NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Review of TA131; Corticosteroids for the treatment of chronic asthma in children under the age of 12 years, and TA138; Corticosteroids for the treatment of chronic asthma in adults and children aged 12 years and over

TA131 was issued in November 2007 and TA138 was issued in March 2008.

The review date for this guidance is November 2012.

1. Recommendation

The guidance should be transferred to the 'static guidance list'.

That we consult on this proposal.

2. Original remit(s)

TA131: To appraise the relative clinical and cost effectiveness of all licensed corticosteroids, including compound preparations, in the treatment of chronic asthma; and if the evidence allows, to advise on the groups of patients who are most likely to benefit from any particular corticosteroid.

TA138: To appraise the relative clinical and cost effectiveness of all licensed corticosteroids, including compound preparations, in the treatment of chronic asthma; and if the evidence allows, to advise on the groups of patients who are most likely to benefit from any particular corticosteroid.

3. Current guidance

TA131

The future discontinuation of CFC-containing inhaler devices will affect the range of devices available but does not affect the guidance.

1.1 For children under the age of 12 years with chronic asthma in whom treatment with an inhaled corticosteroid (ICS) is considered appropriate, the least costly product that is suitable for an individual child (taking into consideration technology appraisal guidance 38 and 10), within its marketing authorisation, is recommended.

1.2 For children under the age of 12 years with chronic asthma in whom treatment with an ICS and long-acting beta-2 agonist (LABA) is considered appropriate, the following apply.

- The use of a combination device within its marketing authorisation is recommended as an option.

- The decision to use a combination device or the two agents in separate devices should be made on an individual basis, taking into consideration therapeutic need and the likelihood of treatment adherence.

- If a combination device is chosen then the least costly device that is suitable for the individual child is recommended.

TA138

The future discontinuation of chlorofluorocarbon (CFC)-containing inhalers will affect the range of devices available, but does not affect this guidance.

1.1 For adults and children aged 12 years and older with chronic asthma in whom treatment with an inhaled corticosteroid (ICS) is considered appropriate, the least costly product that is suitable for an individual, within its marketing authorisation, is recommended.

1.2 For adults and children aged 12 years and older with chronic asthma in whom treatment with an ICS and long-acting beta-2 agonist (LABA) is considered appropriate, the following apply.

- The use of a combination device within its marketing authorisation is recommended as an option.

- The decision to use a combination device or the two agents in separate devices should be made on an individual basis, taking into consideration therapeutic need and the likelihood of treatment adherence.

- If a combination device is chosen then the least costly device that is suitable for the individual is recommended.

4. Rationale[1]

There is no new evidence to suggest that the recommendations of TA131 and TA138 should change nor any ongoing trials that might be expected lead to a change in the recommendations.

5. Implications for other guidance producing programmes

There is no proposed or ongoing guidance development that overlaps with this review proposal.

[1] A list of the options for consideration, and the consequences of each option is provided in Appendix 1 at the end of this paper

6. New evidence

The search strategy from the original assessment reports was re-run on the Cochrane Library, Medline, Medline In-Process and Embase. References from January, 2007 onwards were reviewed. Additional searches of clinical trials registries and other sources were also carried out. The results of the literature search are discussed in the 'Summary of evidence and implications for review' section below. See Appendix 2 for further details of ongoing and unpublished studies.

7. Summary of evidence and implications for review

No new evidence has been identified that would be likely to change the recommendations in the two pieces of guidance.

Current clinical guidelines

Current British guidelines for the management of asthma continue to recommend a stepwise approach to treatment in both adults and children (British Thoracic Society and Scottish Intercollegiate Guidelines Network, 2012). Inhaled corticosteroids are the recommended preventer drug for achieving treatment goals for adults and children (5–12 years) who need regular preventer therapy. In people whose asthma is not adequately controlled with inhaled corticosteroids, an inhaled long-acting beta-2 agonist is the first-choice add-on therapy for adults and children (5–12 years).

Marketing authorisations for included technologies

In the final scope for TA131, it was noted that ciclesonide could receive an extension to its marketing authorisation to include children under the age of 12 within the time frame for the appraisal, which is why it was included at that time. However, the current UK marketing authorisation for ciclesonide states that it is for the treatment of persistent asthma in adults and adolescents (12 years and older), and that there are currently insufficient data in children under 12 years. However, any review of the guidance would be unlikely to lead to a change in the guidance in this regard because the relevant recommendation in TA131 states that the inhaled corticosteroids should be used within their marketing authorisations.

New marketing authorisations

Two new combination products have received a relevant UK marketing authorisation since the two appraisals were conducted: beclometasone dipropionate/formoterol (Chiesi Limited) and fluticasone propionate/formoterol (Napp Pharmaceutical Group) are indicated in the regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta-2 agonist) is appropriate. The individual component drugs of these two combinations were appraised in the original pieces of guidance.

Choice of corticosteroid

Several studies have compared ciclesonide, a newer inhaled corticosteroid, with older agents. A Cochrane systematic review concluded that its results gave some support to ciclesonide as an equivalent therapy to other inhaled corticosteroids in patients whose asthma required treatment with low doses of steroids. It noted that the role of ciclesonide in the management of asthma required further study, especially in children (Manning et al. 2008).

Several studies have demonstrated equivalent efficacy between fluticasone and ciclesonide in people aged over 12 years with persistent asthma (Bateman et al. 2008; Boulet et al. 2007; FitzGerald et al. 2007; Magnussen et al. 2007). In people with well-controlled asthma, similar asthma control was maintained in people who underwent a step-down dose from fluticasone to lower-dose ciclesonide compared with people who continued to receive standardised fluticasone treatment (Knox et al. 2007).

Compared with fluticasone, ciclesonide showed significant improvements in oral candidiasis and health-related quality of life (Boulet et al. 2007), fewer local adverse events (Bateman et al. 2008), reduced effect on the hypothalamic–pituitary–adrenal axis function (FitzGerald et al. 2007) and no significant effect on lower-leg growth rate in children aged 6–12 years with mild asthma (Agertoft and Pedersen 2010). One study found that ciclesonide showed comparable tolerability to fluticasone in people aged 12 years and older with persistent asthma (Magnussen et al. 2007).

Compared with budesonide, one study in adolescents with severe asthma showed ciclesonide had similar efficacy, was well tolerated and, (unlike budesonide) had no effect on urine cortisol levels (Vermeulen et al. 2007). Another study showed ciclesonide was more effective than budesonide in improving several measure of lung function with similar safety and tolerability profiles (Ukena et al. 2007).

British Thoracic Society and Scottish Intercollegiate Guidelines Network guideline concluded that the evidence from clinical trials suggests that ciclesonide has less systemic activity and fewer local oropharyngeal side effects than conventional inhaled steroids. However, it adds that the clinical benefit of this is not clear because the exact efficacy-to-safety ratio compared with other inhaled corticosteroids has not been fully established.

Other comparisons between older agents have been conducted. A Cochrane systematic review that evaluated fluticasone versus beclometasone and budesonide in adults and children did not identify any major differences in efficacy or safety, and noted that the randomised trials included in the review did not provide sufficient data to address concerns about adrenal suppression in children with fluticasone at doses greater than 400 µg/day (Adams et al. 2007).

A study that compared beclometasone with fluticasone in children with moderate asthma found that symptoms and pulmonary function tests results were improved with both drugs but that the study suggested fluticasone was more effective (Ahmadiafshar et al. 2010). However, another study comparing these drugs in children with mild-to-moderate asthma found that both drugs were well tolerated and equally effective at improving asthma control (van Aalderen et al. 2007).

Combination therapy

Several studies have evaluated budesonide/formoterol compared with salmeterol/fluticasone. It has been demonstrated that adjustable-dose and fixed-dose budesonide/formoterol showed no differences in asthma control (exacerbations, symptoms or lung function) or tolerability versus fixed-dose fluticasone propionate/salmeterol (Busse et al. 2008). This was partly supported by third study that showed no difference between budesonide/formoterol and

salmeterol/fluticasone in measures of lung function or symptoms but also found that budesonide/formoterol reduced the incidence of severe asthma exacerbations and hospitalisation/emergency treatment compared with sustained high-dose salmeterol/fluticasone plus short-acting beta-2 agonist (Bousquet et al. 2007).

A systematic review and meta-analysis concluded that the adjustable maintenance dosing with budesonide/formoterol in adults with moderate/severe asthma offered advantages over fixed dosing with fluticasone/salmeterol and budesonide alone in relation to exacerbation prevention and reduced treatment load (Edwards et al. 2007). However, a Cochrane systematic review found that the odds of an exacerbation requiring oral steroids, of an exacerbation leading to hospital admission and of serious adverse events did not differ significantly between budesonide/formoterol and salmeterol/fluticasone. Other secondary outcomes were also not significantly different between treatments (including lung function, symptoms and adverse events). It concluded that although the evidence indicated that differences in the requirement for oral steroids and hospital admission did not reach statistical significance, it did not exclude clinically important differences between treatments in reducing exacerbations or causing adverse events (Lasserson et al. 2008)

A study comparing beclometasone/formoterol with fluticasone/salmeterol inhaled in moderate to severe asthma found that a new combination of extrafine beclomethasone/formoterol was not inferior to the combination of fluticasone and salmeterol in terms of efficacy and tolerability, and had a faster onset of bronchodilation (Papi et al. 2007).

8. Implementation

A submission from Implementation is included in Appendix 3.It is not possible to draw any conclusions on the impact of NICE guidance from the data presented in Appendix 3. This is because the data are for total prescriptions of inhaled corticosteroids and it cannot be ascertained how many of these were for asthma and how many were for other respiratory conditions, such as chronic obstructive pulmonary disease.

9. Equality issues

No equalities issues were raised in either NICE technology appraisal guidance 131 or NICE technology appraisal guidance 138.

GE paper sign off: Janet Robertson, 16th October 2012

Contributors to this paper:

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Appendix 1 – explanation of options

When considering whether to review one of its Technology Appraisals NICE must select one of the options in the table below:

Options	**Consequence**	**Selected – 'Yes/No'**
A review of the guidance should be planned into the appraisal work programme.	A review of the appraisal will be planned into the NICE's work programme.	No
The decision to review the guidance should be deferred to [specify date or trial].	NICE will reconsider whether a review is necessary at the specified date.	No
A review of the guidance should be combined with a review of a related technology appraisal.	A review of the appraisal(s) will be planned into NICE's work programme as a Multiple Technology Appraisal, alongside the specified related technology.	No
A review of the guidance should be combined with a new technology appraisal that has recently been referred to NICE.	A review of the appraisal(s) will be planned into NICE's work programme as a Multiple Technology Appraisal, alongside the newly referred technology.	No
The guidance should be incorporated into an on-going clinical guideline.	The on-going guideline will include the recommendations of the technology appraisal. The technology appraisal will remain extant alongside the guideline. Normally it will also be recommended that the technology appraisal guidance is moved to the static list until such time as the clinical guideline is considered for review. This option has the effect of preserving the funding direction associated with a positive recommendation in a NICE technology appraisal.	No
The guidance should be updated in an on-going clinical guideline.	Responsibility for the updating the technology appraisal passes to the NICE Clinical Guidelines programme. Once the guideline is published the technology appraisal will be withdrawn. Note that this option does not preserve the funding direction associated with a positive recommendation in a NICE Technology Appraisal. However, if the recommendations are unchanged from the technology appraisal, the technology appraisal can be left in place (effectively the same as incorporation).	No

Options	Consequence	Selected – 'Yes/No'
The guidance should be transferred to the 'static guidance list'.	The guidance will remain in place, in its current form, unless NICE becomes aware of substantive information which would make it reconsider. Literature searches are carried out every 5 years to check whether any of the Appraisals on the static list should be flagged for review.	Yes

NICE would typically consider updating a technology appraisal in an ongoing guideline if the following criteria were met:

i. The technology falls within the scope of a clinical guideline (or public health guidance)

ii. There is no proposed change to an existing Patient Access Scheme or Flexible Pricing arrangement for the technology, or no new proposal(s) for such a scheme or arrangement

iii. There is no new evidence that is likely to lead to a significant change in the clinical and cost effectiveness of a treatment

iv. The treatment is well established and embedded in the NHS. Evidence that a treatment is not well established or embedded may include;

- Spending on a treatment for the indication which was the subject of the appraisal continues to rise
- There is evidence of unjustified variation across the country in access to a treatment
- There is plausible and verifiable information to suggest that the availability of the treatment is likely to suffer if the funding direction were removed
- The treatment is excluded from the Payment by Results tariff

v. Stakeholder opinion, expressed in response to review consultation, is broadly supportive of the proposal.

Appendix 2 – supporting information

Relevant Institute work

Published

TA10 Guidance on the use of inhaler systems (devices) in children under the age of 5 years with chronic asthma. Issued: August 2000. Reviewed: May 2005. It was decided to move the guidance to the static list.

TA38 Inhaler devices for routine treatment of chronic asthma in older children (aged 5–15 years). Issued: March 2002. Reviewed: May 2005. It was decided to move the guidance to the static list.

TA133 Omalizumab for severe persistent allergic asthma. Issued: November 2007. Reviewed: August 2020. Review decision: A review of the technology appraisal guidance 133 should be combined with the review of technology appraisal guidance 201. It is accepted that the amount of new evidence available to inform this review is relatively limited; however, a combined review has been explicitly recommended by the Appraisal Committee (TA201), to ensure that there is no inequality in guidance for adult and paediatric populations.

TA201 Omalizumab for the treatment of severe persistent allergic asthma in children aged 6 to 11 years. Issued: 2010. The guidance on this technology will be considered for review together with NICE technology appraisal guidance 133 (October 2010).

In progress

Omalizumab for the treatment of severe persistent allergic asthma in children aged 6 and over and adults (review of TA133 and TA201). Expected date of issue: April 2013

Referred - QSs and CGs

QS Asthma (including children) - referred to NICE before March 2012

No relevant clinical guidelines

Details of new products

Drug (manufacturer)	Details (phase of development, expected launch date,)
Beclometasone dipropionate / formoterol (Chiesi Limited)	This ICS/LABA combination was licenced in November 2007. [redacted]

Drug (manufacturer)	Details (phase of development, expected launch date,)
Flutiform (combination of fluticasone propionate and formoterol (Napp Pharmaceutical Group)	This ICS/LABA combination was granted market authorisation in August 2012``
Mometasone furoate / formoterol combinations (Merck Sharp & Dohme)	Approved by FDA in June 2010. No UK launch available

Registered and unpublished trials

Trial name and registration number	Details
A 6 Month Safety Study Comparing Symbicort With Inhaled Corticosteroid Only in Asthmatic Adults and Adolescents (NCT01444430)	Estimated Enrolment: 11700 Estimated Study Completion Date: December 2016
A U.S. Retrospective Database Analysis Evaluating the Comparative Effectiveness of Budesonide/Formoterol Combination (BFC) and Fluticasone Propionate/Salmeterol Combination (FSC) Among Asthma Patients (NCT01623544)	Estimated Enrolment: 6000 Estimated Study Completion Date: September 2012
A Study Evaluating the Effect of Inhaled and Nasal Corticosteroids on Short Term Growth in Pediatric Subjects With Mild Asthma & Allergic Rhinitis (NCT01550471)	Estimated Enrolment: 60 Estimated Study Completion Date: March 2013
Efficacy Study of the Product "CHF 1535" Versus Beclomethasone (BDP) and Free Combo in Asthmatic Children (PAED2/FRESH) (NCT01475032)	Estimated Enrolment: 699 Estimated Study Completion Date: September 2012
Comparison of Combination of Beclomethasone Dipropionate and Formoterol Fumarate Versus Single Components Assessed by Knemometry and Urinary Cortisol Measurements in Asthmatic Children (NCT01658891)	Estimated Enrolment: 60 Estimated Study Completion Date: February 2016
Efficacy and Safety of CHF 1535 200/6µg in Not Adequately Controlled Asthmatic Patients (NCT01577082)	Estimated Enrolment: 540 Estimated Study Completion Date: November 2013

Trial name and registration number	Details
6-month Safety and Benefit Study of ADVAIR in Children 4-11 Years Old (VESTRI) (NCT01462344)	A 6-month safety and benefit study of inhaled fluticasone propionate/salmeterol combination versus inhaled fluticasone propionate. Estimated Enrolment: 6200 Estimated Study Completion Date: February 2017
Comparison of Flutiform, Fluticasone and Seretide in Treatment of Moderate to Severe Asthma in Paediatric Patients (NCT01511367)	Estimated Enrolment: 498 Estimated Study Completion Date: April 2013
The Clinical Effect in Asthma of Inhaled Fluticasone Propionate Delivered as Monodisperse Aerosols (NCT01662778)	The objective here is to determine that the efficiency of inhaled drug delivery can be improved by using a fine mist cloud of drug particles (as opposed to a coarse mist cloud of drug particles). Estimated Enrolment: 24 Estimated Study Completion Date: December 2012
A Study Comparative of Formoterol/Fluticasone Foraseq® and Fluticasone in Asthma Patients (NCT01202084)	Estimated Enrolment: 222 Estimated Study Completion Date: November 2012
Evaluating the Efficacy and Safety of Fluticasone Furoate in the Treatment of Asthma in Adults and Adolescents (NCT01431950)	Estimated Enrolment: 220 Estimated Study Completion Date: October 2012
Asthma Comparative Effectiveness Study (Asthma CER) (NCT01623544)	A U.S. retrospective database analysis evaluating the comparative effectiveness of budesonide/formoterol combination (BFC) and fluticasone propionate/salmeterol combination (FSC) Estimated Enrollment: 6000 Estimated Study Completion Date: September 2012
Effect of High Dose Ciclesonide on Asthma Control (CONTRAST) (NCT01455194)	Estimated Enrolment: 450 Estimated Study Completion Date: November 2013

Trial name and registration number	Details
A Serious Asthma Outcome Study With Mometasone Furoate/Formoterol Versus Mometasone Furoate in Asthmatics 12 Years and Over (P06241 AM3) (SPIRO) (NCT01471340)	Estimated Enrolment: 11664 Estimated Study Completion Date: February 2017
Study of Mometasone Furoate/Formoterol Fumarate (MF/F) Metered Dose Inhaler (MDI) in Adolescents & Adults With Persistent Asthma (P08212) (NCT01566149)	Estimated Enrolment: 40 Estimated Study Completion Date: October 2012
A 6 Month Safety Study Comparing Symbicort With Inhaled Corticosteroid Only in Asthmatic Adults and Adolescents (NCT01444430)	Estimated Enrolment: 11700 Estimated Study Completion Date: December 2016

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Ahmadiafshar A, Mogimi HM, Rezaei N (2010) Comparison of effectiveness between beclomethasone dipropionate and fluticasone propionate in treatment of children with moderate asthma. *World Allergy Organization Journal.* 3 (10): 250-252.

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Boulet LP, Bateman ED, Voves R et al. (2007) A randomized study comparing ciclesonide and fluticasone propionate in patients with moderate persistent asthma. *Respiratory Medicine.* 101 (8): 1677-1686.

Bousquet J, Boulet LP, Peters MJ et al. (2007) Budesonide/formoterol for maintenance and relief in uncontrolled asthma vs. high-dose salmeterol/fluticasone. *Respiratory Medicine.* 101 (12): 2437-2446.

British Guideline on the Management of Asthma: a national clinical guideline. The British Thoracic Society and Scottish Intercollegiate Guidelines Network. SIGN

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Edwards SJ, Gruffydd-Jones K, Ryan DP (2007) Systematic review and meta-analysis of budesonide/formoterol in a single inhaler. *Current Medical Research and Opinion.23 (8) (pp 1809-1820), 2007.Date of Publication: August 2007.* (8): 1809-1820.

FitzGerald JM, Magnussen H, Engelstatter R (2007) Comparative safety and efficacy of ciclesonide and fluticasone propionate in the management of adult persistent asthma. *Chest.* 132 (4): 508c-5509.

Knox A, Langan J, Martinot JB et al. (Oct. 2007) Comparison of a step-down dose of once-daily ciclesonide with a continued dose of twice-daily fluticasone propionate in maintaining control of asthma. *Current Medical Research & Opinion.* 23 (10): 2387-2394.

Lasserson TJ, Cates CJ, Ferrara G et al. (2008) Combination fluticasone and salmeterol versus fixed dose combination budesonide and formoterol for chronic asthma in adults and children. *Cochrane database of systematic reviews (Online).* (3): CD004106-.

Magnussen H, Hofman J, Staneta P et al. (Sept. 2007) Similar efficacy of ciclesonide once daily versus fluticasone propionate twice daily in patients with persistent asthma. *Journal of Asthma.* 44 (7): 555-563.

Manning P, Gibson PG, Lasserson TJ (2008) Ciclesonide versus other inhaled steroids for chronic asthma in children and adults. *Cochrane database of systematic reviews (Online).* (2): CD007031-.

Papi A, Paggiaro P, Nicolini G et al. (2007) Beclomethasone/formoterol vs fluticasone/salmeterol inhaled combination in moderate to severe asthma. *Allergy.* 62 (10): 1182-1188.

Ukena D, Biberger C, Steinijans V et al. (2007) Ciclesonide is more effective than budesonide in the treatment of persistent asthma. *Pulmonary Pharmacology & Therapeutics.* 20 (5): 562-570.

van Aalderen WM, Price D, De Baets FM et al. (2007) Beclometasone dipropionate extrafine aerosol versus fluticasone propionate in children with asthma. *Respiratory Medicine.* 101 (7): 1585-1593.

Vermeulen JH, Gyurkovits K, Rauer H et al. (2007) Randomized comparison of the efficacy and safety of ciclesonide and budesonide in adolescents with severe asthma. *Respiratory Medicine.* 101 (10): 2182-2191.

Appendix 3 – Implementation submission

Implementation feedback: review of NICE technology appraisal guidance 131 & 138

NICE Technology Appraisal 131 Asthma (in children) – corticosteroids & NICE Technology Appraisal 138 Asthma (in adults) - corticosteroids
Implementation input required by 13/08/2012
Please contact Rebecca Lea regarding any queries rebecca.lea@nice.org.uk

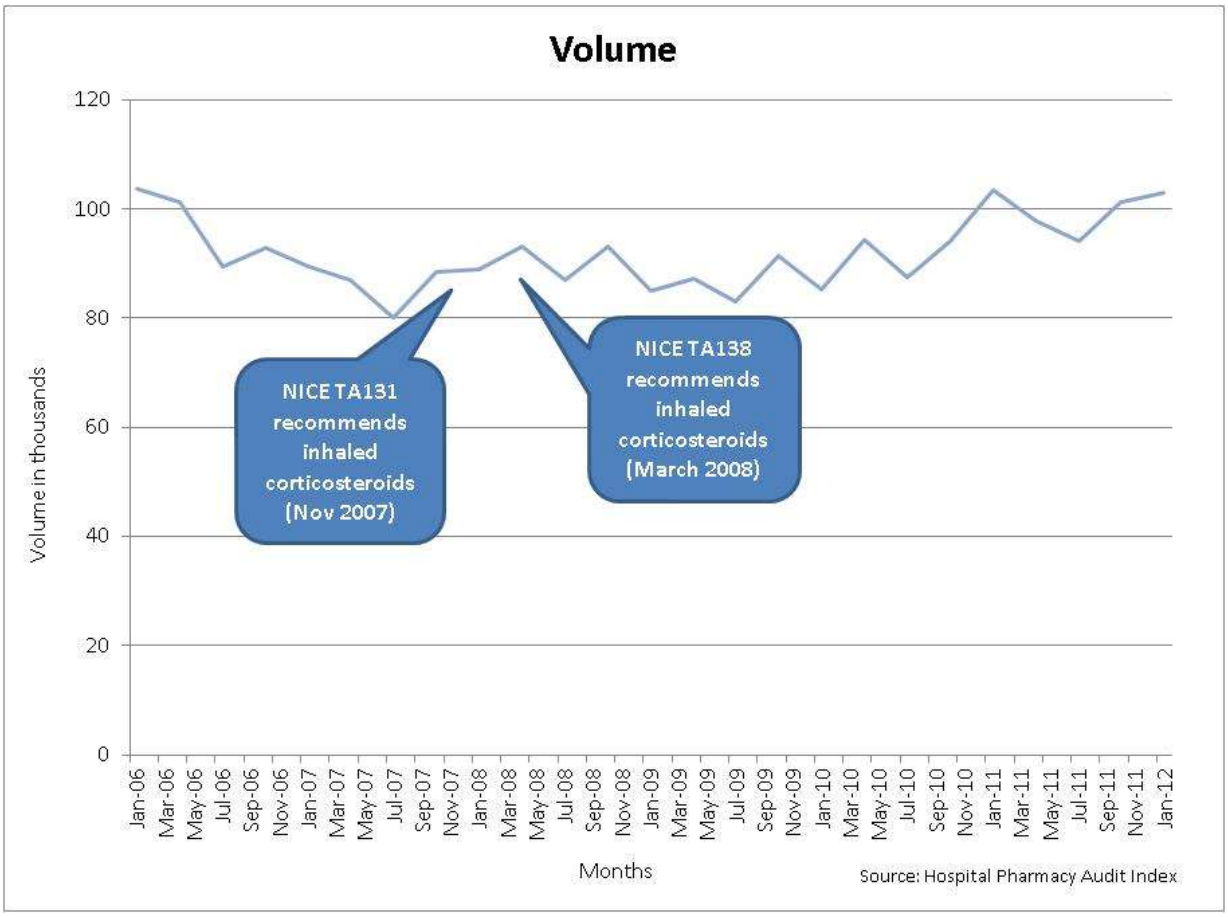
Contents

1 Routine healthcare activity data

1.1 Hospital Pharmacy Audit Index data

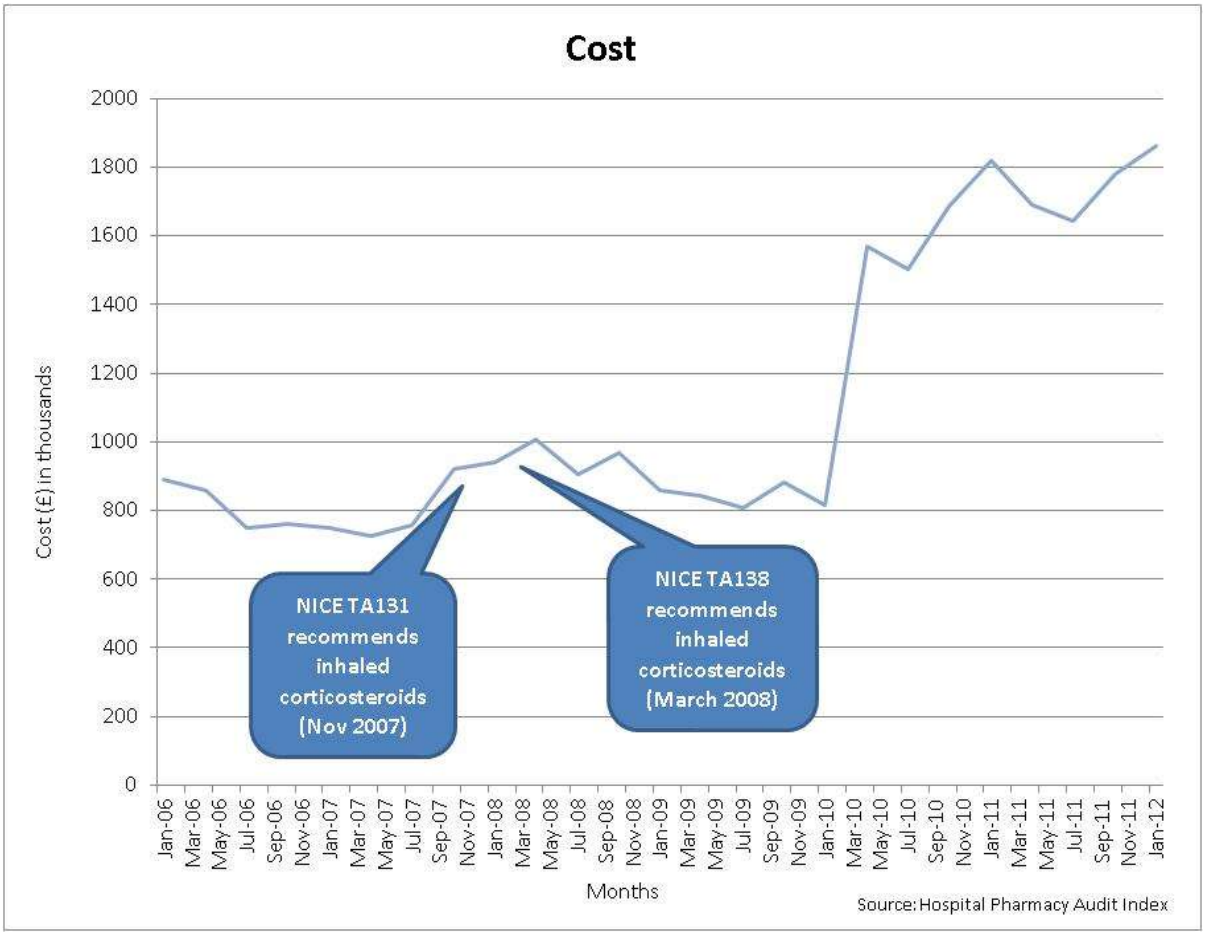
This section presents hospital pharmacy audit index data (HPAI) data on the cost and volume of inhaled corticosteroids[2] prescribed and dispensed by hospital pharmacies in England between January 2006 and January 2012.

Figure 1 Volume of Inhaled corticosteroids prescribed and dispensed in hospitals in England



[2] Inhaled Corticosteroids include Beclametasone dipropionate, Beclometasone Formoterol, Budesonide, Budesonide Formoterol, Fluticasone propionate and Mometasone furoate.

Figure 2 Cost of Inhaled corticosteroids prescribed and dispensed in hospitals in England

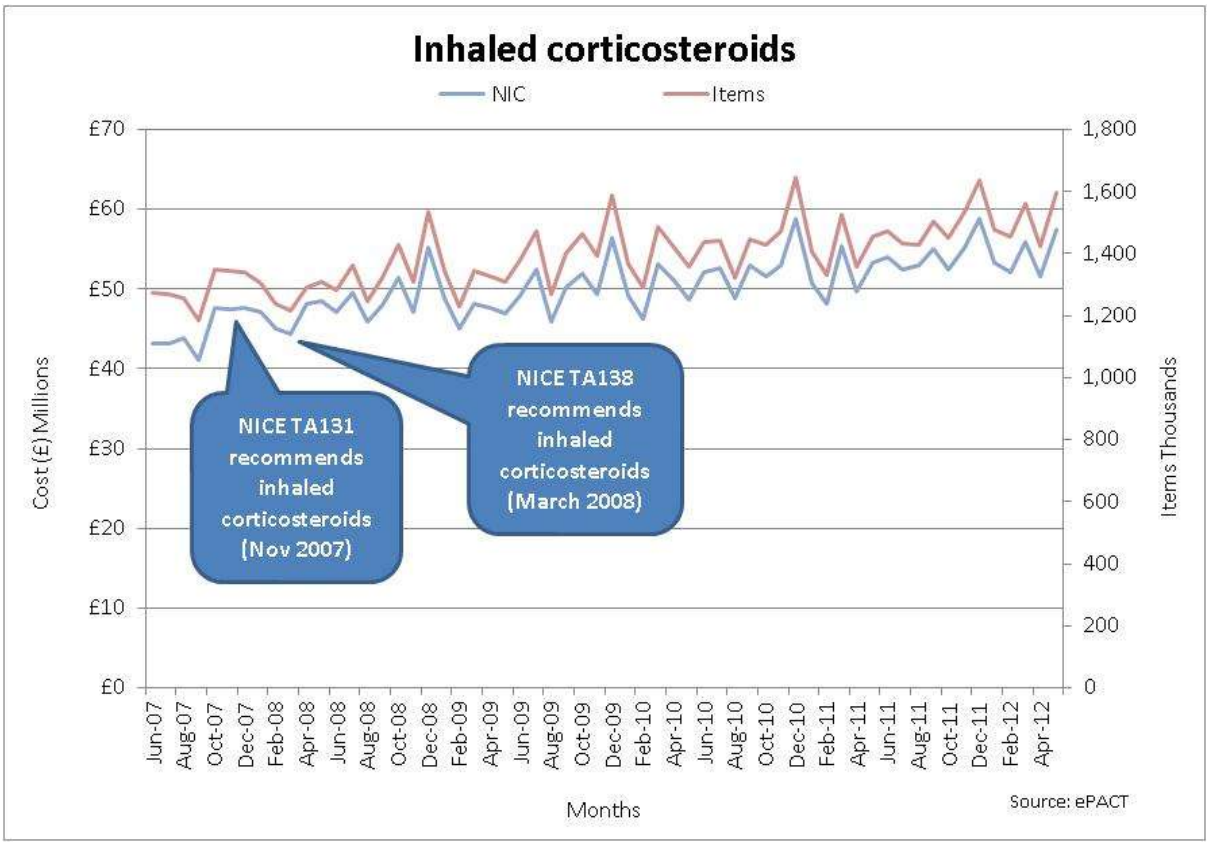


1.2 ePACT and hospital ePACT data

This section presents net ingredient cost and volume data for inhaled corticosteroids[3] prescribed in primary care and in hospitals that have been dispensed in the community in England between June 2007 and May 2012.

[3] Inhaled corticosteroids include Beclametasone dipropionate, Budesonide, Fluticasone propionate, Mometasone furoate and Ciclesonide.

Figure 3 Cost and volume of Inhaled corticosteroids prescribed in primary care and in hospitals that have been dispensed in the community in England



2 Implementation studies from published literature

Information is taken from the uptake database (ERNIE) website.

Nothing to add at this time.

3 Qualitative input from the field team

The implementation field team have recorded the following feedback in relation to this guidance:

Nothing to add.

Appendix A: Healthcare activity data definitions

Prescribing analysis and cost tool system

This information comes from the electronic prescribing analysis and cost tool (ePACT) system, which covers prescriptions by GPs and non-medical prescribers in

England and dispensed in the community in the UK. The Prescription Services Division of the NHS Business Services Authority maintains the system. PACT data are used widely in the NHS to monitor prescribing at a local and national level. Prescriptions written in hospitals but dispensed in the community (FP10 [HP]) are not included in PACT data. Prescriptions dispensed in hospitals or mental health units, and private prescriptions, are not included in PACT data.

Measures of prescribing

Prescription Items: Prescriptions are written on a prescription form. Each single item written on the form is counted as a prescription item. The number of items is a measure of how many times the drug has been prescribed.

Cost: The net ingredient cost (NIC) is the basic price of a drug listed in the drug tariff, or if not in the drug tariff, the manufacturer's list price.

Data limitations (national prescriptions)

PACT data do not link to demographic data or information on patient diagnosis. Therefore the data cannot be used to provide prescribing information by age and sex or prescribing for specific conditions where the same drug is licensed for more than one indication.

IMS HEALTH Hospital Pharmacy Audit Index (IMS HPAI)

IMS HEALTH collects information from pharmacies in hospital trusts in the UK. The section of this database relating to England is available for monitoring the overall usage in drugs appraised by NICE. The IMS HPAI database is based on issues of medicines recorded on hospital pharmacy systems. Issues refer to all medicines supplied from hospital pharmacies: to wards; departments; clinics; theatres; satellite sites and to patients in outpatient clinics and on discharge.

Measures of prescribing

Volume: The HPAI database measures volume in packs and a drug may be available in different pack sizes and pack sizes can vary between medicines.

Cost: Estimated costs are also calculated by IMS using the drug tariff and other standard price lists. Many hospitals receive discounts from suppliers and this is not reflected in the estimated cost.

Costs based on the drug tariff provide a degree of standardization allowing comparisons of prescribing data from different sources to be made. The costs stated in this report do not represent the true price paid by the NHS on medicines. The estimated costs are used as a proxy for utilization and are not suitable for financial planning.

Data limitations

IMS HPAI data do not link to demographic or to diagnosis information on patients. Therefore, it cannot be used to provide prescribing information on age and sex or for prescribing of specific conditions where the same drug is licensed for more than one indication.