NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

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.

Background

At the GE meeting of 23 October 2012 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

Proposal put to consultees:	The guidance should be transferred to the 'static guidance list'.
Rationale for selecting this proposal	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.

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

Recommendation post consultation:	The guidance will be transferred to the 'static guidance list'.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Department of Health	Agree	The Department of Health has no comments to make, other than to confirm agreement that the guidance on corticosteroids in asthma should move to the static list.	Thank you for your response. No action required.
Royal College of Nursing	No comment	Feedback received from nurses working in this area of health suggest that there are no additional comments to submit in response to the review proposal of the above appraisal.	Thank you for your response. No action required.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Royal College of Paediatrics & Child Health	Agree (but comment on the usefulness of a HTA focusing on devices)	We accept that there is no new evidence regarding combination inhalers. Lack of evidence is not evidence of lack of benefit. This is a generic weakness of NICE methodology. Current guidance allows clinicians to use separate LABA and inhaled steroid or combination. Every patient that has ever been asked by one of our contributors says they would prefer one inhaler to two. The contributors practice is therefore to use a combination because it will improve concordance and therefore reduce the hidden cost of exacerbations. Please consider guidance becoming patient focused by recommending that patients are asked whether they would prefer a combination inhaler or two separate ones. The emphasis should be patient choice not inhaler cost.	Thank you for your comments. The recommendations in TA131 and TA138 make reference to patient choice and treatment adherence with respect to combination inhalers. They state that for adults and children in whom treatment with an ICS and long-acting beta-2 agonist (LABA) is considered appropriate, "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". The recommendations also state that "if a combination device is chosen, then the least costly device that is suitable *for the individual (child – TA131 only)* is recommended", further emphasising that the decision should be made on individual clinical circumstances in the first instance, with cost as a secondary consideration. More information on the Committee's consideration of the importance of patient choice can be found in the original guidance (section 4.3 in both TA131 and TA138).

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Royal College of Paediatrics & Child Health (continued)	Agree (but comment on the usefulness of a HTA focusing on devices)	A review at this stage is unlikely to lead to any changes in recommendations. However, there is now an NEJM publication (Kelly et al N Engl J Med 2012; 367: 904-12) from the CAMP study showing that ICS do have a small effect on ultimate adult height which is generated when the treatment is first commenced but is not cumulative. It emphasises the need to titrate the lowest dose to achieve control. The other issue which is maybe not clear in the current HTA is dose equivalence in terms of both efficacy and systemic activity between different products. Thus, for instance, Qvar is twice as potent as for instance Clenil at the same dose of beclomethasone. There are also differences dependent on the use of spacers or powder compared with MDI alone. These differences are due to particle size and consequent airway distribution. Maybe an HTA based on these issues would be of value?	Thank you for highlighting the paper by Kelly et al. It is noted that the authors conclude: “In the information about inhaled glucocorticoids and their side effects that is provided to parents, the potential effect on adult height must be balanced against the large and well-established benefit of these drugs in controlling persistent asthma. It is appropriate to use the lowest effective dose for symptom control in order to minimise concern about the effects of inhaled glucocorticoids on adult height.” We therefore agree with your conclusion that the evidence at this time indicates that a review would be unlikely to lead to a change in the recommendations and that transferring the guidance to the static list is the most appropriate course of action. We would like to clarify that transferring guidance to the static list does not mean that a review could not happen in the future. If a significant change to the evidence base is identified at any stage within the next 5 years (either by NICE’s Information Services team or by external stakeholders), then this would trigger another review proposal that would undergo consultation. We particularly welcome the assistance of professional groups in ensuring we are aware of the latest evidence.

No response received from:

Manufacturers/sponsors

- Allen and Hanburys (beclometasone dipropionate, fluticasone propionate, salmeterol/fluticasone combination)
- AstraZeneca (budesonide, formoterol/budesonide combination)
- Chiesi (beclometasone dipropionate)
- Meda Pharmaceuticals (beclometasone dipropionate, budesonide)
- Merck Sharp & Dohme (mometasone)
- Takeda (ciclesonide)
- Orion Pharma (UK) (beclometasone dipropionate, budesonide)
- Sandoz (beclometasone dipropionate)
- Teva UK (beclometasone dipropionate)

Patient/carer groups

- Action Against Allergy
- Action for Children
- Action for Sick Children
- Afiya Trust
- Allergy UK
- Asthma UK
- Black Health Agency
- British Lung Foundation
- Children's Society
- Counsel and Care
- Equalities National Council
- European Federation of Asthma & Allergy Association
- Muslim Council of Britain

General

- Allied Health Professionals Federation
- Board of Community Health Councils in Wales
- British National Formulary
- Care Quality Commission
- Commissioning Support Appraisals Service
- Department of Health, Social Services and Public Safety for Northern Ireland
- Healthcare Improvement Scotland
- Medicines and Healthcare Products Regulatory Agency
- National Association of Primary Care
- National Pharmacy Association
- NHS Alliance
- NHS Commercial Medicines Unit
- NHS Confederation
- Public Health Wales NHS Trust
- Scottish Medicines Consortium

Possible Comparator manufacturer(s)

- Chiesi (formoterol/beclometasone combination)
- Napp Pharmaceuticals (formoterol/fluticasone combination)

Relevant research groups

- David Hide Asthma and Allergy Research Centre
- MRC Clinical Trials Unit
- National Institute for Health Research
- Research Institute for the Care of Older People

• Muslim Health Network • National Children's Bureau • National Parent Partnership Network • South Asian Health Foundation • Specialised Healthcare Alliance • WellChild <u>Professional groups</u> • Association of Respiratory Nurse Specialists • British Association for Services to the Elderly • British Geriatrics Society • British Paediatric Respiratory Society • British Thoracic Society • Primary Care Respiratory Society UK • Royal College of General Practitioners • Royal College of Pathologists • Royal College of Physicians • Royal Pharmaceutical Society • Royal Society of Medicine • United Kingdom Clinical Pharmacy Association <u>Others</u> • Hertfordshire PCT Cluster • South Essex PCT Cluster • Welsh Government	<u>Assessment Group</u> • Assessment Group tbc • National Institute for Health Research Health Technology Assessment Programme <u>Associated Guideline Groups</u> • National Clinical Guideline Centre <u>Associated Public Health Groups</u> • None

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