this. The committee are concerned that a product that uses an alternative corticosteroid may receive licensing authorisation within the lifetime of this version of the guideline and therefore do not wish to specify budesonide in the recommendation, but in the explanatory text immediately below it is now pointed out that budesonide is currently the only licensed medicine.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				In addition, it is well established that there could be intra-class differences in the efficacy and safety profile of ICS. This relates, in particular, to combinations with high-potency steroids like fluticasone [11, 12] (i.e., fluticasone/formoterol combination inhalers) and could pose a patient safety risk should they be used as MART therapy. Clinicians have also expressed that it is important to specify "budesonide" in the ICS/formoterol combination to avoid potential patient safety risks due to unintended off-label use. This could happen, for example, with beclomethasone/formoterol. For this combination, only the lower strength 100/6 is indicated for use as reliever as part of MART therapy (and not the higher 200/6 dose). In contrast, 200/6 budesonide/formoterol is the approved dose as both AIR and MART. Therefore, by not clarifying that "ICS-formoterol" refers to "budesonide-formoterol", there is a risk of unintentionally prescribing 200/6 beclomethasone/formoterol and using a	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				medication off-licence with very little supportive evidence. The specification of budesonide/formoterol in recommendation 1.7.1 will help towards addressing this safety issue. PCRS [3] and BTS/SIGN 2019 [13] guidelines also note that it is good practice to prescribe inhalers by brand name and device to prevent patients from accidentally being given an alternative device. Considering the above, the guideline should specify that recommendation 1.7.1 is for the use of budesonide/formoterol as needed only: 'Offer a low-dose budesonide/formoterol combination inhaler to be taken as needed …'	
AstraZeneca UK	Guideline	012	005	**Recommendation 1.7.1:** Nomenclature referring to ICS/formoterol taken as needed for 'symptom relief' does not fully reflect the clinical effect of the approach nor does it differentiate from SABA monotherapy reliever, given ICS/formoterol's effect on reduction in exacerbations vs SABA monotherapy.	Thank you for your comment This is now described as AIR therapy.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				We propose 'anti-inflammatory reliever therapy (AIR therapy) to be used instead. We have explained elsewhere why we propose 'budesonide/formoterol' instead of 'ICS/formoterol' to be used throughout. Taken together, we propose the following wording: 'Offer a low-dose budesonide/formoterol combination inhaler to be taken as needed, in response to symptoms, as anti-inflammatory reliever therapy (AIR therapy) for people aged 12 and over with newly diagnosed asthma.'	
AstraZeneca UK	Guideline	012	007	**Recommendation 1.7.1:** We have explained elsewhere why it should be specified that only budesonide can be used in combination with formoterol (i.e., budesonide/formoterol) for as-needed use as anti-inflammatory reliever therapy (AIR therapy). See below for reference* To accurately reflect this, we suggest that the wording in the draft guidance is 'In June 2024, only budesonide/formoterol inhalers were licensed with supporting efficacy and safety evidence, for use as needed, as AIR therapy in	Thank you for your comment The wording you referred to is intended to cover the licensing issue only. The evidence supporting this is in Evidence Review P.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				the UK. The use of any other ICS/formoterol inhalers is off-label' *All evidence of ICS/formoterol combination inhalers use as needed, as AIR therapy, exists only with budesonide/formoterol. There is no evidence for non-budesonide/formoterol combination inhalers for use as needed and, to our knowledge, no on-going studies. This is reflected in the committee's robust evidence review (Evidence review: P, Table 2) whereby all evidence informing the recommendation for as-needed AIR therapy includes budesonide/formoterol studies only. In addition, it is well established that there could be intra-class differences in the efficacy and safety profile of ICS. This relates, in particular, to combinations with high-potency steroids like fluticasone [11, 12] (i.e., fluticasone/formoterol combination inhalers) and could pose a patient safety risk should they be used as MART therapy. Clinicians have also expressed that it is important to specify "budesonide" in the	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				ICS/formoterol combination to avoid potential patient safety risks due to unintended off-label use. This could happen, for example, with beclomethasone/formoterol. For this combination, only the lower strength 100/6 is indicated for use as reliever as part of MART therapy (and not the higher 200/6 dose). In contrast, 200/6 budesonide/formoterol is the approved dose as both AIR and MART. Therefore, by not clarifying that "ICS/formoterol" refers to "budesonide/formoterol", there is a risk of unintentionally prescribing 200/6 beclomethasone/formoterol and using a medication off-licence with very little supportive evidence.	
AstraZeneca UK	Guideline	012	015	**Recommendation 1.7.2:** We have explained elsewhere why it should be specified that only budesonide can be used in combination with formoterol (i.e., budesonide/formoterol) for as-needed use as AIR therapy. See below for reference*	Thank you for your comment The wording of 1.7.2 has been changed. However, the committee do not wish to specify that the inhaler has to contain budesonide as other inhalers may be licensed during the lifetime of this guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				We suggest that the guideline wording is changed to: 'Consider stepping down to a low-dose budesonide-formoterol combination inhaler…' *All evidence of ICS/formoterol combination inhalers use as needed, as AIR therapy, exists only with budesonide/formoterol. There is no evidence for non-budesonide/formoterol combination inhalers for use as needed and, to our knowledge, no on-going studies. This is reflected in the committee's robust evidence review (Evidence review: P, Table 2) whereby all evidence informing the recommendation for as-needed AIR therapy includes budesonide/formoterol studies only. In addition, it is well established that there could be intra-class differences in the efficacy and safety profile of ICSs. This relates, in particular, to combinations with high-potency steroids like fluticasone [11, 12] (i.e., fluticasone/formoterol combination inhalers) and could pose a patient safety risk should they be used as MART therapy.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Clinicians have also expressed that it is important to specify "budesonide" in the ICS/formoterol combination to avoid potential patient safety risks due to unintended off-label use. This could happen, for example, with beclomethasone/formoterol. For this combination, only the lower strength 100/6 is indicated for use as reliever as part of MART therapy (and not the higher 200/6 dose). In contrast, 200/6 budesonide/formoterol is the approved dose as both AIR and MART. Therefore, by not clarifying that "ICS/formoterol" refers to "budesonide/formoterol", there is a risk of unintentionally prescribing 200/6 beclomethasone/formoterol and using a medication off-licence with very little supportive evidence.	
AstraZeneca UK	Guideline	012	015-016	**Recommendation 1.7.2:** Nomenclature referring to ICS/formoterol taken as needed for 'symptom relief' does not fully represent the clinical effect of the approach nor does it differentiate from SABA monotherapy reliever, given ICS/formoterol's effect on reduction in exacerbations vs SABA monotherapy.	Thank you for your comment The term "AIR" is now included in the guideline

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				We propose 'anti-inflammatory reliever therapy (AIR therapy)' to be used instead. We have explained elsewhere why we proposed budesonide/formoterol instead of ICS/formoterol. Taken together, we propose the following wording: 'Consider stepping down to a low-dose budesonide/formoterol combination inhaler used only as needed, as anti-inflammatory reliever therapy (AIR therapy) at a later date if their asthma is controlled'	
AstraZeneca UK	Guideline	025	General	We note that the terms 'low dose' and 'moderate dose' MART are not formally defined in the draft guidance. On p.25, under 'terms used in this guideline', it is stated that 'the terms low dose and moderate dose MART refer to the dosage of the maintenance component of MART'. However, these terms and dosages are not formally defined anywhere in the document. It is recommended that definitions of low and moderate-dose ICS/formoterol are specified in the 'terms used in this guideline' section to provide further clarity on recommended doses for recommendations made in Section 1.7.	Thank you for your comment The term "moderate dose" is used consistently in the guideline. The examples you have used in your comment are both from SIGN158 and are included in a table which explains why some of the recommendation in SIGN158 have been deleted in this guideline update. The Table accurately reflects the deleted wording, not the new terminology. Please also note that a link to "Inhaled corticosteroid doses for the BTS, NICE and SIGN asthma guideline" has been added to the guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				A further point of note is that the term 'moderate' and 'medium' have been used inconsistently in the draft guidance. The term 'moderate' is generally used with relation to severity of disease/asthma and dosage more commonly referred to as 'low, medium, high'. The GINA recommendations guide includes stepping up to 'medium dose' maintenance ICS/formoterol at step 4 [15]. SIGN 158 [13] also refers to dosing as 'medium dose' and use the term 'moderate' in context of severity of disease. The current draft guideline includes references to both 'medium' and 'moderate' dosing interchangeably, for example, it is stated in Table 1b, p.67: '**medium** dose ICS or ICS/LABA' and 'increase the dose of inhaled corticosteroids from low dose to **medium** dose in adults'. The same dosage is referred to as 'moderate' overwhelmingly throughout the draft guidance and treatment algorithms for asthma management. A consistent nomenclature with regards to medium/moderate dose MART is critical to ensure medicines are used correctly in clinical	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				practice and to support optimal adoption and clarity of the guidance. We note that both the PCRS consensus paper [3] on national guidelines and previous NICE NG80 [16] refer to 'moderate dose' but suggest that definitions reflect those on p.80 in the most recent GINA guideline, https://ginasthma.org/wp-content/uploads/2023/07/GINA-2023-Full-report-23_07_06-WMS.pdf to align with more commonly used nomenclature.	
AstraZeneca UK	Guideline	041	030	The draft NICE/BTS/SIGN guidelines recommend to 'refer people to a specialist in asthma care' if uncontrolled on 'moderate' dose MART (newly diagnosed). We support the progressive move towards additional review of patients uncontrolled at moderate doses of ICS. However, we recommend including a disclaimer to clarify that 'specialist' refers to health care professionals in Primary Care (e.g., a GP with specialist interest in asthma, asthma nurse, etc.) to avoid inappropriate referrals to severe asthma services that may create capacity constraints for management of patients with severe asthma.	Thank you for your comment This recommendation does not suggest that a referral should be made to severe asthma services. Severe asthma is out of scope.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				In addition, AstraZeneca recommends highlighting the definition of severe asthma (asthma that is uncontrolled despite adherence with maximal optimised therapy and treatment of contributory factors, or that worsens when high dose treatment is decreased [15]) and encourage prompt referral for patients with suspected severe asthma to severe asthma services. Finally, highlighting biologics currently approved for treatment of severe asthma in the guideline provides an opportunity to raise awareness of the available treatment options amongst healthcare professionals in primary care. This would enable the guidance to serve as an educational tool and support the upskilling of primary care clinicians regarding possible treatment options that they may not be fully aware of. Familiarity and awareness of treatment options available to patients with severe asthma will facilitate rapid referral to correct specialists leading to overall improved asthma outcomes. The list of biologics include:	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				• Benralizumab for treating severe eosinophilic asthma (TA565) • Dupilumab for treating severe asthma with type 2 inflammation (TA751) • Mepolizumab for treating severe eosinophilic asthma (TA671) • Resilzumab for treating severe eosinophilic asthma (TA479) • Tezepelumab for treating severe asthma (TA880) • Omalizumab for treating severe persistent allergic asthma (TA278)	
AstraZeneca UK	Guideline	General	General	There are some inconsistencies in the lexicon used when referring to ICS/formoterol as needed which may cause confusion for those new to or less experienced in asthma management. For example, on page 39 line 20, 'ICS/LABA combination inhaler as needed' was used instead of 'ICS/formoterol combination inhaler as needed'. We propose correcting all such instances to ensure consistency and to avoid confusion. Other instances where this occurred: page 43 line 12; page 43 line 13 etc. We suggest that the	Thank you for your comment. This has been checked.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				use of 'MART' is replaced with 'ICS/formoterol maintenance and reliever (MART)' across the guideline recommendations for clarity, clinical benefit and to ensure patient safety.	
AstraZeneca UK	Guideline	General	General	It is recommended that definitions of 'maintenance' and 'reliever' therapy are made explicit, both prior to introducing guidelines for the pharmacological treatment for asthma (1.6) and in the glossary section of the guideline (p.25). This would provide further clarity to the recommendations made in Section 1.7. We note the definitions used in the most recent GINA recommendations, p.56 (https://ginasthma.org/wp-content/uploads/2023/07/GINA-2023-Full-report-23_07_06-WMS.pdf) and suggest similar wording: • *Maintenance – asthma treatment that is prescribed for use every day (or on a regularly scheduled basis. Medications intended to be used continuously, even when the person does not have asthma symptoms. Examples include ICS-*	Thank you for your comment The committee are not convinced that this is necessary and not that no other stakeholder has suggested this.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				containing medications (ICS, ICS-LABA, ICS-LABA-LAMA), as well as LTRA and biologic therapy. • *Reliever – asthma inhaler taken as needed, for quick relief of asthma symptoms. Examples includes SABA only inhalers that are no longer recommended (e.g., salbutamol (albuterol), terbutaline, ICS-salbutamol) and as needed ICS-SABA. Although as needed ICS-formoterol is better described as an anti- inflammatory reliever, it would still fall under the general "reliever" umbrella too.* Should the term "anti-inflammatory reliever therapy (AIR therapy)" be introduced into the guideline and associated document (e.g., treatment algorithm), we recommend this is also defined. We note the definition used in the most recent GINA recommendations, p.56 (https://ginasthma.org/wp-content/uploads/2023/07/GINA-2023-Full-report-23_07_06-WMS.pdf) and suggest similar	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				wording: • *Anti-inflammatory reliever – reliever inhaler that contains both a low-dose ICS and a rapid-acting bronchodilator. Patients can also use these inhalers as needed before exercise or allergen exposure to prevent asthma symptoms and bronchoconstriction. Non-formoterol LABAs in combination with ICS cannot be used as relievers.* We suggest adding 'only budesonide can be used in combination with formoterol (i.e., budesonide/formoterol) for as-needed use as anti-inflammatory reliever therapy' to the GINA definition above.	
AstraZeneca UK	Guideline, Algorithm (Treatment)	General	General	AstraZeneca strongly supports the treatment pathway and algorithm that are recommended in the draft guideline. The one-track pathway, recommending inhaled corticosteroids (ICS)/formoterol as needed and as part of maintenance and reliever therapy (MART) therapy, provides clarity on the optimal approach to asthma management reflecting both clinical	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and economic considerations, therefore avoids any tendency to continue with current practice and 'business as usual'. This approach has the potential to genuinely transform asthma outcomes in the UK (currently one of the worst in Europe[1]) and address the significant variation in care if implemented systematically. In addition, the proposed guideline reflects several important recent developments: • The safety warning added to the European Medicines Agency (EMA)/ Medicines and Healthcare products Regulatory Agency (MHRA) summary of product characteristics (SmPC) across all short-acting beta-agonist (SABA)-only inhalers highlighting the dangers posed by their over-use without appropriate anti-inflammatory treatment with ICS (SmPC section 4.4 special warnings and precautions for use). The regulators have acknowledged that overuse of SABA-only inhalers may disguise the progression of the underlying disease and contribute to the deterioration of	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				asthma control, increasing the risk of severe asthma exacerbations and death. • The recommendation by the Scottish Medicines Consortium (SMC) supporting the use of ICS/formoterol in the anti-inflammatory reliever space [2]. • The consensus paper [3] published by the Primary Care Respiratory Society (PCRS) earlier this year acknowledged regular inhaled corticosteroids as the mainstay of asthma pharmacological treatment and the risk posed by over-reliance on SABA only inhalers. PCRS has also launched a suite of webinars and online modules to support education and implementation of this approach Asthma and Lung UK have launched anti-inflammatory reliever (AIR) and MART asthma plans with guidance for clinicians to support discussions with patients and adoption of this approach in clinical practice	
AstraZeneca UK	Guideline, Algorithm (Treatment)	General	General	AstraZeneca strongly supports the treatment pathway and algorithm that are recommended in the draft guideline. The one-track pathway provides clarity on the optimal approach to asthma management reflecting both clinical and	Thank you for your comment AIR therapy has now been defined in the guideline and budesonide has been noted as

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				economic considerations, therefore avoids any tendency to continue with current practice and 'business as usual'. However, the pathway could be further optimised to support implementation. Below is the summary of key comments for consideration: I. **Initial management (1.7.1 & treatment algorithm):** It should be made clear that only budesonide/formoterol (BUD/FORM) combination inhalers can and should be used as-needed as anti-inflammatory reliever therapy. There is no clinical evidence (now or in development) to support the efficacy and safety of any other ICS/formoterol (ICS/FORM) combination inhaler for as-needed use in asthma. II. **Treatment algorithm only**: 'Symptom relief' should be replaced with 'Anti-inflammatory reliever (AIR) therapy' in the treatment algorithm for people aged 12 years and over. The term "anti-inflammatory" clearly distinguishes this approach vs SABA monotherapy reliever since SABA monotherapy relievers have no anti-inflammatory properties. The	the only ICS currently licensed. Formoterol is specified as the only LABA to be used in MART.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				nomenclature more accurately reflects the evidence supporting the use of AIR which clearly demonstrates that the approach also prevents exacerbations in addition to symptom relief. III. **MART (1.7.3 & treatment algorithm)**: It should be made clear that only ICS/FORM combination inhalers, with a MART licenced indication, should be used as MART therapy: a. MART should be amended to 'ICS/formoterol maintenance and reliever (MART)' wherever it is referenced b. **AND/OR** there is a clear explanatory text box on the first mention of MART which highlights that only ICS/formoterol combination inhalers with a MART indication should be used. **Choice of inhaler (1.6.4):** AstraZeneca also strongly supports the draft guideline recommendation on inhaler choice which focuses on correct inhaler technique and patient preference. This approach will allow patients and physicians to choose the optimal treatment	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and as a result maximise patient outcomes and benefits to the health care system. As highlighted in the draft guidance, adopting these recommendations represents a good use of NHS resources and as a result the outlined criteria should be the primary driver of inhaler choice.	
Barrett McGrath Education and Mentoring Services Ltd	Guideline – supporting documentation algorithm Diagnosis	002	General	Absolutely excellent algorithm for the diagnosis of asthma for both children from 5 yrs. to 12 yrs. and from 12 to adulthood – I was just wondering if the experts would agree that evidence of significant variability or reversibility is adequate to confirm non-T2 (intrinsic) asthma as their FeNO or eosinophils won't be elevated but they can still have variable airflow obstruction – it's just a concern that some of these patients may be missed. High FeNO or elevated eosinophils is likely to occur in T2+ve (extrinsic) asthma, but potentially not the case in non-T2+ve (intrinsic) asthma.	Thank you for your comment. High FeNO or elevated eosinophils will not capture everyone with asthma, but these are used as a rule-in test. Those with suspected asthma who do not have elevated levels proceed to further testing so would not be missed by virtue of the first test alone.
Barrett McGrath Education and Mentoring Services Ltd	Guideline – supporting documentation algorithm treatment	003	General	I am delighted to see a 'straightforward' treatment algorithm for asthma – this will serve enhance the standardisation of the management of asthma moving forward – and I commend you on this – however I have a few points that I think you might need to consider	Thank you for your comment. The algorithms will be reviewed although clarity of the text will be the priority.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Firstly, the colour of the box that is entitled 'symptom relief' might be best in another colour as 'Blue' might well imply SABA – and that would be a significant risk – I might consider 'amber' reflecting green, amber and red on an action plan perhaps	
Barrett McGrath Education and Mentoring Services Ltd	Guideline – supporting documentation algorithm treatment	003	General	This recommendation in the blue box suggests any ICS/Formoterol – and whilst today that is likely to be Budesonide or Beclomethasone my concern is that if an ICS like Fluticasone were to be added to Formoterol could this pose a risk – just a thought for consideration	Thank you for your comment This concern is noted. However, if a fluticasone inhaler becomes licensed for AIR or MART the ICS dose in that licensed inhaler should be an appropriate one.
Barrett McGrath Education and Mentoring Services Ltd	Guideline – supporting documentation algorithm treatment	003	General	In the descriptor boxes alighted to both MART Low dose and moderate dose the recommendation is and ICS/LABA – I think this could also be a risk as many non-specialised clinicians may not appreciate that this Formoterol only has the MART licence because of it quick onset of action – perhaps you should specify Formoterol as the LABA part – otherwise this is an excellent fairly straightforward treatment algorithm – thank you	Thank you for your comment Agreed. Formoterol is now specified for MART
Barrett McGrath Education and	Overall Guidelines	General	General	Overall, this is a significantly improved asthma guideline – and largely reflects GINA – which is	Thank-you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Mentoring Services Ltd				what many clinicians are using currently – so a massive well done and thank you	
Barts Health NHS Trust	Guideline	004	013	Rec 1.1.3: We agree on the importance of recording in the medical records the basis on which an asthma diagnosis is made. Given the importance of being able to evaluate changes in asthma care, we recommend that both the clinical symptoms underpinning the diagnosis and the supporting objective test are SNOMED coded as well as the diagnosis itself. Would it be within the remit of NICE to suggest the relevant SNOMED codes? Heterogeneity of coding currently limits evaluations.	Thank you for your comment. The committee agree that recording both symptoms and tests would be useful but do not wish to specify exactly how this should be done. NICE guidelines do not usually include advice about SNOMED coding and this BTS/NICE/SIGN guidance is the same.
Barts Health NHS Trust	Guideline	005	026	Rec 1.2. 1: We are concerned the guideline appears to recommend that asthma-like symptoms together with an eosinophil count above local normal range could be sufficient diagnostic testing for a 'confirmed' diagnosis of asthma. Evidence review G itself notes the studies are of low quality and "The committee agreed peripheral eosinophil count does not offer a sufficiently good balance between sensitivity and specificity ratio to inform a diagnosis of asthma as a standalone test" yet this is currently pitched in	Thank you for your comment. Well spotted. Some of the studies in that review attempted to find a compromise value with the best combination of sensitivity and specificity and reported cut-off values below the upper limit of the normal range. The 2 studies which used higher cut-offs both showed good specificity. The sentence you quote should have stated that the studies overall did not suggest that

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Rec 1.2.1. We would suggest the evidence review needs to consider racial variability in blood eosinophil counts (often raised in SE Asian patients) and whether this might impact the recommendation. We are also concerned that there is no mention in the recommendation of considering other common causes of eosinophilia before attributing to asthma. The danger here is that patients with other conditions (e.g. eczema) are labelled as also having asthma without further testing being considered. We would suggest diagnosis by eosinophil count is 'lower' down the diagnostic algorithm after attempted diagnosis by FeNO / spirometry / PEFR variability.	eosinophil count alone could be diagnostic. It has been amended. The committee agrees that other conditions may cause the eosinophil count or the FeNO to be raised, but there are potential confounding factors with most diagnostic tests. Other causes of eosinophilia have been noted in the Terms Used section.
Barts Health NHS Trust	Guideline	005	General	Use of a validated asthma control score (eg ACT, ACQ, RCP3) before and after commencing treatment, and assessing whether MCID improvement is achieved on commencing asthma treatment, could potentially be added to diagnostic algorithms such that patients not achieving clinical response to treatment undergo further investigation. This would extend Rec 1.5.2 and Rec 1.6.3 to conducting such validated symptom scores at first assessment	Thank you for your comment. This is a reasonable suggestion but the value of validated symptom scores during initial assessment was not part of the scope.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				before treatment started and comparing score upon treatment.	
Barts Health NHS Trust	Guideline	012	General	(Rec 1.7.1 - 1.7.4) We strongly support the move to MART / anti-inflammatory relievers as first line in asthma as suggested by GINA and as already supported in local guidelines such as those of Barts Health / North East London ICB.	Thank you for your comment
Barts Health NHS Trust	Guideline	013	013	Rec 1.7.6: The guideline is not clear on how LAMA is added to ICS-LABA. As currently worded it suggests a regular LAMA mono-inhaler should be added to a separate ICS-formoterol MART combination inhaler. There is potential for patients to then accidentally end up on LAMA monotherapy with adverse effect (if they accidentally stop taking the ICS-formoterol once started on LAMA). For many patients moving to a regular ICS-LABA-LAMA inhaler with as needed ICS-formoterol reliever would be better and achieve the same sequencing, but might require re-wording of this recommendation.	Thank you for your comment 1.7.6 (in the draft guideline) suggests a trial of the addition of a LAMA, so it would seem easier to add in a LAMA-only inhaler to the current MART rather than changing inhalers completely for what might be a relatively short period of time. However, there is no evidence to prefer this to the option of changing to a triple maintenance inhaler as you describe, and so the recommendation leaves this open. There is always the possibility of errors if a clear explanation of the treatment is not given, with checks that this has been understood. Might a person given a triple inhaler use this as their reliever and the reliever as maintenance?

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Barts Health NHS Trust	Guideline	013	019	Rec 1.7.7: Suggesting patients try all of ICS-LABA, LAMA and LTRA before referral to secondary care may delay referrals, with clinical impact. Referral may be more appropriate after ICS-LABA and trying either LAMA/LTRA but not necessarily both.	Thank you for your comment Although the guideline says that referral should be made at this point there is nothing to stop an earlier referral if it is agreed that this might be beneficial. In addition, recommendations 1.7.6 and 1.7.7 have been amended in response to stakeholder comments, and the possibility of an earlier referral is now specified.
Barts Health NHS Trust	Guideline	013	General	(Rec 1.7.5 - 1.7.7) As noted on Page 123 of Evidence Review Q, there is little evidence for the sequencing of LTRA vs LAMA in patients with uncontrolled symptoms despite ICS-LABA therapy. Trying LTRA or trying LAMA first may be more appropriate in patients with different treatable traits e.g. LAMA first in those with persistent airflow limitation. As there is equipoise at this step shouldn't the clinician be able to make a shared-decision with the patient on which to try first? That could easily be incorporated into the treatment algorithm.	Thank you for your comment The committee did not feel that advice to base the decision on treatable traits would help most users of the guideline without a lot of extra explanation. The recommendations on LTRA and LAMA trials have been reconsidered and have been changed as you suggest.
Barts Health NHS Trust	Guideline	015	001	Rec 1.7.12: We would suggest adding that patients whose asthma is not controlled on a	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				high-dose ICS-LABA, with good adherence, should not be changed to MART pending specialist review. There is a danger that patients on high-dose ICS-LABA combinations might accidentally be stepped down to MART, without consideration that this will reduce ICS dose. It is also worthwhile considering an off-licence recommendation to try a maximum-dose ICS-LABA(-LAMA) preventer with separate ICS-formoterol reliever in these patients.	There are any number of accidental errors that might occur, and the guideline cannot list all imaginable "do not" recommendations. The off-licence suggestion you make is reasonable, but NICE cannot make off-licence recommendations in the absence of a review of published evidence.
Bedfont Scientific Ltd	Guideline	General	General	We are pleased to see the importance of spirometry as a diagnostic tool for asthma reduce in importance, as many key opinion leaders have fed back to us if the patient presents for testing at a routine appointment on a day when they are asymptomatic, it can frequently be unhelpful as a normal spirometry test does not rule out asthma, but is sometimes interpreted that way.	Thank you for your comment
Bedfont Scientific Ltd	Guideline	General	General	We are pleased to see FeNO as the first line investigation for asthma after history and examination.	Thank-you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Bedfont Scientific Ltd	Guideline	General	General	Feedback from key opinion leaders and market have implied that in children, second line testing of blood eosinophils can be time consuming and an unpleasant experience for patients, so instead of suggesting a costly and scarce alternative, resource allocation for FeNO needs consideration. The evidence base for blood IgE is also not strong. Skin prick testing is a scant resource in primary care and would be a costly alternative to FeNO.	Thank you for your comment The guideline recognises that FeNO is a useful test, but it is not going to suffice on its own for all patients with suspected asthma and these other tests will be required. The rationale sets out the reasons they are recommended.
Bedfont Scientific Ltd	Guideline	General	General	We welcome the recommendation to consider FeNO in routine management. Many key opinion leaders have fed back to us FeNO is a useful tool to guide medication increases, encourage safe reduction in medication when appropriate, as a tool in patient education to help them understand the airway inflammation we see in asthma, and as a tool to open honest conversations regarding poor adherence with prescribed asthma medication.	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Bedfont Scientific Ltd	Question 1	General	General	Although this will have some resource implications that will need considering and addressing, including access to FeNO testing and FeNO training in primary care settings, although AAC have already done an amazing job in creating awareness for FeNO and offering funding opportunities to adopt FeNO. We think similar grant funding schemes will help with access to FeNO testing, especially in primary care. More visibility of FeNO training programs will also help promote effective FeNO adoption in primary care settings. Additionally, better collaboration with industry FeNO manufacturers will highlight additional training and educational materials available for FeNO, which will help understanding and adoption. For example, Bedfont have a free educational platform and offer training programmes as part of sales aftercare support.	Thank you for highlighting this. Respiratory experts from the committee identified this as an area for resource impact. The draft resource impact picks up potential costs in primary and secondar care settings for both monitoring and diagnosis.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Bedfont Scientific Ltd	Question 2	General	General	FeNO will have some resource implications that will need considering and addressing, including access to FeNO testing and FeNO training, especially in primary care settings. We think similar grant funding schemes as previously designed will help with access to FeNO testing, especially in primary care. More visibility of FeNO training programs will also help promote effective FeNO adoption in primary care settings.	Thank you for highlighting this**.** This is picked up for assessment in the draft RI tools. Training is assumed to be part of qualification costs of GPs. Additional ongoing training was not identified by experts as having additional significant resource impact.
Betsi Cadwaladr University Health Board	Guideline	001	016	For who this guideline is for, it would be useful to include pharmacists as they too are involved in managing patients with asthma, not just nurses and GPs.	Thank you for your comment. This has been changed.
Betsi Cadwaladr University Health Board	Guideline	005	009	We feel that peak flow with bronchodilator reversibility should be removed from the guideline as there are no quality standards related to the stand alone measurement of peak expiratory flow and measurements are highly variable.	Thank you for your comment. The committee believes this should remain. This recommendation deals with the less frequent situation where a person presents with acute symptoms requiring immediate treatment. Whilst the committee would not advise measuring change in PEF in other circumstances, here it is more likely to be

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					possible to measure PEF than FEV1, and the acute response could provide valuable diagnostic information. NICE quality standards are based on NICE guideline recommendations. The current NICE asthma quality standard (QS25) includes a statement on objective tests for diagnosis which includes peak exploratory flow. This statement will be updated to reflect the new guideline.
Betsi Cadwaladr University Health Board	Guideline	005	028	>200mL and ≥12% increase in FEV1 and/or FVC criteria is confounded by age and sex bias. Consideration could be given to acknowledging this in the main body of the guideline. Without qualification, practitioners may be less likely to recognise the limitations of this approach if they then do not go on to read the associated evidence review.	Thank you for your comment. This is the criterion for abnormal reversibility accepted by ERS/ATS and the ARTP.
Betsi Cadwaladr University Health Board	Guideline	005	029	The greater than 10% of predicted normal criteria was not initially clear to us on first read of the guideline. Without qualification, practitioners may be similarly confused if they then do not go on to read the associated evidence review with an explanation of how the percentage change	Thank you for your comment. We have tried to make this clearer.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				relative to the patients predicted value is derived.	
Betsi Cadwaladr University Health Board	Guideline	024	017	The term 'reversibility' is qualitative and may imply normalisation; consideration could be given to replacing this term with response or responsiveness.	Thank you for your comment Reversibility is preferred because there is less chance of confusion with bronchial responsiveness which measures bronchoconstriction rather than dilatation.
Boehringer Ingelheim Limited	Guideline	013	013	Boehringer Ingelheim support NICE's recommendation to consider adding a long-acting muscarinic receptor antagonist (LAMA) to moderate-dose MART plus an LTRA, or to moderate-dose MART alone if an LTRA has proved ineffective, for adults with asthma that is not controlled on current treatment.	Thank you for your comment
Boehringer Ingelheim Limited	Guideline	013	019	Boehringer Ingelheim support NICE's recommendations to refer people to a specialist in asthma care when asthma is not controlled despite treating with moderate dose ICS, LABA (long-acting beta2 agonist), LTRA and a LAMA.	Thank you for your comment
Boehringer Ingelheim Limited	Guideline	General	General	Boehringer Ingelheim welcome the invitation to respond to this NICE NG80 guideline update consultation. We note that this guideline covers diagnosing, monitoring and managing asthma in	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				adults, young people and children and does not cover managing severe asthma.	
Boehringer Ingelheim Limited	Guideline	General	General	Boehringer Ingelheim support the new recommendations on treatment sequencing in Section 1.7, which supports and empowers primary care in the management of uncontrolled asthma	Thank you for your comment
Bristol Royal Hospital for Children	Guideline	005	022	We are concerned that since eosinophils OR FeNO is the first line test for adults, practices may choose Eosinophil measurement as cheaper and easier which will offer a route not to invest in FeNO monitoring effectively placing a barrier to following the guideline for children. A potential consequence of this will be children will remain undiagnosed to comply with the QoF stipulation of objective testing required for diagnosis which is unsatisfactory for them, and dangerous since they might then be untreated and unmonitored.	Thank you for your comment. The committee understand the concern you raise, but do not think that including eosinophil level as an alternative test in adults is a legitimate reason for failing to invest in FeNO equipment. Not only is FeNO recommended as the first test in children, but it is also recommended for monitoring purposes in adults.
Bristol Royal Hospital for Children	Guideline	006	005	We are concerned about access to and experience interpreting FeNO in primary care. Regarding access we are concerned that this will place capacity and cost pressures on secondary care to achieve a diagnosis of asthma by providing FeNO testing for patients	Thank you for your comment The committee acknowledges that access to FeNO is limited in primary care in some areas. Interpretation of results of FeNO is easier than

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				felt in primary care to have consistent symptoms.	that of tests such as spirometry and PEF variability.
Bristol Royal Hospital for Children	Guideline	006	007	We are concerned that there was not suffcient evidence considered to address whether BDR is needed in all children with normal or no FeNO or whether the diagnosis of asthma could simply be diagnosed in some children by normal FEV1. Primary care often use a nebuliser to assess BDR and this is costly and makes it difficult to identify poor prescribing of nebulisers which should not be used in the community. If an MDI is used it is often considered single use as is the spacer which is again costly.	Thank you for your comment You make a valid point in that the presence of obstructive spirometry alone in a child with a history suggesting asthma has some value. The committee still feel that having gone to the trouble of arranging spirometry, it would be better to obtain the extra information from reversibility testing. The estimation of the cost of BDR can be viewed in evidence review B and the economic report and includes the cost of the inhaler (either single use or reusable) and spacer. The committee noted that using a nebuliser to measure BDR is rarely done. Nevertheless, the potential cost per patient of using a nebuliser would be minimum (<£1) since the cost of the device would be spread across all the patients using it during its device lifetime. This cost would certainly be offset by the advantages of accurate diagnosis targeting treatment more appropriately.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Bristol Royal Hospital for Children	Guideline	006	010	We are concerned that measuring skin prick testing in primary care is rarely available. This may result in further cost pressures in secondary care particularly if further allergy tests are requested at the same time which will need to be interpreted in terms of clinical significance.	Thank you for your comment You are correct, but skin prick testing is just one option at this step in the diagnostic process.
Bristol Royal Hospital for Children	Guideline	010	008	We are concerned that the statement 'do not prescribe beta agonists to anyone of any age with asthma without concurrent prescription of an inhaler steroid' will be applied non-critically and applied to children with transient self-limiting viral wheezing. Even the clarification later in the guideline to start inhaled steroids for children with interval symptoms with another atopic disorder or severe wheeze requiring admission (particularly the latter id the sever is subjectively interpreted and focus on the admission portion) is quite a low bar. Resulting in large numbers of very young children being started on steroids. The guideline does highlight a trial off steroids more than any previous guideline but this is a change in culture and will potentially require patient 3 contacts to assess this which will impact on services. There are not enough specialist practitioners to complete this work so	Thank you for your comment. The committee is sympathetic to the point you make, but this recommendation clearly states that it applies to people with asthma and is therefore valid. We recognise that it can be difficult to distinguish from other wheezing illnesses, particularly in the very young, hence the series of recommendations describing a trial of inhaled steroids in this age group.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				a great deal will be devolved to non-specialists so the wording is critical.	
Bristol Royal Hospital for Children	Guideline	015	010	We are concerned that the evidence for MART dosing is almost entirely in the adult population and does not acknowledge the significant differences between children and adults in terms of adherence, attack frequency and releiver use. This may well be the correct strategy but this change in practice is being driven by adult data.	Thank you for your comment The adult data is compelling but there is also evidence in children (evidence review Q)
Bristol Royal Hospital for Children	Guideline	020	024	We are concerned that there are few services to refer adolescents that vape to. Our local smoking cessation services offer almost exclusively swap to stop and are very focused on starting rather than stopping vaping!	Thank you for your comment. Your point is correct and recommendation 1.13.2 has been amended.
Bristol Royal Hospital for Children	Guideline	General	General	We are concerned that the guideline implies no further testing after a FeNO >35 in ppb, without further guidance this might result in children with rhinitis being erroneously diagnosed with asthma or a large number of referrals to secondary care of children with cough due to rhinits being referred to secondary care because of failure to respond to asthma therapy.	Thank you for your comment The guideline says that there must also be a history suggestive of asthma. A cough alone, unless it displays the characteristic variability, is not suggestive of asthma. A child may present with symptoms of rhinitis, possible asthma and an elevated FeNO, and in that event a clinician may decide to treat one site first and see if this improves symptoms and lowers FeNO. There are a lot of possible scenarios, but sound

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					clinical judgement has to play a role. The guideline should not lead to a flood of referrals of children with rhinitis.
Bristol Royal Hospital for Children	Rationale	036	016	We are concerned that the data on FeNO monitoring has been misinterpreted. The data in the appendix is looking at studies designed to use frequent FeNO measures to adjust asthma therapy to achieve control. There is very little evidence that asthma therapy can be adjusted using FeNO measurements, particularly in children. Where these studies have been performed monitoring has largely been conducted at 8-12 week intervals not annually. What will be detected annually will most likely be poor adherence or rhinitis comorbidity and the response to this is different than the response to FeNO raised due to poor control of airway inflammation. The information in the guideline page 9 line 1 is appropriate stating consider adherence technique etc if FeNO is high but does not match the evidence this was derived from. There is a strong body of evidence describing how FeNO can be used to assess control and this would be a more credible basis to make this recommendation on.	Thank you for your comment. It is true that the studies of FeNO monitoring used testing intervals less than once per year. However, the practical consequence of recommendation 1.5.4 would be a FeNO test at a person's regular review with a high reading prompting questions about adherence or the possible need for a treatment increase. If treatment is changed, the second part of 1.5.4 states that FeNO should be rechecked which would be done after 8-12 weeks (recommendation 1.6.3). In practice then, FeNO monitoring in those who need treatment adjustment would be done at shorter intervals.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Bristol Royal Hospital for Children	Rationale	037	007	We are concerned that the move away from PEFR for diagnosis will lead to repeat appointments at best and diagnostic confusion at worst since PEFR better captures variable airways obstruction than one of spirometry.	Thank you for your comment PEF variability has been added to the diagnosis sections.
British Paediatric Respiratory Society	Flowchart	General	General	Both flow sheets could do with someone with IT skills to spruce up - things like having all text aligned to left and lack of capital letters at beginning of text boxes in the treatment pathway are not currently aesthetically pleasing. Given most boxes are centralised and formatted correctly in the diagnosis sheets, needs conforming. The bottom central box in the 5-16 diagnostics is not centralised. The vast majority of people who will be referring to these guidelines with only be looking at the flow sheets so worth investing some more time to look better. The formatting and colour are very unimaginative at the moment so could be improved. Is it worth adding z scores also? Mentioned in text but not in flow sheets	Thank you for your comment. These were draft versions.
British Paediatric Respiratory Society	General	General	General	We agree this should be updated and would recommend option A. Option B is complicated, does not clearly differentiate the differences between adults and children and is vulnerable to	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				misreporting. We would suggest putting spirometry with reversibility first as this is the key identifier of the underlying airway problem (smooth muscle bronchial constriction). Should it not be adults and children for this measure? Perhaps it would be clearer to have separate impact assessment statements for adults and children given the differences in the recommendations and the differences in the evidence base for different age groups.	
British Paediatric Respiratory Society	Guideline	004	004	Whilst the guideline advises a structured clinical history asking about symptoms (Page 4) it is not clear what a history suggestive of asthma is for children aged 5-16 years on which a FeNO level of more than 35 ppb is diagnostic. We would suggest clearer information about when to suspect asthma when there are respiratory symptoms such as: Suspect asthma if >1 of the following symptoms are occurring ≥ 3 times a week, or if severe, or causing waking at night: - Wheeze (especially if heard by a healthcare professional) - Breathlessness - Chest tightness - Cough	Thank you for your comment Waking at night has been added to the recommendation. The other symptoms are already there. There was no evidence review of symptoms for this update and the committee is not sure that adding the specific numbers that you include is justifiable.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Paediatric Respiratory Society	Guideline	005	007	I would suggest that "peak flow with bronchodilator reversibility" is removed from page 5, 1.1.5, line 9-10	Thank you for your comment. The wording used in the draft guideline is potentially misleading and has been changed. The recommendation deals with the less frequent situation where a person presents with acute symptoms requiring immediate treatment. Whilst the committee would not advise measuring the change in PEF in other circumstances, here it is more likely to be possible to measure PEF than FEV1, and the acute response could provide valuable diagnostic information.
British Paediatric Respiratory Society	Guideline	006	005	The ERS published guidance for diagnosis in this age group: ERJ 2021;58:2004173 (Gaillard et al) and these have been widely accepted across Europe. This group found that a FeNO level of 25 ppb had a mean sensitivity of 0.57. A level of 35 will have significantly lower sensitivity for asthma in this age group and thus be of limited value in detecting asthmatics. It is also important to note that a raised FeNO level whilst supportive of a diagnosis of asthma is not diagnostic and that many children with asthma	Thank you for your comment Any cut-off value for FeNO is a compromise between sensitivity and specificity. As FeNO is the first test recommended, and may therefore be the only test done, the committee agreed that it would be better to set the cut-off level at a higher, more specific value. Asthma will not be excluded (the child with lower FeNO will

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				will not have raised levels. It is perhaps worth pointing out that higher levels are more indicative of asthma but that levels might also be raised in children with allergic rhinitis, eczema and atopy irrespective of whether they have asthma, and that levels are highly sensitive to inhaled steroids.	proceed to other tests) but a positive diagnosis will be more secure.
British Paediatric Respiratory Society	Guideline	006	007	It should be recommended the GLI reference values are used for spirometry. We would suggest that BDR recommendations are consistent with 'ERS/ATS technical standard on interpretive strategies for routine lung function tests' ERJ 2022;60:2101499 and that BDR be primarily classified as 'a change of >10% relative to the predictive value of FEV1 **or FVC.'** This is a more sensitive measure and a simple example of how to do the maths could be included.	Thank you for your comment This is an unfamiliar metric to many, and the committee prefer to stick with FEV1 changes in this iteration of the guideline.
British Paediatric Respiratory Society	Guideline	006	007	It suggests starting off with FeNO and if negative and history suggests asthma to then to measure BDR, but it isn't clear if this is from spirometry or PEFR or either. The evidence review suggests this is referring to spiro, but this is not clear from the guideline. This will be important to spell out clearly as FeNO and PEFR can be realistically done in a primary care setting, but spirometry is	Thank you for your comment The words "with spirometry" have been added.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				more challenging and will require more involved solutions (eg CDC or hublets etc)	
British Paediatric Respiratory Society	Guideline	006	010	Skin prick testing is poorly predictive of asthma in children and a negative atopic status does not exclude asthma as suggested in the guideline. We do not think that there is sufficient evidence to diagnose asthma on the basis of IgE levels and eosinophil counts which are just as likely to be associated with other atopic causes in children.	Thank you for your comment Recommendation 1.2.6 applies to children with a history suggesting asthma who have already had a negative test with FeNO, spirometry and reversibility testing. In this situation the committee believes the recommendation is valid.
British Paediatric Respiratory Society	Guideline	006	010	Skin prick testing is never done locally in primary care and allergy services in general are hugely overwhelmed. Adding this to the diagnostic pathway will require huge investment as I assume the intention is for this to be done in primary care which will require a lot of training and up-skilling FeNO cut-offs if different for age and height should have a table of normal values	Thank you for your comment You are correct, but skin prick testing is just one option at this step in the diagnostic process. The committee agrees that ideally FeNO levels would be corrected for age, height and gender, but this would require an agreed set of standardised data, and ideally FeNO machines which calculate the observed versus predicted values in the way electronic spirometers do for lung function values. At present neither is available.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Paediatric Respiratory Society	Guideline	006	017	We suggest referral for bronchial challenge testing is highly aspirational and unrealistic as most secondary care services will not be able to provide this. Even if the guideline is suggesting referral straight to a 'paediatric respiratory specialist' providing tertiary care, this test will still not be available in most of the UK. We suggest that there is still a place for an 8 week trial of treatment, stopping and then re-evaluating for symptoms when tests are inconclusive but symptoms are highly suggestive. This is mentioned in the pre-school age group but there is also a place for this in older children where objective testing is inconclusive, but symptoms are highly suggestive. If there is no improvement then referral to secondary care to consider alternative diagnoses would then be appropriate. If symptoms improve but re-occur after stopping treatment then this information could be used to support a diagnosis and justify restarting low dose prevention treatment. Whilst fully supportive of an emphasis towards the use of objective testing to secure a diagnosis of asthma, there is a danger that children will not be treated on a trial basis when	Thank you for your comment The evidence shows that bronchial challenge is the best single test for asthma and the committee believe it should be included, albeit at the end of the testing pathway when other investigations have not been conclusive. PEF variability has now been added to the diagnosis section.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				symptoms are highly suggestive but objective testing is inconclusive or not readily available. This might result in some children being at increased risk of asthma attacks. The guideline as currently written is likely to drive a large number of referrals to secondary/tertiary care for specialised diagnostic testing that is not necessarily available. Many health care professionals working in primary care continue to use peak flow monitoring to support a diagnosis of asthma. Whilst FeNO and BDR are preferred first line tests there is limited evidence to support PEFR monitoring as an additional asthma-diagnostic tool (See - European Respiratory Society clinical practice guidelines for the diagnosis of asthma in children aged 5-16 years).	
British Paediatric Respiratory Society	Guideline	008	018	Needs to be passive exposure to smoking AND vaping	Thank you for your comment. On reconsidering this, the reference to smoking has been removed from 1.5.1. The recommendation is about indices of control, and smoking was therefore out of place there (and it is covered in other recommendations).

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Paediatric Respiratory Society	Guideline	008	019	What about CYP? Worth including what ages ACQ and ACT for and when to use cACT	Thank you for your comment Children's questionnaires have been added although an exact age for using these has not been included.
British Paediatric Respiratory Society	Guideline	009	016	Occupational exposures and seasonal factors seem outliers for not having examples in brackets; environmental factors not limited to those 2 - would suggest, etc after the 2 given examples).	Thank you for your comment. This appears to refer to recommendation 1.6.1. There are 8 bullet points in the draft recommendation and only 3 of them feature an example, so occupational and seasonal factors are not outliers. The committee believe they are self-explanatory. Adding "etc" in the context of examples would be tautological.
British Paediatric Respiratory Society	Guideline	010	008	The statement to not prescribe a SABA in any age with 'asthma' without an ICS might create some confusion when treating the pre-school age group. There will be some children in this age group who will have episodic viral associated wheezing and not meet the criteria for a trial of regular inhaled steroids. In these circumstances there will be a case for using intermittent SABA. These criteria are very clearly	Thank you for your comment. The committee is sympathetic to the point you make, but this recommendation clearly states that it applies to people with asthma and is therefore valid. We recognise that it can be difficult to distinguish from other wheezing illnesses, particularly in the very young, hence

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				stated in the published Beat Asthma guidelines (beatasthma.co.uk/wp-content/uploads/2024/05/clinicians-information-BA-FINAL.pdf) which were developed nationally. We think this needs clarifying albeit that these children will not be labelled as having asthma or suspected asthma.	the series of recommendation describing a trial of inhaled steroids in this age group.
British Paediatric Respiratory Society	Guideline	010	017	We agree that choice of inhalers should be those with the lowest environmental impact but argue that prescribers need this information readily available to inform their treatment decisions with shared decision making working with families. We would strongly recommend including gCO2Eq data for recommended inhalers.	Thank you for your comment. This would cause difficulty as the guideline will not be updated for a period of time and could therefore not provide information on new inhalers (which would be unfair to them) or to any change to current inhalers.
British Paediatric Respiratory Society	Guideline	011	015	We question the advisability of recommending 'the same type of device to deliver the preventer and reliever treatments where more than one inhaler is needed' in children aged 6-11 years. Most 6-11 year old children will be well controlled on regular inhaled corticosteroids and many will be able to use a dry powder device within licence for prevention treatment (Flixotide accuhaler or Pulmicort turbohaler). There is no evidence about how SABA can be given through	Thank you for your comment. Several stakeholders have raised this issue and 1.6.8 in the draft guideline has been amended.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				these devices for acute episodes of wheeze. These children will require and MDI and spacer for the treatment of breakthrough symptoms according to their action plans for the treatment of acute exacerbations of wheeze. We thinks this needs highlighting.	
British Paediatric Respiratory Society	Guideline	011	021	We think the statement about the use of digital inhalers should be clearer. The evidence review for these devices identified a clear signal for a harmful effect with increased exacerbations. There is good evidence that health care professionals are unable to correctly suspect when poor adherence is a problem and there is little evidence that using these devices to identify poor adherence is likely to improve outcomes. We would strongly recommend limiting the recommendation for the use of these devices in children to those patients in specialist centres in whom biologic therapy is being considered. These devices are expensive and poor adherence is commonly suspected in children with asthma. Whilst not recommending their routine use the current statement has the potential to encourage a significant increase in	Thank you for your comment. The committee has reconsidered this recommendation, and it has been changed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				their use for which there is little evidence for likely benefit and major cost implications.	
British Paediatric Respiratory Society	Guideline	013	011	Whilst Montelukast is a licenced asthma drug for children there is no evidence that it reduces asthma attacks. Three months is a long trial of treatment during which a patient with poorly controlled symptoms will be at continued risk of acute severe asthma attacks. We would suggest a shorter trial period for children.	Thank you for your comment The period of time has been adjusted to 8-12 weeks to be consistent with recommendation 1.6.3. A shorter trial has the disadvantage of being more open to misinterpretation given that asthma is naturally a variable disease. Shorter periods are also less likely to allow evaluation of exacerbation reduction.
British Paediatric Respiratory Society	Guideline	015	010	We agree with the second line off licence use of MART in 6-11 year olds, but would urge caution when using the Symbicort MDI. Unlike the turbohaler for which there is licenced use in this age group for fixed dose combination treatment and a clinical trial with evidence of effectiveness for a MART regime, there is no such research for the MDI. The licenced doses for MDI in those aged 12 and above are very high and there is a danger that such high doses will be used in younger children.	Thank you for your comment The footnote to 1.8.2 now states that the evidence for MART in children is based on use of a DPI.
British Paediatric Respiratory Society	Guideline	016	012	See comments above about the length of trial of treatment of an LTRA.	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					The period of time has been adjusted to 8-12 weeks to be consistent with recommendation 1.6.3. A shorter trial has the disadvantage of being more open to misinterpretation given that asthma is naturally a variable disease. Shorter periods are also less likely to allow evaluation of exacerbation reduction.
British Paediatric Respiratory Society	Guideline	017	004	Stick to 8 weeks rather than range to keep clear	Thank you for your comment. The range is consistent with recommendation 1.6.3 and the committee cannot see any reason to specify exactly 8 weeks.
British Paediatric Respiratory Society	Guideline	017	017	We suggest the line about environmental sources of symptoms including pets should be omitted. The current BTS guidelines found no evidence that pet removal improved outcomes in these circumstances and in some cases the effects were paradoxical. This intervention is unlikely to be of benefit and especially if a much-loved pet is wrongly implicated as the cause of continuing symptoms. There is a huge amount of literature showing the association between antenatal/post-natal stress and wheeze in childhood. If symptoms do not	Thank you for your comment The reference to pets has been removed

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				resolve it should be acknowledged that this is a likely contributory factor and the importance of providing supportive care to address this should be emphasized.	
British Paediatric Respiratory Society	Guideline	018	017	Worth mentioning that there is no evidence for weaning compared to stopping but should be individualised and agreed with the CYP and family	Thank you for your comment There is indeed no evidence for weaning rather than stopping. It is not an issue that has provoked much comment, and it is probably sensible not to complicate the recommendation further.
British Paediatric Respiratory Society	Guideline	019	014	This section isn't just about adherence as in the heading but includes other subjects i.e. inhaler technique and shared decision making.	Thank you for your comment These are closely related topics. Adherence is featured in the treatment sections even though it is not in itself a treatment.
British Paediatric Respiratory Society	Guideline	020	024	Signpost them to local NHS stop smoking services" - not universally available for adolescents and either needs acknowledging or rephrasing	Thank you for your comment. Your point is correct and recommendation 1.13.2 has been amended.
British Paediatric Respiratory Society	Guideline	021	004	I would stick with the terminology of personalised asthma action plan as much as	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				possible (rather than "asthma self-management programme" which sounds much more American and unnecessary different terminology	Provision of a personal action plan is part of the self-management programme. They are not alternative terms for the same thing.
British Paediatric Respiratory Society	Guideline	021	024	First mention of virtual wards - should this not be mentioned prior? Perhaps in monitoring?	Thank you for your comment There is no obvious need to mention these in any preceding recommendation.
British Paediatric Respiratory Society	Guideline	022	012	Examples of structured protocols for asthma reviews would be fantastic	Thank you for your comment. This recommendation is taken from the BTS/SIGN guidance. Unfortunately, the committee are not sure which protocols informed that advice.
British Paediatric Respiratory Society	Guideline	022	022	Needs to refer to Asthma Friendly Schools as per the national CYP deliverables	Thank you for your comment. This is a legacy recommendation with no associated evidence review and the wording has not been changed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Paediatric Respiratory Society	Guideline	023	002	It would be useful to have some cut-ffs for SABA over-use; would also be helpful to provide some guidance on how this risk-stratified care can be done (and by who!)	Thank you for your comment. A value for SABA overuse has been added. Detail on how to implement this recommendation is outside the guideline remit, as is who should do it. This will have to depend to some extent on resources (including personnel) that are already available and will differ between practices. Your comments will be considered by NICE where relevant support activity is being planned.
British Paediatric Respiratory Society	Guideline	024	004	Tele-health needs a section in the "Terms Used in this guideline" section - is it referring to telephone only or all virtual modalities?	Thank you for your comment All virtual modalities. This recommendation is taken from SIGN158, and this includes plentiful explanatory text in its chapter 14.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Paediatric Respiratory Society	Guideline	034	021	This suggests that FeNO equipment is hard to come by but paediatric phlebotomy is "easily obtainable everywhere". Locally there has been a huge drive to provide FeNO provision so is easily accessible but paediatric phlebotomy is hugely problematic and the suggested pathway would require a lot more CYP to have bloods	Thank you for your comment The guideline does not contain a sentence stating that paediatric phlebotomy is easily obtainable. This sentence refers to the availability of eosinophil counts and IgE level measurement once blood is obtained. In fact, the rationale for testing in children mentions the problem of getting blood from children 3 times in 5 paragraphs.
British Paediatric Respiratory Society	Guideline	080	025	There is not good evidence that FeNO monitoring in children with asthma is likely to improve outcomes. Whilst the 2016 Cochrane review suggested that tailoring asthma treatment based on FeNO levels reduced exacerbations, close examination of these data reveals that this positive outcome is a result of large FeNO monitoring benefits in 3 very small studies. The large, and until that time definitive, US study (Szefler 2008) was unambiguously negative as was the 2013 Pike UK study. Sine then we have had Steve Turner's 2022 Lancet Respir Medicine 10(6):584-592 UK study recruiting 535 children. It did not reduce asthma exacerbations compared to symptom guided asthma treatment.	Thank you for your comment. Several stakeholders have raised a similar point. The UK study you cite was negative, but overall, the studies show a slight benefit, albeit that increased ICS doses were required to achieve this. It is true however, that FeNO monitoring in children was less cost-effective than in adults. The recommendation has been reviewed and the committee have decided it should be limited to adults.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				This study built on the experience of all of the previous research into regular FeNO monitoring to prove its effectiveness and is of bery high quality. It is entirely negative. It is very hard to see how the addition of this definitive UK study in the analysis for this guideline still results in a recommendation for FeNO monitoring in children. We would suggest focusing on the results from the well conducted UK studies that are most relevant to UK practice, and which do not show benefit. We recognise that these conclusions might contradict the findings from adult studies, but children are not mini-adults and there are many reasons why FeNO monitoring is unlikely to be effective in improving outcomes in younger asthmatics. The introduction of regular FeNO testing will have huge resource implications in primary care with likely little impact on asthma attacks or any other clinically important outcomes. As the analysis shows, the increased use of FeNO is likely to result in increased doses of inhaled corticosteroids being used in children which will have further increased cost implications.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				These increased doses of steroids are unlikely to improve asthma outcomes because we know from the Cochrane meta-analyses of RCTs comparing low versus higher doses of inhaled beclomethasone, budesonide and fluticasone in adults and children, there is no difference in the occurrence of asthma exacerbations between high and low doses (80 randomised controlled trials with 79 showing negative outcomes and just 1 study showing benefit of very high versus low doses of budesonide). Finally it is important to note that these new guidelines are driving a major change in practice towards the increased use of MART. Whilst fully supportive of this, it should be recognised that the FeNO studies did not include children on this type of treatment approach and there is no evidence that FeNO monitoring of such children will improve outcomes above that which can be achieved with a symptom based MART approach to day-to-day asthma treatment based on symptoms.	
British Society for Allergy and Clinical Immunology	General	General	General	Would it be challenging to implement of any of the draft recommendations? Please say why and for whom. Please include any suggestions that could help users overcome these	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				challenges (for example, existing practical resources or national initiatives A greater network of national lung function testing facilities would facilitate lung function testing in organisations where it is not immediately available.	
British Society for Allergy and Clinical Immunology	General	General	General	Would implementation of any of the draft recommendations have significant cost implications? Increased referrals to Occupational Medicine due to deleted recommendations on PEF monitoring to screen for occupational asthma.	Thank you for your comment
British Society for Allergy and Clinical Immunology	General	General	General	A. The percentage of patients with asthma on the register from (start date) with a record of fractional exhaled nitric oxide (FeNO) (adults and children) or blood eosinophil count (adults) or spirometry with bronchodilator reversibility (children), between 3 months before or 3 months after diagnosis. B. The percentage of patients with asthma on the register from (start date) with a record of an objective test (eosinophil count, fractional exhaled nitric oxide (FeNO), spirometry, peak	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				flow with bronchodilator reversibility, bronchial responsiveness (in adults), skin prick test or blood IgE level (in children)) between 3 months before or 3 months after diagnosis. Peak flow with or without bronchodilator reversibility, with bronchial hyperresponsiveness measured rarely when variability is still equivocal. However, option 2 may provide greater flexibility to GPs to target objective measures depending on presenting history.	
British Society for Allergy and Clinical Immunology	Guideline	00	1.1.1	This is inadequate clinical information and should also include symptoms of rhinitis, hay fever, nasal polyps, NSAIDs induced asthma, onset of sx and relieving factors	Thank you for your comment. The symptoms of rhinitis, hay fever, nasal polyps, NSAIDs induced asthma which suggest asthma are already included in 1.1.1 (i.e. where rhinitis causes a cough, it is included; where it causes sneezing, that symptom does not suggest asthma). Triggers are already included, and the committee is not sure what relieving factors you are referring to in a person who is presenting for the first time and does not have an inhaler.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Allergy and Clinical Immunology	Guideline	000	Deleted in table 3.2.3	Deleting this recommendation is surprising – do the committee know how many occupational medicine respiratory specialists there are in the UK – Screening for Occupational Asthma should be something that every respiratory service should be able to offer otherwise underdiagnosis of occupational asthma will only continue.	Thank you for your comment. The committee is well aware that occupational medicine services are overstretched, but also aware of the huge consequences of getting a diagnosis of occupational asthma. This must be done properly. There is nothing to stop a clinician from asking for PEF monitoring while awaiting a referral, but if there is a clinical suspicion of occupational asthma the referral still needs to stand.
British Society for Allergy and Clinical Immunology	Guideline	004	010	A personal or family history of "atopic disorders" is not relevant to the diagnosis of asthma	Thank you for your comment. The wording has been changed.
British Society for Allergy and Clinical Immunology	Guideline	005	008	Blood eosinophil count and FeNO are not objective tests for the diagnosis of asthma.	Thank you for your comment. The committee believes that they are tests which can aid the diagnosis of asthma, and the evidence review supports this.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Allergy and Clinical Immunology	Guideline	005	023	An elevated (absolute) blood eosinophil count and FeNO support a possible diagnosis of asthma but are not essential for the diagnosis and may reflect other diseases. They may also be altered by exposure to drugs, e.g. inhaled or systemic corticosteroids.	Thank you for your comment. The committee agrees that other conditions may cause the eosinophil count to be raised, but there are potential confounding factors with most diagnostic tests
British Society for Allergy and Clinical Immunology	Guideline	005	026	Asthma cannot be confirmed by "eosinophil count or FeNO level". Bronchodilator reversibility must be demonstrated from PEF monitoring, laboratory spirometry or, if these are not clear, measurement of bronchial smooth muscle hyperresponsiveness in the respiratory laboratory, as stated in the following section of the guideline (1.2.3).	Thank you for your comment. The committee believes that they are tests which can aid the diagnosis of asthma, and the evidence review supports this.
British Society for Allergy and Clinical Immunology	Guideline	005	1.2.1	Eosinophilia is not a specific test for asthma and is elevated in many other disorders – this advice will lead to even more people with an incorrect diagnosis of asthma. It can be used to support a diagnosis of asthma in conjunction with other objective measures and clinical history	Thank you for your comment. The committee believes that they are tests which can aid the diagnosis of asthma, and the evidence review supports this.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Allergy and Clinical Immunology	Guideline	006	010	A positive skin prick test to house dust mite allergen, elevated total serum IgE concentration and blood (absolute) eosinophil count >0.5x10^9/l neither confirm nor exclude a diagnosis of asthma.	Thank you for your comment The committee believes that they are tests which can aid the diagnosis of asthma, and the evidence review supports this.
British Society for Allergy and Clinical Immunology	Guideline	006	015	Children in this age group are not all allergic and remember eosinophil count can be be low due to recent corticosteroid use.	Thank you for your comment The rationale to the diagnosis recommendation explicitly acknowledges that some childhood asthma is non-atopic. Prior treatment will alter the results of most of the available tests.
British Society for Allergy and Clinical Immunology	Guideline	006	1.2.6	Why HDM? - patients may develop seasonal asthma due to pollens, severe asthma due to Aspergillus or with their pets eg cats and dogs without allergy to HDM. These guidelines clearly did not have allergy representation. Allergic sensitisation triggering asthma must correlate with clinical history as above. An elevated total IgE can be due to other factors such as eczema, opiates, hay fever etc	Thank you for your comment Children may have asthma without house dust mite sensitization. However, this recommendation is for those who have already have negative FeNO testing and bronchodilator reversibility testing and if they also have no HDM sensitisation and a normal IgE level, the committee believe asthma is unlikely. In the same way, a positive diagnosis of asthma in children with elevated total IgE would not be

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					made unless asthma was already suspected on clinical grounds
British Society for Allergy and Clinical Immunology	Guideline	009	001	Poor adherence and/or inhaler technique are by far the commonest reasons for poor control of established asthma, and the importance of regular assessment of inhaler technique by an appropriately trained individual cannot be over-emphasised (Inhaler technique: facts and fantasies. A view from the Aerosol Drug Management Improvement Team (ADMIT).Levy ML et al. NPJ Prim Care Respir Med 2016;26:16017; Is inhaler technique adequately assessed and reported in clinical trials of asthma and chronic obstructive pulmonary disease therapy? A systematic review and suggested best practice checklist. Dekhuijzen PNR et al. ADMIT Working Group. J Allergy Clin Immunol Pract 2022;10(7):1813-1824). This section does not specifically mention the establishment and documentation of clinically relevant, Type 1 hypersensitivity ("allergic") reactions to environmental allergens when managing patients with asthma, which the BSACI would argue is an indispensable aspect of management of children and adults with	Thank you for your comment. The committee agree with your comment on the importance of assessing inhaler technique and the role of non-adherence. Management of allergen exposure is outside the scope of this guideline. Non-pharmacological management will be covered by BTS/SIGN in separate guidance. Allergen immunotherapy was not prioritised for evidence review during scoping. You may wish to suggest that it is considered during the scoping process of the next update of the guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				asthma. Asthma control may be compromised by exposure of clinically sensitised patients to inhaled, seasonal and perennial aeroallergens. This should be anticipated and managed, and appropriate allergen avoidance procedures undertaken where possible. Food allergies may compromise asthma control, while systemic anaphylactic reactions to foodstuffs or other environmental stimuli (such as bee or wasp stings) in allergic asthmatic patients may be fatal. Finally, allergen immunotherapy of suitably sensitised allergic asthmatics may improve asthma control (Allergen immunotherapy for asthma. Kappen JH et al. J Allergy Clin Immunol Pract 2024;12(1):23-30).	
British Society for Allergy and Clinical Immunology	Guideline	010	006	All patients with asthma should be assessed for clinically relevant sensitisation to environmental seasonal, perennial and food allergens.	Thank you for your comment. Recommendation 1.6.1 prompts readers to consider seasonal and environmental factors.
British Society for Allergy and Clinical Immunology	Guideline	010	015	When choosing which inhaler device to prescribe to patients with asthma, it is obviously essential to prescribe a device that they (or their parents) can use consistently reliably. There is	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				persuasive evidence that metered-dose aerosol devices with a spacer, rather than dry powder devices, deliver inhaled therapy most reliably in a majority of patients, and we would suggest that these are preferred (Spacer devices for inhaled therapy: why use them, and how? Vincken W et al. ERJ Open Res 2018;4:00065-2018). The possible environmental impact of these devices, we would suggest, has been over-emphasised in a climate of escalating particulate pollution and given the fact that 3 patients still die every day because of uncontrolled asthma in the UK alone.	Recommendation 1.6.4 does not preclude the use of MDI plus spacer if this is the best option for a person. The article you reference is not a comparison of spacer+MDI with other devices. The committee note your comments about over-emphasis of the environmental impact of MDIs and, without entering the argument, would point out that many other stakeholders disagree with you.
British Society for Allergy and Clinical Immunology	Guideline	011	018	Taking used inhalers to a pharmacy should not be part of this guideline as it is simply best practice as noted on several other deleted sections compared to the previous guideline on asthma. In addition, where is the evidence that used inhalers cannot simply be recycled rather than send for incineration by pharmacies which will only increase their carbon footprint?	Thank you for your comment. Your opinion on whether this should be included is noted, but the committee disagrees. The recommendation is to take used inhalers to the pharmacy for disposal which is better than putting them in with household waste. Some of the used inhaler is recycled after being received by the pharmacy.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Allergy and Clinical Immunology	Guideline	012	004	The usage of a long-acting bronchodilator such as formoterol, which is typically effective for 12 hours, so that twice daily dosing may provide 24 hour bronchodilator cover, on an "as required" basis seems illogical. Prescribing these medications regularly and twice daily, when they can usually be taken at home without having to transport ancillary devices such as spacers, would seem to maximise the chances of optimal compliance with therapy as well as delivery of the inhaled drug. We would not insist that regular long-acting bronchodilators and corticosteroid should be inhaled from the same device: ciclesonide, for example, an excellent inhaled corticosteroid, may be taken just once daily.	Thank you for your comment The evidence shows that ICS/formoterol used as required is the best initial therapy for people with mild asthma. This is explained in the associated rationale and in evidence review P.
British Society for Allergy and Clinical Immunology	Guideline	014	004	Again, there is a rationale to transfer all patients taking "as required" inhaled medication for asthma to regular, 12 hourly treatment with inhaled formoterol/corticosteroid.	Thank you for your comment There is no evidence comparing transferring this group of people to AIR vs transferring to MART. As they have not been on ICS in any form the committee believe they should try AIR first.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Allergy and Clinical Immunology	Guideline	015	005	Again, there is a rational for treating all children with asthma initially with low dosage maintenance and reliever therapy, although we acknowledge that no asthma inhalers are currently licensed for MART use in children under 12. Correct, monitored usage by the carers of devices and spacers is critical.	Thank you for your comment The committee are sympathetic to your suggestion. However, there is no evidence on AIR in children, and although there is some evidence on MART the treatment is not licensed for those aged 5-11. This was discussed at some length by the committee before settling on the current recommendations.
British Society for Allergy and Clinical Immunology	Guideline	021	001	Self-management asthma plans for patients of all ages should include a full knowledge of clinically relevant sensitisation to environmental and dietary allergens as well as strategies for management of allergic symptoms and strategies to avoid or minimise exposure.	Thank you for your comment. This is a legacy recommendation from the 2017 guidance. No new evidence review was undertaken, and we cannot make substantial additions to it. However, the recommendation has been changed slightly to indicate that other triggers should be considered.
British Society for Allergy and Clinical Immunology	Guideline	021	1.14.3	The self-management plan must also include a description of known triggers and eg pets, seasonal factors HDM, occupational factors etc	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					1.14.3 is a legacy recommendation which is not part of this consultation.
British Society for Allergy and Clinical Immunology	Guideline	029	001	Other recommendations for research: The NICE/BTS might consider the possibility of investigating the development of inhaled calcilytics for asthma therapy: These drugs antagonise the calcium sensing receptor, over-expression of which appears to underlie bronchial smooth muscle hyperresponsiveness in asthma, and so when administered topically could eliminate the risk of bronchospasm causing breathlessness or death in patients with asthma (Topical therapy with negative allosteric modulators of the calcium-sensing receptor (calcilytics) for the management of asthma: the beginning of a new era? Riccardi D et al. Eur Respir J 2022;20:2102103).	Thank you for your comment The research recommendations are based on a literature search that was performed for the guideline, but which did not reveal adequate evidence. This is standard NICE methodology which has also been used in this BTS/SIGN/NICE process and research recommendations cannot be put forward to address a question that was not part of the guideline.
British Society for Allergy and Clinical Immunology	Guideline	031	023	This statement suggests that there are only 20% false positives if eosinophil count is taken in isolation. - other causes for eosinophilia are: • Parasitic and fungal diseases. • Allergic reactions. • Adrenal conditions. • Skin disorders.	Thank you for your comment Your list of other reasons for a raised eosinophil count is compatible with the statement that a raised count has 80% specificity for asthma in the context of an appropriate history. The rationale acknowledges that there is no perfect

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				• Toxins. • Autoimmune disorders. • Endocrine conditions. • Tumours. etc	test for asthma, but that does not mean that a test does not improve diagnostic accuracy above reliance on clinical features alone.
British Society for Allergy and Clinical Immunology	Guideline	032	003	Since neither elevated blood eosinophils nor exhaled FeNO are diagnostic of asthma, the question arises what these add to the diagnostic procedure. Not all asthmatic patients are atopic.	Thank you for your comment The rationale acknowledges that there is no perfect test for asthma, but that does not mean that tests do not improve diagnostic accuracy reliance on clinical features alone
British Society for Allergy and Clinical Immunology	Guideline	032	010	Spirometry without reversibility should be the first test and the FV loop provides evidence of airflow obstruction	Thank you for your comment You have stated your own belief without any explanation why this should be a first test. The rationale to the guideline explains why it should not be first.
British Society for Allergy and Clinical Immunology	Guideline	032	012	Which is the first test that reflects atopy? I hope you are not referring to total IgE	Thank you for your comment The first test will be either FeNO and/or an eosinophil count, not a total IgE. The sentence says "reflect" atopy, not "define" atopy.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Allergy and Clinical Immunology	Guideline	032	018	Methacholine and mannitol are different tests, not entirely comparable providing different information with methacholine resulting in directly triggered bronchoconstriction and mannitol causing an indirect effect through mucosal mast cells / basophils	Thank you for your comment The committee agrees.
British Society for Allergy and Clinical Immunology	Guideline	032	024	It is hard to see that testing children for sensitisation to house dust mite, which may or may not have clinical sequelae according to whether or not the sensitisation is clinically relevant, and elevated total serum IgE concentration have high specificity for the diagnosis of asthma in children.	Thank you for your comment Please see the relevant evidence reviews
British Society for Allergy and Clinical Immunology	Guideline	033	010	The committee are wrong to consider that atopy alone gives rise to a raised FeNO in children which of course is also found in eosinophilic asthma which is non-atopic	Thank you for your comment The developers think this is a reference to the sentence which says a raised FeNO is unlikely in non-atopic children. This is not the same as saying only atopic children have raised FeNO, but it has been changed to "less likely". It does not affect the argument laid out in this paragraph for recommending spirometry with reversibility.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Allergy and Clinical Immunology	Guideline	033	016	The committee appear to have been misled into thinking that HDM is the only relevant allergen in asthma and that the diagnosis of asthma should be confirmed without seeking other allergic triggers for asthma and therefore whenever allergic asthma is suspected , whether in children or adults, SPT must include all the allergens the person may be allergic to from clinical history eg pollen in seasonal asthma, pets Aspergillus or other fungal spores etc	Thank you for your comment The committee have not been misled. HDM is highly relevant to asthma in many people and is therefore singled out. There is nothing to stop clinicians from skin prick testing to other allergens.
British Society for Allergy and Clinical Immunology	Guideline	033	017	Total IgE by itself does not provide specific or sensitive information and which cut-off is the committee suggesting?	Thank you for your comment Please read Evidence review E.
British Society for Allergy and Clinical Immunology	Guideline	033	021	Contradictory as previously stated that a single cut-off for eosinophil count would not be given?	Thank you for your comment You are taking a quote from the adult section and applying it to children. This is not contradictory. The committee discussed this and decided that a single level should be specified in children because normal levels vary during childhood years, and this would be an unnecessary complication for users.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Allergy and Clinical Immunology	Guideline	036	010	Is the committee suggesting that there is no routine measure of lung function even at annual review – this is a dangerous precedent as some asthmatics who are not good at perceiving asthma symptoms have a slow decline in airway calibre and these will not be picked up unless they have at least one annual measure of peak flow or preferably spirometry. It will become increasingly important to measure lung function with the recommendation of an earlier introduction of combination inhalers as this practice although reduces exacerbations may lead to decreased lung function	Thank you for your comment PEF variability has now been added to the diagnosis section. The evidence review on monitoring lung function in all people with asthma did not find that this was beneficial.
British Society for Allergy and Clinical Immunology	Guideline	049	015	These are outdated figures and do not reflect the whole picture on asthma mortality. NICE should obtain figures for 2023 before publishing this guideline. There should also be a comparison on deaths in each age group as asthma deaths have halved in the under 75y age group in the past 25 years reflecting the great strides made by the asthma community during this time-frame.	Thank you for your comment This is a high-level overview of the reasons for updating the guideline and a detailed breakdown of deaths by age group is not appropriate here

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Allergy and Clinical Immunology	Guideline	051	Deleted in table 1.1.9	This statement from P51 should not be deleted as chronic management includes avoidance of triggers which can only be identified in many cases by skin testing. Skin testing is more cost effective than specific IgE testing.	Thank you for your comment It was deleted for the reasons given in the table
British Society for Allergy and Clinical Immunology	Guideline	052	Deleted in table 1.3.8	PEF variability remains a useful test for occupational asthma or when returning from university or when visiting relatives in order to assess the impact of environment. Also it remains correct that Obstructive spirometry with positive bronchodilator reversibility increases the probability of asthma (deleted P 61)	Thank you for your comment It was deleted from the draft guideline for the reasons given in the table
British Society for Allergy and Clinical Immunology	Guideline	062	Deleted in table 3.3.3	Difficult to understand this statement as all clinical diagnoses are divided according to probability after taking a clinical history and subsequent investigations tailored depending on likelihood of a specific diagnosis.	Thank you for your comment This refers to the formal decision to categorise probability followed in SIGN158 and its predecessors.
British Society for Allergy and Clinical Immunology	Guideline	064	Deleted in table 4.3.3	Can the committee kindly appraise us on the difference between risk stratification and assessment of risk of future asthma attacks.	Thank you for your comment The deleted recommendation advises asking about risk factors at every review. Risk stratification is about using risk factors to identify people whose care should be organised

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					more intensively (for example, priority appointments). As the table says, the two are related since one uses the information from the other.
British Society for Allergy and Clinical Immunology	Guideline	064	Deleted in table 7.1.1	This is a good recommendation deleted from the previous guideline and allows a targeted approach to identifying high risk patients which the current guideline has advocated.	Thank you for your comment Identifying high risk people and targeting care is the point of 1.15.1, and this includes overuse of SABA
British Society for Allergy and Clinical Immunology	Guideline	065	GPP, 7.2.2	This conclusion cannot be supported and assumes that asthma is always mild/moderate severity at first diagnosis. The committee should remember that NRAD demonstrated that patients with apparently mild asthma can die from their first severe attack. Therefore, initial treatment should always be at an appropriate level and dependent on asthma severity and in some cases may require medium to high dose ICS/MART.	Thank you for your comment The deleted Good Practice Points were about starting doses of ICS, and they are replaced by the recommendations in section 1.7. It is not clear what conclusion you feel cannot be supported as the old and the new say much the same thing.
British Society for Allergy and Clinical Immunology	Guideline	071	Deleted in table 12.5	All medications should are not always used in line with manufacturers' Recommendations The statement above is not quite correct as the extracts from the SPCs below demonstrate:	Thank you for your comment. The developers agree. The comment in the table has been changed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				1)Theophylline should not be administered during pregnancy unless clearly necessary. 2) Formoterol should not be recommended for use during pregnancy and particularly at the end of pregnancy or during labour unless there is no other (safer) established alternative. AND because of later recommendations regarding LTRA and LAMAs show 1.12.5: If leukotriene receptor antagonists or long-acting muscarinic receptor antagonists are needed to achieve asthma control, they should not be stopped during pregnancy. [1.12.5]	
British Society for Allergy and Clinical Immunology	Guideline	078		Table P 78 – suggest change to - Take into account and try to address the possible reasons for uncontrolled asthma before starting or adjusting medicines for asthma in adults, young people and children ***or before referring to specialist services***. These may include……. [1.6.1]	Thank you for your comment The advice in 1.6.1 should be followed whenever medication is adjusted, and therefore it should have been done several times before a referral is made. The committee do not think it would be a useful addition.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Society for Allergy and Clinical Immunology	Guideline	084	1.10.1	At annual review…. This is a rather inflexible recommendation and not at all patient-centred and suggests that doses can only be changed once per year – what about seasonal asthma or if known triggers have been removed etc?	Thank you for your comment 1.10.1 does not say that stepping down should only be done at annual review. It says that this is a good time to discuss stepping down, which is true.
British Society for Allergy and Clinical Immunology	Guideline	General	General	The asthma guideline is a useful summary for non-experts and particularly primary care treating asthma. It introduces the concept of confirming the diagnosis of asthma at the very core of management and is simpler than the previous NICE guidance which suffered from being over-complex and hence little used.	Thank you for your comment
British Society for Allergy and Clinical Immunology	Guideline	General	General	BSACI fully concurs with the earlier use of combination inhalers in both adults and children thereby reducing the role of SABAs. However, there remains confusion within the guideline on whether identification of triggers lies within chronic management and monitoring. BSACI would argue that if triggers are not specifically investigated and every patient endotyped then chronic asthma management is	Thank you for your comment The guideline does not go into detail on the issue, but it does recommend assessing possible triggers at presentation and when considering asthma control. The section on non-pharmacological management of asthma which was part of SIGN158 is not in the scope for this

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				severely compromised and easily identified triggers such as pets or occupational factors etc will be overlooked. Identification of triggers and endotyping is an essential part of asthma diagnosis and ongoing management.	update. BTS & SIGN will produce future guidance on this.
British Society for Allergy and Clinical Immunology	Guideline	General	General	The committee has made no mention of the fact that using MART often requires the prescription of >1 combination inhaler per month and GP surgeries should be advised to prescribe an appropriate number of inhalers – as this is a major cause of loss of control when a MART inhaler runs out before the end of the month	Thank you for your comment. Healthcare professionals may need to be educated on MART (although it has been around for nearly 20 years). This is an implementation issue. Your comments will be considered by NICE where relevant support activity is being planned.
British Society for Allergy and Clinical Immunology	Guideline	General	General	This guideline will result in increased referrals to specialist care when centres are already at capacity resulting in increased costs at least initially and may disadvantage patients with severe asthma due to longer waiting times. Therefore the guideline must include details of adherence before referring for a specialist opinion and the information incorporated into the referral letter if	Thank you for your comment There is no obvious reason why referrals to severe asthma services should increase as a consequence of the new recommendations, although referrals to asthma specialists may well. However, these will be referrals for

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				referral is still considered despite inadequate adherence.	appropriate reasons and should benefit patient care overall. The need to check adherence is referred to multiple times in the guideline.
British Society for Allergy and Clinical Immunology	Guideline	General	General	The guideline lacks diagrams which would increase impact and accessibility and provide a teaching aid.	Thank you for your comment There are flowsheets to support the text.
British Society for Allergy and Clinical Immunology	Guidleine	006	006	Elevated FeNO, in children as in adult, is not specifically diagnostic of asthma.	Thank you for your comment Elevated FeNO is not definitively diagnostic but in the presence of a supportive history it is an extremely useful marker of asthma.
British Society for Immunology	Guideline	005	1.2 full section	Regarding the guidance for children aged 5 to 16 "If asthma is not confirmed by FeNO or BDR but still suspected on clinical grounds, either perform skin prick testing to house dust mite or measure IgE level and eosinophil count." we are concerned that this is going to unnecessarily increase the need for total IgE and house dust mite allergy testing in these patients. In our experience sensitisation to house dust mite is common and often encountered in patients without asthma. Raised total IgE is also not	Thank you for your comment. The committee agrees that house dust mite allergy and raised total IgE level are not specific to asthma, but in the context of a child with symptoms suggestive of asthma they believe that they are helpful, particularly if negative.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				uncommon and is seen in various conditions, including parasitic infections and other atopic diseases like eczema, NSAID-exacerbated respiratory disease and allergic rhinitis. We believe that total IgE does not progress diagnosis of asthma per se but it does help phenotype the type of asthma and guide biological or desensitisation therapies. However, if these treatments are not required it may be perfectly possible to diagnose and treat most asthma.	
British Thoracic Society	General	General	General	Would it be challenging to implement of any of the draft recommendations? Please say why and for whom. Please include any suggestions that could help users overcome these challenges (for example, existing practical resources or national initiatives. 1. The use of FeNO in primary care is still not widespread. The FeNO AAC programme successfully increased the use of FeNO in primary care, however, further implementation is needed for these guidelines to be implemented. This could involve similar programmes of work such as the AAC and/or support through Health	Thank you for your comments. The committee agrees with the implementation issues you identify, and also that many prescribers will not wish to prescribe MART to children aged 5-11. A separate set of recommendations has therefore been provided which does not include MART. Your comments will be considered by NICE where relevant support activity is being planned.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Innovation Networks. Subsidising the cost of consumables would be helpful and further education would be essential. 2. Diagnosis in children a) Timely access to FeNO, spirometry test in the community is still problematic b) paediatric phlebotomy service availability in primary care is sparse c) Allergy services/skin prick tests for paediatric patients are not available in primary care. Secondary care allergy services are overwhelmed d) Spirometry/FeNO tests are usually normal in children as they are performed when children are asymptomatic Due to the above factors, the utility and implementation of objective tests in primary care for diagnosis of asthma remains problematic. 3. Treatment regimens in children Recommending MART in 5-11 yr olds when no licensed inhaler is available in the UK is problematic. Health professionals in primary care are unlikely to prescribe 'off label/ licence' inhaler for MART	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				regimen. If 'specialists' prescribe off label inhaler, the GPs are unlikely to provide repeat prescriptions. This will have huge implications on secondary care or result in poor implementation Research recommendation: Further research on the safety, efficacy and economic impact of MART regimens in children aged 5-11 is needed.	
British Thoracic Society	General	General	General	Would implementation of any of the draft recommendations have significant cost implications? 1. There will be a cost implication to increase use of FeNO (machine, consumables and education) 2. It is likely that MART/low dose ICS-formoterol will be associated with increased prescribing costs	Thank you for your comment. The resource impact of the increase of FeNO has been discussed in the chapter, in the section entitled 'Committee Discussion of the Evidence'. For MART/low dose ICS-formoterol, these recommendations are primarily for newly diagnosed asthma and were not considered to have a significant resource impact by the committee and were found to be cost-effective treatment options. **A resource impact summary report and local template will be produced** as part of this guideline.
British Thoracic Society	General	General	General	The updated recommendations in this guideline will require the NICE indicator on asthma diagnosis (NM166), currently included in NHS England's Quality and Outcomes Framework	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				(QOF AST011), to be amended. The current wording for NICE indicator NM166 is: The percentage of patients with asthma on the register from (start date) with a record of spirometry and one other objective test (FeNO or reversibility or variability) between 3 months before or 3 months after diagnosis. Please indicate whether you would prefer an updated indicator to focus on the initial diagnostic test (option A) or any objective test (option B) around the time of diagnosis, and why: A. The percentage of patients with asthma on the register from (start date) with a record of fractional exhaled nitric oxide (FeNO) (adults and children) or blood eosinophil count (adults) or spirometry with bronchodilator reversibility (children), between 3 months before or 3 months after diagnosis. B. The percentage of patients with asthma on the register from (start date) with a record of an objective test (eosinophil count, fractional exhaled nitric oxide (FeNO), spirometry, peak	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				flow with bronchodilator reversibility, bronchial responsiveness (in adults), skin prick test or blood IgE level (in children)) between 3 months before or 3 months after diagnosis.	
British Thoracic Society	Guideline	000	000	'Referral to a specialist in asthma care' is mentioned a few times in the guideline and also in the treatment flow chart. We recommend including a list on 'when to refer to a specialist in asthma care' to ensure referrals are made appropriately and in a timely way. • Diagnostic uncertainty and for additional investigations • Patient who are symptomatic and have experienced >1 exacerbation despite optimised adherence to moderate dose ICS/LABA (patients should be referred whilst LTRA or LAMA is initiated) • Patients who are symptomatic despite moderate dose ICS, LTRA and LAMA • Patients who are not controlled despite optimised adherence to high-dose ICS (optimised adherence implies that adherence has been assessed and there has been some	Thank you for your comment. The committee was not asked to consider indications for referral. A link has been added to the AAC pathway document which covers the issue.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				attempt at improving it but it may be that it is not good; poor adherence itself should not be a barrier to referral)	
British Thoracic Society	Guideline	004	004	The guideline advises a structured clinical history for diagnosing asthma in children aged 5-16, yet lacks clarity on what constitutes a suggestive history, specifically with FeNO levels over 35 ppb. Clearer criteria include frequent or severe symptoms like wheeze, breathlessness, chest tightness, and cough. ERS guidelines suggest a lower FeNO cut-off of 25 ppb, more sensitive for this age group. Raised FeNO supports but does not confirm asthma diagnosis, as levels can also rise due to allergic rhinitis, eczema, atopy	Thank you for your comment Ideally, we would include a FeNO cut-off which is adjusted precisely for age, but currently this is not possible. The committee agreed a cut-off of 35ppb which is less sensitive but more specific for asthma because this is the first, and potentially the only, diagnostic test in children and setting it lower will increase false positive diagnoses.
British Thoracic Society	Guideline	005	009	Recommendation 1.1.5: PEFR with bronchodilator reversibility: add definition of what constitutes PEF reversibility	Thank you for your comment. The committee believes this should remain. This recommendation deals with the less frequent situation where a person presents with acute symptoms requiring immediate treatment. Whilst the committee would not advise measuring change in PEF in other circumstances, here it is more likely to be

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					possible to measure PEF than FEV1, and the acute response could provide valuable diagnostic information.
British Thoracic Society	Guideline	005	017	Recommendation 1.1.7: 'Be aware that the results of spirometry and FeNO may be affected in people who have been treated with inhaled corticosteroids'. This should be further clarified to state: Be aware that the results of spirometry and FeNO may be affected in people treated with inhaled corticosteroids (both tests maybe normal).	Thank you for your comment. This has been added.
British Thoracic Society	Guideline	006	003	Bronchial hyper-responsiveness testing Clarify that at this stage patients will be referred to secondary care for the test.	Thank you for your comment. This is correct at present and has been added to 1.2.4.
British Thoracic Society	Guideline	006	010	Skin prick testing is not predictive of asthma in children, and a negative atopic status does not exclude asthma. The ERS task force found skin prick tests unsuitable for asthma diagnosis due to their non-specific nature, potentially leading to overdiagnosis and unnecessary asthma treatment, increasing costs with little benefit.	Thank you for your comment These tests should be performed after negative FeNO and BDR, and in that situation negative atopic status makes asthma unlikely.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Evidence for diagnosing asthma based on IgE levels and eosinophil counts is insufficient in children.	
British Thoracic Society	Guideline	006	012	Should read 'total' IgE	Thank you for your comment This has been corrected
British Thoracic Society	Guideline	006	017	Referral for bronchial challenge testing is unrealistic as most UK secondary and even tertiary care services lack this capacity. An 8-week trial of treatment, stopping, and re-evaluating symptoms when initial tests are inconclusive but suggestive of asthma, is recommended for older children, aligning with GINA guidance despite limited evidence. Watchful waiting could also be considered. If no improvement, referral to secondary care is advised. If symptoms recur after stopping treatment, this supports a diagnosis and restarting low-dose prevention treatment.	Thank you for your comment The evidence shows that bronchial challenge is the best single test for asthma and the committee believe it should be included, albeit at the end of the testing pathway when other investigations have not been conclusive.
British Thoracic Society	Guideline	007	003	Could include characteristics that increase the probability of an asthma diagnosis eg. Atopy, and confirmed triggers like: exercise, pets, family history	Thank you for your comment These have already been mentioned in the non-age specific recommendation 1.1.1.
British Thoracic Society	Guideline	008	004	Recommendation 1.4.1	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Suggest the bullet points are reworded to include current occupation and also make the question easier for the clinician: - If they are employed and what sort of work they do - Are symptoms the same, better or worse on days away from work such as rest days or holidays?	The wording of this recommendation is taken from the previous BTS/SIGN and NICE guidelines and was not reviewed in detail by the committee. Unless there is evidence that a different form of words is better, the recommendation should be retained as it is.
British Thoracic Society	Guideline	008	019	Recommendation 1.5.2 A validated symptom questionnaire should be used to assess asthma control in adults. Therefore, suggest removing the word 'Consider'. This will ensure that 'asthma control' as defined on page 25 is assessed	Thank you for your comment The committee sympathises with your point, but in the evidence review the benefit of using standard questionnaires was not as strong as might have been expected. In this circumstance NICE policy is to use the word "Consider" in its recommendations, therefore this terminology is used in this BTS/NICE/SIGN guidance.
British Thoracic Society	Guideline	008	020	Recommendation 1.5.2 Include child ACT (cACT) as a validated tool in children	Thank you for your comment Children's questionnaire has been added to the examples.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
British Thoracic Society	Guideline	008	025	Recommending FeNO testing for monitoring asthma in children is problematic. A large UK randomised control study clearly demonstrated the FeNO guided treatment, when compared to symptom based treatment did not reduce asthma attacks. (Turner et al, Lancet:2022). Indeed, many children may unnecessarily prescribed higher dose of ICS.	Thank you for your comment. Several stakeholders have raised a similar point. The study you cite was negative, but overall, the studies show a slight benefit, albeit that increased ICS doses were required to achieve this. It is true however, that FeNO monitoring in children was less cost-effective than in adults. The recommendation has been reviewed and the committee have decided it should be limited to adults.
British Thoracic Society	Guideline	009	019	Recommendation 1.6.1: In addition to 'obesity' other conditions that can present with breathlessness should be listed to encourage the clinician to consider them e.g. reflux, breathing pattern disorder. It may be more suitable to list these in the appendix as 'differential diagnosis' or 'asthma mimics' as the list would also include anxiety, laryngeal dysfunction	Thank you for your comment. Several stakeholders have suggested additions which might be made to this bullet point, and on reflection the committee have agreed that no examples are necessary, the meaning of the recommendation being clear without them.
British Thoracic Society	Guideline	011	000	The use of a spacer device with a pMDI needs to be emphasised. Suggest added a recommendation between 1.6.7 and 1.6.8 that states:	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				For any patient using a pMDI, ensure a spacer is also prescribed, and that they can use inhaler and spacer device effectively	Neither the latest BTS/SIGN guideline nor the NICE guideline recommended that adults should always use an MDI via a spacer, and this topic was not prioritised for evidence review during scoping. It is therefore difficult to make a firm recommendation.
British Thoracic Society	Guideline	011	018	Recommendation 1.6.8 If possible, this statement should be further clarified- 'Encourage people to take their used inhalers to their pharmacy for disposal/ recycling and inform patients that inhalers cannot be recycled in household recycling services	Thank you for your comment. The wording has been changed
British Thoracic Society	Guideline	012	004	Recommendation 1.7.1 and 1.7.2 It should be emphasised that this is a SABA free approach. Suggest: Offer a low-dose ICS/formoterol combination inhaler to be taken as needed for symptom relief to people aged 12 and over with newly diagnosed asthma. This is a SABA free approach so no salbutamol inhaler is required.	Thank you for your comment SABA inhalers are not required for AIR or MART, and this has been added to the descriptions in the glossary. Instruction regarding the amount of medication to prescribe is beyond the remit of the guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				It also needs to clarify that >1 inhaler may need to be issued per repeat prescription to allow adherence to MART regimes	
British Thoracic Society	Guideline	013	000	Section on medicine combination and sequencing: We welcome the emphasis on low dose ICS/formoterol and MART. However, in some cases once daily preparations maybe preferred and should be considered to help adherence. The guideline should mention this to help guide primary care	Thank you for your comment The evidence shows MART to be superior to regimens of maintenance ICS/LABA with SABA as reliever. The various MART studies were all performed when twice daily maintenance therapy was the standard, and the committee therefore did not see evidence comparing MART with once daily maintenance regimens. It would therefore be problematic to make evidence based recommendations. The committee also did not find enough evidence to recommend MART with a once daily maintenance dose, although this may work for some people with asthma.
British Thoracic Society	Guideline	013	006	Recommendation 1.7.4, 1.7.5, 1.7.6 If patients are not controlled on moderate dose MART there should be 2 recommendations:	Thank you for your comment The committee agrees that your suggestion would be a sensible form of practice. However,

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				1. Check FeNO. If it is raised, increase to fixed high-dose ICS/LABA. If FeNO is not raised, trial of LTRA and LAMA for a maximum of 3 months 2. If FeNO testing unavailable, trial of LTRA and LAMA for a maximum of 3 months We agree with the committee that patients should not be increased to high-dose ICS/LABA without checking FeNO. However, the guideline recommends checking FeNO before and after treatment changes (receommendation 1.5.4), and therefore, at this stage, for these high-risk patients, FeNO should be checked to help guide the next treatment change	tying treatment increases to FeNO levels has been avoided because at present a majority of practices do not have ready access to FeNO measurements. It should also be noted that most of the evidence on which treatment steps are based is from studies which did not incorporate FeNO. There is of course, nothing to stop those with access to FeNO from using the additional information.
British Thoracic Society	Guideline	013	008	Recommendation 1.7.5, 1.7.6 Trial of LTRA and LAMA should be for a maximum of 3 months, not a minimum of three month to avoid unnecessary delay in referral of patients. (also, recommendation 1.6.3 recommends that the response to any treatment change is reviewed in 8-12 weeks. Therefore a 3 month	Thank you for your comment The recommendations have been changed to be consistent with 1.6.3

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				time period for assessing response to LTRA and LAMA is appropriate)	
British Thoracic Society	Guideline	013	019	Recommendation 1.7.7 This treatment trial sequence can lead to considerable and unnecessary delay in the referral of high-risk patients. We suggest the below statement is added in: Patients who are symptomatic and have experienced >1 exacerbation despite optimised adherence to moderate dose MART should be referred to a specialist in asthma whilst LTRA or LAMA is initiated	Thank you for your comment You are effectively saying that people should be referred if their control is poor on medium dose MART, irrespective of how long they have been well controlled on this treatment. There may be a simple explanation which is well within the ability of primary care to deal with. Note that although the guideline says that referral should be made at the point where LTRA and LAMA have been tried, there is nothing to stop an earlier referral if it is agreed that this might be beneficial. Having said this, your concern is recognised and recommendation 1.7.6 has been amended so that the possibility of an earlier referral is now included.
British Thoracic Society	Guideline	014	004	Recommendation 1.7.8 This statement should not start with 'Consider' given that the document already states that no-	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				one with asthma should be treated with only SABA. Suggest: People with confirmed asthma who are currently using a SABA only should be moved to a low-dose ICS/formoterol combination inhaler.	The word "consider" in NICE guidelines is used when evidence is lacking and the same applies to this collaborative guideline. However, in this instance the developers agree that there is a major safety issue and the wording has been changed.
British Thoracic Society	Guideline	016	001	Recommendation 1.7.12 Suggest reword to include 'optimised adherence to high-dose ICS'	Thank you for your comment Adherence is listed as one of the factors which should always be considered when asthma is not controlled (recommendation 1.6.1) and it covers those on high dose ICS who are the subject of 1.7.12 as it does those uncontrolled on any treatment step.
British Thoracic Society	Guideline	016	025	Referral of children with uncontrolled asthma should be made after *adherence* to moderate dose ICS therapy has been confirmed	Thank you for your comment Recommendation 1.6.1 sets out the principles which should be applied whenever asthma control is poor, and it therefore applies to

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					recommendation 1.8.7. This includes addressing adherence.
British Thoracic Society	Guideline	017	004	Recommendation 1.9.1 Paediatric low dose for <5 year needs to be clarified	Thank you for your comment A link is now included to the "Inhaled corticosteroid doses for the BTS, NICE and SIGN asthma guideline" table.
British Thoracic Society	Guideline	018	006	Recommendation 1.9.4 The rationale for a trial without treatment at this stage (in patients with established symptoms, triggers, atopy) may not be appropriate	Thank you for your comment The committee debated these recommendations at length. If diagnosis in this age group was easy the process of stopping and starting treatment would not be necessary. There are conflicting risks around treating a non-asthmatic child for a prolonged period with inhaled steroids versus symptoms relapsing in an asthmatic child when treatment is stopped. The committee decided that a trial without treatment is justified.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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British Thoracic Society	Guideline	018	008	Should also include link to MHRA alert on neuropsychiatric side effects	Thank you for your comment A link to the MHRA DSU is included in the guideline
British Thoracic Society	Guideline	018	011	Link to MHRA report on neuropsychiatric adverse effects with montelukast. Parents / carers should be advised to report behaviour changes or sleep disturbances.	Thank you for your comment. A link to the MHRA DSU is included in the guideline.
British Thoracic Society	Guideline	018	014	'or LTRA is not tolerated' should be added to clarify that being on a LTRA is not a pre-requisite for referral	Thank you for your comment. The wording has been clarified as you suggest.
British Thoracic Society	Guideline	019	014	1.11 Suggest adding here (or elsewhere as appropriate)- Check for SABA overuse by reviewing prescription records	Thank you for your comment Checking for SABA overuse is covered in sections 1.5 and 1.10.
British Thoracic Society	Guideline	020	022	1.13.1 *Discuss future career choices with adolescents with asthma and highlight occupations that might increase susceptibility to work-related asthma symptoms.*	Thank you for your comment The recommendations in this section have been transferred from the BTS/SIGN guidance. Your

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				We suggest removing 1.13.1 as (1) there is wide variation in the work roles in different occupations (2) it is unlikely that the individual advising would have sufficient expertise about these variations to be able to appropriately counsel a young person (3) adjustments may be possible in occupations under the Equality Act to allow a young person to fulfil their career choices.	points are acknowledged but the recommendation just suggests highlighting potential problems (i.e. informing the person with asthma), not barring certain careers to young people with asthma.
British Thoracic Society	Guideline	021	008	Add that other environmental factors may trigger symptoms/exacerbations such as high pollen count	Thank you for your comment. This is a legacy recommendation from the 2017 guidance. No new evidence review was undertaken, and we cannot make substantial additions to it. However, the recommendation has been changed slightly to indicate that other triggers should be considered.
British Thoracic Society	Guideline	023	01	Recommendation 1.15: Risk-stratified care In addition to 'repeated episodes of unscheduled care for asthma', this list should also include: Repeated courses of oral corticosteroids for asthma	Thank you for your comment The committee supports the NICE Quality statements and the BTS Care Bundle for asthma attacks, but neither of these refers to

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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					entering people on a risk stratification system, which is the purpose of 1.15.1.
Cardiff and Vale UHB	Guideline	005	019	We are pleased to see a focus on biomarkers early in the diagnosis of asthma. There will be ongoing challenges in access to FeNO but agree the inclusion of this test high in the diagnostic pathway by NICE will encourage fundholders to further develop this service in primary care. We are interested to see that peak flow diary is no longer included in the guideline. This is surprising given it is a cheap, easy and in our experience clinically useful test. We feel it still has a place in diagnosis alongside looking for biomarkers of type 2 inflammation which of course may be related to other causes such as rhinitis or co-existent eczema. It is also a helpful test in establishing best lung function which will then influence asthma management plans and so is useful to perform at diagnosis. We wonder if there should be a comment around proceeding with further tests in the diagnostic pathway if an individual does not gain	Thank you for your comment. The committee recognise that access to FeNO and bronchial challenge tests is inadequate at present but hope that recommending them here will help to increase provision. Measurement of PEF variability has been added to the diagnosis sections. Some text to address this in principles of treatment (6.1). Also relevant to possible differential diagnosis table. This is enough, no need for separate rec.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				the expected response to inhaled therapy, particularly if the diagnosis has only been made through eosinophils or FeNO – we would advocate then checking reversibility for example. The recommendation that patients without elevated biomarkers or evidence of reversibility in FEV1 should have a bronchial challenge test will be challenging to implement due to the availability of these tests and based on current models of care will result in significant referrals to secondary care respiratory clinics to access this. Despite this we welcome the increased focus on objective confirmation of asthma diagnosis and agree this test is needed for this population.	
Cardiff and Vale UHB	Guideline	General	000	We welcome the updated asthma guideline and in particular strongly welcome the inclusion of anti-inflammatory reliever therapy as a treatment strategy for mild asthma. We have adopted a similar strategy in the All Wales asthma guidelines and feel this will ultimately improve patient outcomes, reduce SABA over-reliance and help address the respiratory carbon footprint (which is greatly influenced by SABA MDi relievers).	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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Chiesi UK	General	General	General	*1.Would it be challenging to implement of any of the draft recommendations? Please say why and for whom. Please include any suggestions that could help users overcome these challenges (for example, existing practical resources or national initiatives.* Chiesi acknowledges some of the changes made to tackle issues currently related to asthma care in the UK such as SABA-overuse and the inclusion of MART. However, we feel the guidelines to do not reflect the heterogenous nature of asthma with the guidelines being potentially perceived as adopting a one-size fits all approach. Nor does it acknowledge the finite resource within primary care. The implementation of these guidelines will require a radical cultural prescribing change and re-education for prescribers and patients. The draft already shows inconsistency with the latest GINA (Global Initiative for	Thank you for your comment. The committee agrees that people with asthma are not all the same, but this argument can be applied to all condition-based guidelines. The recommendations point out which diagnostic or therapeutic actions are most likely to benefit most people, but it is always up to the responsible clinician to decide if this should be applied to an individual person bearing in mind comorbidities, patient-choice etc. The statement that some of the recommendations are based purely on cost is false. NICE guidelines take cost-effectiveness into account, but not cost alone, and this is the same for this collaborative guideline. The use of FeNO in diagnosis is as a rule-in test and will not cause a diagnosis of asthma to be rejected. Your comments will be considered by NICE where relevant support activity is being planned.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Asthma) guidelines and various regional guidelines which collectively may lead to poor acceptance or uptake of these guidelines. Patients should be at the centre of every treatment decision which is strongly correlated to improved adherence and outcomes. Prescribers must be aware of the various differing treatments available to them and recognise patient needs. There is a concern that some of the suggestions within the draft do not reflect evidence-based medicine and choices are decided purely on cost. It is well recognised that the preference for FeNO/eosinophil testing is indicative of TH2 inflammation, but this does not provide the complete picture and fails to recognise non-TH2 inflammation phenotypes.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Chiesi UK	General	General	General	1. Would implementation of any of the draft recommendations have significant cost implications? The advocation for FeNO/Eosinophil testing may have significant cost implications.	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned.
Chiesi UK	General	General	General	2. Please indicate whether you would prefer an updated indicator to focus on the initial diagnostic test (option A) or any objective test (option B) around the time of diagnosis, and why: Chiesi do not adopt a position and therefore do not have a comment	Thank you for your comment
Chiesi UK	Guideline	009	019	**Inhaler Switching & Unconsented Switching** We support the inclusion of identifying reasons for uncontrolled asthma, but suggest including as a separate bullet point: • **Recent inhaler switching especially unconsented inhaler switching**	Thank you for your comment. The committee agrees that this can be a problem but does not believe that a separate bullet point is necessary when both adherence and inhaler technique are both already highlighted.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				Rationale: Unconsented inhaler switching or switching inhaler treatments can lead to poor adherence and a loss of control which in turn, effectively harms the HCP-patient relationship.[1,2] Involvement of patients in their respiratory care is essential as evidence suggests this may promote adherence to treatment.[3] Chiesi understands the growing prominence of unconsented inhaler switching which leads to poorer asthma outcomes. We have documented insights from healthcare professionals in primary care being asked to switch patients via text or letter without patient acceptance or follow-up of their condition by the prescriber.[4] 1. Gilbert I et al. The Impact of a Forced Non-Medical Switch of Inhaled Respiratory Medication Among Patients with Asthma or Chronic Obstructive Pulmonary Disease: A Patient Survey on Experience with Switch, Therapy Satisfaction, and Disease Control. Patient Prefer Adherence. 2020 Aug 20;14:1463-1475	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				2. Usmani OS et al. Real-World Impact of Nonclinical Inhaler Regimen Switches on Asthma or COPD: A Systematic Review. J Allergy Clin Immunol Pract. 2022 Oct;10(10):2624-2637 3. Capstick TGD et al. Demystifying Dry Powder Inhaler Resistance with Relevance to Optimal Patient Care. Clin Drug Investig. 2024 Feb;44(2):109-114 4. Chiesi Data on File 2023	
Chiesi UK	Guideline	010	016	**Patient Preference & Enivronmental Factors** Whilst we agree with all points listed, we strongly recommend: **Placing 'preference of the person receiving the treatment' above 'lowest environmental impact among suitable devices.** **Rationale:** Patient-centred factors should be prioritised over environmental factors in the choice of treatments. In a survey conducted,	Thank you for your comment. The order of bullets is not supposed to reflect importance. However, as several stakeholders have requested this, it has been altered.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				environmental impact was the least important factor for patients, HCPs and NHS managers when considering the appropriate inhaler choice for respiratory conditions whereas efficacy and safety were considered paramount.[1] 1. Lewis H et al. Opinions on the environmental impact of inhaler devices in UK respiratory care. European Respiratory Journal. Sep 2019;54 (suppl 63) PA4196	
Chiesi UK	Guideline	010	016	**Dose Counters** We strongly recommend including: • **Inhalers with dose counters should be the preferred inhaler choice wherever possible.** **Rationale:** Dose counters minimise inhaler wastage by notifying the patient when their inhaler is empty, ensuring appropriate frequency for prescription ordering. It minimises waste and allows for dose monitoring by the patient.[1,2]	Thank you for your comment. A bullet point has been added to 1.6.5.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				1. Wasserman RL et al. Real-world assessment of a metered-dose inhaler with integrated dose counter. Allergy Asthma Proc. 2006 Nov-Dec;27(6):486-92 Chiesi Data on file	
Chiesi UK	Guideline	011	001	**Inclusion of Personalised Asthma Action Plans (PAAPs)** Whilst we agree with the paragraph, Chiesi recommends to include using Personalised Asthma Action Plans (PAAPs). PAAPs are a key tool in asthma management and should be utilised.	Thank you for your comment. PAAPs are recommended further on in the guideline (section 1.14)
Chiesi UK	Guideline	011	013	**Maintenace of Molecular Continuity** We also would include as separate text after 013: • **When switching between different inhaler devices outside of a clinical rationale, it is important to maintain**	Thank you for your comment. The phrase "molecular continuity" is not in common use and the committee believe this addition would not be helpful.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				molecular continuity wherever possible to minimise variable factors which can lead to loss of control.	
Chiesi UK	Guideline	011	014	**Patient Acceptance and Device Suitability** Chiesi supports device suitability and the importance of the right patient suited for the right device. In addition, we recommend including as a separate statement after 014: • **Care should be taken when patients are switched. Prescribers should be mindful of the importance of patient acceptance to switches and switches should not be done for economical or environmental reasons alone.** **Rationale:** Important that any treatment changes are accepted by the patient and in the best interests of the patient's clinical status. Switching stable patients can lead to poorer clinical outcomes and wider economic implications for the NHS.[1,2]	Thank you for your comment. The series of recommendations on inhaler devices make it clear that the person's ability to use their inhaler correctly is of paramount importance and the committee is not convinced that this addition is necessary.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Chiesi UK	Guideline	012	006	**Monitoring of ICS/Formoterol As Needed** Whilst we recognise the placement of ICS/Formoterol as needed in the treatment pathway, we recommend the mention that patients prescribed ICS/Formoterol as needed should be regularly monitored to ensure the safe use of this treatment regime and considered for escalation to a regular maintenance dose ICS/Formoterol if uncontrolled. **Rationale:** Patients considered mild may still require maintenance ICS to suppress underlying inflammation and not just introduce ICS/formoterol therapy beyond the threshold	Thank you for your comment The guideline states that people should be reviewed after any treatment is commenced or changed (recommendation 1.6.3), that they should have regular review at least annually (section 1.16) and that they should receive self-management advice and support (section 1.14) so the people who need to go onto regular maintenance therapy should be identified.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				where symptoms are clinically apparent. At the other end of the spectrum, patients may continuously reach maximum daily dosages of their as needed regime in which a more regular treatment regime would be more appropriate.	
Chiesi UK	Guideline	012	007	**ICS/Formoterol As Needed** Chiesi supports the inclusion of ICS/Formoterol as needed in the format presented as this reflects currently licensed treatments for this regime as well as treatments undergoing further clinical development.[1] Chiesi Data on File	Thank you for your comment
Chiesi UK	Guideline	013	008	**Placement of LAMAs Above LTRAs** Chiesi recommends the committee consider the evidence and the safety implications for choosing LTRAs over LAMAs. We suggest after moderate-dose MART, that LAMAs are the preferred step-up treatment. **Rationale:** Chiesi recognises the placement of LTRAs in asthma treatment, with insights gathered from healthcare professionals demonstrating that prescribers choose an LTRA	Thank you for your comment The available evidence comparing addition of LAMA or LTRA, to ICS/LABA was very limited. The Wang et al 2015 study included in Evidence Review Q does not report on exacerbations as an outcome (instead only asthma control and FeNO). Hoshino et al 2019 did report on exacerbations for the comparison of ICS/LABA plus montelukast versus ICS/LABA plus LAMA. The result favoured

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				in children or with co-associated symptoms such as allergic rhinitis.[1] Nevertheless, this is not necessarily reflective of the wider asthmatic population, especially those diagnosed as an adult. The committee's choice of an LTRA as an additional add-on treatment to a patient uncontrolled on moderate dose MART is not an evidence-based recommendation. The committee has declared that the available evidence on how best to introduce treatment in this scenario is less clear cut, citing only one study which directly compared the two options.[2] As this study (Wang K et al, 2015) showed a reduction in exacerbations with a LAMA compared to an LTRA,[2] we recommend that the committee does not discount this evidence in their decision. In absence of any strong clinical data assessing the efficacy of LTRAs over LAMAs, the safety of the two treatments should be considered as a priority. In addition, there are well established neuro-psychiatric safety concerns surrounding LTRAs which should be taken in account when	LAMA, but was based on a single small study with very low certainty of evidence. The committee did not have much confidence in this result because of the small study population The practical arguments for choosing one over the other do not clearly come down on either side. LTRA's are cheaper and it is easier to give a trial of an additional tablet than of a LAMA which involves prescribing an additional inhaler (with environmental consequences) or changing inhalers with the associated time taken to teach the person how to use the new device. However, LTRAs are more likely to cause side effects. In this regard we note that you refer to data you hold on file suggesting a high rate of problems following montelukast. This is well above the frequency in published data, and it is hard to comment further without seeing your document. After further discussion the GC have amended the recommendations and now suggest an equal choice between adding an LTRA or a LAMA.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				prescribing these medications, although as highlighted by the MHRA[3] and FDA[4] (Food & Drug Administration), worryingly these concerns are not well known amongst prescribers. A recent MHRA safety alert (April 2024)[3] highlighted these well-established risks in all patients, including children and adolescents when prescribing an LTRA which include sleep disorders, hallucinations, anxiety and depression as well as changes in behaviour and mood. The MHRA Pharmacovigilance Expert Advisory Group (PEAG) advised that "Montelukast should be immediately withdrawn due to the nature of the neuropsychiatric reactions, and that immediate withdrawal may help prevent escalation to more serious events." With additional prominent warnings to be included on packaged leaflets. Furthermore, the FDA directed a boxed warning to be added to notify prescribers of these risks.[4] Retrospective analysis of primary care population data conducted by Chiesi showed that 43% of patients with asthma, prescribed Montelukast [n=5847] are then subsequently	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				initiated on an anti-depressant/anti-psychotic/anxiolytic or insomnia medication.[1] It is imperative that NICE considers the wider economical and societal cost of drug safety and polypharmacy, especially with the current mental health crisis in the UK. Furthermore, six individuals after initiating Montelukast were diagnosed with Chugg-Strauss Syndrome.[1] Holistically, this presents a greater healthcare resource utilisation which we recommend NICE should consider. A UK HCP consensus was reached on the optimal prescribing of medium strength triple therapy (ICS/LABA/LAMA) in uncontrolled adult asthma patients amongst a cohort of 314 primary and secondary care HCPs using a modified Delphi Methodology.[5] There was very strong consensus amongst HCPs (90% in agreement) that a LAMA as part of medium strength single-inhaler triple therapy should be considered for patients with uncontrolled asthma at the current Step 3 of the BTS/SIGN (2019) guidelines, with healthcare professionals acknowledging the role and importance of LAMAs in the reduction of exacerbations and improvement of lung function.[5]	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				1. Chiesi Data on File 2. Wang K et al. Assessment of second-line treatments for patients with uncontrolled moderate asthma. Int J Clin Exp Med. 2015 Oct 15;8(10):19476-80. 3. MHRA Drug Safety Update: Montelukast: Reminder of the Risk of Neuropsychiatric Reactions – April 2024 4. FDA Drug Safety Update: FDA requires Boxed Warning about serious mental health side effects for asthma and allergy drug montelukast (Singulair); advises restricting use for allergic rhinitis – January 2022 5. Chiesi Data on File – Delphi Consensus	
Chiesi UK	Guideline	013	008	**Additional Safety Wording for Prescribing LTRAs** Whilst Chiesi recognise the place for LTRAs in the treatment pathway, the MHRA have released a safety update stating, 'Healthcare professionals must make patients and their caregivers aware of this information.' It is good	Thank you for your comment A link to the MHRA DSU has been added within the recommendation sections.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				clinical practice to also include this information on any prospective guidelines. Therefore, we recommend including below 008: **Patients should be advised when prescribed LTRAs to be alert to serious behaviour and mood-related changes (neuropsychiatric reactions) and to speak to their prescriber or seek urgent medical attention if neuropsychiatric reactions occur.** **Rationale:** Advice for healthcare professionals should be included in the guidance in line with recommendations from the MHRA in their recent Drug Safety Update (April 2024) to alert healthcare professionals to important safety concerns surrounding the use of LTRAs.[1] MHRA Drug Safety Update: Montelukast: Reminder of the Risk of Neuropsychiatric Reactions – April 2024	
Chiesi UK	Guideline	013	013	**Inclusion of Single-Inhaler Triple Therapy** In addition to Chiesi's position on LTRAs, the inclusion of a LAMA should be prioritised as single triple therapy inhaler. Therefore, we	Thank you for your comment 1.7.6 suggests a trial of the addition of a LAMA, so it would seem easier to add in a LAMA-only

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				advocate for the addition of a LAMA to be within a single-inhaler triple therapy (ICS/LABA/LAMA) + SABA or /ICS-Formoterol as needed **Rationale:** Whilst we advocate for the placement of LAMAs over LTRAs, we agree with point 1.6.7 made by the committee and thus recommend patients are prescribed options for the addition of a LAMA therapy in the same inhaler device. Single inhaler triple therapy removes the need for a separate LAMA inhaler, with evidence suggesting that single inhaler therapy may be more convenient and effective than multiple inhalers,[1] with better adherence and persistence.[2] These guidelines will be used in primary care, which holds a rich resource of respiratory specialists including GPs, Nurses and Pharmacists. The current proposals shift initiation of single-inhaler triple therapy into secondary care placing the burden and weight of referrals into secondary care. Experienced	inhaler to the current MART rather than changing inhalers completely for what might be a relatively short period of time. However, there is no evidence to prefer this to the option of changing to a triple maintenance inhaler as you describe, and so the recommendation leaves this open. The guideline does not shift this decision point into secondary care. LAMAs are available for prescription in primary care.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and established usage of single-inhaler triple therapy already exists in primary care. 1. Zhang S et al. Impact of Single Combination Inhaler versus Multiple Inhalers to Deliver the Same Medications for Patients with Asthma or COPD: A Systematic Literature Review. Int J Chron Obstruct Pulmon Dis. 2020 Feb 26;15:417-438. Busse WW et al. Adherence and Persistence to Single-Inhaler Versus Multiple-Inhaler Triple Therapy for Asthma Management. J Allergy Clin Immunol Pract. 2022 Nov;10(11):2904-2913.e6.	
Chiesi UK	Guideline	013	019	**Clarity on Rereferring to Specialist Care** On this particular point, further clarity is needed regarding when to refer for specialist care and clarity is needed on the utilisation of primary care respiratory specialists.	Thank you for your comment 1.7.7 gives a recommendation based on one reason for referral i.e. inadequate control despite trials of the listed medication. A further possible referral point has been added to recommendation 1.7.6. General recommendations on reasons for referral was not part of the scope for this update of the guideline. A link has been added to the AAC document which includes advice on referral.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Chiesi UK	Guideline	014	003	**Patient Centered Approach to Treatment Decisions** Chiesi would like the committee to emphasise at this point, the importance of patient-centered decision making. Please consider for use within the guidelines: • **Patients should not be switched onto different devices and/or treatment regimens without patient consultation and acceptance.** **Rationale:** A patient-centred approach may be pivotal to improving health outcomes. Patients who have accepted their treatment regimen may feel more empowered and confident to use their treatments, improving adherence.[1,2] Lack of patient acceptance in any treatment decisions may lead to loss of control and further clinical and economical costs.[3] 1. Hickmann, E et al. All together now – patient engagement, patient empowerment, and associated terms in personal healthcare. *BMC Health Serv Res. 2022;* 22, 1116	Thank you for your comment The committee agrees that any switching should be discussed and agreed. This is a basic principle of medical care and applies in numerous places in the guideline. At the start of the guideline there is statement "People have the right to be involved in discussions and make informed decisions about their care, as described in NICE's information on making decisions about your care." It should not be necessary to state it against all relevant recommendations.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				2. Baptist A et al. Understanding the Perspectives of Asthma Patients and Caregivers to Improve Shared Decision-Making and Satisfaction with Care. J Allergy Clin Immunol. 2022 Feb; 149 Issue 2 (AB211) 3. Orlovic M et al. Environmental, healthcare, and societal impacts of asthma: a UK model-based assessment. ERJ Open Research. Jan 2024;00577-2023	
Chiesi UK	Guideline	014	004	**Preference for Two-Treatment Pathway** Whilst Chiesi wish to acknowledge a SABA-free pathway and greater flexibility in regards to treatments, Chiesi believes it is imperative that patients are not funnelled into a one-size fits all approach and that the guidelines reflect the heterogenous nature of asthma, Chiesi strongly advocates for: A two-pathway model with a SABA-free pathway and a more traditional pathway:	Thank you for your comment The committee believes that the evidence in adults strongly favours the AIR then MART strategy over the traditional treatment pathway and have therefore recommended this. The remit of BTS/NICE/SIGN guideline is to offer guidance on the most cost-effective management strategy. The description of MART in the guideline now advises that SABA should not be needed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				<u>Proposed Traditional Pathway</u> **Step 1 – SABA + ICS** **Step 2 – Low dose ICS/LABA + SABA** **Step 3 – Medium dose ICS/LABA+ SABA** **Step 4 – Single Inhaler Triple Therapy + SABA** **Step 5 – Specialist Care** **Or at the very least, include text which acknowledges that not all patients are clinically suited to a SABA-free pathway and there is a need for SABA use amongst patients with adopting traditional treatment regimes.** **Rationale:** There is a need for consistency across guidelines such as GINA[1] and we recommend these proposed guidelines align to ensure consistent respiratory prescribing from a national and local perspective. To ensure acceptance and adoption of these guidelines, they should reflect current clinical practice and not propose radical changes which may over-burden primary care.	The importance of small airways in asthma is not a new concept. The recommendations in this update are driven by clinical studies and the participants in those were not investigated to determine how much their airflow limitation derived from small airways, and the relevance of the ATLANTIS study is therefore not clear. Your description of the findings of the Sygma trials is correct. These helped inform the recommendations in the guideline, but other evidence was also used (evidence review P).

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Whilst Chiesi supports the move to tackle issues of SABA overuse, we recognise there is still a place for SABA inhalers. These proposed guidelines will require a huge resource to educate and change prescribing culture amongst prescribers and treatment use amongst patients. An online survey to understand real-world treatment approaches and alignment to GINA guidelines revealed the majority of patients, 85% (79-91%), considered to be using maintenance and reliever therapy (MART), were also prescribed a non-ICS rescue inhaler.[2] Chiesi values patient-centric decision making and acknowledges the heterogenous nature of asthma,[3] The right patient, the right device, the right regime. There is emerging evidence, in which Chiesi are playing a lead role, about the prominence of small airways disease (SAD). The ATLANTIS study highlights that 91% of asthma patients have SAD, with an increased prevalence in more severe disease states.[4] A proportion of	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				mild patients with asthma however are not immune to the effects of SAD and would be more appropriate with a regular ICS to suppress underlying inflammation before symptoms become clinically apparent. In the first SYGMA study, ICS/Formoterol as needed was inferior to maintenance ICS with regards to weeks of well-controlled asthma per patient (34.4% vs 44.4%; OR 0.64; 95% CI 0.57 to 0.73) and did not differ significantly vs ICS maintenance with time to first exacerbation and rate of severe exacerbations.[5] In the second SYGMA study, ICS/Formoterol as needed was non-inferior to ICS maintenance for severe exacerbations with no differences seen in the annualised rate of severe exacerbations.[6] Whilst advances have been made recently to address SABA overuse, it is imperative that patients prescribed ICS/Formoterol as needed are regularly monitored to ensure control of their condition and avoid regular daily usages of their inhaler which may indicate a need for further control via maintenance therapy.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The proposal by Chiesi opens up treatment choices for the prescriber and patient whilst ensuring patients who have habitually recognised SABA as their rescue medication of choice can continue to do so. Approximately, 36% of patients prescribed a SABA are currently considered to be overusing their rescue medication[7] whereas the other 64% who still rely on their SABA maybe using their rescue medication responsibly. Not all patients are the same and with emerging evidence that asthma is seen as heterogenous within the mild, moderate, and severe category[1,2], it is important prescribers have the flexibility to adopt different regimes and to be able to move between regimes as appropriate. 1. Global Initiative for Asthma (GINA) 2024 Asthma Guidelines Main Report 2. Chapman KR et al. Patients' and physicians' perspectives on the burden and management of asthma: Results from the APPaRENT 2 study. Respir Med. 2022 Sep;201:106948	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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				3. Scherzer R et al. Heterogeneity and the origins of asthma. Ann Allergy Asthma Immunol. 2018 Oct;121(4):400-405. 4. Kraft M et al. ATLANTIS study group. The role of small airway dysfunction in asthma control and exacerbations: a longitudinal, observational analysis using data from the ATLANTIS study. Lancet Respir Med. 2022 Jul;10(7):661-668. 5. O'Byrne PM et al. Inhaled Combined Budesonide-Formoterol as Needed in Mild Asthma. N Engl J Med. 2018 May 17;378(20):1865-1876 6. Bateman ED et al. As-Needed Budesonide-Formoterol versus Maintenance Budesonide in Mild Asthma. N Engl J Med. 2018 May 17;378(20):1877-1887. 7. Worth H et al. Prevalence of overuse of short-acting beta-2 agonists (SABA) and associated factors among patients with asthma in Germany. Respir Res. 2021 Apr 16;22(1):108	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Chiesi UK	Guideline	014	013	**Treatment Equivalence** Chiesi advocates for the removal of 'regular low-dose ICS/LABA combination inhaler and supplementary therapy (LTRA and/or LAMA) plus SABA as needed' **Rationale:** The switch to a low-dose MART regime from a regular low-dose ICS/LABA combination inhaler with supplementary therapy (LTRA and/or LAMA) plus SABA as needed is not therapeutically equivalent. This treatment may be considered at a higher step on numerous guidelines with the risk of further destabilisation of the patient if abruptly changed.	Thank you for your comment There is no data specifically looking at switching between these regimens, but the subjects in the seminal papers on SMART had been on other treatment before starting on MART. For example, in O'Byrne et al (AJRCCM 171:129-36) The mean dose of maintenance ICS on entry to the study was over 600mcg per day, and over 25% were on maintenance LABA as well yet they improved on switching to MART with a maintenance dose of 160mcg per day. It is therefore wrong to say that no data supports this recommendation. The recommendation referred to LTRA and LAMA use with low-dose maintenance steroids

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Furthermore, there is no data to support this recommendation to a low-dose MART regime with this switch.	because there are a few people taking this. Low-dose ICS maintenance (with or without a LABA, and as fixed dose or in MART) plus an LTRA is part of current guidelines, but low-dose ICS plus LAMA is not. The reference to LAMA within 1.7.9 has therefore been removed
Chiesi UK	Guideline	014	022	**Treatment Equivalence** Similarly to the point above, Chiesi advocates for the removal of 'regular moderate dose ICS/LABA combination inhaler and supplementary therapy (LTRA and/or LAMA) plus SABA as needed' **Rationale:** The switch to a medium-dose MART regime from a regular moderate-dose ICS/LABA combination inhaler with supplementary therapy (LTRA and/or LAMA) plus SABA as needed may not be therapeutically equivalent. In addition, there's a risk of further destabilisation of the patient if abruptly changed. Furthermore, there is no data to support this recommendation to a moderate-dose MART regime with this switch.	Thank you for your comment As with the response to your previous comment (ID801), the papers on moderate dose MART recruited subjects who had previously been on a higher (mean) dose of maintenance ICS. This shows that switching to MART is safe and will benefit some people.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Chiesi UK	Guideline	015	003	**Inclusion of MDIs With Spacers for Paediatric Use** Chiesi recommends including the following statement: **MDIs with spacers should be the preferred treatment option for children aged 5-11.**	Thank you for your comment Choosing the appropriate inhaler device is covered in section 1.6.
Chiesi UK	Guideline	015	010	**Paediatric Low-Dose/Moderate-Dose MART** Chiesi are concerned with the recommendation to push treatment regimes where there's a lack of data to support use in paediatrics. We strongly recommend changing paediatric low-dose and moderate-dose MART regimes to regular low-dose and moderate-dose ICS use **Rationale:** No data in the public domain exists for the support of low or moderate-dose MART in paediatrics. Furthermore, MART regimes have a maximum daily dose threshold, there is no threshold set for use within paediatrics which presents as a clear safety issue and can cause confusion for healthcare professionals.	Thank you for your comment There is data on MART in children in the public domain (evidence review Q)

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
College of General Dentistry	Guideline	038	002	Consequential effects of medication on oral health may have "cascade" financial implications	Thank you for your comment The treatment recommendations aim to manage asthma on the least amount of medication compatible with good control.
College of General Dentistry	Guideline	73	1st para in RH box	Consequential effects of medication on oral health may have to be considered as part of shared decision making	Thank you for your comment The treatment recommendations aim to manage asthma on the least amount of medication compatible with good control.
College of General Dentistry	Guideline	General	General	*"The guidelines do not make a specific mention of possible consequential effects of pharmacological management of asthma on Oral Health, both in children and adults. Most practitioners involved in prescribing are likely to be aware of these and Oral Health practitioners especially so. It might be worth emphasising, in a single sentence, that the patient(or parents/carer where appropriate) be informed of the advisability of seeking oral health advice and care on a regular basis while having their asthma managed pharmaceutically."*	Thank you for your comment The treatment recommendations aim to manage asthma on the least amount of medication compatible with good control.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Education for Health	General	019	000	**1.2 Objective tests for diagnosing asthma in adults, young 20 people and children aged 5 to 16** **1.2.1 – 1.2.7:** Positioning FeNO as the recommended first line test for children with a history suggestive of asthma may have resource implications. Though a consistent approach to diagnosis for all age groups would be welcomed, the confounding factors associated with FeNO testing need to be recognised. Whilst we welcome the use of FeNO, through delivering our educational interventions across the United Kingdom we have anecdotally heard of the limited access to FeNO. The practical implementation may therefore be challenging, alongside the cost of implementation and ongoing costs associated with FeNO if it is to be completed before and after a change in pharmacological intervention. This may impact smaller practices and broaden health inequalities across the country and the devolved nations.	Thank you for your comment. The committee agrees with much of what you say. There are drawbacks to all the available tests for asthma, and these are referred to in the guideline and in the associated evidence reviews. PEF monitoring is readily available as you say, but it too has drawbacks, in particular its very poor sensitivity. PEF monitoring was considered in various potential diagnostic sequences in the cost-effectiveness model, but none of the sequences which included it rated among the optimal diagnostic pathways. However, in response to stakeholder concerns it has now been added. The committee would also argue that availability of FeNO will never improve if it is not clearly recommended in guidance. In relation to your point on non-eosinophilic asthma, please note that FeNO is not used as a rule-out test, only as a means of confirming a diagnosis, so this group should not be misdiagnosed as a consequence of including FeNO.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The guideline suggests that changes to FeNO levels in adults for diagnosis has changed from 40ppb to 50 ppb or more. This needs to be prominent within the document to ensure changes in practice take place which will reduce the risk of over-diagnosis. The draft guidelines also highlight the use of blood eosinophil count. Whilst this is important, consideration needs to be made to the practicalities of delivering this on the frontline. The implications for lab resources and GPN time for appointments for IgE BT may be challenged. Recognition of the different reference ranges across the various laboratories needs to be considered. There will need to be dialogue with local laboratories for clarification of reference equations to reduce error. There is a risk that non-eosinophilic asthma, Type-2 low phenotype, may be misdiagnosed if there is a general reliance on FeNO testing. This increases the risk of patients not having access to appropriate pharmacological interventions, potentially increasing the risk of morbidity and mortality.	In relation to your point of skin prick test and IgE, please note that this is used late in the diagnostic algorithm and only as a rule-out test. Therefore, a positive result due to comorbidities would not prompt a diagnosis of asthma but require further investigation. Your comments will be considered by NICE where relevant support activity is being planned.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The default is bronchodilator reversibility (BDR) with spirometry. Establishing diagnostic hubs has been removed as a recommendation, due to implementation concerns. Access to spirometry services is highly variable across the UK and accessing quality assured diagnostic spirometry will potentially have an impact on primary care service provision. The cost implications for performing skin prick testing to house dust mite or measuring total IgE needs consideration. Measuring total serum IgE may be misleading if the patient has co-morbidities. An additional sentence may be advisable, such as "the importance of total serum IgE results should be considered in the context with any co-existing conditions which have the potential to elevate total IgE such as atopic eczema, parasitic infections or allergic bronchopulmonary aspergillosis (ABPA)." Education for Health questions why PEF monitoring as an objective test for diagnosing asthma has been removed. Anecdotal feedback confirms access to FeNO is limited and waiting	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				lists for spirometry testing are long. As an alternative, could PEFmonitoring be considered for patients not able to access FeNO or spirometry, particularly at a time when there is a regional variability of spirometry as documented by the BMJ?	
Education for Health	General	General	General	**1.5.1 Monitoring asthma control** 1.5.4: Education for Health supports the recommendation to consider FeNO testing for monitoring purposes at regular reviews, before and after changing asthma therapy, though recognises this will have significant cost implications.	Thank you for your comment.
Education for Health	General	General	General	**1.6 Principles of pharmacological treatment** 1.6.2: Education for Health welcomes the introduction of ICS at any age for people prescribed a SABA. We believe that providing healthcare professionals with the knowledge and skills to educate patients is key if we are to implement these guidelines successfully.	Thank you for your comment The committee agrees with the issues you mention regarding patient education, inhaler licences and supply chains. In relation to the impact of FeNO testing on the environment, the committee would argue that more accurate diagnosis will help by reducing inhaler

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				It is important to note that not all the inhalers used for the treatment of asthma in these guidelines are licensed. Whilst the guidelines recognise the use of off-label medications, it is imperative to note that this may prove challenging for some prescribers since "Making decisions using NICE guidelines" encourages healthcare professionals to follow relevant professional guidelines which may compromise access for patients and enhance healthcare equalities. In addition, it is important to consider how supply chains affect the distribution of inhalers recommended within the guidelines. We have currently seen several medicine shortages across the board. It is essential that, for a smooth transition to new ways of prescribing such as AIR and increasing MART prescribing regimes, the pharmaceutical industry and pharmacies are prepared for the possibility of higher demand for devices to avoid any shortages. The NHS has set the target of reaching net zero by 2040 for the greenhouse gas emissions it can	prescription to people whose symptoms are not caused by asthma.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				control, and net zero by 2045 of the emissions for which it can influence, as documented on Greener NHS » National ambition (england.nhs.uk). Inhalers are included in this scope and currently account for 13% of the carbon footprint. We believe the new guidelines will provide prescribers with the opportunity to consider the importance of environmental prescribing, to begin the negotiations with the patient for their inhaler regime, considering a dry powder inhaler (DPI) from the outset as the preferred choice. However, the guidelines provide little or no evidence of how the prominent role of objective tests such as FeNO will influence the net zero ambition. Further clarity would be welcome around how these changes could affect the net zero strategy.	
Education for Health	General	General	General	**1.7: Pharmacological management in people aged 12 and over** **1.7.1-1.7.5:**	Thank you for your comment. AIR is now referred to and described in the guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The implementation of low-dose ICS/formoterol combination inhaler to be taken as needed for symptom relief to people aged 12 and over with newly diagnosed asthma (AIR) is welcomed. Education for Health would like the emphasis on the acronym AIR to be positioned from the outset. Using unified language (as with MART therapy) will ensure clinicians are aligned and can differentiate between other treatment options. This will also remove any element of confusion for the patient as all patient-facing charities and healthcare professionals will be referencing the same terminology. It is imperative that healthcare professionals have the knowledge and skills to support patients to embrace a differing management approach, to ensure they can adopt the new recommendations which may be quite different to the advice they have been offered in the past. We welcome the introduction of low dose MART for people 12 and over as a next step for highly symptomatic patients. The addition of an LTRA at a moderate dose of MART for 3m is welcomed. Education for Health would like to	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				see the warning from the MHRA for neuropsychiatric reactions reiterated in the recommendations to enable the patient to make an informed choice after considering the risks/benefits profile.	
Education for Health	General	General	General	**1.8.2-1.8.3 Medicine combination and sequencing in children aged 5 to 11** See comment under 1.6.2	Thank you for your comment
Education for Health	Guideline	004	000	1.1.1- 1.1.3 **Clinical History** We welcome the emphasis placed on clinical history taking before physical examination and objective testing as this considers the variability of the disease and excludes other differential diagnoses. We would encourage the addition of an algorithm to structure this process as this would support the variability of the knowledge and skills of the workforce in an evolving healthcare landscape.	Thank you for your comment. There is no algorithm covering a structured clinical history because there was no evidence review on signs and symptoms for this update, and no algorithm in the last version of either NICE or BTS/SIGN guidelines. Unfortunately, if one is produced now it will not be subject to Stakeholder review. Your comments will be considered by NICE where relevant support activity is being planned.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Education for Health	Guideline	006	000	**1.1.5 – 1.1.6** **Initial treatment and objective tests for acute symptoms at presentation** This section may require further clarity around acute assessments as this will enable healthcare professionals to treat presenting symptoms promptly and follow objective testing once the patient is stabilised to ensure prompt and appropriate pharmacological interventions are put in place. Acute assessments should include heart rate, respiratory rate, oxygen saturations, chest examination, consciousness levels and peak flow (where appropriate). Where appropriate, considerations should be given to start initial pharmacological treatments where there is a high probability of asthma as the cause of symptoms. This ensures patients are receiving prompt treatment, particularly where access to objective testing is variable across the United Kingdom. Taking this approach may also help to reduce health inequalities and helping to reduce the risk of deterioration leading to death.	Thank you for your comment. These recommendations were not part of this update and comment on them was not invited (please see page 2 of the draft guideline). Management of acute asthma is not in the scope of this update.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Education for Health	Question 1	General	General	Primary care faces perceived challenges, such as access to FeNO equipment and spirometers. While some practices have these investigative tools, anecdotal feedback from our students across the UK, who use our education and training resources, suggests there is an inequality in healthcare provision that could be exacerbated if FeNO becomes a preferred investigation method. As a charity, our focus is to deliver quality outcomes for patients which stems from healthcare professionals having the necessary knowledge, skills and behaviours. These qualities come from developing and delivering high quality education. For these guidelines to be adopted successfully, healthcare professionals must be encouraged to undertake the necessary training around key components of the guidelines including (but not limited to) FeNO testing, spirometry and the importance of the results in the context of the assessment and examination and possible differential diagnosis.	Thank you for highlighting these implementation issues. Your comments will be considered by NICE where relevant support activity is being planned.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Additionally, laboratories may face resource implications due to an influx of blood test requests for eosinophils. These blood tests would also necessitate separate appointments with general practice nurses (GPNs), directly impacting the availability of appointments. A potential solution could be to reinstate home PEF monitoring for 2-4 weeks as a widely available third alternative in general practices. Prescribing off-label medications may generate concern among prescribers. Although NICE discusses off-label or unlicensed use in their document "Making decisions using NICE guidelines" and emphasizes following relevant professional guidance, the MHRA confirms that healthcare professionals may bear more responsibility when prescribing unlicensed or off-label medications. This situation could deter prescribers who are reluctant to assume additional responsibility, especially when regimes like AIR or MART occupy a different position in prescribing recommendations. Moreover, it would require negotiation with the patient and their family or carer to implement the	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				change in practice. This could widen the gap around healthcare inequalities. With many practices in primary care operating virtual asthma consultations, it is difficult to see how implementation of these guidelines would align with this delivery model. This may increase the workload in already pressurised healthcare environment.	
Education for Health	Question 2	General	General	The new guidelines will require significant investment of time and money to buy and maintain equipment, provide access to laboratory services, and report and interpret the findings in the clinical context. Having been involved in the delivery of academic and CPD education for over 36 years old, we recognise that education and training must be a key focus for the successful roll out of the guidelines particularly around the interpretation of FeNO and eosinophil levels. The guidelines for children now recommend skin prick testing or measure eosinophils if asthma is	Thank you for highlighting this. Equipment costs and costs of testing are included in the draft RIA tools for local assessment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				not confirmed with FeNO or BDR. There are again training implications for clinicians carrying out SPT which is not readily available in primary care. There will be a direct effect on available appointments in primary care for blood tests, adding to the pressure of primary care appointments. Reintroducing home PEF monitoring as an alternative diagnostic tool may be a solution to this.	
Faculty of Occupational Medicine	General	General	General	We agree that the 2024 delete statements from the 'occupational asthma' section and refer the reader to a document specific for the occupational medicine specialist. The committee stated that this is to avoid the reader managing this specific type of asthma and to ensure it is referred to a specialist at an early stage. The Faculty of Occupational Medicine agrees with this 2024 update to the Guidance. The document referred to contains updated information that is relevant and thorough.	Thank you for your comment
Fair Treatment for the Women of Wales	EQIA	002	3.2	We are concerned that nowhere in the draft guideline is there any reference to the specific experiences and differences in outcome experienced by women and people registered female at birth. We would like to draw the	Thank-you for your comment The problem is that although there is evidence of worse outcomes in some groups (you give one example, people of SE Asian origin would

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Committee's attention to Asthma and Lung UK's 2023 report entitled 'Asthma is Worse for Women': https://www.asthmaandlung.org.uk/sites/default/files/2023-02/asthma-is-worse-for-women-report-1.pdf - in short, 'Women are more likely to have asthma, have more severe symptoms, and are more likely to die from their asthma'.	be another) we identified no evidence to show that using different treatment options is of any benefit in these groups. Further research would be needed to establish reasons and show how treatment might be amended.
Fair Treatment for the Women of Wales	EQIA	002	3.4	We note that adherence is cited as an area of inequity in asthma management and would like to see the inclusion of people who are homeless / with no fixed address here, given reported difficulties in either accessing or ensuring continuity of monitoring and ongoing management in primary care.	Thank-you for your comment The list of people who might be more likely to exhibit poor adherence was based on suggestions made during consultation on the scope. Those who are homeless were not mentioned at the time, although the committee agree that they might also have been included. However, adherence was not a topic area updated in this version of the guideline, the recommendation is unchanged from the 2017 guideline.
Fair Treatment for the Women of Wales	Guideline	008	013	The section on Monitoring Asthma Control would do well to make specific reference to the potential link between asthma symptom exacerbation and the menstrual cycle in girls, women, and people registered female at birth, as per	Thank you for your comment There was no equivalent recommendation in the latest version of BTS/SIGN or NICE guidance, and the topic was not subject to evidence

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				https://www.asthmaandlung.org.uk/sites/default/files/2023-02/asthma-is-worse-for-women-report-1.pdf. We would suggest that consideration be given to including the menstrual cycle and menopause status (including hormonal contraception and HRT usage) in both questionnaires and monitoring appointments, to establish whether or not symptoms are worse at certain times of the month and if this might potentially help to predict asthma attacks. We would echo Asthma and Lung UK's recommendations that more research be undertaken to investigate the influence of sex and gender differences on adult asthma, and that all future studies analyse their datasets by sex to identify differences. We would suggest that this latter approach extend to NICE guidance on asthma diagnosis, monitoring, and management, and request that the Committee includes a recommendation for more research into sex and gender differences in adult asthma – thank you.	review for this update. We therefore cannot make the recommendations you suggest.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Fair Treatment for the Women of Wales	Guideline	020	015	We would suggest that the section on Asthma in Adolescents should also flag up consideration of any potential link between onset of menstrual periods and asthma emergence or exacerbation. Again, a recommendation that more research be undertaken would be helpful, including whether onset of periods (and onset / worsening of asthma) indicates an increased risk of other inflammatory conditions, and if hormonal triggers for asthma might open up other possible treatment avenues.	Thank you for your comment The recommendations in this section have simply been transferred from the BTS/SIGN guidance. While the wording has been slightly amended for some, the committee are not able to add completely new recommendations without formally reviewing evidence.
Fair Treatment for the Women of Wales	Guideline	021	001	In light of reports such as Asthma and Lung UK's, 'Worse for Women', we would suggest that self-management plans and reviews should also include questions about menstrual cycle / status, hormone-mediated contraception or HRT, and provide links to period-trackers, both to help ascertain if there is any connection for patients and to inform future research. This is particularly important given the NICE recommendation that self-management plans be reviewed during hospital admission and data demonstrating that women aged 20-50 years are three times more likely than men to be admitted to hospital for asthma (Zein JG, Denson JL, Wechsler ME. 'Asthma over the	Thank you for your comment. This is a legacy recommendation from the 2017 guidance. No new evidence review was undertaken, and we cannot make substantial additions to it. However, the recommendation has been changed slightly to indicate that other triggers should be considered.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Adult Life Course: Gender and Hormonal Influences'. Clin Chest Med 2019; 40(1):149-61. doi: 10.1016/j.ccm.2018.10.009 [published Online First: 2019/01/30].	
Global Initiative for Asthma	Cost implications	000	000	We have not commented on this issue, as it is UK-specific	Thank-you
Global Initiative for Asthma	Evidence review N (FeNO-guided treatment)	005	000	Evidence supporting 1.5.4: The pre-specified criteria for the selection of studies included that the comparator was "*Usual care: e.g. clinical symptoms (with or without PEF) according to guidelines (including BTS/SIGN, GINA)*". However, the evidence review included several studies in which, as identified in the Petsky 2016 Cochrane review and in GINA 2024, the comparator algorithm was very different from current guidelines-based treatment. These studies included Powell 2011; Syk 2013; and Honkoop 2015. This problem was recognised in the footnote on page 26 of the evidence document (N), which noted that the study by Szefler et al was excluded because it "does not match BTS/SIGN on dose titration". The same approach should be taken consistently in the present evidence review, with exclusion of studies that did not approximate BTS/SIGN or GINA for dose titration steps and	Thank you for your comment. The guideline committee agreed that an inclusive approach should be used for the comparator for Evidence Review N. Evidence comparing FeNO monitoring to usual care with use of asthma control questionnaires and other definitions of usual care, with variable treatment steps, were combined. The reference to BTS/SIGN guidelines in the protocol is an example only. The review was not limited to specific definitions of usual care because the amount of evidence was limited and the Guideline Committee preferred not to set limits on the comparator, to limit the amount of evidence further. We have added comments to Evidence Review N to highlight this limitation to the evidence-base (sections 1.1.4 and 1.1.12).

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				therefore did not satisfy the pre-specified inclusion criteria for this systematic review. This issue is just as important when comparing treatment algorithms as when comparing individual medications: for example, if a study finds that treatment A is better than treatment B, but treatment B is never used in clinical practice, no conclusions can be drawn about whether treatment A would be better or worse than treatment C which is used in clinical practice.	Szefler 2008 is included in both the clinical and health economics evidence reviews. The footnote on page 26 refers to a limitation of Szefler 2008 which was noted in the Harman 2015 analysis; this is relevant to the health economic analysis.
Global Initiative for Asthma	Guideline	004	002	The guideline should include the definition of asthma, as this is an integral element of diagnosis. Health professionals should not have to refer back to the 2019 guideline to find out what definition of asthma is assumed by the 2024 diagnostic process.	Thank you for your comment The 2019 BTS/SIGN guideline has a section on definition of asthma but this outlines components of various definitions rather than settling on one itself. NICE's 2017 guideline does not define asthma.
Global Initiative for Asthma	Guideline	004	004	*1.1.1 Initial clinical assessment*. This recommendation currently specifies only the types of items that should be included in a structured clinical history. It is essential to also state the features that would comprise a "history suggestive of asthma" (e.g. referred to in 1.2.1), as this is the starting point for the diagnostic	Thank you for your comment The first 3 bullet points of 1.1.1 are positive indicators suggesting asthma.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				algorithm. Providing this additional information will be particularly important for implementation.	
Global Initiative for Asthma	Guideline	004	015	*1.1.3. "Record the basis for a diagnosis of asthma in the person's medical records, alongside the coded diagnostic entry*." Please provide advice for what to do if the patient needs treatment but a diagnosis is not yet confirmed, e.g. "If objective tests are not available at this time, document a possible/provisional diagnosis of asthma, treat the patient and arrange for further investigations." This would help to reduce any delays in addressing the patient's immediate needs, provide for safety netting advice and education as well as follow up, as well as timely confirmation of the diagnosis later.	Thank you for your comment The purpose of this recommendation is that the evidence supporting a diagnosis of asthma should be available in case it needs reviewing at a later date. It refers to a point at which asthma has been confirmed, and this has now been made clearer. The need to treat in some cases before testing is possible is covered by 1.1.5 and 1.1.6.
Global Initiative for Asthma	Guideline	005	023	1.2.1 (Adults) "*Diagnose asthma if the eosinophil count is above the laboratory reference range or the FeNO level is 50 ppb or more*." General comment: No convincing evidence (on sensitivity, specificity, positive predictive value and negative predictive value of BEC or FeNO) is provided to support this recommendation in the accompanying drafts for consultation regarding "Evidence reviews for diagnostic accuracy of eosinophil blood count measures in the diagnosis of asthma" or "In people under	Thank you for your comment. The evidence reviews on eosinophil count and on FeNO consider the performance of those tests in isolation. The justification for using eosinophil count or FeNO as the first test in adults is best given in the rationale section within the guideline, or in more detail in the evidence review on the combination of tests, particularly in the cost-effectiveness analysis.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				investigation for asthma, what is the diagnostic test accuracy of FeNO measures?" (where, in the conclusion, no recommendation is made). There seems thus to be a gap in the Evidence to decision framework. Specific comments: A) Blood eosinophil count (BEC): The most common causes of elevated blood eosinophil count, including in the UK, are allergic diseases (including allergic rhinitis and atopic eczema), parasitic infections (particularly Strongyloides, which can be asymptomatic for decades), drug reactions, and skin conditions. Although parasitic infections are much more prevalent in tropical countries than in the UK, international travel by UK residents and migration from tropical countries to the UK are common, and an article from the Hospital for Tropical Diseases (London) published in 2017 (https://doi.org/10.1016/j.jinf.2017.08.007) reported that a parasitic cause was found in over 50% of patients presenting with eosinophilia. British Infection Association recommendations also use travel history to guide investigation of eosinophilia. Blood eosinophils may also be elevated in patients with allergic rhinitis during	The committee agrees that other conditions may cause the eosinophil count or the FeNO to be raised, but there are potential confounding factors with most diagnostic tests. Parasitic infections are indeed a cause of eosinophilia, but a paper from a highly specialised hospital looking at people with unexplained eosinophilia is hardly representative of people with a raised eosinophil count across the country, and the proportions you quote will not apply across the UK. The committee agree that ideally FeNO cut-off points would be given separately by gender, and also by age and height. However, generally accepted tables of these values are not available. The single FeNO level is simple and set at a value which is on the high side and should not lead to a large number of people being over-diagnosed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				the relevant pollen season, and in patients with eczema. Hence, a finding of blood eosinophilia may support a diagnosis of *allergic* asthma in patients with a typical clinical history, but investigations should be initiated for other potential causes, including parasitic infections requiring specific treatment. B) FeNO: There are many non-asthma causes of elevated FeNO, including allergic rhinitis, nasal polyposis, and eosinophilic bronchitis, all of which may be associated with respiratory symptoms; and eczema. The prognosis and treatment implications for these conditions compared with asthma are substantially different. As is the case for elevated BEC, an elevated FeNO can support a diagnosis of *allergic* asthma in a patient with a typical clinical history, but it cannot rule in asthma. There is a significant impact of sex on FeNO levels in ICS-naïve subjects, both in healthy persons and in patients with asthma. Sex-specific reference values and cut-offs of FeNO - instead of a fixed cut-off value of 50 ppb -	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				should be used in men and women under investigation for asthma. A similar approach is used to define anemia (in men as opposed to women).	
Global Initiative for Asthma	Guideline	005	026	1.2.2. "If asthma is not confirmed by eosinophil count or FeNO level, measure bronchodilator reversibility (BDR) with spirometry. Diagnose asthma if reversibility is greater than 12% from baseline and greater than 200 ml (or greater than 10% of predicted normal)" • The clinical context of a patient with a history suggestive of asthma should be repeated in each of 1.2.2 and 1.2.3 • A spirometric printout includes multiple metrics, so the relevant metric should be stated (FEV1 and/or FVC). • The word "baseline" should be defined as the pre-bronchodilator measurement (to avoid confusion with the first time the patient was seen in the practice). • The standard criterion for bronchodilator responsiveness as part of clinical diagnosis of asthma from ERS/ATS guidelines is change ≥12% and ≥200 mL (not >12% and >200 mL).	Thank you for your comment. These are helpful comments. The committee don't think the clinical context needs to be added to 1.2.3 (the wording already covers this) but it has been added to 1.2.2. FEV1 has been specified, "pre-bronchodilator" included, and the standard definition of increased reversibility corrected. However, the 10% of predicted criterion has been retained after further discussion within the committee.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				• With regard to the proposal by the ERS/ATS Technical Standards Committee about a criterion of >10% predicted, please read the comments by the GINA Science Committee on page 29 of the GINA 2024 report. In brief, the ERS/ATS Technical Standards Committee proposal for a criterion of >10% predicted was based on data for mortality, not on data for diagnosis of asthma, and even the Technical Committee itself did not recommend use of this criterion in diagnosis of asthma. This criterion was also not recommended by the ERS Guidelines on diagnosis of asthma which were published in the following year. Initial analyses suggest that tall young men are more likely to have the diagnosis of asthma confirmed with the current criteria for bronchodilator responsiveness, and shorter or older women are more likely to have the diagnosis confirmed with the criterion of >10% predicted. Therefore, further data on the association between reversibility of >10% predicted and other diagnostic tests are needed before it can be recommended for	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				clinical practice as an alternative to or as well as the current criterion. • Do all UK GPs have immediate access to spirometry? If not, alternative criteria for confirmation of excessive variability of lung function using PEF (bronchodilator testing, or variation over time) should be provided, rather than having no lung function testing at all. This is an important issue for implementation. ERS/ATS lung function committees consistently recommend use of the term "bronchodilator responsiveness" rather than "bronchodilator reversibility".	
Global Initiative for Asthma	Guideline	006	001	1.2.3. "*If asthma is not confirmed by eosinophil count, FeNO or BDR but still suspected on clinical grounds, measure bronchial responsiveness. Diagnose asthma if bronchial hyper-responsiveness is present*" • It is assumed from the context that "bronchial responsiveness" means bronchial challenge testing, but this should be clarified in order to distinguish it from bronchodilator responsiveness • Since some bronchial provocation tests (mannitol, exercise) could potentially be	Thank you for your comment. 1.2.3 now specifies that this entails a bronchial challenge test. Detail on safety aspects should not be necessary as these tests should only be done by personnel with appropriate training and competencies.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				performed outside a respiratory function laboratory, it is critically important to add safety criteria (or a link to clear safety criteria) relevant to challenge testing, including minimum FEV1, not pregnant, no recent myocardial infarction etc; and to specify (or provide a link to) withholding durations for SABAs and LABAs, since these need to be longer than for bronchodilator responsiveness testing. Explain that bronchial hyperresponsiveness may be absent if the patient is already on ICS.	
Global Initiative for Asthma	Guideline	006	004	There is a recommendation missing: if 1.2.1; 1.2.2; 1.2.3 are not available or negative despite a history suggestive of asthma, there should be a recommendation to start empiric treatment with ICS and refer to a specialist respiratory service.	Thank you for your comment. Recommendation 1.2.4 is now the last in the diagnostic sequence for adults and this indicates that a referral will be needed. It does not specify that empiric treatment should be started as this may not be necessary in all cases.
Global Initiative for Asthma	Guideline	006	004	1.2.4 There are many non-asthma causes of elevated FeNO, including allergic rhinitis, nasal polyposis, and eosinophilic bronchitis, all of which may be associated with respiratory	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				symptoms; and eczema. The prognosis and treatment implications for these conditions compared with asthma are substantially different. As is the case for elevated BEC, an elevated FeNO can *support* a diagnosis of *allergic* asthma in a patient with a typical clinical history, but it cannot rule in asthma. 1.2.5 should be ≥12% (not >12%)	1.2.4 The committee accepts that ideally evidence of variable airflow obstruction would be obtained, but in practice the tests for this are insensitive. Pragmatically, a good history of asthma plus an elevated FeNO allows a diagnosis without performing multiple tests. 1.2.5. Thank-you. Corrected
Global Initiative for Asthma	Guideline	006	010	1.2.6 • The evidence base does not support these recommendations • Skin prick testing is not usually available in primary care. It is a test for atopy, not for asthma. • IgE is elevated in many non-asthma allergic conditions • House dust mite is not the only common allergen that contributes to asthma and allergic rhinitis in the UK: cat and grass pollens are also highly relevant. • The negative predictive value of HDM skin testing and serum IgE is not sufficient to support a recommendation to exclude asthma if these are negative	Thank you for your comment Recommendation 1.2.6 applies to children with a history suggesting asthma who have already had a negative test with FeNO, spirometry and reversibility testing. In this situation the committee believes the recommendation is valid.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				There are many other causes of elevated blood eosinophil count, including in the UK, are allergic diseases (including allergic rhinitis and atopic eczema), parasitic infections (particularly Strongyloides, which can be asymptomatic for decades), drug reactions, and skin conditions. Although parasitic infections are much more prevalent in tropical countries than in the UK, international travel by UK residents and migration from tropical countries to the UK are common, and an article from the Hospital for Tropical Diseases (London) published in 2017 (https://doi.org/10.1016/j.jinf.2017.08.007) reported that a parasitic cause was found in over 50% of patients presenting with eosinophilia. British Infection Association recommendations also use travel history to guide investigation of eosinophilia. Blood eosinophils may also be elevated in patients with allergic rhinitis during the relevant pollen season, and in patients with eczema. Hence, a finding of blood eosinophilia may support a diagnosis of *allergic* asthma in patients with a typical clinical history, but investigations should be initiated for other potential causes, including parasitic infections requiring specific treatment.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Global Initiative for Asthma	Guideline	007	000	1.3.2 If a child is unable to perform objective tests when they are aged 5 • continue to treat based on observation and clinical judgement • try doing the tests again every 6 to 12 months until satisfactory results are obtained • refer for specialist assessment if the child's asthma is not responding to treatment. [NICE 2017, BTS/SIGN 2019, amended 2024] This is unclear – what diagnosis should be entered in the record? What should the parents be told? Without a diagnosis or provisional diagnosis of asthma, the child will be denied reviews, self management education, and the parents will not know how to manage severe attacks or what to say to emergency crews when trying to get assistance.	Thank you for your comment Your comment on recommendation 1.3.2 ignores the immediately preceding 1.3.1 which states that a child with suspected asthma under the age of 5 should be treated empirically. All the information to parents, review arrangements etc should already be in place because suspected asthma is being treated in accordance with 1.3.1.
Global Initiative for Asthma	Guideline	008	001	1.4.1. Occupational asthma. • Diagnosis of occupational asthma should not be based only on symptoms Add a recommendation to measure lung function, including on work and non-work days. This is particularly important since there may be a long delay in obtaining specialist referral.	Thank you for your comment. The guideline is not attempting to lead people through the process of diagnosing occupational asthma, but to indicate when it should be suspected and onward referral made.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Global Initiative for Asthma	Guideline	008	012	1.5 Monitoring asthma control • 1.5.1: For asking about symptoms at every review, the relevant symptom control tools (e.g. ACQ or ACT) should be recommended; they are currently described in 1.5.2 only for consideration at annual review. • "Amount of reliever inhaler used" – instead of just documenting this, recommend an evidence-based criterion for specific action related to SABA inhalers, e.g. refer for expert advice if patient has used more than two short-acting beta2-agonist inhalers in 12 months • "Number of courses of oral corticosteroids" – instead of just documenting this, recommend an evidence-based criterion for action, e.g. "refer to an asthma expert (asthma-trained doctor or nurse or specialist) if patient has required two or more courses of oral corticosteroids in 12 months". Such patients are at high risk for another exacerbation, and are at increased risk of adverse effects of OCS. • Note the recommendation of the National Review of Asthma Deaths in 2014 to utilise UK's electronic medical record system to	Thank-you for your comment: • Recommendation 1.5.2' has been amended. • This section suggests what information should be collected. Actions are in following sections. The committee are also not convinced that every patient who uses too much SABA needs referral – if there is a simple explanation it could be sorted out at the same visit in primary care. • This section suggests what information should be collected. Actions are in following sections. • The committee support the 2014 NRAD recommendation. • The list in 1.5.1 is information which should be collected at every asthma review, not a comprehensive list of risk factors. GINA box 2.2B includes items such as a level of BDR or high eosinophil count which the committee are not recommending for every review.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				flag patients at increased risk of asthma attacks and asthma mortality on an ongoing basis, rather than waiting for an annual review. The list of risk factors in 1.5.1 is very brief; please see GINA 2024 Box 2.2B for a list of risk factors that are independent of the level of symptom control	
Global Initiative for Asthma	Guideline	008	022	1.5.3: "Do not use regular peak expiratory flow (PEF) monitoring to assess asthma control unless there are person-specific reasons for doing so". This is inconsistent with the later recommendation in 1.14.1 which says that personalised action plans in asthma for adults may be based on symptoms and/or peak flows. PEF should remain as part of action plans and for acute care. This means 1.5.3 would need to be clarified.	Thank you for your comment The evidence (Evidence Review M) did not show any overall benefit of regular PEF monitoring. The draft version of recommendation 1.5.3 allowed that some people may find that using PEF helps ("person-specific reasons") and it was therefore entirely compatible with 1.14.1, but this has now been made more readily apparent.
Global Initiative for Asthma	Guideline	008	025	1.5.4. Consider FeNO monitoring for people with asthma: at their regular review, and before and after changing their asthma therapy. [2024] The individual trials assessing the role of FeNO-directed management to reduce exacerbations were negative with a small benefit in the meta-	Thank you for your comment. Several stakeholders have raised a similar point. Overall the studies show a slight benefit, albeit that increased ICS doses were required to achieve this. It is true however, that FeNO

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				analysis of these trials. In particular, the higher quality trials did not show benefit. As written, the timing interval for FeNO testing would be variable and likely infrequent. It is not clear from the recommendation what to do with the result and how this should change management. There is a cost for undertaking the test without clarity for the benefit. In mild-to-moderate disease the evidence is very weak for a role in disease monitoring and not tested for the timing intervals suggested in the recommendation. By contrast, the role of FeNO monitoring in severe disease is clear and part of the indications for some biologic therapies.	monitoring in children was less cost-effective than in adults. The recommendation has been reviewed and the committee have decided it should be limited to adults.
Global Initiative for Asthma	Guideline	009	016	*1.6.1 Take into account and try to address the possible reasons for uncontrolled asthma before starting or adjusting medicines for asthma in adults, young people and children. These may include:• alternative or additional diagnoses (for example, obesity)…* The list of alternative or additional diagnoses that can potentially impact on asthma symptoms, exacerbations, quality of life, or treatment interactions, is very long. It is unclear why obesity is singled out here as the only additional diagnosis for mention. It would be	Thank you for your comment. "Obesity" has been removed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				more appropriate to either include a longer list or none at all.	
Global Initiative for Asthma	Guideline	010	008	*1.6.2 Do not prescribe short-acting beta2 agonists to people of any age with asthma without a concomitant prescription of an inhaled corticosteroid (ICS). [2024]* Clarify whether "of any age" includes infants and pre-school children. If this was not the intention, please make the age-group more specific, noting that recommendations are often read in isolation from surrounding text.	Thank you for your comment. The statement is intended to cover all ages. The committee believes it is a valid recommendation in people of any age with a diagnosis of asthma. There is a statement at the start of the guideline pointing out that recommendations apply to all age groups unless stipulated otherwise in the heading of a section.
Global Initiative for Asthma	Guideline	010	015	*1.6.4 Base the choice of inhaler(s) for asthma on:* *•an assessment of correct technique* *•the lowest environmental impact among suitable devices* *•the preference of the person receiving the treatment.* • This list should include (and start with) what is by far the most important consideration, namely the choice of the medication itself for the individual patient. Appropriateness of the medication for the patient's asthma is also missing from the Decision Aid.	Thank you for your comment. This recommendation is about the device, not the medicine it contains. The committee agree with you about the order of the bullet points and have changed this.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				• Patient preference markedly affects adherence (Ref Plaza V, et al, Impact of patient satisfaction with his or her inhaler on adherence and asthma control. Allergy Asthma Proc. 2018;39(6):437-44), so consideration should be given to placing patient preference second in this list. Cost is also a substantial consideration for many patients.	
Global Initiative for Asthma	Guideline	011	012	*1.7.2 If the person needing asthma treatment presents highly symptomatic (for example, regular nocturnal waking) or with a severe exacerbation, start treatment with low-dose MART (maintenance and reliever therapy). Consider stepping down to a low-dose ICS/formoterol combination inhaler used only as needed for symptom relief at a later date if their asthma is controlled. [2024]* Those patients that are highly symptomatic with severe exacerbations are likely to be at highest risk. Rather than starting these patients on low dose MART (which would deliver a maintenance dose of only 160 or 320mcg budesonide per day), moderate dose MART should be considered, then stepping down once good control is achieved.	Thank you for your comment. Several factors affect the severity of symptoms at presentation (e.g. length of time present, the nature and intensity of any precipitating trigger) and severity does not predict how much inhaled steroid will ultimately be needed. Advice has been added to the recommendation specifying that a course of oral steroids should be given if necessary.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Global Initiative for Asthma	Guideline	011	015	*1.6.7 Prescribe the same type of device to deliver preventer and reliever treatments where more than one inhaler is needed. [BTS/SIGN 2019, 16 amended 2024]* Qualify this recommendation with "if possible", and "provided the patient can use the device correctly"	Thank you for your comment. The committee agrees that this may not always be possible, but the stipulation that the patient can use the device properly has been covered in the preceding recommendations.
Global Initiative for Asthma	Guideline	011	016	1.6.8 Encourage people to take their used inhalers to their pharmacy for 18 disposal. [BTS/SIGN 2019, amended 2024] Change "used inhalers" to "used or expired inhalers"	Thank you for your comment. The words "or expired" have been added
Global Initiative for Asthma	Guideline	013	001	*Medicine combination and sequencing for newly diagnosed asthma in 1 people aged 12 and over 1.7.3. Offer low-dose MART to people aged 12 and over with asthma that is not controlled on a low-dose ICS/formoterol combination inhaler used only as needed. [2024]* [and each of the subsequent recommendations] These recommendations should be prefaced by strong advice to **first** check inhaler technique, adherence, and other factors that may be contributing to poor asthma control or exacerbations, before considering a step-up in dose or addition of an extra medication.	Thank you for your comment This is sound advice and is already included in the guideline in section 1.6. Section 1.6 is relevant to every recommendation in sections 1.7 and 1.8 but realistically cannot be repeated every time.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Recommendations are often read in isolation from other sections of a guideline.	
Global Initiative for Asthma	Guideline	013	008	*1.7.5 Consider adding a leukotriene receptor antagonist (LTRA) to moderate-dose MART for people aged 12 and over with asthma that is not controlled on moderate-dose MART alone. Give the LTRA for a minimum trial period of 3 months (unless there are side-effects) and then stop it if it is ineffective. [2024]* • The evidence is greater for exacerbation reduction for LAMA vs LTRA. If the aim at this treatment step is for exacerbation reduction, adding LAMA could be the preferred option. • Rather than referral only after failure of LAMA and LTRA, earlier review by a specialist would enable further assessment and consideration of broader treatment options e.g., checking diagnosis, adherence, consideration of the merit of LTRA, LAMA, macrolide and possibly immunotherapy; or, if appropriate, biologic therapy. • Based on the recommendations herein the patient could be at this stage of their management without ever having had any lung function (PEF, spirometry, airway	Thank you for your comment The available evidence comparing addition of LAMA or LTRA, to ICS/LABA was very limited. The Wang et al 2015 study included in Evidence Review Q does not report on exacerbations as an outcome (instead only asthma control and FeNO). Hoshino et al 2019 did report on exacerbations for the comparison of ICS/LABA plus montelukast versus ICS/LABA plus LAMA. The result favoured LAMA, but was based on a single small study with very low certainty of evidence. The committee did not have much confidence in this result because of the small study population The practical arguments for choosing one over the other do not clearly come down on either side. LTRA's are cheaper and it is easier to give a trial of an additional tablet than of a LAMA which involves prescribing an additional inhaler (with environmental consequences) or changing

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				hyper-responsiveness) earlier specialist review would likely be helpful. Add a recommendation to advise the patient/caregiver about the risk of neuropsychiatric adverse events with LTRA	inhalers with the associated time taken to teach the person how to use the new device. However, LTRAs are more likely to cause side effects. In this regard we note that you refer to data you hold on file suggesting a high rate of problems following montelukast. This is well above the frequency in published data, and it is hard to comment further without seeing your document. After further discussion the GC have amended the recommendations and now suggest an equal choice between adding an LTRA or a LAMA. Although the guideline says that referral should be made at this point, there is nothing to stop an earlier referral if it is agreed that this might be beneficial.
Global Initiative for Asthma	Guideline	013	013	1.7.6 and 1.7.7 Earlier specialist referral should be considered before adding a fourth or fifth medication	Thank you for your comment Although the guideline says that referral should be made at this point there is nothing to stop an earlier referral if it is agreed that this might be beneficial

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Global Initiative for Asthma	Guideline	014	004	*1.7.8 Consider changing treatment for people with confirmed asthma who are currently using a short-acting beta2 agonist (SABA) only to a low-dose ICS/formoterol combination inhaler used as needed. [2024]* This recommendation should be stronger and not use the word consider. Compared with SABA alone, as-needed-only low-dose ICS-formoterol reduces the risk of severe exacerbations requiring OCS by 65% and reduces asthma-related emergency visits or hospitalisations by 65%.	Thank you for your comment. The word "consider" in NICE guidelines is used when evidence is lacking which is the situation here. However, in this instance the developers agree that there is a major safety issue and the wording has been changed.
Global Initiative for Asthma	Guideline	014	007	1.7.9 and 1.7.10 and 1.7.11. • The inclusion of this advice for how to switch across from conventional SABA-based treatment to treatment with an anti-inflammatory reliever is a great idea, and will assist in implementation. • Consider adding an extra category for switching across, namely patients who are poorly adherent with their maintenance ICS-containing medication. For 1.7.11, add cost and patient preference as other considerations when deciding whether or not to continue an additional therapy when switching across	Thank you for your comment Adding the extra category you suggest is interesting, but it isn't the only option for addressing poor adherence in these patients and introduces a separate issue into the series of recommendations. 1.7.11 is about evaluating whether an LTRA or LAMA had been of any value rather than just continuing it blindly. It is not about choosing between them.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Global Initiative for Asthma	Guideline	015	000	"MART pathway", and "non-MART pathway" Please reconsider these terms, to avoid confusion with adult recommendations, where as-needed-only treatment with ICS-formoterol is available; this cannot be described as MART since no Maintenance treatment is used.	Thank you for your comment The term AIR therapy is now used which should help address the point you make. The term "fixed maintenance dose" is sometimes used for "non-MART" but in fact this does not distinguish the 2 options as the maintenance component of MART is fixed. The term has been changed to Conventional pathway.
Global Initiative for Asthma	Guideline	015	001	*1.7.12 Refer people with asthma that is not controlled on high dose ICS to a specialist in asthma care. [2024]* To avoid ambiguity, change "ICS" to "ICS-containing therapy"	Thank you for your comment Thank you. Agreed – the wording has been changed
Global Initiative for Asthma	Guideline	015	005	*1.8.1. Offer a twice-daily paediatric low-dose inhaled corticosteroid (ICS), with a short-acting beta2 agonist (SABA) as needed, as initial treatment for children aged 5 to 11 years with newly diagnosed asthma. [2024]* • This statement suggests an assumption that all patients in this age group present with relatively mild disease that should be treated with low-dose ICS, and fails to acknowledge a range of symptom/severity presentations. Clarification is needed to indicate this	Thank you for your comment There is no evidence that people who present with an exacerbation will require more maintenance treatment than those who present with milder symptoms (they will of course need initial treatment with oral steroids, but acute treatment is not part of this guideline update).

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				recommendation would not apply to children who present with very poorly controlled asthma symptoms or with an exacerbation • This recommendation would result in daily ICS treatment being initiated in a large number of children, particularly in primary care, who have a history of very few symptoms e.g. only with viral infection, resulting in higher risk of adherence-to-treatment issues, and more exposure to corticosteroids with no clinical justification. For such children, did the Committee consider the evidence from TREXA and ASIST about taking ICS whenever SABA is taken? Although separate inhalers are more cumbersome, the open-label pragmatic ASIST study showed that children and parents had greater satisfaction compared with physician-adjusted treatment, and asthma outcomes were similar. Add a link to a list of "paediatric low-dose" ICS options, to avoid too-high doses being used.	It is correct that some children with very mild symptoms may not need daily ICS. However, TREXA concluded that the daily ICS regimen was best of the 4 options it tested. ASIST included children over and under the age of 11 and is not directly applicable to 1.8.1.
Global Initiative for Asthma	Guideline	015	010	*1.8.2. Consider paediatric low-dose MART (maintenance and reliever therapy) for children with asthma that is not controlled on paediatric low-dose ICS plus SABA as needed, as long as*	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				they are assessed to have the ability to manage a MART regimen. [2024] • The qualifier about 'the ability to manage a MART regimen' needs clarification, since a MART regimen is simpler than a conventional regimen that requires two different inhalers Again add a link to what is meant by 'paediatric low-dose MART' options and doses	Given that this is not a licensed option at present, it was felt appropriate to emphasise that education and a proper assessment are carried out rather than simply issuing a prescription. MART in children will also involve use of a DPI, and not all children manage these well.
Global Initiative for Asthma	Guideline	016	005	*1.8.3. Consider increasing to paediatric moderate-dose MART if asthma is not controlled on paediatric low-dose MART* [and recommendations that follow through to p16 line 21] These recommendations should be prefaced by strong advice to **first** check inhaler technique, adherence, and other factors that may be contributing to poor asthma control or exacerbations, before considering a step-up in dose or addition of an extra medication. Recommendations are often read in isolation from other sections of a guideline.	Thank you for your comment Your point regarding recommendations being read in isolation is acknowledged, but the principles set out in 1.6.1 apply to every recommendation on treatment escalation in sections 1.7 and 1.8. It would be repetitive and irritating to users to say it as part of every relevant recommendation, and there is no reason why it should be included in 1.8.3 rather than any other recommendation.
Global Initiative for Asthma	Guideline	016	008	*1.8.4. Consider adding a leukotriene receptor antagonist (LTRA) to twice daily paediatric low-dose ICS plus SABA as needed when a child has uncontrolled asthma and is assessed as*	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				unable to manage the MART regimen. Give the LTRA for a trial period of 3 months (unless there are side-effects), then stop it if it is ineffective. [2024] • Add advice about neuropsychiatric adverse effects of LTRA. Clarify what is meant by "unable to manage the MART regimen" (also an issue for 1.8.5).	A link to the MHRA DSU on LTRAs is now included in the guideline. "Unable to manage" is deliberately open. It could be due to poor technique with the relevant inhaler, parental concern about ad-hoc use of a steroid containing inhaler etc.
Global Initiative for Asthma	Guideline	016	023	*1.8.7 Refer children to a specialist in asthma care if their asthma is not controlled on paediatric moderate dose MART or paediatric moderate dose ICS/LABA maintenance treatment.* This recommendation suggests referral only for those with quite significant disease, leading to delayed referral. Suggest referral should be considered for children who require moderate dose ICS-containing therapy, irrespective of whether this results in good asthma control or not.	Thank you for your comment 1.8.7 says that referral should definitely be made at this point. An earlier referral might be appropriate depending on factors including the experience and expertise of the primary care team, and there is nothing to stop such a referral being made if it is thought it would be beneficial.
Global Initiative for Asthma	Guideline	017	013	1.9.2 If symptoms do not resolve during the trial period, take the following sequential steps: • check inhaler technique and adherence • check whether there is an environmental source of their symptoms (for example mould in the home, cold housing, smokers or pets)	Thank you for your comment 1.9.1 is for infants with suspected asthma. As per section 1 of this update, for asthma to be suspected there needs to be an appropriate

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				• review whether an alternative diagnosis is likely. The second and third of these bullet points should PRECEDE initiation of therapy with low dose ICS (as in 1.9.1). The current wording suggests that one should treat with ICS before considering appropriateness of diagnosis, environmental exposures, and appropriate use of medications.	clinical presentation, a consideration of triggers etc. The inclusion of these bullet points in 1.9.2 is an acknowledgement of the particular difficulty of diagnosis in under 5s, and essentially says "you've checked once but it's worth checking again"
Global Initiative for Asthma	Guideline	017	022	*1.9.3 Consider stopping ICS and SABA treatment after 8-12 weeks if symptoms are resolved. Review the symptoms after a further 3 months.* [followed by 1.9.4] • The period of treatment for 8-12 weeks seems too short. It basically returns asthma care to an intermittent approach: the child would get better for a few weeks, then stop treatment, and if they became sick again, restart. This approach, given the safety of low-dose ICS, seems to place children at an unnecessary risk of exacerbations. A longer period of control seems more appropriate before stepping down/off. We also suggest that the timing for discontinuation of • controller treatment should take into account the time of year, considering the high	Thank you for your comment. This was discussed at length. There is no formal evidence by which to set the time period and committee consensus was that 8-12 weeks for an initial trial is the right compromise taking into account concerns about potentially unnecessary treatment, natural recovery from viral infections etc

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				prevalence of respiratory viral infections in children. If ICS are ceased, consider adding advice for parents/caregivers such as 'seek immediate advice/consultation if symptoms recur'	
Global Initiative for Asthma	Guideline	018	008	*1.9.5 and 1.9.6.* These recommendations for referral seem inconsistent with 1.9.2, which suggests to refer to an asthma specialist if the child doesn't respond to low dose ICS. In addition, earlier referral in young children should be recommended, rather than adding additional medications.	Thank you for your comment 1.9.2 suggests referral when symptoms continue despite the first trial of ICS. 1.9.5 and 1.9.6 are for children who did respond (or appeared to respond) to initial treatment with ICS.
Global Initiative for Asthma	Guideline	018	018	*1.10.1 At annual review discuss with the person with asthma (or their family or carer, if appropriate) the potential risks and benefits of decreasing their maintenance therapy when their asthma has been well controlled on their current maintenance therapy. [NICE 2017, BTS/SIGN 2019, amended 21 2024]* • It is essential to include a timeframe for the period of asthma control before and between medication reduction steps, particularly for ICS. Otherwise, "When their asthma has been well-controlled" could be interpreted as	Thank you for your comment. The points you make are acknowledged. An 8–12-week minimum interval between steps down has been included in 1.10.2.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				meaning a period as short as one week (e.g. using ACQ) or 4 weeks (e.g. using ACT). • The GINA recommendation for 2-3 months of good asthma control before considering ICS down-titration is because the improvement in airway hyperresponsiveness after initiation of ICS treatment takes longer than improvement in symptom control or lung function (see ATS/ERS Task Force on asthma outcomes, Reddel et al, AJRCCM 2009). For the time between dose reduction steps, there is evidence for safety of reducing ICS dose by 25-50% at intervals of 3 months (Hagan et al, Allergy 2014), whereas rapid reduction (e.g. halving of ICS dose every 2 weeks) has been used in several studies as a research strategy to deliberately induce exacerbations.	
Global Initiative for Asthma	Guideline	019	001	1.10.2 If is unclear why the only specific down-titration step described is from low-dose ICS or low-dose MART to as-needed-only ICS-formoterol. Clinicians need more advice than this. GINA 2024 Box 4-13 provides suggestions for down-titration options from each treatment step, with evidence where available and consensus where not. The factors stated as	Thank you for your comment The specific item of advice you refer to is added because AIR therapy is new to most people and the committee felt it would be useful to remind users of its availability.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				considerations for order of step-down should include the high priority for reducing or stopping maintenance OCS.	People on regular oral steroids are not covered by this guidance as severe asthma is outside the scope.
Global Initiative for Asthma	Guideline	020	005	*1.12.3 Advise using the following medicines as normal during pregnancy:* *-short-acting and long-acting beta-agonists* *-inhaled corticosteroids* *- oral theophyllines. [BTS/SIGN 2019]* • Given the evidence-based recommendations elsewhere in the guideline, and the evidence that lack of ICS treatment increases the risk of exacerbations during pregnancy and adverse outcomes for the baby, it should be clearly stated here that SABAs and LABAs should not be used on their own without ICS. • There is no role for oral theophyllines in management of asthma, given their toxicity compared with inhaled therapies, and particularly not in pregnancy as they do not protect against exacerbations Biologic therapies for severe asthma should also be mentioned	Thank you for your comment The wording on SABA and LABA use has been amended. The advice on oral theophyllines is taken directly from BTS/SIGN guidance. Theophyllines are not recommended in the treatment pathways in this guidance, but if someone is taking them, and their asthma is well controlled, the committee do not wish to advise that they are stopped. Biologic therapies are not included in the scope of this update.
Global Initiative for Asthma	Guideline	021	008	*1.14.1.* The only triggers mentioned here are air pollution and smoking; no mention of allergen exposure or viral infections. Outcomes during	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				COVID-19 demonstrated the relevance of strategies for avoiding viral infections	This is a legacy recommendation from the 2017 guidance. No new evidence review was undertaken, and we cannot make substantial additions to it. However, the recommendation has been changed slightly to indicate that other triggers should be considered.
Global Initiative for Asthma	Guideline	021	019	*1.14.2. Review self-management plans during:* *- hospital admission, including virtual wards – ensure the person has a written personalised asthma action plan and check inhaler technique* *- acute consultations in primary care or emergency department* *- annual reviews. [BTS/SIGN 2019, amended 2024]* • A post-exacerbation review visit would be a good time for review of the action plan • It is essential to explain that action plans for patients on AIR-only or MART are substantially different from those for patients prescribed traditional treatment with a SABA reliever. One key difference is that in a conventional action plan, extra ICS is provided via the patient's maintenance inhaler (or by adding a separate ICS inhaler) whereas in an AIR-only/MART action plan,	Thank you for your comment Action plans have to be personalised, and as you say this means that they must cater for the different treatment options including AIR and MART. A link to the Asthma + Lung UK website will be included in the Asthma Pathway and different templates are available there.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				the patient receives extra ICS plus extra formoterol via their reliever inhaler, and the incremental doses of the ICS and the formoterol contribute to the reduced risk of severe exacerbations (e.g. see Rabe et al, Lancet 2006). We suggest adding a link to examples of suitable action plans for MART, e.g. from Asthma+Lung UK.	
Global Initiative for Asthma	Guideline	023	001	*1.15.1. Consider actively identifying people with asthma who are at risk of poor outcomes and tailor care to their needs. Risk factors should include:* *- non-adherence to medication* *- over-use of SABA inhalers* *- repeated episodes of unscheduled care for asthma. [2024]* • This is an extremely short list of risk factors that are associated with increased risk of exacerbations. See GINA 2024 Box 2-2B for factors that are independently associated with increased risk of severe exacerbations, and Box 3-5 for potential risk mitigation strategies.	Thank you for your comment The list in GINA Box 2-2B is a good list of factors associated with exacerbations, but that does not necessarily mean that they would be useful on an alert system. 1.15.1 lists factors which indicate that asthma is not well controlled, and this is more relevant to this recommendation than some of the personal factors in GINA 2-2B. The word "consider" is used in NICE guidance when the evidence for an intervention is not unequivocal and is therefore used similarly in this BTS/NICE/SIGN guidance.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Change "Consider actively identifying people…" to "Ensure that there is a process for actively identifying people .."	
Global Initiative for Asthma	Guideline	023	008	*1.16.1. In primary care, people with asthma should be reviewed at least annually by a healthcare professional with appropriate training in asthma management. The review should incorporate a written personalised action plan. [BTS/SIGN 2019, amended 2024]* • An action plan is the only item specified for inclusion in a routine review. It should also include at least an assessment of symptom control and risk factors for exacerbations, including occurrence of exacerbations since the last review, and a check of inhaler technique and adherence. • A review by a suitably trained healthcare professional should also be recommended after any asthma attack, as it may be months until the next scheduled review. Routine reviews should be more frequent than yearly for patients with severe asthma. Although these patients may also be under the care of a respiratory specialist, the GP is well-positioned to identify emerging problems.	Thank you for your comment Checking asthma control and inhaler technique are covered in earlier sections. The committee agrees that reviews after asthma attacks should be added. Severe asthma is outside the scope.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Global Initiative for Asthma	Guideline	023	012	1.16.2 While we appreciate the efforts to use plain language in the guideline, it is not clear what thinking about something would achieve.	Thank you for your comment Agreed. The wording has been changed.
Global Initiative for Asthma	Guideline	023	012	1.16.3 There is no mention under Organisation and delivery of care about referral to a respiratory physician	Thank you for your comment A list of reasons for referral was not suggested for inclusion during scoping and was not part of the existing NICE or BTS/SIGN guidelines.
Global Initiative for Asthma	Guideline	024	017	This definition of bronchodilator reversibility does not provide sufficient information for a health professional to be able to conduct the test that is recommended in 1.2.2. This will be a major problem for implementation.	Thank you for your comment The criteria for diagnostic levels of reversibility are given in section 1.2. it is unclear to the developers how not listing them again in the Terms Used section represents a major barrier to implementation.
Global Initiative for Asthma	Guideline	025	004	A non-expert reading the definitions of a LABA and a LAMA would think that their effects appear appropriate for sole treatment of asthma. The definition of LABA and LAMA should state that they must not be used without concomitant ICS.	Thank you for your comment It is unlikely that a non-expert would decide to treat asthma based solely on the Terms Used section of a guideline

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Global Initiative for Asthma	Guideline	025	010	Definition of MART: *A form of combined ICS + LABA treatment in which a single inhaler, containing both ICS and a fast-acting LABA, is used for both daily maintenance therapy and the relief of symptoms as needed.* • It is essential to change "a fast-acting LABA" to "formoterol", because there are other combinations of ICS with fast-acting LABAs (e.g. fluticasone furoate+vilanterol) that cannot be used as MART. This is an issue for safety and efficacy - these other fast-acting LABAs cannot be safely used more than once a day, and there is no evidence that using them more often than once in any day would reduce exacerbations. This contrasts with the extensive evidence for safety, efficacy and effectiveness of doses of formoterol in combination with ICS, up to a maximum total of 72 mcg formoterol in a single day, in reducing the risk of progression to severe exacerbation or need for urgent health care. This is a critically important safety issue for understanding of and implementation of the guideline	Thank you for your comment Agreed. This has been changed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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Global Initiative for Asthma	Guideline	025	015	*Peak expiratory flow (PEF) variability.* *A measure of the maximum speed of expiration, generally expressed in litres per minute. PEF variability is a measure of the extent to which this varies over time.* Change to "PEF is a measure of the maximum speed…."	Thank you for spotting this. This was a typo and has been changed.
Global Initiative for Asthma	Implementation difficulties?	000	000	This has been addressed in the individual comments.	Thank-you for your comment.
Global Initiative for Asthma	Question about NICE indicator NM 166	000	000	We have not commented on this issue, as it is UK-specific	Thank you for your comment.
Global Initiative for Asthma	Supporting documentation Algorithm (diagnostic)	General	General	• Many users of the guideline will look only (or mainly) at the figure, without reading the relevant sections of the guideline itself, so for implementation, it is essential that the algorithm should be sufficiently complete within itself. At present, the diagnostic algorithm implies that any patient with an elevated blood eosinophil count or with FeNO >50ppb would automatically be given a diagnosis of asthma. The diagnostic algorithm should therefore include the initial	Thank you for your comment Agreed. Clinical history is noted as important within the Figures. The committee does not wish to specify that treatment should be commenced while awaiting a referral appointment, although neither is this excluded. It will depend on individual circumstances such as the waiting time, intensity of symptoms etc.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				criterion, which from section 1.2.1 – 1.2.3 is "Adults with a history typical of asthma". • Alternative diagnoses should be considered before any testing is conducted, if the patient's clinical features are more consistent with a diagnosis other than asthma • If the diagnosis is not confirmed, the only option currently indicated by the algorithm is "Consider alternative diagnoses". There should be an option for referral, and for treating as asthma while awaiting referral, if the history is suggestive and clinical urgency warrants it. • Comments about the individual elements of the diagnostic algorithm are recorded against the relevant recommendation. The algorithm diagrams must be much more clinically relevant than at present, in order to allow implementation.	
Global Initiative for Asthma	Supporting documentation Algorithm (diagnostic)	General	General	• Many users of the guideline will look only (or mainly) at the figure, without reading the relevant sections of the guideline itself, so for implementation, it is essential that the algorithm should be sufficiently complete within itself. At present, the diagnostic	Thank you for your comment Agreed. Clinical history is noted as important within the Figures.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				algorithm implies that any patient with an elevated blood eosinophil count or with FeNO >50ppb would automatically be given a diagnosis of asthma. The diagnostic algorithm should therefore include the initial criterion, which from section 1.2.1 – 1.2.3 is "Adults with a history typical of asthma". • Alternative diagnoses should be considered before any testing is conducted, if the patient's clinical features are more consistent with a diagnosis other than asthma • If the diagnosis is not confirmed, the only option currently indicated by the algorithm is "Consider alternative diagnoses". There should be an option for referral, and for treating as asthma while awaiting referral, if the history is suggestive and clinical urgency warrants it. • comments about the individual elements of the diagnostic algorithm are included in comments on the text recommendations. • The algorithm diagrams must be more clinically relevant than at present, in order to allow implementation.	The committee does not wish to specify that treatment should be commenced while awaiting a referral appointment, although neither is this excluded. It will depend on individual circumstances such as the waiting time, intensity of symptoms etc. An absolute cut-off value for eosinophils is given for children because the normal range varies with age across childhood years as well as varying slightly between laboratories. This makes a recommendation to apply a cut-off value of "above the normal range" in children much more complicated for users and the committee agreed by consensus to use a single value.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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				There are some inconsistencies between paediatric and adult algorithms: an absolute value of blood eosinophils is stated for children, whereas for adults, the criterion is greater than the laboratory reference value; the algorithm for children includes the possibility of blood eosinophils and FeNO not being available, but this is not included in the adult algorithm.	
Global Initiative for Asthma	Supporting documentation Algorithm (treatment)	001	Children under 5 years	• Figures and flow-charts are very commonly read in isolation from the text, so they should be sufficiently complete within themselves to be understood, and should include links to critically important information. In this case, the "symptoms indicating need for maintenance therapy" need to be stated. Our comments on the elements of the algorithm for this agegroup are listed against the relevant recommendations	Thank you. Responses are given against the relevant comments.
Global Initiative for Asthma	Supporting documentation Algorithm (treatment)	002	Children 5-11 years-	Figures and flow-charts are very commonly read in isolation from the text, so they should be sufficiently complete within themselves to be understood, and should include links to critically important information. Our comments on the elements of the algorithm for this agegroup are listed against the relevant recommendations It is	Thank you. Responses are given against the relevant comments.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				particularly important to clarify what 'ability to manage MART regimen' means.	
Global Initiative for Asthma	Supporting documentation Algorithm (treatment)	003	Adults and adolescents	• Figures and flow-charts are very commonly read in isolation from the text, so they should be sufficiently complete within themselves to be understood, and should include links to critically important information. • It is an excellent innovation to include advice in the algorithm about how to switch patients from conventional SABA-based treatment to an anti-inflammatory reliever regimen. However, the presence of uncontrolled asthma should not be the only criterion for switching. For example, if a patient is noted to be poorly-adherent with their traditional maintenance ICS-containing treatment, a proactive switch to MART could avert the development of poor symptom control or prevent an exacerbation occurring • Consideration could be given to reducing the number of treatment options listed on the right hand side of the algorithm • The colour coding of maintenance therapy, symptom relief and MART in the algorithm is not intuitive, and the blue colour for symptom relief may lead to confusion with SABA,	Thank you for these thoughts. The committee agree that there might be reasons for switching other than poor control; adherence as you mention, or by patient request e.g. if they know someone who uses MART and feel it would suit them. The Figure is already a bit busy and it was thought best not to include a comprehensive list. The colour coding has also been reconsidered,,,

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				given the common colour coding of inhalers in the UK. Additional feedback on elements of the algorithm are provided against the relevant recommendations.	
GSK	Guideline	008	019	**Rec 1.5.2: Monitoring asthma control** **Suggestion:** GSK note in the committee's rationale for the use of asthma control questionnaires which indicate a 'recommend' for these tools as part of an annual review of asthma. This does not appear to have translated through to the guideline where the term 'consider' is applied. • GSK believe changing the term "consider" for "recommend" will improve the implementation of these tools in clinical practice and the management of asthma. **Rationale:** GSK notes that composite measures of asthma control have been shown to be more sensitive than single measures (e.g., rescue medication use) and can be assessed in clinical practice with validated structured questionnaires such as	Thank you for your comment The committee sympathises with your point, but in the evidence review the benefit of using standard questionnaires was not as strong as might have been expected. In this circumstance NICE policy is to use the word "Consider" in its recommendations, therefore this terminology is used in this BTS/NICE/SIGN guidance.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Asthma Control Test (ACT) or Asthma Control Questionnaire (ACQ). [1] Uncontrolled asthma is common in the UK with HCPs and patients overestimating asthma control. Validated structured questionnaires help to provide a common understanding of asthma control between patient and HCP and a benchmark for goal setting as well as further investigations when this is not achieved. [2] [1] Bateman et al, Eur Resp J 2001 ; 17 : 589-595] 589.full.pdf (ersjournals.com) [2] Menzies-Gow, A., Chiu, G. Perceptions of asthma control in the United Kingdom: a cross-sectional study comparing patient and healthcare professionals' perceptions of asthma control with validated ACT scores. *npj Prim Care Resp Med* **27**, 48 (2017). https://doi.org/10.1038/s41533-017-0050-x	
GSK	Guideline	010	015	**Rec 1.6.4: Principles of pharmacological treatment** **Inhalers** **Suggestion:**	Thank you for your comment. The recommendation does not limit the device options as it stands, and the committee do not

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				GSK recommends the inclusion of alternative options to enable patient choice and preference, both dry powder and metered dose inhalers (DPI's and MDI's). **Rationale:** GSK is concerned that the treatment algorithm has limited inhaler choice, this could make it challenging to choose an inhaler based on technique and preference. Many inhaler types will be excluded, and this will limit patient choice. GSK agrees that the aims of asthma management are to achieve good symptom control and to minimise the future risks, and that asthma is an inflammatory condition and therefore ICS-containing therapy is the cornerstone of asthma management. GSK also agrees that patients should not be on SABA monotherapy alone due to potential dangers of this practice related with underuse of inhaled corticosteroids and over reliance on beta-agonists. GSK welcomes the guidance related to inhaler devices, which, highlights the importance of patient preference, device continuity and environmentally friendly options.	think that it would be improved by listing all the available device types.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				GSK believes that the treatment choice should depend on the HCP's clinical judgement based on the patient's traits, needs and preferences. GSK is concerned the perceived imbalanced proposal, may limit medical decision making for certain medicines and inhaler devices.	
GSK	Guideline Algorithm	012	004	**Rec 1.7.1: Pharmacological management in people aged 12 and over.** **Initial management of newly diagnosed asthma in people aged 12 and 3 over.** **Suggestions:** • GSK recommends the inclusion of an option of regular daily ICS/LABA (with rescue short acting beta-2 agonist), as an *equal* choice treatment option along with MART. This will allow HCPs this option for patients for whom this would be an effective treatment approach. • GSK believe where it is mentioned "Offer a low-dose ICS/formoterol combination inhaler to be taken as needed", a flexible treatment choice is added, that can best suit the lifestyle of patient. This would be instead of "as needed treatment", as	Thank you for your comment The committee believes that the evidence in adults strongly favours the AIR then MART strategy over the traditional treatment pathway and have therefore recommended this. The remit of NICE is to offer guidance on the most cost-effective management strategy and therefore the remit of this BTS/NICE/SIGN guidance.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				some patients may prefer a regular ICS treatment with SABA as reliever. • GSK also recommends aligning treatment algorithms with globally recognised asthma guidelines. **Rationale:** GSK is pleased to see the draft guideline's position continue the previous work of BTS/SIGN Asthma Guideline 2019 to include inhaled corticosteroids (ICS) as the cornerstone of pharmacotherapy for patients with asthma and that rescue medication (e.g., short acting beta agonists) alone are inadequate. GSK recognises the heterogeneity of asthma and supports the stratification of patients to improve clinical outcomes. We also recognise and agree that different treatment strategies and approaches may be required to meet the needs of individual patient and their healthcare providers. Poor adherence to pharmacotherapy is common and contributes to poor asthma outcomes with the National Review of Asthma Deaths (NRAD) highlighting that underuse of	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				ICS maintenance treatment is associated with poor outcomes including death. [1] <u>Comments related to: "Offer a low-dose ICS/formoterol combination inhaler to be taken as needed".</u> Effective pharmacotherapy for patients with asthma, considering its heterogeneity and the importance of shared decision making between HCPs and their patients, may require different strategic approaches including proactive regular dosing of ICS containing treatments. [2] The use of 'as required' (PRN) ICS/formoterol has been shown to be *non-inferior* to regular twice daily ICS in relation to severe exacerbations in patients with 'mild' asthma, and delivered worse outcomes in regard of asthma control, quality of life and spirometric assessments. [3] Whilst we acknowledge the use of "as required" (PRN) ICS/formoterol is appropriate for some patients, it should be noted that for informed decision making it has not shown to be superior	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				to standard practice of regular daily dosing of ICS. Additionally, current definitions of asthma control, including what is proposed in the current draft guideline, include a requirement for little or preferably no need for rescue medication use. Therefore, GSK have serious concerns that the only preferred recommendation for physicians and patients in the algorithm is low-dose ICS/formoterol combination inhaler as needed. Some patients and physicians prefer a regular ICS treatment with SABA as reliever. Notably, in a citation looking at the overall evidence available in 2019, it was concluded that compared to budesonide maintenance therapy, the combination of ICS-LABA as needed, provided inadequate asthma control. Also, it should be noted that the SYGMA studies which are the main basis for these recommendations, do not report the effects on control of inflammation, hyperresponsiveness, remodelling and asthma mortality compared with regular ICS usage beyond 1 year. The long-term safety of this approach is thus unknown. [4] Comments related to: "Offer low dose MART"	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				MART (Maintenance and Reliever Therapy) relies on the patient taking twice daily maintenance treatment but is defined by its use of rescue therapy. It is unclear how this reactive symptom driven approach is aligned with the goals of asthma management outside the prevention of exacerbations. This may lead to inadequate control and therefore patients experiencing symptoms on a regular basis. An appraisal of MART studies highlighted asthma control is generally poor with 17.1% achieving 'well controlled asthma'. [5] GSK believes it is important to consider, that since the introduction of MART there have been significant advances in proactive regular daily dosing with the introduction of once daily ICS/LABA with 24-hour duration of action and low systemic activity. [6,7,8,9]. Assessment of the *effectiveness* of one inhalation, once daily fluticasone furoate/vilanterol [FF/VI] compared to 'usual care' (GP titrated therapy) in a prospective open label pragmatic RCT (Salford Lung Study in Asthma) demonstrated an improvement in asthma control (as measured by asthma control test) [odds ratio [OR] 2·00 [95%	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				CI 1·70–2·34], p<0·0001 at week 24] for patients randomised to once daily FF/VI, with no increase in serious adverse events. The improvements in asthma control between groups was consistent at 12, 24, 40, and 52 weeks in favour of FF/VI compared to optimised usual care. [10] A paper published in 2021 concluded that the molecule fluticasone furoate (FF) could provide more protection against airway hyper-responsiveness with less systemic activity, than either fluticasone propionate (FP) or budesonide (BUD). This suggests that inhaled corticosteroids are not therapeutically similar and may differ in their therapeutic index [11] In a retrospective cohort UK study, adherence was measured in terms of discontinuation, comparing once-daily FF/VI with other available treatments including twice-daily budesonide/formoterol (BUD/FORM) and beclomethasone dipropionate/formoterol (BDP/FORM). The study indicated that patients who initiated FF/VI were less likely to discontinue treatment (defined as a >60 day gap in prescription or switch to another index therapy in this period) and showed greater adherence	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				compared to patients who initiated BUD/FORM or BDP/FORM. [12] The recent APPaRENT 1 and 2 studies have shown that **physicians** preferred the regular ICS dosing regimen as initial treatment for moderate-to-severe asthma. [13] APPaRENT 2 study further showed that may **patients** on MART requested additional rescue inhalers, suggesting that MART is being misapplied and that patients may perceive their asthma as inadequately controlled with MART. [14] GSK believes that in addition to the above, it is also important that the committee considers alignment with international asthma guidance, Global guidelines/recommendations (GINA) do not suggest that MART regimens are more effective than regular ICS-containing regimens for asthma management. [15]	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				[1] Why asthma still kills, National Review of Asthma Deaths 2014 Why asthma still kills full report (1).pdf [2] Chapman, Kenneth R., et al. "Patients' and physicians' perspectives on the burden and management of asthma: Results from the APPaRENT 2 study." *Respiratory Medicine* 201 (2022): 106948. https://doi.org/10.1016/j.rmed.2022.106948 [3] Bateman, Eric D., et al. "As-needed budesonide–formoterol versus maintenance budesonide in mild asthma." *New England Journal of Medicine* 378.20 (2018): 1877-1887. https:// [4] Domingo C *et al*. Drugs (2019) 79:1729–1737 - https://doi.org/10.1007/s40265-019-01202-0 [5] Chapman, Kenneth R., et al. "Single maintenance and reliever therapy (SMART) of asthma: a critical appraisal." *Thorax* 65.8 (2010):	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				747-752. https://doi.org/10.1136/thx.2009.128504 [6] Relvar Ellipta 92 micrograms/22 micrograms inhalation powder, pre-dispensed - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) [7] Relvar Ellipta 184 micrograms/22 micrograms inhalation powder, pre-dispensed - Summary of Product Characteristics (SmPC) - (emc) (medicines.org.uk) [8] Bardsley, George, et al. "Anti-inflammatory duration of action of fluticasone furoate/vilanterol trifenatate in asthma: a cross-over randomised controlled trial." *Respiratory Research* 19 (2018): 1-11. https://doi.org/10.1186/s12931-018-0836-6 [9] Daley-Yates, Peter, et al. "Therapeutic index of inhaled corticosteroids in asthma: A dose–response comparison on airway hyperresponsiveness and adrenal axis suppression." *British Journal of Clinical*	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				Pharmacology 87.2 (2021): 483-493. https://doi.org/10.1111/bcp.14406 [10] Woodcock, Ashley, et al. "Effectiveness of fluticasone furoate plus vilanterol on asthma control in clinical practice: an open-label, parallel group, randomised controlled trial." *The Lancet* 390.10109 (2017): 2247-2255. https://doi.org/10.1016/S0140-6736(17)32397-8 [11] Daley-Yates P et al. "Therapeutic index of inhaled corticosteroids in asthma: a dose-response comparison on airway hyperresponsiveness and adrenal axis suppression" *British Journal of Clinical Pharmacology. 2021; 87:483-493* https://doi.org/10.1111/bcp.14406 [12] Parimi M et al. "Persistence and Adherence to ICS/LABA drugs in UK patients with asthma: a retrospective new-user cohort study" *Adv.Ther (2020) 37:2916-2931* https://doi.org/10.1007/s12325-020-01344-8	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				[13] Chapman K.R. *et al.* Respir Med 2021 Sep: 186:106524 doi: 0.1016/j.rmed.2021.106524. Epub 2021 Jun 29. [14] Chapman K.R. *et al.* Respir Med 2022 Sep: 201:106948 doi: 0.1016/j.rmed.2022.106948. Epub 2022 Aug 6. [15] 2022 GINA Report, Global Strategy for Asthma Management and Prevention; Last Accessed 23rd July 2024 at: https://ginasthma.org/gina-reports	
GSK	Guideline Algorithm	012	004	**Rec 1.7.1: Pharmacological management in people aged 12 and over** **Initial management of newly diagnosed asthma in people aged 12 and over** **Suggestion:** • GSK recommends the positioning of LAMA addition to ICS/LABA prior to that of LTRA addition, in the algorithm for patients aged 12 years and over, where asthma is uncontrolled. **Rationale:**	Thank you for your comment. The paper you cite (Kaplan et al, 2020) states that there is no head-to-head comparison of the 2 options and bases its preference for a LAMA on "opinion". There is a published comparison of LAMA vs LTRA and neither was clearly superior to the other (please see Evidence Review Q)

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				It is unclear why LTRAs appear to be positioned in the management algorithm ahead of LAMAs; although both are considered as options, a paper published in 2020 cited: "If asthma remains uncontrolled despite medium-dose ICS, increasing the dose of ICS may not be appropriate due to an increased risk of local and systemic side effects and variation in individual ICS dose-responsiveness between patients. Therefore, the addition of an add-on therapy which could be either a LAMA or LTRA may be considered as a more effective and safer treatment strategy. Although there is lack of head-to-head studies comparing addition of LTRA versus LAMA to ICS it is generally believed adding a LAMA is a better strategy given the robust evidence supporting improvement in lung function and exacerbation with dual maximal bronchodilation by the addition of LAMA to the ICS/LABA treatment." [1] [1] Kaplan A *et al.* Primary Care Respiratory Medicine (2020) 30:50 ; https://doi.org/10.1038/s41533-020-00205-9	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
GSK	Guideline	024	004	**Rec 1.5.1: Monitoring Asthma Control** GSK are fully supportive of the guideline's definition of asthma control to include the composite measure comprising: • No daytime symptoms • No night-time awakening due to asthma • No asthma attacks • No need for rescue medication • No limitations on activity including exercise • Normal lung function (in practical terms forced expiratory volume in 1 second [FEV1] and/or peak expiratory flow [PEF] more than 80% predicted or best) • Minimal side-effects from treatment. As research progresses definitions of asthma control are beginning to consider remission as a treatment goal. Having ambitious targets will help advance outcomes for patients, like other chronic inflammatory diseases such as rheumatoid arthritis, as well as stimulate research to provide new therapeutic strategies and options. [1]	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				[1] Menzies-Gow et al. An expert consensus framework for asthma remission as a treatment goal, Journal of Allergy and Clinical Immunology, Volume 145, Issue 3, 2020, Pages 757-765. https://doi.org/10.1016/j.jaci.2019.12.006	
Lactation Consultants of Great Britain	Guideline	071	Row 5	The recommendation to breastfeed is due to antenatal conversations that midwives have with pregnant people, and midwives, other healthcare professionals, and pregnant people accessing this guidance should be encouraged to continue in breastfeeding advocacy conversations in cases of pregnant people with asthma.	Thank you for your comment. This previous recommendation has been deleted because breastfeeding is encouraged generally, not just for people with asthma.
Lactation Consultants of Great Britain	Guideline	071	Row 6	12.5 should perhaps be renamed "Asthma in Pregnancy and During Breastfeeding", as these two periods of time are often coupled together in advice around medication due to concerns or reassurance needed around transmission to both the fetus and then the breastfeeding child. Therefore, it would be appropriate to include the line stating to continue to use asthma medications as normal in lactation. Breastfeeding Network's Drugs in Breastmilk specialist service and the UK Drugs in Lactation	Thank you for your comment The advice to continue asthma medication during breastfeeding has been reinstated

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Advice Service (UKDILAS service from SPS) could be signposted to.	
Medicines and Healthcare products Regulatory Agency	Guideline	010	014	The MHRA has received reports of serious patient harm resulting from the use of empty or near empty asthma rescue pressurised metered dose (pMDI) inhalers. These incidents involved the use of pMDI devices which were not fitted with an integral dose counter and therefore patients/parents/carers were unaware that the device was not delivering the correct dose of asthma rescue medication. Wording should be included in the guidelines to raise awareness of the risks associated with the absence of dose counters on pMDI inhaler devices and that appropriate information should be provided to patients/parents/carers if an inhaler without a dose counter is prescribed.	Thank you for your comment. A bullet point has been added to 1.6.4 recommending devices with a dose counter.
Montelukast Side Effects (Singulair) Support and Discussion Group	Guideline	General	General	The revelation that montelukast not only distributes into the brain, but also accumulates there was a pivotal point presented and discussed at the September 2019 Joint Meeting of the US Food and Drug Administration (FDA) Pediatric Advisory Committee (PAC) & Drug Safety and Risk Management Advisory Committee (DSaRM). This was outlined on page 14 of the USA FDA Briefing Document	Thank you for the detailed comment. A link to the MHRA DSU on montelukast has been added.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				(https://www.fda.gov/media/131035/download) and table showing Montelukast Distribution in Rats after Oral Administration (https://www.fda.gov/media/132468/download). Montelukast's impact on the brain played a crucial role in the US FDA's decision to issue a Boxed Warning for montelukast, announced in March 2020, and to recognize the occurrence of severe mental health issues in individuals who have taken montelukast, even after discontinuing the treatment. We remain concerned regarding the impact on LTRA's on the brain (and the developing brain) during treatment and after treatment has stopped and respectfully request that consideration be given to the following research: Marques et al Oct 2022 (https://www.sciencedirect.com/science/article/pii/S0024320522007561). The mechanisms underlying montelukast neuropsychiatric effects – new insights from a combined metabolic and multiomics approach. Life Sciences Vo. 110. Dec 2022, 121056. Key findings: The multi-omics approach employed confirmed that	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				montelukast interferes with the glutathione detoxification system in the brain. Moreover, montelukast is also able to dysregulate various neurostransmitter and neurosteroid pathways, particularly those involved in regulation of the hypothalamic-pituitary-adrenal axis, also interfering with mitochondrial function in neuronal cells. Significance: Results clearly indicate that montelukast therapeutic effects are accompanied by a strong modulation of specific processes in the central nervous system that may explain the observed neuropsychiatric reactions. Moreover, the results also suggest that adverse drug reactions are more likely to occur in children, due to the early maturation stage of their brains. Tseng et.al (https://www.sciencedirect.com/science/article/abs/pii/S0009279720300326?via%3Dihub) In vitro cytotoxicity of montelukast in HAPI and SH-SY5Y cells. Chemico-Biological Interactions, Volume 326, 1 August 2020, 109134 This study "provides the first in vitro evidence on Montelukast toxicity to microglial and neuronal	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				cells. Provides evidence that this toxicity may be mediated by inflammatory response. Suggests that the inflammatory response and toxicity may contribute to neuropsychiatric events seen with montelukast use." Eriksson, Kalm et al.(https://pubmed.ncbi.nlm.nih.gov/29991719/) The anti-asthmatic drug, montelukast, modifies the neurogenic potential in the young healthy and irradiated brain. Cell Death Dis. 2018 Jul; 9(7): 775. This study found detrimental effects in the developing brains of juvenile healthy control mice, including inhibited cellular growth in the hippocampus under conditions of typical development. Marschallingar et al.(https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4639806/) Structural and functional rejuvenation of the aged brain by an approved anti-asthmatic drug. Oct 2015. Nat Commun, 2015;6: 8466 conducted an extensive analysis, including a re-examination of Merck NDA 20-829's 1998 original CNS pharmacology data, revealing that montelukast's distribution across	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				the blood-brain barrier (BBB) is significant rather than minimal. Marschallinger, et al. also confirmed that montelukast exerts structural and functional impacts on the central nervous system, mediated through the GPR17 receptor. It also suggests the existence of an active transport mechanism for Montelukast through the BBB. We are also aware that the US National Center for Toxicological Research (NCTR) Division of Systems Biology (DSB) of the US FDA is conducting "multiple studies to evaluate concerns of potential drug-induced neuropsychiatric risks associated with montelukast, including verification of montelukast's binding potential to candidate protein targets in human neural cells" We would like to see further research to improve understanding of the true incidence of neuropsychiatric side effects to montelukast and the impact of montelukast on the brain.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Montelukast Side Effects (Singulair) Support and Discussion Group	Evidence Review Q	116	02 to 014	The Paragraph 1.1.12.1 "The outcomes that matter most" is focussed on the purpose of the asthma medication to relieve symptoms, improve quality of life and prevent exacerbations. Consideration is given to a limited number adverse reactions in which specific adverse events considered were: linear growth, pneumonia, adrenal insufficiency, bone mineral density and inflammatory markers. These specific adverse events have a bias towards concerns with ICS. We are concerned that limited consideration has been sought in relation to the specific adverse reactions to LTRAs such as montelukast. The MHRA has conducted a further review to evaluate new evidence, taking into consideration the experiences of patients and caregivers and independent clinical advice from paediatricians, specialists in mental health and respiratory health, as well as experts in medicines safety at the Expert Advisory Groups (EAG) of the Commission on Human Medicines (CHM). The DSU in April 2024 highlights a range of neuropsychiatric reactions have been reported	Thank you for your comment In the evidence review the committee focussed on the side effects which were thought to be most widely reported as outcome measures in clinical trials. They agree that some other side effects may be under-reported in trials and were certainly well aware of the problems you identify with montelukast and discussed these when making recommendations. It is usual NICE practice, and therefore the same methodology has been used in this BTS/NICE/SIGN guideline, to defer to the BNF in terms of listing cautions and side effects which might occur with any prescribed medication. Thank you for the references. You will note that the committee agrees with the various papers, which show ICS to be superior to montelukast, and montelukast is only recommended as one option for additional therapy when ICS alone is proving inadequate.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				in association with montelukast. Among these are: sleep disturbances, depression and agitation including aggressive behaviour (may affect up to 1 in 100 people taking montelukast), disturbances of attention or memory (up to 1 in 1,000 people), very rarely, hallucinations and suicidal thinking and behaviour (up to 1 in 10,000 people). We do not feel the evaluation of evidence has sufficiently considered specific adverse events related to LTRAs when comparing LTRAs against ICS, nor has the economic assessments taken into account the economic impact of neuropsychiatric side effects both in terms of increased burden on stretched NHS mental health and neurological services but the wider economic burden on schools, potential for lower academic attainment, workplace absence and caring requirements from the wider family. **We would like to recommend that in considering the effectiveness of LTRAs in comparison to ICS wider consideration is given to economic burden of adverse side effects relevant to both LTRAs and ICS.**	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				We would draw attention to: Bush. 2023 – Basic Clinical Management of Preschool Wheeze Pediatric Allergy and Immunology. Vol 34 Iss 7/e13988 (https://doi.org/10.1111/pai.13988). This paper discusses the two largest recent trials (Valovirta and Nowokoro) recruiting over 3000 children, have failed to show benefit for either intermittent or continuous montelukast. It goes on to say parents should be warned about the behavioural side effect which have a prevalence of around 20% and can be very distressing (Benard). This study references: - Valovirta et al. Intermittent or daily montelukast versus placebo for episodic asthma in children. Ann Allergy Asthm Immunol. 2011; 106:518-526 - Nowokoro et al. Intermittent montelukast in children aged 10 months to 5 years with wheeze (WAIT trial): a multicentre, randomised, placebo-controlled trial. Lancet Respir Med. 2014; 2: 796-803 - Benard et al. Neuropsychiatric adverse drug reactions in children initiated on montelukast in real-life practice. Eur Respir J. 2017;50:1700148.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Further research to consider is: Brand 2011 Inhaled corticosteroids should be the first line of treatment for children with asthma. Paediatric Respiratory Reviews Vol. 12 Iss 4 Dec 2011 P245-249. (https://www.sciencedirect.com/science/article/abs/pii/S1526054211000510) This research suggests that in comparative trials and systematic reviews, inhaled corticosteroids are more effective than montelukast in reducing asthma exacerbations, improving lung function, symptom scores and rescue medication use. Mayoral et al. Montelukast in paediatric asthma and allergic rhinitis: a systematic review and meta-analysis. European Respiratory Review 2023: 32:230124 (https://err.ersjournals.com/content/32/170/230124.article-info). This concluded that montelukast was effective in controlling asthma symptoms when compared to a placebo, but inhaled corticosteroids were superior in controlling symptoms, especially at night-time.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Chauhan and Ducharme. Anti-leukotriene agents compared to inhaled corticosteroids in the management of recurrent and/or chronic asthma in adults and children. Cochrane Database Sys Review. 2012 CD002314 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4164381/). As monotherapy, inhaled corticosteroids display superior efficacy to anti-leukotrienes in adults and children with persistent asthma; the superiority is particularly marked in patients with moderate airway obstruction. On the basis of efficacy, the results support the current guidelines' recommendation that inhaled corticosteroids remain the preferred monotherapy. Hussein et al. A meta-analysis of montelukast for recurrent wheeze in pre-school children. Eur K Pediatr 2017; 176(7): 963-969 (https://pubmed.ncbi.nlm.nih.gov/28567533/). The recommendation from this study was no benefit was seen with montelukast for pre-school wheeze from limited well conducted RCTs over at least 12 months in preschool children with recurrent wheeze. Further research was recommended.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Salehain et al. Phenotype and endotype based treatment of preschool wheeze. Expert Review of Respiratory Medicine. Vol 17, 2023. Iss 10 (https://pubmed.ncbi.nlm.nih.gov/37873657/). This reviews observable features and characteristics used to ascribe phenotypes in children with preschool wheeze and available pathobiological evidence to identify possible endotypes. These are considered in the context of treatment options and future research directions. Palijarvi et al. Analysis of Neuropsychiatric diagnoses after montelukast initiation. May 2022. JAMA Netw Open. 2022;5(5):e2213643. (https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2792596) This study found that patients with asthma or allergic rhinitis had increased odds of adverse neuropsychiatric outcomes after montelukast initiation. These findings suggest that clinicians should consider monitoring potential adverse mental health symptoms during montelukast treatment, particularly in individuals with a history of mental health or sleep problems.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Montelukast Side Effects (Singulair) Support and Discussion Group	Evidence Review Q	General	General	In Evidence Review Q, the evidence supporting cost assessments is Lenney 2013 (Page 124, Line 33), however this and the NICE review 2017 (Page 104, Line 9) all pre-date the increased warnings by the MHRA about neuropsychiatric side effects given in 2019 and 2024. Our understanding is also that the studies referred to in Evidence Review Q relate to the relative cost of one asthma treatment compared with another or other treatments. What consideration do these costs analysis make of the impact and burden on the NHS for the treatment of neuropsychiatric side effects, the economic impact on wider government departments (such as education, social services and benefits) and further still the economic impact of reduced educational outcomes or lost working time? In Evidence Review Q, Page 124, Line 36 Lenney 2013 was assessed as partially applicable with potentially serious limitations. If this is the case and with the added knowledge of the risks of potential neuropsychiatric side effects why is there not a further discussion	Thank you for your comment The evidence on cost-effectiveness was not limited to the 2 papers you refer to. In relation to LTRAs the Price paper was also included. However, you are correct in stating that these all predate the MHRA DSUs. There was no updated economic review including montelukast so your question on the impact of neuropsychiatric side effects on a cost-effectiveness analysis cannot be answered. However, as noted in responses to some of your other comments, the committee were aware of these side effects and considered them in making their recommendations.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				about the risk balance between ICS exposure and neuropsychiatric side effects of LTRAs excluding cost as a deciding factor? This question applies to the Guidelines produced for all age groups.	
Montelukast Side Effects (Singulair) Support and Discussion Group	Guideline	004	001	We agree that people have the right to be involved in discussions and make informed decisions about their care. Our unpublished study "Montelukast – the side effects, a patient's perspective in the UK" issued to the Medicines Healthcare and Products Regulatory Authority (MHRA) in September 2023, it included analysis of 46 detailed questionnaires from patients (or their carers) who are believed to have suffered severe adverse side effects. It reported that 40 out of 46 responses were given no information about the side effects; for the 6 responses where information was provided the information was limited. **No respondents reported adequate advice being given regarding the potential for neuropsychiatric adverse side effects.** Of the 20 responses where patients were prescribed montelukast after the MHRA's September 2019 drug safety update 80% of patients were not told about the side effects and	Thank you for your comment In the evidence review the committee focussed on the side effects which were thought to be most widely reported as outcome measures in clinical trials. They agree that some other side effects may be under-reported in trials and were certainly well aware of the problems you identify with montelukast and discussed these when making recommendations. It is usual NICE practice and now adopted for the BTS/NICE/SIGN guideline to defer to the BNF in terms of listing cautions and side effects which might occur with any prescribed medication. However, a link to the MHRA DSU has been added to the guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				where information was provided it was limited to a doctor saying some parents thought montelukast caused hyperactivity or being told about the potential for night terrors. The MHRA has issued a new Drug Safety Update in April 2024 https://www.gov.uk/drug-safety-update/montelukast-reminder-of-the-risk-of-neuropsychiatric-reactions noting that Yellow Card data indicated a potential lack of awareness of the risk of neuropsychiatric reactions with montelukast amongst healthcare professionals, patients and their care givers. The MHRA gives clear advice for healthcare professionals to give patients and caregivers including advising about new or worsening changes in mood, sleep or behaviour such as nightmares, aggression, anxiety or thoughts about self-injury. It also suggests advice is given about seeking immediate medical attention (for advice on stopping if needed), telling family and friends because patients themselves may not notice changes in mood, sleep and behaviour. The Drug Safety Update (DSU) indicates reports amongst all age groups.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				In addition, based on the overall evidence, the Pharmacovigilance Expert Advisory Group (PEAG) advised that montelukast should be immediately withdrawn due to the nature of the neuropsychiatric reactions, and that immediate withdrawal may help prevent escalation to more serious events. In 2017 the Montelukast Side Effects Support and Discussion Group submitted a response to NICE as part of a previous consultation on Asthma Guidelines. It raised concerns about the impact of adverse side effects and concerns about the National Health Service (NHS) being able to deal with them. It particularly noted limited resources within the NHS for mental health service being cause for concern. Given the recent communication from the MHRA reviewing Yellow Card data that has indicated a lack of awareness of the risks of neuropsychiatric reactions, in spite of the September 2019 DSU, we recommend that NICE considers more broadly how it supports communication of the MHRAs April 2024 DSU to ensure patients or their carers receive sufficient	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				information to allow them to have "discussions and make informed decisions about their care". Our request is that the different treatment options are discussed along with the risks and benefits to allow patients to reach a decision **with** their health care professional. We also note that whilst the BNF https://bnf.nice.org.uk/drugs/montelukast/ does highlight in the important safety information section the MHRA/Commission for Human Medicines (CHM) communications about the risks of neuropsychiatric side effects it does not share the detailed "Advice for healthcare professionals to give to patients and caregivers" or provide a direct link to the DSU. We remain concerned about the effectiveness of the DSU communication in reaching the necessary healthcare professionals, particularly given the well documented pressures on the NHS. We therefore feel more needs to be done within the relevant governmental organisations to maximise visibility of these important safety signals from the MHRA/CHM, to assure that healthcare professionals have sufficient	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				awareness of the issues so as to minimise the risks to patients. We believe National Institute for Health and Care Excellence (NICE) have an important role to play both through the Clinical Knowledge Summaries and the British National Formulary (BNF) in supporting onward communication of DSUs especially when they are providing guidance on a particular treatment.	
Montelukast Side Effects (Singulair) Support and Discussion Group	Guideline	004	003	In Para 1.1.1 In the Initial Clinical Assessment, we suggest consideration of the risk of mental health sequelae and a personal or family mental history should be included in the initial clinical assessment of the patient prior to considering use of LTRAs.	Thank you for your comment This section is about establishing a diagnosis of asthma, not about assessing which treatments might be used for those in whom the diagnosis is confirmed
Montelukast Side Effects (Singulair) Support and Discussion Group	Guideline	018	008	Refers to Children under 5. We are concerned by anecdotal reports of primary care settings refusing to refer children to specialist asthma care for further investigation and management without having first tried an LTRA. We feel given the potential for neuropsychiatric side effects a trial of an LTRA should be optional having first followed the MHRA advice in the April 2024 DSU by advising carers about the potential for neuropsychiatric	Thank you for your comment Recommendation 1.9.6 says that children should be referred at this point. It does not say that a referral cannot be made at an earlier timepoint if this is thought to be potentially beneficial. A trial of an LTRA is not mandatory. The recommendation says to consider this. The

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				side effects. Should a carer raise concerns and not consent to a trial of an LTRA then onward referral to a specialist in asthma care should not be further delayed. Our families (patients of all ages) have described life changing impacts following use of LTRAs, in some cases children no longer living with their parents, strain on wider relationships, children who have been excluded from school, impact on ability to work (both patients and families), self harm, aggression towards others/objects, risk taking behaviours, suicidal ideation and suicide. We feel this is appropriate noting in Evidence Review Q, Page 126 Line 14-17, the consensus view [was] that side effects [to montelukast] are common in practice. We are also concerned that patients (of all ages) may struggle to communicate the impact of the adverse side effects, particularly those relating to night terrors and hallucinations. This is especially concerning for those aged 5 and under.	problem of side effects was considered by the committee as you point out, but the same review also mentions potential benefits of an LTRA. Links to the MHRA DSU are included in the guideline

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Our request is that Para 1.9.5 Page 16 should include wording to reinforce the need to discuss neuropsychiatric side effects and not trialling an LTRA should not preclude the referral to specialist asthma care detailed in Para 1.9.6	
Montelukast Side Effects (Singulair) Support and Discussion Group	Guideline	022	012 to 021	Paragraph 1.14.6 suggests approaches to implementing self-management interventions. What consideration has been given when implementing self-management interventions in primary care to include advisory reminders related to adverse side effects to ensure patients and their carers who are taking montelukast are reminded about the potential for neuropsychiatric side effects, noting the MHRA comment in the April 2024 DSU that individuals themselves may not notice changes in mood, sleep or behaviour? Anecdotally from our unpublished research patients and their carers have reported both sudden onset of side effects and insipid onset. In addition, carers of children and adolescents have noted that it can be difficult for behavioural changes to be separated initially from what may be considered typical developmental behaviours	Thank you for your comment 1.14.6 is a legacy recommendation listing approaches from the BTS/SIGN guideline. It is about strategies to aid in implementing self-management, not about the details of self-management interventions. The other areas noted in this comment are out of scope of this guideline but should be raised if the guideline is ever updated. A link to the MHRA DSU is included in the guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				meaning significant escalation occurs before montelukast may be considered as a cause of neuropsychiatric symptoms. This is supported by the Medscape article Scudder, 2015 https://www.medscape.com/viewarticle/840302#vp_2 Notably our research found it was patients and carers who were identifying and researching the side effects, rather than the advice coming from medical professionals. Respondents found out about the side effects from the following sources: - Online – 25 respondents undertaking online searches, 6 people noting the use of google, 6 people mentioning Facebook as the source of information. - Friends and Family – 6 respondents of which 3 noted their source had some medical training. - Patient Information Leaflet – 6 respondents. - Media – 2 respondents noted magazine or newspaper articles. - Research (not identified) – 1 respondent	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				- Discussed change in behaviour with medical professional - 2 respondents - Not disclosed – 3 respondents Respondents reported raising concerns with medical professionals, typically a General Practitioner (GP), Nurse or Consultant. In our research we have evidence where either incorrect information has been provided or the medical professionals have been dismissive of the side effects and subsequently montelukast has been found to be a cause. We feel more needs to be done to assure that there is awareness of the risks so that informed decisions can be made by patients and their carers together with medical professionals. In addition to remind patients, carers and healthcare professionals of adverse side effects to montelukast, so that should neuropsychiatric symptoms occur a review of medication is undertaken and appropriate action is taken to exclude the LTRA as a cause. We feel that more needs to be done to allow early identification of side effects and that	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				patients and their families need to be supported during their recovery. We remain concerned patients are experiencing long term side effects; in unpublished research we have received a number of testimonies where patients have had long term mental health interventions (including in-patient treatment) without montelukast being considered as a cause. Where montelukast was stopped subsequent improvement was reported. We also remain concerned about the lack of appropriate treatment pathways to support patients during their recovery. Some people report side effects are quick to resolve, some report they experience worsening neuropsychiatric symptoms on stopping before improvements are seen (withdrawal). For some people it takes several years to recover and others report long term issues. Often patients report feeling unsupported with no clear treatment pathway. Patients and their carers report a life changing impact. We recommend that self-management interventions should include information	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				regarding the April 2024 MHRA DSU to support patient safety and reduce the risks for patients.	
Montelukast Side Effects (Singulair) Support and Discussion Group	Guideline	029	001	Other Recommendations for Research: Within the Evidence Review there has been significant analysis of the research available comparing the effectiveness of one asthma treatment with another in terms of benefit to the asthmatic condition. In addition, the relevant costs of treatments are compared, together with assessments relating to the Quality of Life. There is also consideration given to a limited number of adverse reactions (referenced in Evidence Review Q Pg116, Para 1.1.12.1 titled "The outcomes that matter most") in which the specific adverse events considered were; linear growth, pneumonia, adrenal insufficiency, bone mineral density and inflammatory markers. These specific adverse events have a bias towards concerns relating to Inhaled Corticosteroids (ICS) rather than those specific to Leukotriene Receptor Antagonists (LTRAs) such as montelukast. We do not feel the evaluation of evidence has sufficiently	Thank you for your comment The committee understands your concern. However, it would be difficult to analyse the incidence and effect on quality of life of montelukast side effects without doing a prospective trial and, given that the side effects would be the only outcome of interest (efficacy has already been studied), it is very unlikely that a funding body would prioritise such research. As NICE guidance, and this collaborative guideline, can only make a limited number of research recommendations, it is not sensible to include ones which have realistically very little chance of progressing.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				considered specific adverse events related to LTRAs, nor has the economic assessments taken into account the impact of neuropsychiatric side effects. We believe there needs to be greater consideration of the holistic view when making such assessments taking into account both the economic impact of adverse side effects and the impact that adverse side effects have on the quality of life of patients and their families. When comparing one treatment regime with another we feel too great an emphasis is being given to the cost of one treatment versus another without taking the wider costs and impacts into consideration. Many of the economic studies reviewed also pre-date the wider awareness of the adverse side effects related to montelukast. We believe that further research should be recommended to support decision making of ICS over LTRAs including: 1. Confirming the true incidents of adverse side effects to montelukast	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				2. Assessing how such adverse side effects impact on quality of life over and above the Asthma Quality of Life assessments. 3. The economic impact of adverse side effects to LTRAs to support a holistic assessment of economic benefit of one medicine against another.	
Montelukast Side Effects (Singulair) Support and Discussion Group	Guidelines	041	022 to 028	Applied to patients aged 12 and over and decision making over whether to consider an LTRA or Long-acting muscarine antagonists (LAMA), it is noted that the direct comparison was between the treatments in one small study. As a consequence, the committee did not have much confidence in the result because of the small study population. This resulted in the committee using its knowledge and experience to recommend a trial of LTRA over LAMA because it was less costly and has environmental advantages. Our families (patients of all ages) have described life changing impacts following use of LTRAs, in some cases children no longer living with their parents, strain on wider relationships, children who have been excluded from school,	Thank you for your comment The sentence you refer to mentions cost and the environment because these are the 2 areas where there is a marked difference between the 2 options, but this does not mean they were the only issues considered. The decision in comparing the two treatment options took into account what was known about their effects on asthma control, exacerbations, lung function, inflammatory markers and side-effects. There was no significant difference between those. The committee were aware of the potential neuropsychiatric side effects of montelukast, but extreme problems are rare. People receiving montelukast should be warned about this. Links

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				impact on ability to work (both patients and families), self harm, aggression towards others/objects, risk taking behaviours, suicidal ideation and suicide. We would like the committee to consider the risks of side effects of LTRA compared with LAMA. LTRA (montelukast) has been subject to two drug safety updates September 2019 and April 2024, with the MHRA reporting "A range of neuropsychiatric reactions have been reported in association with montelukast. Among these are: sleep disturbances, depression and agitation including aggressive behaviour (may affect up to 1 in 100 people taking montelukast); disturbances of attention or memory (up to 1 in 1,000 people); very rarely, hallucinations and suicidal thinking and behaviour (up to 1 in 10,000 people)." Whereas a LAMA treatment Tiotropium has advice in 2018 (May and July) related to a risk of inhalation of the capsule if placed in the mouthpiece of the inhaler with the need for patients to be trained in the correct use.	to the MHRA DSU have been added to the guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Otherwise adverse side effects for all antimuscarinics (inhaled) are: Common or very common: Arrhythmias; constipation; cough; dizziness; dry mouth; headache; nausea Uncommon:Dysphonia; glaucoma; palpitations; skin reactions; stomatitis; urinary disorders; vision blurred And for tiotropium specifically: Uncommon:Gastrointestinal disorders; increased risk of infection; taste altered Rare or very rare:Bronchospasm; dysphagia; epistaxis; insomnia; oral disorders Frequency not known: Dehydration; joint swelling; skin ulcer Source: https://bnf.nice.org.uk/drugs/tiotropium/ Please can the committee clarify how it considered the potential consequence of adverse reactions in proposing the guideline for LTRA over LAMA? It appears the reference only focuses on cost and environmental factors. We feel the potential for serious adverse drug reactions (ADRs) should also be considered.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Our concern is that as written the healthcare professional is led to offer LTRA (Para 1.7.5 Page 13) without discussing with the patient (or their caregiver) the potential of LAMA as an alternative treatment option (Para 1.7.6). **Our request is that the patient should be involved with this decision making having been given the full disclosure of the risks associated and consideration is given to offering and discussing the two treatment options detailed in Para 1.7.5 and 1.7.6, including the potential for adverse side effects, ease of taking the medication, cost and environmental factors.** This would be consistent with the opening statement on page 4 of the Guidelines about people having the right to be involved in discussions and make informed decisions about their care.	
Montelukast Side Effects (Singulair) Support and Discussion Group	Guidelines	044	020 to 030	The committee have noted the possible neuropsychiatric problems in the section related to children aged 5-11 providing a link to the MHRA's September 2019 DSU.	Thank you for your comment No extra information was requested from MHRA for any medicine. This is not part of NICE's

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				What further information was requested from the MHRA in developing the current guidelines (for all age groups) given the MHRA's own review of montelukast resulting in a new and strengthened DSU in April 2024? Has the April 2024 DSU been considered, and if not, will this be further considered now?	methodology and therefore was not necessary for this collaborative guideline. The link to the MHRA DSU has been updated and a link to the update has now been included within the recommendations. The committee were aware of this DSU during their deliberations.
Montelukast Side Effects (Singulair) Support and Discussion Group	Guidelines	044	026 to 030	We are concerned that greater emphasis is being given to lower cost treatments rather than fully exploring the relevant impact on patients and their families of the different adverse side effects with different asthma treatment regimes. Our families (patients of all ages) have described life changing impacts, in some cases children no longer living with their parents, strain on wider relationships, children who have been excluded from school, impact on ability to work (both patients and families), self harm, aggression towards others/objects, risk taking behaviours, suicidal ideation and suicide. It is noted that the Maintenance and Reliever Therapy (MART) regimen is the recommended	Thank you for your comment Cost is just one aspect considered when making decisions, not the overriding one. Adverse side effects are taken into account. These are important of course, but the MHRA DSU that you have referred to indicates that 1,223 side effect notifications have been received from 44 million prescriptions for montelukast. There should be discussions on the potential benefits and side effects of medicines with the patient and/or their carer whenever a new treatment is proposed. This does not just apply to LABAs or montelukast and is a basic

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				treatment (1.8.2 Pg15), however should a child not be able to manage the MART regimen, (1.8.4 Pg 16) Non-MART pathway suggests considering an LTRA plus Short-acting beta2-agonists (SABA) before (1.8.5 Pg 16) low-dose ICS/Long-acting beta-adrenoceptor agonists (LABA) combination inhaler plus SABA then (1.8.6 Pg 16) moderate dose ICS/LABA plus SABA. The later options with or without LTRA. For ICS the risk is in taking a high dose for a long time, there may be some of the side effects of a steroid tablet, such as increased appetite, mood changes and difficulty sleeping and for children and teenagers it can slow normal growth, hence growth is monitored. https://cks.nice.org.uk/topics/corticosteroids-inhaled/ For LABA the risks can include feeling shaky, headache, palpitations or muscle cramps. https://cks.nice.org.uk/topics/asthma/prescribing-information/beta-2-agonists/ Fine tremor often wears off. Side effects like thrush or a sore mouth can be avoided by rinsing mouth after using the inhaler. With rare or very rare side	principle of medical practice which should not need repeating in every recommendation. As you point out, the need for shared decision making is pointed out at the beginning of the guideline, and this principle is supposed to apply to every decision point covered by the guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				effects for some constituents of LABA adrenal suppression. Our concern is that as written, the healthcare professional is led to offer LTRA without discussing the recommended treatment in 1.8.5 or 1.8.6 an alternative treatment option. **Our request is that the carer should be involved with this decision making having been given the full disclosure of the risks associated with the treatment options. We feel that consideration should be given to discuss both 1.8.4 and 1.8.5 (without LTRA) with the carer as a next step, so they are involved in the decision making. They should be advised of the potential for adverse side effects, ease of taking the medication and cost. If choosing 1.8.5 without LTRA then should the treatment be unsuccessful stepping back and adding an LTRA or stepping up to 1.8.6 without an LTRA could potentially be offered.** **We feel this would be consistent with the opening statement on page 4 of the**	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Guidelines about people having the right to be involved in discussions and make informed decisions about their care. We feel this is additionally important noting in Evidence Review Q, Page 126 Line 14-17, the consensus view [was] that side effects [to montelukast] are common in practice. This is consistent with other research for example: Erdem et al, Allergol Immunopathol (Madr) 2023 which considered subjects aged 4-18 years with asthma or asthma and allergic rhinitis using montelukast or ICS as a monotherapy. https://pubmed.ncbi.nlm.nih.gov/36916083/ A total of 468 cases (365 montelukast, 112 ICS). In this study it was observed there was a higher drug discontinuation rate due to ADR in montelukast compared with ICS (1.333 times higher). In the first 3 months of treatment, the rate of drug discontinuation due to ADR was 5.9% in the montelukast group. Almost all of the ADRs in the montelukast group were neuropsychiatric in nature.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
National Child Mortality Database (NCMD) Programme	Guideline	004	003	Rec 1.1.1 – we would like to suggest that an additional bullet point is added for children for information on the family's background to include home living conditions (e.g. overcrowding, property in poor repair and excessive mould, temporary accommodation, whether the family could afford to heat their house) and whether the family is known to social services so these issues related to vulnerability are identified at the initial history taking so help is provided to the families to minimise the risks these may pose on asthma control.	Thank you for your comment This section is about establishing a diagnosis of asthma. The factors you allude to are part of recommendation 1.6.1.
National Child Mortality Database (NCMD) Programme	Guideline	007	002	We suggest 2 more sentences are added after "Diagnosis is hard in this age group because it is difficult to do the tests and there are no good reference standards "stating *"Children with symptoms are recorded as suspected asthma until satisfactory results are obtained." and "Any preschool child with two or more admissions to hospital or ED with wheeze in 12 months should be referred to a specialist respiratory paediatrician to confirm a diagnosis."*	Thank you for your comment The first sentence you suggest is covered by 1.1.2 (for all ages). The second sentence has been added (with a minor alteration).
National Child Mortality Database	Guideline	008	012	Rec 1.5.1 – admissions to ED / hospital should be an automatic consideration for those monitoring how well asthma symptoms are	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
(NCMD) Programme				controlled. We suggest that an additional bullet point is added *Admissions to ED / hospital.*	The committee agrees and a bullet point has been added.
National Child Mortality Database (NCMD) Programme	Guideline	010	015	Rec 1.6.4 – the safety of the device linked to the presence of dose counters on the device should be included as a consideration for the patient's choice. We noted that there is guidance on this provided here by BNF - Respiratory system, inhaled drug delivery | Treatment summaries | BNF | NICE – which outlines advice to be given to patients covering information on the number of medication doses in their inhaler device. The information is clear from this that there is no accurate way of knowing the remaining number of therapeutic doses "other than by either recording every actuation used, or by calculating when the inhaler is likely to become "empty". "Shaking, weighing or floating the inhaler device, or using it until it no longer actuates are not accurate and not recommended."	Thank you for your comment. A bullet point has been added to 1.6.4 recommending devices with a dose counter.
National Child Mortality Database (NCMD) Programme	Guideline	010	020	We would like to see the risks associated with using inhalers without dose counters highlighted in this document - NG80 Patient decision aid on asthma inhalers and climate change (nice.org.uk) so people can make an informed decision based on this information as well.	Thank you for your comment. A bullet point has been added

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
National Child Mortality Database (NCMD) Programme	Guideline	011	001	Rec 1.6.5 – the information given to the patients and their family / carers should include information on the dangers of using inhalers which have no dose counters on them.	Thank you for your comment. A bullet point has been added
National Child Mortality Database (NCMD) Programme	Guideline	017	013	Rec 1.9.2 – 2nd bullet point should also include indoor and outdoor air pollution. For example: 'Check whether there is an environmental source of their symptoms (for example, *indoor and outdoor air pollution*, mould in the home, cold housing, smokers or pets).	Thank you for your comment "indoor air pollution has been added".
National Child Mortality Database (NCMD) Programme	Guideline	019	015	Rec 1.11 – We therefore would like to suggest a guidance to be included on the management of children who are not brought for routine asthma reviews. We recommend that it should be ensured that 'Was not Brought' policies are followed when asthma review appointments are not booked for children or they are not brought by caregivers to their appointments. Repeated requests for reliever medication should trigger review appointments.	Thank you for your comment. "Was not brought" policies already exist and should be followed. They are not asthma-specific, and, like many excellent generic policies, it is not really appropriate to place them all in a guideline on asthma.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
National Child Mortality Database (NCMD) Programme	Guideline	020	024	Rec 1.13.2 – adolescents should also be asked if they smoke other substances, not only tobacco, and the risks highlighted.	Thank you for your comment The committee discussed this following your comment. On balance it was felt that this needs careful handling and should not be done unless it is by someone who has already established a rapport with the adolescent with asthma. "Other substances" has therefore not been added to the recommendation.
National Child Mortality Database (NCMD) Programme	Guideline	023	002	Rec 1.15.1 – we suggest that an additional bullet point is added *'Previous admissions to critical care'.*	Thank you for your comment "Any hospital admission" has been added which will encompass a critical care admission.
Neonatal & Paediatric pharmacists Group	Guideline	001	Table	Who is it for? There is no mention of primary care **pharmacists**, 2 or 3 care pharmacists will be covered in healthcare professionals but not primary care pharmacists as community or clinical pharmacists in GP surgeries who are doing structured medication reviews for asthma. Please consider adding in **pharmacists and other healthcare professionals in primary care**. This will also allow inclusion of physicians associates & other health care professionals	Thank you for your comment. This has been changed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				who undertake asthma reviews. They were all included in the NICE guideline in 2021 so unsure why no longer included in this document.	
Neonatal & Paediatric pharmacists Group	Guideline	004	012	Include vital signs – oxygen saturations, RR, BP	Thank you for your comment This would be applicable if the presentation was with acute or severe symptoms (and acute asthma is outside the scope) but not in the majority of cases.
Neonatal & Paediatric pharmacists Group	Guideline	005	019	1.2 – the diagnostic tests imply that this is a one off test, could mention be made of **ongoing monitoring** please	Thank you for your comment. Monitoring is covered in section 1.5
Neonatal & Paediatric pharmacists Group	Guideline	006	006	1.2.4 -FENO >35ppb in children as a **stand alone test** cannot be used as a diagnosis of asthma as it is suggestive of rhinitis, post nasal drip and without a confirmed history cannot be exclusively used to diagnose asthma as suggested in the summary of objective tests for diagnosing asthma 5-16 years. This just needs rephrasing with – 'FENO >35ppb long with a **good clinical history in the Flowsheet.**	Thank you for your comment The first sentence of 1.2.4 specifies that there should be a history suggesting asthma. Thank you for the comment regarding point of care eosinophil testing. This may be of value in the next update of this guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Additionally, it is easier to do an eosinophil count than a FENO in children especially with point of care eosinophil tests will be available soon and a re currently being tested in children.	
Neonatal & Paediatric pharmacists Group	Guideline	006	009	1.2.5 These tests can be done in **diagnostic hubs** – please could reference be made to this on this point about use of diagnostic hubs for testing	Thank you for your comment Reference to diagnostic hubs has been removed because this guideline has been jointly produced by BTS/NICE/SIGN, to cover the whole of the UK, and diagnostic hubs are not applicable to all 4 nations.
Neonatal & Paediatric pharmacists Group	Guideline	006	011	1.2.6 – skin prick testing only mentions house dust mite, what about **other allergens** like cats, dogs,….	Thank you for your comment The purpose of this recommendation is not to identify triggers, but to help make a diagnosis. In this respect it is house dust mite sensitivity which is most likely to be useful.
Neonatal & Paediatric pharmacists Group	Guideline	008	018	1.5.1 active or passive exposure to smoking – Please could **vaping** be added.	Thank you for your comment. On reconsidering this, the reference to smoking has been removed from 1.5.1. The recommendation is about indices of control, and

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					smoking was therefore out of place there (and it is covered in other recommendations).
Neonatal & Paediatric pharmacists Group	Guideline	008	019	Validated symptom questionnaire – please add **Childhood asthma control test for children (c-ACT)**	Thank you for your comment Children's questionnaire has been added to the examples.
Neonatal & Paediatric pharmacists Group	Guideline	008	022	1.5.3 – would be useful to add that peak flow plans for children are useful for escalating treatment in children with **poor symptom perception** or for children with poor symptom perception	Thank you for your comment The committee sympathises with this point. This could be one of the person-specific reasons for monitoring PEF. There was a discussion in committee on adding examples which included this, but it was felt that this would then lead to detailed questions about how to identify poor symptom perception which go beyond the simple question the committee was asked to address i.e. should all people monitor PEF.
Neonatal & Paediatric pharmacists Group	Guideline	010	017	In children it is essential to ensure an appropriate device for the individual is prescribed – one that the child can and will use. There are limited options available and concerns over environmental impact should be secondary to this. Suggest swapping order of lines 17 and	Thank you for your comment. The order of bullets is not supposed to reflect importance. However, as several stakeholders have requested this, it has been altered.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				18. It is important to also stress that although pMDI and spacer are not the most environmental option, for children 5-11 this may be the most appropriate choice.	
Neonatal & Paediatric pharmacists Group	Guideline	011	004	1.6.5 Information on their inhaler treatment should also address managing **side effects**, please consider adding this.	Thank you for your comment. This recommendation is about device-related factors rather than the medicine.
Neonatal & Paediatric pharmacists Group	Guideline	011	004	1.6.5 – Provide information on recognising when the inhaler needs to be changed e.g dose counters, counting number of doses	Thank you for your comment. A bullet point has been added to 1.6.5 advocating that devices with dose-counters should be prescribed.
Neonatal & Paediatric pharmacists Group	Guideline	011	018	1.6.8 Encourage people to take to pharmacies for disposal or **Recycling** – please consider adding this	Thank you for your comment. The wording has been changed
Neonatal & Paediatric pharmacists Group	Guideline	012	004	1.7.1 – The licensed AIR regimens would mostly be categorised as moderate or high doses, which inhaler would you recommend as low dose. Is there a categorisation of the **potency of drugs included** in the guidelines? The original BTS/SIGN differ from the previous NICE guidance and GINA so a clarification here would be useful	Thank you for your comment A link is provided within the guideline to the "Inhaled corticosteroid doses for the BTS, NICE and SIGN asthma guideline" table which categorises the available ICS containing inhalers. However, the categorisation in the

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					table is based on the maintenance dose of ICS. The currently licensed inhalers for AIR contain 200mcg budesonide or less, and if this is used less than once a day it is low-dose. If a person is using it once a day or more they aren't suitable for AIR and should be on MART.
Neonatal & Paediatric pharmacists Group	Guideline	013	008	1.7.5 – LRTA – Consider adding discussion of **side effects** in view of MHRA? Add link to MHRA neuropsychiatric disorders & suicidal ideation.	Thank you for your comment A link has been added to the MHRA DSU.
Neonatal & Paediatric pharmacists Group	Guideline	013	008	1.7.6 – This recommendation allows prescribing of LAMA before any of spirometry is conducted in children over 12yrs in primary care. It would be more appropriate to refer children 12-16 years to specialist care at this stage before starting a LAMA	Thank you for your comment If the guideline is followed correctly, by the time the person reaches this stage their diagnosis should have been reviewed several times, adherence checked etc (see recommendation 1.6.1). In addition, although the guideline says that referral should be made at this point there is nothing to stop an earlier referral if it is agreed that this might be beneficial
Neonatal & Paediatric pharmacists Group	Guideline	013	013	In practice a LAMA is used before a LTRA – could this be changed especially in view the MHRA alert. Additionally, by this stage, would it be appropriate to refer here?	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					Using a LAMA before an LTRA is not everyone's practice. Although the guideline says that referral should be made at this point there is nothing to stop an earlier referral if it is agreed that this might be beneficial
Neonatal & Paediatric pharmacists Group	Guideline	015	001	1.7.12 – What dose would you consider as high dose in children >12 years, there is no link to direct anyone to a **potency table/cha** 1.7.13 **rt?** NICE definitions of low/ moderate / high, were not in-line with BTS/SIGN recommendations of v.low/low/med(no high dose) for 5-11s where NICE consider >400 BDPE/day high but BTS consider it moderate. Both of these guidelines were also not in agreement with the definitions presented by GINA Clarification of this would be really useful especially for those 12-17 year olds and <5 years	Thank you for your comment A link to the NICE table "Inhaled corticosteroid doses for the BTS, NICE and SIGN asthma guideline" has been added to the guideline

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Neonatal & Paediatric pharmacists Group	Guideline	015	012	Clarity needed as to how to assess ability to manage a MART regimen. This does not come down just to ability to use DPI as pMDI spacer budesonide/formoterol is available (licensed ≥12) and may be appropriate to enable a MART regimen in children unable to use DPI / who dislike it.	Thank you for your comment There is no formal scoring tool to assess ability to manage MART so this will rely on the treatment being instituted by suitably trained healthcare professionals (as it should be). MDI+spacer does not lend itself as well to MART as does a DPI because it is not as easy to carry the spacer around. The study on MART in children used a DPI.
Neonatal & Paediatric pharmacists Group	Guideline	016	008	1.8.4 and 1.8.5 should be changed over as we would add a LABA before a LTRA.	Thank you for your comment In children the evidence for superior efficacy of LABA over LTRA is debatable. BTS/SIGN guidance said either was acceptable as first choice. NICE, which also considered cost-effectiveness, said try LTRA first. There has not been an updated evidence review on this particular step.
Neonatal & Paediatric pharmacists Group	Guideline	017	016	1.9.2 – consider adding triggers such as home, cold housing etc… Also add, check inhaler technique, **correct spacer** and adherence	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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					The list in brackets offers examples; it is not meant to be exhaustive
Neonatal & Paediatric pharmacists Group	Guideline	017	017	1.9.3 -add review symptoms after a further 3 months or sooner if acute episodes or symptomatic	Thank you for your comment This is covered in 1.9.4
Neonatal & Paediatric pharmacists Group	Guideline	022	006	Quadrupling the ICS dose in adolescents– please may I ask what is the evidence behind this as using ICS alone will reach a plateau effect.	Thank you for your comment This is a legacy recommendation, and the detailed evidence is given in the Evidence review for the 2017 guideline. The key paper within that is McKeever et al, N Engl J Med 2018, 378:902-910. Please note that the recommendation specifies people aged 17 and over.
Neonatal & Paediatric pharmacists Group	Guideline	022	022	1.14.7 –a link to **asthma friendly schools** which is currently being revised by NHSE – London could be added	Thank you for your comment. This is a legacy recommendation with no associated evidence review and the wording has not been changed.
Neonatal & Paediatric pharmacists Group	Guideline	023	008	1.16.1 We would recommend that annual asthma reviews are **conducted face to face** –	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				so that inhaler technique can be properly accessed. Please consider adding this. Additionally in terms of training – a link to the national asthma capabilities framework Tier training would be useful	The term "face to face" is open to interpretation. There is a risk that some users may feel the terms contradicts the following recommendation on telehealthcare. NICE recommendations do not incorporate training issues and therefore the same is true for this BTS/NICE/SIGN guidance.
Neonatal & Paediatric pharmacists Group	Supporting/ summary documentation on objective tests	5- 16 years	Flowsheet	Flowsheet – summary of objective tests for diagnosing asthma –we are concerned that a **FENO used alone without a context of a clinical history** cannot be used to make a diagnosis of asthma. Could a text box be added to re-iterate this. I am aware it I in the body of the guidelines, however, if the flowsheet is used alone and interpreted then the diagnosis would not be accurate. Additionally, **spirometry** would be a better indicator to confirm diagnosis of asthma than FENO and easier to perform than FENO in children. Skin prick testing – this is not easily accessible in primary care, should the referral be made before a skin prick test is done in children?	Thank you for your comment Agreed. The importance of the history has been included. The reasons FeNO is preferred as the first test in children is set out in the rationale within the guideline. The committee do not agree that children find FeNO harder to do than spirometry. They do agree that skin prick testing is not readily available in primary care, but this is not the only option for testing at this step.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Neonatal & Paediatric pharmacists Group	Supporting/ summary documentation pharmacological management	≥ 12 years	Flowsheet	Flowsheet – the information n the right hand side of the flowsheet is slightly confusing, it would probably be easier to link back to the main guideline regarding this.	Thank you for these thoughts. The committee agree that there might be reasons for switching other than poor control; adherence as you mention, or by patient request e.g. if they know someone who uses MART and feel it would suit them. The Figure is already a bit busy and it was thought best not to include a comprehensive list. The colour coding has also been reconsidered,,,
Neonatal & Paediatric pharmacists Group	Supporting/ summary documentation pharmacological management	5-11 years	Flowsheet	Flowsheet - Unable to manage MART, an MDI via spacer could be tried? Clarity needed as to how to assess ability to manage a MART regimen. This does not come down just to ability to use DPI as pMDI spacer budesonide/formoterol is available (licensed ≥12) and may be appropriate to enable a MART regimen in children unable to use DPI / who dislike it. Additionally, if they cannot manage MART at this step, we would usually recommend a **LABA before LRTA** especially in view of the recent MHRA warning. We would recommend offer twice daily low dose ICS/LABA to be moved u before LRTA.	Thank you for your comment Assessing the ability to manage MART has always been part of the decision to start this, but no standard method of defining this has been developed. It has been based on judgement in each individual case and might relate to many factors e.g. technique with inhalers licensed for MART, evidence of understanding the principle of MART during initial education etc. There is no clear superiority of LABA over LTRA in children.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Neonatal & Paediatric pharmacists Group	Supporting/ summary documentation pharmacological management	Under 5 years	Flowsheet	Flowsheet: Consider stopping and reviewing after 3 months – would it be better to review sooner in case? Or maybe add in **'or sooner if symptomatic'**? What is a **moderate dose for an under 5 year** only – is there a link to a potency table? Flowsheet - With SABA – does this mean at the same time as ICS?	Thank you for your comment This has been changed to 8-12 weeks to be consistent with recommendation 1.6.3. The guideline now refers readers to the document Inhaled corticosteroid doses for NICE's asthma guideline. It means with SABA as reliever when required. Clarified in Figure
NHS England	Guidance	000	000	The guidance and its recommendations are welcomed. We can see that the proposal to give FeNO and eosinophil equivalence in the diagnostic pathway, and the evidence that underpins it, has been carefully considered.	Thank you for your comment.
NHS England		007	005	Suggest add in: with an initial trial of treatment if indicated and review of response'	Thank-you for your comment The guideline avoids the term "trial of treatment" as this is the basis of a lot of false positive diagnoses. The need to reconsider the

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					diagnosis if initial treatment is not working well is part of recommendation 1.6.1
NHS England		008	019	What about CYP? Worth including what ages ACQ and ACT for and when to use cACT	Thank you for your comment The cACT has been added as an example of a children's questionnaire.
NHS England	Equality Impact Assessment Guidance	001	3.1 1.6	Some DPIs contain lactose (Lactose monohydrate). As lactose intolerance and/or allergy (Lactase nonpersistence) is more common in people of non-European descent, pharmacological management should consider this in recommendations, and understand whether the concentrations of Lactose monohydrate within inhalers are large enough to cause issue in patients with lactase nonpersistence) as this could negatively impact adherence to medication in certain population groups. • Lactose intolerance: MedlinePlus Genetics • Prescribing in lactose intolerance and how to identify lactose free medicines – SPS - Specialist Pharmacy Service –	Thank-you for your comment. As the SPS document you reference points out, the amount of lactose in tablets or capsules is small, usually less than 2gm, and not enough to cause symptoms in anyone other than those with severe lactose intolerance. The amount per dose from an inhaler varies between devices but is far less than this by a factor of at least a hundred, and most of the dose will not be ingested. The long experience of using DPIs containing lactose has not identified this as a problem.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The first stop for professional medicines advice Relatedly, suggest that reference to patient allergies should be made within this section (1.6), to support shared decision-making regarding inhaler choice. More information available on the SPS website: Prescribing in lactose intolerance and how to identify lactose free medicines – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice	
NHS England	Evidence Review	000	000	Following a review of the economic report and of Evidence Review P, there remains outstanding questions relating to the impact on the NHS, particularly prescribing costs compared to current practice. Therefore, to support planning by systems and NHSE, it would be beneficial for NICE to share a resource impact report that assesses additional cost of complying with the guidance compared to current practice for patients aged 12+, focusing on the use of: (i) ICS/LABA as needed for newly diagnosed patients	Thank you for your comment. A resource impact document will be produced, this is done following stakeholder consultation. No significant change in practice to the use of ICS/LABA was highlighted by experts. MART is included in the draft RI tools and additional costs can be assessed locally. Costs can be modelled over a five-year timeframe and the there is a split between settings. Financial impact (cash) and capacity impacts can also be assessed separately along with potential resources released.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				(ii) Escalation to MART for uncontrolled asthma HE It would be beneficial for this impact report to differentiate between drug costs, impact on GP practices workload/time, and savings elsewhere in the health and care system. Additionally, a profile over time would be welcomed; as the costs and savings may occur at differing times.	
NHS England	Guidance	009	1.6 - Principles of pharmacological treatment	There is disparity in patient belief about asthma control and clinically uncontrolled asthma. It would be helpful to define and further expand on this within 1.6.	Thank you for your comment. There are descriptions of good control and poor control in the Terms Used section. NICE guidelines do not usually enter into explanations within a recommendation itself, and this is the same for this collaborative guideline
NHS England	Guidance	009	1.6 - Principles of pharmacological	It would be helpful within the guideline if the mutually beneficial relationship between bettering patient care (via inhaler choice and adherence) and reducing environmental impact is made more explicit. Currently, the guidelines note that environmental impact is one consideration (out of three) for inhaler choice,	Thank you for your comment. These BTS/NICE/SIGN recommendations only focus on what should be done. Explanations are offered elsewhere, either in the rationale

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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			treatment	but – as noted within the patient decision aid on asthma and climate change- better controlled asthma is also better for the environment. A summary sentence within 1.6 would be welcomed.	sections or, as in this case, by linking to a related document.
NHS England	Guidance	009	1.6 - Principles of pharmacological treatment	Included within the list of possible reasons for uncontrolled asthma, "environmental factors (for example, air pollution, indoor mould exposure)" is listed. Considering there is a section later in the guidance (1.14.1) which includes helpful resources about air pollution and asthma, it would be helpful for 1.6.1 to hyperlink to these resources/section later in the document.	Thank you for your comment. 1.6.1 is a list of factors which should be considered when control is poor, and there is no attempt to explain what actions might be taken for these. Any actions come later, in the case of pollution avoidance in the section on self-management. The hyperlink is more appropriate there.
NHS England	Guidance Evidence Review	009	1.6 (guidance) 1.7.1 (guidance)	In Evidence Review P, the studies included regarding ICS + formoterol were all listed to be 200 mcg budesonide/6 mcg formoterol. It would be useful to outline within the evidence review whether the studies used dry powder "200 mcg budesonide/6 mcg formoterol" inhalers, or metered dose inhalers. Noted that in the evidence review it is stated that 96% of budesonide/formoterol 200/6 is prescribed as	Thank you for your comment. A sentence has been added to 1.7.1 indicating that subjects used a DPI in the supporting trials. Recommendation 1.6.4 (1.6.5 in the revised guideline) lists factors which should be taken into account when deciding which inhaler device

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
			1.1.5 Summary of studies included in the effectiveness evidence (Evidence review P)	DPI, and therefore think it pertinent to include in the evidence review whether the studies were using DPI or MDI for which the guidelines are based. If the studies included within Evidence review P (which formed the basis of the pharmacological management section of the guidance) used dry powder ICS + formoterol, suggest that 1.7.1 makes it clear that the evidence is based on the use of DPI inhalers, and to reiterate that MDI should only be used where a patient is unable to use a DPI, and this will be (currently) off-label. More generally, we would welcome a stronger position within the guidance (within 1.6) regarding the use of DPI inhalers (where clinically appropriate) and their beneficial environmental impact, and to be aligned on this topic, as much as is possible, with guidelines from across the Devolved Administrations. For example, the All Wales Adult Asthma Management and Prescribing Guideline (AWTTC asthma management and prescribing guidelines) outlines: *"The default option should*	to prescribe. It includes environmental impact. However, the predominant consideration is which device the person with asthma can use most effectively. The committee does not believe that this recommendation should be changed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				be to prescribe a DPI, unless a patient has a better technique, or prefers, an MDI."	
NHS England	Guidance	010	1.6.2	The guidance currently states that "Do not prescribe short-acting beta2 agonists to people of any age with asthma without a concomitant prescription of an inhaled corticosteroid". Considering the pharmaceutical management steps outlined in the document in 1.7, it may be useful to re-frame this sentence in 1.6.2, as the word "concomitant" can be defined as "to naturally follow", so it puts wrong emphasis on the sequence of prescribing if used to describe ICS in relation to SABA. This sentence therefore could be updated to: "An Inhaled corticosteroid (ICS) must always be prescribed when a short-acting beta agonist is prescribed."	Thank you for your comment. The Oxford English Dictionary does not subscribe to this definition of concomitant. It says "going together, accompanying, concurrent.". The wording therefore seems appropriate.
NHS England	Guidance	010	1.6.2	The guidance outlines that where a SABA is prescribed, an ICS should also be prescribed (i.e., the avoidance of SABA-only treatment). Could it please be clarified whether, in situations whereby a patient has previously been	Thank you for your comment. Changing treatment for people who are on the treatment recommended in previous guidelines

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				prescribed SABA only as "as-required" reliver therapy (as per current guidance) and therefore, in line with this updated guidance, an ICS is also prescribed, is the intent that this newly prescribed "concomitant" ICS should be used "whenever SABA is used" or as a daily ICS? (i.e., the distinction made in GINA 2024 guidelines- pp75).	is covered in recommendations 1.7.7 to 1.7.10. The action to be taken where a person is currently on SABA only is covered in Recommendation 1.7.7.
NHS England	Guidance	010	1.6.4 – Choice if inhaler	It is positive that the environmental impact of inhalers is included in key principle of choice of inhaler. However, to make the clearer regarding how it should be applied by clinicians and avoid the principle being misapplied, we recommend including examples of what "environmental impact" is being referenced within the bullet point. This example could build upon the text included in the previous BTS/SIGN guideline, i.e., the lowest environmental impact among suitable devices ***such as dry powder inhalers, soft mist inhalers, or lower volume HFA134a inhalers.*** Furthermore, we recommend the	Thank you for your comment. NICE recommendations avoid including explanatory text unless absolutely essential. And therefore this collaborative guideline is the same. They confine themselves to the recommended action.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				patient decision aid hyperlink, which is included later in the section, being included within the bullet point itself.	
NHS England	Guidance	011	1.6.4-1.6.6 Evidence review	Within the guidance (p 67 and 72) it is noted that reference to using a spacer with high dose corticosteroid/ β2 agonists (in children) has been removed, with the rationale provided being that this is a statement of effectiveness rather than a recommendation, and that choice of inhaler. remains important for all ages and is covered in recommendations 1.6.4 to 1.6.8. Also, within Evidence review P (p 40) the document outlines that some people with asthma would still need to have an MDI SABA available to use via a spacer in the event of a severe asthma attack. These are almost all children, some of whom find it difficult to use a DPI during an attack. As such, it may be helpful to reiterate that some patients may benefit from the use of a spacer. This could be within the following in 1.6.5:	Thank you for your comment. Recommendations 1.6.5 and 1.6.8 have been expanded to cover these points

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Give people with asthma information on their inhaler treatments. This should include the medicines they contain, how they work and ***whether the use of a spacer would be beneficial****, when they should be taken, the correct technique to use for each device,* ***environmental impact, and correct inhaler disposal.***	
NHS England	Guidance	011	1.6.5	Patients should also be aware of their inhalers environmental impact, and correct disposal. As such suggest changing "*Give people with asthma information on their inhaler treatments. This should include the medicines they contain, how they work, when they should be taken and the correct technique to use for each device"* to: *"Give people with asthma information on their inhaler treatments. This should include the medicines they contain, how they work, when they should be taken, the correct technique to use for each device,* ***environmental impact, and correct inhaler disposal****".*	Thank you for your comment. Correct disposal is covered in recommendation 1.6.8. The committee believe that, while knowing the environmental impact of an inhaler might be important, it is less essential to the patient than the other items of information currently listed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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NHS England	Guidance	011	1.6.6	We welcome the increased focus and opportunity of inhaler technique checks.	Thank you for your comment
NHS England	Guidance	011	1.6.6	Considering that patients may use multiple inhaler types, would "observe the person using their inhaler device**(s)** (and spacer if used) …" be more applicable?	Thank you for your comment. The point is acknowledged but changing to "devices" may cause confusion given that the next recommendation advises sticking to one device if at all possible. The committee thinks that most HCPs will understand that, where people do have more than one device type, all should be checked.
NHS England	Guidance	011	1.6.6	The guidelines list several events which should trigger an inhaler technique check, including "when an inhaler device is changed". Suggest that changing device type should be spelled out more in this example, especially considering the guidelines for transferring patients from other treatment pathways (1.7.8) recommending the move from SABA to use of ICS+ formoterol. As such, this text could be updated as follows:	Thank you for your comment. The committee do not think the examples add to the recommendation which is easily understandable without them.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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				"*When the inhaler device is changed (for example, when a person moves to a generic device* ***or changes device type (e.g., from an MDI to DPI)"***	
NHS England	Guidance	011	1.6.8	We welcome 1.6.8 highlighting that patients should bring their used inhalers back to pharmacy for disposal. However, we suggest further information on this may be useful to include (such as rationale) to support this information being shared and encourage the appropriate actions from patients, such as: "Encourage people **to not dispose of their inhalers in household waste and to instead** take their used inhalers to their pharmacy for disposal, **so that they may be disposed of in the more environmentally friendly way**".	Thank you for your comment. NICE recommendations avoid including explanatory text unless absolutely essential, and therefore this collaborative guideline is the same. They confine themselves to the recommended action.
NHS England	Guidance	012	1.7	It may be helpful to reiterate at the beginning of this section the principle outlined in 1.6.4 that review of response to inhaler medication change should be reviewed after 8-12 weeks.	Thank you for your comment. The point of having the "principles" section is that those actions do not need to be repeated in the sections for adults and the 2 childhood age groups.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS England	Guidance	019	1.10.2	The guidance currently states that "If considering step down treatment for people who are using low dose inhaled corticosteroid alone or low dose MART (maintenance and 6 reliever therapy), step down to low dose ICS/formoterol combination inhaler as needed.". Could what is meant by "ICS alone" be explained further? As it currently reads, it is not clear whether this "alone" is patients only prescribed ICS (no other inhalers), or whether this includes patients prescribed ICS+SABA.	Thank you for your comment. All people with asthma on a preventer inhaler also have a reliever. However, additional wording has been added for complete clarity.
NHS England	Guidance	020	1.12.3 - 1.12.5	Considering 1.12.5 outlines that patients should continue to use their leukotriene receptor antagonists or long-acting muscarinic receptor antagonists if they are needed to achieve asthma control, suggest that it may be clearer to include these in the bullet point list of 1.12.3.	Thank you for your comment. These are legacy recommendations. The committee believes that the intent of the BTS/SIGN committee was that the medicines listed in 1.12.3 could be used as normal including starting treatment with them if necessary, whereas those in 1.12.5 would not usually be started in pregnancy.
NHS England	Guidance	020	1.13.2	The guideline currently outlines that adolescents who currently smoke or vape should be	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				signposted to smoking cessation services. However, it is unclear whether smoking cessation services provide advice/support on vaping cessation, and therefore this- as written- could cause confusion regarding available services and next steps. Suggest it may be clearer to outline: Ask adolescents with asthma if they smoke or vape **and** encourage them to stop. **If they smoke,** give them advice, and signpost them to local NHS stop smoking services.	You are correct and the recommendation has been amended.
NHS England	Guidance	037	Principles of pharmacological treatment- Why the committee made	"The evidence review showed that clinical outcomes were poorest in all age groups with asthma when using SABA alone, although it was the cheapest option". Suggest it would be useful to clarify that the "cheapest option" is in reference to inhaler device alone- and does not consider the whole pathway cost (i.e., the costs impact of exacerbations, hospital stays etc) of uncontrolled asthma.	Thank you for your comment. Your point is acknowledged, and the sentence has been amended.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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			the recommendation		
NHS England	Guideline	000	000	We recommend including a section on 'when to refer to a specialist in asthma care' to ensure referrals are made appropriately and in a timely way. • Diagnostic uncertainty • ≥2 exacerbations treated with OCS despite moderate dose ICS/LABA +/- LTRA +/- LAMA Poor lung function	Thank you for your comment. The committee was not asked to consider indications for referral. A link has been added to the AAC pathway document.
NHS England	Guideline	004	004	Whilst the guideline advises a structured clinical history asking about symptoms (Page 4) it is not clear what a history suggestive of asthma is for children aged 5-16 years on which a FeNO level of more than 35 ppb is diagnostic. We would suggest clearer information about when to suspect asthma when there are respiratory symptoms such as: Suspect asthma if >1 of the following symptoms are occurring ≥ 3 times a week, or if severe, or causing waking at night: - Wheeze (especially if heard by a healthcare professional) - Breathlessness - Chest tightness – Cough	Thank you for your comment Waking at night has been added to the recommendation. The other symptoms are already there. There was no evidence review of symptoms for this update and the committee is not sure that adding the specific numbers that you include is justifiable.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS England	Guideline	005	009	It is not clear if all tests apply to all age groups. We would suggest this is clarified in the text	Thank you for your comment. The "recommendations" section at the start of the guideline points out that sections apply to all age groups unless stated in the section heading.
NHS England	Guideline	006	007	What is meant by BDR needs clarification Does this mean 'with spirometry', as is explained in the section above relating to adults, or does it mean peakflow with BDR, as is suggested on page 5, lines 9 -10 (where it is referring to objective testing in the context of acute symptoms). Whilst FeNO and BDR with spirometry are preferred first line tests there is limited evidence to support PEFR monitoring as an additional asthma-diagnostic tool (See - European Respiratory Society clinical practice guidelines for the diagnosis of asthma in children aged 5-16 years). This may provide a reasonable alternative to spirometry in primary care settings where pathways to provide spirometry are not yet well established. Without this, there is a risk that, until objective testing pathways for asthma are better established,	Thank you for your comment The words "with spirometry" have been added. PEF variability has been added to the diagnosis section.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				children are not given a diagnosis of asthma as objective testing is not possible, and therefore do not get access to the structured care that comes with a formal diagnosis.	
NHS England	Guideline	006	007	It should be recommended the GLI reference values are used for spirometry. We would suggest that BDR recommendations are consistent with 'ERS/ATS technical standard on interpretive strategies for routine lung function tests' ERJ 2022;60:2101499 and that BDR be primarily classified as 'a change of >10% relative to the predictive value of FEV1 or FVC.' This is a more sensitive measure and a simple example of how to do the maths could be included.	Thank you for your comment This is an unfamiliar metric to many and the committee prefer to stick with FEV1 changes rather than adding the option of using FVC.
NHS England	Guideline	006	011	There is widespread concern about the recommendation to perform skin prick testing and IgE and eosinophils in the diagnostic pathway for CYP. The quality of the evidence that has led to this recommendation is very poor. Skin prick testing is poorly predictive of asthma in children and a negative atopic status does not exclude asthma as suggested in the guideline. We do not think that there is sufficient evidence	Thank you for your comment The GRADE criteria are stringent, and many NICE reviews (not just in asthma) produce low or very low-quality evidence as judged by this standard. The evidence shows that a majority of children with asthma have evidence of house dust mite sensitisation and/or raised general

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				to diagnose asthma on the basis of IgE levels and eosinophil counts which are just as likely to be associated with other atopic causes in children. It was suggested more research is needed into its use in children and young people as a diagnostic tool before it is recommend in this guideline. On a practical level, skin prick testing can currently only be achieved by referral to a specialist allergy clinic and this guideline will likely lead to these clinics being overwhelmed. Furthermore, allergy guidance indicates that this is a specialist test that should only be performed and interpreted by a specialist, indicating that access to this in primary care even in the long term is not likely to be realistic. In the future, diagnostic hubs and hublets may provide the solution, but again, similar to spirometry, pathways are currently not developed and an alternative must be provided to enable clinicians to suspect and treat a child or young person if indicated in the absence of these tests. Similarly, paediatric phlebotomy is not widely and easily available from primary care, and is a potentially distressing test for a child. The	atopic markers. If a child has a history suggesting asthma, is sensitive to house dust and has a raised eosinophil count, the committee would argue that they probably have asthma. They would also agree with you that the diagnostic pathway needs to be tested, but not that it should be shelved in the meantime. This would put us back to the status quo whereby most children (and adults) receive a diagnosis of asthma without any tests. If it is not possible to get skin prick testing or to take blood, then recommendation 1.2.8 (numbering has changed due to post-stakeholder revisions) cannot be applied to that child. This does not mean that the recommendation is useless in all children

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				evidence of its usefulness in the diagnosis of asthma in this age group is lacking and therefore it is not felt this test is justified in this context at present.	
NHS England	Guideline	008	018	Suggest add in 'or vaping' to the 4th bullet point	Thank you for your comment. On reconsidering this, the reference to smoking has been removed from 1.5.1. The recommendation is about indices of control, and smoking was therefore out of place there (and it is covered in other recommendations).
NHS England	Guideline	008	025	There is not good evidence that FeNO monitoring in children with asthma is likely to improve outcomes. Whilst the 2016 Cochrane review suggested that tailoring asthma treatment based on FeNO levels reduced exacerbations, close examination of these data reveals that this positive outcome is a result of large FeNO monitoring benefits in 3 very small studies. The large, and until that time definitive, US study (Szefler 2008) was unambiguously negative as was the 2013 Pike UK study. Since then we have had Steve Turner's 2022 Lancet Respir Medicine 10(6):584-592 UK study recruiting 535 children. It did not reduce asthma exacerbations	Thank you for your comment. Several stakeholders have raised a similar point. The UK study you cite was negative, but overall, the studies show a slight benefit, albeit that increased ICS doses were required to achieve this. It is true however, that FeNO monitoring in children was less cost-effective than in adults. The recommendation has been reviewed and the committee have decided it should be limited to adults.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				compared to symptom guided asthma treatment. This study built on the experience of all of the previous research into regular FeNO monitoring to prove its effectiveness and is of very high quality. It is entirely negative. It is very hard to see how the addition of this definitive UK study in the analysis for this guideline still results in a recommendation for FeNO monitoring in children. We would suggest focusing on the results from the well conducted UK studies that are most relevant to UK practice, and which do not show benefit. We recognise that these conclusions might contradict the findings from adult studies, but children are not mini-adults and there are many reasons why FeNO monitoring is unlikely to be effective in improving outcomes in younger asthmatics. The introduction of regular FeNO testing will have huge resource implications in primary care with likely little impact on asthma attacks or any other clinically important outcomes. As the analysis shows, the increased use of FeNO is likely to result in increased doses of inhaled corticosteroids being used in children which will have further increased cost	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				implications. These increased doses of steroids are unlikely to improve asthma outcomes because we know from the Cochrane meta-analyses of RCTs comparing low versus higher doses of inhaled beclomethasone, budesonide and fluticasone in adults and children, there is no difference in the occurrence of asthma exacerbations between high and low doses (80 randomised controlled trials with 79 showing negative outcomes and just 1 study showing benefit of very high versus low doses of budesonide). Finally it is important to note that these new guidelines are driving a major change in practice towards the increased use of MART. Whilst fully supportive of this, it should be recognised that the FeNO studies did not include children on this type of treatment approach and there is no evidence that FeNO monitoring of such children will improve outcomes above that which can be achieved with a symptom based MART approach to day-to-day asthma treatment based on symptoms	
NHS England	Guideline	008	028	Recommendation 1.5.5:	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				'Suboptimal control'/ uncontrolled asthma- this needs to be defined: ≥2 exacerbations treated with OCS in the previous 12 months ≥6 prescriptions for short-acting beta-2 therapy On maintenance OCS for asthma This definition is needed as it is also relevant when recommendations on referrals are made later in the guideline. (there is a definition in the appendix, I think it needs more)	Thank you for your comment. The committee prefers the definition of uncontrolled asthma already referenced in the guideline in the Terms Used section. The definition you suggest represents extremely poor control. Assessment with a view to possibly changing treatment is required sooner.
NHS England	Guideline	009	019	Recommendation 1.6.1: In addition to 'obesity' other conditions that can present with breathlessness should be listed to encourage the clinician to consider them e.g. breathing pattern disorder	Thank you for your comment. Several stakeholders have suggested additions which might be made to this bullet point, and on reflection the committee have agreed that no examples are necessary, the meaning of the recommendation being clear without them.
NHS England	Guideline	010	008	The statement to not prescribe a SABA in any age with 'asthma' without an ICS might create some confusion when treating the pre-school	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				age group. There will be some children in this age group who will have episodic viral associated wheezing and not meet the criteria for a trial of regular inhaled steroids. In these circumstances there will be a case for using intermittent SABA. These criteria are very clearly stated in the published Beat Asthma guidelines (beatasthma.co.uk/wp-content/uploads/2024/05/clinicians-information-BA-FINAL.pdf) which were developed nationally. We think this needs clarifying albeit that these children will not be labelled as having asthma or suspected asthma.	The committee is sympathetic to the point you make, but this recommendation clearly states that it applies to people with asthma and is therefore valid. We recognise that it can be difficult to distinguish from other wheezing illnesses, particularly in the very young, hence the series of recommendation describing a trial of inhaled steroids in this age group.
NHS England	Guideline	010	017	We agree that choice of inhalers should be those with the lowest environmental impact but argue that prescribers need this information readily available to inform their treatment decisions with shared decision making working with families. We would strongly recommend including gCO2Eq data for recommended inhalers.	Thank you for your comment. This would cause difficulty as the guideline will not be updated for a period of time and could therefore not provide information on new inhalers (which would be unfair to them) or to any change to current inhalers.
NHS England	Guideline	011	001	We would like to see the potential dangers of a lack of dose counter on Salbutamol pMDI inhalers mentioned here. The evidence tells us	Thank you for your comment. A bullet point has been added

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				that up to 40% of patients use an empty inhaler *(Jill B. Conner & Philip O. Buck (2013) Improving Asthma Management: The Case for Mandatory Inclusion of Dose Counters on All Rescue Bronchodilators, Journal of Asthma, 50:6, 658-663)*, 25% found the inhaler to be empty when needed acutely and 8% of these went on to require emergency assistance as a result *(Nancy Sander, Sandra J. Fusco-Walker, Julia M. Harder, Bradley E. Chipps. Dose counting and the use of pressurized metered-dose inhalers: running on empty. Annals of Allergy, Asthma & Immunology, Volume 97, Issue 1, 2006,34-38).* Furthermore, review of the National Child Mortality Database has revealed that 9 children and young people have died from asthma in the last 5 years where a lack of dose counter on the salbutamol pMDI was implicated as a significant contributor to the fatal outcome at the CDOP review. There are also environmental impacts of using an empty inhaler, expelling propellant but not active ingredient into the atmosphere with no beneficial effect to the patient.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The FDA and the EMA have both issued guidance over the use of dose counters on salbutamol pMDIs. The BNF and BNFc now have included a paragraph to alert health care professionals to the dangers of a lack of dose counters, and patient information is available (https://www.beatasthma.co.uk/wp-content/uploads/2022/11/How-can-I-tell-if-my-inhaler-is-empty.pdf). We would suggest paragraph 1.6.5 should have an additional point stressing that people should be given information on the dangers of the lack of dose counters and steps to take to mitigate this danger.	
NHS England	Guideline	011	015	We question the advisability of recommending 'the same type of device to deliver the preventer and reliever treatments where more than one inhaler is needed' in children aged 6-11 years. Most 6-11 year old children will be well controlled on regular inhaled corticosteroids and many will be able to use a dry powder device within licence for prevention treatment (Flixotide	Thank you for your comment. Several stakeholders have raised this issue and 1.6.8 in the draft guideline has been amended.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				accuhaler or Pulmicort turbohaler). There is no evidence about how SABA can be given through these devices for acute episodes of wheeze. These children will require and MDI and spacer for the treatment of breakthrough symptoms according to their action plans for the treatment of acute exacerbations of wheeze. We thinks this needs highlighting.	
NHS England	Guideline	011	021	We think the statement about the use of digital inhalers should be clearer. The evidence review for these devices identified a clear signal for a harmful effect with increased exacerbations. There is good evidence that health care professionals are unable to correctly suspect when poor adherence is a problem and there is little evidence that using these devices to identify poor adherence is likely to improve outcomes. We would strongly recommend limiting the recommendation for the use of these devices in children to those patients in specialist centres in whom biologic therapy is being considered. These devices are expensive and poor adherence is commonly suspected in children with asthma. Whilst not recommending their routine use the current statement has the	Thank you for your comment. The committee has reconsidered this recommendation, and it has been changed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				potential to encourage a significant increase in their use for which there is little evidence for likely benefit and major cost implications.	
NHS England	Guideline	012	014	There is no guidance on the action to take if low-dose MART is required but not tolerated by the patient. This is something that is seen in practice, that not all patients can use a MART regime	Thank you for your comment This recommendation is for people starting asthma treatment for the first time. There is evidence that some people do not like to be switched to MART from traditional regimens but that is not relevant here.
NHS England	Guideline	013	000	Section on medicine combination and sequencing: We welcome in the emphasis on low dose ICS/formoterol and MART. However, in some cases once daily preparations maybe preferred and should be considered. The guideline should mention this to help guide primary care	Thank you for your comment The evidence shows MART to be superior to regimens of maintenance ICS/LABA with SABA as reliever. The various MART studies were all performed when twice daily maintenance therapy was the standard, and the committee therefore did not see evidence comparing MART with once daily maintenance regimens. It would therefore be problematic to make evidence based recommendations. The committee also did not find enough evidence to recommend MART with a once

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					daily maintenance dose, although this may work for some people with asthma.
NHS England	Guideline	015	001	Definition of uncontrolled asthma in the appendix includes 'any asthma exacerbation requiring treatment with oral corticosteroids'. This would lead to huge numbers of referrals, many of which would be unnecessary. Suggest the definition is modified or the criteria for referral are clearly listed separated (see below)	Thank you for your comment The committee is not convinced that the definition will lead to huge numbers of referrals. The only point at which poor control is linked to referral is when people have reached the end of the treatment pathways (1.7.6 or 1.7.7 for the MART pathway, 1.7.12 for people on traditional pathway) and if they are still having exacerbations at that stage a referral is appropriate.
NHS England	Guideline	015	005	Suggest making the messaging more clear here that this age group is different to the 12+ age group in terms of regular ICS with as needed SABA as apposed to as needed ICS plus SABA for mild symptoms following an initial diagnosis. As it is currently written, there is a concern that this message may be over looked.	Thank you for your comment Recommendations 1.7.1 and 1.8.1 both contain the target age range within their wording, and they are in different sections of the guideline labelled as being for different age groups. The committee is not sure how much clearer this can be.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS England	Guideline	015	010	We agree with the second line off licence use of MART in 6-11 year olds, but would urge caution when using the Symbicort MDI. Unlike the turbohaler for which there is licenced use in this age group for fixed dose combination treatment and a clinical trial with evidence of effectiveness for a MART regime, there is no such research for the MDI. The licenced doses for MDI in those aged 12 and above are very high and there is a danger that such high doses will be used in younger children.	Thank you for your comment There is data on MART in children in the public domain (evidence review Q). The footnote to 1.8.2 now states that the evidence for MART in children is based on use of a DPI.
NHS England	Guideline	017	017	We suggest the line about environmental sources of symptoms including pets should be omitted. The current BTS guidelines found no evidence that pet removal improved outcomes in these circumstances and in some cases the effects were paradoxical. This intervention is unlikely to be of benefit and especially if a much-loved pet is wrongly implicated as the cause of continuing symptoms	Thank you for your comment The reference to pets has been removed
NHS England	Guideline	023	000	For sections 1.15 and 1.16, think you could put more guidance into this section as the improvement of care for people with asthma will come from how practices and PCNs risk stratify	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				patients and then improve how they both organise and deliver the care they give to patients This could link to several concurrent health care themes including health inequalities and population health management and the development of a care bundle which would include the pharmacological guidance you have put in, but also link it to other work going on around vaccines (flu and covid), smoking cessation and things like warmth on prescription (particularly for deprived populations in the severe segment offered through social prescribing). Could you recommend that the care bundle is actively managed by a care coordinator which could be funded out of ARR monies. In addition, think you are missing the opportunity set out in the Fuller Stocktake around Integrated Neighbourhood Teams for chronic disease management. We would like to see much greater integration of how we deliver care to cohorts and include community respiratory teams as well as specialist outreach to help us optimise care especially for the severe risk strat cohort. This NICE review offers a real opportunity to influence how we think differently about how we organise and deliver	These initiatives relate to organisation and delivery of care, of asthma. The scope indicates that this section would merely be editorially refreshed without an evidence review. So, we are unable to incorporate the suggested additions.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				care otherwise fear we get more important guidance but how we actually work doesn't change. My comments are informed from my work as GP for the past 20 years as well as being a Deputy MD for NHS England with a background in PHM.	
NHS England	Guideline	023	001	Recommendation 1.15: Risk-stratified care In addition to 'repeated episodes of unscheduled care for asthma', this list should also include: • Repeated courses of oral corticosteroids for asthma • Poor lung function	Thank you for your comment Poor lung function is a risk factor for exacerbations but only spirometry at a low level. Moreover, we have not found evidence that measuring lung function regularly helps, and if we include this it will undoubtedly confuse many people who will feel it contradicts 1.5.3. Oral corticosteroid courses have been added
NHS England	Guideline	1.1.1	1.1.1	Should there be a wider range of physical health factors considered? Including reflux and chest infections	Thank you for your comment This is a legacy recommendation which was not reviewed in detail for this update, and it is not appropriate to make extensive changes to the considered wording agreed by the previous committee

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS England	Guideline	1.1.1	1.1.2	We suggest reference is made to what reasonable adjustments could be made to support people with a disability including those who are autistic and have a learning disability	Thank you for your comment Reasonable adjustments are mandatory under the Equality Act and apply across medical conditions. It is not necessary to recommend them here.
NHS England	Guideline	1.1.4	1.1.4	Should chest tightening be added here?	Thank you for your comment Chest tightness is already in 1.1.1
NHS England	Guideline	1.14	1.14	We suggest reference to self management and the consideration for children and adults with a disability. some adults with a severe learning disability might not be able to use a peak flow. Consideration of how self management programmes can adjust for people who may lack capacity to manage their health	Thank you for your comment Personalised action plans are personalised by definition and should be adapted to the individual whether they have a learning disability or not.
NHS England	Guideline	1.16.3	1.16.3	We suggest that this sentence around 'think about computerised decision support systems for patient use to support self-management', needs to make clear that this will not be appropriate for all groups of people and	Thank you for your comment The recommendation does not say that these must be used for all people. It specifically states that they are an option.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				alternative arrangements to support self-management put in place.	
NHS England	Guideline	1.6.9	1.6.9	We suggest including the potential value of use of digital inhalers in selected people, it may be worth flagging use amongst people with a learning disability and autistic people may be helpful to explore as part of future research proposals.	Thank you for your comment Although those with learning disability are not mentioned specifically, the 4th research recommendation is to explore which groups would benefit from digital inhalers.
NHS England	Guideline	General	General	Detail and consideration of recommendations for children and young people show a good understanding that many children and young people may find some tests difficult to perform and be unwilling to have blood tests and so the recommendation that professionals may need to manage individuals based on what tests can be undertaken as well as based on symptoms and signs, is an approach which would be helpful for autistic children and young people, and those with a learning disability or complex needs.	Thank you for your comment
NHS England	Guideline	General	General	We would wish to see the voice of children and adults and their families who have asthma in this guidance there needs to be a reference to the	Thank you for your comment The committee members are all aware of the frightening nature of asthma and deeply

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				fact that this can be s a very distressing and scary condition for individuals.	sympathetic to their patients. However, this is a guideline and designed to offer recommendations on management rather than a narrative on the disease and its emotional effects.
NHS England	Guideline	General	General	We suggest reference is made to Ask Listen do – the use of feedback, concerns and complaints to improve care for this group including Ask Listen Do NHS England » Ask Listen Do – feedback, concerns and complaints	Thank you for your comment This is a guideline on asthma. It would be swamped if links to all forms of generic advice, however worthy, were included.
NHS England	Guideline	General	General	We suggest that mental capacity must be taken into account and the relevant legislation Mental Capacity Act 2005 (legislation.gov.uk) applied with young people and adults with a disability, in deciding matters about self-management and other things about ongoing care. Where adults have a Care and Welfare Deputy these should be actively involved Deputies: make decisions for someone who lacks capacity: Overview - GOV.UK (www.gov.uk).	Thank you for your comment The Mental Capacity Act is not specific to asthma and compliance with it is obligatory. It should not be necessary to re-state the content in this guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS England	Guideline	General	General	We strongly suggest schools and the role of education providers need to be mentioned in this guidance as they have a role in supporting care for CYP with asthma	Thank you for your comment Please see recommendation 1.14.7
NHS England	Guideline	General	General	Evidence from the LeDeR report shows that around 4% of people whose deaths are notified to LeDeR and who have a review have asthma as a LTC. It is important that learning disability and ethnicity are being captured for all patients and that the guideline considers the reasonable adjustments that may be needed for a person with a learning disability and autistic people to do spirometry	Thank you for your comment Reasonable adjustments are mandatory under the Equality Act and not specific to asthma. It should not be necessary to add details into this guideline.
NHS England	Guideline	General	General	Weather and sharp changes in temperature should be added to triggers if not already along with stress.	Thank you for your comment There are numerous potential triggers for people with asthma and the guideline has not attempted to list them. It does suggest that they should be sought when taking a history.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS England	Guideline	General	General	Communication: We recommend reference is made to the need of following guidance of reasonable adjustments in clinical care for autistic people e.g., NEG. • Check if person has a communication passport – ideally ahead of time • Check communication needs and preferences – verbal followed by written summary/ video/visual formats • Establish that the person with communication differences fully understands the questions • P21 personalised action plan – be aware of language used and possibility that autistic person may be literal in understanding and following of programme/recommendation • May be more anxious about symptoms	Thank you for your comment Reasonable adjustments are mandatory under the Equality Act and not specific to asthma. It should not be necessary to add details into this guideline. There is a link to the shared decision making webpage which lists NICE's guidance on patient experience in adult NHS services which fully covers communication Shared decision making | NICE guidelines | NICE guidance | Our programmes | What we do | About | NICE
NHS England	Guideline	General	General	We recommend reference is made to encouraging the use of reasonable adjustments in order to support people with a disability and autism to attend appointments:	Thank you for your comment Reasonable adjustments are mandatory under the Equality Act and not specific to asthma. It should not be necessary to add details into this

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				• To support the person in attending appointments, participating in assessment and treatment, make reasonable adjustments: • Establish ability to self-monitor • Work out with the person and/or carer how best to identify and describe symptoms and changes – visual rather than verbal for instance. • Consider preference for sameness – same clinicians and location • Consider sensory factors – distress at being touched; being uncomfortable in the environment (lights/smells and sounds) • Refer to guidance and training on the presentation and needs of autistic people and people with intellectual disability (e.g., Oliver McGowan Mandatory training on Learning Disability and Autism and RCGP Autistic Spectrum conditions course)	guideline. The guideline contains a relevant link as learning difficulties are covered in NICE's CG138 guidance which can be found here Shared decision making | NICE guidelines | NICE guidance | Our programmes | What we do | About | NICE

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS England	Guideline	General	General	Treatment adherence: • Consider any patterns to non-compliance – what else might be going on for the person? • Discomfort/smell/taste of inhaler and medication • Question if not attending appointments – is it the appointment or the hospital environment or the journey to the hospital? • Establish if anything has change, e.g., changes in routine or environment that affects non-compliance	Thank you for your comment The guideline refers users to NICE's guidance on shared decision making and medicines adherence.
NHS England	Guideline	General	General	We suggest reference is made to the importance of listening to parents and carers. We suggest the following text: **Listen to parents and carers:** Families and carers have a wealth of information about the individual and how their health has been, including any comorbidities and the medication that the person is taking. Listen to them as well as the person you are caring for. They know the	Thank you for your comment This is advice which is not specific to asthma. It is a basic part of good medical care and taught to medical undergraduates and to post-graduate trainees. It should not be necessary to state this in the guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				person well and how to look after them when they are not in hospital. They also know how the person's current behaviour may differ from usual, as an indication that they are unwell. The family or carer may have short videos of the person to give you an idea of their usual self. Remember that the carer they come into hospital with may not be their usual carer at this unusual time. You may wish to talk to their usual carer as soon as is practicable.	
NHS England	Guideline	General	General	A person with a learning disability and some autistic people may not be able to articulate their response to pain or symptoms in the expected way and some may be non-verbal. Given that people with a learning disability and autistic people may have challenges engaging with the standard tools of assessment and treatment in asthma and because of the potential risks of diagnostic overshadowing, we suggest that consideration is given to the merit of having a lower threshold for medical intervention and hospitalisation for asthma treatment in people with a learning disability and autistic people. We wish to see greater evidence of current	Thank you for your comment Reasonable adjustments are mandatory under the Equality Act and not specific to asthma. It should not be necessary to add details into this guideline. A link is included to NICE's shared decision making guidance. Please also note that the guideline does not cover acute exacerbations of asthma and the need for hospitalisation.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				applicability for people with a learning disability and autistic people	
NHS England	Guideline	Section 1.14.7	1.14.7	1.14.7 – Mention of Asthma Friendly Schools and associated resources would be helpful in this section. Asthma friendly schools - Transformation Partners in Health and Care Partnership	Thank you for your comment This is a legacy recommendation with no associated evidence review and the wording has not been changed
NHS England	Guideline	Section 1.15	1.15	Whilst there is an assumption as part of Equality Impact Assessment that consideration around learning disability would be expected as part of risk stratified care, we think there would be significant benefit in specifically mentioning the needs of autistic people, those with a learning disability and others where self-management and asthma control may be more difficult. (see section 1.15). Additional risk factors covering issues such as, uptake of flu/covid/pneumococcal vaccination etc, smoking, physical fitness and obesity would be beneficial to mention.	Thank you for your comment The purpose of a Risk stratification system is to augment care for those whose asthma control is at risk. There are numerous items which might prompt a practice to add a person to their system, but the committee have elected to suggest only those which clearly indicate poor control of asthma rather than set out all the possible items. The bullet points in 1.15.1 do not exclude adding other items.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS England	Guidelines	Section 1.4	Self Management	We suggest further reference and – additional consideration and mention around self-management amongst autistic people and those with a learning disability (of all ages) and wider groups of disabled people. Ensuring information and advice is in formats that is accessible and can easily be understood is essential. Consideration of support that is also not only telephone based, will help those who may struggle to access this provision, some autistic people, those who are Deaf and hearing impaired etc. Additional mention is needed around information, support and advice to parents/carers and wider support or care providers e.g. school nurses, social services, care home staff, residential schools etc.	Thank you for your comment Reasonable adjustments are mandatory under the Equality Act and not specific to asthma. It should not be necessary to add details into this guideline.
NHS England	Indicator	General	General	We suggest that examples of reasonable adjustments for disabled people who cannot cooperate with these tests because of their disability	Thank you for your comment Reasonable adjustments are mandatory under the Equality Act and not specific to asthma. It should not be necessary to add details into this guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
NHS England	Question 1	General	General	Currently, pathways that allow CYP access to objective testing for asthma in primary care are not widely available, and where they are, are under-developed. There is a need to incentivise areas to develop these, and work is underway at a national level to support local areas to do this. But this will take several years, at best. In the meantime, there does need to be a realistic alternative for primary care health providers to diagnose a child with asthma and treat on clinical suspicion using a trial of treatment, whilst these pathways as being established. This alternative may need to be pragmatic and based on expert opinion. We suggest a recommendation of what action should be taken if FeNO and spirometry are not available. This could be a statement similar to what is said for a child aged 5 if they are not able to perform objective tests (recommendation 1.3.1). Or, it could suggest the use of peakflow and BDR as an alternative to spirometry and BDR or reduction in peak flow variability over a 8 week timeframe. There is widespread concern that, without this, children and young people who live in areas	Thank you for highlighting this. Your comments will be considered by NICE where relevant support activity is being planned.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				where pathways are not currently operating, will either be referred to secondary care which is not set up to cope with the numbers, or worse still, the child will not be given a diagnosis of asthma, and the structured care that comes with a diagnosis, leading to worse care and outcomes. We know from patient experience studies (I can provide the papers if required) that delays in diagnosis result in significant distress to the family and suffering to the child and only when a formal diagnosis is made, is there a turning point in disease control. We are concerned, that as it stands, without a statement similar to recommendation 1.3.2, this guideline may perversely encourage this outcome further..	
NHS England	Question 1	General	General	There is concern that, even if diagnostic pathways are established, a child referred from primary care for FeNO and spirometry will likely face a delay between the initial consultation and objective testing be performed. This may result in delays in starting effective treatments. It is suggested that there is a statement as to whether treatment should be delayed pending the results of objective testing, or not. If not, a	Thank you for your comment Recommendation 1.1.5 states that significant symptoms should be treated if present at first presentation, and 1.1.7 points out that treatment alters test results.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				statement that interpretation of results will need to take into account any potential treatment effects and normalisation of results.	
NHS England	Question 1	General	General	There was a common opinion is that FeNO is often difficult to perform in a child under 8 years of age. The current guideline recommending FeNO as a first line test is aimed at children aged 5 and over. We recommend a statement outlining the potential difficulties in performing this test in this age group	Thank you for your comment It is no more difficult to do a FeNO test than to use an inhaler properly.
NHS England National Patient Safety Team	Guideline	010	015	The NHSE National Patient Safety Team have been working with colleagues across the NHSE, the MHRA and the National Child Mortality Database (NCMD) in relation to the risk of patient harm from inhalers that do not currently have an integrated dose counter. We have been made aware by the NCMD that 9 children and young people had died from asthma in the last 5 years where a lack of dose counter on the salbutamol pMDI was implicated as a significant contributor to the fatal outcome at the CDOP review. We therefore seek NICE support to highlight the potential dangers of a lack of a dose counter on	Thank you for your comment. A bullet point has been added to 1.6.4 recommending devices with a dose counter.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				these inhalers, and there is significant evidence to support the need for this: • 40% of patients use an empty inhaler.[1] • 25% found the inhaler to be empty when needed acutely and 8% of these went on to require emergency assistance as a result.[2] • The FDA and EMA have both issued guidance over the use of dose counters on salbutamol pMDIs. EMA states "*For multidose inhalation medicinal products each unit should have a dose counter to give the patient indication of when the number of actuations stated on the label has been delivered*".[3] • The BNF/BNFc have included information on the dangers of a lack of dose counters - *For inhalers without a dose counter, there is no accurate way to gauge the remaining number of therapeutic doses other than by either recording every actuation used, or by calculating when the inhaler is likely to become 'empty' according to their standard usage. Shaking, weighing or floating the inhaler device, or using it*	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				until it no longer actuates are not accurate and not recommended.[4] We would therefore such the following amendments to the guidance: *1.6.4 – Base the choice of inhaler(s) for asthma on*: … please consider including reference to choose an inhaler with a dose counter where possible. *1.6.5 – Give people with asthma information on their inhaler treatments. This should include …* Please consider including need to supply information on the dangers of the lack of dose counters and steps to take to mitigate this danger. References: 1. *Conner J. B. & Buck P. O. Improving Asthma Management: The Case for Mandatory Inclusion of Dose Counters on All Rescue Bronchodilators, 2013. Journal of Asthma, 50:6, 658-663* 2. *Sander N, Fusco-Walker S.J., Harder J.M., Chipps B.E. Dose counting and the use of pressurized metered-dose inhalers: running on empty. 2006. Annals*	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				of Allergy, Asthma & Immunology, Volume 97, Issue 1,34-38 3. *EMA. Guideline on the pharmaceutical quality of inhalation and nasal medicinal products, EMA/CHMP/20607/2024 4.2.2.20* *BNF. Respiratory system, inhaled drug delivery. Online*	
NHS South Yorkshire ICB	Guideline	004	000	Objective tests for diagnosing asthma Home monitoring of peak flow (PEF) is a big omission across all these groups and it is a very practical tool used by many in primary care. It is low-cost patient-centred way to readily identify triggers (including occupational, which would then guide potential referral for specialist confirmation) and diurnal variability which confirms diagnosis and guides management. Only two weeks are needed for monitoring as per the global initiative for asthma (GINA): Adults: average daily diurnal peak flow (PEF) variability >10% Children: average daily diurnal peak flow (PEF) variability >13% This is based on high quality evidence and should not be discounted just because not enough training or support is given to clinician to help conduct the analysis of the data. The measure is not completely perfect but is highly	Thank you for your comment The committee agree with much of what you say. There are drawbacks to all the available tests for asthma, and these are referred to in the guideline and in the associated evidence reviews. PEF monitoring is readily available as you say, but it too has drawbacks, in particular its very poor sensitivity. However, in view of comments from multiple stakeholders it has now been added. The committee would also argue that availability of FeNO will never improve if it is not clearly recommended in guidance. In relation to your point on non-eosinophilic asthma, please note that FeNO is not used as a rule-out test, only as a means of confirming a diagnosis, so this group should not be

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				practical in primary care. Tools provided by NHSE should be given to support the accurate data collection for clinicians and help them to interpret the information. The lack of these tools is the main barrier. If tools were integrated in clinical systems, then the time for analysis can be reduced and improve patient care. PEF also serves to educate the patient about their lung physiology and how peak flow (PEF) varies and correlation (or not) with symptoms. All the other tests are reliant on a snapshot test which might not reflect medium-longer term disease patterns. The evidence presented as informing this decision is scanty and poor quality. There are issues of compliance and health/digital inequality here, but actually future research needs to focus on reducing these through utilising technology and making home diagnosis and monitoring easier for patients, not taking it out of the guideline. Furthermore, in primary care this is often the only test available with limited access to fractional exhaled nitric oxide (FeNO), spirometry and provocation testing – without it, the only easily available objective test is blood eosinophil count and using this will miss	misdiagnosed as a consequence of including FeNO.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				those with non-eosinophilic asthma. And it's the most applicable to children	
NHS South Yorkshire ICB	Guideline	004	013	The guideline does not at any point refer to levels of probability of asthma – when clinical history is taken and probability of asthma is high surely a trial of treatment can support a diagnosis. To not be able to make a clinical diagnosis of asthma in patients who have successfully trailed treatment will lead to many patients remaining as "suspected asthma" and potentially never being given a confirmed astha diagnosis	Thank you for your comment The problem of using levels of probability as was once recommended in the BTS/SIGN guideline is that, although it is an excellent idea, in practice very few people were deemed to have intermediate probability and to require objective tests. This raises questions about how probability was being interpreted. Trials of treatment are flawed because people with other diagnoses, for example viral-induced wheeze, can improve naturally leading to a spurious conclusion that the improvement is due to asthma therapy.
NHS South Yorkshire ICB	Guideline	005	007	This is suggesting a trial of treatment if people are acutely unwell at presentation which is likely to be most presentations – then to arrange tests at a later date which we then know are all going to be negative because of the treatment. The inability to make a clinical diagnosis based on response to treatment will lead to under	Thank you for your comment. This section is about making an initial diagnosis of asthma. The committee do not agree that most people first present with acute symptoms requiring immediate treatment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				diagnosis or people remaining as "suspected asthma"	
NHS South Yorkshire ICB	Guideline	005	017	We like this comment as I think people forget that results can be affected once a person has started preventive treatment. This statement needs to be more prominent throughout the diagnosis section of the guideline as there is a real risk of people ending up undiagnosed once treatment has commenced if this guideline is followed	Thank you for your comment.
NHS South Yorkshire ICB	Guideline	005	019	This section should acknowledge the limited access to objective tests in primary care especially for children. In addition the whole diagnosis section focuses on diagnosing patients with atopic/eosinophilic T2-high asthma. What about those with T2 low asthma – there is no mention of the 2 main asthma phenotypes and the high focus on T2 high asthma could lead to patients being inappropriately labelled as not having asthma	Thank you for your comment. The limited access to some tests is acknowledged in the rationale section and in the relevant evidence reviews. The diagnosis section does not focus on atopic/eosinophilic asthma. It includes tests for Th2 markers because these can help, but they are used to confirm a diagnosis when positive, not as rule-out tests. The diagnosis is not excluded without further testing.
NHS South Yorkshire ICB	Guideline	005	022	Eosinophil laboratory range will vary across the country – there should be a definitive number	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				here. Additionally there needs to be an acknowledgement of false positives as there are many other things more than asthma that can raise blood eosinophil count. This statement could lead to over diagnosis if there is no acknowledgement of the alternative causes of raised blood eosinophils which need to be rules out.	It is precisely because the laboratory range varies that the committee have not given a single value for an abnormal eosinophil count. The committee agrees that other conditions may cause the eosinophil count to be raised, but there are potential confounding factors with most diagnostic tests.
NHS South Yorkshire ICB	Guideline	005	026	Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Adults) Why is peak flow (PEF) reversibility acceptable for patients with acute symptoms (section 1.1.5) but not for a routine objective test? Ranked 3rd most cost effectiveness strategy in evidence and 80% specificity. Why not use this in primary care when bronchial hyper-responsiveness (BDR) and bronchial challenge testing are not easily available?	Thank you for your comment. The PEF reversibility referred to in 1.1.5 is an opportunistic single measurement of reversibility in an acutely unwell person, not PEF variability derived from serial PEF measurements.
NHS South Yorkshire ICB	Guideline	005	026	Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Adults) Bronchial hyper-responsiveness (BDR) and fractional exhaled nitric oxide (FeNO) are a snapshot in the natural history of asthma. If the patient is well, these tests may not be positive. Currently availability of either test in primary	Thank you for your comment. Your comments on the "snapshot" nature of most tests for asthma is correct. However, measuring PEF variability is also problematic as it has been shown to be highly insensitive.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				care is very patchy in England. Peak flow is universally available in primary care and PEF and/or reversibility measured over time in primary care, especially testing the patient when symptomatic. This acknowledges the variable nature of the disease over time and cheap (ranked 3rd in cost-effectiveness in adults).	Nonetheless, numerous stakeholders have pointed out its advantages and it has now been added to the diagnosis section.
NHS South Yorkshire ICB	Guideline	006	001	There is no access to bronchial hyper responsiveness testing in primary care and little available for children u16 in secondary care. As many patients in primary care may not have raised fractional exhaled nitric oxide (FeNO)/BDR or raised eosinophils, or testing not available, this might increase pressure on secondary care and increase costs of diagnosing asthma. Also, will delay diagnosis of patients in primary care	Thank you for your comment. The committee acknowledges this. It is however the best single test for asthma and it would be remiss not to include it, albeit at the end of the testing sequence.
NHS South Yorkshire ICB	Guideline	006	005	We think this could make people too reliant on FeNO when the result can be raised for a variety of reasons and could lead to over diagnosis. More emphasis is needed on the alternative reasons FeNO could be raised such as rhinitis/nasal inflammation to rule these out	Thank you for your comment The guideline clearly states that the person should have a history suggesting asthma.
NHS South Yorkshire ICB	Guideline	006	010	Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16) Skin prick testing is	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				impractical, not available in primary care and very few clinics in secondary care provide it. In addition, as quoted by yourself in the consultation documents: "quality of the evidence was very low across studies as it was downgraded for risk of bias, most frequently due to concerns surrounding the method of participant selection or a lack of clarity over blinding of the index test and reference standard results. Indirectness was also present in all evidence due to not reporting the ICS use of participants prior to the study. Less frequently occurring was the inclusion of participants <5 years of age, a lack of clarity over the definition of asthma, and the inclusion of allergens not specified in this review protocol, all of which led to further downgrading for indirectness." "No relevant clinical studies were identified comparing the clinical effectiveness of diagnosis of asthma based on skin prick tests for any of the allergens specified in the review protocol" Should this therefore be reconsidered as a diagnostic tool?	Skin prick testing is only one option given in recommendation 1.2.6 and the committee feel it is important to include it as a means of avoiding a blood test in a child who is reluctant to have this. The lines you quote regarding evidence quality are correct, but the GRADE criteria are stringent and many NICE reviews (not just in asthma) produce low or very low quality evidence. The sentence on clinical effectiveness is taken out of context; it applies to test and treat studies, not to tests of diagnostic accuracy.
NHS South Yorkshire ICB	Guideline	006	012	Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16) The evidence used to	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				inform a recommendation in using total allergen-specific immunoglobulin (IgE) as a diagnostic tool for Asthma is very low quality and there is little heterogeneity in the population of the patients in the studies. No international documents recommend the use of such tests as part of the diagnostic criteria/work up for asthma. It is strongly advised that this is reviewed and await further studies on a wider population at primary care level to determine the specificity and sensitivity of the test	The GRADE criteria are stringent, and many NICE reviews (not just in asthma) produce low or very low quality evidence as judged by this standard. Other guidelines have focused on measures of airflow obstruction and variability of this, but the committee believe that this does not give due account to the strong relationship between atopy and asthma, particularly in childhood, which can be used to help strengthen or refute a diagnosis of asthma.
NHS South Yorkshire ICB	Guideline	006	015	This reads unclearly regarding the IgE. Is this about total IgE or specific IgE to house dust mites	Thank you for your comment This has been amended
NHS South Yorkshire ICB	Guideline	008	025	As with diagnosis we have had patients referred into secondary care purely based on raised FeNo levels despite otherwise good asthma control (symptoms and PEF). We could see that this will potentially increase the workload for secondary care due to primary care wanting to get an objective test performed to help assess good asthma control	Thank you for your comment. The committee acknowledge that FeNO may occasionally produce unhelpful results, but in most cases, it is useful and it was a cost-effective test in adults in our analysis.
NHS South Yorkshire ICB	Guideline	009	005	If routine PEF, FeNO or spirometry not recommended, it may miss those who do need their treatment increasing when they are reviewed infrequently (e.g. only seen for annual	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				reviews) and if they are poor at recognising that their asthma is deteriorating.	Monitoring of FeNO is recommended in adults. Routine PEF or spirometry is not recommended, but this does not preclude measuring them if a person is known to be a poor perceiver of their own control (hence "person-specific reasons"). The evidence review did not support the use of regular lung function monitoring for all people with asthma.
NHS South Yorkshire ICB	Guideline	009	021	Principles of pharmacological treatment State the importance of spacers, particularly in the young, and ensure this emphasizes the need for them to be using the correct spacer, in the correct size. This will avoid school aged children remaining on baby spacers with masks because this has not been routinely assessed during asthma reviews.	Thank you for your comment. The following page contains separate recommendation around inhalers with the intention of ensuring that the correct devices are used and that this is periodically reviewed.
NHS South Yorkshire ICB	Guideline	010	008	We agree in principle however it is sometimes challenging to know if a young child is having just viral wheeze episodes or asthma from their history.	Thank you for your comment. The committee is sympathetic to the point you make, but this recommendation clearly states that it applies to people with asthma and is therefore valid. We recognise that it can be difficult to distinguish from other wheezing illnesses, particularly in the very young, hence

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					the series of recommendation describing a trial of inhaled steroids in this age group.
NHS South Yorkshire ICB	Guideline	012	000	Pharmacological management in people aged 12 and over Overall, from a management perspective it is great to see the incorporation of AIR and MART and a very clear statement in the document regarding no one being treated with SABA alone. However, this appears to have been made a one size fits all approach which does not align with the global initiative for asthma (GINA) recommendation that an alternative pathway be considered where necessary (although we note that a non-MART pathway has been suggested for children of 5-11 (page 16))	Thank you for your comment The committee believes that the evidence in adults strongly favours the AIR then MART strategy over the traditional treatment pathway and have therefore recommended this. The remit of NICE is to offer guidance on the most cost-effective management strategy and therefore this is also the same for this BTS/NICE/SIGN guidance.
NHS South Yorkshire ICB	Guideline	012	004	This could be challenging in those who are under 18 years of age and are unable to use a DPI device due to the licencing of ICS/Formoterol inhalers. The lack of a second alternative treatment pathway in this age group is surprising. Whilst we fully support the guidelines great emphasis on the use of ICS formoterol combination inhalers there appears to be little recognition for those patients for whom the treatment strategy may not be appropriate and for example where a once daily treatment	Thank you for your comment The committee believes that the evidence in adults strongly favours the AIR then MART strategy over the traditional treatment pathway and have therefore recommended this. The remit of NICE and BTS/SIGN is to offer guidance on the most cost-effective management strategy.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				may be appropriate. This is a once size fits most treatment but not a once size fits all	
NHS South Yorkshire ICB	Guideline	015	010	We are concerned that the guidelines are advising unlicensed treatment in this age group when there is currently less evidence for its use. Currently the only devices licensed under 18 are DPIs which will be challenging for many much younger children to use. We acknowledge that the guideline has to have longevity and are aware of the future licensing pipeline and we also acknowledge that the guideline highlights the off licence nature of this treatment option however we feel there should be a greater emphasis on this as well as an emphasis that DPI's may not be appropriate for younger children	Thank you for your comment The recommendation includes the statement that children must have been assessed as able to manage the MART regimen. This will include the fact that a DPI will be part of the treatment.
NHS South Yorkshire ICB	Guideline	023	001	Should the number of courses of oral steroids being prescribed (within a defined period of time) also fall into this list?	Thank you for your comment This has been added
NHS South Yorkshire ICB	Question 1	000	000	Question 1: *Would it be challenging to implement of any of the draft recommendations? Please say why and for whom.* Please include any suggestions that could help users overcome	Thank you for highlighting this. Your comments will be considered by NICE where relevant support activity is being planned.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				these challenges (for example, existing practical resources or national initiatives. The lack of many of the recommended objective testing in primary care will make implementing the diagnosis section challenging in particular for children and could lead to an increase in referrals to secondary care. Peak flow (PEF) variability needs to be included as it's the only thing available immediately for primary care which will pick up non-eosinophilic asthma	
NHS South Yorkshire ICB	Question 2	000	000	Question 2: *Would implementation of any of the draft recommendations have significant cost implications?* Testing requires more provision and resources many of which are not currently freely available – this has the potential to have significant cost implications. As above, peak flow (PEF) variability needs to be included as it is easily available to primary care and cost effective.	Thank you for highlighting this. Testing is a key area for resource impact picked up by respiratory experts from committee. This is included for local resource impact assessment in the draft RI tools because practice varies widely.
NICE GP panel	Guideline	General	General	Thank you. We welcome the unification of national guidance on asthma.	Thank-you for your comment.
NICE GP panel	Guideline	General	General	We felt that this guideline is a significant improvement to the previous NICE guidance. This version is clear, helpful and easy to understand.	Thank-you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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NICE GP panel	Guideline	General	General	We welcome the inclusion of cost and cost effectiveness	Thank-you for your comment.
NICE GP panel	Guideline	General	General	Structure: Many guidelines start with children and work up the ages: this guideline does the opposite and might be confusing.	Thank you for your comment The BTS/SIGN guideline, the previous NICE guideline, and the GINA guideline all deal with adults first, so in asthma terms this is the expected order.
NICE GP panel	Guideline	General	General	Overall this is a useful guideline (with specific provisos) but we will need a shorter CKS to make it useable in our short GP consultations.	Thank you for highlighting this.
NICE GP panel	Guideline	General	General	Referrals: we really need a unifying section on referral to secondary care in its own section. Whilst each section addresses referral for those who remain uncontrolled, clear unified advice is important for both primary care (who/ when to refer) and secondary care (who to retain clinical responsibility for). Primary care is currently asked to manage, inappropriately, some very high-risk patients.	Thank you for your comment A link to the AAC document, which cover s referral, has been included.
NICE GP panel	Guideline	General	General	Please include guidance on managing asthma triggers e.g. mould in houses. Guidance would help GPs when producing supporting evidence for housing improvements.	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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					The non-pharmacological management of asthma is not in the scope for this guideline. BTS & SIGN will produce guidance on this.
NICE GP panel	Guideline	General	General	It is very disappointing to see that our previous concerns (NG80 consultation) on access to diagnostic testing and lack of consideration of primary care tools are again missing from this guideline. This time we again received very many comments on access to diagnostics and the emphasis on secondary care-based investigations. This exactly mirrors comments we made for the previous guideline.	Thank you for your comment Blood sampling for eosinophil count is available to primary care. FeNO is currently not available in many places, but it is a small piece of equipment, and the test is not difficult to perform, so (with investment) it could be used in primary care. "Primary care tools" for asthma usually refers to PEF measurement. PEF variability has now been included in the diagnostic pathways.
NICE GP panel	Guideline	General	General	The emphasis on investigations unavailable to primary care will cause long waiting lists, significantly increased referrals to paediatricians (as direct access to hospital-based investigations is unusual/ impossible?) and referrals to respiratory physicians. This situation is also a safety risk.	Thank you for your comment. Blood sampling for eosinophil count is available to primary care. FeNO is currently not available in many places, but it is a small piece of equipment, and the test is not difficult to perform, so (with investment) it could be used in primary care. The guidance states that if

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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					symptoms warrant it treatment should be started before testing. Your comments will be considered by NICE where relevant support activity is being planned.
NICE GP panel	Guideline	004	006	Clinical History. We felt this was a very important but underemphasised part of the guideline. We would appreciate concrete guidance on common signs and symptoms and risk factors making a diagnosis of asthma more or less likely, and whether the symptoms need to be present recurrently.	Thank you for your comment The importance of the clinical history is stated clearly in the guideline. However, reviewing the evidence on symptoms and risk factors was not included in the scope so the recommendation is carried over from the previous version.
NICE GP panel	Guideline	005	General	Please state clearly: if there are features suggestive of asthma do we only need one positive test to confirm a diagnosis? In the rationale/impact section you say 'no test showed high enough values of sensitivity and specificity to be diagnostic when used alone, and therefore a combination of tests would be needed'	Thank you for pointing this out. The sentence in the rationale was intended to mean that it is not possible to use just one test for all and do away with all other tests. As written, it can be misconstrued and has been changed. In some people a suggestive history and a single test will suffice (recommendations 1.2.1 and 1.2.4).

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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NICE GP panel	Guideline	005	General	Peak Flow readings: we are surprised at the omission of peak flow readings for diagnosis. This is a very easy cheap and accessible test for general practice (and many comments emphasise the inaccessibility of the recommended tests) The diagnostic evidence, sensitivity and specificity for pretty much all the recommended diagnostic tests are quite poor, so why not keep this easy test, even if second line?	Thank you for your comment PEF variability measurement has now been included.
NICE GP panel	Guideline	005	022	For many in General Practice diagnosis according to guidance will be based on the eosinophil count, as the other recommended tests are not available (see previous 'General' comments). We received several comments questioning the reliability and specificity of this test. It was especially noted that eosinophilia counts are affected (up or down) by other atopic disease, the use of medicines (related or unrelated to symptoms), parasitic disease, malignancy.	Thank you for your comment None of the diagnostic tests is without potential flaws. Eosinophil count is not 100% specific, but it performed well as a test in the studies reviewed.
NICE GP panel	Guideline	005	022	Please clarify when eosinophilia test can be tested – during/ after/ between symptoms/ historical tests?	Thank you for your comment Eosinophil testing is suggested a first test for adults when the person presents with

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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					symptoms, so if blood sampling is organised then it will be done reasonably close to a symptomatic period (it does not need to be done at the precise time a person has wheeze or chest tightness). Historical eosinophil counts are potentially useful as long as the medical records are good enough to show whether any other potential causes of eosinophilia were present at the time.
NICE GP panel	Guideline	005	022	Please comment on how eosinophilia should be interpreted when where symptoms occur in response to specific trigger factors, which may often lead to false negative tests	Thank you for your comment Most people with asthma do not have strictly demarcated periods when they are unaffected by symptoms, but in those who do all tests may become negative during the asymptomatic phases.
NICE GP panel	Guideline	005	022	Please clarify if there is a hierarchy eg if FeNO available do we use this for diagnosis, or are the tests of equal value? If one test is negative should the other be undertaken? Or do both tests have to be negative to rule out asthma? Even in our responses there were different	Thank you for your comment The recommendation says "or". It does not say do both.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				interpretations suggesting that this guidance is unclear	A negative test in this recommendation does not rule out asthma. It says that a positive result, together with a supporting history, allows a diagnosis to be made.
NICE GP panel	Guideline	005	026	Suggest similar wording is used here as on Page 6 line 7 draft guideline in the light of comments about eosinophilia and the lack of availability of FeNO.	Thank you for your comment Comments about eosinophilia are noted, but an eosinophil count is readily available.
NICE GP panel	Guideline	005	026	Spirometry is poorly accessible, nowadays based predominantly in secondary care with long waiting lists, and is usually normal. Some of our commentators described it as useless for primary care diagnosis.	Thank you for your comment. Spirometry is recommended in NICE guidance for other conditions, and it is disappointing that access is so poor. The guideline is not for primary care only. Your comments will be considered by NICE where relevant support activity is being planned.
NICE GP panel	Guideline	006	General	Most of these tests cannot be accessed by GPs (paediatric secondary care-based investigations are rarely directly accessible). Are you, therefore, effectively suggesting that any diagnosis of asthma in children <10/12/16 should be done by a specialist who has access to these tests and more clinical experience to	Thank you for your comment. The committee are recommending the best way of diagnosing asthma. It is regrettable that FeNO and spirometry are not easily obtainable,

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				determine diagnosis? This is what the guideline will lead to.	and investment will be needed if the guideline is to be implemented. Your comments will be considered by NICE where relevant support activity is being planned.
NICE GP panel	Guideline	006	003	What does bronchial (hyper-)responsiveness mean? Could this relate to peak flow readings – if so please specify	Thank you for your comment It is described in the Terms Used section.
NICE GP panel	Guideline	006	011	Skin prick testing is unlikely to be available to GPs and unlikely to be acceptable/ feasible in younger children. House dust mite allergy might be coincidental rather than causal.	Thank you for your comment Skin prick testing is not the only option given in this recommendation. HDM sensitisation is a reasonably sensitive test in children.
NICE GP panel	Guideline	006	012	Eosinophilia: we received several comments questioning the reliability and specificity of this test, and a similar comment on IgE. It was especially noted that eosinophilia counts are affected (up or down) by other atopic disease, the use of medicines (related or unrelated to symptoms), parasitic disease, malignancy.	Thank you for your comment None of the diagnostic tests is without potential flaws. Eosinophil count is not 100% specific, but it performed well as a test in the studies reviewed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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NICE GP panel	Guideline	006	012	Please clarify when eosinophilia (and Ig E?) test can be tested – during/ after/ between symptoms/ historical tests?	Thank you for your comment Eosinophil testing is suggested a first test for adults when the person presents with symptoms, so if blood sampling is organised then it will be done reasonably close to a symptomatic period (it does not need to be done at the precise time a person has wheeze or chest tightness). Historical eosinophil counts are potentially useful as long as the medical records are good enough to show whether any other potential causes of eosinophilia were present at the time.
NICE GP panel	Guideline	006	013	Please comment on how eosinophilia (IgE?) should be interpreted when where symptoms occur in response to specific trigger factors, which may often lead to false negative tests	Thank you for your comment Most people with asthma do not have strictly demarcated periods when they are unaffected by symptoms, but in those who do all tests may become negative during the asymptomatic phases.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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NICE GP panel	Guideline	007	001	Please consider incorporating the GINA probability table 6.1 (p147) from the 2021 guide which gives features of high/intermediate/low probability for risk stratification	Thank you for your comment The assessment of probability of diagnosis in under 5s was not in the scope for this update and evidence was not reviewed. Probability was not used in this age group in either SIGN158 or the previous NICE guideline, and GINA have not included this figure in their latest guidance.
NICE GP panel	Guideline	008	001	Please also add questions on what specific substances or activities at work seem to trigger symptoms, and the presence and effectiveness of workplace safety measures or protective equipment. There is no mention of initial management which could include managing time off work and negotiating necessary workplace accommodations with employers.	Thank you for your comment. Management of occupational asthma is outside the scope of this update.
NICE GP panel	Guideline	008	022	Suggest you omit this sentence- is it either necessary or helpful? What are 'person-specific reasons'? Also, in the light of the next comment, the only available objective method of monitoring asthma control in primary care is excluded.	Thank you for your comment The sentence has been amended

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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NICE GP panel	Guideline	008	025	The cost-effectiveness of this measure appears uncertain: 'routine measurement at annual review' suggested by committee is only 'potentially cost effective' (quoted from your evidence review)	Thank you for your comment This is correct. The evidence was based on studies which looked at FeNO more frequently than annually. However, the committee spent some time discussing this and concluded that it should be recommended.
NICE GP panel	Guideline	008	025	FeNO monitoring has very major resource implications for primary and secondary care (very long waiting lists) and unlikely to be feasible for the vast majority of/ all(?)GPs.	Thank you for your comment. Some investment will be required to fully implement the guidance. Your comments will be considered by NICE where relevant support activity is being planned.
NICE GP panel	Guideline	008	025	If this recommendation is retained in some form it requires information about interpretation & action.	Thank you for your comment The recommendation cannot describe this in detail. Education will be required as part of implementation of the guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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NICE GP panel	Guideline	008	025	How would this be used if the initial diagnosis didn't include FeNO testing? In this situation what test would be used for monitoring?	Thank you for your comment You are correct insofar as interpretation of FeNO levels is easier if a baseline level is known. However, the studies in the evidence review were not confined to people in whom FeNO was used for diagnosis.
NICE GP panel	Guideline	009	016	There is no mention of testing for Alpha1Antitrypsin Deficiency (AATD) in adult-onset asthma with poor control. BMJ Best practice statement of 2023 suggests we test all adult-onset asthma patients for AATD. An AATD level is simple and inexpensive.	Thank-you for your comment. Testing for AATD is outside of the scope of this guideline update.
NICE GP panel	Guideline	010	001	Use of e-cigs. The wording for recording the use of e-cigs could be strengthened in line with MHRA. https://www.gov.uk/drug-safety-update/e-cigarette-use-or-vaping-reminder-to-remain-vigilant-for-suspected-adverse-reactions-and-safety-concerns-and-report-them-to-the-yellow-card-scheme	Thank you for your comment The MHRA update is not asthma-specific and stands in its own right. This recommendation is about considering the list of possible reasons for poor control rather than about recording them.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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NICE GP panel	Guideline	010	008	One respondent described this as the main 'stand out change'. The rationale and explanation are clear.	Thank-you for your comment.
NICE GP panel	Guideline	010	008	One respondent noted in some patients a pattern of habitual use and psychological dependence on SABAs. While this situation is often difficult to unravel it would be helpful to have NICE look at the evidence in this area and provide some recommendations.	Thank-you for your comment. Psychological dependence on SABA is outside the scope of this guideline update.
NICE GP panel	Guideline	011	008	It is completely unrealistic to observe inhaler technique at every consultation (even if this is interpreted as every consultation about respiratory symptoms)	Thank you for your comment The committee agrees that this should refer to consultations for asthma and have amended the wording. However, they respectfully disagree with you – it is possible to check inhaler technique quickly, as long as the person with asthma has their inhaler with them.
NICE GP panel	Guideline	011	015	In general, we agree with the recommendation to use the same type of inhaler device when more than one is needed but at times there can be good reasons for using different devices for different purposes.	Thank-you for your comment. This is a generally applicable recommendation, but the committee accept that there occasionally may be person specific reasons for supplying different devices.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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NICE GP panel	Guideline	011	020	There is ambiguity over the use of the term 'SMART' which may refer to a variation of MART or digital inhalers.	Thank you for your comment Unfortunately, this word is used in two different contexts in asthma management. The guideline has avoided both.
NICE GP panel	Guideline	012	004	The change to using a combination ICS/formoterol inhaler as first line is a major change. One respondent commented that they could see the rationale for this but GP drug costs will rise significantly and ICBs will need to be aware of this.	Thank you for your comment Drug costs will not rise hugely as this recommendation only applies to newly diagnosed adult asthma. Moreover, if AIR works well fewer people will move onto daily ICS plus SABA, and this will mitigate the effect of a more expensive PRN inhaler. It is not safe to recommend SABA only prescription as was once common practice.
NICE GP panel	Guideline	012	014	Many who use these guidelines will not be familiar with the concept of 'MART'. Please add additional information on the regimes to that provided in the text and hyperlinks.	Thank you for your comment Detailed education on MART is beyond the remit of the guideline and best left to documents designed specifically for that purpose. MART is not new – it has been an option for nearly 20 years and many clinicians are familiar with it. A

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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					definition of MART is included in the terms used section.
NICE GP panel	Guideline	013	General	"Asthma that is not controlled". Previously the pragmatic definition of this was based on the use/ overuse of salbutamol. Please state in the guideline how control is diagnosed now.	Thank you for your comment Control and Uncontrolled are both included in the Terms Used section.
NICE GP panel	Guideline	013	003	For safety reasons: please clarify how long patients, during exacerbations, can use the reliever element of MART for.	Thank you for your comment Strictly speaking this question is outside the scope which excludes acute asthma. If by "exacerbation" you mean a period of time when symptoms are worse but do not require emergency treatment, then the reliever can be used each relevant day. However, everyone with asthma should have a personalised action plan which covers this (recommendation 1.14.1) and if they are needing excessive reliever prescription this should be picked up and acted on (1.15)
NICE GP panel	Guideline	013	008	Please include details of patient characteristics /subgroups/phenotypes for those, who are most likely to benefit from LTRA?	Thank you for your comment That would be useful, but an evidence search on this question was not part of the scope. The

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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					informal opinion of the committee is that there is no hard evidence to guide this.
NICE GP panel	Guideline	013	008	We suggest you include the link to MHRA advice: https://www.gov.uk/drug-safety-update/montelukast-reminder-of-the-risk-of-neuropsychiatric-reactions	Thank you for your comment There is already a link, but another has been added within the recommendations themselves
NICE GP panel	Guideline	013	016	Please alter this to a specific period of review (three months) to ensure all parties understand that this is a trial of treatment.	Thank you for your comment This has been altered to be consistent with recommendation 1.6.3.
NICE GP panel	Guideline	014	001	We welcome the recommendations on transferring patients from their current treatments but please also provide guidance on how to manage those who have long standing good control on old style regimens. Please provide further information of changes on the consequent risk/benefits for this sub-group of patients	Thank you for your comment The text at the start of this section says that the recommendations on transferring are only for people who are not controlled on their current medication. Those who are well controlled continue on their "old style" treatment.
NICE GP panel	Guideline	018	017	Please clarify whether this should only occur at annual review or at other times and if the latter when/after what period of good control we should consider stepping down treatment.	Thank you for your comment It can happen at other times, but it was felt that, if nothing else, it should be thought about at annual review. A literature search on stepping

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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					down was not performed for this update, but the opinion of the committee is that there is no hard evidence on the optimum interval between treatment changes. There is a little evidence that it is safe to consider stepping down at three month intervals.
NICE GP panel	Guideline	019	024	Please be more specific about the terms "early pregnancy" and "postpartum period" referring here to the timing of asthma review, and the level of recommended review	Thank you for your comment This recommendation has been transferred from SIGN158 and the current committee have not reviewed the evidence behind it. Early pregnancy is usually defined as the first 12 weeks of pregnancy. Postpartum is usually considered to refer to the 6 weeks after delivery. The purpose of the review is to ascertain control (section 1.5) and to convey the information in 1.12.1.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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NICE GP panel	Guideline	019	027	We suggest that NICE and the BNF wording are consistent to avoid confusion	Thank you for your comment The BNF does not say the same for montelukast and for tiotropium, so the wording will have to be different in some respect.
NICE GP panel	Guideline	021	004	Please consider resources for those who cannot use written information. Please also consider links to to further Lifestyle Medicine advice e.g. safe physical activity, managing mindset/stress, healthy diet, mindfulness meditation Examples sent to us: **https://www.asthmaandlung.org.uk/living-with/keeping-active** **https://www.nhs.uk/conditions/asthma/living-with/** **https://www.asthmaandlung.org.uk/groups-support/mindfulness-lung-health** **https://www.asthmaandlung.org.uk/conditions/asthma/asthma-triggers/stress** **https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6876140/**	Thank you for your comment Non-pharmacological management of asthma is not in the scope of the guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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NICE GP panel	Guideline	021	006	It appears incongruous that peak flow readings appear in patient self-management plans but this is a test that their GP will not be offering	Thank you for your comment Recommendations 1.5.3 and 1.14.1 both say that PEF measurement is useful in some people but is not necessary for everyone. PEF variability has now been added to the diagnosis sections.
NICE GP panel	Guideline	023	005	This is a potentially useful paragraph, but the statement is currently vague e.g."tailor care to their needs"; "at risk of poor outcomes" but risk stratification is not defined.	Thank you for your comment This recommendation has been altered, but it is hard to be specific about some of the phrases. How care needs tailoring will be very different for someone who does not pick up prescriptions as compared to someone who is overusing their reliever.
NICE GP panel	Guideline	052	000	"Peak flow variability for 2-4 weeks to be deleted." One respondent commented: this is a useful and AVAILABLE test, really cheap, and less environmentally unfriendly than spirometry (whole SABA mdi plus large spacer, which are not used for treatment, are thrown away for every patient)	Thank you for your comment The PEF reversibility referred to in 1.1.5 is an opportunistic single measurement of reversibility in an acutely unwell person, not PEF variability derived from serial PEF measurements.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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					PEF variability has now been added to the diagnosis sections.
Niox Healthcare Ltd	Evidence Review F	039	017-025	• The guidance states that 'In adults, the economic analysis found that blood eosinophils was a more cost-effective alternative as an initial test.' • The analysis of the cost of blood eosinophil count testing in the draft guidelines is incomplete. Referring to Evidence Review G, page 14, Section 1.1.10, relating to blood tests, only the unit costs of the blood analysis are shown and omits significant other costs. Taking a blood eosinophil count will require two GP or nurse consultations separated by a period of days / weeks for the necessary laboratory processing and logistics, of which no costs are included. • In comparison, in Evidence review F, page 35, Table 10, the cost that has been associated with FeNO as 'Cost of delivering the test' for a GP Practice Nurse is 15 minutes, at a cost of £15.84.	Thank you for your comment. The cost of a blood test and phlebotomy were collected from the National Collection Cost for the NHS, which comprises aggregated costs across the country and includes healthcare professional and devices/consumables costs. The GP visit for the referral to the first diagnostic test in the algorithm was not included, as this visit would be required for any strategy and would, therefore, be cancelled out in the incremental analysis. The committee agreed that after receiving the result of a blood test, the patient would be referred to the next step without the need of a further visit. However, to address the concerns raised in this comment, a further sensitivity analysis was added where either an additional nurse or GP appointment is required after a blood test. The results of this analysis can be reviewed in the

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				NIOX submit that a FeNO test takes up to 10 seconds with a short 70 second wait for the result. Therefore the 15 minutes assumed for a FeNO test in the draft appears to be vastly overstated, resulting in the draft assuming a falsely high associated cost for FeNO testing. • For blood eosinophil tests, there is no inclusion of the cost of Healthcare Professional time involved for the initial consultation, for the blood test (The NHS website (https://www.nhs.uk/conditions/blood-tests/), in the section '**What happens at a blood test'** – states that a blood test usually takes about 10 minutes), for the necessary follow up and for processing the blood to the laboratory. The blood eosinophil test process takes up significant time and resource, puts further pressure on the healthcare system and means a delayed process to any treatment decision. Compare this to a simple, non-invasive, point of care FeNO test allowing immediate decisions.	amended economic report and did not affect the conclusions. The cost of FeNO was not available from the National Collection Cost and was estimated using manufacturer data and expert opinion from the committee. The committee agreed that delivering FeNO is quick but that, on average, 15 minutes will be required to set up the test, deliver it, and explaining the results.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Further supported as FeNO is recognised in the draft guidelines as the most cost-effective test compared to other tests (Table 8 – Evidence Review F, page 32). • The costs for blood eosinophils appear to be incomplete and, therefore understated in the draft. Conversely, the cost assumptions (HCP time required) have been significantly overstated. This results in an inaccurate and misleading cost comparison between the two tests. • On this basis NIOX request that NICE include the full costs of a blood eosinophil test (including an additional HCP consultation etc) and revise the assumption regarding the time taken to reflect the actual time taken in practice.	
Niox Healthcare Ltd	Guideline	005	022-025	**1.2.1:** • Testing for blood eosinophils is invasive and may be a barrier for diagnosis as it may not	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				be acceptable for a significant number of asthma patients. • NIOX recommend making FeNO the first line objective test for diagnosing asthma in Adults, to match the recommendation for children. This would simplify the guidelines and therefore make implementation consistent in approach with patients having a simple, non-invasive, point of care FeNO test allowing an immediate clinical decision to be made.	Blood eosinophil measurement is invasive, but it is more readily available than FeNO testing. The 2 tests perform equally well in our model.
Niox Healthcare Ltd	Guideline	005-006	019-016	• **Objective tests for diagnosing asthma in adults, young people and children aged 5 to 16** • The draft guideline recommends FeNO as the first line test for children (Draft guidelines, page 6, line 5). However, in adults (Draft guidelines, page 5, line 22) the recommendation is to measure blood eosinophils or FeNO level.	Thank you for your comment. The committee do not agree that the process of diagnosis should be exactly the same in children as in adults. The evidence is not identical and there are other considerations to take into account e.g. ability to perform tests. Including blood eosinophil level as an alternative first step in adults is included because FeNO is less readily available and they

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				• NIOX recommend making FeNO the first line objective test for diagnosing asthma for adults, to match the draft recommendation for children. This would simplify the guidelines and therefore make implementation consistent in approach. FeNO testing is simple, non-invasive and point of care which enables an immediate clinical decision to be made. o FeNO provides a point of care, direct measurement of airway inflammation, allowing an immediate informed prescribing decision in line with the NHS Get it right first time (GIRFT https://gettingitrightfirsttime.co.uk/) Blood eosinophil count is not specific to airway inflammation. It is invasive and there are various factors that can affect blood eosinophil levels ranging from allergy to infection. If there is a period of time before the blood test is performed, the result may not potentially relate to the presenting symptoms on the day, due to the variable nature of asthma. There is also	are less likely to be reluctant to give blood than children.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				potential for patients' symptoms to develop or have an exacerbation whilst they are awaiting blood test results.	
Niox Healthcare Ltd	Guideline	006	007		Thank you for your comment
Niox Healthcare Ltd	Guideline	008	025-027	• The draft document states to 'consider' FeNO monitoring at regular review, and before and after a change in therapy. • NIOX recommend removing the word 'consider' and that recommendations should be much clearer. i.e. Monitor FeNO at regular review, and before and after a change in therapy. .	Thank you for your comment. It is standard practice in NICE guidance to use the word "Consider" for recommendations where the supporting evidence is positive but not unequivocally so and therefore this terminology will remain in the BTS/NICE/SIGN guidance.
Niox Healthcare Ltd	Guideline	024	003-008	• Normal lung function is included as an assessment of good asthma control. • NIOX suggest including a low FeNO level as another indicator of good control. According to the 2011 ATS recommendations, this would be a FeNO value of less than 25ppb in adults and less than 20ppb in children under 12 years of age. ○ (Ref: https://www.thoracic.org/statements/reso	Thank you for your comment Consideration of different definitions of control was not one of the primary tasks of the committee. There is an argument for including FeNO, but it has not been part of traditional definitions and FeNO is not available in many settings. On balance it is preferred not to include it at this stage.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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				urces/allergy-asthma/feno-document.pdf , Page 609, table 5)	
Niox Healthcare Ltd	Guideline response document (This document)	002	Question 1	**1. Would it be challenging to implement of any of the draft recommendations? Please say why and for whom. Please include any suggestions that could help users overcome these challenges (for example, existing practical resources or national initiatives).** • Having thoroughly reviewed the draft guidelines NIOX are of the view that it will be challenging to implement them as drafted, for the reasons outlined below. Furthermore, the challenges will extend to all Healthcare Professionals involved in the implementation of the draft guidelines, in particular General Practitioners, Nurses and personnel involved in the blood analysis process. Challenges implementing the draft guidance. 1. Blood eosinophil count testing	Thank you for your comment. The arguments made against eosinophil testing are overstated. The sequence would be: visit 1, could this be asthma? Visit 2 blood test; visit 3 (which need not be long after visit 2 - eosinophil results are rapidly available online) to confirm/refute diagnosis and agree next management step. For FeNO there is the potential for a GP to use point of care testing and do all this in one go, but realistically this will not happen in the vast majority of cases. The patient will have a visit 2 appointment with someone other than the GP (practice nurse, diagnostic hub etc) and then a visit 3 appointment as with the eosinophil option. The laboratories process numerous full blood counts every day and the few extra ones for people with suspected asthma would be a drop in the ocean. The great advantage of the eosinophil option is that it is available now. The committee

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				• Taking a blood eosinophil count will require two GP or nurse consultations separated by a period of days / weeks for the necessary laboratory processing and logistics. This will impose a significant additional burden on the primary care health system. • The implementation of the draft blood eosinophil count recommendation will result in delayed asthma diagnosis and management decisions (given the time required for a blood eosinophil count test per the point above). The consequence of delayed decision making will be a deterioration of asthma care and consequent poorer outcomes for asthma patients. • Increased workload and pressure on blood analysis laboratories in an already overburdened NHS. • The challenges associated with the interpreting of blood eosinophil counts and making asthma diagnosis and management decisions.	would like to see better access to FeNO but progress to date has been slow. Your comments will be considered by NICE where relevant support activity is being planned.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				2. The inconsistent recommendation in the use of FeNO testing in children versus adults • The draft guidelines recommend: 'Measure the FeNO level in children with a history suggestive of asthma' allowing a simple, non-invasive, point of care FeNO test and immediate clinical decision. In adults, the draft guidelines recommend 'Measure the blood eosinophil count or FeNO level'. Implementation of the draft blood eosinophil count recommendation will impose a significant additional burden on the primary care health system and will result in delayed asthma diagnosis and management decisions as described in point 1 above. 3. Universal access to FeNO testing in primary care: • A separate challenge in implementing these draft guidelines, is ensuring universal access to FeNO testing for asthma patients across England and	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Scotland in Primary Care. Despite the best efforts of the Accelerated Access Collaborative (AAC) to improve access to FeNO for diagnosis and management of Asthma, FeNO testing is still not universally available. Recommendations • NIOX recommend making FeNO the first line objective test for diagnosing asthma for adults, to match the draft recommendation for children. This would simplify the guidelines and therefore make implementation consistent. FeNO testing is simple, non-invasive and point of care which enables an immediate clinical decision to be made. Adopting this recommendation will also address the implementation challenges that have been described in point 1 and point 2 in the challenges section. • In terms of existing practical resource to help users, NIOX employ a Respiratory Nurse Specialist who supports	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				implementation and training of FeNO to ensure optimal usage, a process that fully supported the Accelerated Access Collaborative (AAC).	
Niox Healthcare Ltd	Guideline response document (This document)	002	Question 2	**2. Would implementation of any of the draft recommendations have significant cost implications?** • Yes, implementation of the draft guidelines will have significant cost implications when the full costs associated with the delivery of blood eosinophil count testing are included in the analysis. • The analysis of the cost of blood eosinophil count testing in the draft guidelines is incomplete. Referring to Evidence Review G, page 14, Section 1.1.10, relating to blood tests, only the unit costs of the blood analysis are shown and omits significant other costs. Taking a blood eosinophil count will require two GP or nurse consultations separated by a period of days / weeks for	Thank you for your comment. The cost of a blood test and phlebotomy were collected from the National Collection Cost for the NHS, which comprises aggregated costs across the country and includes healthcare professional and devices/consumables costs. The GP visit for the referral to the first diagnostic test in the algorithm was not included, as this visit would be required for any strategy and would, therefore, be cancelled out in the incremental analysis. The committee agreed that after receiving the result of a blood test, the patient would be referred to the next step without the need of a further visit. However, to address the concerns raised in this comment, a further sensitivity analysis was added where either an additional nurse or GP appointment is required after a blood test. The results of this analysis can be reviewed in the

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				the necessary laboratory processing and logistics, of which no costs are included. • In comparison, in Evidence review F, page 35, Table 10, the cost that has been associated with FeNO as 'Cost of delivering the test' for a GP Practice Nurse is 15 minutes, at a cost of £15.84. NIOX submit that a FeNO test takes up to 10 seconds with a short 70 second wait for the result. Therefore the 15 minutes assumed for a FeNO test in the draft appears to be vastly overstated, resulting in the draft assuming a falsely high associated cost for FeNO testing. • For blood eosinophil tests, there is no inclusion of the cost of Healthcare Professional time involved for the initial consultation, for the blood test (The NHS website (https://www.nhs.uk/conditions/blood-tests/), in the section '**What happens at a blood test'** – states that a blood test usually takes about 10 minutes), for the necessary follow up and for processing	amended economic report and did not affect the conclusions. The cost of FeNO was not available from the National Collection Cost and was estimated using manufacturer data and expert opinion from the committee. The committee agreed that delivering FeNO is quick but that, on average, 15 minutes will be required to set up the test, deliver it, and explaining the results. Respiratory experts from committee identified that blood testing for eosinophilia is currently available and used, therefore it is assumed no significant change to current practice resulting in material resource impact. The costs of FeNO testing are included in the resource impact spreadsheet tool. These are based on the economic evidence which can be amended locally. Assumptions will be tested when the draft RIA tools are consulted on.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				the blood to the laboratory. The blood eosinophil test process takes up significant time and resource, puts further pressure on the healthcare system and means a delayed process to any treatment decision. Compare this to a simple, non-invasive, point of care FeNO test allowing immediate decisions. Further supported as FeNO is recognised in the draft guidelines as the most cost-effective test compared to other tests (Table 8 – Evidence Review F, page 32). • In conclusion, the costs for blood eosinophils appear to be incomplete and, therefore understated in the draft. Conversely, the cost assumptions (HCP time required) have been significantly overstated. This results in an inaccurate and misleading cost comparison between the two tests. • On this basis NIOX request that NICE include the full costs of a blood eosinophil test (including an additional	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				HCP consultation etc) and revise the assumption regarding the time taken to reflect the actual time taken in practice.	
Niox Healthcare Ltd	Supporting Documentation: Algorithm (Diagnostic)	Slide 1	Interpretation of the results: Is eosinophil count above the laboratory range or are FeNO levels 50ppb or more?	• *On this slide, it states: Is eosinophil count above the laboratory range or are FeNO levels 50 ppb or more?* • Elevated FeNO levels are clearly defined as 50 ppb or higher; however, there is no standardised range for eosinophil count. Without a defined range, decisions may be inconsistent, as different laboratories might use varying approaches and reference values. • NIOX recommend making FeNO the first line objective test for diagnosing asthma for adults and to match the draft recommendation for children. This would simplify the guidelines and therefore make implementation consistent in approach and remove any ambiguity in blood eosinophil count level interpretation.	Thank you for your comment Laboratory ranges might differ, but the decision is based on a raised eosinophil count, and this will be consistent everywhere. The fact that the value concerned might differ slightly is irrelevant – the level is raised.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
North-East and North Cumbria ICB	Algorithm - Diagnostic	General	General	The diagnostic algorithm is going to have huge logistics impact in terms of getting blood tests; won't be easy for primary care as many young children end up being referred to secondary care paediatric day units for routine blood tests generally and smaller units especially will struggle to accommodate more requests for blood tests.	Thank-you for your comment Blood tests are not necessary in first 2 steps of the children's algorithm. In adults, taking blood is easier to arrange than spirometry with reversibility and obtaining a result is as quick or quicker than instituting a trial of treatment.
North-East and North Cumbria ICB	Algorithm - Diagnostic	General	General	In relation to skin prick tests; these are not readily available in primary care	Thank-you for your comment Skin prick tests are an option; there are alternatives at the same diagnostic step.
North-East and North Cumbria ICB	Algorithm - Diagnostic	General	General	Evidence (including from my own practice) is not as clear cut for FeNo both as diagnosis and monitoring for children and young people. In paediatrics it is only one part of jigsaw but definitely not the diagnostic tool itself and comes with lot of uncertainty. The cut off for FeNO in children is not the same across all guidelines and FeNO in children should not be used on its own to diagnose asthma; it should be used as part of the assessment in conjunction with the clinical history and other tests such as spirometry.	Thank-you for your comment. The committee agree that evidence of FeNO monitoring for children is weak, so they made the recommendation for adults only. Regarding diagnosis, the committee agrees that clinical history is paramount and the guideline states that tests must be viewed together with a history suggestive of asthma. The FeNO cut-off has been set at a high value so a measurement will only be taken as diagnostic when the result is reasonably specific

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
North-East and North Cumbria ICB	Guideline	005	026	This part of the adult guidelines doesn't define the blood eosinophil count as a numerical value in the same way as it does in the 5-16 year age group- ie "eosinophil count is more than 0.5 x 10^9 per litre-" the lack of consistency in guidance may lead to confusion in general practice	Thank you for your comment. The FeNO level is also different. Children are different than adults.
North-East and North Cumbria ICB	Guideline	006	005	In the NENC Geography, primary care teams do not have ready access to FeNO in house currently. In some cases there are diagnostic hubs but it is rare that these hubs diagnose or see children. There will be a significant financial implication in the implementation of this across the footprint. Locally we have offered advice regarding a range of considerations to consider in the absence of objective testing.	Thank you for your comment The committee acknowledges that access to FeNO is limited in some areas. It is hoped that further investment might be prompted by the positive recommendations in this guideline.
North-East and North Cumbria ICB	Guideline	008	022	Do not use regular peak flow monitoring to assess asthma control unless there are person specific reasons for doing so – Please can examples be given of when peak flow monitoring would be done	Thank you for your comment The commonest example has been added.
North-East and North Cumbria ICB	guideline	009	012	Not all asthma inhalers are licensed for use in line with the recommendations in this guideline – this comment or similar , e.g. p12, line 8 is also repeated within the draft guideline. The GMC guidance https://www.gmc-uk.org/professional-	Thank you for your comment. The only area where there is no licensed inhaler option is that of MART in children, and a non-

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				standards/professional-standards-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines is used when unlicensed prescribing is used. Many primary care nurses will be making prescribing decisions, and will not be a prescriber. Although if unlicensed prescribing is part of NICE guideline then there is support for undertaking unlicensed prescribing, but this is against the approach that has been taken in a lot of clinical areas, and carries greater risk for the prescriber, so will be more difficult if the person making the prescribing decision is not a prescriber. Can steps be made with manufacturers to get licensed in the UK? If not can there be a clear statement as to rationale and support for prescribing unlicensed therapy?	MART option is therefore included in the guideline. The rationale for MART in children explains why the committee believe that this should be an option. However, NICE is not responsible for approaching regulators to obtain new licences.
North-East and North Cumbria ICB	Guideline	010	008	does this include those with " suspected asthma"? Often clinicians will empirically treat cough with a SABA, or PPI or INS, sequentially, to determine the cause of cough and if it is related to bronchodilation. Does this imply that an ICS/formoterol should be trialled at the very outset prior to diagnostics and diagnosis? Or for suspected asthma is the guidance to use SABA	Thank you for your comment. It does include those with suspected asthma. The recommendations do not support a trial of treatment as an initial diagnostic step, except in the qualified case of under-5s. Unless symptoms demand treatment it would be better

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and ICS whilst waiting for diagnostics (with the latter possibly affecting FENO and spirometry).	to obtain diagnostic tests first, and if symptoms have to be treated and the clinician suspects asthma the treatment should include an inhaled steroid, not a SABA alone.
North-East and North Cumbria ICB	Guideline	011	008	every consultation" implies any appointment, eg a contraception review, acute UTI, this does not seem relevant /practical in general practice. Could this be re-worded to use the words "every acute/chronic respiratory consultation	Thank you for your comment. Agreed - the wording has been amended
North-East and North Cumbria ICB	Guideline	011	011	Switches to a generic device – generic prescribing of inhalers is a patient safety risk as there have been incidents when generic prescribing has resulted in the patient having a different device dispensed and were not familiar with the device or how to use it. Can the guideline please support branded prescribing of inhaler devices to support patient safety	Thank you for your comment. This was not intended as a recommendation for generic devices but was offered as an example because generic switching can sometimes occur without the original prescriber's knowledge, is potentially hazardous, and the committee wished to remind people of this. Since its purpose seems to have caused confusion, the reference to generics has been removed.
North-East and North Cumbria ICB	Guideline	011	015	Prescribe the same device to deliver preventer and reliever treatments – suggest; *where possible prescribe the same type of device*	Thank you for your comment. The words "if possible" have been added.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Suggest also changing reference to preventer and reliever treatments to *treatment and rescue* as this supports ongoing treatment of a chronic condition, and rescue helps to identify when not controlled	The term "reliever" is well established and has not been changed.
North-East and North Cumbria ICB	Guideline	011	018	Suggest Encourage people to take their used and unwanted inhalers to the pharmacy for **'appropriate environmental disposal'**	Thank you for your comment. The wording has been changed
North-East and North Cumbria ICB	Guideline	013	013	is there a concern here that patient's may use a single LAMA over SIT AIR/SIT MART? Could "single inhaled therapy" for ICS/LABA get confused by patients when adding in LAMA, such that they mistakenly stop their ICS/LABA and just take the LAMA (as single inhaler therapy)?	Thank you for your comment 1.7.6 suggests a trial of the addition of a LAMA, so it would seem easier to add in a LAMA-only inhaler to the current MART rather than changing inhalers completely for what might be a relatively short period of time. However, there is no evidence to prefer this to the option of changing to a triple maintenance inhaler as you describe, and so the recommendation leaves this open. There is always the possibility of errors if a clear explanation of the treatment is not given, with checks that this has been understood.
North-East and North Cumbria ICB	Guideline	021	019	, in general practice written plans can be pre-populated from a patient's records from the	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				clinical systems, hence they do "appear" personalised, however it might be worthwhile stating that annual reviews should include a "written PAAP with a verbal explanation/to check the persons understanding of that PAAP	Wording has been added to 1.14.2. to cover this point
Orion Pharma (UK) Ltd	Guideline	012	1.6	Inhaled corticosteroid doses have been categorised according to https://www.nice.org.uk/guidance/ng80/resources/inhaled-corticosteroid-doses-pdf-4731528781. Please include these doses as a link directly within the guideline for clinician reference.	Thank you for your comment A link to this document is now included in the guideline.
Orion Pharma (UK) Ltd	Guideline	012	1.7.1	Given the new approach of 'as-needed' inhaled corticosteroid-Formoterol therapy, a clinician with no respiratory specialist knowledge may be unfamiliar with this term. Please include a definition of what 'as needed' therapy is and how this is different to a maintenance and reliever therapy regime.	Thank you for your comment The committee do not think that the words "as needed" require definition. AIR therapy is described in the Terms Used section.
Orion Pharma (UK) Ltd	Guideline	012	1.7.1	We suggest removing the term 'low-dose' for as needed therapy, as only one strength of Budesonide-Formoterol is licensed for this regime.	Thank you for your comment Other inhalers may be licensed for AIR during the lifetime of this guideline and the committee did not want to limit the recommendation to

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					nothing other than the currently licensed product
Orion Pharma (UK) Ltd	Guideline	012	1.7.2	We recommend including clear and objective definitions of what a highly symptomatic patient is other than regular nocturnal waking. This will expedite decision making and/or referral processes in non-specialised settings.	Thank you for your comment What objective measure can be used in a person who is on no current treatment for asthma, does not have a PEF meter etc? The committee feel that this has to be a judgement based on individual circumstances.
Orion Pharma (UK) Ltd	Guideline	013	1.7.2	We recommend including clear and objective definitions of what a severe exacerbation is. This will expedite decision making and/or referral processes in non-specialised settings.	Thank you for your comment Management of acute asthma attacks (and definitions pertaining to this) is beyond the scope of this update of the guideline.
Orion Pharma (UK) Ltd	Guideline	015	1.6.7	We believe there should be more emphasis placed on prescribing by brand and teaching the specific technique for each inhaler. This is to ensure patients adhere to their inhaler therapy and maintains device consistency and technique required by the patient.	Thank you for your comment 1.6.7 is about prescribing the same type of device for preventer and reliever wherever possible, and this is perhaps obvious since the device the person uses best will be the same for both. Prescribing by brand is appropriate but a

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					different point as is teaching technique (covered in separate recommendation).
Orion Pharma (UK) Ltd	Guideline	016	1.6.4	There are many inhalers a clinician may select from to prescribe. This may add complexity to prescribing and knowledge of correct inhaler technique. We therefore suggest including the following statement within the first bullet point – 'See manufacturers guidance on inhaler technique to assess this'.	Thank you for your comment This action should be carried out by suitably trained professionals (this applies to all recommendations) and it should not be necessary to point out where to find information on individual inhalers.
Orion Pharma (UK) Ltd	Guideline	017	1.6.4	We believe the term 'suitable devices' may be a challenge for a non-specialist respiratory clinician to comprehend. Please include further details of how a clinician can assess the suitability of a device for a patient.	Thank you for your comment All recommendations, including this one, should only be carried out be suitably trained healthcare professionals and we do not think your concern is necessary.
Orion Pharma (UK) Ltd	Guideline	017	1.6.4	A clinician with no respiratory specialist knowledge may be unable to differentiate between what the lowest environmental impact inhaler may be. We therefore suggest including the following within the second bullet point – 'Dry powder inhalers have the lowest carbon footprint of all inhaler types'.	Thank you for your comment All recommendations, including this one, should only be carried out be suitably trained healthcare professionals and we do not think your concern is necessary.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Orion Pharma (UK) Ltd	Guideline	017	1.6.4	As per the British Thoracic Society 2024 Position Statement on Sustainability and the Environment: Climate Change & Lung Health 2024 (Position Statement on Sustainability and the Environment Climate Change & Lung Health 2024.pdf), we suggest including the statement "Initiation of a new inhaler is an opportunity to find the right device for the patient. This should preferentially be a dry powder inhaler or soft mist inhaler where the patient is able to use these device types effectively.".	Thank you for your comment 1.6.4 recognises the importance of environmental concerns. The committee agree with the BTS position statement but cannot go into the same level of detail as it does.
Orion Pharma (UK) Ltd	Question 1 Response	022	1.2.1	We have concerns regarding the focus of objective testing on FeNO level. This is because FeNO testing is less accessible, particularly for primary care centres and clinicians. We would suggest placing national initiatives to ensure primary care centres have access to FeNO testing.	Thank you for highlighting this. Your comments will be considered by NICE where relevant support activity is being planned.
Orion Pharma (UK) Ltd	Question 2 Response	022	1.2.1	Implementation of FeNO testing will have significant cost implications relative to spirometry (the most readily available form of testing available).	Thank you for highlighting this. The cost of FeNO testing is included in the draft resource impact work. These costs need to be assessed locally due to variations in practice.
PrescQIPP CIC	Guideline	005	022	1.2.1 Whilst we appreciate that this an either/or option, we understand that there is currently	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				variation in the availability of FeNO in clinical practice.	The committee acknowledges this.
PrescQIPP CIC	Guideline	006	005	1.2.4 We understand that there is currently variation in the availability of FeNo in clinical practice	Thank you for your comment The committee acknowledges that access to FeNO is limited in some areas. It is hoped that further investment might be prompted by the positive recommendations in this guideline.
PrescQIPP CIC	Guideline	008	019	1.5.2 Suggest adding hyperlinks to the Asthma Control Questionnaire and Asthma Control Test so these can be directly accessed.	Thank you for your comment The questionnaires given as examples are just examples. There are other validated questionnaires, and it would be better for practices to link to their preferred tool on their in-house system.
PrescQIPP CIC	Guideline	008	022	1.5.3 More detail on person-specific reasons and examples of where PEF should be used should be included. This is a major shift from historic practice and so further details are warranted.	Thank you for your comment The committee does not believe this is a major shift in practice. Many people with asthma do not measure PEF regularly. The most common reason for doing so has been added to the recommendation

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
PrescQIPP CIC	Guideline	010	008	1.6.2 This is an important principle and we suggest this statement is repeated in sections 1.7 and 1.8.	Thank you for your comment. All the principles in section 1.6 are important and it would be inappropriate to repeat one of them in other sections and not the others.
PrescQIPP CIC	Guideline	010	015	1.6.4 Inhalers should be prescribed in line with local formularies. Assessment for inclusion on local formularies will include a review of the environmental impact as well as the cost of inhalers. We suggest adding an extra bullet point to section 1.6.4 that states: in line with local formulary	Thank you for your comment. The committee realises that choice may be limited by local formularies, but do not think that adding this would improve the recommendation.
PrescQIPP CIC	Guideline	010	015	1.6.4 An additional statement is needed around prescribing the least costly option for the NHS. e.g. Where more than one inhaler is suitable for the patient, prescribe the inhaler with the lowest acquisition cost	Thank you for your comment. This is not as straightforward as you suggest. If the cheapest inhaler is not used as well by a person with asthma, downstream costs will be higher.
PrescQIPP CIC	Guideline	011	015	1.6.7 There may be occasions where different delivery devices for preventer and reliever treatments may be better for the patient. The we suggest amending this statement from	Thank you for your comment. The words "if possible" have been added.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				'Prescribe' to 'Where possible, prescribe the same type of device ....'.	
PrescQIPP CIC	Guideline	011	018	1.6.8 We suggest expanding this statement to: 'Encourage people to take their used or no longer needed inhalers to their pharmacy or dispensary for environmentally safe disposal'	Thank you for your comment. The wording has been changed
PrescQIPP CIC	Guideline	012	001	1.7 We suggest that the statement under point 1.6.2 is repeated in this section, as this is an important principle. 'Do not prescribe short-acting beta2 agonists to people of any age with asthma without a concomitant prescription of an inhaled corticosteroid (ICS). [2024]'	Thank you for your comment The principles in section 1.6 apply to adults and children. If added here it would also have to be added to the children's section. It is preferable not to repeat recommendations multiple times.
PrescQIPP CIC	Guideline	013	013	1.7.6 The following ICS/LABA/LAMA (triple) inhalers are licensed for use in asthma: Enerzair Breezhaler (with sensor) Enerzair Breezhaler (without sensor) Trimbow 172 micrograms/ 5 micrograms/ 9 micrograms pressurised inhalation, solution Trimbow 87 micrograms/ 5 micrograms/ 9 micrograms pressurised inhalation, solution The guideline implies that the use of these 'triple' inhalers is not recommended at any stage in the pathway, however it would be useful to have a	Thank you for your comment 1.7.6 suggests a trial of the addition of a LAMA, so it would seem easier to add in a LAMA-only inhaler to the current MART rather than changing inhalers completely for what might be a relatively short period of time. However, there is no evidence to prefer this to the option of changing to a triple maintenance inhaler and so the recommendation leaves this open.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				statement to this effect to ensure there is no ambiguity as to their place in therapy.	
PrescQIPP CIC	Guideline	015	003	1.8 We suggest that the statement under point 1.6.2 is repeated in this section, as this is an important principle. 'Do not prescribe short-acting beta2 agonists to people of any age with asthma without a concomitant prescription of an inhaled corticosteroid (ICS). [2024]'	Thank you for your comment All the principles in section 1.6 are important and they should not need to be repeated in both sections 1.7 and 1.8.
PrescQIPP CIC	Guideline	017	013	1.9.2 Suggest adding an additional bullet point to this section for completeness: 'consider prescribing an alternative device or spacer that can be used by the child/parent/carer.'	Thank you for your comment In this age group it is highly unlikely that anything other than an MDI+spacer will be used.
PrescQIPP CIC	Guideline	018	018	1.10.1 Current guidance states: "Consider decreasing maintenance therapy when a person's asthma has been controlled with their current maintenance therapy for at least 3 months." This statement in the updated guideline implies that maintenance therapy should only be	Thank you for your comment. The points you make are acknowledged. An 8–12-week minimum interval between steps down has been included in 1.10.2.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				reviewed and decreased at the patient's annual asthma review. We suggest that this statement is reviewed and amended if necessary to ensure there is no ambiguity around reviewing and reducing maintenance therapy.	
PrescQIPP CIC	Guideline	General	General	We welcome a joint guideline from NICE, BTS and SIGN that will help promote best practice, and reduce variation in the management of patients with asthma.	Thank you for your comment
Primary Care Respiratory Society-UK (PCRS-UK)]	Evidence A-K	General	General	**Evidence A-K** How much of this evidence is from studies done in primary care? This is where the majority of patients with asthma are going to be diagnosed. If not done in primary care – this is not real-world evidence. See link to Thorax paper above.	Thank-you for your comment Some of the evidence is from UK primary care. Evidence from secondary care was also regarded as relevant as long as the entry criteria limited subjects to those who might well be seen in primary care (e.g. for diagnostic test papers, subjects had to have no prior diagnosis). There are insufficient quality studies available anyway, and the committee does not agree that evidence from other sources should be disregarded.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					The Thorax paper referenced in comment 1102 considers issues outside of scope for this guideline.
Primary Care Respiratory Society-UK (PCRS-UK)]	General	General	General	**Question 1:** Would it be challenging to implement of any of the draft recommendations? Please say why and for whom. Please include any suggestions that could help users overcome these challenges (for example, existing practical resources or national initiatives. **PCRS response** There are currently scant resources available for spirometry, provocation or bronchial challenge testing or fractional exhaled nitric oxide (FeNO) in primary care. Including it in guidance may help drive provision, but there has been little change in this since the previous guidelines in 2017. Spirometry is extremely difficult to acquire in either primary or secondary care following COVID. Either airway reversibility or variability are advocated by most reputable guidelines. Peak flow variability is a useful tool in assisting diagnosis in the untreated patient: reversibility is often possible to demonstrate in the patient who is	Thank you for your comment. The committee agrees that more resource will be needed to make these recommendations work. The evidence suggests that eosinophil count and IgE, if taken with a history suggesting asthma, are helpful in confirming a diagnosis. The committee acknowledge the wealth of experience at PCRS-UK but, as it is not common practice to measure eosinophils when people present with possible asthma, do not see on what you base the statement that the count is usually normal. PEF variability is an insensitive test and the analysis of various testing strategies (see evidence review K) showed that the best test sequences did not include it. However, numerous stakeholders have supported its use, and it is now included in the diagnostic section.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				symptomatic thus the recommendation of Peak flow (PEF) variability should be included as it is immediately available in primary care. Diagnosis of asthma when using total allergen-specific immunoglobulin (IgE) is a new departure and severely flawed. It is useful for deciding the dose of biologic treatment. The inclusion of blood eosinophils is useful in phenotyping but most patients with asthma have an eosinophil in the normal range. It is not a substitute for lung function testing. Neither the positivity of a skin prick test nor a positive IgE test can be used to confirm asthma. They are a measure of sensitistion and not of causation, although patients with one or more sensitisations have an increased risk of developing or having asthma. Provision for skin prick testing in primary care is minimal – this needs to be considered for this guidance. Providing additional guidance on where tests (specifically fractional exhaled nitric oxide (FeNO) and blood eosinophils) may produce false positives or negatives of asthma may additionally help more accurate delivery of these diagnostic tests although sensitivity is much	The resource impact tools have focus in this area. Some data is available on primary care access to diagnostic tests for example: Improving access to FeNO testing in primary care - The Health Innovation Network Assumptions and estimates will be tested when the tools are consulted on. Your comments will be considered by NICE where relevant support activity is being planned.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				higher when combined with a carefully taken history.	
Primary Care Respiratory Society-UK (PCRS-UK)]	General	General	General	**Question 2:** Would implementation of any of the draft recommendations have significant cost implications? **PCRS response** Testing as described requires more provision and resources and needs to be rapidly available in order that treatment is commenced. If done at a practice level, the financial and skill resources will need to be provided which itself creates an argument for a rapid access hub (one or two days). As above, peak flow (PEF) variability needs to be included as it is easily available to primary care and cost effective.	Thank you for your comment. The committee agree that more resource will be needed. PEF variability is an insensitive test and the analysis of various testing strategies (see evidence review K) showed that the best test sequences did not include it. However, numerous stakeholders have supported its use and it is now included in the diagnostic section. Your comments will be considered by NICE where relevant support activity is being planned.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	004	002	**Initial clinical assessment** Given that most GPs are not experts in asthma and much of the UK asthma work is delegated to non-medical staff – a clear definition of asthma would be helpful at this point, together with a statement that the disease is diagnosed clinically on the basis of clinical history, response to medication, reversible airflow	Thank you for your comment The 2019 BTS/SIGN guideline has a section on definition of asthma but this outlines components of various definitions rather than settling on one itself. NICE's 2017 guideline does not define asthma.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				obstruction, and supported by tests for Type 2 inflammation (fractional exhaled nitric oxide (FeNO)/Eosinophils). Plus, the fact that there is no single test that alone can be used to diagnose asthma.	
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	004	004	**Initial clinical assessment** It would be good to include some guidance on the structured clinical history for asthma in children aged 5-16 years on which a fractional exhaled nitric oxide (FeNO) level of more than 35 ppb is diagnostic. We would suggest clearer information about when to suspect asthma when there are respiratory symptoms such as: Suspect asthma if >1 of the following symptoms are occurring ≥ 3 times a week, or if severe, or causing waking at night: - Wheeze (especially if heard by a healthcare professional) - Breathlessness - Chest tightness - Cough	Thank you for your comment Waking at night has been added to the recommendation. The other symptoms are already there. There was no evidence review of symptoms for this update and the committee is not sure that adding the specific numbers that you include is justifiable.
Primary Care Respiratory	Guideline	004	006	**Initial clinical assessment** Provide clarity on patient description of wheeze as often incorrectly described by patients	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Society-UK (PCRS-UK)]				(maybe not necessary for the guidelines). The word "episodic" have historically been useful, now more inferred: by "any variation". Could this again be included? It is of particular relevance in the pre-school child.	The committee agrees that wheeze does not always mean the same to the person presenting the symptom and their healthcare professional, but attempting to define wheeze in the guideline is unlikely to help
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	004	013	**Initial clinical assessment** This leaves little room for manoeuvre where clinical need (symptoms) requires treatment with inhaled corticosteroids (ICS) whilst enduring the long current wait for diagnostic tests, especially if initial tests are not positive/borderline/sub-optimally performed. Global Initiative for Asthma (GINA) includes this element; this guideline does not appear to consider current limited access in primary care (and being seen by someone with the necessary diagnostic skills), or patients long wait before tests are complete and they remain symptomatic. Furthermore, many tests (e.g., FeNO, Total IgE, SIgE blood eosinophils levels) are variable over time, not conclusive and may need repeating if requiring (as exampled well in the asthma diagnosis study published in JAMA PMID: 28114551). This guideline suggests that the investigations suggested are binary in nature when this is patently not the case. Asthma is a	Thank you for your comment It is true that there can be a long wait for some diagnostic tests at present, and optimal implementation of this guideline requires increased resource. However, the wait for some tests is not long at all – eosinophil counts can be obtained quickly. Recommendation 1.7.2 explains that treatment should be started if symptoms necessitate this. The committee agree however that asthma diagnosis is far from straightforward and diagnostic tests may be equivocal. In these instances, clinical judgement, which might include a trial of treatment, may be required. It should be emphasised however, that trials of treatment are flawed because people with other

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				syndrome, and symptom complex which requires many pieces of information to complete the diagnostic picture. There is also no advice about what to do with these patients who have a clinical profile in keeping with asthma but negative/borderline tests. Where there is a high probability of asthma after thorough clinical history, a properly managed trial of treatment with concomitant monitoring of peak flow diary plus symptom score for a period of 4-6 weeks should be undertaken and could be considered for all age.	diagnoses, for example viral-induced wheeze, can improve naturally leading to a spurious conclusion that the improvement is due to asthma therapy. Furthermore, although treatment trials are often advocated, there is no data on how much improvement is required in peak flow variability to constitute a positive trial of treatment and it is difficult to recommend a test without also indicating what is a significant result.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	004	015	**Initial clinical assessment** Section 1.1.3 could also include that there may be uncertainty over nomenclature/diagnostic coding for these patients. For example, can suspected asthma be used until confirmation with objective tests? No coding often means no follow up / no asthma reviews. We need a system where follow up is automatically prompted, and these are very often missed if not coded. But potential delay in diagnosis where objective testing not immediately accessible.	Thank you for your comment. Advice on coding as suspected asthma has been added to 1.1.2.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	004	015	**Initial clinical assessment** Diagnosis of asthma is a clinical one. GPs are often faced with patients presenting for the first time with a suggestive history of asthma. Treatment is often necessary at this stage. Rather than deny the ability for the attending doctor to make a clinical diagnosis - this recommendation should state, something along the lines of: If objective tests are not available at this stage, make a provisional diagnosis of asthma, treat the patient and arrange for further investigations. This would help to reduce any delays in addressing the patient's immediate need, provide for safety netting advice and education as well as follow-up, as well as timely confirmation of the diagnosis later. Also see comment 41 of this document.	Thank you for your comment. Recommendations 1.1.5 and 1.1.6 cover the situation in which treatment is judged to be necessary before objective testing can be carried out.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	004	Sections 1.1 – 1.4	**Objective tests for diagnosing asthma** Home monitoring of peak flow (PEF) is a big omission across all these groups, and it is a very practical tool used by many in primary care. It is low-cost patient-centred way to readily identify	Thank you for your comment. The committee agrees with much of what you say. There are drawbacks to all the available

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				triggers (including occupational, which would then guide potential referral for specialist confirmation) and diurnal variability which confirms diagnosis and guides management. Only two weeks are needed for monitoring as per the global initiative for asthma (GINA): Adults: average daily diurnal peak flow (PEF) variability >10% Children: average daily diurnal peak flow (PEF) variability >13% This is based on high quality evidence and should not be discounted just because not enough training or support is given to clinician to help conduct the analysis of the data. The measure is not completely perfect but is highly practical in primary care. Tools provided by NHSE should be given to support the accurate data collection for clinicians and help them to interpret the information. The lack of these tools is the main barrier. If tools were integrated in clinical systems, then the time for analysis can be reduced and improve patient care. PEF also serves to educate the patient about their lung physiology and how peak flow (PEF) varies and correlation (or not) with symptoms.	tests for asthma, and these are referred to in the guideline and in the associated evidence reviews. PEF monitoring is readily available as you say, but it too has drawbacks, in particular its very poor sensitivity. However, in view of comments from multiple stakeholders supporting its use, PEF variability has been included. The committee would also argue that availability of FeNO will never improve if it is not clearly recommended in guidance. In relation to your point on non-eosinophilic asthma, please note that FeNO is not used as a rule-out test, only as a means of confirming a diagnosis, so this group should not be misdiagnosed as a consequence of including FeNO.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				All the other tests are reliant on a snapshot test which might not reflect medium-longer term disease patterns. The evidence presented as informing this decision is scanty and poor quality. There are issues of compliance and health/digital inequality here, but actually future research needs to focus on reducing these through utilising technology and making home diagnosis and monitoring easier for patients, not taking it out of the guideline. Furthermore, in primary care this is often the only test available with limited access to fractional exhaled nitric oxide (FeNO), spirometry and provocation testing – without it, the only easily available objective test is blood eosinophil count and using this will miss those with non-eosinophilic asthma. And it's the most applicable to children.	
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	005	000	**Objective tests for diagnosing asthma** This focuses on diagnosing patients with atopic/eosinophilic T2-high asthma. What about those with T2-low asthma? No mention of the 2 main asthma phenotypes.	Thank you for your comment. This section does not focus on atopic/eosinophilic asthma although it does recognise that this is common, and that the

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					presence of features associated with atopy can be utilised to help in a diagnosis of asthma.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	005	000	**Objective tests for diagnosing asthma** With the incorporation of eosinophils as a diagnostic tool, there needs to be more advice over when this is/isn't appropriate including the possibility of positives which may not be asthma e.g. other inflammatory disease.	Thank you for your comment. All tests are imperfect to some degree. A brief summary of other reasons for an elevated eosinophil count is now given in the guideline.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	005	000	**Objective tests for diagnosing asthma** Diagnosis has challenges in terms of access to tests (is eosinophil evidence really as good as fractional exhaled nitric oxide (FeNO) in general population). It is very clear from the literature that peripheral eosinophilia is consistent in the Type 2 inflammation but may occur in the absence of pulmonary eosinophilia (as suggested by elevated FeNO) but that the two taken together is an often-greater indication of inflammation- glad to see downgrading of spirometry. It should be remembered that both FeNO and peripheral eosinophil counts may vary over time. Spirometry is frequently performed when the patient is asymptomatic, well controlled	Thank you for your comment. The committee concur with most of these comments and agree that all the available tests have some disadvantages. However, although they are not exactly the same there is a correlation between FeNO and eosinophil results and it is therefore suggested that one or the other is performed, not both. The committee agree that the ideal situation would be to have FeNO available on site to reduce the need for multiple visits, but at present more practices are able to measure eosinophils than FeNO.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				providing a negative result. The impact of testing across UK will be varied - and are we now looking to do blood test on any patient with asthma symptoms (remember many think normal) before appointment (cost implications for NHS and patients) or sending them off and bringing back (3 appointments) rather than doing fractional exhaled nitric oxide (FeNO) at the time.	
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	005	021	**Objective tests for diagnosing asthma in adults, young people and children aged 5 - 16** Section 1.2.1 diagnosing asthma if eosinophil count is above the reference range. I would consider that a suggestive clinical history together with an eosinophil count greater than or equal to 0.4 would be sufficient for diagnosis of asthma. It may also not be necessary to repeat the eosinophil count if there are previous records indicating higher eosinophil levels, along with a suggestive history currently.	Thank you for your comment. This is an interesting point, and the committee is inclined to agree with you providing the historical records are sufficient to exclude any other cause for an elevated eosinophil count at the time the blood was taken.
Primary Care Respiratory	Guideline	005	021	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16)**	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Society-UK (PCRS-UK)]				Given the statement on line 2 (1.1.4) that a person may still have asthma despite having normal tests – it is illogical that not one of the recommendations for diagnosing asthma state that the person may still in fact have asthma. This was proved so eloquently in the NICE feasibility study where less than 30% of those diagnosed with asthma had abnormal spirometry. So, these statements all need to have an addendum stating clearly that if the clinical history is suggestive of asthma and all tests are normal or unavailable, the person should be referred to an asthma specialist. Given that line 7 page 5 (1.1.5) has been amended in 2024 to include (or peak flow with 9 bronchodilator reversibility) if the equipment is available. **[NICE 2017,** 10 **amended 2024]"** See above comment (comment 22) re the inclusion of peak expiratory flow (PEF) in this guideline.	The diagnostic sequencing clearly recognises that asthma may still be present despite normal test results since further testing is recommended after negative results. The final test suggested is a bronchial challenge test which is highly sensitive. Practically speaking, at present this will require referral as you suggest

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	005	022	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Adults)** Rec 1.2.1 - vague with eosinophil count, reference ranges differ significantly in different trusts.	Thank you for your comment. It is precisely because the laboratory range varies that the committee have not given a single value for an abnormal eosinophil count. The committee agrees that other conditions may cause the eosinophil count to be raised, but there are potential confounding factors with most diagnostic tests.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	005	022	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Adults)** Is the recommendation that diagnosis of asthma can be made with appropriate symptoms and eosinophil count of 0.3 (low to very low-quality evidence) without any objective test for airflow variation? This may lead to many patients with cough and slightly raised eosinophils being diagnosed with asthma in primary care. If eosinophils are normal, is the recommendation to also check fractional exhaled nitric oxide (FeNO)? If not, is the guideline suggesting that the 2 tests are equivalent?	Thank you for your comment. It is true that there can be a long wait for some diagnostic tests at present, and optimal implementation of this guideline requires increased resource. However, the wait for some tests is not long at all – eosinophil counts can be obtained quickly. Recommendation 1.7.2 explains that treatment should be started if symptoms necessitate this. The committee acknowledge that there will be some people with borderline test results in whom clinical judgement will need to be

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					exercised. No guideline (for any condition) can cover all possible individual variations. The guideline should not lead to people with cough and a raised eosinophil count being incorrectly diagnosed with asthma. The recommendations are for people with a history suggestive of asthma, and an isolated cough should not suggest asthma (particularly in adults) unless it has unusual features such as marked variability. Recommendation 1.2.1 clearly states that either FeNO or eosinophil count should be measured, not both. The 2 measures correlate well but are not identical.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	005	022	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Adults)** Assuming the GP has access to fractional exhaled nitric oxide (FeNO) and the test is negative. The recommendation does not provide any guidance for a non-specialist doctor (or in the UK a PA, NA or HCA delegated to care for people with asthma) on repeating the test –	Thank you for your comment. The guideline clearly states that if diagnosis is not confirmed after measuring FeNO or eosinophil count, proceed to measure BDR (recommendation 1.2.2). The committee agrees that other conditions may cause the eosinophil count to be raised,

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				because there may be a number of reasons for the normal test (including being on treatment, having a good day without any inflammation). The guideline should explain further steps in more detail – follow up with more test(s)/ stop treatment for a while then test etc) Raised Eosinophils may be due to other causes (strongyloides/ other parasites etc) a) suggesting asthma should be confirmed may result in someone with a paracytic infection being treated with high dose inhaled corticosteroid (ICS) with adverse consequences; and b) What if there was a raised eosinophil count 4 months before the presentation with symptoms suggestive of asthma (which is the criterion listed later in the guideline).	but there are potential confounding factors with most diagnostic tests. Using a historic eosinophil is potentially useful as long as the clinician can be confident that they can assess whether or not there were confounding factors present when the blood was taken.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	005	026	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Adults)** Why is peak flow (PEF) reversibility acceptable for patients with acute symptoms (section 1.1.5) but not as routine? Objective test loses its power	Thank you for your comment. The PEF reversibility referred to in 1.1.5 is an opportunistic single measurement of reversibility

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				in the patient with no symptoms/well controlled/adequately treated. Ranked 3rd most cost effectiveness strategy in evidence and 80% specificity. Why not use this in primary care when bronchial hyper-responsiveness (BDR) and bronchial challenge testing are not easily available?	in an acutely unwell person, not PEF variability derived from serial PEF measurements.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	005	026	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Adults)** Bronchial hyper-responsiveness (BDR) and fractional exhaled nitric oxide (FeNO) are a snapshot in the natural history of asthma. If the patient is well, these tests may not be positive. Currently availability of either test in primary care is very patchy in England. Peak flow is universally available in primary care and PEF and/or reversibility measured over time in primary care, especially testing the patient when symptomatic. This acknowledges the variable nature of the disease over time and cheap (ranked 3rd in cost-effectiveness in adults).	Thank you for your comment. Your comments on the "snapshot" nature of most tests for asthma is correct. However, measuring PEF variability is also problematic as it has been shown to be highly insensitive. Nonetheless, numerous stakeholders have pointed out its advantages and it has now been added to the diagnosis sections.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	005	026	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Adults)** Peak Expiratory Flow (PEF) must be included as one of the objective tests for confirming bronchodilator. General Practitioners in the UK do not all have access to the objective tests recommended in this update or if they do, there may be very long waits for those tests, and furthermore, these may be done on a day when the patients' asthma is controlled and will then be negative. Failure to recognize this practical issue will result in many patients being treated with inhalers, without a diagnosis (or provisional diagnosis) and therefore without any education, or opportunities for asthma reviews or the ability to communicate with emergency staff when they or their child is having an asthma attack without a previous diagnosis.	Thank you for your comment. There are numerous comments extolling the virtue of serial PEF measurements and the test has now been added to the diagnosis section.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	006	001	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16)**	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Test for bronchial hyper-responsiveness (BDR) not generally available in primary care and limited in secondary care due to lack of methacholine for testing. As some patients in primary care may not have raised fractional exhaled nitric oxide (FeNO)/BDR or raised eosinophils, or testing not available, this might increase pressure on secondary care and increase costs of diagnosing asthma. Also, will delay diagnosis of patients in primary care.	The committee acknowledges this. It is however the best single test for asthma and it would be remiss not to include it, albeit at the end of the testing sequence.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	006	001	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16)** This assumes access to the test is available. This is impractical in the UK at present and to insist on objective tests that are not or may not be available puts patients at risk of being treated without a diagnosis and access to appropriate self-management education. There is a recommendation missing – if 1.2.1; 1.2.2; 1.2.3 are not available or normal despite a history suggestive of asthma – start empiric treatment with antiasthma medication (i.e.	Thank you for your comment. Please note that this is a guideline. It does not insist on anything. The difficulty in getting a bronchial challenge test is acknowledged, but it is the best single test for asthma and it would be remiss not to include it. PEF variability has now been added to the diagnosis section. This therefore now includes 2 readily available tests. If both these are normal the committee does not wish to recommend empiric treatment; this may be appropriate for

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				inhaled corticosteroids (ICS)) and refer to specialist respiratory service.	some people depending on symptoms, but not necessary for everyone.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	006	004	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16)** The guidance does not cover children who are unable to perform tests or have blood tests done. Would this mean we should refer all children to secondary care for assessment for suspected asthma and not consider trial of treatment. The cohort of patients this may impact are those with learning disabilities (LD) or children with autism. The Guideline makes no mention of impulse oscillometry which is easy to use in those who are unable to develop a respiratory effort to perform with PEF or spirometry.	Thank you for your comment All guidelines offer advice on the best management options for the majority of people with the relevant condition, but the applicability of any recommendation to an individual needs consideration of personal factors, usually comorbidity. If a child, for any reason, cannot perform any of the tests the responsible clinician will have to make a judgement on the best course of action for that individual child. Impulse oscillometry is an interesting test, but it was not included in the scope of this guideline so recommendations cannot be made. We will suggest it to our surveillance team for possible inclusion in future versions.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	006	005	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16)** Recent ERS published guidance for diagnosis in this age group: ERJ 2021;58:2004173 (Gaillard et al) have been widely accepted across Europe found that a fractional exhaled nitric oxide (FeNO) level of 25 ppb was more sensitive to detect asthma in children, compared to a higher threshold of 35pp. Fractional exhaled nitric oxide (FeNO) levels will also be higher in children with allergic rhinitis, eczema and atopy anyway.	Thank you for your comment Any cut-off value for FeNO is a compromise between sensitivity and specificity. As FeNO is the first test recommended, and may therefore be the only test done, the committee agreed that it would be better to set the cut-off level at a higher, more specific value. Asthma will not be excluded (the child with lower FeNO will proceed to other tests) but a positive diagnosis will be more secure.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	006	005	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16)** Same comments as above apply to children 5-16, especially the availability of spirometry as most association for respiratory technology and physiotherapy (ARTP) trained staff in primary care are for adults.	Thank you for your comment The committee acknowledge that access to spirometry for children is limited in many areas. Assessment of airflow obstruction has been part of previous guidelines (NICE and BTS/SIGN) which is testament to its potential value in diagnosis, and it is regrettable that access has not improved.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	006	007	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16)** Bronchodilator responsiveness (BDR) with spirometry in children as second choice if fractional exhaled nitric oxide (FeNO) not conclusive. How realistic is this in primary care? Very rarely happens currently. Therefore, potential delay in treatment unless chose to commence treatment without confirmation in which case will obstruction/ BDR still be conclusive?	Thank you for your comment The difficulty of arranging assessment of BDR relates to the difficulty in arranging spirometry in children. The committee acknowledge that access is limited in many areas. Assessment of airflow obstruction has been part of previous guidelines (NICE and BTS/SIGN) which is testament to its potential value in diagnosis, and it is regrettable that access has not improved. Measurement of PEF variability has now been added to the diagnosis section.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	006	007	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16)** There are many different guidelines on the interpretation of spirometry. ERS/ATS technical standard on interpretive strategies for routine lung function tests' (ERJ 2022;60:2101499) suggest that Bronchodilator responsiveness (BDR) be primarily classified as 'a change of >10% relative to the predictive value of FEV1 **or FVC.'** This is a more sensitive measure and a	Thank you for your comment This is an unfamiliar metric to many, and the committee prefer to stick with FEV1 changes rather than adding the option of using FVC.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				simple example of how to do the maths could be included.	
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	006	007	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16)** We assume this means with either spirometry or PEF. Could this be more explicitly stated given the amended statement lines 9/10 page 5.	Thank you for your comment The words "with spirometry" have been added.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	006	010	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16)** Skin prick testing is impractical, not available in primary care and very few clinics in secondary care provide it and in any case is not diagnostic. In addition, as quoted by yourself in the consultation documents: *"Quality of the evidence was **very low across studies** as it was downgraded for risk of bias, most frequently due to concerns surrounding the method of participant selection or a* *lack of clarity over blinding of the index test and reference standard results. Indirectness was*	Thank you for your comment Skin prick testing is only one option given in recommendation 1.2.6 and the committee feel it is important to include it as a means of avoiding a blood test in a child who is reluctant to have this. The lines you quote regarding evidence quality are correct, but the GRADE criteria are stringent and many NICE reviews (not just in asthma) produce low or very low quality evidence. The sentence on clinical effectiveness is taken out of context; it applies to test and treat studies, not to tests of diagnostic accuracy.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				also present in all evidence due to not reporting the ICS use of participants prior to the study. Less frequently occurring was the inclusion of participants <5 years of age, a lack of clarity over the definition of asthma, and the inclusion of allergens not specified in this review protocol, all of which led to further downgrading for indirectness." ***"No relevant clinical studies were identified comparing the clinical effectiveness of diagnosis of asthma based on skin prick tests for any of the allergens specified in the review protocol"*** Should this therefore be reconsidered as a diagnostic tool?	
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	006	010	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16)** Is it worth adding 'or other allergens relevant to the patient' to include e.g. moulds, foods, horse, cat or dog dander if the patients have these	Thank you for your comment These other allergens may be of interest in an individual person with suspected asthma, but in terms of a general recommendation it is house

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				pets, or pollens (tree, grass) if asthma symptoms only in hay fever season?	dust mite sensitivity which is most likely to be of help in diagnosis.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	006	010	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16)** These tests are not available in Primary care except in specialist GP allergy practices and a history suggestive of allergies especially food allergy in someone with a clinical history suggestive of asthma should result in referral to an allergy specialist – however with waits of 6-18 months to be seen. Should the guidance state to treat for asthma until the diagnosis can be confirmed?	Thank you for your comment Skin prick tests are only one option in recommendation 1.2.6. IgE and eosinophil counts are available within a much shorter time frame.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	006	012	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16)** The evidence used to inform a recommendation in using total allergen-specific immunoglobulin (IgE) as a diagnostic tool for Asthma is very low quality and there is little heterogeneity in the population of the patients in the studies. No international documents recommend the use of	Thank you for your comment The GRADE criteria are stringent, and many NICE reviews (not just in asthma) produce low or very low quality evidence as judged by this standard. Other guidelines have focused on measures of airflow obstruction and variability of this, but the committee believe that this does not give due account to the strong relationship

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				such tests as part of the diagnostic criteria/work up for asthma. It is strongly advised that this is reviewed and await further studies on a wider population at primary care level to determine the specificity and sensitivity of the test.	between atopy and asthma, particularly in childhood, which can be used to help strengthen or refute a diagnosis of asthma.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	006	016	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16)** What if the allergen-specific immunoglobulin (IgE) is normal but blood eosinophils are raised does that diagnose asthma or not? There are currently no clear cut off ranges to work from and this is all dependent on local lab cut offs. Is there a standard we should be aware off or range as a reference? What if the results are borderline, does the diagnosis get missed or delayed?	Thank you for your comment If the results of the allergy tests disagree then recommendation 1.2.8 has not helped in the diagnosis. The fact that it won't help in every case is not a reason to discard it. It would indeed be easier if every laboratory used exactly the same techniques and produced the same normal ranges. They don't, and all we can say is that a result is high if it is high by the testing laboratory's standard.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	006	017	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16)** Bronchial Challenge testing is not readily available in most secondary and tertiary settings for paediatric respiratory medicine.	Thank you for your comment The evidence shows that bronchial challenge is the best single test for asthma and the committee believe it should be included, albeit

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				A monitored 8-week trial of treatment can still be useful to detect asthma in school children and is a familiar process for both primary and secondary care. If symptoms improve with treatment but reoccur after stopping treatment this can be used to support a diagnosis of asthma. Potentially spirometry testing could be revisited later if unavailable. Spirometry, fractional exhaled nitric oxide (FeNO) testing and skin prick testing isn't widely available in primary care and will need resource and funding. Spirometry and diagnostic hubs have not been set up in our area to include children, and the NHS Trusts do not have additional capacity to test these children. We also do not want to delay a possible start of treatment in a symptomatic child, who could potentially have a life-threatening asthma attack while waiting for tests.	at the end of the testing pathway when other investigations have not been conclusive.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	006	018	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16)** In relation to spirometry in children and young adults aged 5-16yrs. Please consider study by *Fillard et al (2023) Sensitivity of FEV1 and*	Thank you for your comment. Fillard 2023 was identified and considered for inclusion in Evidence review B on bronchodilator responses. It was excluded

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Clinical Parameters in Children with Suspected Asthma Diagnosis. Jn Allergy Clin Immun: In practice [online]. 11(1), pp. 238-247 Highlights consideration of lowering diagnostic bronchodilator responsiveness (BDR) diagnostic threshold in children. The current spirometric 12% FEV1 reversibility criteria is of limited value in paediatric asthma diagnosis – demonstrated through sensitivity and specificity. UK multicentre study – concern is that some children may be underdiagnosed if remaining with 12% bronchodilator responsiveness (BDR) reversibility.	because the population was not relevant to the review protocol (all participants had asthma rather than suspected asthma).
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	007	001	**Diagnosing asthma in children under 5** This is a very grey area where children may be over-and underdiagnosed, not receive the appropriate treatment and are at a higher risk of attending A&E. If children have intermittent wheeze outside of viral infections and have a clear atopic history with family history (FHx) then diagnosis could be made clinically, and treatment should not be delayed. There are high-risk children in this group which will fall through the cracks and will be inappropriately over prescribed antibiotics/oral corticosteroids	Thank-you for your comment The committee agrees, both that this is difficult and with your concerns. The diagnosis at this age does indeed need to made clinically, including a careful assessment of the response to empirical treatment, and that is what the guideline describes in section 1.9 to which recommendations 1.3.1 refers the reader. Section 1.9 recognises the potential problems of both over and under-diagnosis.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				when seeing out of hours (OOH), A&E and even GPs.	
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	007	001	**Diagnosis asthma in children under 5** The proposed wording in this area is vague, for example 'treat symptoms according to clinical judgement'. Although we appreciate a link is then given to the management section for inhaled steroids, 'clinical judgement' could mean that they are given beta-2 agonists for the symptoms of wheeze, but not inhaled corticosteroids (ICS) and a diagnosis of asthma could be delayed with dangerous consequences. Could this wording be replaced with something more explicit to ensure that the guidance in this area is clear and emphasises the fact that if you think it's asthma, they should be on a inhaled corticosteroid (ICS) – for example 'A diagnosis of asthma in Under 5's is based on a characteristic history and exam and positive trial of inhaled steroids (see section .....)..'	Thank you for your comment There is a very clear signpost to the treatment section. However, the committee agrees that it would be better to also add the words "with inhaled corticosteroids" to 1.3.1 and this has been done.
Primary Care Respiratory	Guideline	007	002	**Diagnosis asthma in children under 5** A serious omission in this section is the fact that 'wheeze' is diagnosed in many of these children.	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Society-UK (PCRS-UK)]				Wheeze is a symptom and not a diagnosis and this practice needs amendment to reduce the numbers of children put at risk by failure to use the diagnostic term asthma or possible asthma and therefore to treat them appropriately. There really needs to be practical advice to deal with this known problem – where diagnosis is not made despite repeated attendances at ED or admissions with 'wheeze' 'viral wheeze' 'acute wheeze' The lack of evidence should not prevent a practical recommendation in this guideline for e.g.: Any child presenting with wheezing twice or more in ED, GP, or admitted in a year should be diagnosed with 'possible asthma' provisionally and referred to a paediatric respiratory specialist.	Recommendation 1.1.2 says that people should be coded as having suspected asthma. The final sentence that you suggest has been added to the guideline.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	007	010	**Diagnosis asthma in children under 5** This is unclear – what diagnosis should be entered in the record? What should the parents be told? Without a diagnosis or provisional diagnosis of asthma – the child will be denied reviews, self-management education, and the parents will not	Thank you for your comment. Recommendation 1.3.2 is a companion to the immediately preceding 1.3.1 which states that a child with suspected asthma under the age of 5 should be treated empirically. Recommendation

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				know how to manage severe attacks or what to say to emergency crews when trying to get assistance.	1.1.2 now states that people with suspected asthma should be coded as suspected asthma. All the information to parents, review arrangements etc should already be in place because suspected asthma is being treated in accordance with 1.3.1.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	008	013	**Monitoring asthma control** This is a missed opportunity to identify risk in a timely manner. Simply counting how many inhalers or attacks once a year is too late. Dynamic identification of those at risk could reduce preventable admissions and emergency attendances. A practical approach is available by adapting and following the recommendations made by the NRAD in 2014. All GP practices/ A&E departments are computerised in the UK. As was recommended in the NRAD (RCP 2014) – computer systems should include a national template for asthma which could be used / programmed to identify risk by raising alerts when excess short-acting beta agonists (SABA) is prescribed (≥3 a year); and once 2 attacks a year have occurred. NRAD	Thank you for your comment Recommendation 1.5.1 does not say that this should be done once a year, but at every review. Section 1.5 is about what should be monitored regularly. Actions which should follow are covered further on. Specifically, active identification of SABA overuse is in section 1.15.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				recommended that anyone having 2 or more attacks in a year should be referred to an asthma specialist (asthma trained GP or Nurse, sec care doctor or respiratory nurse).	
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	008	019	**Monitoring asthma control** The current use of asthma management plans is often based around peak flow (PEF) as a percent of predicted or best preferably combined with a deterioration of symptoms (Cochrane) Is this to be abandoned?	Thank you for your comment The evidence (Evidence Review M) did not show any benefit of regular PEF monitoring. The committee is not sure which Cochrane review you are referring to and is not aware of one which contradicts this conclusion. Some people (not all) benefit from use of PEF levels as part of their personalised action plan. This was already acknowledged in the guideline but has now also been made explicit in recommendation 1.5.3.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	008	025	**Monitoring asthma control** The large trial on monitoring fractional exhaled nitric oxide (FeNO) for asthma control (DEFINE) has just met target recruitment so this is likely to have results in due course, although not before guideline publication.	Thank you for your comment. Most of the time FeNO monitoring is useful in that a high level indicates the more anti-inflammatory therapy is needed (either because the person is not taking the treatment already prescribed or because the dose needs to be

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Blood eosinophil counts have not been mentioned but do also seem to predict poor control (particularly those who will not respond to inhaled therapy/don't necessarily have a very high fractional exhaled nitric oxide (FeNO) so we would also add blood eosinophils here as a way of monitoring. Can a comment be made on what to do on those patients (asthma or no asthma) who have very high eosinophils/ fractional exhaled nitric oxide (FeNO) +- lung function abnormalities – should we be testing and treating these patients to reduce their levels? There is undoubtedly a cohort of patients with high levels of inflammation which doesn't correlate well with symptom burden but may be causing longer term irreversible lung damage and put them at risk of unexpected sudden severe asthma attacks. This could be discussed with the patient that there is limited evidence so far in this area but to treat high biomarkers even when relatively asymptomatic. Also please be aware that both high doses of inhaled corticosteroids and/or use of oral steroids may depress the level of eosinophils.	increased). The committee agree that occasionally high FeNO levels appear to be out of proportion to symptom or lung function findings. A systematic search on this was not part of our scope, and in any case it is likely that further research is needed on how to manage this, so it is not possible to make evidence-based recommendations.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	008	025	**Monitoring asthma control** There is not good evidence that fractional exhaled nitric oxide (FeNO) monitoring in children with asthma is likely to improve outcomes. The 2016 cochrane review was based on 3 small studies, whereas larger studies (Szefler 2008 and Pike 2013) were negative. Also, Steve Turner's 2022 Lancet Respir Medicine 10(6):584-592 UK study recruiting 535 children did not reduce asthma exacerbations compared to symptom guided asthma treatment. We would advocate applying paediatric UK trial evidence to the UK paediatric population, rather than adult research evidence. The use of fractional exhaled nitric oxide (FeNO) is costly and may only be useful to staff with effective training and skills. It has not been widely implemented because of this in primary care. fractional exhaled nitric oxide (FeNO) may lead to the overuse of high dose inhaled steroids and other treatments, which may lead to adverse effects. There is strong evidence that low dose inhaled corticosteroids (ICS) is highly effective in paediatric asthma treatment.	Thank you for your comment. Several stakeholders have raised a similar point. The UK study you cite was negative, but overall, the studies show a slight benefit, albeit that increased ICS doses were required to achieve this. It is true however, that FeNO monitoring in children was less cost-effective than in adults. The recommendation has been reviewed and the committee have decided it should be limited to adults.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	009	000	**Principles of pharmacological treatment** **Patient feedback** From a patient perspective I would prefer to emphasise the use of spacers equally for all metered dose inhalers in **all patients**. While I understand that they are particularly relevant to children with asthma, they are still important for adults using meter dosed inhalers and I am concerned that by emphasizing their greater relative importance in children it implies they are not important in adults. The message is also simplified if the requirement is for all patients to use them. PCRS comment: It should be recommended that spacers should be used in any metered dose inhalers.	Thank you for your comment. Neither the latest BTS/SIGN guideline nor the NICE guideline recommended that adults should always use an MDI via a spacer, and this topic was not prioritised for evidence review during scoping. It is therefore difficult to make a firm recommendation.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	009	000	**Principles of pharmacological treatment** Focus is mainly on steroid responsive T2-high phenotype of asthma, but no mention is made of management of T2-low asthma and how treatment can be different (nor of specific co-morbidities associated with T2-low asthma and management of these can improve asthma control).	Thank you for your comment. The treatment sections offer general advice, which is for all asthma sub-types, not just T2-high asthma. It is true however that co-morbidities which might affect different sub-groups are not mentioned. This is because this issue was not prioritised during scoping. If you

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					feel it is sufficiently important you may wish to suggest that it is part of the next update of this guideline.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	009	016	**Principles of pharmacological treatment** Managing Gastro-oesophageal reflux disease (GORD), Allergic rhinitis – These are very important conditions to manage to control asthma and should be considered for inclusion in this list.	Thank you for your comment. To be pedantic, they need managing to control the symptoms they cause which may be mistaken as being due to asthma, not to control asthma itself. Several stakeholders have suggested additions which might be made to this bullet point, and on reflection the committee have agreed that no examples are necessary, the meaning of the recommendation being clear without them.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	009	019	**Principles of pharmacological treatment** In addition to example of obesity also include: - rhinitis / hay fever, - gastroesophageal reflux - Chronic obstructive pulmonary disease (COPD) - Breathing pattern disorder (BDP). as prompts in this list.	Thank you for your comment. Several stakeholders have suggested additions which might be made to this bullet point, and on reflection the committee have agreed that no examples are necessary, the meaning of the recommendation being clear without them.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				No mention of alternative causes or differential diagnosis. BPD underdiagnosed and needs to be considered.	
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	009	021	**Principles of pharmacological treatment** **It is important to note that the use of mixed devices (MDI and DPI) is highly associated with poor asthma control and 25% increase in exacerbation rate.** State the importance of spacers, particularly in the young, and ensure this emphasizes the need for them to be using the correct spacer, in the correct size. This will avoid school aged children remaining on baby spacers with masks because this has not been routinely assessed during asthma reviews. In addition, some clear guidance on when it is appropriate for a child to move from a mask to a mouthpiece spacer is needed. Very often children of 8+ continue to use masks which is inappropriate pharmacological management of their asthma.	Thank you for your comment. Recommendations 1.6.5 to 1.6.9 give advice on inhalers with the intention of ensuring that the correct devices are used and that this is periodically reviewed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	010	006	**Principles of pharmacological treatment** Be more explicit regarding writing housing letters with a link to a template, otherwise this can be easily missed. Does say "try to address" (line 16, page 9), but this could be more explicit.	Thank you for your comment. Recommendation 1.6.1 is concerned with prompting readers to consider these factors rather than detail about recording them or managing them.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	010	008	**Principles of pharmacological treatment** Needs more clarity of using short-acting beta agonists (SABA) in the pre-school wheeze age group where inhaled corticosteroids (ICS) are not required. This might be helpful and has been developed nationally: (beatasthma.co.uk/wp-content/uploads/2024/05/clinicians-information-BA-FINAL.pdf)	Thank you for your comment. The committee is sympathetic to the point you make, but this recommendation clearly states that it applies to people with asthma and is therefore valid. We recognise that it can be difficult to distinguish from other wheezing illnesses, particularly in the very young, hence the series of recommendation describing a trial of inhaled steroids in this age group.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	010	015	**Principles of pharmacological treatment (Inhalers)** Patient preference is important for adherence. We suggest a change to the order of the items to: • an assessment of correct technique • the preference of the person receiving the treatment	Thank you for your comment. The order of bullets is not supposed to reflect importance. However, as several stakeholders have requested this, it has been altered.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				• the lowest environmental impact among suitable devices Ref : Plaza V, Giner J, Calle M, Rytila P, Campo Ribo P, Valero A. Impact of patient satisfaction wit or her inhaler on adherence and asthma control. A Asthma Proc. 2018;39(6):437-44.	
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	010	016	**Principles of pharmacological treatment (Inhalers)** 'By an appropriately trained clinician' should be added, as well as signposting to approved videos to support this e.g. Asthma and Lung UK. https://www.asthmaandlung.org.uk/living-with/inhaler-videos	Thank you for your comment. All the recommendations in the guideline should be carried out by an appropriately trained person. The committee understand why you are suggesting emphasising it in this section but it is a general principle which applies across NICE guidance and is therefore also adopted by this BTS/NICE/SIGN guidance.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	010	017	**Principles of pharmacological treatment (Inhalers)** We would strongly recommend including gCO2Eq data for recommended inhalers.	Thank you for your comment. This would cause difficulty as the guideline will not be updated for a period of time and could therefore not provide information on new

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					inhalers (which would be unfair to them) or to any change to current inhalers.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	011	015	**Principles of pharmacological treatment (Inhalers)** In our experience, children can effectively use dry powder device (DPI) to control their asthma. There is a lack of evidence in using short-acting beta agonists (SABA) as a dry powder inhaler (DPI) in children, so we would advise children should be prescribed a meter-dosed inhaler (MDI) and spacer for breakthrough symptoms.	Thank you for your comment. Several stakeholders have raised this issue and 1.6.8 in the draft guideline has been amended.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	011	021	**Principles of pharmacological treatment (Inhalers)** Consider limiting the recommendation for the use of digital inhalers in children to those patients in specialist centres in whom biologic therapy is being considered. These devices are expensive and may lead to the negative healthcare experience for the patient and carer, if there are suspicions, they are not using the inhalers appropriately.	Thank you for your comment. The committee has reconsidered this recommendation, and it has been changed.
Primary Care Respiratory	Guideline	012	Section 1.7	**Pharmacological management in people aged 12 and over**	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Society-UK (PCRS-UK)]				Overall, from a management perspective it is great to see the incorporation of AIR and MART and a very clear statement in the document regarding no one being treated with SABA alone. However, this appears to have been made a one size fits all approach which does not align with the global initiative for asthma (GINA) recommendation that an alternative pathway be considered where necessary (although we note that a non-MART pathway has been suggested for children of 5-11 (page 16)). It is important to ensure that the right treatment is targeted to the right patient irrespective of their age, rather than a stepwise approach regardless – which is what there is currently. Should all patients be initiated on inhaled corticosteroids (ICS) even in the absence of evidence of steroid-responsive inflammation in a raised fractional exhaled nitric oxide (FeNO)/eosinophil count? Even with the limited evidence in this area, it would be helpful to give flexibility to the clinician to prioritise the non-ICS-based management options. Specifically (page 13, section 1.7.4) stepping up to moderate dose maintenance and reliever therapy (MART) in a	The committee believes that the evidence in adults strongly favours the AIR then MART strategy over the traditional treatment pathway and have therefore recommended this. The remit of NICE and therefore of this BTS/NICE/SIGN guideline is to offer guidance on the most cost-effective management strategy. Your comment regarding varying the approach depending on factors such as FeNO or eosinophil count is interesting and was debated by the committee. Although there are logical reasons to justify this, the studies of treatment escalation were mostly not performed with knowledge of FeNO or eosinophil measurements so evidence-based recommendations would not be easy to support. The limited availability of FeNO is also an issue and, although the committee hopes that this will improve, on balance it was felt that it would not help most users of the guideline if inflammatory markers were included within the treatment escalation recommendations.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				patient with low eosinophils and fractional exhaled nitric oxide (FeNO) before moving to long-acting muscarinic antagonists (LAMA)/leukotriene receptor antagonists (LTRA) seems inappropriate. Patient choice also needs to be a factor here. https://ginasthma.org/2023-gina-main-report/	
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	012	Section 1.7	**Pharmacological management in people aged 12 and over** At the moment, there is a strong focus on symptoms but no mention of how much to manage the biomarker-high symptom-free/low patients. Is it worth adding that in some patients' disease activity may not correlate well with symptoms and biomarkers levels should be taken into account when stepping up or down treatment (linking in with monitoring section above).	Thank you for your comment Please see immediately preceding response. The committee felt on balance that it would not help most users of the guideline if inflammatory markers were included within the treatment escalation recommendations
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	013	11	**Pharmacological management in people aged 12 and over** There is no evidence that it reduces asthma attacks. Three months is a long trial of treatment during which a patient with poorly controlled symptoms will be at continued risk of acute	Thank you for your comment The period of time has been adjusted to 8-12 weeks to be consistent with recommendation 1.6.3. A shorter trial has the disadvantage of

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				severe asthma attacks plus potentially serious side effects. We would suggest a shorter trial period for children.	being more open to misinterpretation given that asthma is naturally a variable disease. Shorter periods are also less likely to allow evaluation of exacerbation reduction.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	013	13-17	**Pharmacological management in people aged 12 and over** The UK guidelines have always said that someone on 3 or more asthma medications is at risk of a life-threatening attack. By this stage the person is already on 3 drugs – surely the recommendation should be to refer the person to an asthma specialist rather than wait another 3 months on a $4^{th}/5^{th}$ drug (if short-acting beta agonists (SABA) is also prescribed in addition to the maintenance and reliever therapy (MART) & Leukotriene Receptor Antagonists (LTRA))	Thank you for your comment Previous guidelines have pointed out that being on 3 or more different medications is one of many risk factors for life-threatening attacks but did not proceed to recommend that anyone on this amount of treatment had to see a specialist. Although the guideline says that referral should be made after trials of the agents in 1.7.7 have proved inadequate, there is nothing to stop an earlier referral if it is agreed that this might be beneficial. In addition, recommendations 1.7.6 and 1.7.7 have been amended in response to stakeholder comments, and the possibility of an earlier referral is now included.
Primary Care Respiratory	Guideline	015		**Pharmacological management in children 5-11**	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Society-UK (PCRS-UK)]				Stepping down treatment if well controlled does not seem to be mentioned in children aged 5-11 – is this a deliberate omission?	Stepping down is covered in section 1.10. The recommendations there are for children and adults.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	015	003	**Pharmacological management in children 5-11** Acknowledging the lack of evidence (yet) and need for research evidence, given the benefit and simplicity in adults we would advocate giving initiation of maintenance and reliever therapy (MART) as an initial option in children. Anti-inflammatory reliever (AIR)/prn salbutamol is also not mentioned here, even as a research recommendation, and it would be worth clarifying this. With regards to ability to use, why can children not be given maintenance and reliever therapy (MART) as meter-dosed inhaler (MDI) to use with a spacer if concerns about technique or ability to manage dry powder inhalers (DPI) when unwell?	Thank you for your comment The committee are sympathetic to your suggestion. However, there is no evidence on AIR in children, and although there is some evidence on MART the treatment is not licensed for those aged 5-11. This was discussed at some length by the committee before settling on the current recommendations.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	015	008	**Pharmacological management in children 5-11**	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Consider adding that spacers should always be used with a pressurised meter-dosed inhaler (pMDi) as per recent BTS statement https://www.brit-thoracic.org.uk/news/2024/bts-launches-its-new-position-statement-on-sustainability-and-the-environment-climate-change-and-lung-health/.	Inhaler device recommendations are in section 1.6.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	015	010	**Pharmacological management in children 5-11** It is well understood that spacers improve the delivery of medication, drug deposition in the lungs and reduce side effects when used with meter-dosed inhalers (MDI's). This should be highlighted if pressurised meter-dosed inhalers (pMDI)'s are prescribed for patients.	Thank you for your comment Inhaler device choice is covered in section 1.6.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	015	010	**Pharmacological management in children 5-11** We would urge caution when using the Symbicort meter-dosed inhaler (MDI). Unlike the Turbohaler where there is good evidence for maintenance and reliever therapy (MART), there is no such research for the meter-dosed inhaler (MDI). The licenced doses for the meter-dosed inhaler (MDI) in those aged 12+ are very high	Thank you for your comment There is data on MART in children in the public domain (evidence review Q). The footnote to 1.8.2 now states that the evidence for MART in children is based on use of a DPI.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and there is a danger that such high doses will be used in younger children.	
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	016	022	**Pharmacological management in children 5-11** Add that spacers should always be used with a pressurised meter-dosed inhaler (pMDI) as per recent BTS statement https://www.brit-thoracic.org.uk/news/2024/bts-launches-its-new-position-statement-on-sustainability-and-the-environment-climate-change-and-lung-health/.	Thank you for your comment Inhaler device recommendations are in section 1.6.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	017	012	**Medicines for management in children under 5** A symptom diary should be used to track use of shorting acting beta2-agonists (SABA) and symptoms where appropriate, which can help aid diagnosis.	Thank you for your comment The recommendation does not preclude use of a symptom diary if this helps.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	017	017	**Medicines for management in children under 5** Current BTS guidelines found no evidence that pet removal improved outcomes.	Thank you for your comment The reference to pets has been removed

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				This intervention is unlikely to be of benefit and especially if a much-loved pet is wrongly implicated as the cause of continuing symptoms. Please consider the evidence of antenatal/post-natal stress and wheeze in childhood. Providing supportive care to address this should be emphasized.	The role of ante or post-natal stress is outside the scope for this update
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	018	000	**Decreasing maintenance therapy** Mention role of fractional exhaled nitric oxide (FeNO)/blood eosinophils in stepping down/monitoring reductions in maintenance therapy.	Thank you for your comment The committee agrees that FeNO or eosinophils may prove useful here. However, their role in this age group is currently unclear.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	018	017	**Decreasing maintenance therapy** This is unclear. Individuals may be 100% well on the annual day of the assessment and this needs to emphasise that risk factors for future attacks (i.e. previous attacks) must be considered when decreasing dosages – that's why a post attack review in addition to / instead of an annual review is important.	Thank you for your comment There are a number of issues which should be discussed before stepping down, encompassed by the phrase "risks and benefits" in the recommendation. This is a decision which will vary between individuals and detailed text about the appropriate discussion would necessarily be rather vague. Note that this is a legacy

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					recommendation based on both previous NICE and previous BTS/SIGN guidance.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	018	018	**Decreasing maintenance therapy** Rec 1.10 – A (in press) study by Chloe Bloom has quantified the risks of cardiovascular disease, pulmonary embolism and pneumonia using a large UK cohort (CI Bloom). This is entitled Association of Dose of Inhaled Corticosteroids and Frequency of Adverse Events. This maybe a helpful reference point for this section and making recommendations around decreasing maintenance therapy. This should be published by the end of the consultation period, certainly before the guideline is finalised and published. It will be published in the American Journal of Respiratory and Critical Care Medicine Journal.	Thank you for your comment and for highlighting this. This paper has been published and reviewed by our team. It does not meet the protocol requirements for any of the evidence reviews conducted for the guideline update.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	018	Section 1.10	**Decreasing maintenance therapy** Is Section 1.10 aimed at everyone or just adults – this needs to be clarified – it advocates stepping down to anti-inflammatory reliever (AIR) approach even if on inhaled corticosteroids (ICS)+short-acting beta2 agonist	Thank you for your comment It is for all ages, but you are correct that the second bullet of 1.10.2 conflicts with the recommendations on treatment in childhood. This has been amended.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				(SABA), which is great but would not then link well with the children guidance above.	
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	019	014	**Adherence** This section isn't just about adherence as in the heading but includes other subjects i.e. inhaler technique and shared decision making.	Thank you for your comment These are closely related topics. Adherence is featured in the treatment sections even though it is not in itself a treatment
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	019	015	**Adherence** **Patient feedback** I feel strongly that inhalers with a dose counter should be recommended. Dose counters have no drawbacks and stop patients from going days or even weeks of accidently under-dosing themselves. PCRS comment; We recommend that, where possible, inhalers with a dose counter are used to preference to those without.	Thank you for your comment This has been added to 1.6.5
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	019	015	**Adherence** There is no mention of monitoring tools for inhaler adherence here (or indeed research need). Devices such as Smart Rescue can be used to track inhaler uses (meter-dosed inhalers	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				(MDI) only) both to aid compliance and be able to tell when device is running low and needs to be replaced. In addition to general advice about medication adherence, already referenced.	The evidence on use of digital inhalers and their use in monitoring adherence was reviewed (see recommendation 1.6.9)
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	019	015	**Adherence** Should inhalers which have a dose counter be mentioned here? This would a good opportunity/drive for inhaler companies to prioritise development of dose counters for inhalers (as well as promoting less wastage feeding into sustainability goals).	Thank you for your comment This has been added to 1.6.5
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	019	Section 1.12	**Asthma in pregnancy** While management of severe asthma in pregnancy is beyond the scope of this guidance, it would be helpful to include guidance for generalists on when patients with asthma should be referred for specialist obstetric care (particularly if there is a group who would not already be under specialist teams). As well as a comment added to Section 1.12/1 flagging that hormonal/physiological changes in the peri-partum period means that asthma control may vary from the patient's established baseline e.g. be better or worse and should be reviewed more	Thank you for your comment The evidence on when to refer to obstetric specialists has not been reviewed. Advice on additional asthma reviews when pregnant is included in 1.12.1, but advice on frequency of reviewing during pregnancy would not be helpful since ultimately this depends on whether, and how much, asthma control deteriorates.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				closely and in responses to changes in symptoms.	
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	019	Section 1.12	**Asthma in pregnancy (Breastfeeding)** It would be very helpful to add e.g. to Section 1.12.3 that these medications are safe and should also be continued during breastfeeding. Would it be worth renaming the entire section 'Asthma in pregnancy and breastfeeding' or 'Asthma in the peri-partum period'?	Thank you for your comment The recommendation on using asthma medicines during breastfeeding (from SIGN158) has now been included and the section title changed.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	019	Section 1.12	**Asthma in pregnancy (Breastfeeding)** Recommendation to breastfeed has been removed because of general guidance in this area, but it is particularly relevant to the asthma population because there will be a higher risk of asthma in the offspring and breastfeeding is well established to reduce this risk and this would be worth stating clearly/linking to evidence. Smoking cessation has been left in as a similar recommendation which is a universal recommendation, so I feel the same applies to breastfeeding.	Thank you for your comment The positioning of the advice on breastfeeding for primary prevention of asthma in offspring, and the advice on not smoking in pregnancy, was not the same in the BTS/SIGN guideline. Smoking in pregnancy was included in the section on Asthma and Pregnancy which has been transferred to this guideline. Breastfeeding for primary prevention was in the non-pharmacological section which is not included

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					here; BTS and SIGN will consider updating the non-pharmacological section in due course.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	021	Section 1.14	**Self-management** Consider including mention of alerts/education to parents about continuing to get inhalers over the summer to prevent late summer exacerbations https://www.sheffield.ac.uk/ctru/completed-trials/pleasant (this may not have been included in the evidence review).	Thank you for your comment This is an interesting point. However, this section was not subject to an evidence review for this update and the detail you suggest cannot be added without a formal review.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	021	Section 1.14	**Self-management** Add mention of weather patterns and potential for apps integrating information on weather, pollen and symptoms. There is always a peak of asthma exacerbations around thunderstorms in the spring/early summer and this feels entirely preventable – even if more research is needed in this area.	Thank you for your comment This is an interesting point. However, this section was not subject to an evidence review for this update and the detail you suggest cannot be added without a formal review
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	022	022	**Self-management** Be more explicit on whether this covers offering school staff training, or just following the individuals PAAP. It would be useful to have a link to asthma friendly schools as per asthma bundle.	Thank you for your comment This is a legacy recommendation with no associated evidence review and the wording has not been changed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				https://www.transformationpartners.nhs.uk/resource/primary-care-children-young-peoples-toolkit/schools/asthma-friendly-schools/ Consider if it is appropriate to mention emergency inhalers in schools.	
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	023	001	**Risk-stratified care** Notably Evidence Review O excludes the Couillard 2022 study around risk prediction due to lack of intervention and this was a severe population BUT findings are very likely to be translatable and I would advocate higher biomarkers of inflammation i.e. fractional exhaled nitric oxide (FeNO)/blood eosinophils – being added to this list of bullet points. There is good evidence from large primary care databases of the risk associated with fractional exhaled nitric oxide (FeNO) and blood eosinophils with severe exacerbations e.g. https://pubmed.ncbi.nlm.nih.gov/31452870/	Thank you for your comment. Yes, the Couillard 2022 study was excluded from Evidence Review O because the study did not use an intervention in line with the protocol. Thank you for highlighting the Price 2019 study; this study also does not meet the protocol for the review protocol because of its observational study design. High FeNO and eosinophils undoubtedly increase the risk of exacerbations, but they will not be independent of the factors already listed in the recommendation. There is however, nothing to stop them being utilised in a practice's risk stratification system if so desired;

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					the factors listed in 1.15.1 are not necessarily exclusive of others.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	023	001	**Risk-stratified care** **Patient feedback** The guidance says risk factors include overuse of SABAs but does not specify a threshold for what counts as overuse (number of inhalers + timeframe for this). I suggest including a clear threshold for identifying at-risk patients which includes the number of inhalers and a timeframe, so reader does not have to find this information elsewhere. **PCRS comment:** The threshold for SABA overuse should be 2 cannisters of SABA in a metered dose inhaler (400 doses) or equivalent in other devices.	Thank you for your comment Thresholds for poor control are given in the Terms Used section.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	023	001	**Risk-stratified care** Consider mentioning primary care based identification systems for identifying patients who might benefit from biologics based on risk factors, as these programmes have been widespread and quite successful, including integration into primary care systems e.g.	Thank you for your comment This is a useful tool, but no literature search was done on this topic, and it is not clear whether there are other comparable systems. It

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				https://www.healthinnovationoxford.org/our-work/respiratory/asthma-biologics-toolkit/clinical-resources/identifying-patients-with-uncontrolled-asthma/ This does focus on severe asthma but identifying patients with severe asthma who would benefit from early specialist referral is appropriate within a general non-specialist guideline. Currently, some 8% of patients who are on step four or five treatment having 2 or more exacerbations annually have never been referred for specialist assessment: https://www.sciencedirect.com/science/article/pii/S2213219820313271.	is also, as you acknowledge, questionable whether it is within the scope. Thank-you for highlighting these studies. However, identification of patients for biologic therapy/severe asthma is outside the scope of this guideline update.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	023	001	**Risk-stratified care** Can the word 'consider' is replaced by 'Ensure that there is a process for' actively identifying people ... 'Consider' implies there is a rational choice – it won't happen unless the doctor is knowledgeable about asthma.	Thank you for your comment The word "consider" is used in NICE guidance to indicate that the evidence for an intervention is not unequivocal, therefore it is similar in this BTS/NICE/SIGN guidance.
Primary Care Respiratory	Guideline	023	007	**Organisation and delivery of care**	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Society-UK (PCRS-UK)]				Add after 'at least annually'...'and after every asthma exacerbation/attack' by a healthcare professional with appropriate,..... There is no practical or safety value in relying entirely on an annual review that is usually timed to maximise QOF points and may occur on a day when the persons asthma is 100% controlled. This was in (and as far as we know, still is) the QOF incentive payment scheme for GPs – has it been removed? If not, then this recommendation is not consistent with the NICE Quality Outcome Framework.	The wording has been added
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	023	007	**Organisation and delivery of care** Many practices are overwhelmed by the number of asthma reviews in quite a transient population, and it would be really helpful to reference/advise on how asthma reviews can safely be carried out using digital consultation tools or systems, as well as prioritising those who would most benefit from face-to-face review. The asthma control test (ACT) score of <20 could be used to determine this, exacerbation count in last 12 months, ACT<20, or patient choice to have review.	Thank you for your comment This is a reasonable question but not one that was included in the scope. We will pass this on to NICE's surveillance team for possible inclusion in a future update.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	038	004	**Digital inhalers** The section on digital inhalers (recommendation 1.6.9) focuses on a specific type of digital inhalers where technique is monitored and fed back live. Is it also worth considering other digital tools for adherence monitoring here? To include both trackers and peak flow (PEF)/spirometry monitors or apps integrating systems with e.g. weather/pollen counts. The guidelines could just include reference to these, and they may be helpful in specific patients, but further evidence needed before wider adoption/roll-out.	Thank you for your comment Evidence reviews L and M included digital tools for monitoring asthma that included monitoring of asthma control symptoms or PEF/spirometry respectively. The available evidence has informed recommendations in section 1.5 of the guideline.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	06	010	**Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16)** Skin prick testing is poorly predictive of asthma in children and a negative atopic status does not exclude asthma as suggested in the guideline. We do not think that there is sufficient evidence to diagnose asthma on the basis of IgE levels and eosinophil counts which are just as likely to be associated with other atopic causes in children.	Thank you for your comment These tests should be performed in children who have already had FeNO and BDR tests. At that stage, skin prick testing or measurement of IgE are helpful as explained in the rationale to these recommendations.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	066	GPP, 7.2.5	**Height and weight** Height and weight should still be recorded to ensure that children are not missed as failing to thrive due to poor disease control. A recent study published in the Thorax in children with asthma found that 40% did not have a single recorded body mass index (BMI) (height and weight) in their medical records in primary care. This is a major risk factor for asthma attacks and is very simple to measure. https://pubmed.ncbi.nlm.nih.gov/38071524/ See in point 3 of 'What this study adds' and Table 1.	Thank you for your comment. This section highlights the recommendations deleted from the previous BTS/SIGN guideline and a reason is provided for each one. Assessment of risk of future asthma attacks is not within scope of this guideline.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	Effective delivery of new asthma guideline	000	**Primary Care Respiratory Society (PCRS) support in delivering new guideline** This new asthma guideline represents considerable change in the way that asthma is diagnosed and managed, and a strong implementation and education plan will be required to deliver it. We at the Primary Care Respiratory Society (PCRS) already provide ongoing information, guidance and education to primary care healthcare professionals across the UK on the provision of evidenced-based	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				respiratory care. With the vast majority of asthma care taking place within the primary care setting, we feel that we are well positioned to support this implementation and education piece and are happy to put ourselves forward to work with healthcare professionals, as well as local and national organisations, to ensure it is delivered effectively.	
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	General	000	There is no information about the encouraged use of low carbon inhalers e.g. dry powder inhalers (DPIs) or soft mist inhalers (SMIs). The majority of environmental damage is done by salbutamol meter-dosed inhalers (MDIs). Salbutamol use is being reduced in pursuit of a maintenance and reliever therapy (MART) philosophy. Correct diagnosis and management of asthma would in any case reduce the need for rescue medications. Currently there is only one soft mist preparation available, tiotropium, the main use of which is in COPD.	Thank you for your comment 1.6.4 states that environmental impact of inhalers should be one of the criteria used in selecting a device and includes a link to NICE's decision aid on inhalers and climate change
Primary Care Respiratory	Guideline	General	000	Further guidance should be included on reviews post hospital admissions, i.e. 48-hour reviews.	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Society-UK (PCRS-UK)]				These are essential but rarely happening which could increase to preventable deaths.	Management of acute asthma is outside the scope of this guideline. We also note that post discharge review is already recommended in NICE's Quality Standard for Asthma
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	General	000	Consider addressing that children from deprived backgrounds are more than twice as likely to require hospitalisation for their asthma. This as a minimum should be acknowledged, but ideally with interventions to challenge this and other health inequality.	Thank you for your comment The point is acknowledged but the committee did not see any evidence that asthma should be treated differently in people from deprived backgrounds per se.
Primary Care Respiratory Society-UK (PCRS-UK)]	Guideline	General	000	Guidelines should emphasize the importance of detailed history taking and examination combined with any objective tests. See the IPCRG Jigsaw as an example of this. Signposting to the NICE clinical knowledge summaries may also be helpful for this - https://cks.nice.org.uk/. Although, NICE CKS on asthma and diagnosis (last updated December 2023) will also need updating as the two documents will contradict each other with different levels for fractional exhaled nitric oxide (FeNO) etc, re starting treatments.	Thank you for your comment The committee agrees that a good history is of paramount importance. Taking a structured history is the first recommendation in the guideline and the rationale to the diagnostic section also starts by emphasising this.
Primary Care Respiratory	Guideline	General	000	Acute asthma admissions should be dealt with in dedicated respiratory wards. This should	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Society-UK (PCRS-UK)]				improve diagnosis (often misdiagnosed by paramedics, PAs, urgent care centres). Patients with repeated panic attacks or severe dysfunctional breathing are often diagnosed as having asthma: they are often on high levels of inhaled steroids and other medications and have frequent courses of oral steroids: they are often not correctly diagnosed until they are seen in a tertiary level clinic (where typically 25-30% have their asthma diagnosis revised) There is a huge amount of education needed to get medical wards, general practice, A&E / emergency services up to speed on this. Is it worth considering some recommendations on how this education piece can be achieved?	Management of acute asthma is outside the scope of this guideline.
Primary Care Respiratory Society-UK (PCRS-UK)]	Supporting documentation – Diagnosis	General	General	Given that most clinicians will simply use the figures without reading the text – these diagrams should include the clinical history as well – to assume that the starting point for diagnosing asthma is by doing a fractional exhaled nitric oxide (FeNO) test or spirometry fails to recognise the practicalities of making a clinical diagnosis. Patients present with symptoms in	Thank you for your comment Agreed. Clinical history is noted as important within the Figures.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				primary care, where these tests are not readily available and if they are, they are only available for a single test without follow up tests if normal despite a suggestive history of asthma. More detailed realistic diagrams need to be produced, or the annually updated ones in GINA (www.ginasthma.org/reports)should be adopted and used.	
Public Health Scotland	Guideline	008	013	Recommendation 1.5.1 should also ask about high levels of environmental exposure to indoor and outdoor air pollution, high levels of mould, occupational exposures.	Thank you for your comment On reconsidering this, the reference to smoking has been removed from 1.5.1. The recommendation is about indices of control, and smoking was therefore out of place there (and it is covered in other recommendations). For the same reason, pollution, moulds etc have not been added.
Public Health Scotland	Guideline	009	016	Recommendation 1.6.1 states that we should "take into account and try to address" these factors, but offers no evidence-based advice on how to address them. The focus seems to be on medications ONLY. While this is needed, we feel that the document should also at least signpost	Thank you for your comment. The point is acknowledged, but on a practical level there is a vast number of conditions which might cause similar symptom to asthma and a

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				to evidence-based non-pharmacological methods for improving asthma control such as avoiding allergens, avoidance of tobacco smoke exposure, healthy diet, avoidance of medications that worsen asthma etc, as appropriate.	vast number of environmental contributors to asthma severity which might benefit from non-pharmacological measures. Signposting or cross-referencing to all these within 1.6.1 would take up several pages.
Public Health Scotland	Guideline	012	004	Recommendation 1.7.1. The recommendation seems to suggest the use of a single ICS/formoterol inhaler ONLY and ONLY "as needed" for first-line treatment in new asthmatics. If this is the case, it should be made very clear that this is WITHOUT regular ICS and WITHOUT regular ICS/formoterol. Secondly, the guidance should also make clear whether or not the newly-diagnosed asthmatic should continue on low-dose ICS/formoterol combination long-term without regular maintenance dosing. If it doesn't, we will see new asthmatics using this LT if not returning for follow-up / decision on maintenance therapy. Thirdly, **recommendation 1.7.1 may be dangerous to health**. The summary of product	Thank you for your comment AIR therapy is described in the Terms Used section. If the new asthmatic is well controlled on this treatment they will continue it. However, the guideline states that people should be reviewed after any treatment is commenced or changed (recommendation 1.6.3), that they should have regular review at least annually (section 1.16) and that they should receive self-management advice and support (section 1.14) so the people who need regular maintenance therapy should be identified. The problem you refer to in relation to paradoxical bronchospasm with Fostair is very rare, and at present Fostair is not licensed for AIR. It is therefore hard to see how 1.7.1 is

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				characteristics for e.g. Fostair, a combination ICS/LABA device, (see section 4.4.), states: *"As with other inhalation therapy paradoxical bronchospasm may occur with an immediate increase in wheezing and rapidness of breath after dosing. This should be treated immediately with a fast-acting inhaled bronchodilator. Fostair should be discontinued immediately, the patient assessed and alternative therapy instituted if necessary.* ***Fostair should not be used as the first treatment for asthma. For treatment of acute asthma attacks patients should be advised to have their rapid-acting bronchodilator available at all times."*** *[emphasis added].* Given the risk of sending a new asthmatic away with only a formoterol/ICS inhaler and causing paradoxical bronchospasm during an acute asthma attack, **this recommendation should be reconsidered and/or clear guidance given to co-prescribe a SABA for use in asthma attack situation** and/or noted in the guidance. While the guidance is not guidance on the	dangerous. If Fostair does receive a licence is due course it will have had to satisfy safety regulations. As noted in the paragraph above, all asthmatics should receive advice regarding self-management and an Asthma Action Plan which will advise on action to take if a significant exacerbation is developing, but the management of acute exacerbations is outside the scope of this guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				management of acute asthma attacks, it should still provide this warning and advise co-prescription of SABA for availability in acute attacks.	
Public Health Scotland	Guideline	012	015	If this is, as noted above, is WITHOUT a regular ICS for maintenance, this needs to be stated.	Thank you for your comment This recommendation mentions both MART and AIR therapy. Regular ICS is part of MART. Both AIR and MART are described in the Terms Used section.
Public Health Scotland	Guideline	013	003	This recommendation suggests that low-dose ICS/formoterol is a legitimate first-tier long-term treatment option. Can I suggest that this is made clear with an additional recommendation such as "For people aged 12 and over with asthma that is well controlled on low-dose ICS/formoterol combination inhaler used only as needed, continue on this therapy."	Thank you for your comment This seems an unnecessary recommendation. The guideline as a whole recommends regular monitoring and review of people with asthma, and the options of adjusting treatment or not. The principle of continuing medication that is working is not stated explicitly at the end of each recommendation but seems inherently obvious.
Public Health Scotland	Guideline	013	013	What is the advice for patients who are on a 3 month trial of LTRA that IS effective (to an extent) but are not adequately controlled?	Thank you for your comment This is part of 1.7.6 (second line of the recommendation). If the LTRA helps but control is still not optimal it should be continued, and

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					the LAMA added. Please note however, that this recommendation has been amended from the draft guidance.
Public Health Scotland	Guideline	014	011	That the latter two bullet points (lines 11-14) are considered inferior to low-dose MART is surprising given that both contain at least 3 medications and low-dose MART contains only two. Can this please be double-checked? Furthermore, the guidance here seems to conflict with lines 25-28 on the same page. The guidance at lines 11-14 seems to suggest stopping these therapies and moving to MART-only, not a switch to MART & LTRA+/-LAMA.	Thank you for your comment Although low dose MART contains only 2 different agents the use of extra doses of ICS/formoterol when reliever is required confers the benefit of the MART regimen. The advice therefore stands. Lines 11-14 are not intended to convey what to do with the LTRA or LAMA; that is dealt with in 1.7.10 (which was 1.7.11 in the draft guideline).
Public Health Scotland	Guideline	017	008	Since this document defines allergic asthma as an atopic disorder, does this sentence here in the guidance mean that children with allergic asthma and interval symptoms need maintenance therapy or should it read "...with at least one other (non-asthma) atopic disorder...")?	Thank you for your comment This is for suspected asthma rather than confirmed asthma, and it is not clear that the additional wording is needed.
Public Health Scotland	Guideline	021	008	This section should also explain that active and passive smoking and vaping can trigger asthma	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				symptoms and should advise the professional to action-plan approaches to avoid passive exposure and quit active exposure to smoking and vaping. Although smoking cessation is mentioned elsewhere in the guidance, it should also be a part of self-management planning. Many users of the guidance document will only access the section(s) relevant to their patient(s), so advice on smoking and reducing environmental exposures should be reiterated throughout.	This is a legacy recommendation from the 2017 guidance. No new evidence review was undertaken, and we cannot make substantial additions to it. However, the recommendation has been changed slightly to indicate that other triggers should be considered.
Public Health Scotland	Guideline	023	004	The reasons for which people with asthma are at risk of poor outcomes goes well beyond 'poor adherence' and repeated episodes of unscheduled care. This section should be expanded to re-include some of the advice included in the now-removed recommendations around passive and active smoking exposure and environmental risks to asthma (i.e. air pollution, damp housing etc). It should be mentioned that, e.g., children living in poor-quality damp housing, children living in poverty, those living in cold homes, etc, are at higher risk of poor outcomes. Also, those exposed to active	Thank you for your comment The risk factors you mention are acknowledged but 1.15.1 is not intended as a comprehensive list of risk factors. The question is whether it is beneficial to have certain high-risk individuals identified for additional measures (e.g. priority appointments) on a practice system. It is possible that some of the issues you identify do not need to be there, bearing in mind that if too many factors are included the list may become so big that it also becomes ineffective. For

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				or passive smoking, vaping, and those with unstable social circumstances that may contribute to poor access to routine medical care and medication are also at risk of poor outcomes. Users of the guidance should also consider these factors and methods to address them, including, e.g. access to benefits maximisation advice, social prescribing, etc, which are already available in primary care. The guidance should note, throughout, the additional risks of overweight and obesity on asthma control and the potential benefits of methods to address these.	example, if those living in cold homes are not needing excess SABA or unscheduled visits for their asthma, do they need to be on the list?
Public Health Scotland	Guideline	023	012	These two recommendations do not seem to say anything active about the care of people with asthma. Merely thinking about these two methods is not a recommendation to e.g. "consider implementing". Why are these two recommendations included? Is there any evidence base for them, or are they perhaps mentioned as potentially-useful but not having a strong evidence base (yet)? An improvement might be to mention the potential benefits of these types of system in improving patient adherence, providing automated expert	Thank you for your comment They were included because they were in the current BTS/SIGN guideline and there is no obvious reason why they should be deleted. The wording has been amended slightly.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				advice/decisions support etc., improved access to beneficial advice etc.	
Public Health Scotland	Guideline	General	General	We note the apparent absence of any mention in the document of either influenza or COVID vaccination. We consider the inclusion of seasonal influenza vaccination to be important in the management of many asthma patients, and recommend that this be included in relevant places throughout the guidance, including in asthma management-planning.	Thank you for your comment NICE and SIGN do not usually advise on vaccination as this is dealt with comprehensively in the Green Book therefore this collaborative guideline follows the same methodology.
RCGP Scotland	Guideline	001	General	RCGP Scotland welcomes the opportunity to respond to the consultation on the draft guidelines on diagnosis, monitoring and management of chronic asthma. RCGP Scotland is the membership body for general practitioners in Scotland, and we exist to promote and maintain the highest standards of patient care." 'Who is it for' – Suggest change 'GPs and practice nurses' to a broader statement involving all primary care clinicians – such as GPs, practice nurses, pharmacists and HCSWs.	Thank you for your suggestion
RCGP Scotland	Guideline	005	007	The recommendation to test immediately only if equipment is available is a considered statement	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				that takes into account the individual circumstances of the clinician assessing an unwell patient. Perhaps a recognition of the time involved when a 'duty' or 'on call' clinician should be included and equipment should be changed to 'resources.'	The committee feels that the change in wording may confuse readers into thinking this is about cost.
RCGP Scotland	Guideline	005	026	Scotland's respiratory care action plan in 2021 recommended that "Primary care spirometry training should be standardised, as well as have a clear quality assurance pathway for non-ARTP (Association for Respiratory Technology & Physiology) accredited practitioners. The group believed that waiting times for spirometry are variable, from few days to 6 weeks or more." During the COVID-19 pandemic the majority of spirometry services in Scotland were stopped. Spirometry is currently not available in the majority of practices in Scotland, and we fear that waiting lists to have this performed in secondary care might sit at over a year. Most spirometry pathways are not available for potential asthmatics (only COPD) given its variable nature. If referred, any potential asthmatic should be diagnosed and well controlled within this time, and you would expect spirometry to be less useful. We note no	Thank you for your comment. There are problems accessing spirometry in other parts of the UK too, and as the same applies to FeNO measurement it would seem that people with suspected asthma are being denied the diagnostic tests important to their situation. The committee take the view that it would be wrong simply to acquiesce to this and produce guidance which accepts the problem and recommends an inferior pathway. Hopefully some improvement may be produced if it is seen how far reality falls short of the ideal. It is hard to recommend a timescale as this would depend on how many tests were needed in an individual case.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				timescales are recommended from first presentation to diagnosis and question if this was considered.	
RCGP Scotland	Guideline	006	001	Bronchial hyper-responsiveness is inadequately defined. Are you suggesting a measurable test for responsiveness of which I'm not aware? If not, this directly contradicts recommendation 1.1.2 that clinicians must not record a diagnosis without objective testing.	Thank you for your comment The recommendation has been changed to make it clear that this involves a bronchial challenge test, and some detail has been added to the description of a challenge test in the Terms Used section.
RCGP Scotland	Guideline	006	004	We accept the arguments for the inclusion of FeNO testing on the grounds of accuracy, cost-effectiveness and being non-invasive, however FeNO is not currently offered in general practice settings, so we would anticipate difficulties in implementation of this recommendation.	Thank you for your comment The committee acknowledge that this is a problem in some areas but hope that recommending its use will lead to improvement.
RCGP Scotland	Guideline	006	007	BDR is not defined as spirometry or peak flow. See above, most GP practices in Scotland do not have access to soon spirometry thus this recommendation, if spirometry, would necessitate a large increase in referrals to secondary care or board level decision to	Thank you for your comment The words "with spirometry" have been added. The difficulty of arranging assessment of BDR relates to the difficulty in arranging spirometry in

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				provide all practices with training and equipment for spirometry.	children. The committee acknowledge that access is limited in many areas. Assessment of airflow obstruction has been part of previous guidelines (NICE and BTS/SIGN) which is testament to its potential value in diagnosis and it is regrettable that access has not improved.
RCGP Scotland	Guideline	006	013	A blanket statement to say we should exclude asthma on the basis of negative IgE to house dust mite is a notable recommendation and likely to lead to some controversy and criticism. We are concerned around the low quality of available evidence and that the use of phlebotomy and laboratory testing here may have implications for cost-effectiveness.	Thank you for your comment Skin prick testing to house dust mite and total IgE measurement are recommended for children who have not had a positive result with FeNO or bronchodilator reversibility. Asthma is therefore not excluded on the basis of a single test.
RCGP Scotland	Guideline	006	017	As above, due to lack of access of certain types testing within primary care, most of the recommendations given (FeNO, BDR with spirometry, skin prick testing and in many places IgE) would necessitate referral to secondary care, likely to a paediatric respiratory specialist. To suggest that those who have been through these tests should be referred if there is uncertainty is therefore paradoxical here.	Thank you for your comment Effectively this is suggesting getting a second opinion in difficult cases, which the committee do not think unreasonable.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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RCGP Scotland	Guideline	008	023	Please can examples be given of person-specific reasons for monitoring Peak Flow (PEF). Given PEF features so heavily in current asthma management, context and when it should still be used is key for clarity for clinicians.	Thank you for your comment The evidence did not show benefit from regular PEF monitoring for all people. The commonest reason why some people might benefit from measuring PEF is now included in the recommendation.
RCGP Scotland	Guideline	010	008	We think the clarity to end prescribing of 'SABA-only' regimes for asthma will be appreciated by many GPs.	Thank-you for your comment
RCGP Scotland	Guideline	011	008	It is impractical to review inhaler technique at every consultation for other reasons. Suggest an amendment 'at every consultation relevant to asthma'.	Thank you for your comment. Agreed - the wording has been amended
RCGP Scotland	Guideline	017	022	The clarity and empowerment given to clinicians to trial off treatment after a set period is really useful.	Thank you for your comment
RCGP Scotland	Guideline	019	General	On Asthma in Pregnancy, the recommendations here are clear and sound easy to implement as a GP in Scotland, although routine antenatal care is provided by community midwifery (and therefore questions whether this staff group	Thank you for your comment The "who is it for" section has been changed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				should be named in the "who is it for" statement on page 1).	
RCGP Scotland	Guideline	021	004	Please define or give examples of a self-management programme for adult, child and adolescent. This would be exceedingly useful. GPs do not have the resources to produce a written personalised plan for every patient without an easy template to refer to.	Thank you for your comment The self-management programme is comprised of provision of an action plan and associated education, which is the first sentence of 1.14.1. There are readily available templates for action plans and a link to the Asthma + Lung UK website will be included in the Asthma Pathway
RCGP Scotland	Guideline	021	General	On Self-management, the recommendation for self-management to involve Peak Flows (PEFs) appears to conflict with the new recommendation 1.5.3 to avoid asthma monitoring with PEF. From reading the review it sounds like the evidence is weak and there have been some assumptions made by the guideline development group on anxiety caused by peak flows.	Thank you for your comment 1.5.3 is about regular, daily PEF monitoring which is not helpful for many people. However, as 1.5.3 states, there may be person-specific reasons for monitoring PEF and there is evidence that some adults feel more comfortable with PEF as part of their action plan. 1.14.1 therefore says that plans for adults **may** include PEF.
RCGP Scotland	Guideline	023	General	On Risk stratifying care 1.15, this is a valuable new section that empowers GPs and	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				pharmacists to conduct searches of their populations to actively identify patients at highest risk and prioritise their review.	
RCGP SPECIAL INTEREST GROUP ON LEARNING DISABILITY	General	000	000	Supportive references: NHS Dec 2023 Health and Care of People with Learning Disabilities. Experimental Statistics, Other reports and statistics reports2022-2023 LeDeR Action from Learning Report 2022 and 2023	Thank you for the references
RCGP SPECIAL INTEREST GROUP ON LEARNING DISABILITY	Guideline	022	002	1.14.1 first bullet point describing personalised action plans should include: Plans should be available in a form tailored and individualised to the person. Use of inhalers should be regularly reinforced by repeated instruction when needed. Education of caregivers and family members should be considered depending on the assessed capacity of the person and shared decision making has to be Triadic when necessary. Davis S et al 2016. Asthma in intellectual disability: are we managing our patients appropriately? Breathe 12(4)	Thank you for your comment The committee agree with the points you make but are not convinced that the wording needs to be added. Personalised action plans are, by definition, tailored to the individual. Inhaler usage is covered in several recommendations in section 1.6. Assessing and allowing for the capacity of the person is a fundamental principle which goes beyond asthma.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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RCGP SPECIAL INTEREST GROUP ON LEARNING DISABILITY	Guideline	023	001	The accompanying quality assessment accepts that people with LD are at increased risk but 1.15.1 makes no specific mention of their needs in spite of the clear evidence that 28% - 50% of preventable premature deaths in patients with LD are due to respiratory causes, 7 times more frequent than for the general population, Glover G and Ayub M How people with Learning Disabilities Die 2010 Improving Health and Lives: Learning Disabilities Observatory and people with LD have twice the incidence of asthma than the general population Gale L et al 2009 Asthma, smoking and BMI in adults with intellectual disabilities: a community based survey J Int Dis Res 53(9) 787-797 1.15.1 should include a 4th bullet point stating • the person has learning disability If the text of the guidelines remains unchanged other than this amendment, then there should be a link to the equality impact assessment at the first bullet point of 1.15.1.	Thank you for your comment The sevenfold increase in premature deaths from respiratory disease that you quote is not specific to asthma. The respiratory condition which the publication identifies principally is pneumonia, especially aspiration pneumonia. Learning disability does not appear as a risk factor in all studies of asthma exacerbations, and it is not mentioned in the detailed list in the GINA guideline (box 2-2B). The items which are listed in 1.15.1 indicate poor control. If a person with Learning disability exhibits one of these then they should be picked up by the Risk Stratification system, but a person with Learning Disability whose asthma is well managed and whose control is good will not be, and this does not seem unreasonable.
RCGP SPECIAL INTEREST GROUP ON	Guideline	023	010	1.16.1 Should include reference to the Reasonable Adjustment Digital Flag to be	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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LEARNING DISABILITY				referred to at the times of acute care and mention that access issues due to learning disability should be considered if a patient does not attend or "was not brought", using the appropriate codes which would trigger appropriate action to ensure monitoring arranged by contacting carers or other supportive agencies together with ensuring access is tailored to each patient's needs. Davis S et al 2016. Asthma in intellectual disability: are we managing our patients appropriately? Breathe 12(4)	"Was not brought" policies already exist and should be followed. They are not asthma-specific, and, like many excellent generic policies, it is not really appropriate to place them all in a guideline on asthma. Reasonable adjustments are mandatory under the Equality Act and apply across medical conditions and, again, it is not necessary to recommend them here.
RCPCH	Guideline	000	000	Classification Guidelines The 2020 NAEPP guidelines [2] and the 2009 VA/DoD asthma management guidelines [45] use the severity of asthma classification below, with features of asthma severity divided into three charts to reflect classification in different age groups (0-4 y, 5-11 y, and 12 y and older). Classification includes (1) intermittent asthma, (2) mild persistent asthma, (3) moderate persistent asthma, (4) and severe persistent asthma. Intermittent asthma is characterized as follows:	Thank you for your comment. There are situations in which it is useful to define categories of severity, but the committee did not judge this necessary for the purposes of this guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				Symptoms of cough, wheezing, chest tightness, or difficulty breathing less than twice a week Flare-ups are brief, but intensity may vary Nighttime symptoms less than twice a month No symptoms between flare-ups Lung function test FEV 1 is 80% or more above normal values Peak flow has less than 20% variability am-to-am or am-to-pm, day-to-day Mild persistent asthma is characterized as follows: Symptoms of cough, wheezing, chest tightness, or difficulty breathing 3-6 times a week Flare-ups may affect activity level Nighttime symptoms 3-4 times a month Lung function test FEV 1 is 80% or more above normal values Peak flow has less than 20-30% variability Moderate persistent asthma is characterized as follows: Symptoms of cough, wheezing, chest tightness, or difficulty breathing daily Flare-ups may affect activity level Nighttime symptoms 5 or more times a month	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				Lung function test FEV 1 is above 60% but below 80% of normal values Peak flow has more than 30% variability Severe persistent asthma is characterized as follows: Symptoms of cough, wheezing, chest tightness, or difficulty breathing that are continual Frequent nighttime symptoms. Lung function test FEV 1 is 60% or less of normal values Peak flow has more than 30% variability.	
RCPCH	Guideline	1.1.1	006	Clinical history: reported wheeze, noisy breathing, cough, breathlessness or chest….our comment, we add sleep disturbance and school absence	Thank you for your comment 1.1.1 covers adults and children so school absence is not appropriate. Night-time symptoms have been added.
RCPCH	Guideline	1.1.1	010	A personal or family history of atopic disorders we add to that social history if there are pets .smoking is important to be asked.	Thank you for your comment These are included via "triggers". This is a legacy recommendation which was not reviewed in detail for this update, and it is not appropriate to make extensive changes to the considered wording agreed by the previous committee.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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RCPCH	Guideline	1.15.1	002	Consider actively identifying people with asthma who are at risk of poor 3 outcomes and tailor care to their needs. Risk factors should include: • non-adherence to medication • over-use of SABA inhalers • repeated episodes of unscheduled care for asthma. [2024] our comment we added to that Climate Change is a challenge for asthmatic patients.	Thank you for your comment Climate change will affect asthma, but it is an external agent rather than a person-specific risk factor and it is these which form a reason for being entered on a risk stratification programme.
RCPCH	Guideline	1.2.3	001	Objective tests for diagnosing asthma in adults, young 20 people and children aged 5 to 16 : we add to that chest x-ray, Radioallergosorbent (RAST) test and blood gases.	Thank you for your comment Chest x-ray and blood gases do not have a role in the diagnosis of asthma in children. A RAST test is an alternative to a skin prick test for HDM but the committee wished to include the skin prick tests as a means of avoiding venepuncture in a child.
RCPCH	Guideline	1.3.2	010	If ,a child is unable to perform objective tests, when they are aged 5: our comment: is to pay attention the history especially family history and the personal history and recurrence of the similar attacks, also chest x-ray to excludes other causes of shortness of breath but normal chest x-ray dose not exclude asthma, the other	Thank you for your comment The process of instigating and then stopping treatment for a trial period is covered in section 1.3.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				indictor for asthma, is the dramatic response to therapy initially and when stop therapy recurrence within few weeks this in favour of asthma.	
RCPCH	Guideline	1.5.1	015	Monitor asthma control at every review. In addition to asking about symptoms, check: our comment in addition what mentioned in lines(15-18) growth parameters is important indicator for severity of asthma or side effect of steroids also sleep interruption.	Thank you for your comment 1.5.1 is for both adults and children, so growth parameters cannot be included. They are, in any case, part of management in all childhood illnesses and not particular to asthma. Sleep interruption is covered within symptoms. Severe asthma is outside the scope and steroid side effects should not be relevant.
Royal College of General Practitioners	Guideline	004	015	We agree. This is important for primary care communication, continuity and the ability to review diagnoses including when tests are inappropriate or unavailable at initial contact.	Thank you for your comment**.**
Royal College of General Practitioners	Guideline	005	002	We agree, in primary care it is common for people with mild or dormant asthma to have no active signs.	Thank you for your comment.
Royal College of General Practitioners	Guideline	005	022	This is clearly worded. However, interpretation of eosinophilia is relatively new to some GPs so it may be useful to have additional information (in the guideline rationale?) about other causes	Thank you for your comment. The other possible causes of a raised eosinophil count are included in the Terms Used section.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				of eosinophilia such as medicines, parasitic diseases, malignancy.	
Royal College of General Practitioners	Guideline	005	026	We question why peak flow variability/ reversibility, a very accessible and moderately accurate test is not mentioned at all. 1) Peak flow reversibility has already been included as an option- 1.1.5 but then omitted it here; 2) Pragmatism appears to have been ignored: for a small theoretical gain in accuracy, a highly accessible tool has been excluded. This is a significant hurdle for good primary care management. We believe it is important to include peak flow in the guideline.	Thank you for your comment. The PEF reversibility referred to in 1.1.5 is an opportunistic single measurement of reversibility in an acutely unwell person, not PEF variability derived from serial PEF measurements. Numerous stakeholders have pointed out the advantages of measuring PEF variability and it has now been added to the diagnosis section.
Royal College of General Practitioners	Guideline	005	026	We believe spirometry with reversibility is not a good test for primary care patients. Unless it is immediately available it has poor sensitivity in a primary care setting. This criticism fits the statement in 1.1.4 where it is stated that examination may be normal and in these circumstances most people with also have little or no reversibility despite a clear history of asthma. We recommend reviewing this statement with application to real world primary care evidence.	Thank you for your comment. Whilst it is true that bronchodilator reversibility is not a sensitive test, the same applies to other available tests with the exception of bronchial challenge (and possibly FeNO). One of the studies in the evidence review was based on referrals from UK primary care, and in the absence of other published evidence we can only use what is available.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Royal College of General Practitioners	Guideline	006	003	The wording of this recommendation is unclear about what is measured "bronchial hyper-responsiveness", the glossary doesn't help – We question if these are PFR readings?	Thank you for your comment. This is correct at present and has been added to 1.2.4.
Royal College of General Practitioners	Guideline	006	004	We would like to make the same comments as for the adult section: We question why peak flow variability/ reversibility, a very accessible and moderately accurate test is not mentioned at all. 1) Peak flow reversibility has already been included as an option- 1.1.5 but then omitted it here; 2) Pragmatism appears to have been ignored: for a small theoretical gain in accuracy, a highly accessible tool has been excluded. This is a significant hurdle for good primary care management. We believe it is important to include peak flow in the guideline. We believe spirometry with reversibility is not a good test for primary care patients. Unless it is immediately available it has poor sensitivity in a primary care setting. This criticism fits the statement in 1.1.4 where it is stated that examination may be normal and in these circumstances most people with also have little or no reversibility despite a clear history of	Thank you for your comment The PEF reversibility referred to in 1.1.5 is an opportunistic single measurement of reversibility in an acutely unwell person, not PEF variability derived from serial PEF measurements. Numerous stakeholders have pointed out the advantages of measuring PEF variability and it has now been added to the diagnosis section.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				asthma. We recommend reviewing this statement with application to real world primary care evidence.	
Royal College of General Practitioners	Guideline	007	009	In contrast to our comments on older children and adults, this is a very pragmatic and helpful statement. Using clinical judgement, trials of treatment, and reconsidering the diagnosis on a regular basis is a very common-sense approach.	Thank-you for your comment
Royal College of General Practitioners	Guideline	008	016	We Would welcome additional information here (FeNO monitoring at review 1.5.4) about interpretation & action.	Thank you for your comment Additional brief guidance on interpretation of FeNO has been added to section 1.6
Royal College of General Practitioners	Guideline	008	024	We agree that regular peak flow monitoring has limited benefit but: 1) it provides a baseline which can be used to help primary care decision-making in and exacerbation of or acute asthma. Intermittent monitoring can also help to document peak flow reduction in patients who might be developing COPD or might need further investigation. It's easy to do and its absence deprives the GP of a useful clinical insight.	Thank you for your comment The evidence did not show benefit from regular PEF monitoring for all people. The commonest reason why some people might benefit from measuring PEF is now included in the recommendation.
Royal College of General Practitioners	Guideline	010	001	Use of e-cigs – The wording for recording the use of e-cigs could be strengthened in line with MHRA.	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				https://www.gov.uk/drug-safety-update/e-cigarette-use-or-vaping-reminder-to-remain-vigilant-for-suspected-adverse-reactions-and-safety-concerns-and-report-them-to-the-yellow-card-scheme (EMIS coding currently allows recording of e-cigs but not the level of detail advised by the alert)	Recommendation 1.6.1 is concerned with prompting readers to consider these factors rather than detail about recording them or managing them.
Royal College of General Practitioners	Guideline	011	008	We believe, it is not realistic to observe inhaler technique at every consultation	Thank you for your comment. Agreed - the wording has been amended
Royal College of General Practitioners	Guideline	012	001	We understand the wish to move to 'MART' therapy. However, we question if there is any good evidence on the risks of steroid overuse and the development of temporary adrenal hypofunction. As this can be a factor in asthma deaths with people given repeat steroids and suffering recurrences on cessation, this therapy may need careful monitoring and this isn't included in the guideline.	Thank you for your comment This was not a problem identified in the studies of MART. MART reduces the incidence of exacerbations and it could therefore be argued that it will reduce the risk of adrenal hypofunction. The doses of inhaled steroid in MART are not high unless a person is frequently using the maximum amount of reliever doses, and this should lead to the addition of further (non-steroid based) treatment in accordance with the recommendations in

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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					sections 1.7 and 1.8 and if this fails to referral for an expert opinion.
Royal College of General Practitioners	Guideline	013	008	What patient characteristics /subgroups/phenotypes who are most likely to benefit from LTRA? We wonder if it would it be useful to include further information.	Thank you for your comment There is no clearcut way of distinguishing between those who will benefit from an LTRA rather than a LAMA.
Royal College of General Practitioners	Guideline	013	016	*Give the LTRA for a minimum trial period of 3 months (unless there are side-effects) and then stop it if it 12 is ineffective. [2024] instead, we* recommend making the review more - E.g. Review at 3 months, assess for benefits and adverse effects. Montelukast has had a recent updated MHRA alert/reminder. Additionally, we know that once medicines are put onto repeat it is difficult to evaluate benefits, difficult to stop, and adds to concerns of problematic polypharmacy and risk of medicines interactions https://www.gov.uk/drug-safety-update/montelukast-reminder-of-the-risk-of-neuropsychiatric-reactions .	Thank you for your comment Recommendation 1.6.3 already states that a review should happen at 8-12 weeks after any change to treatment (the time frame in 1.7.6 has been amended to be consistent with this). A link to the updated MHRA DSU has been added.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Royal College of General Practitioners	Guideline	013	018	We agree, but it is important to note individual differences - A burly male prop forward will need and tolerate higher doses than a frail underweight elderly lady. Whilst it may be argued that this is just a guideline and that individual judgement is important, NICE guidance is often not seen like that by users or by those scrutinising the users. Extra qualitative recommendations are needed here.	Thank you for your comment It is unfortunately not clear what this refers to. This line is part of recommendation 1.7.6 in the draft guideline and the comment about higher doses does not seem relevant there.
Royal College of General Practitioners	Guideline	013	general	"Asthma that is not controlled" We could give clear advice to patients about poor control of asthma such as salbutamol use 2-3/week. Is there an equivalent for MART in this guideline?	Thank you for your comment Poor control is explained in the Terms Used section. The MART equivalent is excess use of reliever doses.
Royal College of General Practitioners	Guideline	019	027	It is important to recognise BNF advice for montelukast pregnancy. Similarly, Rec 1.12.5 suggests use BNF wording which is clearer	Thank you for your comment The BNF says it can be taken in women "who have shown a significant improvement in asthma not achievable with other drugs before becoming pregnant". The committee do not believe that is clearer than "are needed to achieve asthma control".

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Royal College of General Practitioners	Guideline	021	019	We recommend rephrasing this in order for it to be realistic	Thank you for your comment This comment appears to relate to recommendation 1.14.2. It is not clear how this is unrealistic. No other stakeholder has suggested this.
Royal College of General Practitioners	Guideline	022	002	We believe, the first bullet point describing personalised action plans should include: Plans should be available in a form tailored and individualised to the person. Use of inhalers should be regularly reinforced by repeated instruction when needed. Education of caregivers and family members should be considered depending on the assessed capacity of the person and shared decision making has to be Triadic when necessary. Davis S et al 2016. Asthma in intellectual disability: are we managing our patients appropriately? Breathe 12(4)	Thank you for your comment The committee agree with the points you make but are not convinced that the wording needs to be added. Personalised action plans are, by definition, tailored to the individual. Inhaler usage is covered in several recommendations in section 1.6. Assessing and allowing for the capacity of the person is a fundamental principle which goes beyond asthma.
Royal College of General Practitioners	Guideline	023	001	The accompanying quality assessment accepts that people with LD are at increased risk but 1.15.1 makes no specific mention of their needs in spite of the clear evidence that 28% - 50% of preventable premature deaths in patients with	Thank you for your comment The sevenfold increase in premature deaths from respiratory disease that you quote is not

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				LD are due to respiratory causes, 7 times more frequent than for the general population, Glover G and Ayub M How people with Learning Disabilities Die 2010 Improving Health and Lives: Learning Disabilities Observatory and people with LD have twice the incidence of asthma than the general population Gale L et al 2009 Asthma, smoking and BMI in adults with intellectual disabilities: a community based survey J Int Dis Res 53(9) 787-797 1.15.1 should include a 4th bullet point stating • the person has learning disability If the text of the guidelines remains unchanged other than this amendment, then there should be a link to the equality impact assessment at the first bullet point of 1.15.1.	specific to asthma. The respiratory condition which the publication identifies principally is pneumonia, especially aspiration pneumonia. Learning disability does not appear as a risk factor in all studies of asthma exacerbations, and it is not mentioned in the detailed list in the GINA guideline (box 2-2B). The items which are listed in 1.15.1 indicate poor control. If a person with Learning disability exhibits one of these then they should be picked up by the Risk Stratification system, but a person with Learning Disability whose asthma is well managed and whose control is good will not be, and this does not seem unreasonable.
Royal College of General Practitioners	Guideline	023	005	This is a useful recommendation but 'Actively identify people who overuse SABA' is not in itself very helpful. We wonder if it can be linked to established audit /medicines safety criteria?	Thank you for your comment The recommendation is not just about identifying people, but also about adjusting care
Royal College of General Practitioners	Guideline	023	010	We believe this should include a reference to the Reasonable Adjustment Digital Flag, to be referred to at the times of acute care and	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				mention that access issues due to learning disability should be considered if a patient does not attend or "was not brought", using the appropriate codes which would trigger appropriate action to ensure monitoring arranged by contacting carers or other supportive agencies together with ensuring access is tailored to each patient's needs. Davis S et al 2016. Asthma in intellectual disability: are we managing our patients appropriately? Breathe 12(4)	"Was not brought" policies already exist and should be followed. They are not asthma-specific, and, like many excellent generic policies, it is not really appropriate to place them all in a guideline on asthma. Reasonable adjustments are mandatory under the Equality Act and apply across medical conditions and, again, it is not necessary to recommend them here.
Royal College of General Practitioners	Guideline	General	General	Supportive references: NHS Dec 2023 Health and Care of People with Learning Disabilities. Experimental Statistics, Other reports and statistics reports2022-2023 LeDeR Action from Learning Report 2022 and 2023	Thank you for your comment
Royal College of General Practitioners	Guideline	General	General	It is very common for people with asthma in primary care, usually with milder chronic or intermittent disease, to have specific triggers eg exercise, or temporary exposure to allergens. This document provides no guidance on how to manage these situations. For some, regular ICS or MART may be appropriate; for others,	Thank you for your comment If all that is needed is a restorative puff, then the person takes whichever reliever they have (SABA in "traditional" pathway, budesonide/formoterol in AIR or MART). This is the same whatever the trigger. If the

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				particularly those with only occasional symptoms (and I count myself amongst these) surely a quick restorative puff of salbutamol makes more sense.	deterioration is worse than this, they follow their action plan as per 1.14.1.
Royal College of Nursing	Guideline	001	007	Under "Who is it for"? Please consider using general practice/ primary care to include other roles like Advanced Nurse Practitioners, Registered Nursing Associates, Physician Assistants etc.	Thank you for your comment This has been changed
Royal College of Nursing	Guideline	004	011	Could this be linked to section 1.4 for adding in occupational history as part of initial consultation – thinking of structuring of practitioner reading the guidance	Thank you for your comment. Whilst occupational asthma is important, in 1.1.1 the aim is to make a diagnosis of asthma irrespective of the cause.
Royal College of Nursing	Guideline	005	022	This recommendation may be challenging depending on the availability for FeNO testing in primary care particularly, as availability varies between practice to practice.	Thank you for your comment. The committee agrees that access to FeNO is limited in many places, hence the inclusion of alternative tests.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Royal College of Nursing	Guideline	007	012	12 months is a long time to wait. At 5years 6 months, if an objective test cannot be undertaken, children should be referred to a specialist team for assessment. Our current waiting lists should also be considered.	Thank you for your comment The 3rd bullet point of this recommendation indicates that a referral should be made if there are concerns about ongoing symptoms.
Royal College of Nursing	Guideline	008	018	Please consider in the review: current housing state, e.g. mould.	Thank you for your comment. On reconsidering this, the reference to smoking has been removed from 1.5.1. The recommendation is about indices of control, and smoking was therefore out of place there (and it is covered in other recommendations).
Royal College of Nursing	Guideline	011	013	To ensure appropriate consideration of different devices, could the developers suggest alternatives such as DPI etc.	Thank you for your comment. It is not appropriate to give a list of devices as new ones may appear within the lifespan of this version of the guideline. The recommendation should be carried out be appropriately trained professionals who will be aware of the available options.
Royal College of Nursing	Guideline	013	013	Review access and skills in primary care as often local guidance suggests addition of LAMA remains with hospital specialists only.	Thank you for your comment Confining LAMA use to secondary care has not been part of previous NICE or BTS/SIGN guidance, and it is also not part of this new

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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					guideline. Local restrictions are beyond the control of the guideline group.
Royal College of Nursing	Guideline	018	016	For primary care purposes, need to consider coding of 'suspected asthma' in age group to prevent risk of loss for follow up.	Thank you for your comment. Advice to code as suspected asthma is given in section 1 which applies to all age groups.
Royal College of Nursing	Guideline	020	011	There is a case within this recommendation to talk about vaccinations that will protect mother and baby for example flu jab, Covid-19 and whopping cough etc. Please consider adding that.	Thank you for your comment This section was not the subject of an evidence review for this update. The recommendations have simply been transferred from the BTS/SIGN guidance and the committee are not able to add new recommendations.
Royal College of Nursing	Guideline	021	008	Please consider other environmental triggers such as extreme temperatures and pollen levels as the world's climate / UK weather has changed in recent years.	Thank you for your comment. This is a legacy recommendation from the 2017 guidance. No new evidence review was undertaken, and we cannot make substantial additions to it. However, the recommendation has been changed slightly to indicate that other triggers should be considered.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Royal College of Nursing	Guideline	022	021	Can consider signposting to external organisations such as Asthma UK for guidance and support as this is often promoted in primary care.	Thank you for your comment.
Royal College of Nursing	Guideline	023	008	We agree with the requirements that appropriately trained professionals must be involved in delivering the appropriate care. However, this needs to be considered across the different levels of healthcare professionals that are working in primary care settings. Application of the PCRS standards in their 'Fit to Care' document can help support this requirement, with appropriate level of authority.	Thank you for your comment NICE recommendations do not incorporate training standards and therefore this BTS/NICE/SIGN guideline is the same.
Royal College of Physicians and Surgeons of Glasgow	General	General	General	We feel the draft guidelines are very sensible and we have no changes to suggest.	Thank you for your comment
Royal Cornwall Hospitals NHS Trust	General	General	General	We are concerned this guideline does not emphasise or promote sufficiently the notion of achieving good asthma control by effectively tackling airways inflammation, the emphasis seems to be on reducing exacerbations rather than people with asthma being symptom free.	Thank you for your comment This comment seems to assume that airway inflammation is relevant to symptoms but not to exacerbations. The treatment pathway is based

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					on treatment being increased when control is not adequate, and the definitions of control include symptoms. In addition, regular FeNO monitoring is recommended, a direct attempt to measure and treat inflammation.
Royal Cornwall Hospitals NHS Trust	General	General	General	We disagree with starting all newly diagnosed people with asthma on as needed treatment – this is a backward step, we are diagnosing an inflammatory disease and should be aiming for control. It also sends the wrong message to the person at diagnosis, asthma is not a mild disease, and we work really hard to help patients understand how serious it can be (asthma still kills). Woolcock showed it can take 18 months of sustained ICS treatment to settle airways hyperresponsiveness (Woolcock et al, What are the important questions in the treatment of asthma? Clinical & Experimental Allergy Reviews 2001. Vol 1, No 2, Pg62-64. Accessed 6th August 2021)	Thank you for your comment The guideline is aiming at control of asthma. Some people will be controlled with intermittent ICS as in AIR, and this will avoid the need for daily therapy in these mild asthmatics. Please see Evidence review P.
Royal Cornwall Hospitals NHS Trust	General	General	General	We continue to have the challenge that many people with asthma accept symptoms and do not know they could be symptom free with appropriate treatment. A MART only based guideline could play to the acceptance of	Thank you for your comment It is true that many people with asthma accept symptoms, but this is the situation after years of

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				symptoms and response to these by taking extra puffs unless there are strict criteria about when to escalate maintenance treatment. We accept the need to tackle salbutamol over use and that a MART strategy can be appropriate for some people with asthma, but this guideline goes too far in recommending this regime for all.	basing treatment on the traditional management pathway. There is no reason why this issue should be worse with MART than with maintenance treatment plus PRN SABA. The committee believes that the evidence in adults strongly favours the AIR then MART strategy over the traditional treatment pathway and have therefore recommended this. The remit of NICE is to offer guidance on the most cost-effective management strategy and the same applies to this collaborative guideline with BTS and SIGN.
Royal Cornwall Hospitals NHS Trust	General	General	General	We have had some good success in using Relvar Ellipta one puff once daily, with people gaining good asthma control because of this simple regime, (particularly people who forget the evening dose in a bd regime). We note some of the Budesonide/ Formoterol options can be used once daily but only in the lower doses and the drug molecules do not have a 24 hour duration of action.	Thank you for your comment The committee agrees that some people with asthma do well on Relvar, and the guideline does not suggest that they should be moved off successful treatment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Royal Cornwall Hospitals NHS Trust	General	General	General	In addition, the MART only approach limits device choice and tailoring of regime for individual patient needs & preference – eg. as far as we are aware there is no ICS/formoterol MDI option licensed for as needed use, the DPI device choice for MART is limited to a few options.	Thank you for your comment This is not quite correct. Fostair is licensed for MART (and therefore can be used when needed as part of MART) but not for AIR. There are DPI options for both AIR and MART.
Royal Cornwall Hospitals NHS Trust	General	General	General	The guidance states it is for healthcare professionals in secondary care and tertiary asthma services but does not give any guidance about options for people requiring high dose Inhaled steroids – these patients do not fit into the general MART licenses and often require a separate SABA to use as rescue in acute situations.	Thank you for your comment The guideline does refer to people on high dose ICS. If uncontrolled they should be referred to a specialist asthma service, but further details are not included because severe asthma is outside the scope.
Royal Cornwall Hospitals NHS Trust	General	General	General	We would like to see a guideline which includes a regular dosing option (as the Wales guideline does) so we can provide personalised care & choices to our patients. Points regarding Diagnosis	Thank you for your comment The committee believes that the evidence in adults strongly favours the AIR then MART strategy over the traditional treatment pathway and have therefore recommended this. The remit of NICE and of this collaborative guideline is to offer guidance on the most cost-effective management strategy.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Royal Cornwall Hospitals NHS Trust	Guideline	General	General	1.2.1 Needs wording around Eosinophil measurement being affected by the use of prednisolone & the need to look at more than one test if normal, we suggest advising on the value of looking at the peak eosinophil count each year over the last few years.	Thank you for your comment This recommendation applies to as yet undiagnosed asthma. The person should not be on prednisolone, and even if it is felt necessary to start prednisolone a blood sample could be taken as well. Historical eosinophil counts would be useful providing that the health care records are comprehensive enough to be able to exclude another cause of eosinophilia at the time the samples were taken.
Royal Cornwall Hospitals NHS Trust	Guideline	General	General	Will FeNO be fully funded by the NHS? Most GP practices in our county do not currently have a FeNO machine – this has potential to drive referral to secondary care for this test and confirmation of diagnosis.	Thank you for your comment There will need to be some investment to fully implement the guideline. Your comments will be considered by NICE where relevant support activity is being planned.
Royal Cornwall Hospitals NHS Trust	Guideline	General	General	1.2.2 Spirometry may be normal when acute symptoms have been controlled and the person attends for a future booked appointment (appointments are already scarce) Will primary	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				care have the resources to respond and perform spirometry when patients are symptomatic in order to confirm diagnosis ?	The guideline does not suggest that attempts should be made to arrange spirometry when a person becomes symptomatic as this would be extremely difficult logistically. 1.2.2 suggests measuring bronchodilator reversibility rather than spirometry alone. This is a relatively insensitive test, but highly supportive of an asthma diagnosis if positive.
Royal Cornwall Hospitals NHS Trust	Guideline	General	General	1.2.3 Testing for bronchial hyper-responsiveness is not available at all in our county. In what setting is it proposed this will this be done? How is this testing going to be funded and how are staff going to be appropriately trained? We do not believe this should be proposed in a new guideline until this in in place – it will cause disruption, confusion, potentially inappropriate referrals and more work for all.	Thank you for your comment. Your comments will be considered by NICE where relevant support activity is being planned. The committee appreciate that bronchial challenge tests are not often performed in this country and that more resource will be needed. However, this is the single best test for asthma. If guidelines continue to ignore it, it will never become available.
Royal Cornwall Hospitals NHS Trust	Guideline	General	General	1.5.3 In the absence of testing for bronchial hyper-responsiveness being widely available we believe peak flow monitoring should remain as a tool to aid diagnosis to demonstrate obstruction, variability and response to treatment. The	Thank you for your comment 1.5.3 refers to peak flow monitoring, not peak flow measurement as part of the diagnostic

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				guideline needs to be more specific giving examples of what 'person specific reasons' might be?	sequence. PEF variability has now been included in the diagnosis sections.
Royal Cornwall Hospitals NHS Trust	Guideline	General	General	1.7.3 - What criteria will be used to determine 'not controlled'? There needs to be specific guidance such as the person needing more than 3 reliever puffs per week. Otherwise we could have a population of asthmatics where symptoms are a daily occurrence and people never achieve sustained asthma control because the maintenance ICS dose is not appropriately adjusted – how will primary care monitor this? Do they have sufficient resource to review? Regular dosing ICS/LABA with SABA should remain an option to enable personalising patient care & meeting individual needs – MART regime is not suitable for all.	Thank you for your comment Control and "uncontrolled" are both defined in the "Terms Used" section of the guideline.
Royal Cornwall Hospitals NHS Trust	Guideline	General	General	1.7.5 & 1.7.6 – Why trial LTRA's & LAMA's for 3 months? Effect on symptoms is usually apparent within a month & most people can clearly say if this has helped or not in this timeframe.	Thank you for your comment Asthma is an intrinsically variable disease and assessing benefit over too short a time period is open to errors in both directions.
Scottish Government	Guideline	001	007	What this guideline covers:	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				"It does not cover the safety of different inhaler device choice in managing severe asthma or acute asthma attacks." (ie. DPI/ MDI devices) AIR is a new asthma management regime therefore it is important that clinicians and patients are aware how to use AIR to manage acute exacerbations and also how MART should be used in acute exacerbations. You could describe the action to take when using either of these regimes in an acute exacerbation and how this can be incorporated into the personalised asthma management plan.	Management of acute asthma is outside the scope. BTS and SIGN will produce guidance covering this.
Scottish Government	Guideline	001	007	Who is it for: GPs and practice nurses are not the only healthcare professionals who see patients with asthma in primary care. Include pharmacists, and also consider paramedics and physiotherapists. Alternatively and inclusively, you could describe this as for the primary care multi-disciplinary team. Also worth noting that there is an expectation in Scotland that all primary care staff have completed the NES respiratory training modules.	Thank you for your comment. This has been changed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Scottish Government	Guideline	005	022	Appreciate that there is an option of 'or FeNO' as FeNO is not widely available in primary care in Scotland what are the pathways and access plans for this nationally, clarify the role of blood eosinophil count. Would rephrase this – 'although we endorse this shift to FeNO, it is not routinely available in Scotland and will require a work with several key stakeholders to ensure capacity can be built into the system.	Thank you for your comment. The committee acknowledges that access to FeNO is limited in Scotland and in many other areas of the UK. Resolving this is beyond the remit of the committee but it is hoped that the recommendations will help drive forward this improvement in asthma care.
Scottish Government	Guideline	006	002	"Measure bronchial responsiveness". It should be made clear that this will require to be done in secondary care	Thank you for your comment. This is correct at present and has been added to 1.2.4.
Scottish Government	Guideline	006	005	Fe NO is not widely available in primary care in Scotland, which would mean all children aged 5 to 16 would have to be referred to secondary care paediatric services for diagnosis. Appreciate that 1.2.5 states that 'if FeNO not available' but this could be acknowledged more clearly in point 1.2.4. e.g. 'Where available, measure FeNO level in children'….(clarify pathway for children)	Thank you for your comment The committee acknowledge that access to spirometry for children is limited in many areas. Assessment of airflow obstruction has been part of previous guidelines (NICE and BTS/SIGN) which is testament to its potential value in diagnosis, and it is regrettable that access has not improved. The committee would prefer not

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					to include the "where available" qualification for FeNO twice.
Scottish Government	Guideline	006	011	Point 1.2.6. Skin prick testing is not widely available on the NHS in Scotland with variation between localities. There is a significant lack of specialist Allergist capacity in Scotland and it could take many years to build a service, even with appropriate funding.	Thank you for your comment Availability of skin prick testing is a problem in many areas, which is why testing for IgE and eosinophils is suggested as an alternative.
Scottish Government	Guideline	008	016	Amount of reliever inhaler used – give an indication of what would be expected for good control and action to take where use exceeds this guide. Also how can this be determined- asking patient, review of prescription records etc (stronger statement on SABA overuse)	Thank you for your comment Poor control is defined in the Terms Used section and the action to take when control is poor is laid out in the sections on treatment. We have added advice on checking prescription records to recommendation 1.5.1.
Scottish Government	Guideline	008	017	Number of courses of oral corticosteroids – given an indication of when this may cause concern, eg more than 2 courses a year for consideration of severe asthma or for consideration of bone protection.	Thank you for your comment The committee do not think that specifying a number of courses is helpful. Any exacerbation requiring oral corticosteroid is a cause for concern and this should be explored at the review.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					The issue of bone protection is noted. This was not prioritised by Stakeholders during the scoping process and evidence has not been considered. It was not covered in the previous version of the NICE asthma guideline and in BTS/SIGN's the only advice was to monitor bone density in people on regular oral corticosteroids. We will pass this on to the NICE surveillance team for consideration when the guideline is next updated.
Scottish Government	Guideline	008	025	Again, FeNO testing provision would not be available routinely in Scotland and would incur a huge financial and training resource.	Thank you for your comment. The committee recognises that more resource would be needed in Scotland (and other areas of the UK). Your comments will be considered by NICE where relevant support activity is being planned.
Scottish Government	Guideline	008	028	If sub optimal control : "review the person's inhaler technique"- Make clear that if inhaler technique is poor with a particular inhaler device type that it may be appropriate to change to an alternative device type with appropriate education provided.	Thank you for your comment. This point is covered in the next section of the guideline, 1.6.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Scottish Government	Guideline	010	008	Very supportive of this strengthening of advice regarding use of short-acting beta2-agonists. Encourage consideration of all those currently prescribed SABAs alone for review and diagnostic testing in practices (retrospectively) (Covered in p14, point 1.7.8)	Thank-you for your comment
Scottish Government	Guideline	010	016/017/018	Very supportive of this approach for choice of inhaler.	Thank-you for your comment.
Scottish Government	Guideline	011	015	Point 1.6.7. Very supportive of this point, avoiding multiple inhaler devices for a patient where possible.	Thank you for your comment.
Scottish Government	Guideline	011	021	Point 1.6.9. Digital inhalers may no longer be available?	Thank you for your comment. The committee has reconsidered this recommendation, and it has been changed.
Scottish Government	Guideline	012	004	Point 1.7.1. Support use of low dose ICS/formoterol combination therapy as needed for symptom relief. GINA refer to this as AIR – Anti-inflammatory reliever therapy and it may avoid confusion to use the same description?	Thank you for your comment This is now identified as AIR therapy
Scottish Government	Guideline	012	012	Point 1.7.2. "If the person needing asthma treatment presents highly symptomatic (for example, regular nocturnal waking) or with a severe exacerbation, start treatment with low-	Thank you for your comment Several factors affect the severity of symptoms at presentation (e.g. length of time present, the

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				dose MART" **If someone is highly symptomatic, would low dose MART be enough? Would moderate-dose MART be a better starting point? Also make clear that acute treatment of severe exacerbation may be needed e.g. oral corticosteroids	nature and intensity of any precipitating trigger) and severity does not predict how much inhaled steroid will ultimately be needed. Advice has been added to the recommendation specifying that a course of oral steroids should be given if necessary.
Scottish Government	Guideline	015	009	MART Pathway- As highlighted MART is unlicensed in children under 12 – Suggest placing the NON MART pathway before the unlicensed regime in the document	Thank you for your comment There is evidence for MART in children. It may become licensed within the UK in the lifetime of this version of the guideline. Since it is the better option in the view of the committee, the order had not been changed.
Scottish Government	Guideline	022	016	Support from pharmacists – does this mean specifically Community pharmacists? Primary care pharmacists are an established part of the MDT in primary care in Scotland.	Thank you for your comment Primary care and community care pharmacists have been added.
Scottish Government	Guideline	022	017	Recommendations for assured educational resources e.g. Asthma Lung UK or CHSS My Lungs My Life would be helpful here. Resources such as the Respiratory section of the Manage Meds app would also be useful,	Thank you for the information. Management of acute asthma is outside the scope of the guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				free to use for all patients and clinicians. No consideration of treatment of acute exacerbations and whether usual treatment should be used (e.g. MART via usual inhaler route, rather than SABA MDI via spacer)	
Scottish Government	Guideline	023	005	Risk stratification. What is classed as overuse of SABA? e.g. >3, >6, or >12?	Thank you for your comment A threshold has been added
Scottish Government	Guideline	023	007	Organisation and Delivery of care. Highlight here that there should be a review within 48hours of A&E, OOH or discharge	Thank you for your comment This is a legacy recommendation for which neither a new evidence review not a cost effectiveness analysis has been performed. A strict time threshold has therefore not been added.
South Yorkshire Childrens and Young People's Alliance	Guideline	004	000	Objective tests for diagnosing asthma - Home monitoring of peak flow (PEF) is a big omission across all these groups and it is a very practical tool used by many in primary care. It is low-cost patient-centred way to readily identify triggers (including occupational, which would then guide potential referral for specialist confirmation) and diurnal variability which confirms diagnosis and	Thank you for your comment The committee agree with much of what you say. There are drawbacks to all the available tests for asthma, and these are referred to in the guideline and in the associated evidence reviews. PEF monitoring is readily available as

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				guides management. Only two weeks are needed for monitoring as per the global initiative for asthma (GINA): Adults: average daily diurnal peak flow (PEF) variability >10% Children: average daily diurnal peak flow (PEF) variability >13% This is based on high quality evidence and should not be discounted just because not enough training or support is given to clinician to help conduct the analysis of the data. The measure is not completely perfect but is highly practical in primary care. Tools provided by NHSE should be given to support the accurate data collection for clinicians and help them to interpret the information. The lack of these tools is the main barrier. If tools were integrated in clinical systems, then the time for analysis can be reduced and improve patient care. PEF also serves to educate the patient about their lung physiology and how peak flow (PEF) varies and correlation (or not) with symptoms. All the other tests are reliant on a snapshot test which might not reflect medium-longer term disease patterns. The evidence presented as informing this decision is scanty and poor quality. There are issues of compliance and health/digital inequality here, but actually future research	you say, but it too has drawbacks, in particular its very poor sensitivity. However, in view of comments from multiple stakeholders it has now been added. The committee would also argue that availability of FeNO will never improve if it is not clearly recommended in guidance. In relation to your point on non-eosinophilic asthma, please note that FeNO is not used as a rule-out test, only as a means of confirming a diagnosis, so this group should not be misdiagnosed as a consequence of including FeNO.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				needs to focus on reducing these through utilising technology and making home diagnosis and monitoring easier for patients, not taking it out of the guideline. Furthermore, in primary care this is often the only test available with limited access to fractional exhaled nitric oxide (FeNO), spirometry and provocation testing – without it, the only easily available objective test is blood eosinophil count and using this will miss those with non-eosinophilic asthma. And it's the most applicable to children	
South Yorkshire Childrens and Young People's Alliance	Guideline	004	013	The guideline does not at any point refer to levels of probability of asthma – when clinical history is taken and probability of asthma is high surely a trial of treatment can support a diagnosis. To not be able to make a clinical diagnosis of asthma in patients who have successfully trailed treatment will lead to many patients remaining as "suspected asthma" and potentially never being given a confirmed astha diagnosis	Thank you for your comment The problem of using levels of probability as was once recommended in the BTS/SIGN guideline is that, although it is an excellent idea, in practice very few people were deemed to have intermediate probability and to require objective tests. This raises questions about how probability was being interpreted. Trials of treatment are flawed because people with other diagnoses, for example viral-induced wheeze, can improve naturally leading to a spurious conclusion that the improvement is due to asthma therapy.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
South Yorkshire Childrens and Young People's Alliance	Guideline	005	007	This is suggesting a trial of treatment if people are acutely unwell at presentation which is likely to be most presentations – then to arrange tests at a later date which we then know are all going to be negative because of the treatment. The inability to make a clinical diagnosis based on response to treatment will lead to under diagnosis or people remaining as "suspected asthma"	Thank you for your comment. The committee do not agree that most people first present with acute symptoms requiring immediate treatment.
South Yorkshire Childrens and Young People's Alliance	Guideline	005	017	We like this comment as we think people forget that results can be affected once a person has started preventive treatment. This statement needs to be more prominent throughout the diagnosis section of the guideline as there is a real risk of people ending up undiagnosed once treatment has commenced if this guideline is followed	Thank you for your comment.
South Yorkshire Childrens and Young People's Alliance	Guideline	005	019	This section should acknowledge the limited access to objective tests in primary care especially for children. In addition the whole diagnosis section focuses on diagnosing patients with atopic/eosinophilic T2-high asthma. What about those with T2 low asthma – there is no mention of the 2 main asthma phenotypes and the high focus on T2 high asthma could	Thank you for your comment. The limited access to some tests is acknowledged in the rationale section and in the relevant evidence reviews. The diagnosis section does not focus on atopic/eosinophilic asthma. It includes tests for Th2 markers because these can help, but they are used to confirm a diagnosis when positive,

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				lead to patients being inappropriately labelled as not having asthma	not as rule-out tests. The diagnosis is not excluded without further testing.
South Yorkshire Childrens and Young People's Alliance	Guideline	005	022	Eosinophil laboratory range will vary across the country – there should be a definitive number here. Additionally there needs to be an acknowledgement of false positives as there are many other things more than asthma that can raise blood eosinophil count. This statement could lead to over diagnosis if there is no acknowledgement of the alternative causes of raised blood eosinophils which need to be rules out.	Thank you for your comment. It is precisely because the laboratory range varies that the committee have not given a single value for an abnormal eosinophil count. The committee agrees that other conditions may cause the eosinophil count to be raised, but there are potential confounding factors with most diagnostic tests.
South Yorkshire Childrens and Young People's Alliance	Guideline	005	026	Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Adults) Why is peak flow (PEF) reversibility acceptable for patients with acute symptoms (section 1.1.5) but not for a routine objective test? Ranked 3rd most cost effectiveness strategy in evidence and 80% specificity. Why not use this in primary care when bronchial hyper-responsiveness (BDR) and bronchial challenge testing are not easily available?	Thank you for your comment. The PEF reversibility referred to in 1.1.5 is an opportunistic single measurement of reversibility in an acutely unwell person, not PEF variability derived from serial PEF measurements. Numerous stakeholders have pointed out the advantages of measuring PEF variability and this has now been added to the diagnosis section.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
South Yorkshire Childrens and Young People's Alliance	Guideline	005	026	Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Adults) Bronchial hyper-responsiveness (BDR) and fractional exhaled nitric oxide (FeNO) are a snapshot in the natural history of asthma. If the patient is well, these tests may not be positive. Currently availability of either test in primary care is very patchy in England. Peak flow is universally available in primary care and PEF and/or reversibility measured over time in primary care, especially testing the patient when symptomatic. This acknowledges the variable nature of the disease over time and cheap (ranked 3rd in cost-effectiveness in adults).	Thank you for your comment. Your comments on the "snapshot" nature of most tests for asthma is correct. However, measuring PEF variability is also problematic as it has been shown to be highly insensitive. However, numerous stakeholders have pointed out the advantages of measuring PEF variability and it has now been added to the diagnosis sections.
South Yorkshire Childrens and Young People's Alliance	Guideline	006	001	There is no access to bronchial hyper responsiveness testing in primary care and little available for children u16 in secondary care. As many patients in primary care may not have raised fractional exhaled nitric oxide (FeNO)/BDR or raised eosinophils, or testing not available, this might increase pressure on secondary care and increase costs of diagnosing asthma. Also, will delay diagnosis of patients in primary care	Thank you for your comment The committee acknowledges this. It is however the best single test for asthma, and it would be remiss not to include it, albeit at the end of the testing sequence.
South Yorkshire Childrens and	Guideline	006	005	We think this could make people too reliant on FeNO when the result can be raised for a variety	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Young People's Alliance				of reasons and could lead to over diagnosis. More emphasis is needed on the alternative reasons FeNO could be raised such as rhinitis/nasal inflammation to rule these out	The guideline clearly states that the person should have a history suggesting asthma.
South Yorkshire Childrens and Young People's Alliance	Guideline	006	010	Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16) Skin prick testing is impractical, not available in primary care and very few clinics in secondary care provide it. In addition, as quoted by yourself in the consultation documents: "quality of the evidence was very low across studies as it was downgraded for risk of bias, most frequently due to concerns surrounding the method of participant selection or a lack of clarity over blinding of the index test and reference standard results. Indirectness was also present in all evidence due to not reporting the ICS use of participants prior to the study. Less frequently occurring was the inclusion of participants <5 years of age, a lack of clarity over the definition of asthma, and the inclusion of allergens not specified in this review protocol, all of which led to further downgrading for indirectness." "No relevant clinical studies were identified comparing the clinical effectiveness of diagnosis	Thank you for your comment Skin prick testing is only one option given in recommendation 1.2.6 and the committee feel it is important to include it as a means of avoiding a blood test in a child who is reluctant to have this. The lines you quote regarding evidence quality are correct, but the GRADE criteria are stringent and many NICE reviews (not just in asthma) produce low or very low quality evidence. The sentence on clinical effectiveness is taken out of context; it applies to test and treat studies, not to tests of diagnostic accuracy.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				of asthma based on skin prick tests for any of the allergens specified in the review protocol" Should this therefore be reconsidered as a diagnostic tool?	
South Yorkshire Childrens and Young People's Alliance	Guideline	006	012	Objective tests for diagnosing asthma in adults, young people and children aged 5 – 16 (Children aged 5-16) The evidence used to inform a recommendation in using total allergen-specific immunoglobulin (IgE) as a diagnostic tool for Asthma is very low quality and there is little heterogeneity in the population of the patients in the studies. No international documents recommend the use of such tests as part of the diagnostic criteria/work up for asthma. It is strongly advised that this is reviewed and await further studies on a wider population at primary care level to determine the specificity and sensitivity of the test	Thank you for your comment The GRADE criteria are stringent, and many NICE reviews (not just in asthma) produce low or very low quality evidence as judged by this standard. Other guidelines have focused on measures of airflow obstruction and variability of this, but the committee believe that this does not give due account to the strong relationship between atopy and asthma, particularly in childhood, which can be used to help strengthen or refute a diagnosis of asthma.
South Yorkshire Childrens and Young People's Alliance	Guideline	006	015	This reads unclearly regarding the IgE. Is this about total IgE or specific IgE to house dust mites	Thank you for your comment This has been amended
South Yorkshire Childrens and Young People's Alliance	Guideline	008	025	As with diagnosis we have had patients referred into secondary care purely based on raised FeNo levels despite otherwise good asthma control (symptoms and PEF). We could see that	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				this will potentially increase the workload for secondary care due to primary care wanting to get an objective test performed to help assess good asthma control	The committee acknowledges that FeNO may occasionally produce unhelpful results, but in most cases it is useful and it was a cost-effective test in adults in our analysis.
South Yorkshire Childrens and Young People's Alliance	Guideline	009	005	If routine PEF, FeNO or spirometry not recommended, it may miss those who do need their treatment increasing when they are reviewed infrequently (e.g. only seen for annual reviews) and if they are poor at recognising that their asthma is deteriorating.	Thank you for your comment. Monitoring of FeNO is recommended in adults. Routine PEF or spirometry is not recommended, but this does not preclude measuring them if a person is known to be a poor perceiver of their own control (hence "person-specific reasons"). The evidence review did not support the use of regular lung function monitoring for all people with asthma.
South Yorkshire Childrens and Young People's Alliance	Guideline	009	021	Principles of pharmacological treatment State the importance of spacers, particularly in the young, and ensure this emphasizes the need for them to be using the correct spacer, in the correct size. This will avoid school aged children remaining on baby spacers with masks because this has not been routinely assessed during asthma reviews.	Thank you for your comment. Recommendations 1.6.5 to 1.6.9 give advice on inhalers with the intention of ensuring that the correct devices are used and that this is periodically reviewed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
South Yorkshire Childrens and Young People's Alliance	Guideline	010	008	We agree in principle however it is sometimes challenging to know if a young child is having just viral wheeze episodes or asthma from their history.	Thank you for your comment. The committee is sympathetic to the point you make, but this recommendation clearly states that it applies to people with asthma and is therefore valid. We recognise that it can be difficult to distinguish from other wheezing illnesses, particularly in the very young, hence the series of recommendation describing a trial of inhaled steroids in this age group.
South Yorkshire Childrens and Young People's Alliance	Guideline	012	000	Pharmacological management in people aged 12 and over Overall, from a management perspective it is great to see the incorporation of AIR and MART and a very clear statement in the document regarding no one being treated with SABA alone. However, this appears to have been made a one size fits all approach which does not align with the global initiative for asthma (GINA) recommendation that an alternative pathway be considered where necessary (although we note that a non-MART pathway has been suggested for children of 5-11 (page 16))	Thank you for your comment The committee believes that the evidence in adults strongly favours the AIR then MART strategy over the traditional treatment pathway and have therefore recommended this. The remit of NICE is to offer guidance on the most cost-effective management strategy and therefore this is also the same for this BTS/NICE/SIGN guidance.
South Yorkshire Childrens and	Guideline	012	004	This could be challenging in those who are under 18 years of age and are unable to use a	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Young People's Alliance				DPI device due to the licencing of ICS/Formoterol inhalers. The lack of a second alternative treatment pathway in this age group is surprising. Whilst we fully support the guidelines great emphasis on the use of ICS formoterol combination inhalers there appears to be little recognition for those patients for whom the treatment strategy may not be appropriate and for example where a once daily treatment may be appropriate. This is a once size fits most treatment but not a once size fits all	The committee believes that the evidence in adults strongly favours the AIR then MART strategy over the traditional treatment pathway and have therefore recommended this. The remit of NICE and BTS/SIGN is to offer guidance on the most cost-effective management strategy.
South Yorkshire Childrens and Young People's Alliance	Guideline	015	010	We are concerned that the guidelines are advising unlicensed treatment in this age group when there is currently less evidence for its use. Currently the only devices licensed under 18 are DPIs which will be challenging for many much younger children to use. We acknowledge that the guideline has to have longevity and are aware of the future licensing pipeline and we also acknowledge that the guideline highlights the off licence nature of this treatment option however we feel there should be a greater emphasis on this as well as an emphasis that DPI's may not be appropriate for younger children	Thank you for your comment The recommendation includes the statement that children must have been assessed as able to manage the MART regimen. This will include the fact that a DPI will be part of the treatment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
South Yorkshire Childrens and Young People's Alliance	Guideline	023	001	Should the number of courses of oral steroids being prescribed (within a defined period of time) also fall into this list?	Thank you for your comment This has been added
South Yorkshire Childrens and Young People's Alliance	Question 1	000	000	Question 1: *Would it be challenging to implement of any of the draft recommendations? Please say why and for whom.* Please include any suggestions that could help users overcome these challenges (for example, existing practical resources or national initiatives. The lack of many of the recommended objective testing in primary care will make implementing the diagnosis section challenging in particular for children and could lead to an increase in referrals to secondary care. Peak flow (PEF) variability needs to be included as it's the only thing available immediately for primary care which will pick up non-eosinophilic asthma	Thank you for highlighting this. Your comments will be considered by NICE where relevant support activity is being planned.
South Yorkshire Childrens and Young People's Alliance	Question 2	000	000	Question 2: *Would implementation of any of the draft recommendations have significant cost implications?* Testing requires more provision and resources many of which are not currently freely available – this has the potential to have significant cost implications. As above, peak flow (PEF)	Thank you for highlighting this. Testing is a key area for resource impact picked up by respiratory experts from committee. This is included for local resource impact assessment in the draft RI tools because practice varies widely.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				variability needs to be included as it is easily available to primary care and cost effective.	
Staffordshire & Stoke on Trent ICB	General	General	General	While making Initial clinical assessment in general practice, proposed guidance leaves little room for where clinical symptoms require treatment with inhaled corticosteroids whilst waiting for the long current wait for diagnostic tests, especially if initial tests are not positive/borderline. GINA includes this element; this guideline does not appear to consider primary care with limited access, or patients long wait before tests are complete and they remain symptomatic. Furthermore, some tests are not conclusive and may need repeating if requiring but this guideline says single negative test is final. There is also no advice about what to do with these patients who have clinical profile in keeping with asthma but negative/borderline tests. Where this is a high probability of asthma after thorough clinical history, a properly managed trial of treatment should be considered for all ages, not just the youngest patients. Is the recommendation that diagnosis of asthma can be made with appropriate symptoms and eosinophil count of 0.3 (low to very low-quality	Thank you for your comment It is true that there can be a long wait for some diagnostic tests at present, and optimal implementation of this guideline requires increased resource. However, the wait for some tests is not long at all – eosinophil counts can be obtained quickly. Recommendation 1.7.2 explains that treatment should be started if symptoms necessitate this. The committee acknowledge that there will be some people with borderline test results in whom clinical judgement will need to be exercised. No guideline (for any condition) can cover all possible individual variations. The guideline should not lead to people with cough and a raised eosinophil count being incorrectly diagnosed with asthma. The recommendations are for people with a history suggestive of asthma, and an isolated cough

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				evidence) without any objective test for airflow variation? This may lead to many patients with cough and slightly raised eosinophils being diagnosed with asthma in primary care. If eosinophils are normal, is the recommendation to also check fractional exhaled nitric oxide (FeNO)? If not, is the guideline suggesting that the 2 tests are equivalent?	should not suggest asthma (particularly in adults) unless it has unusual features such as marked variability. Recommendation 1.2.1 clearly states that either FeNO or eosinophil count should be measured, not both. The 2 measures correlate well but are not identical.
Surrey Heartlands ICB	Economic report diagnostic	019	Table 4	**Costs**: The cost of a FeNO test is listed as £22.21 The cost of monitoring asthma Without FeNO = £58.54 and With FeNO = £62.53. Which suggests the cost of FeNO is £3.99. This makes no sense when the cost of FeNO is listed as a much greater price higher in the table.	Thank you for your comment. The table included a few errors. The costs of monitoring with and without FeNO are, respectively, £34.25 and £27.26. The additional cost of £6.99 is higher than the unit cost of FeNO, as it was assumed that some people would receive 2 reviews in a year and, therefore, receive FeNO twice. It was also assumed that adding FeNO to an annual review would not lead to an increase in the duration of the review.
Surrey Heartlands ICB	Guideline	004	016	**Recommendation: 1.1.3**: We would suggest adding additional wording to the recommendation: Either add "Upon completion of diagnosis" Or start the	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				recommendation " When diagnosis is confirmed record the basis…". We would suggest adding a second point " Prior to confirmed diagnosis recommend coding for suspected asthma."	The committee agrees. 1.1.3 has been changed. Coding suspected asthma is already covered in 1.1.2.
Surrey Heartlands ICB	Guideline	005	019	**Recommendation 1.2**: A recommendation should be made to say that all clinicians interpreting FeNO and spirometry, in adults and children, should be appropriately trained.	Thank you for your comment. All NICE guidance assumes that the recommendations will be carried out by appropriately trained people and therefore this BTS/NICE/SIGN guidance is the same.
Surrey Heartlands ICB	Guideline	005	024	**Recommendation 1.21**: A FeNO level of 50ppb or more for adults is different to the previous NICE guideline recommendation and is not well explained in the evidence review or rationale as to why the change in FeNO level threshold. We are concerned that this will cause confusion without better explanation.	Thank you for your comment. This is an update of the previous NICE guideline and looked at new evidence. The level should not necessarily be expected to be unchanged. The rationale explains why the level was set at a relatively high level.
Surrey Heartlands ICB	Guideline	005	026	**Recommendation 1.2.2**: Please clarify if BDR should be performed regardless of whether spirometry result is showing obstruction or not, in adults or children.	Thank you for your comment. The committee believes that practice differs in this regard. It is not within NICE's remit to make

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					recommendations on the technical aspects of the test.
Surrey Heartlands ICB	Guideline	006	002	**Recommendation 1.2.3:** We are concerned that bronchial hyper-responsiveness is a high-risk test and usually only available at tertiary care level, not at local hospitals. There is not enough capacity within our DGHs to implement this recommendation. This makes the recommendation challenging to implement. Mannitol based hyperresponsiveness tests are used in DGHs locally, however this is not included in the recommendations. There should be an explanation about why this is not recommended in the rationale section, and possibly a do not do recommendation in 1.2.3.	Thank you for your comment The committee acknowledges this. It is however the best single test for asthma, and it would be remiss not to include it, albeit at the end of the testing sequence. The method of measuring bronchial responsiveness is not specified in the guideline. Mannitol is acceptable (testing with mannitol is less sensitive than using methacholine, but it still represents a better test for asthma than those covered in recommendations 1.2.1 and 1.2.2)
Surrey Heartlands ICB	Guideline	006	010	**Recommendation 1.2.6:** We have concerns about the service provision of skin prick test and capacity of the service. Often only provided by a Clinical Nurse Specialist at secondary care level. We are also concerned that access to Phlebotomy for children is poor, in our area it requires a hospital appointment with 4 to 8 weeks wait time.	Thank you for your comment Skin prick testing is only one option in recommendation 1.2.6. and the committee feel it is important to include it as a means of avoiding a blood test in a child who is reluctant to have this

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				We would suggest measuring total IgE level and specific IgE to house dust mite, and eosinophil count.	
Surrey Heartlands ICB	Guideline	006	013	**Recommendation 1.2.6:** Clarify whether specific IgE to house dust mite should also be measured, it looks like it from evidence review. Total IgE maybe indicative of other atopy.	Thank you for your comment The guideline suggests testing house dust mite sensitivity via skin testing because this could be used in children who refuse a blood test. Measuring specific IgE to house dust mite is not part of the guideline but would give equivalent information.
Surrey Heartlands ICB	Guideline	006	017	**Recommendation 1.2.7:** We are concerned that a bronchial challenge test is a high-risk test and usually only available at tertiary care level, not at local hospitals. This makes the recommendation challenging to implement	Thank you for your comment The evidence shows that bronchial challenge is the best single test for asthma and the committee believe it should be included, albeit at the end of the testing pathway when other investigations have not been conclusive.
Surrey Heartlands ICB	Guideline	008	018	**Recommendation 1.5.1**: We suggest adding in vaping, to "active or passive exposure to smoking", this particularly applies to children and young people.	Thank you for your comment. On reconsidering this, the reference to smoking has been removed from 1.5.1. The

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					recommendation is about indices of control, and smoking was therefore out of place there (and it is covered in other recommendations).
Surrey Heartlands ICB	Guideline	008	022	**Recommendation 1.5.3**: We suggest that more detail is added to this recommendation about the person-specific reasons for doing so – for example the rationale states that this applies to people who are poor at perceiving change in airway.	Thank you for your comment The commonest example has been added.
Surrey Heartlands ICB	Guideline	008	025	**Recommendation 1.5.4:** We agree with this recommendation on FeNO monitoring but this is currently not feasible in most GP practices due to both the cost of and the availability of FeNO.	Thank you for your comment. The committee recognises that more resource would be needed to implement this recommendation. Of note a resource impact report will be produced as part of this guideline. Your comments will be considered by NICE where relevant support activity is being planned.
Surrey Heartlands ICB	Guideline	009	010	**Recommendation 1.6:** There should be a description of what is meant by low dose ICS or MART, moderate dose MART etc.	Thank you for your comment. The guideline now refers readers to the document "Inhaled corticosteroid doses for the BTS, NICE and SIGN asthma guideline".

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Surrey Heartlands ICB	Guideline	009	010	**Recommendation 1.6:** It would be helpful to include a recommendation on which patients using MART should have SABA plus spacer for severe exacerbations.	Thank you for your comment. This is extremely difficult to define precisely, and the decision needs to be made on an individual basis.
Surrey Heartlands ICB	Guideline	009	010	**Recommendation 1.6:** We suggest that a recommendation is made on starting treatment in suspected asthma, while waiting for fully confirmed diagnosis, as patients may have to wait many months for access to appropriate diagnostic tests.	Thank you for your comment. As covered in recommendation 1.1.5, if symptoms are bad enough to need treatment this should be started, otherwise wait for testing. Note that even if access to other tests is difficult (this will vary) there should be little delay in getting an eosinophil count in an adult.
Surrey Heartlands ICB	Guideline	010	011	**Recommendation 1.6.3:** We agree with reviewing response to treatment at 8 to 12 weeks, but we are concerned this is not happening in practice due to lack of capacity in primary care.	Thank you for your comment. Unfortunately, there may be a capacity problem in some practices, but this is an important recommendation to include. Your comments will be considered by NICE where relevant support activity is being planned.
Surrey Heartlands ICB	Guideline	010	020	**Recommendation 1.6.4:**	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				We like the patient decision aid, and think you should include advice to give the PDA to patients prior to their appointment, especially in secondary care.	The point is appreciated but preparation for appointments goes beyond the committee's remit.
Surrey Heartlands ICB	Guideline	011	005	**Recommendation 1.6.6:** We like the recommendation to observe the person using their inhaler. We are concerned this does not happen often enough as asthma reviews are often carried out remotely.	Thank you for your comment. The committee agrees with you.
Surrey Heartlands ICB	Guideline	011	015	**Recommendation 1.6.7:** This recommendation should be more sensitive to the needs of different patient groups. For example it may not always be appropriate to prescribe the same type of device in children and young people. Children of secondary school age can be poor adherers to their preventer pMDI and are sometimes embarrassed to use a spacer with a pMDI as a reliever in front of their friends. If the child's technique is not suitable for any of the dry powder devices it is possible that the child will more likely use their preventer with a spacer in the privacy of their home but would prefer a device such as an Easi-breathe or Easyhaler for use as their reliever for school.	Thank you for your comment. Your comment presents situations in which a prescriber may decide to issue different devices to the same person. This is a guideline, and it is always appropriate for the healthcare professional to decide how it should be applied to an individual patient. However, for most people the principle is that they should have the device they use best, and if that is the device they use best then any medication they need should be given through it.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Surrey Heartlands ICB	Guideline	012	004	**Recommendation 1.7.1**: This recommendation should be clearer that it is for patients displaying milder symptoms. Describing the level of symptoms would also make it more consistent with recommendation 1.7.2, that describes the level of asthma symptoms and level of treatment needed.	Thank you for your comment It is extremely difficult to define exactly where the cut-off is between people who need the additional treatment described in 1.7.2 rather than AIR therapy.
Surrey Heartlands ICB	Guideline	012	013	**Recommendation 1.7.2:** We are concerned that this recommendation does not refer to the need for OCS treatment for severe exacerbation or refer to other guidance for management of exacerbation. Some readers may think ICS/LABA is treatment for an exacerbation.	Thank you for your comment The possibility that oral steroids might be needed has been added to 1.7.2.
Surrey Heartlands ICB	Guideline	013	008	**Recommendation 1.7.5:** We have concerns that the recommendation to add in a LTRA is made with no consideration or reference to the MHRA warning of neuropsychiatric reactions. The evidence review supporting the recommendations does not appear to have considered the additional concerns or economic implications of the work load (numbers of patients suffering harm, stopping treatment etc) associated with initiation of a LTRA.	Thank you for your comment The available evidence comparing addition of LAMA or LTRA, to ICS/LABA was very limited. The Wang et al 2015 study included in Evidence Review Q does not report on exacerbations as an outcome (instead only asthma control and FeNO). Hoshino et al 2019 did report on exacerbations for the comparison of ICS/LABA plus montelukast versus ICS/LABA plus LAMA. The result favoured

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The recommendation to use a LTRA rather than a LAMA as a first step add-in therapy is out of kilter with the GINA guidance. Patients on a LTRA are required to pay an additional prescription charge, whereas patients having a LAMA as add-in therapy can benefit from one prescription charge for single inhaler triple therapy.	LAMA, but was based on a single small study with very low certainty of evidence. The committee did not have much confidence in this result because of the small study population The practical arguments for choosing one over the other do not clearly come down on either side. LTRA's are cheaper and it is easier to give a trial of an additional tablet than of a LAMA which involves prescribing an additional inhaler (with environmental consequences) or changing inhalers with the associated time taken to teach the person how to use the new device. However, LTRAs are more likely to cause side effects. In this regard we note that you refer to data you hold on file suggesting a high rate of problems following montelukast. This is well above the frequency in published data and it is hard to comment further without seeing your document. After further discussion the GC have amended the recommendations and now suggest an equal choice between adding an LTRA or a LAMA.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Surrey Heartlands ICB	Guideline	014	001	**Transferring people from other treatment pathways** How are the recommendations in this section fit with the recommendation in 1.14.4.? We do not think this is consistent advice and is potentially confusing to continue to keep recommendation 1.14.4.	Thank you for your comment Please note that the guideline is not recommending changing everyone onto MART. People currently on other regimens will outnumber those on MART for some time and 1.14.4 is therefore still relevant.
Surrey Heartlands ICB	Guideline	015	001	**Recommendation 1.7.12**: Is this recommendation for people already treated on high dose ICS, as there is no mention of high dose ICS earlier in the pathway. We think there should be a list of modifiable risk factors to consider before referring, as wait lists can be long, up to one year.	Thank you for your comment 1.7.12 refers to people treated in accordance with previous guidelines, and high dose ICS was an option in SIGN158. The actions to take when asthma is uncontrolled have already been covered in recommendation 1.6.1.
Surrey Heartlands ICB	Guideline	015	008	**Medicine combination and sequencing in children aged 5 to 11**	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Please define what is paediatric low dose MART, and paediatric low dose ICS	A link is now included to the "Inhaled corticosteroid doses for the BTS, NICE and SIGN asthma guideline" table.
Surrey Heartlands ICB	Guideline	016	008	**Recommendation 1.8.4:** We have concerns that the recommendation to add in a LTRA is made with no consideration or reference to the MHRA warning of neuropsychiatric reactions. The evidence review supporting the recommendations does not appear to have considered the additional concerns or economic implications of the work load (numbers of patients suffering harm, stopping treatment etc) associated with initiation of a LTRA. This recommendation is out of kilter with the GINA guidance preferred treatment track.	Thank you for your comment A link to the MHRA DSU has now been added to the guideline. The committee discussed the potential for side effects when making their recommendations, but also took into account the frequency of adverse events and the potential benefits of an LTRA.
Surrey Heartlands ICB	Guideline	016	023	**Recommendation 1.8.7**: Should this recommendation refer to with or without an LRTA? It is not clear.	Thank you for your comment This has now been spelled out.
Surrey Heartlands ICB	Guideline	018	008	**Recommendation 1.9.5:** We have concerns that the recommendation to add in a LTRA is made with no consideration or reference to the MHRA warning of	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				neuropsychiatric reactions. The evidence review supporting the recommendations does not appear to have considered the additional concerns or economic implications of the work load (numbers of patients suffering harm, stopping treatment etc) associated with initiation of a LTRA. This recommendation is out of kilter with the GINA guidance preferred treatment track.	Please see evidence review Q. The committee discussed these recommendations at length including consideration of side effects. The recommendation is not out of kilter with GINA; their guideline says increase the ICS dose (which is what we say in 1.9.5) and then says adding an LTRA is an option (which is what we say in 1.9.6). A link to the MHRA DSU is included in the guideline.
Surrey Heartlands ICB	Guideline	023	002	**Recommendation 1.15.1:** This recommendation should include patients without formal diagnosis, but with suspected asthma, or on treatment for asthma. We've found cohorts of patients who are poorly controlled but no formal diagnosis / not on QoF register. This is particularly problematic in children, where a significant proportion of children.	Thank you for your comment This is potentially unhelpful. Some of these patients may not have asthma. It would be better to establish a diagnosis and if they have asthma to then add to the risk stratification system (after first determining that they are on appropriate treatment, taking this properly etc). Those without asthma can be managed accordingly.
Surrey Heartlands ICB	Guideline	023	012	**Recommendation 1.16.2**:	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				This recommendation on telehealthcare does not align with earlier recommendation on observing inhaler technique.	It is possible to observe inhaler technique remotely if there is a video link.
Surrey Heartlands ICB	Guideline	023	014	**Recommendation 1.16.3:** What evidence is there to support this recommendation on CDS systems?	Thank you for your comment 1.16.3 is taken from SIGN158. Please see the evidence statements there.
Surrey Heartlands ICB	Guideline	026	004	**Recommendations for research:** We think there should be a recommendation for research on the use of artificial intelligence for spirometry testing and reporting.	Thank you for your comment The research recommendations are based on a literature search that was performed for the guideline, but which did not reveal adequate evidence. This is standard NICE methodology which has also been used in this BTS/SIGN/NICE process and research recommendations cannot be put forward to address a question that was not part of the guideline.
Surrey Heartlands ICB	Guideline	General	General	Overall, we are supportive of the guidance and this it makes sense. However we are concerned that there are risks to the supply of inhalers containing ICS/formoterol licensed for AIR and MART if there is a large scale implementation of the guideline across the country.	Thank you for your comment They will be prescribed more, but the guideline does not advocate switching everyone to

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					MART. Those well controlled on current medication will stay on it.
Surrey Heartlands ICB	Guideline	General	General	**Would it be challenging to implement the draft recommendations**: Access to spirometry and FeNO in primary care is an issue. We need properly funded Locally Commissioned Services (LCS) for GP practices to be able to undertake diagnosis of asthma. Coding of suspected asthma should be supported, and diagnostic tests paid for when coded done. ICBs need sufficient funding to be able to pay for a primary care based diagnostic service that includes FeNO and spirometry for asthma.	Thank you for your comment. The committee agrees that extra resource will be needed to fully implement the recommendations. Your comments will be considered by NICE where relevant support activity is being planned.
Taskforce for Lung Health	Evidence review A	017	037 – 041	The committee's emphasis on the importance of spirometry as a test for assessing other causes of breathlessness including COPD suggests that the use of eosinophil testing or FeNO as the first course of objective testing is insufficient and that without spirometry, people may be misdiagnosed as having asthma.	Thank-you for your comment. Evidence review A considers spirometry, not other tests. Evidence on eosinophils and FeNO is presented in other reviews. The diagnostic pathway in the guideline is based on people in whom the history suggests asthma. If other conditions are suspected other tests will be required (the rationale to the diagnosis section in the guideline states this) and in line with this,

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					if COPD is suspected spirometry should be obtained.
Taskforce for Lung Health	Evidence review A	017	042 - 051	The committee's recommendation that children being tested with spirometry could be referred to secondary care until diagnostic hubs are more widely available risks increasing demand upon secondary care diagnostics significantly.	Thank-you for your comment The committee acknowledges this. However, misdiagnosis in children and adults can result in later referrals after a period of time in which unnecessary treatment has been given to some and no, or incorrect, treatment to others. It is better to get it right at the onset.
Taskforce for Lung Health	Evidence review A	General	General	Evidence review A includes no mention of costs including training or accreditation, both of which are significant barriers to correct, widespread implementation.[xli] While these are beyond the scope of this guideline, they must be acknowledged as practical barriers to implementing the guideline's diagnostic pathway. If NICE feel that spirometry in children is a suitable diagnostic test, even if this were to only be within a secondary care setting, this recommendation should be overt and greater availability of spirometry should be advocated.	Thank-you for your comment The guideline recommends spirometry as part of BDR testing, not on its own. By doing so it does in effect recommend greater access to spirometry. We agree that training and accreditation costs represent a practical barrier to implementation. Your comments will be considered by NICE where relevant support activity is being planned.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Taskforce for Lung Health	Evidence review C	005	013 - 016	PEF's role as a useful measure of airway calibre variability highlights its utility as an objective test for diagnosing asthma, suggesting that it should be included within the draft guideline's suggested diagnostic pathway.	Thank you for your comment PEF variability is an insensitive test and the analysis of various testing strategies (see evidence review K) showed that the best test sequences did not include it. However, numerous stakeholders have supported its use and it is now included in the diagnostic section.
Taskforce for Lung Health	Evidence review C	014	025 - 032	The factors discussed in section 1.2.5 of Evidence Review C outline a strong case for including PEF within the draft guideline's suggested diagnostic pathway.	Thank you for your comment. PEF variability is an insensitive test and the analysis of various testing strategies (see evidence review K) showed that the best test sequences did not include it. However, numerous stakeholders have supported its use and it is now included in the diagnostic section.
Taskforce for Lung Health	Evidence review E	General	General	The quality of evidence presented in Evidence Review E was low. In both pieces of evidence, there is imprecision within the estimates of specificity. Section 1.2.5 includes "IgE is also raised in other common childhood conditions and the committee emphasised that it should	Thank you for your comment IgE is not the first test in the sequence and the guideline does not recommend it as the only test. The guideline states that all tests, not just

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				only be used as a test for asthma when there is also a good history to support the diagnosis." This raises further concerns about test accuracy when using IgE as an objective test for diagnosing asthma. This is also evidenced by the fact that the committee were not able to specify which IgE cut-off point should be used to support an asthma diagnosis because the normal range for IgE levels varies considerably over childhood years.	IgE, should be combined with a history suggestive of asthma.
Taskforce for Lung Health	Evidence review F	032	Table 8	Table 8 states that FeNO was the most cost-effective test compared with other tests, further evidencing its suitability for both the adult and 5-16-year-old diagnosis pathways.	Thank you for your comment
Taskforce for Lung Health	Evidence review F	037	036 - 040	It is essential that the guidance reflect the evidence that FeNO is not "an appropriate test for ruling out an asthma diagnosis in adults that smoke". Smoking, as well as smoking cessation, is not heavily featured within the draft guidance. The impact of smoking status on the utility of FeNO testing must be clearly highlighted to clinicians in order to ensure that the diagnostic pathway (and diagnostic resources) are correctly used and to ensure that patients can benefit from an accurate diagnosis.	Thank you for your comment The guideline does not use FeNO as a rule out test. It suggests that a positive diagnosis can be made if FeNO is high. Since smoking lowers FeNO level the advice is more robust still in smokers.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Taskforce for Lung Health	Evidence review F	038	006 - 010	The Taskforce is concerned about the use of lower quality studies' findings to overrule or impugn the findings of higher-quality studies. The maximum specificity of 0.94 at 40ppb or below suggests a well-evidenced reason for using a lower threshold in FeNO tests when diagnosing asthma.	Thank you for your comment The committee weighed up several factors in setting a FeNO threshold. In particular, because it may be the first and only objective test they set the threshold for diagnosis at a high level so that fewer people will get a false positive diagnosis on the basis of a single test.
Taskforce for Lung Health	Evidence review F	039	021 - 025	The committee stated that at sufficient specificity, FeNO can be a cost-effective alternative to a blood test in diagnosing asthma. The evidence review should also consider that, where this is the case, the utility of FeNO is increased as it is a faster testing process than blood eosinophil testing due to the lack of need for a follow-up appointment. This speed must be counted as a positive factor, promoting higher patient safety and a better patient experience, ensuring quicker diagnosis (if positive) or progression along the diagnostic pathway (if negative). NICE should also consider the need for further tests/follow up due to tests having a higher threshold. It seems counter-intuitive for the	Thank you for your comment The committee agrees that obtaining an immediate result can be a benefit of FeNO (although it depends on the presence of someone able to interpret the result in a clinical context if feedback is to be given there and then). The committee acknowledges that a higher threshold may mean that some people get further tests that might have been avoided, but this is more cost-effective and clinically more desirable than other people starting on asthma treatment with an incorrect diagnosis.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				benchmark for good quality care to be based on the cheapest available test.	
Taskforce for Lung Health	Evidence review F	039	032 - 033	Section 1.2.5 highlights that the ideal diagnosis of asthma should include a measure of inflammation and pulmonary function. This contradicts elements of the diagnostic pathway that would confirm a positive diagnosis upon positive results of a single objective test.	Thank you for your comment The key word is "ideal". If all tests were quickly available this would be recommended, but the committee have to balance this with practical considerations.
Taskforce for Lung Health	Evidence review F	039	043 - 045	The guidance given on FeNO thresholds draws from contrasting examples within the evidence review and the conclusion of suggested cut-offs of 50 ppb in adults and 35 ppb in children also vary from the figures given within NICE's diagnosis guidance in April 2014.[xlii]	Thank you for your comment The evidence has been updated since 2014.
Taskforce for Lung Health	Evidence review F	General	General	By including FeNO within regular asthma reviews, these reviews would have to be conducted face-to-face. In-person reviews provide a more comprehensive review of the patient's condition[xliii] and would pair well with more regular inhaler technique checks.	Thank you for your comment The committee agrees.
Taskforce for Lung Health	Evidence review F	General	General	Evidence included within the evidence review showed that implementing routine FeNO monitoring would likely reduce the risk of exacerbations in adults and children, and reduce the average ICS dose in adults. This should	Thank you for your comment The committee agrees. However, NICE currently uses the word "consider" to indicate

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				increase the quality of life of people with asthma and reduce healthcare spending associated with asthma exacerbations and ICS prescribing. Lower ICS doses could also have other positive impacts, for instance, on the environment. These are significant reasons for increasing the use of FeNO in asthma care and suggest that phrasing in the draft guidance allowing clinicians to "consider" using FeNO should be strengthened.	the certainty of the evidence base behind a recommendation and it is the correct word to apply in this instance. Please note also that following representation from other stakeholders and a review of the evidence, the recommendation for FeNO monitoring in children has been removed.
Taskforce for Lung Health	Evidence review F	General	General	The committee's agreement that FeNO has a potential place as an education tool to better inform patients of their condition and of treatment's effectiveness highlights further benefit of FeNO. This is a key reason for the increasing use of FeNO.	Thank you for your comment The committee agrees.
Taskforce for Lung Health	Evidence review G	016	022 - 024	The evidence review explains that blood eosinophil tests are of use when performed alongside other objective testing. This contradicts the draft guideline's diagnostic pathway wherein blood eosinophil testing is used in isolation.	Thank you for your comment Well spotted. Some of the studies in that review attempted to find a compromise value with the best combination of sensitivity and specificity and reported cut-off values below the upper limit of the normal range. The 2 studies which used higher cut-offs both showed good specificity.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					The sentence you quote should have stated that the studies overall did not suggest that eosinophil count alone could be diagnostic. It has been amended.
Taskforce for Lung Health	Evidence review G	016	024 - 026	The evidence review explains that there is variation between the normal ranges used by different laboratories. The use of varying laboratories' upper limits as the threshold for a positive asthma diagnosis builds inconsistency within the diagnostic pathway and introduces a geographic disparity which will impact patients directly and will also potentially reduce the utility of national data.	Thank you for your comment The recommendation has to cope with the fact that there is slight variation between laboratories in normal ranges for adults. If one of the upper limits was chosen this would compromise the use of eosinophil level far more, since it would be incorrect for people whose samples go to one of the other labs.
Taskforce for Lung Health	Evidence review G	016	039	The evidence review highlights that caution is needed when interpreting results from eosinophil tests. This highlights that eosinophil testing requires skilled, trained clinicians to ensure effective use of testing. Without specifying this within the draft guidance, clinicians will potentially be unaware of this, risking over-diagnosis.	Thank you for your comment All NICE guidance assumes, and this BTS/NICE/SIGN guidance is similar, that it will be applied by healthcare professionals who are appropriately trained.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Taskforce for Lung Health	Evidence review G	016	039 - 045	The evidence review explores the variability of eosinophil levels and the mitigation/discretion needed to be used by trained clinicians when assessing test results. This reduces the specificity of eosinophil tests and will require significant education for the clinicians making asthma diagnoses.	Thank you for your comment All NICE guidance assumes, and this BTS/NICE/SIGN guidance is similar, that it will be applied by healthcare professionals who are appropriately trained.
Taskforce for Lung Health	Evidence review H	017	045 - 047	The evidence review notes that the availability of bronchial challenge testing may vary nationally and that, as a result, clinicians should reserve referrals to ensure capacity for those with a complex clinician history and uncertain diagnosis. However, the "rule-in" approach of the diagnosis pathway and the poor availability of other objective tests presents the possibility of very high demand for bronchial challenge testing capacity regardless. Evidence review K highlights that around 30% of children with suspected asthma will need a referral to secondary care for a bronchial challenge test.[xliv]	Thank you for your comment. The committee agrees. It is regrettable that the single best test for asthma is not more readily available. The figure of 30% of children potentially needing a bronchial challenge test is based on the health-economic model, and as the diagnostic algorithm has not been formally tested as yet, it may not be correct. Moreover, the figure of 30% is for referral to a paediatrician for assessment and possible bronchial challenge test rather than straight to a challenge test, and it was derived before measuring PEF variability was added to the diagnostic sequence.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Taskforce for Lung Health	Evidence review H	018	029 – 031	The evidence review also notes that bronchial challenge testing will require repeated spirometry measurements. With spirometry access slow to recover post-Covid, this further limits access to bronchial challenge testing.	Thank you for your comment. The repeated spirometry measurements are all done within a single bronchial challenge test on the same day, so access to spirometry alone is a separate issue. Your comments will be considered by NICE where relevant support activity is being planned.
Taskforce for Lung Health	Evidence review I	040	004	The Taskforce agrees with the committee regarding their note that "some people with asthma would still need to have an MDI and SABA available to use via a spacer in the event of a severe asthma attack". This is not referenced sufficiently within the guidance itself. The Taskforce recommends adding this statement to the guideline, as we believe that its omission will put patients at risk.	Thank you for your comment Recommendation 1.6.8 has been expanded.
Taskforce for Lung Health	Evidence review K			Evidence review K uses contrasting data to attempt to make comparative assessments between various diagnosis pathways: in the section exploring FeNO alone, the evidence cites up-to-date costs (lower than in the studies evaluated). In the section on using combinations of tests, it appears that combinations of tests	Thank you for your comment. This area was prioritised for an original economic analysis by NICE as the committee were interested in finding the most cost-effective diagnostic algorithm for asthma in adults and children. A robust economic analysis

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				including FeNO used the study costs and not current costs. This significantly reduces the utility of any results from this comparison and may have massively skewed the results of this section away from using combinations of tests. In any case the use of economic modelling around the use of tests deviates from any focus on the patient and the disease ie: a variable condition with elements of inflammation and obstruction. This section seems overly focused on economic analysis. The evidence review highlights the robust nature of the Harnan paper and highlights that FeNO+BDR was the most cost-economic option in their paper, but the committee felt it to be of limited value due to the fact they were not evaluating a sequential diagnostic pathway. The committee evaluated the evidence for using spirometry and FeNO together with the study using thresholds of FEV1 88.4% and FeNO 19.6ppb. This FeNO level is significantly lower than most levels used by clinicians and suggested by NICE elsewhere in the guideline. It may have been appropriate for NICE to adjust	is required to support strong recommendations particularly in areas of potentially large impact. The cost of FeNO used in the model was estimated using up-to-date information obtained from manufacturers and expert opinion from the committee. Harnan paper was included in the review but, as highlighted in the comment, used old estimations for cost and thresholds for spirometry and FeNO that are not commonly used in the NHS. This prompted us to develop an original analysis that looked at two different thresholds for FeNO. Review F included a detailed estimation of the cost of FeNO used in the economic analysis. A combination of BDR and FeNO was included in several of the diagnostic strategies assessed in adults: 6, 7, 8 and 9. Two different thresholds of FeNO were included, 40ppb and 50ppb, both used by clinicians. The full economic report is

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				this data to account for this inconsistency and improve the sensitivity of combined testing.	published alongside the guideline for public review.
Taskforce for Lung Health	Evidence review K	005	006 - 008	The review's introduction correctly acknowledges that no single test can accurately diagnose asthma (owing to the need for testing of pulmonary function and inflammation). This contradicts the draft guideline's diagnosis pathway.	Thank you for your comment. Unfortunately, combinations of tests are also not 100% accurate because of the variable nature of asthma. The guidance is attempting to reconcile the desirability of obtaining some supportive objective evidence with the simplicity of relying on clinical history alone. The committee decided that in people with a good clinical history and a single test result showing strong evidence of eosinophilic inflammation, this would suffice. Other people require further tests.
Taskforce for Lung Health	Evidence review K	031	002 - 005	The evidence review discusses the poor and inconsistent availability of FeNO as a barrier to CYP diagnosis. However, the review doesn't highlight that spirometry for CYP is also far from universally available and that this will also have a knock-on impact on the diagnosis of asthma in CYP. Some consideration should be given to strengthening the language around FeNO's	Thank you for your comment The guideline recommends FeNO as the first line test in children and one of two options as first line test in adults. This should help in making FeNO more widely available.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				inclusion in the adult diagnostic pathway to bolster the argument for greater availability of FeNO nationally. The evidence review highlights that around 30% of children with suspected asthma will need a referral to secondary care for a bronchial challenge test. This presents a significant number of referrals and a potential strain upon test capacity.	Access to bronchial challenge (for adults and children) is a major problem. The committee recognises this and discussions did touch on whether it should be included, but it is the single best test for asthma and therefore appears at the end of the diagnostic pathway for use when other tests have not helped.
Taskforce for Lung Health	Evidence review Q	125	032 - 046	Evidence review Q's exploration of treatment escalation is detailed and covers points that should be explicitly covered in the draft guideline. The role of DPIs and their potential limitation for people suffering a severe exacerbation is vital information when prescribing inhaled therapies, and the role of SABA is also discussed in more detail in this review – clarity is needed in the draft guideline on the use of SABA during exacerbations.	Thank you for your comment Treatment of exacerbations is not in the scope of this guideline. Complementary guidance on acute asthma will be produced by BTS/SIGN.
Taskforce for Lung Health	Evidence review Q	General	General	The guideline should highlight that patients with montelukast (LTRA) as part of their maintenance therapy should have all potential side effects explained to them by their clinicians.	Thank you for your comment. This is a general principle which applies to any medicine.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Taskforce for Lung Health	Guideline			**1.2.5** FeNO is a key diagnostic tool that forms an essential part of the 5-16-year-old diagnostic pathway outlined in this guidance. It is also a key inclusion in the adult pathway and must be offered as a truly accessible alternative to blood eosinophil testing. Patient representatives have expressed that FeNO is their preferred diagnostic test, due to their dislike of blood tests/needles. As such, Taskforce recommends that the phrase "or if FeNO is not available" has no place in this guidance and must be removed.	Thank you for your comment. The committee are very sympathetic to your comment but are aware that FeNO availability is currently limited (as numerous other Stakeholders have emphasised). They believe that an alternative should be included.
Taskforce for Lung Health	Guideline	004	004 - 012	**1.1.1** The Taskforce recommends of an addition to the final guideline around healthcare professionals considering asthma and other respiratory conditions whenever a person presents with any respiratory symptoms including cough, wheezing, breathlessness, chest tightness, chest infection, and sputum production. Clinicians may be guided by the NHS England breathlessness pathway support tool in	Thank you for your comment. Some of the symptoms you list are already in 1.1.1. The committee does not wish to add "chest infections"; if these were recurrent (and therefore possibly indicative of asthma) they would cause some of the symptoms already listed. Sputum production without any of the other symptoms is more likely to represent an alternative condition.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				diagnosing alternative (non-asthma-related) causes of respiratory symptoms and should be aware of red flags for acute breathlessness.	The committee agrees that the NHS England document is a useful tool.
Taskforce for Lung Health	Guideline	004	004 - 012	**1.1.1** The Taskforce recommends that healthcare professionals review a patient's clinical record for previous episodes which can suggest recurrent respiratory symptoms indicative of asthma. These include a previous respiratory diagnosis, suspected respiratory diagnosis and prescriptions for inhalers, oral corticosteroids and antibiotics, professional-recorded wheeze, or previous testing suggestive of an attempt to make a respiratory diagnosis such as peak flows as these can often provide important clues regarding potential diagnosis.	Thank you for your comment. The features you list are unlikely in someone presenting for the first time.
Taskforce for Lung Health	Guideline	004	004 - 012	**1.1.1** This guideline places considerable emphasis on clinical history and examination ahead of objective testing. The lack of an algorithm within the updated guideline is concerning as these provide helpful guidance for healthcare professionals. It is crucial that the guideline explicitly states that history and examination	Thank you for your comment All NICE guidance assumes that the recommendations will be carried out by people with appropriate training, and this BTS/NICE/SIGN guidance is the same

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				need to be carried out by someone with the appropriate training and skills needed to identify asthma and the wide range of differential diagnoses and co-morbidities that cause the same symptoms. Appropriate detailed history and further testing/referral should be considered where there are risk factors or factors suggesting an alternative or co-existing condition. This is because numerous other conditions can all present similarly to asthma, including cancer, pulmonary embolism, cardiac, chronic obstructive pulmonary disease, idiopathic pulmonary fibrosis, gastro-oesophageal reflux, ear, nose and throat causes/post-nasal drip, mental health conditions, and breathing pattern disorders.	The rationale for the diagnosis recommendations notes that other diagnoses might need to be considered, but guidance on investigating other conditions is outside the scope of this asthma guideline.
Taskforce for Lung Health	Guideline	004	009	**1.1.1** The Taskforce suggests the addition of "potential occupation triggers" within 1.1.1's specified checklist. This would prompt clinicians to consult section 1.4 of the guidance if relevant.	Thank you for your comment. There are numerous potential triggers. Whilst occupational asthma is important, in 1.1.1 the aim is to make a diagnosis of asthma irrespective of the cause. Occupational asthma is highlighted separately in section 1.4.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Taskforce for Lung Health	Guideline	004	013 - 014	**1.1.2** The Taskforce suggests adding a read code of "suspected asthma" until a supporting objective test result is available. Patient records should be updated to provide supporting details and to outline the basis for suspicion. This will help the clinician and/or wider team understand the rationale for considering asthma as a diagnosis. This read code will also enable healthcare providers to monitor people who may have asthma but are not formally diagnosed. This is important due to the variable nature of asthma (diagnosis may take a long time), for people who are not routinely followed up or choose not to be followed up, and where there is a delay in accessing objective testing. This guideline places considerable emphasis on clinical history and examination ahead of objective testing. It is crucial that the guideline explicitly states that history and examination need to be carried out by someone with the appropriate training and skills needed to identify asthma and the wide range of differential	Thank you for your comment. Advice on coding as suspected asthma has been added to 1.1.2. NICE guidance assumes that all recommendations will be carried out by people with appropriate training and therefore this BTS/NICE/SIGN guidance does the same.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				diagnoses and co-morbidities that cause the same symptoms. Appropriate detailed history and further testing/referral should be considered where there are risk factors or factors suggesting an alternative or co-existing condition (cancer, pulmonary embolism, cardiac, chronic obstructive pulmonary disease, idiopathic pulmonary fibrosis, gastro-oesophageal reflux, ear, nose and throat causes/post-nasal drip, mental health conditions, and breathing pattern disorders).	
Taskforce for Lung Health	Guideline	005	007 - 011	**1.1.5** Taskforce is concerned that a lack of clarity in this section on treating someone who is acutely unwell may put patients at risk of not getting appropriate acute management, increasing their risk of death.[xlv] The Taskforce recommends specifying that if a patient is suspected as potentially having asthma then they need assessing and treating as if they were already diagnosed. This may include oral steroids at the correct dose for asthma and/or inhalers as appropriate. Acute assessment should presume a diagnosis of asthma and include peak flow,	Thank you for your comment. Please note also that acute management of asthma is outside the scope, but BTS and SIGN will be producing guidance on this. However, the possible need for oral steroids has been added to 1.1.5.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				heart rate, respiratory rate, oxygen saturation and chest examination. Chest examination is important as asthma symptoms can overlap with many other conditions including pulmonary embolism, pneumothorax, and chest infection/pneumonia. This face-to-face contact also provides an opportunity to demonstrate any inhaler devices and observe inhaler techniques where these are being prescribed. Multiple patient surveys conducted by Taskforce member Asthma + Lung UK highlight the positive correlation between in-person appointments and improved access to proper treatment and basic asthma care.[xlvi]	
Taskforce for Lung Health	Guideline	005	009 - 010	**1.1.5** Greater clarity is needed within lines 9 and 10: "spirometry or peak flow with bronchodilator reversibility [BDR]) if the equipment is available". Currently, this suggests that peak flow readings can be used to demonstrate BDR. This would be an important and practical step to improving diagnosis but is at odds with the proposed diagnostic process.	Thank you for your comment. This recommendation deals with the less frequent situation where a person presents with acute symptoms requiring immediate treatment. Whilst the committee would not advise measuring change in PEF in other circumstances, here it is more likely to be possible to measure PEF than FEV1, and the acute response could provide valuable

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Given that peak flow is an essential part of assessing acute asthma symptoms (or suspected asthma) this approach should be highlighted. BDR could be demonstrated by peak flow before and after bronchodilator medication, as part of a peak flow diary while starting preventer medication or before and after a course of oral steroids. The importance of peak flow assessment in acute asthma is highlighted in Scenario: Acute exacerbation of asthma | Management | Asthma | CKS | NICE The guideline should provide clarity on what percentage of reversibility and variability would support a diagnosis of asthma. The guideline must also emphasise that FeNO, eosinophil and spirometry testing do not demonstrate variability unless the patient is symptomatic at the time of testing, whereas the use of PEF can demonstrate variability.	diagnostic information. It does not apply to situations where the person is not acutely unwell, lung function is less likely to be highly abnormal, and there is time for better standardised testing,
Taskforce for Lung Health	Guideline	005	009 – 010	**1.1.5** The draft guideline should include prescriptive guidance for bronchodilator reversibility.	Thank you for your comment. Recommendation 1.1.5 is not part of the current update. It deals with opportunistic measurement

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					of reversibility when a person presents with an acute attack. The regular use of BDR is dealt with in recommendations 1.2.2 and 1.2.5.
Taskforce for Lung Health	Guideline	005	012 - 016	**1.1.6** The Taskforce recommends that the guideline should clarify that acute presentations where asthma is suspected must be followed up routinely within an appropriate timescale, with clear instructions to the patient about when follow-up will happen and when to seek help in the meantime. This should be in line with NICE QS Quality statement 4: Follow-up by general practice after emergency care | Asthma | Quality standards | NICE	Thank you for your comment. This is a legacy recommendation, not part of the update.
Taskforce for Lung Health	Guideline	005	012 - 016	**1.1.6** The Taskforce recommends that patients be given information about their suspected diagnosis so that they understand the condition that they are being investigated for, are safety-netted in terms of worsening symptoms, understand how to use any inhalers they have been prescribed, triggers to avoid, and the availability of smoking cessation services.	Thank you for your comment. This is a legacy recommendation, not part of the current update.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Potential guidance could include Asthma + Lung UK's patient-focused resources on diagnosing asthma: Diagnosing asthma | Asthma + Lung UK (asthmaandlung.org.uk)	
Taskforce for Lung Health	Guideline	005	017 - 018	**1.1.7** The Taskforce recommends that the guidance should specify that normal test results do not necessarily exclude asthma. Asthma is a variable condition that may present at some points and not present at others.	Thank you for your comment. This is true, but also obvious from the diagnostic sequence recommended in this guideline in which investigation continues despite normal test results.
Taskforce for Lung Health	Guideline	005	022 - 025	**1.2.1** This section needs to be more specific regarding eosinophil counts and laboratory reference ranges. The draft guideline suggests that it should be based on local reference ranges; this creates a postcode lottery and inconsistencies in diagnosis. National standards should be set by this guideline and laboratories must report according to those standards. By increasing the eosinophil level required for a positive result, the test's specificity is increased, which will lead to fewer false positive diagnoses, but also the increased likelihood of false	Thank you for your comment. It would be helpful if every laboratory used exactly the same techniques and reported exactly the same normal range, but at present this is not the case. The health economic analysis took into account all costs related with the diagnostic algorithm, including the cost of each test and the consequences of misdiagnoses. Blood eosinophils was found to be cost-effective as a first test, due to its high specificity and low cost. It is important that the first test of the sequence is highly specific, or there is a risk of

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				negative results. Taskforce is concerned that this will cause both delays in patients receiving the care they need and increased costs in the system as additional objective tests are required to secure a diagnosis. It is not clear whether the sequence of testing evaluated in this guideline includes the costs of all tests done in the sequence. Eosinophil levels of between 0.15 and 0.3 are commonly used and should be specified within the guidance as affording sufficient test specificity and accuracy of diagnosis.[xlvii] The guideline should also explain the expected proportion of suspected asthma patients who will need each test. Elements of this are discussed throughout various evidence reviews (evidence review K explains that around 30% of children will need to be referred to secondary care for bronchial challenge testing) but this should be consistent.	overdiagnosis and overtreating asthma. False negative results are expected to be corrected, in large part, by further tests whose costs and implications are accounted for in the analysis described in the economic report.
Taskforce for Lung Health	Guideline	005	022 - 025	**1.2.1** Taskforce recommends that 1.2.1 explains that there are other causes of raised eosinophil levels and that these must be differentiated from	Thank you for your comment. The committee agrees that other conditions may cause the eosinophil count to be raised,

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				asthma to avoid giving false-positive diagnoses based on eosinophil levels alone. This was a concern shared by our patient representatives, who highlighted the point that eosinophils can be raised for a number of reasons unrelated to asthma and using eosinophil count may increase the rate of misdiagnosis. Other potential causes of high eosinophils include sinusitis, nasal polyps, allergic bronchopulmonary aspergillosis, and eosinophilic granulomatosis with polyangiitis, which can also cause chest symptoms that mimic asthma. Similarly, smoking can also significantly decrease blood eosinophil levels.	but there are potential confounding factors with most diagnostic tests. Other causes of eosinophilia have been noted in the Terms Used section.
Taskforce for Lung Health	Guideline	005	022 - 025	**1.2.1** Feedback from our patient representatives in response to this consultation was that blood tests might not be acceptable to people with suspected asthma due to a dislike of blood tests/needles, and confusion around the use of blood tests as a diagnostic tool for asthma. They are concerned that this could serve as a barrier to diagnosis.	Thank you for your comment. The committee agrees that some people are not willing to have blood tests, and recommendation 1.2.1 gives FeNO as an alternative.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				FeNO testing must be made universally available to meet the needs of the diagnosis pathway outlined for those aged 5-16, but must also be available to diagnose adult patients for whom a blood test is not an acceptable or preferred test. Ensuring informed patient choice is central to providing a quality service within the NHS and must be a key consideration when providing diagnostic tests for asthma.	
Taskforce for Lung Health	Guideline	005	022 - 025	**1.2.1** Taskforce recognises the importance of a patient's detailed clinical history which relies on sufficient training and experience to be correctly utilised in a patient's diagnosis and treatment There are different types of asthma which may present with inflammation and/or airway obstruction; diagnosis should therefore be made using both a measure of inflammation and a measure of airway obstruction. NICE's April 2014 diagnostic guidance on the use of FeNO highlights its utility but suggests that it shouldn't be used in isolation from other objective testing.[xlviii]	Thank you for your comment. This is an update of NICE's earlier guideline. It contains new evidence and need not be expected to come to exactly the same conclusions as its predecessor.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Taskforce for Lung Health	Guideline	005	022 - 025	**1.2.1** Diagnosing asthma using the patient's clinical history and eosinophil count alone is likely to miss other causes of respiratory symptoms such as COPD. COPD can mimic asthma and can co-exist with asthma.[xlix] Although initial management would be similar (use of ICS, smoking cessation), the failure to diagnose and read code COPD could inhibit access to appropriate education and self-management and access to specific treatments such as pulmonary rehabilitation. The Taskforce recommends that the draft guideline inform clinicians of the potential to misdiagnose COPD in this way.	Thank you for your comment. The rationale for recommendation 1.2.1 acknowledges that when a person first presents with symptoms compatible with asthma there may well be other conditions which should be considered in the differential diagnosis.
Taskforce for Lung Health	Guideline	005	022 - 025	**1.2.1** Evidence of airway obstruction through peak flow testing can be useful for monitoring disease stability and is essential as part of the assessment of asthma exacerbations.[l] Peak flow should be employed as part of the diagnostic process in conjunction with testing for airway inflammation.	Thank you for your comment. Recommendation 1.2.1 is about diagnosis, not monitoring nor assessment of exacerbations. PEF variability is now included in the diagnosis sections.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Taskforce for Lung Health	Guideline	005	022 - 025	**1.2.1** Taskforce recommends that the guidance specify that non-T2 asthma will show negative eosinophil and FeNO test results and that the use of objective testing must account for all types of asthma. By not identifying non-T2 asthma (i.e. negative eosinophils / FeNO testing), a greater number of people with suspected asthma will remain off medication or need a referral to already-stretched secondary care services.	Thank you for your comment. The diagnostic test sequence accounts for all types of asthma. The FeNO or eosinophil count is used as a rule-in test, not to rule out the diagnosis. If negative, the person will proceed to the next test (reversibility measurement).
Taskforce for Lung Health	Guideline	005	024	**1.2.1** A FeNO threshold of 50ppb or more differs from previous NICE guidance which suggested 40ppb. Similarly, 50ppb also differs from the ranges discussed in NICE's April 2014 diagnostic guidance for FeNO.[li] By increasing the threshold required for a positive result, the test's specificity is increased, leading to fewer false positive diagnoses. However, Taskforce is concerned that this will also result in false negatives, causing both delays in patients receiving the care they need	Thank you for your comment. Any cut-off value chosen would be a compromise between perfect sensitivity and perfect specificity. The level was set at a slightly high value since this may be the only test people get and the committee therefore wished to err on the side of specificity. This will mean extra tests for some, but getting the diagnosis correct at the start will reduce future problems. Also note that in the last version of the NICE guideline multiple tests were more likely; the current recommendations are more

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and increasing costs in the system as additional objective tests are required to secure a diagnosis. It is not clear whether the sequence of testing evaluated in this guideline includes the costs of all tests done in the sequence. Incorrect and delayed diagnosis prevents people from accessing appropriate care and treatment and puts patients at risk. The Taskforce recommends that FeNO thresholds be re-evaluated to better balance test specificity with a threshold low enough to prevent patients unnecessarily slipping through the net and escalating along the diagnosis pathway. Evidence review F explains that thresholds as low as 37 ppb can produce specificity values of 0.96; compared with the 0.99 of a far higher ppb.[lii]	straightforward for patients and healthcare professionals.
Taskforce for Lung Health	Guideline	005	026 - 029	**1.2.2** Asthma may be hard to confirm with eosinophil count, FeNO or BDR if the person is already on treatment. The Taskforce recommends that the guideline should clarify the necessary adjustments to	Thank you for your comment. It is true that treatment is likely to normalise most of the available tests. The guideline is aimed at people at first presentation with symptoms. Recommendations on re-assessing the diagnosis in people on treatment were not

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				diagnosis for patients who are already on medication, for example, should patients continue with objective tests, or should they be guided to have tests only after they have reduced/stopped treatment? These points must be clarified within the guideline, and guidance on timeframes should be included as a decision aid for clinicians. This guideline recommends FeNO for routine monitoring as well as before and after changing treatment. If FeNO is available in primary care for these purposes, then it would make sense to standardise its use in adult and child diagnosis. FeNO would enable a point-of-care diagnosis and immediate start of medication. In comparison, using a blood test to diagnose asthma would delay diagnosis and treatment as the patient would need a subsequent appointment(s) and wait for results. Universal access to FeNO should therefore can be encouraged within this guideline by recommending it outright where appropriate, rather than as an alternative to blood eosinophil	part of the scope and no evidence search has been done. We will suggest this to NICE's surveillance team to consider for the next iteration of this guideline. The committee agree that diagnosis would be facilitated if point of care tests were available.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				tests. We know that if FeNO were made available to all GPs across England, for example, its use could save almost £100m by optimising asthma treatment.[liii]	
Taskforce for Lung Health	Guideline	005	026 - 029	**1.2.2** Spirometry is not recommended 4-6 weeks post-infection/acute exacerbation.[liv] Diagnostic pathways need to consider this when arranging follow-up testing for people with suspected asthma. The Taskforce recommends an inclusion of this guidance, with signposting to PCRS's position statement if possible, within 1.2.2 in order to fully inform clinicians.	Thank you for your comment. Spirometry should only be performed by trained personnel, and they will be aware of this restriction.
Taskforce for Lung Health	Guideline	005 - 007		**1.2** The inclusion of a chart or flow diagram to clearly show the stepwise diagnostic pathway for both adults and children should be included to aid clinician comprehension and to allow easy explanation of diagnosis to people with suspected asthma. The NHS England breathlessness pathway support tool may be used as a good example.	Thank you for your comment. There is a diagnostic flowchart.
Taskforce for Lung Health	Guideline	005 - 007	022 - 019	**1.2**	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Consistency across the diagnosis pathways for adults and those aged 5-16 would simplify this guideline and the provision of asthma diagnosis in primary care. People aged 5-16 and under are recommended FeNO as first-line tests; this should be the case for adults, too. This guideline recommends FeNO for routine monitoring as well as before and after changing treatment. If FeNO is available in primary care for these purposes, then it would make sense to standardise its use in adult and child diagnosis. FeNO would enable a point-of-care diagnosis and immediate start of medication. In comparison, using a blood test to diagnose asthma would delay diagnosis and treatment as the patient would need a subsequent appointment(s) and wait for results. The inclusion of FeNO as a rapid uptake product under the Accelerated Access Collaborative has seen an increase in access to FeNO, with 53% of PCNs in England now estimated to have access to testing.[lv] Increased uptake of FeNO between April 2021 and March 2023 resulted in	The committee do not agree that the process of diagnosis should be exactly the same in children as in adults. The evidence is not identical and there are other considerations to take into account e.g. ability to perform tests.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				an estimated 58,000 people being newly diagnosed with asthma, further highlighting the test's utility.[lvi] We know from our 'Saving Your Breath' report that if FeNO were made available to all GPs across England its use could save almost £100m by optimising asthma treatment.[lvii] Table 8 [Evidence review F] states that FeNO was the most cost-effective test compared with other tests, further evidencing its suitability for both the adult and 5-16-year-old diagnosis pathways.	
Taskforce for Lung Health	Guideline	006	001 - 003	**1.2.3** This element needs to clarify whether the patient is symptom-free and/or on medication prescribed to alleviate asthma symptoms at a previous presentation. If a patient is symptom-free and/or has tested negative in objective testing, this could be due to the variable nature of asthma,[lviii] or due to medication. Including a link to NICE's CKS on when to suspect asthma would be helpful for clinicians. This may require another step to explain what to do if tests are negative for either reason: guiding	Thank you for your comment. It is not clear which part of the guideline this comment refers to. Recommendation 1.2.3 in the draft for consultation relates to measuring bronchial responsiveness. At this stage the person with suspected asthma will have been referred to a specialist which is the appropriate action if the correct diagnosis is elusive. There is a diagnostic flowchart.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				clinicians to consider other conditions, the potential for intermittent symptom presentation, and whether the patient is taking medication that might need to be reduced or stopped before repeating testing. The inclusion of a chart or flow diagram to clearly show the stepwise diagnostic pathway for both adults and children should be included to aid clinician comprehension and to allow easy explanation of diagnosis to people with suspected asthma. The NHS England breathlessness pathway support tool may be used as a good example.	
Taskforce for Lung Health	Guideline	006	001 – 003	**1.2.3** This element must also specify that clinicians must refer to secondary care to measure bronchial responsiveness as this test is not available in primary care.	Thank you for your comment. This is correct at present and has been added to 1.2.4.
Taskforce for Lung Health	Guideline	006	005 - 006	**1.2.4** Consistency across the diagnosis pathways for adults and those aged 5-16 would simplify this guideline and the provision of asthma diagnosis in primary care. People aged 5-16 and under are recommended FeNO as first line tests; this should be the case for adults, too.	Thank you for your comment The committee do not agree that the process of diagnosis should be exactly the same in children as in adults. The evidence is not identical and there are other considerations to take into account e.g. ability to perform tests.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				This guideline recommends FeNO for routine monitoring as well as before and after changing treatment. If FeNO is readily available in primary care for these purposes then it would make sense to standardise its use in adult and child diagnosis. FeNO would enable a point-of-care diagnosis and immediate start of medication. Alternatively, if diagnosis relies upon a blood test then the patient would need another appointment for results and starting medication. Table 8 [Evidence review F] states that FeNO was the most cost effective test compared to other tests, further evidencing its suitability for both the adult and 5-16 year old diagnosis pathways. FeNO testing must be made universally available in order to meet the needs of the diagnosis pathway outlined for those aged 5-16.	
Taskforce for Lung Health	Guideline	006	007 - 009	**1.2.5** Consistency across the diagnosis pathways for adults and those aged 5-16 would simplify this guideline and the provision of asthma diagnosis in primary care. People aged 5-16 and under	Thank you for your comment. Recommendation 1.2.5 in the draft guideline relates to bronchodilator reversibility, not FeNO. The committee do not agree that the recommendations should be the same in

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				are recommended FeNO as first-line tests; this should be the case for adults, too. This guideline recommends FeNO for routine monitoring as well as before and after changing treatment. If FeNO is readily available in primary care for these purposes then it would make sense to standardise its use in adult and child diagnosis. FeNO would enable a point-of-care diagnosis and immediate start of medication. Alternatively, if diagnosis relies upon a blood test then the patient would need another appointment for results and starting medication. Table 8 [Evidence review F] states that FeNO was the most cost-effective test compared to other tests, further evidencing its suitability for both the adult and 5-16-year-old diagnosis pathways. FeNO testing must be made universally available in order to meet the needs of the diagnosis pathway outlined for those aged 5-16.	children as in adults. The evidence is not identical and there are practical considerations such as the greater difficulty in taking blood from children.
Taskforce for Lung Health	Guideline	006	010 - 016	**1.2.6** Skin prick testing is widely acknowledged to be impractical within primary care due to the	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				required training and facilities needed and is often referred to secondary care as a result.[lix]	Skin prick testing is only one option in recommendation 1.2.6. and the committee feel it is important to include it as a means of avoiding a blood test in a child who is reluctant to have this.
Taskforce for Lung Health	Guideline	006	010 - 016	**1.2.6** Blood tests are not always accepted by children which may prevent the use of tests for IgE or eosinophil levels. This should be reflected in the guideline to advise clinicians on the potential practical difficulties of these diagnostic tests.	Thank you for your comment This may be a problem and is why the committee included skin prick testing as a possible alternative.
Taskforce for Lung Health	Guideline	006	010 - 016	**1.2.6** The guideline should include additional, common environmental allergens. When conducting skin prick testing to house dust mites, the guideline should also include further triggers such as pollens and moulds. GINA 2023 includes skin prick evaluation for pest rodents as an asthma trigger.[lx]	Thank you for your comment The purpose of this recommendation is not to identify triggers, but to help make a diagnosis. In this respect it is house dust mite sensitivity which is most likely to be useful.
Taskforce for Lung Health	Guideline	007	001 - 015	**1.3** The Taskforce recommends that the trial of treatment be specified within section 1.3 to	Thank you for your comment Recommendation 1.3.1 directs the reader to section 1.9 which deals with a trial of treatment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				ensure the guidance is pragmatic, reflects clinicians' real-world experience, and meets the needs of the age group in question.	in detail. The committee do not think it appropriate to repeat all this information in 1.3 as well.
Taskforce for Lung Health	Guideline	007	004	**1.3.1** The Taskforce recommends that the use of the term "clinical judgement" should be revised; this guideline should help support clinical judgement, not defer to it as it can vary and may be skewed by knowledge and experience.	Thank you for your comment This recommendation has been amended.
Taskforce for Lung Health	Guideline	007	004 - 009	**1.3.1** The Taskforce recommends that the guideline needs to clarify whether to read code "asthma" or "suspected asthma" in this age group. Adding a read code is essential for arranging follow-up in primary care. It is important that this age group is followed up regularly and confirmatory tests performed once old enough.	Thank you for your comment Coding is covered (for all age groups) in 1.1.2 and 1.1.3.
Taskforce for Lung Health	Guideline	007	004-009	**1.3.1** The Taskforce recommends that 1.3.1 must be more specific about the symptoms and signs to look out for in this age group.	Thank you for your comment. Signs and symptoms are covered in the earlier section.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Taskforce for Lung Health	Guideline	007	010 - 015	**1.3.2** The Taskforce recommends that 1.3.2 should specify whether trials away from treatment should be attempted.	Thank you for your comment Recommendation 1.3.1 directs the reader to section 1.9 which deals with a trial of treatment in detail, including trials off treatment. The committee do not think it appropriate to repeat all this information in section 1.3 as well.
Taskforce for Lung Health	Guideline	008	010 - 011	**1.4.2** The Taskforce recommends amending 1.4.2 to specify that patients with suspected or confirmed occupational asthma should have any occupational sensitisers identified and removed as soon as possible to limit risk to the patient.[lxi]	Thank you for your comment. The guideline is not attempting to lead people through the process of diagnosing occupational asthma, but to indicate when it should be suspected and onward referral made.
Taskforce for Lung Health	Guideline	008	010 - 011	**1.4.2** The Taskforce recommends that 1.4.2 specify whether to commence treatment while awaiting specialist referral for suspected occupational asthma.	Thank you for your comment. Recommendation 1.4.2 is not an updated recommendation and comment on it was not invited. Please note that section 1.4 is about people with a diagnosis of asthma in whom an occupational cause is suspected. Since there is already a diagnosis of asthma, treatment will

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					have been commenced in accordance with sections 1.6 and 1.7.
Taskforce for Lung Health	Guideline	008	013 - 014	**1.5.1** The Taskforce recommends amending the wording of 1.5.1 to also specify that a clinician who has undertaken post-graduate training in asthma should check asthma control whenever the person presents with respiratory symptoms. The Taskforce also recommends that 1.5.1 include a time frame within the review structure to guide clinicians. To read: "Monitor asthma control at every review and at any presentation by a patient with respiratory symptoms. Review for confirmed asthma should be within 12 months of the previous review.	Thank you for your comment The timing of review and the point about an appropriate reviewer are covered in 1.16.1.
Taskforce for Lung Health	Guideline	008	013 – 018	**1.5.1** The Taskforce recommends that this element be more precise in its instruction to clinicians, advising them to check the amount of reliever inhalers used and check prescribing records for reliever inhalers issued.	Thank you for your comment. These items have been added to 1.5.1.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Taskforce for Lung Health	Guideline	008	017	**1.5.1** The Taskforce recommends that a time frame be included to guide an accurate review of the number of courses of oral corticosteroids a patient has been prescribed in order to allow overuse indicative of poor condition management to be addressed.[lxii]	Thank you for your comment The committee do not think this is helpful. Any exacerbation requiring oral corticosteroid is a cause for concern and this should be explored at the review.
Taskforce for Lung Health	Guideline	008	019 - 021	**1.5.2** The Taskforce recommends that 1.5.2 be amended to include the Children's Asthma Control Test (cACT) for monitoring asthma control in 4-11 year olds.[lxiii]	Thank you for your comment Children's questionnaire has been added to the examples.
Taskforce for Lung Health	Guideline	008	025 - 027	**1.5.4** FeNO is a key diagnostic tool that forms an essential part of the 5-16-year-old diagnostic pathway outlined in this guidance. It is also a key inclusion in the adult pathway and must be offered as a truly accessible alternative to blood eosinophil testing. Patient representatives have expressed a dislike of needles and voiced concerns that high eosinophil count may be caused by other factors than asthma. Therefore,	Thank you for your comment. It is standard practice in NICE guidance to use the word "Consider" for recommendations where the supporting evidence is positive but not unequivocally so and therefore this terminology will remain in the BTS/NICE/SIGN guidance.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				it is imperative that FeNO is universally available. As such, the Taskforce recommends that the language in the guideline be strengthened to more strongly advocate the use of FeNO by replacing "consider FeNO monitoring" with instructions to use FeNO.	
Taskforce for Lung Health	Guideline	009	001 - 008	**1.5.5** The Taskforce recommends including guidance to review a patient's diagnosis when control is suboptimal and assess whether it is likely to be correct.	Thank you for your comment. After further consideration the committee have agreed that there was a lot of overlap between 1.5.5 and 1.6.1 in the draft guideline. 1.5.5 has now been shortened markedly and the points are covered in 1.6.1.
Taskforce for Lung Health	Guideline	009	001 - 008	**1.5.5** Include within 1.5.5's bullet points: "Assess whether current symptoms are consistent with asthma or another cause"	Thank you for your comment. After further consideration the committee have agreed that there was a lot of overlap between 1.5.5 and 1.6.1 in the draft guideline. 1.5.5 has now been shortened markedly and the points are covered in 1.6.1.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Taskforce for Lung Health	Guideline	009	001 - 008	**1.5.5** Include within 1.5.5's bullet points guidance instructing clinicians to ask about changes in lifestyle, medication, air quality, occupation, housing, health, and mental health to identify potential reasons for poor control.	Thank you for your comment. After further consideration the committee have agreed that there was a lot of overlap between 1.5.5 and 1.6.1 in the draft guideline. 1.5.5 has now been shortened markedly and the points are covered in 1.6.1.
Taskforce for Lung Health	Guideline	009	001 - 008	**1.5.5** Include within 1.5.5's bullet points guidance to see a review of the patient's diagnosis using objective tests to assess whether poor control is truly due to asthma.	Thank you for your comment. After further consideration the committee have agreed that there was a lot of overlap between 1.5.5 and 1.6.1 in the draft guideline. 1.5.5 has now been shortened markedly and the points are covered in 1.6.1.
Taskforce for Lung Health	Guideline	009	010 - 015	**1.6** 1.6's inclusion of off-license medication, though helpful, may need further exploration in implementation as some prescribers may feel unhappy or unwilling to prescribe in this way, especially with a completely novel way of approaching asthma management with	Thank you for your comment. The committee agrees that AIR is relatively new (MART is less so) and that clinician education will be needed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				AIR/MART. Similarly, non-prescribing asthma clinicians such as nurses, and pharmacists may rely on other prescribers for their medication choices. A significant communication strategy with education and training will be needed to ensure that a lack of understanding of different inhaler choices, and NICE's information on off-license prescribing does not impact patient access to guideline-level care.	Your comments will be considered by NICE where relevant support activity is being planned.
Taskforce for Lung Health	Guideline	009	019	**1.6.1** The Taskforce recommends extending the list of examples of additional diagnoses given on line 19. Consider including deconditioning, COPD, gastro-oesophageal reflux, rhinosinusitis, mental health, and breathing pattern disorder.	Thank you for your comment. Several stakeholders have suggested additions which might be made to this bullet point, and on reflection the committee have agreed that no examples are necessary, the meaning of the recommendation being clear without them.
Taskforce for Lung Health	Guideline	009 - 101	016 - 007	**1.6.1** The Taskforce recommends using objective measures such as FeNO or peak flow to demonstrate whether symptoms are due to asthma and to establish a baseline ahead of a change in therapy.	Thank you for your comment. A recommendation to monitor FeNO is made in 1.5.4. The significance of an elevated FeNO has now been added to section 1.6.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Taskforce for Lung Health	Guideline	010	008 - 010	**1.6.2** The Taskforce are strongly supportive of the inclusion of guidance to limit SABA-only therapy for treating asthma symptoms. We recommend augmenting 1.6.2 by adding "using MART or AIR in patients 12 or above where possible." AIR's efficacy is well-proven and has been evidenced by a reduction in FeNO by multiple studies.[lxiv] MART's inclusion as the preferred controller in Step 3 of GINA's treatment pathway should be mirrored and MART should be prescribed when a patient's symptoms are present most days or wake them once per week or more.[lxv]	Thank you for your comment. The committee understands why you suggest this, but if the initial treatment steps for those aged 12 and over are added to this recommendation then the same would have to be done for those aged 5-11 and the recommendation would be unwieldy and repetitive.
Taskforce for Lung Health	Guideline	010	011 - 013	**1.6.3** The Taskforce recommend that 1.6.3 explicitly advises the use of Asthma Control Tests for adolescents and adults and the use of Children's Asthma Control Tests for those aged 4-11. The Taskforce agrees that PEF will not be helpful within a normal asthma review, but FeNO or peak flow should be tested before a change	Thank you for your comment. 1.6.3 refers the reader to the preceding section on monitoring control. There are several things which should be done when reviewing whether a treatment change has been beneficial (those you mention as well as checking inhaler technique); these are covered in other recommendations and it is inappropriate to repeat them all here.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				of treatment and at review and this should be stated within 1.6.3.	
Taskforce for Lung Health	Guideline	010	011 - 013	**1.6.3** The Taskforce recommends that patients be given information about their change of treatment to better inform them of what to expect from the next step of their care and when/how to seek help if their symptoms worsen or if their new treatment is unsuitable or ineffective. Potential guidance could include Asthma + Lung UK's patient-focused resources on changing asthma treatment: Changing asthma medicines | Asthma + Lung UK (asthmaandlung.org.uk)	Thank you for your comment. Giving information when a new medication is offered (whether first treatment or change in treatment) is a basic principle which applies across all branches of medicine, and this should not need to be stated.
Taskforce for Lung Health	Guideline	010	015 - 021	**1.6.4** The Taskforce recommends including "appropriate drug(s) and dose" within 1.6.4's bullet points.	Thank you for your comment. The recommendation is about the type of device, not about the medicine it contains.
Taskforce for Lung Health	Guideline	010	015 - 021	**1.6.4** The Taskforce recommends including "previous medications and intolerances" within 1.6.4's bullet points.	Thank you for your comment. The recommendation is about the type of device, not about the medicine it contains, and reference to previous medications and intolerances is therefore not appropriate.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Taskforce for Lung Health	Guideline	011	001 - 004	**1.6.5** The Taskforce recommends that the guideline includes a link to the Asthma + Lung UK website and its resources, or that the guideline includes a suggestion to clinicians to make this information available to patients: Changing asthma medicines | Asthma + Lung UK (asthmaandlung.org.uk)	Thank you for your comment. Asthma + Lung UK is listed as one of the patient organisations with a link to your website.
Taskforce for Lung Health	Guideline	011	001 - 004	**1.6.5** The Taskforce believes that spacers are not sufficiently mentioned within this guideline. Spacers are crucial to optimising medicine use in patients using pressurised metered-dose inhalers (pMDIs), as they help these patients waste less medicine and reduce side effects from their preventer inhaler. [lxvi] The Taskforce recommends amending the phrasing to "correct technique for each device – including in combination with a spacer where appropriate using an MDI, which should be demonstrated by a trained healthcare professional.". This point of the guideline should also include signposting to Asthma and Lung UK resources	Thank you for your comment. Recommendations 1.6.4 to 1.6.8 do not specify any inhaler type or system. They apply equally to MDI+spacer.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				on spacers to ensure patients receive education on how to use their space properly. How to Use a pMDI Inhaler with a Spacer/ Asthma + Lung UK (asthmandlung.org.uk)	
Taskforce for Lung Health	Guideline	011	001 - 004	**1.6.5** The Taskforce recommends that the guideline include information about how long inhalers last and how people can tell when they are empty. We know from patient survey data that only 36% of people with asthma strongly agree that they can self-manage their condition.[lxvii] Patients deserve guidance that helps them improve their ability to self-manage their condition. The Taskforce recommends that the guideline includes a direct reference to the role played by a personalised asthma action plan (PAAP) in informing patients, guiding their care and reflecting changes in the treatment regime. PAAPs are a key element of basic asthma care but our 2024 survey of over 12,000 people found that only 50% across the UK were provided with one as part of their asthma care and that only 86% of those with a PAAP have a	Thank you for your comment. PAAP's are recommended further on in the guideline (section 1.14).

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				say in its content and, thus, their asthma care.[lxviii] If a child has a personalised asthma action plan they are four times less likely to have an asthma attack that requires emergency hospital treatment.[lxix]	
Taskforce for Lung Health	Guideline	011	001 - 004	**1.6.5** The Taskforce recommends that in addition to the information given to patients on their inhalers, steps should be taken to ensure that patients are prescribed enough medication to ensure that they can take it as instructed up to the date of their follow-up appointment without running out.	Thank you for your comment. This is important but applies to treatment for any condition, and the committee feels that is goes beyond their remit to advise prescribers on the amount of medication to supply.
Taskforce for Lung Health	Guideline	011	001 - 004	**1.6.5** The Taskforce recommends that all medicines be prescribed with adequate instructions and guidance for safe, effective use. This includes ensuring that all prescriptions for inhaler asthma therapies are paired with in-person guidance of inhaler technique on the same type of inhaler, with the patient's technique monitored (and, if necessary, corrected) by a clinician who has undertaken post-graduate training in asthma.	Thank you for your comment. The points you make are all covered in the guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Asthma + Lung UK's 2024 Life with a Lung Condition survey found that only 50% of people with asthma across the UK had their inhaler technique reviewed in the last year, and that only 4% of those had it done remotely, emphasising the need for in-person reviews. [lxx]	
Taskforce for Lung Health	Guideline	011	005 - 014	**1.6.6** The Taskforce recommends including links to the Asthma + Lung UK website to provide patient-facing guidance on how to correctly use each type of inhaler. How to use your inhaler | Asthma + Lung UK (asthmaandlung.org.uk) Though comprehensive, this guidance should only be used to supplement correct inhaler technique guidance provided in primary care, including ensuring a clinician who has undertaken post-graduate training in asthma sees the patient demonstrate the use of their inhaler.	Thank you for your comment. Asthma + Lung UK is listed as one of the patient organisations with a link to your website. The committee agrees that all its recommendations should be carried out by appropriately trained people.
Taskforce for Lung Health	Guideline	011	005 - 014	**1.6.6** The Taskforce recommends including guidance within 1.6.6 that Community Pharmacy optimise adherence and inhaler technique at every	Thank you for your comment. 1.6.6 already covers the role of community pharmacists. The recommendation does not specify who should carry it out and therefore if

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				opportunity. Community Pharmacy is well placed to support general practice and funding should be optimised to allow this.	someone is seeing a pharmacist on an asthma-related issue 1.6.6 is applicable.
Taskforce for Lung Health	Guideline	011	005-004	**1.6.6** This is the first mention of a spacer within the guideline. As mentioned above, the Taskforce believes that spacers must be referenced more within this guideline. The Taskforce recommends amending the wording of this point to reflect GINA 2024. GINA 2024 states that for patients prescribed MDIs the use of a spacer improves the delivery of medicines to the lung, and for inhaled corticosteroids (ICs) spacers can help to reduce the potential effects such as dysphonia and oral candidiasis.[lxxi] The Taskforce therefore recommends rewording point 1.6.6 to: "For pMDIs, use of a spacer improves delivery and (with ICS) reduces the potential for side-effects."	Thank you for your comment. Recommendations 1.6.4 to 1.6.8 do not specify any inhaler type or system. They are intended to apply to all, and they fail to mention DPI's just as much as they fail to mention MDI+spacer. Rationales are not included within recommendations in NICE guidance and therefore the same methodology is adopted in this BTS/NICE/SIGN guideline. The committee agrees that all its recommendations should be carried out by appropriately trained people.
Taskforce for Lung Health	Guideline	011	005-024	**1.6.6**	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The Taskforce recommends inhalers only be prescribed by their brand name to prevent patients from accidentally being given an alternative device. Pharmacists should, however, be able to maintain suitable autonomy to prescribe available medicines that meet the person's prescription where necessary. The Taskforce recommends removing the reference to "generic device" to ensure that patients receive the same inhaler with each prescription. This is to ensure consistency in people's prescriptions, preventing changes in inhalers that may limit a person's ability to correctly use their treatments.	The committee agrees that brand name prescribing is advisable, and this has been recommended by others. However, putting this in the guideline will not prevent "accidentally being given an alternative device" and as you point out, pharmacists may occasionally have no option but to offer an alternative.
Taskforce for Lung Health	Guideline	011	015 - 017	**1.6.7** Include "where possible, such as where a LAMA is added."	Thank you for your comment. The words "if possible" have been added.
Taskforce for Lung Health	Guideline	011	018 - 019	**1.6.8** The Taskforce recommends explaining the importance of returning inhalers and reinforcing messaging that they are not to be disposed of in general domestic waste or domestic recycling.	Thank you for your comment. The wording has been changed

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Patients should also be clearly informed that correct adherence and technique are essential to reducing unnecessary greenhouse gas emissions: the 'greenest' asthma treatment is that which provides optimum symptom control.[lxxii]	
Taskforce for Lung Health	Guideline	012	004 - 011	**1.7.1** The Taskforce recommends that guidance be explicit to ensure clarity to novice clinicians: suggest including the wording "Offer a low-dose ICS/formoterol combination inhaler to be taken as needed for symptom relief to people aged 12 and over with newly diagnosed asthma. This is a SABA-free approach, so no salbutamol inhaler is required."	Thank you for your comment SABA inhalers are not required for AIR or MART, and this has been added to the descriptions in the Terms Used section. Instruction regarding the amount of medication to prescribe is beyond the remit of the guideline.
Taskforce for Lung Health	Guideline	012	004 - 011	**1.7.1** The Taskforce recommends providing information to patients on why and how AIR works to ensure patients feel in greater control of their condition and its treatment. AIR (anti-inflammatory reliever) | Asthma + Lung UK (asthmaandlung.org.uk)	Thank you for your comment. We agree, and a link to Asthma + lung UK's website should be included in the Asthma Pathway.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Taskforce for Lung Health	Guideline	012	004 - 011	**1.7.1** The Taskforce recommends including guidance that personalised asthma action plans specifically designed for patients using an AIR inhaler should be given to patients prescribed AIR. Download AIR asthma action plan | Asthma + Lung UK (asthmaandlung.org.uk)	Thank you for your comment The committee agrees that personalised action plans should be offered to all people with asthma (section 1.14). Since these are personalised by definition, for those on AIR they should be designed for AIR.
Taskforce for Lung Health	Guideline	012	004 - 011	**1.7.1** The Taskforce recommends that accessible education and instructions about inhaler technique should be provided to ensure that patients fully understand how to use their inhaler.	Thank you for your comment This is covered earlier in the guideline (recommendations 1.6.4 to 1.6.8)
Taskforce for Lung Health	Guideline	012	004 - 011	**1.7.1** The Taskforce recommends that prescribing be set up to allow patients to be able to take their inhalers as often as needed within both MART and AIR treatment regimes.	Thank you for your comment The committee agrees, but instruction on how to organise prescription services is beyond its remit.
Taskforce for Lung Health	Guideline	012	004 - 011	**1.7.1** The Taskforce recommends that inhaler overuse is monitored and that this is tailored to the	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				patient's treatment regime and reviewed regularly at asthma reviews.	Inhaler usage should be monitored, and this is referred to in recommendations 1.5.1 and 1.15.1.
Taskforce for Lung Health	Guideline	012	004 - 011	**1.7.1** The Taskforce recommends that the guideline specifies that patients must know how to manage an asthma attack using an AIR inhaler if prescribed. Air (Anti-inflammatory reliever)/Asthma + Lung (asthmanadlung.org.uk)	Thank you for your comment This should be part of the personalised asthma action plan as referred to in your previous comment (ID689)
Taskforce for Lung Health	Guideline	012	004 - 011	**1.7.1** The Taskforce recommends that the guideline define what good asthma control looks like for patients on AIR.	Thank you for your comment Asthma control (and a description of poor control) is described in the Terms Used section. This is the same for people on AIR as it is for those on other regimens
Taskforce for Lung Health	Guideline	012	012 - 017	**1.7.2** The Taskforce recommends providing information to patients on why and how MART works to ensure patients feel in greater control of their condition and its treatment. Maintenance and Reliever Therapy (MART) | Asthma + Lung UK (asthmaandlung.org.uk)	Thank you for your comment. A link to the Asthma + Lung UK website will be included in the Asthma Pathway.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Taskforce for Lung Health	Guideline	012	012 - 017	**1.7.2** The Taskforce recommends including within this guideline that personalised asthma action plans specifically designed for patients using an AIR inhaler should be given to patients who are prescribed MART. Download MART asthma action plan | Asthma + Lung UK (asthmaandlung.org.uk)	Thank you for your comment The committee agrees that personalised action plans should be offered to all people with asthma (section 1.14). Since these are personalised by definition, for those on MART (we assume you mean MART rather than AIR) they should be designed for MART.
Taskforce for Lung Health	Guideline	012	012 - 017	**1.7.2** The Taskforce recommends patients be provided with accessible information about inhaler techniques to ensure that patients fully understand how to use their inhaler.	Thank you for your comment This is covered earlier in the guideline (recommendations 1.6.4 to 1.6.8)
Taskforce for Lung Health	Guideline	012	012 - 017	**1.7.2** The Taskforce recommends that prescribing be set up to allow patients to be able to take their inhalers as often as needed within both MART and AIR treatment regimes.	Thank you for your comment The committee agrees, but instruction on how to organise prescription services is beyond its remit.
Taskforce for Lung Health	Guideline	012	012 - 017	**1.7.2** The Taskforce recommends that the guideline specifies that patients must know how to	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				manage an asthma attack using a MART inhaler if prescribed.	This should be part of the personalised asthma action plan which all people with asthma should have (recommendation 1.14.1)
Taskforce for Lung Health	Guideline	012	012 - 017	**1.7.2** The Taskforce recommends that the guideline provides clear guidance to clinicians about when a patient can move from MART to AIR, and what good control on MART looks like.	Thank you for your comment Decreasing therapy is covered in section 1.10
Taskforce for Lung Health	Guideline	012	Lines across multiple pages	**1.7** The draft guideline doesn't include an alternate treatment pathway for patients who are unable to be treated with formoterol. GINA 2023 outlines an alternate pathway using SABA as the reliever.[lxxiii] While efforts to reduce SABA prescribing are laudable and in line with Asthma + Lung UK's preferences for asthma care, care must be patient-centric and allow for variation in treatment to meet patient need.	Thank you for your comment The committee believes that the evidence in adults strongly favours the AIR then MART strategy over the traditional treatment pathway and have therefore recommended this. The remit of NICE and therefore of this BTS/NICE/SIGN guideline is to offer guidance on the most cost-effective management strategy.
Taskforce for Lung Health	Guideline	013	008 - 012	**1.7.5**	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The Taskforce recommends that the guideline mandates that clinicians counsel the person on the potential rare side effects on LTRA. Share information about the medication Montelukast | Asthma + Lung UK (asthmaandlung.org.uk)	A link to the MHRA DSU has been added.
Taskforce for Lung Health	Guideline	013	016 - 018	**1.7.6** The Taskforce recommends that the guideline gives explicit advice to clinicians on giving the LAMA as a separate inhaler to ensure that the patient is on MART plus LAMA rather than a closed triple therapy (ICS/LABA/LAMA) which is not appropriate for MART.	Thank you for your comment 1.7.6 suggests a trial of the addition of a LAMA, so it would seem easier to add in a LAMA-only inhaler to the current MART rather than changing inhalers completely for what might be a relatively short period of time. However, there is no evidence to prefer this to the option of changing to a triple maintenance inhaler as you describe, and so the recommendation leaves this open.
Taskforce for Lung Health	Guideline	013	019 - 021	**1.7.7** The Taskforce recommends that this guideline must align with the Severe Asthma pathway AAC-Pathway-Overview_v.1.pdf (healthinnovationoxford.org) so that the same criteria are used to ensure a timely referral. The guideline also needs to stipulate not just	Thank you for your comment This recommendation is compatible with the AAC pathway. In addition, it is worded so as to allow that the person has either had a trial of the listed medication or is still on them.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				whether a person is on a specific medication, but whether they have had trials of medicines.	
Taskforce for Lung Health	Guideline	013	019 - 021	**1.7.7** The Taskforce recommends that patients' inhaler technique be reviewed at every possible contact and that the inhaler choice should also be reviewed before making a referral.	Thank you for your comment Recommendation 1.6.6 covers this (it doesn't specifically mention referral, but it does mention poor control which would be the reason for referral in the context of 1.7.7)
Taskforce for Lung Health	Guideline	013	019 - 021	**1.7.7** The Taskforce recommends that all changes from one treatment pathway to another should be made in consultation with the patient and that appropriate information and support should be given throughout to inform the patient of this process, about why the change is important, and providing information and the new treatment pathway.	Thank you for your comment This is an overarching principle and not confined to asthma management. The committee does not think it needs to be stated here.
Taskforce for Lung Health	Guideline	013	019 - 021	**1.7.7** The Taskforce recommends that the guideline should explicitly state that it is not appropriate to switch a patient's treatment without consultation with the patient.	This is an overarching principle and not confined to asthma management. The committee does not think it needs to be stated here

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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Taskforce for Lung Health	Guideline	013	019 - 021	**1.7.7** The Taskforce recommends that clinicians are advised to document all factors that are suggestive of poor control and the potential reasons for this, as well as any objective evidence to support this including Asthma Control Test, Childhood Asthma Control Test, FeNO, Peak Flow).	Thank you for your comment Adequate documentation is a core part of good medical practice in any branch of medicine, and the committee does not think it needs to be stated here.
Taskforce for Lung Health	Guideline	013	019 - 021	**1.7.7** The Taskforce recommends clinicians are advised to initiate follow-up appointments with patients to assess control and satisfaction with new any treatment and that this should be documented along with any objective evidence to support this.	Thank you for your comment Recommendation 1.6.3 states that there should be follow up after any treatment change.
Taskforce for Lung Health	Guideline	014	004 - 006	**1.7.8** The Taskforce recommends that the guideline includes the consideration that it may be difficult for patients to understand a significant change in approach by moving to MART or AIR and that this can be alleviated by providing an appropriate asthma action plan and information from Asthma + Lung Completing a Mart Asthma	Thank you for your comment. A link to the Asthma + Lung UK website will be included in the Asthma Pathway

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Action Plan with Your Patients/ Asthma + Lung UK (asthmaandlung.org.uk)	
Taskforce for Lung Health	Guideline	014	007 - 014	**1.7.9** The Taskforce recommends that the guideline includes the consideration that it may be difficult for patients to understand a significant change in approach by moving to MART or AIR and that this can be alleviated by providing an appropriate asthma action plan and information from Asthma + Lung UK. Completing a Mart Asthma Action Plan with Your Patients/ Asthma + Lung UK (asthmaandlung.org.uk)	Thank you for your comment. A link to the Asthma + Lung UK website will be included in the Asthma Pathway
Taskforce for Lung Health	Guideline	014	015 - 024	**1.7.10** The Taskforce recommends that the guidance include the consideration that it may be difficult for patients to understand a significant change in approach by moving to MART or AIR and that this can be alleviated by providing an appropriate asthma action plan and information from Asthma + Lung UK. Completing an Asthma Action Plan/ Asthma + Lung UK (asthmandlung.org.uk)	Thank you for your comment. A link to the Asthma + Lung UK website will be included in the Asthma Pathway All people with asthma should have a personalised action plan (recommendation 1.14.1)
Taskforce for Lung Health	Guideline	015	001 - 002	**1.7.12**	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The Taskforce recommends that this guideline must align with the Severe Asthma pathway AAC-Pathway-Overview_v.1.pdf (healthinnovationoxford.org) so that the same criteria are used to ensure a timely referral. The guideline also needs to stipulate not just whether a person is on a specific medication, but whether they have had trials of medicines.	1.7.12 refers to one specific situation where a referral is indicated. It is compatible with the AAC pathway document.
Taskforce for Lung Health	Guideline	015	003	**1.8** The Taskforce recommends suggesting that an MDI and spacer should be the first choice of inhaler for children aged 5-11.[lxxiv]	Thank you for your comment Choosing the appropriate inhaler device is covered in section 1.6.
Taskforce for Lung Health	Guideline	015	003	**1.8** The Taskforce recommends that the guideline should advise clinicians to provide information about the medicines prescribed and their effect on patients' conditions. Asthma and your child | Asthma + Lung UK (asthmaandlung.org.uk)	Thank you for your comment. Asthma + Lung UK is listed as one of the patient organisations with a link to your website.
Taskforce for Lung Health	Guideline	015	003	**1.8** The Taskforce recommends that the guideline mandates that patients be provided with an appropriate asthma action plan that provides	Thank you for your comment Provision of Asthma Action Plans is covered in section 1.14

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				adequate information on their condition, care, and what to do in the event of an asthma attack.	
Taskforce for Lung Health	Guideline	015	003	**1.8** The Taskforce recommends that the guideline mandates that clinicians ensure children are prescribed adequate inhalers so that the child has access at all times in multiple settings including at school, with carers, etc.	Thank you for your comment This is very reasonable but advice about numbers of inhalers to provide is not in the scope for this guideline update and there are no equivalent recommendations in the current versions of NICE or BTS/SIGN guidelines.
Taskforce for Lung Health	Guideline	015	003	**1.8** The Taskforce recommends that the guideline advises that clinicians should provide information to support parents/carers' liaison with schools and nurseries so that they all know how to use the inhalers both routinely and in an emergency. Asthma at school and nursery | Asthma + Lung UK (asthmaandlung.org.uk) and Asthma friendly schools - Transformation Partners in Health and Care	Thank you for your comment. Asthma + Lung UK is listed as one of the patient organisations with a link to your website.
Taskforce for Lung Health	Guideline	015	010 - 013	**1.8.1** The Taskforce recommends that guideline 1.8.1 is amended to include via MDI and spacer. This	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				is because effective delivery of medication to younger children requires the use of a spacer device, as recognised by the National Bundle of Care for Children and Young People with Asthma.[lxxv]	Choice of inhaler device is covered in section 1.6
Taskforce for Lung Health	Guideline	015	010 - 013	**1.8.2** 1.8.2's inclusion of off-license medication, though helpful, may need further exploration in implementation as some prescribers may feel unhappy or unwilling to prescribe in this way, especially with a completely novel way of approaching asthma management with MART for children. Similarly, non-prescribing asthma clinicians such as nurses, and pharmacists may rely on other prescribers for their medication choices. A significant communication strategy with education and training will be needed to ensure that a lack of understanding of different inhaler choices, and NICE's information on off-license prescribing does not impact patient access to guideline-level care.	Thank you for your comment The guideline recognises that not all prescribers will be willing to use MART in children and has therefore included an alternative pathway.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Taskforce for Lung Health	Guideline	016	018 - 021	**1.8.7** The Taskforce recommends that the guideline be amended to advise that children should also be referred to an asthma specialist if their diagnosis is uncertain.	Thank you for your comment 1.8.7 is about one specific reason for referring. It isn't intended as a list of all the possible reasons for referral.
Taskforce for Lung Health	Guideline	018 - 019	023 - 007	**1.10.2** The Taskforce recommends that clinicians be advised to document all factors that are suggestive of poor control and the potential reasons for this, as well as any objective evidence to support this including the Asthma Control Test, Childhood Asthma Control Test, FeNO, Peak Flow).	Thank you for your comment It is for all ages, but you are correct that the second bullet of 1.10.2 conflicts with the recommendations on treatment in childhood. This has been amended.
Taskforce for Lung Health	Guideline	018 - 019	023 - 007	**1.10.2** B Provide clear instructions on what to do if control is lost. Arrange follow-up to assess control and satisfaction with the new treatment and document along with any objective evidence to support this.	Thank you for your comment Good documentation is a core principle of medical practice and should not need a recommendation here.
Taskforce for Lung Health	Guideline	019	008 - 011	**1.10.3**	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The Taskforce recommends including the use of the Asthma Control Test, the Childhood Asthma Control Test, and the Peak flow within 1.10.3 to ensure that when a patient's maintenance therapy is decreased, their symptoms and ability to self-manage are properly monitored and reviewed.	As this recommendation says that the method of monitoring the reduction should be agreed with the patient, it would be contradictory to specify how this should be done.
Taskforce for Lung Health	Guideline	019	012 - 013	**1.10.4** The Taskforce recommends that the guideline includes links to Asthma + Lung UK's Asthma Action Plans and that the appropriate plan (matching the patient's course of treatment) is provided and explained to patients.	Thank you for your comment Apart from the fact that one particular plan is not mentioned, this is what 1.10.4 says.
Taskforce for Lung Health	Guideline	019	019 - 022	**1.12** The Taskforce recommends that additional guidance and tailored information be provided to patients during their pregnancy explaining how asthma is affected by pregnancy Asthma and pregnancy | Asthma + Lung UK (asthmaandlung.org.uk)	Thank you for your comment. The recommendations in section 1.12 have been transferred from SIGN158, but the topic area was not reviewed as part of this update. The supporting text remains available in SIGN158.
Taskforce for Lung Health	Guideline	020	027 - 028	**1.13.3**	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The Taskforce recommends that 1.13.3 should be expanded to include further detail and examples of why and how some adolescents struggle with their inhalers. This must include tailored information. Asthma and young people | Asthma + Lung UK (asthmaandlung.org.uk)	NICE recommendations focus on the action to be performed and not on the reasoning behind this. The committee agree that tailored information is important.
Taskforce for Lung Health	Guideline	021	002 - 018	**1.14.1** The Taskforce recommends that 1.14.1 includes links to Taskforce member Asthma + Lung UK's asthma action plans. These are available for adults and children, for AIR, MART, Preventer & reliever treatment plans, in a number of languages and in a number of formats. The provision of these should be tailored to suit the patient.	Thank you for your comment. A link to the Asthma + Lung UK website will be included in the Asthma Pathway
Taskforce for Lung Health	Guideline	021	002 – 018	**1.14** To aid patient self-management, the Taskforce recommends the guideline to advise the use of airway diagrams and models to explain airway inflammation in asthma and how inhalers work. It should explain that SABA alone does not treat the underlying airway inflammation which causes symptoms and risks flare-ups, and that	Thank you for your comment Section 1.14 recommends self-management education programmes but details about what these should cover is outside our scope.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				overuse of SABA is associated with increased risk of asthma attacks. We know from patient surveys that only 36% of people strongly feel they can self-manage their condition.[lxxvi] Measures like this could improve patients' abilities to confidently perform self-management.	
Taskforce for Lung Health	Guideline	021	002 – 018	**1.14.1** The guideline recommends education but doesn't specify what kind and how this should be delivered to clinicians. Asthma + Lung UK recommends that the guideline addresses this, providing clarity and signposting to Asthma and Lung UK resources as an addition to any education provided.	Thank you for your comment Section 1.14 recommends self-management education programmes but details about what these should cover is outside our scope.
Taskforce for Lung Health	Guideline	021	002 – 018	**1.14.1** The Taskforce recommends that 1.14.1. should include other triggers too as these may have a greater impact on certain patients. Guidance should also be provided on understanding asthma triggers. More information is available at Asthma triggers | Asthma + Lung UK (asthmaandlung.org.uk)	Thank you for your comment. This is a legacy recommendation from the 2017 guidance. No new evidence review was undertaken, and we cannot make substantial additions to it. However, the recommendation has been changed slightly to indicate that other triggers should be considered.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Taskforce for Lung Health	Guideline	021	002 – 018	**1.14.1** The Taskforce recommends that 1.14.1 should also include guidance to clinicians to prompt asthma patients to have relevant vaccinations; this ask should be tailored to the patient and consider their eligibility for suggested vaccinations.	Thank you for your comment Vaccination advice is not regarded as part of self-management plans.
Taskforce for Lung Health	Guideline	021	002 – 018	**1.14.1** The Taskforce recommends that weight management be included within 1.14.1 and the guideline should include weight reduction in the treatment plan for obese patients with asthma.[lxxvii]	Thank you for your comment Weight reduction is very important, but it this is about management of a comorbidity rather than asthma itself. There is guidance elsewhere on weight reduction and it is inappropriate to include it in general advice about self-management.
Taskforce for Lung Health	Guideline	021	002 – 018	**1.14.1** The Taskforce recommends that exercise is included within 1.14.1 and aerobic and strength exercises are included in tailored treatment plans for obese patients. Asthma + Lung UK's physical activity resources are patient-focused	Thank you for your comment Exercise is important, but this point is not specific to asthma, nor just to people with asthma who are living with obesity. There is guidance elsewhere on exercise and the

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and should be included within the draft guidance.	committee do not think it is necessary to include it in general advice about self-management.
Taskforce for Lung Health	Guideline	021	002 – 018	**1.14.1** The Taskforce recommends that 1.14.1 should specifically explain what patients need to do to stay well, what to do when they get symptoms and what to do during an asthma attack. This guidance should be tailored and included in their asthma action plan.	Thank you for your comment What to do when symptoms arise and what to do during an asthma attack are both part and parcel of standard action plans. The committee do not think this needs stating.
Taskforce for Lung Health	Guideline	021	002 – 018	**1.14.1** The Taskforce recommends that the guideline should advise clinicians to specifically explain how the person should access more medication and when/how to access NHS services. This should be explained in a way that ensures clarity for the patient and tailored if necessary to meet individuals' access needs.	Thank you for your comment 1.14.1 offers generalisable advice about action plans and education. How to access medication and access NHS services is (a) subject to local or individual variation (b) not just about asthma.
Taskforce for Lung Health	Guideline	021	019 - 023	**1.14.2** Taskforce believes the phrasing in this point should be amended as follows: Change "check inhaler technique" to "observe inhaler technique". The inhaler technique must be	Thank you for your comment The advice to check inhaler technique in these circumstances is already given earlier in the

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				demonstrated by the patient and approved or corrected by a clinician who has undertaken post-graduate training in asthma.	guideline (section1.6). The wording of 1.14.2 has been changed accordingly.
Taskforce for Lung Health	Guideline	022	012 - 021	**1.14.6** Taskforce believes the phrasing in this point should be amended as follows: Change "Structured protocols for asthma reviews" to read "Structured protocols and templates for asthma reviews".	Thank you for your comment This recommendation is taken from the BTS/SIGN guidance. There has not been an evidence review for this update and the recommendation has therefore not been amended.
Taskforce for Lung Health	Guideline	022	012 - 021	**1.14.6** The Taskforce recommends including the use of apps within the guideline.	Thank you for your comment This recommendation is taken from the BTS/SIGN guidance. There has not been an evidence review for this update and the recommendation has therefore not been amended.
Taskforce for Lung Health	Guideline	022	012 - 021	**1.14.6** The Taskforce recommends including Asthma + Lung UK Breathe Easy groups and online support groups.	Thank you for your comment This recommendation is taken from the BTS/SIGN guidance. There has not been an evidence review for this update and the

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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					recommendation has therefore not been amended.
Taskforce for Lung Health	Guideline	022	012 – 021	**1.14.6** The Taskforce recommends that the guideline specify here that asthma reviews must be conducted in person to ensure they are of the highest possible quality and comprehensively cover the patient's condition and management.	Thank you for your comment The committee agrees, but 1.14.6 is more about novel ideas that should aid implementation of reviews rather than emphasising a long-established principle (albeit one which is not always carried out).
Taskforce for Lung Health	Guideline	022	016	**1.14.6** The Taskforce recommends that line 16 be amended to provide specific detail and clarity about what pharmacists' roles are and how they can best support patients.	Thank you for your comment 1.14.6 is about strategies to aid in implementing self-management, not about details of the roles of healthcare professionals.
Taskforce for Lung Health	Guideline	023	002 - 006	**1.15.1** The Taskforce recommends that a single episode of unscheduled care for asthma should trigger action as per Quality Statement 4: Follow-up by general practice after emergency care | Asthma | Quality standards | NICE BTS	Thank you for your comment The committee supports the NICE Quality statements and the BTS Care Bundle for asthma attacks, but neither of these refers to

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Asthma Care Bundle. Poor follow-up care after unplanned or emergency admissions increases patients' risk of mortality.[lxxviii]	entering people on a risk stratification system, which is the purpose of 1.15.1.
Taskforce for Lung Health	Guideline	023	002 - 006	**1.15.1** The Taskforce recommends that 1.15.1 should include the "number of oral corticosteroid doses in last 12 months" within its risk factors.	Thank you for your comment The committee supports the NICE Quality statements and the BTS Care Bundle for asthma attacks, but neither of these refers to entering people on a risk stratification system, which is the purpose of 1.15.1.
Taskforce for Lung Health	Guideline	023	008 - 011	**1.16.1** The Taskforce recommends including "observe inhaler technique" within all contacts. Inhaler technique must be demonstrated by the patient and approved or corrected by a clinician who has undertaken post-graduate training in asthma.	Thank you for your comment Inhaler use has been covered in section 1.6 of the guideline
Taskforce for Lung Health	Guideline	023	012 - 013	**1.16.2** The Taskforce recommends including the use of apps within the guideline.	Thank you for your comment This is a rather vague request. The guideline cannot recommend apps non-specifically. Apps did feature in the evidence for some questions

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					(e.g. digital inhalers) but the committee did not feel that any particular app should be recommended in those instances.
Taskforce for Lung Health	Guideline	General	General	The Taskforce would have liked acute asthma and severe asthma to have been included in the guideline to create a single set of guidelines for all asthma patients. Correct treatment of severe asthma relies upon the proactive identification of patients with poor asthma control and the ability to optimise their treatment.[lxxix] This, in turn, relies upon a detailed understanding of the condition within primary care. Given this guidance's focus on clinicians using patients' clinical history to inform diagnosis in conjunction with objective testing, we would have hoped to see a similar pathway outlined within this guidance for diagnosis and treating severe asthma.	Thank you for your comment The decision reached jointly by BTS, SIGN and NICE is to produce guidance on acute asthma separately.
Taskforce for Lung Health	Guideline	General	General	We welcome the inclusion of smoking cessation advice targeted at pregnant women (1.12.2), but we believe the final guideline should emphasise the importance of smoking cessation throughout, as an essential part of good asthma care.	Thank you for your comment Smoking is referred to at several points in the guideline, including those you mention. The dangers of smoking are well documented and there are useful resources available from other

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Smoking cessation could be included where smoking is mentioned in 1.5 and should be explored in 1.14. The Taskforce recommend the draft guidance advises clinicians to undertake very brief advice (VPA) at any appropriate appointment and/or review in primary care, and that comprehensive smoking cessation support be recommended for people with asthma when in secondary care. Further detail should be included within the draft guideline from the NICE smoking cessation guideline.	sources about preventing or quitting smoking. The committee has tried to balance the number of references to this, paying it due regard but not turning an asthma guideline into a smoking cessation guideline.
Taskforce for Lung Health	Guideline	General	General	There is concern that trial of treatment is not featured within the draft guideline. This does not reflect the pragmatic use of the trial of treatment in real-world asthma care and should be addressed; the trial of treatment dovetails well with guidance to treat people immediately if they are acutely unwell at presentation (1.1.5) and can provide relief for asthma symptoms quickly. NICE's December 2023 Clinical Knowledge Summary for newly diagnosed asthma recommends a trial of treatment for add-on therapies if low-dose ICS doesn't allow	Thank you for your comment NICE's CKS on newly diagnosed asthma advocates a trial of an LTRA, and then other agents if this does not achieve control, in people who are already diagnosed with asthma and are receiving an inhaled steroid. This is in keeping with the previous version of NICE's asthma guideline. The management recommendations have now been changed and the CKS will change accordingly when this guideline update is published.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				adequate asthma control[lxxx] – this contrasts with the guidance's omission of the trial of treatment.	
Taskforce for Lung Health	Question 1	000	000	**Would it be challenging to implement of any of the draft recommendations? Please say why and for whom. Please include any suggestions that could help users overcome these challenges (for example, existing practical resources or national initiatives.** The draft guideline would see significant changes made to the diagnosis and treatment of asthma. This guideline will be challenging to implement successfully and with optimum patient benefit without a detailed implementation plan and appropriate clinician education. To ensure the stepwise diagnostic pathway works, the new guideline must be paired with clear, accessible resources that clarify how to progress a person's diagnosis. Taskforce member Asthma + Lung UK has undertaken qualitative research with clinicians, which found that the use of a diagnostic algorithm helps novice clinicians and those who have limited experience in diagnosing asthma.[lxxxi]	Thank you for highlighting these implementation issues. Your comments will be considered by NICE where relevant support activity is being planned.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				A challenge of implementing the guideline may be in changing clinician behaviour around the use of SABA inhalers. Many clinicians will have been routinely prescribed SABA for their whole careers so information and guidance will be needed to support them to highlight the shortcomings of SABA use (and especially of its overuse) and explain the benefits of MART and AIR treatment regimes. Taskforce member Asthma + Lung UK is well placed to help with this, having developed detailed resources for both clinicians and patients, which explain newer inhaled therapies for asthma. Taskforce member and patient representative Casey, who has severe asthma, is supportive of the move towards MART: "I think the shift away from SABA relievers to combination inhalers and a MART approach is really positive. Supporting GPs to gradually implement this change is key, ensuring that patient preference is still considered. Inhaler change should only be done in a face-to-face appointment such as during a yearly asthma review where the reasons for	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				change can be explained alongside technique advice." Increasing patient confidence in alternatives to SABA and their ability to help them manage their condition will also be important. Clinicians must approach changing patients' inhalers from SABA to MART and ICS inhalers carefully. The Taskforce believes that the decision to switch inhalers must be taken in consultation with patients in an in-person appointment, where patients are provided with advice about inhaler technique. Primary care must be incentivised to provide high-quality annual reviews so that patients who are switched to MART or ICS inhalers are properly supported. The role of SABA must also be carefully dealt with because of patients' potential concerns about being moved away from a treatment they trust. We know that a factor contributing to SABA overuse is the relationship between SABA use and near-immediate relief in many people, and at the same time, many patients do not understand the danger of SABA overuse.[lxxxii] Asthma + Lung UK's patient-facing resources	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				would help address patient's concerns about being switched to MART or ICS inhalers and we have recommended that these be included in the draft guidance. The role of a person's clinical history has been changed within the draft guidance, presenting a further potential obstacle to their implementation. The draft guideline recommends that clinical history alongside a supporting objective test must be used to diagnose asthma. Clinicians must have protected training time and sufficient funding as well as experience with asthma so they can effectively use clinical history to diagnose asthma. A significant challenge to the successful implementation of this guideline will be having sufficient capacity in the system, both at the primary and secondary care levels. Primary care is already unable to meet the demand for key diagnostic tests, including FeNO and spirometry, neither of which are universally available[lxxxiii] despite their inclusion in the draft guideline and FeNO's key role in the children's diagnostic	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				pathway. Likewise, secondary care's capacity is also already of concern, and proposals in the guideline will place an increased strain on already limited resources. It is therefore vital that the proposed changes are adequately funded. The Taskforce was also disappointed that patients with severe asthma weren't included in this guidance. Leaving these patients out of the guideline risks referral delays and an increase in emergency admissions.	
Taskforce for Lung Health	Question 2	000	000	**Would implementation of any of the draft recommendations have significant cost implications**? We believe that the cost of successfully implementing the draft recommendations would be significantly outweighed by the cost of inaction or failed implementation. The Taskforce's Saving Your Breath' report shows the scale of savings that can be made by funding and providing better care earlier through an increased focus on proper implementation of diagnostic pathways and correct prescribing. We	Thank you for highlighting this. The potential resource benefits (reduced exacerbations leading to hospital admission) from improved diagnosis and monitoring from implementing the guideline are picked up in the draft RIA tools. This is based on published economic evidence. Training is anticipated to be part of qualifications. Ongoing training was not indicated as having significant resource impact from experts.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				know that if FeNO were made available to all GPs across England, for example, its use could save almost £100m by optimising asthma treatment.[lxxxiv] The same paper recommended that spirometry also be fully funded across the country, an essential element to ensuring the success of the draft guideline given the role of spirometry and FeNO in the diagnostic pathway. Appropriate funding must be given to ensure that clinicians are trained to provide good-quality asthma care. This would include standardising training standards and educating clinicians on the key changes being made within the draft guideline (SABA-free prescribing, changes to the diagnostic pathway, guiding patient self-management) and providing good quality, accessible patient-facing resources that can aid clinicians in explaining asthma and its treatment to people. Standardised training is also essential to ensure clinicians can correctly diagnose and treat asthma in children In the submission below our member Asthma and Lung UK resources have been highlighted where appropriate.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The inconsistent and disparate funding of objective tests such as FeNO and spirometry must also be changed for this guideline to be successfully implemented. Such service readiness work is essential given that FeNO is only estimated to be accessible in 53% of PCNs across the country,[lxxxv] though this is an improvement upon FeNO accessibility before the Accelerated Access Collaborative was published ICBs have been slow to resume pre-pandemic levels of spirometry (itself insufficient)[lxxxvi] and significant improvement must be made nationally to ensure spirometry is accessible for use in diagnosing asthma as the guideline dictates. The Taskforce has called for ICBs to recognise all costs involved in providing spirometry, including training and accreditation, and for ICBs to develop local payment mechanisms to ensure no one is disadvantaged when setting up a service to meet local needs. Similarly, we have called for NHS England to incentivise spirometry within the GP contract and to provide specific funding to improve spirometry training within primary care.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
The Association of Clinical Psychologists	Guideline	004	002	**1.1 Initial clinical assessment – general comment** There is no mention of psychological testing or consideration of biopsychosocial factors in screening, which are critical for an asthma care plan. Psychological factors can enter and affect the course of asthma; the clinical significance of these should be incorporated within the initial clinical assessment and be targeted for treatment. The evidence available regarding the bidirectional link between asthma (in terms of severity and control), psychological aspects (subjective perception, alexithymia and coping style) and mental health (anxiety, depression) must be considered.[8] There should also be screening of the mental health symptoms and psychological aspects related to asthma, in order to support the planning of appropriate interventions to better control asthma and to improve the patient's well-being. Screening tools of anxiety and depression	Thank you for your comment This section is about establishing a diagnosis of asthma, not about producing a care plan for those in whom the diagnosis is confirmed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				such as the General Health Questionnaire (adult), Hospital Anxiety and Depression Scale (adult), Revised Children's Anxiety and Depression Scale (child) should be considered. **References** 5. Chida, Y., Hamer, M., & Steptoe, A. (2008). A bidirectional relationship between psychosocial factors and atopic disorders: A systematic review and meta-analysis. *Psychosomatic Medicine*, *70*(1), 102–116. https://doi.org/10.1097/PSY.0b013e31815c1b71	
The Association of Clinical Psychologists	Guideline	004	002	**1.1 Initial clinical assessment – general comment** Patients with asthma are more liable to psychiatric disorders; there are high levels of depression and anxiety, both of which have serious adverse effects on a patient's quality of life.[5,9] For instance, there is an increased experience of anxiety associated with more recognition of asthma-specific panic-fear and	Thank you for your comment The committee agrees that asthma can be associated with depression and anxiety. The guideline recognises that these need addressing as well as directly treating the airways (e.g. recommendation 1.6.1) but

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				hyperventilation symptoms during an asthma attack, regardless of the depressive status – this must be included within diagnosis and treatment planning. Asthma is not a wholly 'biological' condition – central cognitive processes influence not only the interpretation of asthma symptoms but also the manifestation of measurable changes in immune and physiologic markers of asthma. Asthma and major depressive disorder share several risk factors and have similar patterns of dysregulation in key biologic systems, including the neuroendocrine stress response, cytokines and neuropeptides.[10] **References** 5. Scott, K. M., Von Korff, M., Ormel, J., Zhang, M., Bruffaerts, R., Alonso, J., Kessler, R. C., Tachimori, H., Karam, E., Levinson, D., Bromet, E. J., Posada-Villa, J., Gasquet, I., Angermeyer, M. C., Borges, G., de Girolamo, G., Herman, A., & Haro, J. M. (2007). Mental disorders among adults with asthma: Results from the World Mental Health Survey. General Hospital Psychiatry, 29(2), 123–133.	detailed description of their management is dealt with in other guidelines.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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				https://doi.org/10.1016/j.genhosppsych.2006.12.006 9. Thomas, M., Bruton, A., Moffatt, M., & Cleland, J. (2011). Asthma and psychological dysfunction. Primary Care Respiratory Journal, 20(3), 250–256. https://doi.org/10.4104/pcrj.2011.00058 10. Van Lieshout, R. J., & Macqueen, G. (2008). Psychological factors in asthma. Allergy, Asthma, and Clinical Immunology: Official Journal of the Canadian Society *of Allergy and Clinical Immunology*, *4*(1), 12–28. https://doi.org/10.1186/1710-1492-4-1-12	
The Association of Clinical Psychologists	Guideline	004	002	**1.1 Initial clinical assessment – general comment** • The impact of past trauma and post-traumatic stress disorder should be considered at presentation and screening as both are linked to asthma and lung function.[11] • The potential for post-traumatic stress reactions following severe asthma attacks and/or ICU stays should also be	Thank you for your comment Section 1 is about initial assessment of the likelihood of asthma, and past trauma is not particularly associated with this rather than alternative diagnoses. Severe asthma is outside the scope.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				considered.[11] **References** Spitzer, C., Koch, B., Grabe, H. J., Ewert, R., Barnow, S., Felix, S. B., Ittermann, T., Obst, A., Völzke, H., Gläser, S., & Schäper, C. (2011). Association of airflow limitation with trauma exposure and post-traumatic stress disorder. European Respiratory Journal, 37(5), 1068–1075. https://doi.org/10.1183/09031936.00028010	
The Association of Clinical Psychologists	Guideline	005	006	**Initial treatment and objective tests – general comment** Initial treatment and objective tests should not just focus on medical/physical aspects. Psychological testing must be included if outcomes are to be impacted as emotions are the most powerful precursor to producing an asthmatic attack, particularly in children and young people. Tests such as: a. the Mini-Mental State Examination (MMSE) – the most commonly used cognitive screening test worldwide (7–10 min to complete) and which tests	Thank you for your comment. The committee do not agree that these tests should be done before a diagnosis of asthma is confirmed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				a broad range of cognitive functions. b. the Beck Depression Inventory (BDI) – a widely used 21-item self-report questionnaire designed to measure the presence and severity of depressive symptoms. c. the Beck Anxiety Inventory – similar to the BDI, a 21-item self-report questionnaire that measures anxiety. d. These are all tools that can be easily administered and indicate a clinical need for psychological/psychiatric treatment planning.	
The Association of Clinical Psychologists	Guideline	005	006	**Initial treatment and objective tests – general comment** Consideration must be given to the co-occurring pathology of anxiety and depression, and also attention deficit hyperactivity disorder in children and young people with asthma. Assessment and	Thank you for your comment. The section "Initial treatment and objective tests" is about making a diagnosis of asthma, irrespective of cause or comorbidity. Anxiety, depression, other comorbidities and socioeconomic issues should all be taken into

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				treatment planning needs to incorporate the holistic assessment of the impact of diagnosis and asthma management on schooling and family; this is particularly important from a health inequalities perspective, as lower socioeconomic status negatively impacts the severity and management of asthma.	account during the management of asthma, and this is covered in recommendation 1.6.1.
The Association of Clinical Psychologists	Guideline	005	006	**Initial treatment and objective tests – general comment** Overuse and psychological dependence on inhalers must be flagged within the guidance. Rates of inhaler misuse are high. Teenagers are more at risk of inhaler overuse and as a means to get high; this correlates with higher levels of psychological distress, which is a further reason for early and accurate identification of psychological distress as part of routine assessment and management.[12,13] **References** 12. Boyd, C. J., McCabe, S. E., & Teter, C. J. (2006). Asthma inhaler misuse and	Thank you for your comment. This section is purely about making an initial diagnosis of asthma. Awareness of inhaler overuse is important in subsequent management.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				substance abuse: A random survey of secondary school students. Addictive Behaviors, 31(2), 278–287. https://doi.org/10.1016/j.addbeh.2005.05.005 13. Perron, B. E., & Howard, M. O. (2008). Endemic asthma inhaler abuse among antisocial adolescents. Drug and Alcohol Dependence, 96(1), 22–29. https://doi.org/10.1016/j.drugalcdep.2008.01.022	
The Association of Clinical Psychologists	Guideline	005	006	**Initial treatment and objective tests – general comment** • Early screening for psychological symptoms and the recognition of nonadherence as part of an asthma assessment and management plan should be routine and an integral part of the management guidelines, since poor adherence to inhalers negatively impacts levels of anxiety and depression among patients with asthma.[14–16]	Thank you for your comment. This section is about making an initial diagnosis of asthma. Comorbidities and adherence are important and are referred to in later sections.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				References 14. Alqarni, A. A., Aldhahir, A. M., Siraj, R. A., Alqahtani, J. S., Alghamdi, D. A., Alghamdi, S. K., Alamoudi, A. A., Mohtaseb, M. A., Majrshi, M., AlGarni, A. A., Badr, O. I., & Alwafi, H. (2024). Asthma medication adherence, control, and psychological symptoms: A cross-sectional study. BMC Pulmonary Medicine, 24, 189. https://doi.org/10.1186/s12890-024-02995-x 15. Dong, R., Sun, S., Sun, Y., Wang, Y., & Zhang, X. (2024). The association of depressive symptoms and medication adherence in asthma patients: The mediation effect of medication beliefs. Research in Social and Administrative Pharmacy, 20(3), 335–344. https://doi.org/10.1016/j.sapharm.2023.12.002 16. d'Ancona, G., & Weinman, J. (2021). Improving adherence in chronic airways disease: Are we doing it wrongly?	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Breathe, *17*(2). https://doi.org/10.1183/20734735.0022-2021	
The Association of Clinical Psychologists	Guideline	005	006	**Initial treatment and objective tests – general comment** • How patients take their prescribed asthma medications is an important predictor of asthma control and exacerbation risk.[17] The guidelines must, therefore, include evidence-based advice on clinical consultation requirements and content. The underuse of controller medications leads to worsening symptom control and more frequent exacerbations, while overuse is similarly problematic. Overuse is associated with more frequent symptoms, exacerbations, and health care utilisation as well as lower mental and physical functioning – these are significant system costs that need to be considered within NICE guidelines to clinicians and services. Older age, male sex, white race, coexisting medical	Thank you for your comment. This section is about making an initial diagnosis of asthma. The issues you describe relate to subsequent management and are covered in later sections.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				conditions, lower educational attainment, current smoking, and physical inactivity have all been associated with inhaler overuse and can act as markers for further assessment and treatment planning.[18–20] **References** 17. Zhang, X., Ding, R., Zhang, Z., Chen, M., Yin, Y., & Quint, J. K. (2023). Medication Adherence in People with Asthma: A Qualitative Systematic Review of Patient and Health Professional Perspectives. *Journal of Asthma and Allergy*, *16*, 515–527. https://doi.org/10.2147/JAA.S407552 18. Diette, G. B., Wu, A. W., Skinner, E. A., Markson, L., Clark, R. D., McDonald, R. C., Healy, J. P., Huber, M., & Steinwachs, D. M. (1999). Treatment patterns among adult patients with asthma: Factors associated with overuse of inhaled beta-agonists and underuse of inhaled corticosteroids. Archives of Internal Medicine, 159(22), 2697–2704.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				https://doi.org/10.1001/archinte.159.22.2697 19. Monteiro, C., Maricoto, T., Prazeres, F., Simões, P. A., & Simões, J. A. (2022). Determining factors associated with inhaled therapy adherence on asthma and COPD: A systematic review and meta-analysis of the global literature. Respiratory Medicine, 191. https://doi.org/10.1016/j.rmed.2021.106724 20. Vanoverschelde, A., van der Wel, P., Putman, B., & Lahousse, L. (2021). Determinants of poor inhaler technique and poor therapy adherence in obstructive lung diseases: A cross-sectional study in community pharmacies. BMJ Open Respiratory Research, 8(1), e000823. https://doi.org/10.1136/bmjresp-2020-000823	
The Association of Clinical Psychologists	Guideline	007	016	**1.4 Diagnosing occupational asthma** • Occupational asthma services must consider the impact of asthma on mental	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				health if a job role has to change or be given up.[21] • Consider an assessment of activities of daily living such as the WSAS (Work and social adjustment scale). **References** 21. Foster, J. M., McDonald, V. M., Guo, M., & Reddel, H. K. (2017). "I have lost in every facet of my life": The hidden burden of severe asthma. European Respiratory Journal, 50(3). https://doi.org/10.1183/13993003.00765-2017	The guideline indicates when occupational asthma should be suspected but management of occupational asthma is beyond our scope.
The Association of Clinical Psychologists	Guideline	010	003	**1:6 Principles of Pharmacological treatments** • ACP-UK agrees with the consideration of psychosocial factors when looking at medication adherence and changes to treatments. • Within psychosocial factors, consider and discuss the potential impact of traumatic asthma attacks and also	Thank you for your comment. Recommendation 1.6.1 is concerned with prompting readers to consider these factors rather than going into detail about managing them.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				parental anxiety in relation to children and young people.	
The Association of Clinical Psychologists	Guideline	019	014	**1.11 Adherence** • Identify other factors impacting on adherence, including psychological and social factors[14] • Ensure carers and parents are involved in shared decision making for children and young people and consider how the beliefs of carers and parents may affect adherence. • Ensure understanding of diagnosis and risks – particularly for children and young people (and their parents and carers) and check adherence. • To enhance adherence interventions, consider questionnaires related to medication beliefs, e.g., Beliefs about Medication Questionnaire or Test of Adherence to Inhalers. • Consider a model to aid with adherence, e.g. Horne, 2006 as stated in the Severe Asthma Toolkit.[22]	Thank you for your comment This is all very reasonable, but this section has not been subject to an evidence review for this update. 1.11.1 is an amalgamation of old recommendations from NICE and BTS/SIGN and it is not appropriate to add too much to it without a formal review.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				References 14. Alqarni, A. A., Aldhahir, A. M., Siraj, R. A., Alqahtani, J. S., Alghamdi, D. A., Alghamdi, S. K., Alamoudi, A. A., Mohtaseb, M. A., Majrshi, M., AlGarni, A. A., Badr, O. I., & Alwafi, H. (2024). Asthma medication adherence, control, and psychological symptoms: A cross-sectional study. *BMC Pulmonary Medicine*, *24*, 189. https://doi.org/10.1186/s12890-024-02995-x 22. Horne, R. (2006). Compliance, adherence, and concordance: Implications for asthma treatment. Chest, 130(1 Suppl), 65S-72S. https://doi.org/10.1378/chest.130.1_suppl.65S	
The Association of Clinical Psychologists	Guideline	020	015	**1:13 Asthma in adolescents** • Consider an assessment of mood, beliefs about medicines and understanding of inhaler use for this age group (similar to adults –see section 1:1).	Thank you for your comment The recommendations in this section have simply been transferred from the BTS/SIGN guidance. While the wording has been slightly

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				• Consider addressing higher level risk behaviours in this population.[23] • Consider the involvement and psychoeducation of parents and carers in this population. • Consider the mental health and wider needs of parents and carers due to the high carer burden.[24] **References** 23. Mansur, A. H., & Prasad, N. (2023). Management of difficult-to-treat asthma in adolescence and young adults. Breathe, 19(1). https://doi.org/10.1183/20734735.0025-2022 24. Majellano, E. C., Clark, V. L., Foster, J. M., Gibson, P. G., & McDonald, V. M. (2021). "It's like being on a roller coaster": The burden of caring for people with severe asthma. *ERJ Open Research*, *7*(2). https://doi.org/10.1183/23120541.00812-2020	amended for some, the committee are not able to add completely new recommendations without formally reviewing evidence.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
The Association of Clinical Psychologists	Guideline	021	001	**1:14 Self-management** • As well as educational and medical settings, working with wider social and mental health care teams is important.	Thank you for your comment Self-management plans should be used in all settings.
The Association of Clinical Psychologists	Guideline	023	001	**1:15: Risk-stratified care** • Co-morbid psychological difficulties may also raise risks of poor adherence, risk taking behaviours and lack of self care.	Thank you for your comment The items already listed in 1.15.1 indicate poor control. If a person with psychological problems exhibits one of these then they should be picked up by the Risk Stratification system, but a person with psychological problems whose asthma is well managed and whose control is good will not be, and this does not seem unreasonable.
The Association of Clinical Psychologists	Guideline	026	003	**2: Recommendations for research** ACP-UK recommends a randomised controlled trial on asthma and psychological therapies to help improve the evidence base for this population.	Thank you for your comment The research recommendations are based on a literature search that was performed for the guideline, but which did not reveal adequate evidence. This is standard NICE methodology which has been used in this joint BTS/SIGN/NICE process and research

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					recommendations cannot be put forward to address a question that was not part of the guideline.
The Association of Clinical Psychologists	Guideline	051	General	**Table 1a and b: items deleted from review** ACP-UK is concerned about the removal of guidance related to culturally appropriate support, psychoeducational interventions and psychological factors in adherence, as clinicians may not then be alerted to these important areas.	Thank you for your comment Unfortunately, we cannot find this on page 51. The tables explain why any recommendations have been omitted.
The Association of Clinical Psychologists	Guideline	General	General	As a general comment ACP-UK feels that this guideline is very medical and that there is very little mention of psychological therapies and their efficacy in asthma or the role of the clinical psychologist.[1–4] **References** 1. Yorke, J., Fleming, S. L., & Shuldham, C. (2007). Psychological interventions for adults with asthma: A systematic review. Respiratory Medicine, 101(1), 1–14. https://doi.org/10.1016/j.rmed.2006.04.003	Thank you for your comment The role of the clinical psychologist was not prioritised for inclusion during the scoping process.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				2. Cooley, C., Park, Y., Ajilore, O., Leow, A., & Nyenhuis, S. M. (2022). Impact of interventions targeting anxiety and depression in adults with asthma. Journal of Asthma, 59(2), 273–287. https://doi.org/10.1080/02770903.2020.1847927 3. Fellows, J. L., Flower, L., Blakey, J., Kurukulaaratchy, R., Howard, R., & Mansur, A. (2015). Case series: The application of "third wave" cognitive behavioural therapies in difficult to treat asthma. Journal of Asthma, 52(9), 905–912. https://doi.org/10.3109/02770903.2014.1003155 4. Parry, G. D., Cooper, C. L., Moore, J. M., Yadegarfar, G., Campbell, M. J., Esmonde, L., Morice, A. H., & Hutchcroft, B. J. (2012). Cognitive behavioural intervention for adults with anxiety complications of asthma: Prospective randomised trial. Respiratory Medicine, 106(6), 802–810. https://doi.org/10.1016/j.rmed.2012.02.006	
The Association of Clinical Psychologists	Guideline	General	General	ACP-UK feels that there a lack of mention of the psychological needs of children and adolescents with asthma and the support	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				psychological therapies can offer. For example, there is nothing about comorbidity with panic attacks. Many of the children we see have asthma but also have panic attacks, and we support them to manage this. For example, St George's runs a joint breathing clinic (nurse and psychologist) that really helps children think about 'breathing' globally and teaches practical strategies	The role of the clinical psychologist was not prioritised for inclusion during the scoping process.
The Association of Clinical Psychologists	Guideline	General	General	There is an absence of integration of psychological morbidity, which is high in this population and can impact on health outcomes and the cost of treatments.[5,6] **References** 6. Scott, K. M., Von Korff, M., Ormel, J., Zhang, M., Bruffaerts, R., Alonso, J., Kessler, R. C., Tachimori, H., Karam, E., Levinson, D., Bromet, E. J., Posada-Villa, J., Gasquet, I., Angermeyer, M. C., Borges, G., de Girolamo, G., Herman, A., & Haro, J. M. (2007). Mental disorders among adults with asthma: Results from the World Mental Health Survey. *General*	Thank you for your comment The role of the clinical psychologist was not prioritised for inclusion during the scoping process.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Hospital Psychiatry, *29*(2), 123–133. https://doi.org/10.1016/j.genhosppsych.2006.12.006 7. *Long-Term Conditions And Mental Health*. (n.d.). The King's Fund. Retrieved 9 July 2024, from https://www.kingsfund.org.uk/insight-and-analysis/reports/long-term-conditions-mental-health	
The Association of Clinical Psychologists	Guideline	General	General	The guideline acknowledges (p10, 60 and 78) that psychosocial factors will influence asthma care but there is no mention of accessing support in relation to this.	Thank you for your comment The role of the clinical psychologist was not prioritised for inclusion during the scoping process.
The Association of Clinical Psychologists	Guideline	General	General	ACP-UK feels the guideline should mention the psychological impact of having a condition such as asthma (adjustment, adherence, impact on identity, potential trauma/PTSD from a severe asthma attack) and the importance of access to psychological therapies. We note a link to adult guidelines (Making Shared Decisions and also Medication Adherence), but nothing paediatric. Signposting to third-sector organisations should	Thank you for your comment The role of the clinical psychologist was not prioritised for inclusion during the scoping process.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				be given to children and young people with asthma in order to promote adherence/self-management, particularly within the school setting, so that children and young people are aware of the available in-school support options.	
The Association of Clinical Psychologists	Guideline	General	General	Quite a lot of information has been removed that pertains to school-based clinics/interventions and behavioural considerations. These have been removed on the basis of lack of strength in evidence and uncertain costs. ACP-UK wonders if this is due to a lack of resources in the NHS?	Thank you for your comment The reason for removal is as given in the table.
The Association of Clinical Psychologists	Guideline	General	General	There is no mention of the health inequalities that may form a barrier to asthma care and adherence.	Thank you for your comment The committee considered whether the evidence indicated that any groups should be managed differently because of health inequality but found very little relevant evidence. Recommendation 1.15.1 suggests that groups at increased risk should be identified and their care adjusted accordingly.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
The Association of Clinical Psychologists	Guideline	General	General	There is no mention of possible psychological and non-psychological co-morbidities, for instance, breathing pattern disorders.	Thank you for your comment Co-morbidities are referred to indirectly in 1.6.1
The Association of Clinical Psychologists	Guideline	General	General	The psychological effects of some common asthma medications are not considered, and how they will interact with existing mental health difficulties, such as Ventolin use in anxiety disorders.[7] **References** 8. Deshmukh, V. M., Toelle, B. G., Usherwood, T., O'Grady, B., & Jenkins, C. R. (2007). Anxiety, panic and adult asthma: A cognitive-behavioral perspective. Respiratory Medicine, 101(2), 194–202. https://doi.org/10.1016/j.rmed.2006.05.005	Thank you for your comment The role of the clinical psychologist was not prioritised for inclusion during the scoping process.
The Breastfeeding Network	Guideline	019	019	Section 1.12, Asthma in Pregnancy; We suggest section 1.12 be renamed "Asthma in Pregnancy **and Breastfeeding**" Line 23: we suggest amending subheading to "Pregnancy **and breastfeeding**"	Thank you for your comment The title of the section has been changed

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				P 19, lines 24-28, section 1.12.1. We suggest amending to: "People with asthma should have an asthma review during early pregnancy and in the postpartum period. Emphasise the importance and safety of maintaining good control of asthma during pregnancy **and the postpartum period**, and of continuing asthma medicines to avoid problems for themselves and their baby. **Inform people with asthma that at a population level, breastfeeding may help protect children against developing asthma**(1,2)**, and that it is possible to breastfeed whilst taking all standard medications for asthma**(3,4)**. The benefits of breastfeeding, especially for a child who may be predisposed to developing asthma due to family history, outweigh any theoretical risks posed by the medication passing into breastmilk**(5)**."** P20, line 1, section 1.12.2. We suggest amending to "Advise anyone who is pregnant **or in the postpartum period** and who smokes..."	The text you have suggested regarding the benefits of breastfeeding in primary prevention of asthma is outside the scope of this guideline. This topic was reviewed in the non-pharmacological management of asthma section of the BTS/SIGN guideline and may be part of the update of that section when it is scheduled. The recommendations to which you want to add references to breastfeeding are legacy recommendations from the BTS/SIGN guideline. An updated evidence review has not been performed and it is therefore not possible to make the changes.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				P20, line 5, section 1.12.3. We suggest amending to "Advise using the following medicines as normal during pregnancy **and breastfeeding**: P20, line 9, section 1.12.4. We suggest amending to "Offer oral corticosteroids during pregnancy **and breastfeeding**..." P20, lines 13-14, section 1.12.5. We suggest amending to "...they should not be stopped during pregnancy **or breastfeeding**..." It is important to include specific reference to breastfeeding here as we know that parents are concerned about the impact of any medication passing though their breastmilk to their child(6), and there can be confusion regarding safety among healthcare professionals. Our Drugs in Breastmilk information service regularly receives enquiries from parents with chronic illnesses, including asthma, questioning whether they can safely use their medication whilst breastfeeding. We received over 360 enquiries through social media alone on this topic in the last year. Our factsheet on breastfeeding with asthma(3) was accessed over 4000 times in the last year.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Whilst the NHS medicines page and BTS/SIGN 158 guideline state that asthma medications can be used whilst breastfeeding, most patient information leaflets state "If you are pregnant or breast-feeding, ask your doctor, nurse or pharmacist for advice before taking this medicine". Information for healthcare professionals from https://www.medicines.org.uk/emc is not reassuring about the use of asthma medications while breastfeeding and the British National Formulary is inconsistent across medications. This causes much concern and confusion for parents and can also lead to healthcare professionals providing poor advice. In fact, all standard asthma medications are compatible with breastfeeding(3,4). We frequently see healthcare professionals and parents taking a "cautious" approach and considering not breastfeeding in order to use medications, without recognising the value of breastfeeding and the risks of not breastfeeding. This is hugely costly, to the families involved, and also the NHS. UNICEF details the millions of pounds of NHS funds and thousands of hours	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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				of healthcare professionals' time that could be saved by increasing breastfeeding rates(7). The pregnancy and postpartum reviews recommended in section 1.12.1 are therefore the perfect opportunity to reassure parents of the safety and importance of continuing to use their asthma medications whilst breastfeeding as well as during pregnancy. 1. Wilson, K., et al. (2022). The association between duration of breastfeeding and childhood asthma outcomes. Annals of allergy, asthma & immunology: official publication of the American College of Allergy, Asthma, & Immunology, 129(2), 205–211. https://doi.org/10.1016/j.anai.2022.04.034 2. https://www.unicef.org.uk/babyfriendly/news-and-research/baby-friendly-research/infant-health-research/infant-health-research-asthma/ 3. https://www.breastfeedingnetwork.org.uk/factsheet/asthma/ 4. https://www.nhs.uk/medicines/ 5. SIGN158 British guideline on the management of asthma (2019)	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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				6. McClatchey, A. K., et al. (2018). Why does the need for medication become a barrier to breastfeeding? A narrative review. Women and birth: journal of the Australian College of Midwives, 31(5), 362–366. https://doi.org/10.1016/j.wombi.2017.12.004 7. Renfrew et al., (2012). Preventing disease and saving resources: the potential contribution of increasing breastfeeding rates in the UK.	
The Breastfeeding Network	Guideline	071	Table	RE: update to BTS/SIGN Guideline; removal of recommendation: Encourage women with asthma to breastfeed. [12.5] We acknowledge that all women, not just women with asthma, should be encouraged to breastfeed. However, we believe it is important to emphasise the value of breastfeeding to women with asthma specifically, and therefore argue that the recommendation should be retained. Asthma has a strong hereditary component, so children of mothers with asthma are more likely to develop asthma themselves(1). Breastfeeding has been shown to protect against childhood asthma and other respiratory infections(2). This information should be shared with pregnant and postpartum women with asthma, to allow them	Thank you for your comment. This previous recommendation has been deleted because breastfeeding is encouraged generally, not just for people with asthma. The advice to continue asthma medication during breastfeeding has been reinstated

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				to make a fully informed decision about feeding their baby. 1. Thomsen S. F. (2015). Genetics of asthma: an introduction for the clinician. European clinical respiratory journal, 2, 10.3402/ecrj.v2.24643. https://doi.org/10.3402/ecrj.v2.24643 2. Wilson, K., et al. (2022). The association between duration of breastfeeding and childhood asthma outcomes. Annals of allergy, asthma & immunology: official publication of the American College of Allergy, Asthma, & Immunology, 129(2), 205–211. https://doi.org/10.1016/j.anai.2022.04.034	
The Breastfeeding Network	Guideline	071	Table	RE: update to BTS/SIGN Guideline; removal of recommendation: Use asthma medications as normal during lactation, in line with manufacturers' recommendations. [12.5]. The rationale given for this removal is "The section covers pregnancy, not post-pregnancy. All medications should be used in line with manufacturers' recommendations."	Thank you for your comment. This previous recommendation has been deleted because breastfeeding is encouraged generally, not just for people with asthma. The advice to continue asthma medication during breastfeeding has been reinstated.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				We accept that a recommendation regarding breastfeeding may not be relevant in a section covering pregnancy. It is therefore unclear whether the information in section 12.5: Drug Therapy for Breastfeeding Mothers is to be retained at all. We suggest that for clarity, this section be renamed Asthma in Pregnancy and Breastfeeding, and that the information and recommendations on breastfeeding be retained. Further, we suggest the recommendation be retained in an amended form, which clarifies that all standard asthma medications can be used as normal during breastfeeding. It is important to include this information here as we know that many pregnant and birthing people are concerned about the impact of any medication passing though their breastmilk to their child(1), and there can be confusion regarding safety among healthcare professionals. Our Drugs in Breastmilk information service regularly receives enquiries from parents with chronic illnesses, including asthma, questioning whether they can safely use their medication whilst breastfeeding. We received over 360 enquiries through social	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				media alone on this topic in the last year. Our factsheet on breastfeeding with asthma(2) was accessed over 4000 times in the last year. Whilst the NHS medicines page and BTS/SIGN 158 guideline state that asthma medications can be used whilst breastfeeding, most patient information leaflets state "If you are pregnant or breast-feeding, ask your doctor, nurse or pharmacist for advice before taking this medicine". Information for healthcare professionals from https://www.medicines.org.uk/emc is not reassuring about the use of asthma medications while breastfeeding and the British National Formulary is inconsistent across medications. This causes much concern and confusion for parents and can also lead to healthcare professionals providing poor advice. In fact, all standard asthma medications are compatible with breastfeeding(2,3). The benefits of breastfeeding, particularly where the child may be redisposed to developing asthma(4), outweigh any theoretical risks posed by the medication passing into breastmilk.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				We frequently see healthcare professionals and parents taking a "cautious" approach and considering not breastfeeding in order to use medications, without recognising the value of breastfeeding and the risks of not breastfeeding. This is hugely costly, to the families involved, and also the NHS. UNICEF details the millions of pounds of NHS funds and thousands of hours of healthcare professionals' time that could be saved by increasing breastfeeding rates(5). It is important that this information is retained and reinforced in this guideline to ensure parents are not given inaccurate information and can breastfeed with confidence. 1. McClatchey, A. K., et al. (2018). Why does the need for medication become a barrier to breastfeeding? A narrative review. Women and birth: journal of the Australian College of Midwives, 31(5), 362–366. https://doi.org/10.1016/j.wombi.2017.12.004 2. https://www.nhs.uk/medicines/	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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				3. https://www.breastfeedingnetwork.org.uk/factsheet/asthma 4. Wilson, K., et al. (2022). The association between duration of breastfeeding and childhood asthma outcomes. Annals of allergy, asthma & immunology: official publication of the American College of Allergy, Asthma, & Immunology, 129(2), 205–211. https://doi.org/10.1016/j.anai.2022.04.034 5. Renfrew et al., (2012). Preventing disease and saving resources: the potential contribution of increasing breastfeeding rates in the UK.	
The Royal College of Pathologists	General	General	General	• For the allergy tests, it's not completely clear from the evidence review why total IgE and skin prick testing for house dust mite as the evidence review also covers specific IgE for house dust mite. However, specific IgE for house dust mite is not mentioned in the draft consultation and only in the evidence reviews. • Skin prick testing for house dust mite in primary care is not generally available and	Thank you for your comments. The comments apply to recommendations for diagnosis in children. It is true that skin prick testing is not readily available, and a referral may be necessary, but the committee were also aware of the difficulty of taking blood from some children and wished to provide an alternative.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				would probably not be practical to set up. Costs per test for skin testing also increase if not all the kit is fully used up due to limited volume of testing. Is the intention or thinking that secondary care should be providing a skin prick testing for house dust mite for asthma diagnosis? • One element that does not seem to have been considered is any additional pathology time required to provide interpretative advice as both total IgE and house dust mite skin prick tests/specific IgE can often give abnormal results without necessarily being of clinical significance	This step is the 3rd in the testing sequence and will not be needed for all children. The issue of taking blood is also relevant to specific IgE to HDM; essentially identical information can be obtained from a skin prick test. Given the wording of recommendation 1.2.6 (1.2.8 in the revised guideline), the committee is not sure what additional pathology time will be required for interpretative advice.
The Royal College of Physicians of Edinburgh	Guideline	005	1.2.1, 1.2.2, 1.2.3	A number of Fellows stated that for objective confirmation of a diagnosis of asthma, the usual practice is to look for evidence of inflammation (blood eos/ FeNO) in association with variable airflow obstruction. They said that while PEFR variability is not included in the recommendations, the evidence review indicates that this is a low cost and highly specific test for asthma. It features in current GINA guidelines and previous NICE guidelines and they would like to see PEFR variability	Thank you for your comment. PEF variability is a specific test, but also insensitive. It has now been added to the diagnosis section.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				included with clear guidance about interpretation of results. Bronchial hyper-reactivity testing has limited access and there are often significant waiting lists which limit application of this type of test.	
The Royal College of Physicians of Edinburgh	Guideline	008	1.5.3	Again, Fellows stated that the use of PEFR measurement to assess asthma control is usual practice and should be retained. They consider it to be low cost, accessible and providing an objective indicator of airway dysfunction.	Thank you for your comment. The evidence (please see Evidence Review M) did not show a benefit of regular PEF monitoring for everyone with asthma.
The Royal College of Physicians of Edinburgh	Guideline	008	1.5.4	Fellows highlighted that FeNO measurement is generally not available in primary care. Some Fellows stated that their clinical experience was that FeNO testing is helpful for diagnosis of asthma but is not useful for monitoring disease activity. A blood eosinophil count is more likely to influence future management if there are features of poor asthma control despite a high dose inhaled corticosteroid.	Thank you for your comment. The committee agree that more resource will be needed if this recommendation is to be implemented. Our analysis showed that regular FeNO monitoring is cost-effective, based on studies of adults with non-severe asthma.
The Royal College of Physicians of Edinburgh	Guideline	013	1.7.7	Fellows said it would seem reasonable to increase therapy to a high fixed-dose ICS/LABA before secondary care referral. Complexity can be reduced by using a once daily fixed dose ICS/LABA inhaler.	Thank you for your comment The increase from moderate to high dose ICS is where adverse effects of ICS become much

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					more likely, and the committee do not wish to recommend this for all people. It might be appropriate for those with an elevated FeNO level, but more practices do not have access to this as yet.
The Royal College of Physicians of Edinburgh	Guideline	General	General	Some Fellows suggested that the draft guideline has shifted to a recommendation for ICS/LABA reliever and MART therapy. They consider that this is a positive move, but there will need to be an education package to go along with the guideline. They emphasise that FeNO testing for diagnosis is not widely available in primary care. Providing this would require a modest financial investment.	Thank you for your comment. MART has been an option for nearly 20 years, but the committee agree that some education would aid implementation. It also agrees that some financial investment would be required. Your comments will be considered by NICE where relevant support activity is being planned.
The Royal College of Speech and Language Therapists	General	General	General	RCSLT is disappointed that there is no mention in this guidance of the importance of differential diagnosis when considering patient symptoms, such as breathlessness. Upper airway disorders, such as chronic cough, breathing pattern disorder and inducible laryngeal obstruction can co-occur with asthma, or mimic symptoms, but are likely to require different treatment (Haines et al, 2020; Halvorsen et al, 2017; Ludlow et al,	Thank you for your comment. There are numerous differential diagnoses, and the guideline acknowledges that other tests may be required. However, covering these, and the different treatments which might then be required, is outside the scope of this guideline

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				2023). Another potential differential diagnosis for asthma is subglottic stenosis (Dreyer et al 2022; Whittet et al 2022) but this is also absent from the guideline. This requires involvement of ENT as part of the diagnostic profile IF asthma has not been confirmed and will often be picked up via spirometry References: Dreyer, N. S., Gregersen, K. G., & Bork, K. H. (2022). Life-threatening idiopathic subglottic stenosis misdiagnosed as asthma. Acta Oto-Laryngologica Case Reports, 7(1), 26–29. https://doi.org/10.1080/23772484.2022.2050374 Haines J, Chua SHK, Smith J, Slinger C, Simpson AJ, Fowler SJ. Triggers of breathlessness in inducible laryngeal obstruction and asthma. Clin Exp Allergy. 2020; 50: 1230–1237. https://doi.org/10.1111/cea.13715 Halvorsen T, Walsted ES, Bucca C, Bush A, Cantarella G, Friedrich G, Herth FJF, Hull JH, Jung H, Maat R, Nordang L, Remacle M, Rasmussen N, Wilson JA, Heimdal JH. Inducible laryngeal obstruction: an official joint European Respiratory Society and European Laryngological Society statement. Eur Respir J.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

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				2017 Sep 9;50(3):1602221. https://doi.org/10.1183/13993003.02221-2016 Ludlow S, Daly R, Elsey L, et al. Multidisciplinary management of inducible laryngeal obstruction and breathing pattern disorder. Breathe 2023; 19: 230088 https://breathe.ersjournals.com/content/breathe/19/3/230088.full.pdf Whittet C, Morris S, Pope L Subglottic stenosis masquerading as asthma in a young adult: an overlooked and delayed diagnosisBMJ Case Reports CP 2022;15:e251581. https://doi.org/10.1136/bcr-2022-251581	
The Royal College of Speech and Language Therapists	General	General	General	RCSLT would like to thank the committee for their detailed document and welcomes areas that have been considered in this update. However, we are disappointed that the guideline is focused on pharmacological management of asthma and does not recognise the role of the multidisciplinary team (including speech and language therapists) in therapeutic management of upper airway disorders. Decisions about increases in medication dosage should also involve considering differential diagnosis of	Thank you for your comment Recommendation 1.6.1 reminds people to consider other reasons for poor symptom control before increasing medication. The guideline does not cover management of upper airway disorders because it is a guideline on asthma.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				other upper airway disorders and alternative management options. See: Ludlow S, Daly R, Elsey L, et al. Multidisciplinary management of inducible laryngeal obstruction and breathing pattern disorder. Breathe 2023; 19: 230088 https://breathe.ersjournals.com/content/breathe/19/3/230088.full.pdf	
Trudell Medical UK Limited	Algorithm (treatment)	General	General	Pharmacological management 12+. "Consider" change to ICS/formoterol PRN/MART – Misses outlining of best practice checks eg: inhaler technique and/or other potential causes for symptoms and should emphasise shared decision with patient. These are listed on the Children under 5 algorithm. Only one treatment pathway for newly diagnosed patients, while potentially acceptable for many patients, it gives no option for those who do can't or don't want to use this approach and lacks consideration of patient preference or shared decision making. We suggest mirroring the draft 5-11 algorithm or 2024 GINA guidance with a preferred and a secondary pathway.	Thank you for your comment The algorithm covers the recommended treatment pathway. Adding best practice checks would complicate it and lose some clarity. NICE's purpose is to make the most cost-effective recommendations for management of a given condition, and for asthma in adults this is the MART pathway.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Trudell Medical UK Limited	Evidence review P	039	046	Query data regarding "***budesonide/formoterol 200/6 as the most common formulation of ICS/formoterol on the market and prescribed as DPI***." Open Prescribing data suggests the most common ICS/formoterol formulation is beclomethasone/formoterol 100/6 pMDI: 4,426,917 items versus 1,919,998 items of budesonide/formoterol 200/6 DPI (June '23 - May '24)	Thank you for your comment. The sentence has been revised to:" By contrast, 96% of budesonide/formoterol 200/6, the only ICS/formoterol currently licensed for AIR therapy in the UK, is prescribed as DPI"
Trudell Medical UK Limited	Evidence review P	040	004	Agree with the committee regarding their note that "***some people with asthma would still need to have an MDI SABA available to use via a spacer in the event of a severe asthma attack"***. This is not referenced within the guidance itself and is a significant omission that may put patients at risk. Suggest adding this statement to the guidance and highlighting this consideration as part of any treatment change or inhaler technique training. ***"These are almost all children, some of whom find it difficult to use a DPI during an attack".*** This is critical information and not sufficiently emphasised in the guideline. We feel this should not just be limited to highlighting the	Thank you for your comment Recommendation 1.6.8 has been expanded.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				issue in children as adults can also be affected by significant drops in inspiratory flow rates during an attack. Previous guidance recommends availability of MDI plus spacer for acute situations.	
Trudell Medical UK Limited	Evidence Review Q	125	032 - 035	***Another consideration was the impact of inhaler choice on environmental factors. The significant carbon emissions of metered dose inhalers (MDIs) was discussed at length, with the committee agreeing that dry powder inhalers (DPIs) are preferable due to their lower carbon footprint. Whilst this is an important consideration, the committee agreed that the most important factor in inhaler choice should be the ability of the patient to use the inhaler to support adequate asthma control.*** DPIs do not contain Global Warming Potential (GWP) gases, however they do impact on the environment at other points in their life cycle (Jeswani HK, Azapagi A. Life cycle environmental impacts of inhalers. Journal of Cleaner Production. Vol 237, 10, Nov 2019; 117733.). With new low GWP propellant gases	Thank you for your comment The committee understands that there is more to environmental impact than GWP gases but took expert advice on this and are happy that at present DPIs have less impact than MDIs. The guideline does not suggest at any point that a person's inhalers should be changed for environmental benefit.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				in development MDIs may have a lower carbon impact than DPIs in the very near future. We have concerns about people's inhalers being changed for perceived environmental benefit when, through effective inhaler checks by appropriately trained healthcare professionals, asthma control could be achieved thereby reducing carbon emissions. The "greenest" inhaler is the one that a person can and will use effectively and a person whose respiratory condition is well-controlled has a significantly lower environmental impact and this is supported in numerous studies and expert position statements. Use of AeroChamber* brand of chambers is a simple and effective way to reduce emissions when using pMDIs. By maximizing the amount of medication reaching the lungs, through use of the AeroChamber Plus* Flow-Vu* spacer, the patient is likely to get relief sooner and use fewer puffs. Suggett J. Assessment of Metered Dose Inhaler (MDI) vs MDI and Spacer – impact on patient, health care system and the environment. CHEST Oct 2023.	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Trudell Medical UK Limited	Evidence Review Q	125	038 - 046	***However, there is a legitimate concern that in the event of a severe exacerbation some people may be unable to generate suitable inspiratory airflow to obtain relief via a DPI, and this may be a greater risk in children. Overall, clinicians on the committee agreed that there are very few cases where adults may be experiencing a severe enough exacerbation that a DPI is not useable. Nonetheless this may necessitate some people having an MDI containing a SABA to be used with a spacer during exacerbations, and this negates the simplicity of MART for those people. It was also noted that personalised action plans for use of MART during asthma exacerbations require careful consideration and clinician-patient collaboration.*** We feel these are key points and an important discussion by the committee. It is disappointing that the recognition of the need for some patients to have an MDI SABA used with a spacer during exacerbations is not referenced anywhere in the draft guideline. We recommend the inclusion of a statement to this effect in the guidance.	Thank you for your comment Treatment of exacerbations is not in the scope of this guideline. Complementary guidance on acute asthma will be produced by BTS/SIGN. However, recommendation 1.6.8 has been amended to specify that some people will need an MDI+spacer for emergency use.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				The ERS position statement on Asthma and Environment – May 2021 includes the following statements: - Ensure patients have a pMDI and spacer emergency treatment pack for self-management of exacerbations especially if using DPIs for regular treatment. - Consider use of spacers to increase clinical effectiveness of pMDIs	
Trudell Medical UK Limited	Evidence Review Q	125 - 126	050 - 003	**1.1.12.5** ***The committee strongly reiterated the need for clinician-patient collaboration in order to select the correct inhaler for the participant, and agreed that the NICE asthma decision aid provided a valuable resource for clinicians and patients*** – We agree that appropriately trained clinician and patient collaboration is vital in selecting the correct inhaler. Please see the previous feedback regarding the NICE asthma decision aid (comment 10).	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Trudell Medical UK Limited	Guideline	009	011 - 015	**1.6** Including information about inhaler licensing in line with the guideline recommendations is important. However, considerations need to be made regarding prescribers' confidence and comfort levels in using products 'off-license'. A programme of education and training will be required for healthcare professionals to understand the position of this guideline and the inhalers available for use as AIR or MART, particularly for those prescribers with limited respiratory expertise but responsibility for supporting other non-prescribing asthma clinicians in their teams.	Thank you for your comment. The committee agrees that AIR is relatively new (MART is less so) and that clinician education will be needed. Your comments will be considered by NICE where relevant support activity is being planned.
Trudell Medical UK Limited	Guideline	009	011 - 015	**1.6** Licensing and testing for Spacer devices with specific inhalers also varies. Regulatory bodies highlight the need for testing and that devices should not be considered as interchangeable: - pMDIs must be tested with at least one Spacer (named on SmPC) before obtaining a license (EMA, 2009).	Thank you for your comment. The guideline does not contradict any of the licensing regulations on spacers which you describe here.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				- In the absence of being on the license; each VHC should be clinically tested to assess medication delivery prior to routine use with a particular pMDI. (Blake K et al. Bioavailability of inhaled fluticasone propionate via chambers/masks in young children. Eur Respir J 2012;39:1). - Spacers are not interchangeable (MHRA, 2008).	
Trudell Medical UK Limited	Guideline	009	013	**Linked document: NICE information on prescribing medicines** This document supports the previous statement regarding differences in licensing: "we expect that healthcare professionals will prescribe or advise their [medicines] use within the terms of their UK marketing authorisations, as described in manufacturers' summaries of product characteristics (SPCs)". It also states that 'off-label' or 'unlicensed' use is appropriate "only if there is enough evidence or experience to support it". We feel this need for sufficient evidence or experience should be noted within the guideline as applying to the entire	Thank you for your comment. There are links within the document to both NICE and SIGN's advice on prescribing medicines and the committee is happy to defer to this.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				medication delivery device/system, i.e. a specific MDI and its licensed or suitably clinically tested spacer.	
Trudell Medical UK Limited	Guideline	010	015 - 018	**1.6.4** We agree with these criteria as a base for the choice of inhaler(s), but believe they are in the wrong order. Whilst we support taking environmental considerations into account, of the three criteria listed this should be the final consideration after ensuring correct technique and preference of the person receiving the treatment, both of which follow the NICE recommendation for adherence. GINA notes a specific order: First, choose the most appropriate medication for the patient to reduce exacerbations and control symptoms. Then, from the inhalers available for that medication, assess which inhaler the patient can use correctly after training. If there is more than one option, which of them has the lowest environmental impact, and whether the patient is satisfied with the inhaler. (GINA 2024)	Thank you for your comment. The order of bullets is not supposed to reflect importance. However, as several stakeholders have requested this, it has been altered.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				GINA also highlights the importance of not green guilting. "Clinicians need to be aware of the potential to place an additional burden on patients of so called **"green guilt"**, which **could impact negatively on adherence and increase the risk of exacerbations**." "For all age-groups, **selecting the right inhaler for the individual patient is crucial** to asthma care, not only to reduce patients' symptom burden, but also to reduce the need for emergency healthcare and hospitalization, **which have even greater environmental impacts than use of pMDIs." (GINA 2024)** We would like to highlight a recent Canadian Thoracic Society position statement supporting the benefits of pMDI + spacer with regard to reducing environmental impact: Ensuring proper inhaler technique by demonstrating and reviewing with patients in clinic and encouraging the use of a spacer when using an MDI can both lead to greater drug delivery, resulting in improved disease control, decrease SABA overuse, fewer exacerbation events and thus reduced GHG emissions. (Canadian Thoracic Society Position Statement on Climate Change	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				and Choice of Inhalers for Patients with Respiratory Disease. Canadian Journal of respiratory, Critical Care, and sleep Medicine. Oct 2023.)	
Trudell Medical UK Limited	Guideline	011	003	**1.6.5** ***"...and the correct technique to use for each device."*** We suggest the addition of: (including in combination with a spacer when using a MDI) - should be demonstrated by a trained healthcare professional. Additional support and information should be provided through trusted resources eg: Asthma + Lung UK	Thank you for your comment. The advice in 1.6.5 covers all inhaler devices and the committee does not think it is appropriate to single out one type.
Trudell Medical UK Limited	Guideline	011	005	**1.6.6** This is the singular reference to use of spacers in this draft guideline, which is surprising given that the guidance covers asthma management in children aged 5 to 11. We suggest rewording the statement to read (and spacer when using an MDI). We would like to see the addition of a statement similar to that used in GINA 2024:	Thank you for your comment. Recommendations 1.6.4 to 1.6.8 do not specify any inhaler type or system. They are intended to apply to all, and they fail to mention DPI's just as much as they fail to mention MDI+spacer. Rationales are not included within recommendations in NICE guidance and

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				"For pMDIs, use of a spacer improves delivery and (with ICS) reduces the potential for side-effects." to provide a clear rationale for spacer use. Several studies have shown the majority of HCPs have inadequate inhaler knowledge to educate their patients effectively or coach them in correct inhaler technique. (Plaza V et al. Errors in the use of Inhalers by Health Care Professionals: A Systematic Review. J Allergy Clin Immunol Pract. 2018 May-Jun;6(3):987-995. Baverstock M, Woodhall N, Maarman VP94 Do healthcare professionals have sufficient knowledge of inhaler techniques in order to educate their patients effectively in their use? Thorax 2010;65:A117-A118.) In order to deliver this guideline, there is a need for any HCP involved in reviewing patients to have undertaken quality, accredited inhaler technique training. This will need investment and support to deliver this education across the NHS.	therefore the same methodology is adopted in this BTS/NICE/SIGN guideline. The committee agrees that all its recommendations should be carried out by appropriately trained people. Your comments will be considered by NICE where relevant support activity is being planned.
Trudell Medical UK Limited	Guideline	011	010	Question – what is meant by ***"When a person switches to a generic device"***? Is this a	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				reasonable recommendation given differences in licensing eg: for MART. Perhaps amending this to read: with any change of inhaler (for example, between types of devices (DPI, MDI) or brands) would be more appropriate.	This was not intended as a recommendation for generic devices but was offered as an example because generic switching can sometimes occur without the original prescriber's knowledge, is potentially hazardous, and the committee wished to remind people of this. Since its purpose seems to have caused confusion, the reference to generics has been removed.
Trudell Medical UK Limited	Guideline	011	015	**1.6.7** Device continuity is important for ensuring correct technique and minimising errors. This may be challenging aligned to the recommendation of adding in a LAMA to moderate-dose MART (1.7.6) given the limited asthma licensed LAMA products and devices available.	Thank you for your comment. The words "if possible" have been added.
Trudell Medical UK Limited	Guideline	015	005	**1.8.1** Offer twice-daily paediatric low-dose ICS with as needed SABA as initial treatment. We would	Thank you for your comment The choice of inhaled device is separate and covered in section 1.6. MDI+spacer may well be

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				encourage the addition of: "via a MDI + spacer" to this statement. The National Bundle of Care for Children and Young People with Asthma: Phase one. Version 1, September 2021 states: Effective delivery of medication to the lungs of younger children and infants requires the use of spacer device. Neither inhaler types or spacer devices are interchangeable without additional training and education and inhaler technique should be checked regularly.	the best choice for most children, but some will be better suited by an alternative device.
Trudell Medical UK Limited	Guideline	015	010	**1.8.2** There is an absence of information in this guideline about management of emergency/acute situations, particularly in the 5 to 11 year age group, and use of MART may conflict with current protocols in schools, where MDI SABA and spacers are held for emergency use.	Thank you for your comment Management of acute asthma attacks is outside the scope of this update. BTS & SIGN will produce separate guidance on this.
Trudell Medical UK Limited	Guideline	016	001 - 002	The draft guideline recommends a MART approach 'off-label' for paediatrics 5-11. We believe clarity is needed around the	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				recommended device type for this age group. MDI + spacer is likely to still be most appropriate device for many patients in this age range.	MDI+spacer does not lend itself as well to MART as does a DPI because it is not as easy to carry the spacer around. The study on MART in children used a DPI and this has now been stated in 1.8.2.
Trudell Medical UK Limited	Guideline	017	004 - 007	**1.9.1** 8-12 week trial of ICS plus SABA – we recommend stating "via MDI + spacer" for absolute clarity.	Thank you for your comment In accordance with the principles in section 1.6, the inhaler device which best suits that person should be used. In this age group that will almost always be a spacer plus MDI.
Trudell Medical UK Limited	Guideline	017	015	**1.9.2** We suggest rewording this to state: "check inhaler and spacer technique and adherence"	Thank you for your comment The extra words are not necessary
Trudell Medical UK Limited	Guideline	019	012	**1.10.4** Suggest including "and what to do if symptoms worsen". What a review and update of a	Thank you for your comment What to do if symptoms worsen is an integral part of an action plan and there is no need to

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				person's asthma action plan looks like in practise should be made more explicit.	state this separately. Since a plan must be personalised, it is not possible to be explicit about its content.
Trudell Medical UK Limited	Guideline	019	015 - 016	**1.11.1** We recommend this be expanded to "demonstrated inhaler technique" and "at every asthma-related healthcare review or touchpoint opportunity eg: community pharmacy"	Thank you for your comment Recommendations around inhaler usage are in section 1.6
Trudell Medical UK Limited	Guideline	020	027 - 028	**1.13.3** This statement provides no guidance on what this means or recommendations/evidence for addressing identified issues with inhaler usage.	Thank you for your comment This recommendation has been transferred from the BTS/SIGN guideline. For further detail and explanations, a reader will have to access SIGN158
Trudell Medical UK Limited	Guideline	021	019	**1.14.2** Suggest that demonstrated check of inhaler technique is included as a key part of self-management plan review and not limited to hospital or virtual ward admission. Effective intervention at an acute primary care or	Thank you for your comment. The committee agrees that the extra wording in bullet point 1 should also apply to the following bullets. In fact the advice to check inhaler technique in these circumstances is already given earlier in the guideline (section1.6). The

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				emergency dept consultation could prevent hospital admissions. Question: how is inhaler technique checked through virtual ward interventions? Training and education will be required for virtual ward staff who may not have in-depth respiratory expertise.	wording of 1.14.2 has been changed accordingly.
Trudell Medical UK Limited	Guideline	022	016	**1.14.6** This is the first mention of pharmacists in this guidance and, as stated previously in this response, pharmacists are a potentially crucial touchpoint for people with asthma. There appears to be some contradiction to this on p76 with the deletion of "Consider training pharmacists to provide education for people with asthma. [14.8]" with the justification This recommendation has been deleted because the training of healthcare professionals is outside guideline remit, and the recommendation was a good practice point (BTS/SIGN guideline recommends further research).	Thank you for your comment The committee agree that pharmacists play an extremely useful role. The reference to them in 1.14.6, which has been retained, and in 1.14.8, which has been deleted, both advised that they might be involved in asthma care. They said much the same thing (and to have both is therefore unnecessary) with the exception that 1.14.8 referred to training, which is outside the guideline remit.
Trudell Medical UK Limited	Guideline	022	022	**1.14.7**	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				We agree and support the statement: ***Schools and health services should work together to provide in-school asthma education…by appropriately trained personnel.*** There may be challenges in delivering this with the significant changes to treatment approaches outlined in this draft guidance that are contrary to current practice in schools (SABA MDI plus a spacer for emergencies), and the variation in school engagement/health service provision for asthma (eg: school nurses, CYP asthma bundle implementation, Asthma Friendly Schools).	The guideline does not cover management of acute asthma. This will be covered in separate guidance and may well refer to MDI+spacer delivered therapy.
Trudell Medical UK Limited	Guideline	022	025 - 028	**1.14.8** Another link to an external document which is not asthma/respiratory specific and requires interpretation for non-respiratory specialist HCPs.	Thank you for your comment The links are intended to be helpful and to avoid the need to reproduce lots of information which is readily available elsewhere. We note that several stakeholders have asked us to add links to a variety of external documents and we assume therefore that others find this useful.
Trudell Medical UK Limited	Guideline	023	002 - 006	**1.15.1** Actively identifying people at risk of poor asthma outcomes is likely to provide benefits to these	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				people and the health economy overall. These criteria are appropriate for assessing risk under current treatment strategies – particularly over-use of SABA. What would the recommendation look like in future when a wide scale MART treatment approach is implemented? Should there be mention of reliever overuse or monitoring with regard to ICS/Formoterol?	This is an interesting point. Overuse of SABA has been repeatedly identified as a risk factor for exacerbations, but overuse of reliever therapy within AIR or MART has not. This may, of course, be because use of MART is less common, but there is also evidence that it is intrinsically safer.
Trudell Medical UK Limited	Guideline	023	008 - 010	**1.16.1** The number of healthcare professionals with appropriate asthma training may be the most significant barrier to implementing this guidance. Asthma care in the UK may be delegated to professionals without adequate training. According to the UK National Review of Asthma Deaths, 46% of nurses who had performed reviews on patients who died from asthma had no formal training in asthma care. (Usmani, O.S., Levy, M.L. Effective respiratory management of asthma and COPD and the environmental impacts of inhalers. npj Prim.	Thank you for your comment Training healthcare professionals is outside NICEs remit and therefore the remit of this BTS/NICE/SIGN guidance.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Care Respir. Med. 33, 24 (2023). https://doi.org/10.1038/s41533-023-00346-7) Addressing this issue of training and education would deliver the greatest benefits in respiratory care in the UK. It would be helpful to understand what plans NICE/BTS/SIGN have around supporting HCP education and the understanding of the final guidance when published.	
Trudell Medical UK Limited	Guideline	025	General	We recommend including a definition of spacers/Valved Holding Chambers (VHCs) in this section, outlining how they work, improve MDI medication delivery and reduce oral side effects.	Thank you for your comment This would go beyond the purpose of a Terms Used section.
Trudell Medical UK Limited	Guideline	042	007 - 008	***People on current pathways who need an increase in treatment will be switched to MART.*** Should there be some recognition of personal preference to treatment here aligned to shared decision making with the individual?	Thank you for your comment Shared decision making is a basic tenet of disease management. There is statement to this effect at the beginning of the guideline and it should not be necessary to state this in every recommendation.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Trudell Medical UK Limited	Guideline	042	017 - 026	***The committee recognised that this [change to MART from previous guidelines strategies] will cause a problem for these people when their asthma is not controlled. They therefore discussed and agreed how treatment should be changed in these circumstances. They noted that the general advice about checking inhaler technique, adherence, etc. (see recommendation 1.6.1) before escalating treatment still applies here***. This is not reflected in the treatment algorithm – particularly the importance of inhaler technique and adherence before changes to treatment are made.	Thank you for your comment The algorithms have been amended but please note that it is not possible to include every word from the guideline within an algorithm.
Trudell Medical UK Limited	Guideline	067	000	**** at high doses of inhaled corticosteroid via a pMDI, a spacer should be used. [D/D, 7.5.2]*** This important point around the benefits of spacers in reducing side effects, especially at higher doses of ICS, has been deleted and spacers are not referenced in sections 1.7 or 1.8 within treatment sequencing as suggested in the comment column.	Thank you for your comment The deleted recommendation refers to **high** doses of inhaled steroids, not **higher** doses. High doses are no longer recommended. The comment column does not say that spacers are referenced in sections 1.7 or 1.8.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Trudell Medical UK Limited	Guideline	072	000	***In young children, a pMDI and spacer is the preferred method of delivery of β2 agonists and inhaled corticosteroids. A face mask is required until the child can breathe reproducibly using the spacer mouthpiece. Not included as this is a statement of effectiveness rather than a recommendation. Choice of inhaler remains important for all ages and is covered in recommendations 1.6.4 to 1.6.8.*** We would argue that the guideline should be highlighting and recommending treatments based on effectiveness and question why this is not included.	Thank you for your comment The previous guideline statements were based on studies in which mean effectiveness was appraised or were good practice points based on opinion. The new recommendations in section1.6 emphasise that the choice of inhaler has to be personalised. In young children the best device is highly likely to be an MDI+spacer, so in practice the advice has not changed.
Trudell Medical UK Limited	Guideline	072	000	***The spacer should be compatible with the pMDI being used. A change in spacer may alter effective dose delivered. The drug should be administered by repeated single actuations of the metered dose inhaler into the spacer, each followed by inhalation. There should be minimal delay between pMDI actuation and inhalation. Tidal breathing is as effective as single breaths. Spacers should be cleaned in accordance***	Thank you for your comment If this level of detail was included for MDI+spacer it would have to be included for every inhaler. This is not a practical suggestion.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				with manufacturer's recommendations. Drug delivery via a spacer may vary significantly due to static charge. Metal and other antistatic spacers are not affected in this way. Plastic spacers should be replaced at least every 12 months but some may need changing at 6 months. [8.5] We feel very strongly that this level of detail should be included in a National Guideline document such as NICE/BTS/SIGN. There is no reference to this degree elsewhere in supporting documentation within this draft guideline (including the patient decision aid) and by deleting this information the importance and value of spacers in effective drug delivery will be lost. Guidance for how to appropriately use spacers is critical; reference to appropriate use via support materials eg: A+LUK would be good to see added.	
Trudell Medical UK Limited	Guideline	079	000	***Give people with asthma information on their inhaler treatments. This should include the medicines they contain, how they work, when they should be taken and the correct technique to use for each device. [1.6.5]***	Thank you for your comment It should not be necessary to single out particular devices in this general recommendation.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				Giving appropriate information is a good general principle. In addition, the Committee consensus is that people are more likely to use inhalers as intended if they understand why they have been prescribed. We fully agree with the principle of educating patients on their inhaler treatments, not limited to the inhaler alone. This statement could be enhanced by ensuring an MDI and spacer are presented as a whole, combined delivery system, to address perceptions of spacers as separate/optional devices.	
Trudell Medical UK Limited	Guideline	General	General	We welcome the collaborative approach of bringing together the BTS/SIGN and NICE guidelines to create a singular, National Guideline for Asthma. We understand the rationale for streamlining the guidance, making it accessible and easily digestible across a broad range of stakeholders. However, in its current form we feel the document is more a series of statements rather than clear guidance for good clinical practice, providing the "What" but not the "How" or "Why" behind the statements.	Thank you for your comment NICE guidelines focus on what should be done and therefore this collaborative guideline follows the same methodology. "Why?" is covered briefly in the rationales and there are links to further information in the Evidence reviews, so the information is there for those who wish to see it. "How" is more difficult since it may be possible to fulfil some of the recommendations in more than one way, and this detail is best left to local implementation.

Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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				The generality of the statements assumes a level of respiratory knowledge and expertise from the reader that is broadly lacking across the UK and will require significant investment in education to effectively deliver these guidelines.	
Trudell Medical UK Limited	Guideline	General	General	Links within the draft guideline to other supporting information or guidance documents mean there are additional steps required for anyone seeking to understand how to deliver the recommendations. For example, within the statement regarding checking adherence there are two links to further documents: *NICE guidance on shared decision making* and *medicines adherence*, which would also require reading and interpretation. This is likely to impact on the usefulness and usability of the guideline as a reference document in practice.	Thank you for your comment Inserting a large amount of supporting information in the guideline itself hinders navigation. Most people access the guideline online and finding the linked evidence therefore requires a single click. Reading it is no more difficult if it is part of the main guideline than if it is accessed via a hyperlink.
Trudell Medical UK Limited	Guideline	General	General	In the Who is it for? list, we question the lack of mention of Pharmacists. Pharmacists play a key role in the management of people with asthma; many are involved in conducting annual reviews in GP practice and Community Pharmacy is a key touchpoint for people and an opportunity for	Thank you for your comment The sentence has been amended.

Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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				supporting quality interventions such as inhaler technique checks.	
Trudell Medical UK Limited	Guideline	General	General	Acute asthma management not included in the scope of this guidance – takes away recommendation (and evidence) for use of SABA pMDI + spacer in acute situations. What are the potential risks for a singular approach with MART that may not be suitable for all and causes confusion for HCPs in how to advise on treatment for specific patients and for patients potentially using different regimen. Is there scope for clarity on a 2 stream approach like GINA?	Thank you for your comment The committee believes that the evidence in adults strongly favours the AIR then MART strategy over the traditional treatment pathway and have therefore recommended this. The remit of NICE is to offer guidance on the most cost-effective management strategy, and the same process has been followed for this collaborative guideline with BTS and SIGN..
Trudell Medical UK Limited	Guideline	General	General	Education and training for HCPs to implement change to MART. Coaching and patient advice for switch of regimen – particularly for those on multiple therapies ICS/LABA + LAMA +/- LTRA to moderate dose MART.	Thank you for the suggestions.
UK Clinical Pharmacy Association (UKCPA) and Royal		000	014	1.1.2 'Do not confirm a diagnosis of asthma without a suggestive clinical history and a supporting objective test' – this may be misconstrued as diagnosis can be made by a single objective test. It is worth stating that often more than one objective test is required for	Thank-you for your comment If there is a history suggestive of asthma, a single supporting test may be enough. In other cases, more tests will be required.

Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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Pharmaceutical Society (RPS)				diagnosis and clinicians require collective information along with the clinical history to make the correct diagnosis– see feedback point echoed in below row	
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Algorithm treatment	003	General	Adults - Right side box has criteria 'Asthma uncontrolled on SABA alone → offer low dose ics/Formoterol as needed' Suggest the 'uncontrolled on SABA alone' criteria is removed as no patients should be on SABA alone	Thank-you for your comment The committee agrees, but the algorithm covers therapy people might be taking at present and regrettably some people are on SABA alone
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Equality impact assessment	General	General	No assessment made of the limited range of patient information and AIR and MART asthma action plans available in languages other than English. As of July 2024, Asthma+Lung UK have these available in only 9 languages (English, Arabic, Bengali, Chinese, Welsh, Gujarati, Polish, Punjabi, Urdu) https://www.asthmaandlung.org.uk/symptoms-tests-treatments/treatments/mart/download#download ; https://shop.asthmaandlung.org.uk/collections/air-action-plans	Thank-you for your comment and for pointing this out.
UK Clinical Pharmacy	Guideline	000	General	Generally, there needs to be more explicit guidance throughout the document in terms of	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Association (UKCPA) and Royal Pharmaceutical Society (RPS)				being SABA free. Whilst it is welcomed that there is a recommendation (1.6.2) suggesting no use of SABA without ICS there is nothing specific thereafter for patients who are on AIR or MAR T and this maybe misinterpreted by health staff. As a result there is a risk that patients may still get issued SABA alongside their ICS/LABA even though we are trying to move away from reliance on SABA and its inappropriate use. More directive advice required around SABA use for children, especially if on ICS/LABA as historically spare SABAs are kept in multiple locations such as schools or different household locations. This will also need consideration for wider NHSE work on asthma CYP ICS deliverables and 'asthma free schools' work stream, including teaching to support school staff in terms of organisation and delivery of care	The description of MART in the Terms Used section now specifies that a SABA should not be needed.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	000	General	There is no real mention of acute severe asthma within guideline and suggest that there is some link to this/acute deteriorating asthma, especially how it might be initially managed in out of hospital settings and incorporated into PAAPs. With respect to the comment about SABA in row prior, it is also important to consider how a patient self manages in an emergency before	Thank you for your comment. Acute asthma is outside the scope. BTS/SIGN will produce guidance on this.

Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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				getting to hospital/ambulance – usually current practice people can use up to 10 puffs of SABA via spacer in emergency if needed but if they don't have SABA they cant which implies to clinicians and patients they might need SABA just in case and negates AIR/MART only prescribing. Appropriated guidance on use of ICS/LABA in this situation should be provided.	
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	000	General	There need to be clearer cut offs for moving from AIR to MART regime. There should also be a suggestion on the number of days they are uncontrolled e.g. 3 days mentioned but this doesn't account for doses taken e.g a patient using maximal MART or greater for 2 days	Thank you for your comment. The committee does not entirely agree. The description of uncontrolled asthma is intended to help, but a decision about increasing treatment will always have to take into account how much the symptoms are bothering the person with asthma. Trying to be too precise may be counterproductive.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	000	General	Pharmacological management section 1.7 – 1.10 there is no mention of shared decision making, this is only mentioned in the adherence section and suggest this is made more explicit in each section where a recommendation to prescribe or escalate/decrease therapy is made	Thank you for your comment. Shared decision making is a general principle which applies to all prescribing encounters (and with which prescribers should be familiar as it applies throughout medical practice, not just in asthma). This point is made right at the start of

Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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					the Recommendations section. It is not necessary to repeat this for each relevant recommendation.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	000	General	Section 1.7 – should specify for adults and children what constitutes low dose, moderate dose and high dose ICS (high >800-1000mcg Beclomethasone diproprionate equivalent in adults)	Thank you for your comment. A link to Inhaled corticosteroid doses for the BTS, NICE and SIGN asthma guideline has been added to the guideline
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	001	General	Title page 'who is it for' – this states 'GPs and nurses or HCPs in secondary and tertiary care'. This has not included Pharmacists who work broadly in primary care (both primary care network/GP setting, community pharmacy or community services where they are involved in monitoring, prescribing for and diagnosis of asthma) or other staff that work in community services (such as community respiratory teams and virtual wards. Suggest the wording is changed to be more inclusive to reflect this	Thank you for your comment. This has been changed.
UK Clinical Pharmacy Association (UKCPA) and Royal	Guideline	004	006	1.1.1 Clinical history - To specifically include 'upper airway disease such as nasal disorders'	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Pharmaceutical Society (RPS)					The committee does not think this is a necessary addition. The relevant nasal disorder is included.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	005	022	Recommendation 1.2.1 We are concerned that asthma diagnosis in adults can be made by a blood eosinophil count measurement **or** a FeNO measurement for a number of reasons: - A raised blood eosinophil above the reference range is not always diagnostic of asthma (e.g allergic rhinitis, inflammatory diseases)? There are other conditions (and drug induced) where eosinophils are elevated that are not diagnostic of asthma. Consider clarifying this to rule out other causes. - Currently the draft guidance suggests that FeNO alone with asthma suggestive symptoms is sufficient to obtain an asthma diagnosis. FeNO is raised in other conditions and other factors aside from asthma and is not valuable in those patients who smoke who may also have asthma. - We feel that asthma diagnosis should continue to include reference to the	Thank you for your comment. You are essentially stating that neither raised FeNO nor raised eosinophil count is specific for asthma, and the committee agrees. However, most diagnostic tests carry a false positive or false negative rate, and clinicians generally cope with this. The alternative is to do no tests, which is surely more likely to lead to misdiagnosis.

Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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				presence of variable airflow obstruction. FeNO and blood eosinophils are helpful in addition to support the diagnosis of asthma and a particular phenotype. Establishing an accurate diagnosis is key to ensure unnecessary escalation of medication with potential adverse effects to patients and cost to the NHS.	
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	005	022	Is a blood eosinophil above the reference range always diagnostic of asthma? There are other conditions where eosinophils are elevated that are not asthma. Consider clarifying this to rule out other causes.	Thank you for your comment. There are other causes of a raised eosinophil count, and these are now mentioned in the guideline. It is important to note that a raised eosinophil count is only indicative of asthma in the presence of a history suggesting the diagnosis.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	006	001	1.2.3 If diagnosis is uncertain then bronchial hyper-responsiveness tests will be required. Resources will be required to implement this recommendation as it usually requires referral to hospital for these tests to be carried out using specific pharmacological agents and cannot routinely be undertaken in primary care.	Thank you for your comment The committee acknowledges this. It is however the best single test for asthma, and it would be remiss not to include it, albeit at the end of the testing sequence.

Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	006	011	Rec 1.2.6 Children 5-16 years – skin prick testing: this will have resource implication – not usually done in primary care and would require referral to hospital and adequate anaphylaxis/resuscitation facilities available during test	Thank you for your comment Availability of skin prick testing is a problem in many areas, which is why testing for IgE and eosinophils is suggested as an alternative.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	008	000	1.5.4 'Consider using FeNO' – There is already little uptake of FeNO testing in primary care due to concerns over the cost of equipment and mouthpieces and unfortunately this wording doesn't sound like it will change practice – we understand the word 'consider' is used based on the strength of evidence available but could this recommendation be reworded to give more emphasis to the clinical utility to support review and adherence?	Thank you for your comment. This may well be an issue, but at present NICE's rules are that this style of wording must be used in the absence of unequivocal supporting evidence as is the case here and therefore this is the same for the BTS/NICE/SIGN guideline.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	008	016	1.5.1 Monitoring asthma control, suggest changing 'amount of reliever inhaler used' to 'amount of reliever **doses** used', as AIR/MART regimens do not have a separate reliever inhaler.	Thank you for your comment This seems an unnecessary addition. The developers believe users of the guideline will easily understand the intent. No other stakeholder has identified this as a problem.
UK Clinical Pharmacy	Guideline	008	022	1.5.3 The recommendation to not use PEFR is confusing especially when they are	Thank you for your comment

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Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Association (UKCPA) and Royal Pharmaceutical Society (RPS)				recommended as part of a personalised asthma action plan. Although PEFR not recommended for regular monitoring the use of PEFR at certain times to help access control is useful, for example – baseline best PEFR and intermittent measurement when symptoms decline.	The evidence (Evidence Review M) did not show any overall benefit of regular PEF monitoring. The draft version of recommendation 1.5.3 allowed that some people may find that using PEF helps ("person-specific reasons") and it was therefore entirely compatible with 1.14.1, but this has now been made more readily apparent.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	008	028	1.5.5 Suggest the wording around inhaler technique is changed to ensure HCPs check and optimise inhaler technique	Thank you for your comment. This point is covered in the next section of the guideline, 1.6.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	009	019	1.6.1 It would be useful to add further examples here as well as obesity, e.g. GORD, nasal disease also include optimisation of co-multimorbidity	Thank you for your comment. Several stakeholders have suggested additions which might be made to this bullet point, and on reflection the committee have agreed that no examples are necessary, the meaning of the recommendation being clear without them.

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18/06/2024 – 30/07/2024

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UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	009	020	1.6.1 Please consider changing the terminology 'lack of adherence' to 'sub-optimal medicine adherence', as some people overuse inhalers (particularly SABAs). Lack of adherence suggests that underuse is the only problem.	Thank you for your comment. The wording has been altered.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	010	015	1.6.4 Consider adding wording: "taking into account the local formulary"	Thank you for your comment. The committee realises that choice may be limited by local formularies, but do not think that adding this would improve the recommendation.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	010	016	1.6.4 consider changing the wording to 'an assessment of correct **inhaler** technique and ability to use the inhaler device' – this accounts for dexterity and ability to actuate the device as well as the correct inspiration. The patient preference bullet point is listed last, suggest moving this further up to give it more importance	Thank you for your comment. The word "technique" does not refer only to inspiration but to the whole process of using the inhaler. The committee does not think that the extra wording provides extra clarity.
UK Clinical Pharmacy Association (UKCPA) and	Guideline	011	001	1.6.5 Give people information about their inhalers – please also include that information should be given on rough duration the inhaler	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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Royal Pharmaceutical Society (RPS)				should last to manage patient expectations e.g. one inhaler shouldn't last them for 6 months.	A bullet point has been added regarding dose counters which should help. The problem with rough estimates of duration is that this could go wrong in people on MART regimens.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	011	011	1.6.6 Statement: For example; when a person switches to a generic device – what does this mean? As all inhalers would be prescribed as brand name including for device	Thank you for your comment. This was not intended as a recommendation for generic devices but was offered as an example because generic switching can sometimes occur without the original prescriber's knowledge, is potentially hazardous, and the committee wished to remind people of this. Since its purpose seems to have caused confusion, the reference to generics has been removed.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	011	015	1.6.7 Although we agree that using one type of device to deliver preventer and reliever treatments s not always possible due to device availability (e.g. no Reliever device available to match preventer) and may not be preferred by the patient. Please amend to where possible.	Thank you for your comment. The words "if possible" have been added.
UK Clinical Pharmacy Association (UKCPA) and	Guideline	011	018	Some areas are introducing inhaler recycling schemes, and it is hoped that these may become more widely available. Suggest amending this text accordingly, e.g. 'Encourage	Thank you for your comment. The wording has been changed

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Royal Pharmaceutical Society (RPS)				people to take their used (once finished/expired) inhalers to their pharmacy for disposal**, or inhaler recycling where available**'	
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	012	012	1.7.2 Whilst we support the use of AIR for patients we are concerned that AIR will be the starting point for the majority of patients. There will be a significant number of patients who are symptomatic and will require MART (regular) therapy starting first. We recommend this section is made clearer to ensure that if patients have had an exacerbation (not just severe) they are started on MART first to support correct use of MART and AIR. Furthermore, many patients do not relate certain symptoms as asthma, such as cough and will not necessarily use their ICS/LABA PRN for this.	Thank you for your comment Recommendation 1.7.2 does not say that starting treatment with MART (as opposed to AIR) is only for those presenting with a severe exacerbation. It also refers to being highly symptomatic. It is hard to define exactly who should have AIR and who should go straight to MART.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	013	008	1.7.5 Consider linking the LTRA recommendation to MHRA advice on the risk of neuropsychiatric reactions https://www.gov.uk/drug-safety-update/montelukast-reminder-of-the-risk-of-neuropsychiatric-reactions	Thank you for your comment. A link to the MHRA DSU has been added.
UK Clinical Pharmacy Association	Guideline	013	008	1.7.5 and 1.7.6 – can we provide more guidance on "ineffective" and monitoring the outcome from the addition of 3 months of addition of LRTA and	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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(UKCPA) and Royal Pharmaceutical Society (RPS)				LAMA. We suggest an improvement in symptoms but not exacerbation frequency.	The committee does not think that healthcare professionals will need more detail, and including this would be cumbersome. The key issue will be to see whether it has improved the feature(s) of the person's asthma which showed that previous control was poor e.g. if they were waking at night, has this got better? If they were using a lot of reliever, has the amount reduced?
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	013	019	1.7.7 This guideline makes no mention of using high-dose ICA/LABA inhalers. It would be useful to mention the limited place of high dose so that it is clear that the authors have specifically not increased the dose prior to referral (although patients may be on high dose through use of MART) Healthcare professionals may question what they should do to try to improve care for adult patients uncontrolled on moderate dose ICS, LABA, LTRA and a LAMA, besides referring to specialists in asthma care. Has the guideline committee considered? 1. Waiting times to specialist asthma clinics 2. Capacity of specialist asthma clinics and whether there is capacity for all to be referred at this step, even if appropriate to do so?	Thank you for your comment A sentence has been added to the rationale indicating that the absence of a recommendation to use high dose maintenance ICS is deliberate. The committee are aware of the capacity problems you list. Please note that the referral does not need to be made directly to a severe asthma service but to an asthma specialist who should be linked to the regional service but also have separate clinics (in secondary care or as part of an integrated service).

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				3. What should primary care do whilst waiting for first appointments at specialist asthma clinics? The role of integrated care respiratory services?	
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	013	019	1.7.7 'Refer people to a specialist in asthma care' – there will be questions as to what the definition of a specialist is – we can understand keeping this broad so as not to restrict to/overwhelm certain sectors such as secondary care but it may be worth adding a comment to the effect of: 'specialists maybe multiprofessional and also based in primary care and community settings', especially as we move to more integrated models of care	Thank you for your comment You are correct that this is deliberately left open. There are healthcare professionals in primary care and community teams with a lot of expertise in asthma management and 1.7.7 permits this interpretation. However, the appropriate specialist should have access to the facilities which the individual patient might need and if the referral is, for example, for consideration of biologic treatment then the specialist should be part of the regional severe asthma service.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	013	General	The recommendation to recommend single-inhaler therapy as either as needed low-dose ICS/formoterol or MART regimens in people aged 12 and over is to be commended. However as the sole recommendation, we have a number of concerns: 2. These regimens are not suitable for all people with asthma. In real world studies,	Thank you for your comment The committee believes that the evidence in adults strongly favours the AIR then MART strategy over the traditional treatment pathway and have therefore recommended this. The remit of NICE and therefore of this BTS/NICE/SIGN guideline is to offer guidance

Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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				such as the AstraZeneca sponsored SENTINEL project specifically designed to transfer people to MART regimens, only 44.7% transitioned to MART (Crooks MG, Crowther L, Cummings H, et al. Improving asthma care through implementation of the SENTINEL programme: findings from the pilot site. ERJ Open Res 2023; 9: 00685-2022 [DOI: 10.1183/23120541.00685-2022]). Clearly there are a significant number of patients not suitable for MART (e.g. patient preference, unable to understand the regimen, unable to self monitor etc). Consequently this guideline should also provide recommendations on fixed dose regimens. Single-inhaler as needed low-dose ICS/formoterol or MART regimens must be supported with the provision of an appropriate asthma action plan to enable self-management. Unfortunately, the availability of these in languages other than English are limited, so may not be appropriate for non-English speakers. As of July 2024, Asthma+Lung UK have these available in only 9 languages (English, Arabic, Bengali, Chinese, Welsh,	on the most cost-effective management strategy. All people with asthma should have a personalised Asthma Action Plan (recommendation 1.14.1) and as these are personalised, they should cover AIR, MART etc as necessary. It is regrettable that all languages are not catered for at present, but this is beyond the committee's control.

Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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				Gujarati, Polish, Punjabi, Urdu) https://www.asthmaandlung.org.uk/symptoms-tests-treatments/treatments/mart/download#download ; https://shop.asthmaandlung.org.uk/collections/air-action-plans	
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	014	001	1.7.8 – 1.7.11 Transferring people from other treatment pathways The aim should be to step down treatment in people with well controlled asthma to the lowest dose possible and if changing prescriptions from ICS/LABA plus SABA to MART after assessment then this should be considered and included in these recommendations. (recommendation 1.10) Potential shortage issues of ICS/formoterol due to increased demand, if widespread adoption. Also possible inappropriate "switching" from ICS/LABA + SABA without training/ appropriate shared decision making, in patients who currently have well-controlled asthma	Thank you for your comment Recommendations 1.7.8 – 1.7.11 and the recommendations in section 1.10 are not dealing with the same population. The first set of recommendations are for people who have inadequate control on their current treatment. Section 1.10 is for people well controlled on current treatment. Since the transferring recommendations are only for poor control a sudden, large surge in ICS/LABA demand is unlikely.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	014	004	1.7.8 We would like to see a stronger recommendation to change treatment from SABA to ICS/LABA rather than the current wording of "consider"	Thank you for your comment The word "consider" in NICE guidelines is used when evidence is lacking which is the situation here. However, in this instance the developers agree that there is a major safety issue and the wording has been changed.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	015	001	1.7.12 Refer to specialist – see comment above for 1.7.7 as to what a specialist might be We agree that patients uncontrolled on high dose ICS should be referred if uncontrolled to a severe asthma clinic. Please provide recommendations for those that are controlled especially as high dose is not a recommendation in the treatment algorithm. For example these could align with the existing AAC uncontrolled asthma consensus pathway https://www.healthinnovationoxford.org/our-work/respiratory/asthma-biologics-toolkit/aac-consensus-pathway-for-management-of-uncontrolled-asthma-in-adults/	Thank you for your comment You are correct that this is deliberately left open. There are healthcare professionals in primary care and community teams with a lot of expertise in asthma management and 1.7.7 permits this interpretation. Please note that the recommendation is to refer to an asthma specialist, not necessarily to a severe asthma clinic. It is not clear what recommendations you have in mind for people who are controlled on high

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					dose steroids (these are not recommended in the new treatment pathway but there may be people who reached this step in accordance with SIGN158, or indeed people who have already seen a specialist and settled on this treatment). There is the possibility of a trial of stepping down covered in recommendation 1.10.1. A link to the AAC document is now included in the guideline.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	022	006	1.14.4 In the context of MART is quadrupling the dose of ICS evidence based and relevant?	Thank you for your comment A majority of people with asthma will continue to be treated along "conventional" lines for some time and 1.14.4. remains relevant for them.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guideline	023	002	1.15.1 Risk stratified care – this should also include 'overuse of MART therapy' which may suggest either suboptimal control or other issues including anxiety, breathing pattern dysfunction (further driven by overuse of betagonists generally) Please also consider including as a criteria here - short course oral corticosteroid use (including rescue packs)	Thank you for your comment This is an interesting point. Overuse of SABA has been repeatedly identified as a risk factor for exacerbations, but overuse of reliever therapy within AIR or MART has not. This may, of course, be because use of MART is less

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
					common, but there is also evidence that it is intrinsically safer Oral steroid use has been added
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Guidelines	023	007	1.16 Consideration should be given to prescribing of AIR and MART on primary care systems to ensure patients can order sufficient in line with their asthma symptoms but also are monitored to ensure that overuse of "reliever" ICS/LABA does not occur. Hybrid/virtual care models aside we should suggest here that the primary care reviews are done face to face and not via telephone to enable observation of inhaler technique as well as any other physical examination and objective testing	Thank you for your comment Detail on organising prescription delivery to patients is beyond the remit of the guideline. The committee agree that review is best done in person. However, this has not been specified in the recommendation because video review might be much easier for some people (those with disability or living in remote locations) and allows assessment of inhaler technique.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Supporting documentation: Algorithm (treatment)	001	General	The algorithms only flow in one direction - to step up treatment if asthma is uncontrolled. They should also include stepping down for those who are controlled as per section 1.10 p18-19.	Thank you for your comment Algorithms have not been produced for every recommendation in the guideline.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Supporting documentation: Algorithm (treatment)	003	General	For newly diagnosed and present as highly symptomatic or with severe exacerbations, low-dose MART is recommended. The pathway only then suggests an option for if asthma is controlled. However, it does not recommend dose escalation if uncontrolled, which would be to medium-dose MART	Thank you for highlighting this. The algorithms have been amended.
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Supporting documentation: Algorithm (treatment)	General	General	This algorithm is hard to read. Healthcare professionals are more familiar with horizontal stepwise algoithms used in the previous BTS/SIGN asthma guidelines and GINA guidelines. To improve implementation, a similar and more familiar algorithm may be more impactful to change practice.	Thank you for your comment. The developers believe users will be able to cope with a vertical algorithm
UK Clinical Pharmacy Association (UKCPA) and Royal Pharmaceutical Society (RPS)	Supporting documentation: Algorithm (treatment)	General	General	Consider reproducing the BTS/SIGN inhaler dose tables, to help readers understand what is a low and medium dose ICS/formoterol inhaler.	Thank you for your comment The guideline now refers readers to the document "Inhaled corticosteroid doses for NICE's asthma guideline".
University College London	Guideline	019	014	Section 1.1: The new guidelines have removed the detail around supporting adherence that was present in the previous 2017 guideline.	Thank you for your comment It is not clear to the developers what you are suggesting. The 2017 guideline offered a single

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Given the importance of maintaining adherence in asthma (e.g., Engelkes et al., 2015), we recommend that some of this detail is bought back in, drawing on the guidance outlined in NICE CG76 Medicines adherence guidelines and based on recent studies showing the importance of medication beliefs in understanding adherence in asthma (Chan et al., 2023). **Suggested text to be inserted into the guidelines**: *Adherence should be discussed at every appointment, with particular attention in cases where poor asthma control is reported. Conversations about adherence should be non-judgemental, acknowledging that non-adherence is common and asking open ended questions rather than making assumptions. Assess adherence using a specific time frame (e.g., in the past week). We recommend that discussions around adherence explore potential barriers, particularly key adherence related perceptions, such as whether the individual sees a need for the treatment, whether they have any concerns about taking it, and whether they have*	recommendation on adherence which was shorter than 1.11.1 in this update. BTS/SIGN included a description of issues around adherence but there were only 2 grade D recommendations both of which are encompassed by 1.11.1

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				any practical difficulties with taking it. Where barriers are reported, tailor support to the specific difficulties the patient is experiencing, and consider using digital tools to support patients. **References** Chan AH, Katzer CB, Pike J, Small M, Horne R. Medication beliefs, adherence, and outcomes in people with asthma: The importance of treatment beliefs in understanding inhaled corticosteroid nonadherence—a retrospective analysis of a real-world data set. Journal of Allergy and Clinical Immunology: Global. 2023 Feb 1;2(1):51-60. Engelkes M, Janssens HM, de Jongste JC, Sturkenboom MC, Verhamme KM. Medication adherence and the risk of severe asthma exacerbations: a systematic review. European Respiratory Journal. 2015 Feb 1;45(2):396-407.	
University College London	Guideline	023	001	Section 1.15: The guidelines recommend that patients who are on SABA monotherapy or whose asthma is not well controlled are switched from their current treatment paradigm to AIR or MART.	Thank you for your comment The committee acknowledges the issues you raise, but a review of possible ways of mitigating the problems was not part of the

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				There is evidence that many patients are attached to their SABA perceiving it to be the most important aspect of their asthma treatment and having few concerns about using it (Chan et al., 2020; Haughney et al., 2004; Blakeston et al., 2021). In contrast, many patients have strong concerns about ICS (Menckeberg et al., 2008; Moon et al., 2024) and prefer to avoid taking steroids (even in inhaled form) if possible (Chan et al, 2023). These perceptions may be reinforced by the placebo-based sensation of relief that many patients experience immediately on using aerosol inhalers. Some patients who have trialled ICS-LABA in an AIR or MART scheme report switching back to SABA as they believe it brings greater symptom relief (Foster et al., 2020; Foster et al., 2022; Moon et al., 2024). This evidence shows that many patients doubt their personal need to take ICS in place of SABA and have strong concerns about ICS. Therefore, simply informing patients of the new guidelines or stopping SABA prescriptions may be insufficient to motivate patients to change familiar patterns of asthma treatment	scope and it is therefore difficult to recommend a specific tool.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				management. NICE medicine guidelines recommend that addressing these doubts about perceived need and concerns about treatment is essential to support adherence and informed choice. Asthma treatment reviews/discussions are likely to be more effective in motivating and enabling sustained change in asthma management (away from SABA and towards ICS) if they take account of these belief barriers. Several tools are available to support this approach, including the IPCRG Asthma Right Care Reliever Reliance Test (RRT; Foot et al., 2024; Horne et al., 2019; Williams et al., 2024). The RRT has so far been translated from English into 8 additional languages (Arabic, Chinese, French, Greek, Malay, Portuguese, Slovenian, Spanish), and is recommended as a way to implement guidelines developed by the Canadian Thoracic Society, signalling its global reach (Ellis et al., 2022). We believe the current wording in the guidelines underestimates the scale of this behavioural challenge. We therefore recommend that the new guidelines explicitly acknowledge that this	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				change may be difficult for patients, providing strategies for how to modify patient beliefs and help align patients with their treatment. Failure to understand and address these beliefs will likely act as a barrier to these new treatment guidelines being implemented. **Suggested text to be inserted into the guidelines**: *Before stopping SABA and switching a patient onto AIR or MART, it is essential to understand that the patient's perceptions of SABA, ICS and ICS-LABA may act a barrier to this being successfully implemented. Patients may be very attached to their SABA, they may have concerns about using an ICS based treatment and they may not see the need to change their current asthma management plan.* *It is therefore essential to identify those whose beliefs may make it more difficult to accept this change, such as those who may be particularly reliant on SABA or particularly concerned about ICS. The rationale for any treatment changes should then be communicated in a way which addresses potentially misplaced perceptions that*	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				SABA is the most important part of treatment, and addressing concerns about ICS. *Consider using tools such as the IPCRG Asthma Right Care Reliever Reliance Test.* **References** Blakeston S, Harper G, Zabala Mancebo J. Identifying the drivers of patients' reliance on short-acting β2 agonists in asthma. Journal of Asthma 2021;58:1094-1101. DOI: 10.1080/02770903.2020.1761382. Chan AH, Katzer CB, Horne R, Haughney J, de Sousa JC, Williams S, Kaplan A. SABA Reliance Questionnaire (SRQ): identifying patient beliefs underpinning reliever overreliance in asthma. The Journal of Allergy and Clinical Immunology: In Practice. 2020 Nov 1;8(10):3482-9. Chan AH, Katzer CB, Pike J, Small M, Horne R. Medication beliefs, adherence, and outcomes in people with asthma: The importance of treatment beliefs in understanding inhaled corticosteroid nonadherence—a retrospective analysis of a real-world data set. Journal of	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				Allergy and Clinical Immunology: Global. 2023 Feb 1;2(1):51-60. Ellis AK, Foran V, Kaplan A, Mitchell PD. Clarifying SABA overuse: Translating Canadian Thoracic Society guidelines into clinical practice. Allergy Asthma Clin Immunol 18, 48 (2022). Foot H, Beyene K, Horne R, Fingleton J, Harrison J, Chan AH. Evaluating the Feasibility of a Community Pharmacy-Delivered Behaviour Change Intervention to Reduce Reliever Reliance in Asthma. Patient preference and adherence. 2024 Dec 31:361-71. Foster J, Beasley R, Braithwaite I, Harrison T, Holliday M, Pavord I, Reddel H. Perspectives of mild asthma patients on maintenance versus as-needed preventer treatment regimens: a qualitative study. BMJ open. 2022 Jan 1;12(1):e048537. Foster JM, Beasley R, Braithwaite I, Harrison T, Holliday M, Pavord I, Reddel HK. Patient experiences of as-needed budesonide-formoterol by Turbuhaler® for treatment of mild	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				asthma; a qualitative study. Respiratory Medicine. 2020 Dec 1;175:106154. Holst SS, Sabedin E, Sabedin E, Vermehren C. A shift in asthma treatment according to new guidelines: an evaluation of asthma patients' attitudes towards treatment change. International Journal of Environmental Research and Public Health. 2023 Feb 16;20(4):3453. Horne R, Chan A, Haughney J, De Sousa JC, Williams S, Kaplan A. Late Breaking Abstract-Identifying and addressing patient beliefs driving SABA use and over-reliance. IPCRG. Website access in July 2024. https://www.ipcrg.org/asthmarightcare/asthma-right-care-key-resources Levy ML, Andrews R, Buckingham R, Evans H, Francis C, Houston R, Lowe D, Nasser S, Paton JY, Puri N, Stewart K. Why asthma still kills: the National Review of Asthma Deaths (NRAD). Nwaru BI, Ekström M, Hasvold P, Wiklund F, Telg G, Janson C. Overuse of short-acting β2-	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				agonists in asthma is associated with increased risk of exacerbation and mortality: a nationwide cohort study of the global SABINA programme. European Respiratory Journal. 2020 Apr 1;55(4). Williams S, Correia de Sousa J, Khoo EM, Ghedira H, Mak V, Martínez Vázquez M, Vicente C, Attar-Zadeh D. How to make Asthma Right Care 'easy'in primary care: learnings from the 2023 Asthma Right Care Summit. NPJ Primary Care Respiratory Medicine. 2024 Apr 26;34(1):4.	
University Hospitals of Leicester NHS Trust	Guideline	005	007	Recs 1.1.5 and 1.1.6 – In all, but particularly those patients that require immediate treatment due to being acutely unwell at presentation, we felt that performing objective tests such as spirometry both at baseline and in response to treatment (e.g. after at least 4 weeks of ICS) could provide supportive evidence for asthma diagnosis, especially as starting inhaled steroids could impact on the results of future bronchodilator reversibility (BDR) or bronchial challenge testing.	Thank you for your comment. These recommendations are from the previous iteration of the guideline and are not part of this review. However, the committee agree with you - measuring baseline lung function, if possible, during an acute presentation could provide useful information for diagnosis.
University Hospitals of	Guideline	005	022	Rec 1.2.1 – We were concerned about the recommendation that an asthma diagnosis could	Thank you for your comment.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Leicester NHS Trust				be made on the basis of clinical history and fractional exhaled nitric oxide (FeNO)/blood eosinophils for a number of reasons: • We felt that the guidelines should state that the gold standard for asthma diagnosis is the presence of typical symptoms with demonstration of variable airflow obstruction by spirometry or bronchial challenge testing. High levels of blood eosinophils or FeNO might be an indicator of, but not a substitute for, these test results in some patients. We agree that the presence of high blood eosinophils and/or high FeNO are consistent with a particular phenotype of asthma but can be elevated in other conditions (see below) which would mean therapy could be introduced and escalated on a presumed diagnosis of asthma without ever having identified the presence of variable airflow obstruction or airway hyper-responsiveness. Furthermore, irrespective of the FeNO and blood eosinophils, spirometry is always required when making a	The committee acknowledges the points you make. Neither FeNO nor eosinophil count is a perfect test for asthma, but nor is spirometry/BDR. If we may turn your argument round, if we recommended that every person with suspected asthma should have a FeNO test (or eosinophil count) AND measure BDR, what would you do with a person who has a history suggesting asthma, a positive FeNO test but no evidence of airways obstruction or reversibility? We cannot keep repeating investigations, and access to bronchial challenge testing is far too limited to be a practical option for most patients. The committee believes that its recommended diagnostic sequences are the best options given current resources.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				diagnosis of airways disease to quantify lung function. • There were concerns that using a 'laboratory defined normal range' for blood eosinophils as the basis of diagnosis could introduce variability between centres and that the guideline should advocate a universal threshold value for normal versus abnormal. • We felt that basing diagnosis on history and biomarkers alone could lead to small numbers of false positive diagnoses in patients with other conditions associated with high FeNO and blood eosinophils that might mimic asthma, such as post nasal drip or other upper airways conditions which could present with intermittent cough. In the context of further recommendations made later in the guideline (page 013, line 019, recommendation 1.7.7) it was of significant concern that a patient could end up on moderate dose inhaled corticosteroid-long-acting beta$_2$-agonist in combination (ICS-LABA), leukotriene receptor antagonist (LTRA) and long-acting muscarinic receptor antagonist (LAMA) without	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				demonstrating any objective evidence of airflow obstruction. We felt that this is particularly relevant with regards to the addition of LAMA, which has a limited rationale in the absence of airflow obstruction.	
University Hospitals of Leicester NHS Trust	Guideline	006	001	Question 1 – As acknowledged by the authors, we felt that the diagnostic algorithm as presented would lead to significantly higher rates of referral for bronchial hyperresponsiveness testing which would be challenging to implement, due to the lack of resources available for performing these tests (there are already significant wait times locally). We felt that in practice, this was likely to lead to delays in diagnosis which could be harmful for patients, so extra resource is required to make access to this widely available. Question 2 – Increasing the capacity of respiratory physiology (space, staff, training) to improve access to bronchial challenge testing is likely to have significant cost implications. National funding for respiratory physiology services should be provided to support this recommendation.	Thank you for highlighting this. An early draft of the local resource impact tools identifies there are resource implications in this area using estimates from committee respiratory experts. The template allows also users to enter their own estimates of the potential increase in referrals. The assumptions made will be tested during the consultation of the tools.
University Hospitals of	Guideline	008	022	Rec 1.5.3 – We felt that the language was confusing around the role of peak flow	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Leicester NHS Trust				monitoring for assessment of asthma control, particularly in the context of the further recommendation 1.14.1 (page 021, line 006) which states personalised action plans in asthma for adults may be based on symptoms and/or peak flows. We suggest amending recommendation 1.5.3 to make it clearer that while regular peak flow monitoring is not recommended, baseline and intermittent measurement at times of increased symptoms are very important for guiding patients using their asthma action plans, and for assessing the severity of acute exacerbations (+/- refer readers to section 1.14).	The committee agree with your point and have changed 1.5.3 to include reference to action plans. The point about a reference point for acute attacks is also valid but hasn't been added to the recommendation as management of acute asthma is not in the remit of this guideline.
University Hospitals of Leicester NHS Trust	Guideline	008	025	Rec 1.5.4 – We felt that the recommendation as currently stated had very limited practical utility (and was unlikely to be cost-effective) without clearly defined timelines, results ranges and specific recommended actions. We feel that the current evidence for monitoring of inflammatory biomarkers (FeNO and blood eosinophils) in mild asthma has demonstrated limited value and therefore the most appropriate use of resources would be for this type of monitoring to be performed and interpreted in the specialist care setting for patients with	Thank you for your comment. The committee agree that FeNO is particularly useful in a severe asthma setting, but our analysis showed it to be cost-effective based on studies of adults with non-severe asthma.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				asthma that is more challenging to manage (as per previous guidelines). We felt therefore, that this recommendation should be removed or further qualified.	
University Hospitals of Leicester NHS Trust	Guideline	008	025	Rec 1.5.4 – We felt that if FeNO monitoring at asthma reviews is recommended, a specific comment could be added that high FeNO (>45ppb) in people using ICS is a strong predictor of non-adherence.	Thank you for your comment. The recommendation considers only the action to be undertaken i.e. monitor FeNO. That a high level might indicate non-adherence is covered in the rationale section, and a sentence to this effect has been added to section 1.6
University Hospitals of Leicester NHS Trust	Guideline	009	016	Rec 1.6.1 Please consider changing the terminology 'lack of adherence' to 'sub-optimal medicine adherence', as some people overuse inhalers (particularly short-acting beta$_2$-agonists (SABAs)). Lack of adherence suggests that underuse is the only problem.	Thank you for your comment. This has been changed.
University Hospitals of Leicester NHS Trust	Guideline	009	016	Rec 1.6.1 – Whilst we acknowledge the importance of keeping the guideline concise we felt that providing just one example within 'alternative or additional diagnoses' was potentially misleading as identifying that particular comorbidity as a priority, therefore we suggest to either include a more comprehensive list or remove the example. Based on the	Thank you for your comment. Several stakeholders have suggested additions which might be made to this bullet point, and on reflection the committee have agreed that no examples are necessary, the meaning of the recommendation being clear without them.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				experience of the team it was felt that co-existent nasal disease and gastro-oesophageal reflux in particular are common, as are breathing pattern disorder and inducible laryngeal obstruction. These warrant specific mention, as there is limited awareness of the importance of optimising treatment of these. It would also be helpful to include (or a link to) a list of other causes of airflow obstruction.	
University Hospitals of Leicester NHS Trust	Guideline	011	015	Rec 1.6.7 – Although we agree that using one type of device to deliver preventer and reliever treatments is the best approach, this is not always possible due to device availability (e.g. no reliever device available to match preventer) and may not be preferred by the patient. Please amend to where possible.	Thank you for your comment. The words "if possible" have been added.
University Hospitals of Leicester NHS Trust	Guideline Algorithm (treatment)	012	001	Rec 1.7.2 – We are fully supportive of the guidelines recommending anti-inflammatory reliever (AIR) or low dose maintenance and reliever therapy (MART) as initial therapy but in the context of this significant change, we had a number of concerns: • We felt that the guidance about which step to start a patient on requires amendment. The guideline currently suggests that AIR be the initial choice	Thank you for your comment The committee does not agree with your suggestions for using MART rather than AIR in people with symptoms twice a month or nocturnal symptoms once a month. These are not particularly high symptom burdens. Additionally, if people have a history of moderate/severe exacerbations then this is not

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				unless the patient presents with an acute exacerbation when MART should be used. This recommendation excludes a proportion of patients where regular treatment is indicated. We recommend that MART is used in people with symptoms more than twice a month, any history of nocturnal waking in the previous month, any history of moderate/severe exacerbation, or evidence of airflow obstruction post beta-agonist. • These regimens are not suitable for all people with asthma. In real world studies, such as the AstraZeneca sponsored SENTINEL project specifically designed to transfer people to MART regimens, only 44.7% transitioned to MART (Crooks MG, Crowther L, Cummings H, et al. Improving asthma care through implementation of the SENTINEL programme: findings from the pilot site. ERJ Open Res 2023; 9: 00685-2022 [DOI: 10.1183/23120541.00685-2022]). Clearly there are a significant number of patients not suitable for MART	their first presentation with asthma. Also please note that the indications for using MART rather than AIR in 1.7.2 is not just presentation with an acute exacerbation, but includes a high level of symptoms (this has to be an individual judgement – there is inadequate evidence to set a specific threshold) The committee believes that the evidence in adults strongly favours the AIR then MART strategy over the traditional treatment pathway and have therefore recommended this. The remit of NICE is to offer guidance on the most cost-effective management strategy and therefore this is also the same for this BTS/NICE/SIGN guidance

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				(e.g. patient preference, unable to understand the regimen, unable to self monitor etc). Consequently this guideline should also provide recommendations on fixed dose regimens. Single-inhaler as needed low-dose ICS/formoterol or MART regimens must be supported with the provision of an appropriate asthma action plan to enable self-management. Unfortunately, the availability of these in languages other than English are limited, so may not be appropriate for non-English speakers. As of July 2024, Asthma+Lung UK have these available in only 9 languages (English, Arabic, Bengali, Chinese, Welsh, Gujarati, Polish, Punjabi, Urdu) https://www.asthmaandlung.org.uk/symptoms-tests-treatments/treatments/mart/download#download ; https://shop.asthmaandlung.org.uk/collections/air-action-plans	
University Hospitals of Leicester NHS Trust	Guideline	013	019	Rec 1.7.7 – We agree with the recommendation that referral to a specialist should be made in patients uncontrolled on moderate dose ICS-LABA but would advocate that referral should	Thank you for your comment

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				not be delayed pending trials of LTRA and LAMA, and would suggest limiting measurement of inflammatory biomarkers to this patient group (rather than FeNO measurement being recommended generically). Trials of LTRA and LAMA may be of limited benefit without more detailed specialist assessment, depending on the objective evidence on which diagnosis was based.	Although the guideline says that referral should be made at this point there is nothing to stop an earlier referral if it is agreed that this might be beneficial. In addition recommendations 1.7.6 and 1.7.7 have been amended in response to the concerns of yourself and other stakeholders and the possibility of an earlier referral is now included, and this is based on measurement of FeNO and eosinophils. There is evidence, described in the guideline and associated evidence review (review N), that regular FeNO monitoring is useful, particularly in adults.
University Hospitals of Leicester NHS Trust	Guideline	014	004	Rec 1.7.8 – We felt that the language recommending a switch from SABA alone to ICS-LABA as needed should be stronger, making it clearer that this is the preferred/safest action to take when transitioning patients from previous pathways.	Thank you for your comment The word "consider" in NICE guidelines is used when evidence is lacking which is the situation here. However, in this instance the developers agree that there is a major safety issue and the wording has been changed.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
University Hospitals of Leicester NHS Trust	Guideline	022	005	Rec 1.14.4 – We felt that the recommendation to quadruple the dose of regular ICS was based on limited evidence and was redundant in the context of MART.	Thank you for your comment A majority of people with asthma will continue to be treated along "conventional" lines for some time and 1.14.4. remains relevant for them.
University Hospitals of Leicester NHS Trust	Guideline	023	002	Rec 1.15.1 – Lung function testing is an important component of risk stratification for poorer outcomes as a low baseline forced expiratory volume in 1 second (FEV_1) indicates an increased risk of developing persistent air flow obstruction and low FEV_1 increases the risk of exacerbations. We recommend that measurement of baseline spirometry to quantify lung function is advocated in all asthma patients and an FEV_1 criteria be included as a risk factor in this specific recommendation.	Thank you for your comment. Risk stratification in 1.15.1 is for the purpose of identifying people whose care needs to be managed differently by practice staff. The items already listed predict poor control, and it is not clear that a low FEV1 would further enhance the prediction of exacerbations. The committee accepts that it would predict persistent airflow obstruction, but that it is not the point of this recommendation.
University Hospitals of Leicester NHS Trust	Guideline	026	003	Recommendations for research – Whilst SABA overuse is clearly defined and well understood to be harmful, we feel similar evidence for AIR/MART overuse is lacking, and it is extremely challenging to characterise the use of these, especially as they may not yet have codes in some primary care IT systems.	Thank you for your comment This is a reasonable question to ask, but only a limited number of research recommendations can be made.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				Highlighting this on a national agenda would prioritise evaluation of the impact of overuse of these therapies on real-world patients.	
University Hospitals of Leicester NHS Trust	Guideline	060	Monitoring asthma control	Decline in lung function in patients with asthma may indicate specific disease mechanisms or alternative/additional diagnoses. We felt that, whilst there may be no evidence for routine monitoring of spirometry, measuring baseline and repeating spirometry at specific points in the disease trajectory, e.g. at the point of loss of disease control or at the point of referral, was important for characterising disease and excluding important differential diagnoses.	Thank you for your comment The committee has sympathy with this point. However, there is no evidence for this, and practically speaking someone who is referred for specialist assessment will have a spirometry measurement.
University Hospitals of Leicester NHS Trust	Guideline	071	Asthma in pregnancy	We felt that the specific recommendation to encourage breastfeeding in women with asthma was extremely useful, based on the experience of the team who find that this is a common concern for patients post-partum. Lack of specific guidance may impact on their decision making and we felt that this recommendation should not be deleted for the current guideline.	Thank you for your comment. This previous recommendation has been deleted because breastfeeding is encouraged generally, not just for people with asthma.
University Hospitals of Leicester NHS Trust	Guideline	081	Asthma in pregnancy	Based on the experience of the team, we felt that the inclusion of the specific statement, 'steroid tablets should never be withheld because of pregnancy' was a useful statement both for healthcare professionals and patients.	Thank you for your comment This is covered by recommendation 1.12.4.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
University of Edinburgh	Guideline	5	7	1.1.5. The language in this recommendation - 'acutely unwell at presentation' is too subjective and open to varied interpretation. Children and young people with asthma often present to primary care with symptoms that represent poorly controlled asthma (night time cough, recurrent daytime wheeze responsive to short acting beta 2 agonist etc), but they and their parents do not consider themselves 'acutely unwell'. I suspect many clinicians also would not consider them acutely unwell. Yet this profile of patient is at high risk of severe asthma attack and at higher risk of asthma death if left untreated. The guideline then strongly infers (1.1.7) that preventative treatment should not be provided (other than I suspect SABA) until a test is performed and confirmatory, as spirometry and FeNO tests may be affected by people who have been treated with inhaled corticosteroids (NICE 2017). In my practice I have already had children presenting to my critical care asthma clinic (a review of all CYP that require critical care with asthma) who have had a clear clinical history of asthma at the point of referral for testing, but have not commenced asthma	Thank you for your comment This is a legacy recommendation which was not part of this update, and comment on it was not invited. However, the developers wish to acknowledge the concerns you express. 1.5.1 is there so that clinicians know that treatment can be started in advance of diagnostic testing if symptoms suggest this is warranted. However, there are a lot of people (all ages) who present with less compelling symptoms and in those it is preferable to wait for testing. Treatment will interfere with test results and asking people to stop treatment 2 weeks before testing will lead to errors e.g. some people will forget to stop leading to wasted visits, repeat appointments etc. "Acutely unwell" may be open to misinterpretation, but what phrase would not be?

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				preventative therapies as the referral was in place to confirm a diagnosis of asthma. The guideline does not risk assess the impact, particularly on children and young people, of a delay to diagnosis and commencing treatment for asthma (other than SABA), particularly where capacity is a problem in providing diagnostic tests (p34, line 25), and in relation to those whose parents poorly access healthcare for their children (marginalised populations, lower socioeconomic status etc). The benefit from the guideline appears to be for those who do not have asthma who are prevented from potential adverse effects of medication that is not appropriate and as currently proposed this outweighs the potential harms of lack of treatment during diagnostic delays which are most weighted to those we understand are most at risk of severe asthma outcomes. It should be possible to provide a better safety net to those at risk, by recommending (until further research to underpin proposals) that those with active symptoms consistent with a clinical diagnosis of asthma are provided with appropriate preventative therapy. It could be proposed that in those not acutely unwell	

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				preventative treatments are stopped two weeks prior to a diagnostic procedure (i.e. as with proton pump inhibitors and upper GI endoscopy, or antihistamines for skin prick testing)	
University of Stirling	Guideline	019	1-18 Part 1.11 Adherence	Consider the option of adherence technologies. While evidence it still not on a level that we would like it to be, there is indication that it is a helpful tool for some patients. Here are some papers: Van de Hei et al. (2023) (https://www.sciencedirect.com/science/article/pii/S221321982300716X "In patients with difficult-to-treat asthma, digital inhaler–based interventions can be cost-saving in the long-term by optimizing medication adherence and inhaler technique and reducing add-on biologic prescriptions" Milne-Ives et al (2021). https://pediatrics.jmir.org/2021/3/e27999 "Most studies found significant evidence for improved adherence to treatment or medications, but there was mixed evidence of the impact of the digital interventions on asthma control and other health outcomes. There are	Thank you for your comment and for the references. The section on adherence was not reviewed for this update of the guideline. This will be useful information if adherence is included in future updates.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Stakeholder	Document	Page No	Line No	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				gaps in the literature relating to cost-effectiveness and integration with existing clinical care pathways. This study will be necessary to determine which digital interventions for children and young people with asthma are worth supporting and adopting in the clinical care pathways" This is different to the idea of smart inhalers or digital inhalers, there is a wide variety of self-management technologies available that can be used for free.	
University of Stirling	Guideline	021	1-14 Part 1.14 Self-management	Consider suggesting different levels of supported self-management, especially for children and young people. Evidence Hodkinson et al (2020) https://www.bmj.com/content/370/bmj.m252 suggests that what they operationalised as "regularly supported self-management" (more than 2 hours of support) is particularly helpful for "… patients with mild to moderate symptoms of asthma". While "Multidisciplinary case	Thank you for your comment These are interesting points. However, this section was not subject to an evidence review for this update and the detail you suggest cannot be added without a formal review.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				management interventions" was better for patients with severe asthma.	
Wrightington Wigan and Leigh NHS FT	Guideline	005	022	Section 1.2.1 - Diagnosis of asthma – if the guideline says that based on asthma sounding history with high Eosinophil count or FeNO>50 is the basis to diagnose asthma then the number of patients diagnosed with asthma will go exponentially up and it is likely that a big percentage will not have asthma. My suggestion is that the guideline should also recommend that *with history and high FeNO/Eosinophil count, the patient should be given trial of inhaled corticosteroids using a device that patient can use properly. After 6 weeks FeNO or Eosinophil count should be repeated. If they have improved then a diagnosis of asthma could be made and if they are not improving, another diagnosis should be considered*	Thank you for your comment. The committee does not agree that the number of diagnoses will increase. At present many people get a diagnosis of asthma without any diagnostic tests.
Wrightington Wigan and Leigh NHS FT	Guideline	012	004	Section 1.7.1 – the recommended therapy is based on AIR (anti-inflammatory reliever) therapy. This AIR therapy is based on the paper O'Bryne et al NEJM 2018; 378:1865-76 (Sygma1 Trial). In the conclusion section of the abstract even the authors write '***In patients***	Thank you for your comment The recommendation is not based on the Sygma 1 trial alone.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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				with mild asthma, as-needed budesonide–formoterol provided superior asthma-symptom control to as-needed terbutaline, assessed according to electronically recorded weeks with well-controlled asthma, but was inferior to budesonide maintenance therapy'. Based on this it is odd that we are accepting the second-best therapy as our primary therapy. We should be recommending regular inhaled corticosteroid therapy as first choice treatment for asthma. This is especially important is the fact early inhaled steroid therapy increases lung function as compared to placebo e.g. Pauwels et al Lancet. 2003 Mar 29;361(9363):1071-6. There is evidence that giving regular ICS therapy early in asthma improves lung function and outcomes (N Engl J Med. 1991 Aug 8;325(6):388-92.)	In Sygma 1 asthma control, as judged by the number of weeks showing good control based on diary records, was better with regular budesonide, but exacerbation rate was not. Even if one considers control as the only parameter, there will be some people in any group of newly diagnosed asthmatics who will do very well on AIR and others who will turn out to need regular maintenance therapy. When grouped together this inevitably leads to the mean improvement being better in the regular maintenance group. If there had been a third randomised group in Sygma 1 who were treated with higher dose maintenance budesonide, a LABA, a LAMA and an LTRA, they would almost certainly show better mean control than the budesonide only group, but no one would advocate starting all newly diagnosed asthmatics on all these agents most of which would be unnecessary in the vast majority of people. The committee believe that starting on AIR and escalating treatment only in those requiring it is the optimal strategy.

Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
18/06/2024 – 30/07/2024

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Asthma: diagnosis, monitoring and chronic asthma management

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18/06/2024 – 30/07/2024

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Asthma: diagnosis, monitoring and chronic asthma management

Consultation on draft guideline - Stakeholder comments table
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