

**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**Proposed Health Technology Appraisal**

**Budesonide for treating eosinophilic oesophagitis**

**Final scope (pre-referral)**

**Remit/appraisal objective**

To appraise the clinical and cost effectiveness of budesonide within its marketing authorisation for treating 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. Adults 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<sup>1</sup>. In 2017, the estimated prevalence for adults in Europe was around 43.4 per 100,000 population, equating to approximately 22,000 in the adult UK population<sup>2, 3</sup>. It has been suggested that eosinophilic oesophagitis is often underdiagnosed or misdiagnosed.

There are currently no standard treatment options available in the NHS for treating eosinophilic oesophagitis. Medical management includes proton pump inhibitors, dietary elimination (in conjunction with an allergy assessment) and topical steroid preparations.

**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 oesophageal epithelium, which results in a reduction of the oesophageal eosinophilic inflammatory infiltrate. Budesonide is administered orally.

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

<b>Intervention(s)</b>	Budesonide (orally dissolving tablet)
<b>Population(s)</b>	Adults with active eosinophilic oesophagitis
<b>Comparators</b>	Established clinical management without budesonide, which may include proton pump inhibitors, other corticosteroid formulations and dietary intervention.
<b>Outcomes</b>	<p>The outcome measures to be considered include:</p> <ul style="list-style-type: none"> <li>• disease activity (remission, response, relapse)</li> <li>• symptoms of oesophagitis</li> <li>• complications such as stricture formation</li> <li>• mortality</li> <li>• adverse effects of treatment</li> <li>• health related quality of life</li> </ul>
<b>Economic analysis</b>	<p>The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year.</p> <p>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.</p> <p>Costs will be considered from an NHS and Personal Social Services perspective.</p>
<b>Other considerations</b>	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.
<b>Related NICE recommendations and NICE Pathways</b>	<p>Related Technology Appraisals:</p> <p>None</p> <p>Related Guidelines:</p> <p>None</p>

<p><b>Related National Policy</b></p>	<p>NHS England (2017) <a href="#">Manual for prescribed specialised services 2017/18</a> Chapter 2A</p> <p>NHS England (2013) <a href="#">2013/14 NHS Standard Contract Paediatric Medicine: Gastroenterology, Hepatology and Nutrition</a></p> <p>Department of Health (2016) <a href="#">NHS outcomes framework 2016 to 2017</a>. Domains 1 and 2</p>
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## References

1. Attwood S. [Eosinophilic oesophagitis – a common disease, newly recognised](#). Clinical Medicine 2013; 13(6):s32-s35
2. Arias A, Perez-Martinez I, Tenias JM et al. Systematic review with meta-analysis: the incidence and prevalence of eosinophilic oesophagitis in children and adults in population-based studies. Alimentary Pharmacology and Therapeutics 2016; 43: 3-15.
3. Office of National Statistics ONS 2016-based National Population Projections (18 years and over UK population projected for 2018)  
<https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationprojections/datasets/z1zippedpopulationprojectionsdatafilesuk>