

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	7 th June 2022
Appraisal & Details	<p>Budesonide orodispersible (Jorveza®) for maintenance treatment of eosinophilic oesophagitis</p> <p>The Northern (NHS) Treatment Advisory Group was requested to conduct an appraisal of and issue a recommendation regarding the use Budesonide orodispersible for maintenance treatment of eosinophilic oesophagitis. This was because the current NICE TA708 does not cover maintenance treatment just the initial 12-week treatment course.</p>
Recommendation	<p>The NHS North East Treatment Advisory Group recommends budesonide orodispersible (Jorveza®) for the maintenance treatment of eosinophilic oesophagitis for patients with a long-standing disease history and/or high extent of oesophageal inflammation in their acute disease state. The duration of maintenance therapy is determined by the discretion of the treating gastroenterologist depending on severity of symptoms and response.</p> <p>The group recommends that budesonide orodispersible for maintenance treatment of eosinophilic oesophagitis should only be initiated by specialists but may be suitable for continuation of therapy in primary care.</p> <p>Budesonide orodispersible tablets should be used in line with NICE guidance for treatment of patients with confirmed eosinophilic oesophagitis.</p>
Clinical evidence summary	<p>An RDTG Medicines in Practice publication summarises the clinical evidence supporting budesonide orodispersible tablets for the maintenance treatment of eosinophilic oesophagitis.</p> <p>A randomised controlled trial found that, among patients who responded to an initial 6-12 induction course, remission was maintained for 48 weeks in around three quarters of treated patients, compared to 4.4% of those receiving placebo.</p> <p>There are limited options for treatment of eosinophilic oesophagitis, and no other pharmacological options are licensed. Patients and clinical experts told NICE that lack of a treatment pathway is one of the biggest challenges in eosinophilic oesophagitis, and NICE concluded that there was unmet need.</p> <p>Treatment options include off-label use of PPIs or topical steroids, although PPIs have typically been trialled prior to diagnosis and are not effective for most people. The most common method of administering off-label topical steroids in the UK is a fluticasone metered-dose inhaler (MDI) sprayed into the mouth and then swallowed. Budesonide nebulas may also be mixed with sucralose or other thickener to form a slurry for oral administration, but NICE heard that this is only used in exceptional cases in the UK.</p> <p>Maintenance treatment with budesonide ODT provides a licensed treatment where none currently exists.</p>

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Safety	Budesonide orodispersible tablets were well-tolerated, and the most frequent adverse effects were mild to moderate candidiasis. Changes in serum cortisol were small, and no patients developed symptoms of adrenal suppression.
Patient Perspective	<p>NTAG was asked to look at Budesonide for Maintenance Treatment of Eosinophilic because NICE Technology Appraisal does not cover maintenance treatment just initial 12-week treatment course. Some patients may require ongoing maintenance treatment depending on their symptoms.</p> <p>There are no other licensed pharmacological options of patients with eosinophilic oesophagitis. Off-label steroids are effective when used appropriately but may be cumbersome and imprecise to administer. Specialist diets may be inaccessible due to cost.</p> <p>Maintenance treatment with budesonide orodispersible tablets provides a licensed treatment where none currently exists.</p>
Cost analysis summary	<p>Jorveza® 1 mg orodispersible tables cost £323 per pack of 90. The recommended dose in maintenance treatment is 0.5 mg or 1 mg twice daily. There is no 0.5 mg formulation available, and no information on splitting the 1 mg tablets. The annual cost is therefore expected to be around £2,600 per person. Off-label fluticasone at a dose of 500 micrograms twice daily costs around £440 per person annually.</p> <p>Eosinophilic oesophagitis has an annual incidence of around 1.7 people per 100,000 in Europe, and a prevalence of 16.1 per 100,000. NICE estimates that 13,000 people in England are affected, which equates to a prevalence of 23 per 100,000.</p> <p>Maintenance treatment with budesonide orodispersible tablets may reduce the need for invasive procedures such as endoscopy and oesophageal dilation. Rates of these outcomes were low in the published trial so it is challenging to estimate how budesonide orodispersible tablets may alter their use. The NICE committee agreed that healthcare costs were challenging to estimate, but that need for endoscopy was likely to be reduced for patients in remission.</p>
Financial impact PbR: Tariff included	<p>Maintenance treatment with budesonide orodispersible tablets provides a licensed treatment where none currently exists, and costs £2,600 per patient per year. It may reduce the need for invasive procedures such as endoscopy and oesophageal dilation, however evidence is lacking.</p> <p>The cost impact of budesonide orodispersible tablets is difficult to estimate due to the variation in estimates of prevalence and lack of a single treatment pathway. These factors mean it is difficult to assess both the current resource impact and potential change due to maintenance treatment with budesonide orodispersible tablets. If uptake of budesonide orodispersible tablets reaches 50% of the prevalent population, the annual cost would be around £30,000 per 100,000 population. This represents an increase of around £25,000 per 100,000 if those people are currently receiving off-label fluticasone.</p>