NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Proposed Health Technology Appraisal

Budesonide for treating active eosinophilic oesophagitis

Draft scope (pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of budesonide within its marketing authorisation for treating active eosinophilic oesophagitis.

Background

Eosinophilic oesophagitis is a chronic, immune-mediated inflammation of the oesophagus. It is caused by the body over-producing white blood cells (eosinophils) in the oesophagus leading to inflammation.

Symptoms of eosinophilic oesophagitis can be unpleasant and socially embarrassing, and have a significant impact on quality of life. People with oesophagitis have difficulty swallowing, eating (they may experience food getting stuck), chest pains, heartburn, upper abdominal pain and food regurgitation. Approximately half of people with eosinophilic oesophagitis also experience other allergies such as hay fever, food intolerances or asthma.

Eosinophilic oesophagitis is considered to be the most frequent eosinophilic gastrointestinal disorder[1]. In 2016, the estimated prevalence for Europe was around 16.1 per 100,000 population, equating to approximately 823 cases in England[2]. Incidence in Europe is estimated at around 2 per 100,000 population, per year. The majority of cases are in children, adolescents and adults under the age of 50, with clinical differences between adults and children[3].

There are currently no standard treatment options available in the NHS for treating eosinophilic oesophagitis. Medical management includes dietary elimination (in conjunction with an allergy assessment) and steroids given topically or systemically in severe cases.

The technology

Budesonide (orally dissolving tablet; Jorveza, Dr Falk Pharma) is a new formulation of an established glucocorticoid receptor agonist (corticosteroid). It inhibits antigen-stimulated secretion of many pro-inflammatory signal molecules in the esophageal epithelium, which results in a reduction of the esophageal eosinophilic inflammatory infiltrate. Budesonide is administered orally.

Budesonide orally dissolving tablet has a marketing authorisation in the UK for treating adults with active eosinophilic oesophagitis.

Intervention(s)	Budesonide (orally dissolving tablet)
Population(s)	Adults with active eosinophilic oesophagitis
Comparators	Established clinical management without budesonide
Outcomes	The outcome measures to be considered include: • disease activity (remission, response, relapse) • mortality • adverse effects of treatment • health related quality of life
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. If the technology is likely to provide similar or greater health benefits at similar or lower cost than technologies recommended in published NICE technology appraisal guidance for the same indication, a cost-comparison may be carried out. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective. The availability of any patient access schemes for the comparator technologies will be taken into account.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations and NICE Pathways	Related Technology Appraisals: None Related Guidelines: None
Related National Policy	NHS England (2017) Manual for prescribed specialised services 2017/18 Chapter 2A NHS England (2013) 2013/14 NHS Standard Contract Paediatric Medicine: Gastoenterology, Hepatology and

	Nutrition Department of Health (2016) NHS outcomes framework 2016 to 2017. Domains 1 and 2

Questions for consultation

Have all relevant comparators for budesonide been included in the scope?

- Which steroids are currently being used in clinical practice in the NHS for active eosinophilic oesophagitis?
- Is budesonide currently being used in other formulations for treating active eosinophilic oesophagitis in the NHS?

Are the outcomes listed appropriate?

Are there any subgroups of people in whom budesonide is expected to be more clinically effective and cost effective or other groups that should be examined separately?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which budesonide will be licensed;

- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;

- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the Committee to identify and consider such impacts.

Do you consider budesonide to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of budesonide can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/article/pmg19/chapter/1-Introduction).

References

1. Attwood S. Eosinophilic oesophagitis – a common disease, newly recognised. Clinical Medicine 2013; 13(6):s32-s35

2. Horizon Scanning Research & Intelligence Centre. Budesonide orodispersible tablet for eosinophilic oesophagitis – first line. NIHR HSRIC ID: 10793

3. Dellon ES. Epidemiology of eosinophilic esophagitis. Gastroeneterology Clinics of North America 2014; 43(2):201-218