Chronic asthma: management

NICE guideline: short version

Draft for consultation, December 2016

This guideline covers managing chronic asthma in adults, young people and children. It aims to improve asthma control and reduce the risk of asthma attacks. It gives advice on the sequence and combinations of medicines that should be offered for asthma that is not well controlled, and on decreasing maintenance treatment for asthma that is well controlled. It does not cover managing severe asthma or acute asthma attacks.

Who is it for?

- GPs, practice nurses and pharmacists
- Healthcare professionals in secondary care and tertiary asthma services
- People with asthma, their families and carers

This version of the guideline contains the draft recommendations, context and recommendations for research. Information about how the guideline was developed is on the guideline's page on the NICE website. This includes the guideline committee's discussion and the evidence reviews (in the full guideline), the scope, and details of the committee and any declarations of interest.

Contents

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in your care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

1.1 Principles of pharmacological treatment

1.1.1 Take into account the possible reasons for uncontrolled asthma, before adjusting maintenance treatment in adults, young people and children. These may include:

- alternative diagnoses
- lack of adherence
- inappropriate inhaler technique
- smoking (active or passive)
- occupational exposures
- psychosocial factors
- seasonal or environmental factors.

1.1.2 After adjusting maintenance treatment in adults, young people and children, review the response to treatment changes in 4 to 8 weeks (NICE is developing a guideline on asthma diagnosis and monitoring, which will include advice on monitoring asthma control).

1.1.3 Offer regular daily, rather than intermittent or when required, inhaled corticosteroids (ICS) to adults, young people and children with asthma who need ICS maintenance treatment.

1.2 Pharmacological treatment pathway for adults (over 16)

1.2.1 Offer a short-acting beta$_2$ agonist (SABA) as reliever therapy to adults (over 16) with newly diagnosed asthma. This should be used for symptom relief alongside all maintenance therapy except maintenance and reliever therapy (MART) regimens.

1.2.2 Offer a low dose of an ICS as the first-line maintenance therapy to adults (over 16) with asthma that is uncontrolled with a SABA alone.

1.2.3 If asthma is uncontrolled in adults on a low dose of ICS as maintenance therapy, offer a leukotriene receptor antagonist (LTRA) in addition to the ICS.

1.2.4 If asthma is uncontrolled in adults on a low dose of ICS and an LTRA as maintenance therapy, offer a long-acting beta$_2$ agonist (LABA) in combination with the ICS, and review LTRA treatment as follows:

- discuss with the person whether or not to continue LTRA treatment
- take into account the degree of response to LTRA treatment (NICE is developing a guideline on asthma diagnosis and monitoring, which will include advice on monitoring asthma control).

1.2.5 If asthma is uncontrolled in adults on a low dose of ICS and a LABA, with or without an LTRA, as maintenance therapy, offer to change the person's ICS and LABA maintenance therapy to a MART regimen[1] with a low maintenance ICS dose.

1.2.6 If asthma is uncontrolled in adults on a MART regimen with a low maintenance ICS dose, with or without an LTRA, consider increasing the ICS to a moderate maintenance dose. The person can continue on a

[1] At the time of publication (December 2016), maintenance and reliever therapy (MART) regimens did not have a UK marketing authorisation for use in children and young people (aged under 18). The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

MART regimen or change to a fixed-dose of an ICS and a LABA, with a SABA as a reliever therapy.

1.2.7 If asthma is uncontrolled in adults on a moderate maintenance ICS dose with LABA, either as MART or a fixed-dose regimen, and with or without an LTRA, consider increasing the ICS to a high maintenance dose. This should only be offered as part of a fixed-dose regimen, with a SABA used as a reliever therapy.

1.3 Pharmacological treatment pathway for children and young people aged 5 to 16

1.3.1 Offer a SABA as reliever therapy to children and young people aged 5 to 16 with newly diagnosed asthma. This should be used for symptom relief alongside all maintenance therapy except MART regimens.

1.3.2 Offer a paediatric low dose of an ICS as the first-line maintenance therapy to children and young people (aged 5 to 16) with asthma that is uncontrolled with a SABA alone.

1.3.3 If asthma is uncontrolled in children and young people (aged 5 to 16) on a paediatric low dose of ICS as maintenance therapy, consider an LTRA[2] in addition to the ICS.

1.3.4 If asthma is uncontrolled in children and young people (aged 5 to 16) on a paediatric low dose of ICS and an LTRA as maintenance therapy, stop the LTRA and consider a LABA[3] in combination with ICS.

1.3.5 If asthma is uncontrolled in children and young people (aged 5 to 16) on a paediatric low dose of ICS and a LABA as maintenance therapy, consider changing their ICS and LABA maintenance therapy to a MART regimen[4] with a paediatric low maintenance ICS dose.

[2] At the time of publication (December 2016), not all leukotriene receptor antagonists (LTRAs) have a UK marketing authorisation for use in children and young people aged under 18 for this indication.
[3] At the time of publication (December 2016), not all long-acting beta$_2$ agonists (LABAs) have a UK marketing authorisation for use in children and young people aged under 18 for this indication.
[4] At the time of publication (December 2016), maintenance and reliever therapy regimens did not have a UK marketing authorisation for use in children and young people (aged under 18) for this

1.3.6 If asthma is uncontrolled in children and young people (aged 5 to 16) on a MART regimen[4] with a paediatric low maintenance ICS dose, consider increasing the ICS to a paediatric moderate maintenance dose. The child or young person can continue on a MART regimen or change to a fixed-dose of an ICS and a LABA, with a SABA as a reliever therapy.

1.3.7 If asthma is uncontrolled in children and young people (aged 5 to 16) on a paediatric moderate maintenance ICS dose with LABA, either as MART[4] or a fixed-dose regimen, consider increasing the ICS dose to paediatric high maintenance dose. This should only be offered as part of a fixed-dose regimen, with a SABA used as a reliever therapy.

1.4 Pharmacological treatment pathway for children under 5

1.4.1 Offer a SABA as reliever therapy to children under 5 with suspected asthma. This should be used for symptom relief alongside all maintenance therapy.

1.4.2 In children under 5 with suspected asthma that is uncontrolled with a SABA alone, consider an 8-week trial of a paediatric moderate dose of an ICS.

1.4.3 After 8 weeks, stop ICS treatment and continue to monitor the child's symptoms:

- if symptoms did not resolve during the trial period, review whether an alternative diagnosis is likely
- if symptoms resolved then reoccurred within 4 weeks of stopping ICS treatment, restart the ICS at a paediatric low dose as first-line maintenance therapy
- if symptoms resolved but reoccurred beyond 4 weeks after stopping ICS treatment, repeat the 8-week trial of a paediatric moderate dose of ICS

indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

- confirm asthma diagnosis once the child is old enough (NICE is developing a guideline on asthma diagnosis and monitoring, which will include advice on diagnosing asthma in children).

1.4.4 If suspected asthma is uncontrolled in children under 5 on a paediatric low dose of ICS as maintenance therapy, consider an LTRA[5] in addition to the ICS.

1.4.5 If suspected asthma is uncontrolled in children under 5 on a paediatric low dose of ICS and an LTRA as maintenance therapy, stop the LTRA and refer the child to a clinician with expertise in asthma for further investigation and management.

1.5 Adherence

1.5.1 For guidance on managing non-adherence to medicines in people with asthma, see the NICE guideline on medicines adherence.

1.6 Self-management

1.6.1 Offer an asthma self-management package, comprising a written personalised action plan with supportive education, to adults, young people and children aged 5 and over with a diagnosis of asthma (and their families or carers if appropriate).

1.6.2 Consider an asthma self-management package, comprising a written personalised action plan with supportive education, for the families or carers of children under 5 with suspected or confirmed asthma.

1.7 Increasing ICS treatment within a self-management package

1.7.1 Within a self-management package, offer an increased dose of ICS for 7 days to adults over 16 who are using an ICS in a single inhaler, for when asthma control deteriorates. Details of how and when to do this

[5] At the time of publication (December 2016), not all leukotriene receptor antagonists (LTRAs) have a UK marketing authorisation for use in children and young people aged under 18 for this indication.

should be clearly outlined in the personal asthma action plan. When increasing the ICS dose:

- consider quadrupling the regular ICS dose
- do not exceed the maximum licensed daily dose.

1.7.2 Within a self-management package, consider an increased dose of ICS for 7 days for children and young people (aged 5 to 16) who are using an ICS in a single inhaler, for when asthma control deteriorates. Details of how and when to do this should be clearly outlined in the personal asthma action plan. When increasing the ICS dose:

- consider quadrupling the regular ICS dose
- do not exceed the maximum licensed daily dose.

1.8 Decreasing maintenance treatment

1.8.1 Consider decreasing maintenance treatment when a person's asthma has been controlled with their current maintenance therapy for at least 3 months.

1.8.2 Discuss with the person, or their family or carer if appropriate, the potential risks and benefits of decreasing maintenance treatment.

1.8.3 Agree with the person, or their family or carer if appropriate, an active review process for monitoring the effects of decreasing maintenance treatment, including self-monitoring and a follow-up with a healthcare professional.

1.8.4 Review and update the person's asthma action plan when decreasing maintenance treatment.

1.9 Risk stratification

1.9.1 Consider using risk stratification to identify people with asthma who are at increased risk of poor outcomes, and use this information to optimise their care.

Terms used in this guideline

ICS dose

ICS doses and their pharmacological strengths vary from formulation to formulation. In general, adults, young people and children with asthma should be using the smallest doses of ICS that provide optimal control for their asthma, in order to reduce the risk of side effects.

The full guideline contains the tables used to categorise the evidence base into low, moderate and high doses. These ranges are not intended to be sharp cut-offs for clinical practice. For adults over 16, less than or equal to 400 micrograms budesonide or equivalent would be considered a low dose, more than 400 to 800 micrograms budesonide or equivalent would be considered a moderate dose and more than 800 micrograms budesonide or equivalent would be considered a high dose. For children aged 16 and under, less than or equal to 200 micrograms budesonide or equivalent would be considered a paediatric low dose, more than 200 to 400 micrograms budesonide or equivalent would be considered a paediatric moderate dose and more than 400 micrograms budesonide or equivalent would be considered a paediatric high dose.

MART

Maintenance and reliever therapy (MART) is a form of combined ICS and LABA treatment in which a single inhaler, containing both ICS and a fast acting LABA, is used for both the daily maintenance therapy and the relief of symptoms as required. MART is only available for ICS and LABA combinations in which the LABA has a fast-acting component (for example, formoterol).

Risk stratification

Risk stratification is a process of categorising a population by their relative likelihood of experiencing certain outcomes. In the context of this guideline, risk stratification involves categorising people with asthma by their relative likelihood of experiencing negative clinical outcomes (for example, severe exacerbations or hospitalisations). Once the population is stratified, the delivery of care for the population can be targeted with the aim of improving the care of the strata with the highest risk.

Suspected asthma

Suspected asthma describes a potential diagnosis of asthma based on symptoms and response to treatment that has not yet been confirmed with objective tests.

Uncontrolled asthma

Uncontrolled asthma describes a situation when asthma is having an impact on a person's lifestyle or is restricting their normal activities. Symptoms such as coughing, wheezing, shortness of breath and chest tightness associated with uncontrolled asthma can significantly decrease a person's quality of life and may lead to a medical emergency. This can be quantified by a number of questionnaires.

This guideline uses the following thresholds to define uncontrolled asthma:

- 3 or more days a week with symptoms **or**
- 3 or more days a week with required use of a SABA **or**
- 1 or more nights a week with awakening due to asthma.

Context

Asthma is the most commonly diagnosed long-term medical condition in the UK, affecting over 5 million people, of whom over 1 million are children (Asthma UK). The underlying pathology varies, but in general there is chronic inflammation of the lining of the airways that releases inflammatory mediators which trigger the smooth muscle of the airway to contract and narrow the air passages. The narrowing results in symptoms such as wheeze, cough, chest tightness and breathlessness. These symptoms can be measured by lung function tests that show evidence of airway obstruction and airway inflammation. A key feature of asthma is that the airway obstruction is reversible with medical treatment that relaxes the airway smooth muscle.

Most people with asthma have an episodic illness with periods of reasonable health interspersed with periods of increased symptoms that occasionally progresses to an asthma attack. The increase in symptoms or asthma attack is usually caused by exposure to a trigger that the person is sensitive to. Triggers may be viral infections, environmental tobacco smoke, aeroallergens or exercise. The cause of asthma is

unclear, but a combination of genetic and environmental factors is thought to make a person more susceptible to triggers that lead to airway narrowing.

The severity of asthma varies; some people have severe asthma that limits normal activities, whereas others are able to lead a relatively normal life. The illness fluctuates during the year and over time, so the level of treatment needs to be tailored to the person's current level of asthma severity. Many people with asthma, particularly children, seem to have fewer symptoms over time, and an important part of their management is the ‘step down’ of treatment if asthma is well controlled.

There is no cure for asthma, so management of the condition focuses on reducing exposure to known triggers if possible, relief of symptoms if there is airway narrowing, and reduction in airway inflammation by regular preventive treatment. Adherence to regular treatment reduces the risk of significant asthma attacks in most people with asthma. The focus of asthma management in recent years has been on developing guidelines that allow people with asthma and their healthcare professional to devise a personalised treatment plan that is effective and relatively easy to implement.

The aim of this guideline is to provide clear guidance for healthcare professionals and people with asthma to develop a personalised action plan. The plan should support self-management of asthma that is mild to moderate in severity, and ensure that the person is receiving the optimal treatment for their current level of illness.

The guideline covers children under 5, children and young people aged 5–16 and adults over 16 with suspected or diagnosed asthma. It focuses on the pharmacological management of chronic asthma, in particular the treatment pathway for people with uncontrolled asthma. It also covers adherence to treatment, risk stratification and self-management. The guideline does not cover the management of acute asthma attacks.

More information

To find out what NICE has said on topics related to this guideline, see our web page on asthma.

Recommendations for research

The guideline committee has made the following recommendations for research. The committee's full set of research recommendations is detailed in the full guideline.

1 Starting asthma treatment

In children, young people and adults with asthma who have not been treated previously, is it more clinically and cost effective to start treatment with a reliever alone (SABA) or with a reliever (SABA) and maintenance therapy (such as ICS)? Are there specific prognostic features which indicate that one of these treatment options may be more appropriate for some groups?

Why this is important

Current best practice is to start treatment with a SABA taken when needed, before offering daily maintenance therapy. This guideline did not find any evidence to support a deviation from this practice. However it has been suggested that some people with asthma may benefit from immediately starting low dose ICS on a daily basis alongside the SABA upon diagnosis.

2 Second-line maintenance therapy in children and young people (under 16)

Is ICS low dose plus LTRA or ICS low dose plus LABA more effective in the treatment of asthma in children and young people (under 16) who are uncontrolled on ICS low dose alone?

Why this is important

Throughout this guideline there is a relative paucity of evidence in children and young people under 16. Many of the recommendations in this guideline for that age group are made on the basis of extrapolations from the adult evidence and the consensus of the guideline committee. The guideline committee would like to encourage more research in this age group throughout this guideline, but have prioritised this particular question as it occurs relatively early on in the treatment pathway and could potentially have significant clinical and cost implications for the management of asthma in this age group.

3 Addition of maintenance therapy beyond ICS high dose plus LABA

What is the clinical and cost effectiveness of offering additional maintenance therapy to adults, young people and children with asthma that is uncontrolled on ICS high dose plus LABA?

Why this is important

There is insufficient quantity and quality of evidence to support recommendations to use any additional maintenance therapy beyond high dose ICS plus LABA. The clinical evidence tends to favour the addition of long-acting muscarinic antagonists (LAMAs) but the guideline committee did not consider this to be conclusive, particularly as compared to placebo the addition of LAMAs is not cost effective. The real world alternative to adding a LAMA is a course of oral steroids and therefore to truly understand the cost effectiveness of LAMAs, an RCT and health economic analysis taking into account the impact of LAMAs on oral steroid use is needed. The guideline committee felt the body of evidence, supported by consensus agreement, was sufficient to recommend the use of ICS high dose plus LABA, as it is current practice. However, a study that compared this strategy with the addition of LAMAs or theophyllines would be informative for the treatment pathway.

4 Decreasing pharmacological treatment

In people with stable asthma, what are the objective measurements and prognostic factors that indicate that a decrease in regular maintenance treatment is appropriate?

Why this is important

There is consensus within the guideline committee and across healthcare professionals managing asthma that people with well-controlled asthma should not be left on high doses or multiple preventer medicines for long periods of time. However, there is little evidence available to guide healthcare professionals to identify which people might benefit most from decreasing regular maintenance treatment. This guideline identified 3 studies attempting to answer this question but none of them included a sufficiently large population, with suitable decrease in treatment throughout and assessment of multiple prognostic markers.

5 Improving adherence to asthma medication

What are the most clinically and cost-effective strategies to improve medicines adherence in children, young people and adults with asthma who are non-adherent to prescribed medicines?

Why this is important

There is a consensus within the guideline committee and healthcare professionals that medication adherence is an important determinant of a patient's asthma control, and that non-adherence is a common problem. This is married with a paucity of high-quality evidence on methods to improve asthma medication adherence. The guideline identified a number of studies focusing on this question, however there was not a strong body of evidence behind any specific intervention strategy. Further, the guideline committee had concerns about the applicability of studies that did not report outcomes after a prolonged follow-up and studies that only used self-reported measures to assess adherence. The guideline committee felt further and higher quality research was required to recommend specific interventions for this common and significant problem.

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