

Briefing Paper for Surrey Heartlands Integrated Care System (ICS) Area Prescribing Committee (APC)

Integrated Care Partnerships (ICPs) (Surrey Downs, Guildford & Waverley, North West Surrey, East Surrey & associated partner organisations. NICE Technology Appraisals: Local implementation

| NICE TA Guidance | Budesonide orodispersible tablet for inducing remission of eosinophilic oesophagitis Technology appraisal guidance TA708 | | |
|------------------|--|-------------------------|----------------------------------|
| Available at | www.nice.org.uk/guidance/ta708 | | |
| Date of issue | Published: 23 June 21 | Implementation deadline | 20 September 21 September APC |

| Medicine details | | | |
|---|---|--|--|
| Name, brand name | Budesonide (Jorveza®) | | |
| Manufacturer | Dr. Falk Pharma UK Ltd | | |
| Licensed indication | Treatment of eosinophilic esophagitis (EoE) in adults - older than 18 years of age (summary of product characteristics(SPC) 5 th July 21) | | |
| Formulation | Orodispersible tablets (SPC 5 th July 2021) | | |
| Usual dosage | Induction of remission 1mg in the morning and 1mg in the evening. The usual duration of induction treatment is 6 weeks. For patients who are not appropriately responding during 6 weeks the treatment can be extended to up to 12 weeks. Maintenance of remission 0.5mg in the morning and 0.5mg in the evening or 1mg in the morning and 1mg in the evening, depending on the individual clinical requirement of the patient. A maintenance dose of 1 mg budesonide twice daily is recommended for patients with a long standing disease history and/or high extent of esophageal inflammation in their acute disease state. The duration of maintenance therapy is determined by the treating physician. | | |
| NICE recommended dosage/schedule | Dosage schedule as in the SPC - for inducing remission of eosinophilic oesophagitis in adults. | | |
| Disease and potential patient group | | | |
| Brief description of disease | Eosinophilic Oesophagitis (EoE) is a rare condition affecting around 13,000 people in England. Sometimes described as Oesophageal Asthma, EoE is a chronic disease that affects the oesophagus, which is the tube that connects the mouth and stomach. Having too many eosinophils, a type of white blood cell, in the oesophagus causes inflammation that makes swallowing difficult. | | |
| Potential patient numbers per 100,000 | 1 in 3000 in the UK (EoE Network information – link from NICE) Therefore 33 people may have EoE in 100,000 population | | |

NICE recommendation

Budesonide as an orodispersible tablet (ODT) is recommended as an option for inducing remission of eosinophilic oesophagitis in adults.

Although budesonide ODT has a marketing authorisation for both inducing and maintaining remission in eosinophilic oesophagitis, at the time this appraisal started it was only licensed for induction. So, the company's evidence is for inducing remission only (with treatment of up to 12 weeks) and the committee is unable to make recommendations for maintenance treatment.

Cost implications*

Cost of product:

The list price is £323 per pack of 90 one-mg tablets (excluding VAT; BNF online, accessed April 2021). Costs may vary in different settings because of negotiated procurement discounts.

Annual cost per patient: or monthly if more appropriate £323 per 6 week course

Has dose escalation been considered as part of the NICE costing template? No

Costing information/100,000 population and per CCG:

NICE do not expect this to have a significant impact on resources; that is, the resource impact of implementing the recommendations in England will be less than £5 million per year in England (or approximately £9,000 per 100,000 population).

For Surrey Heartlands populations of around 250 - 300,000 people this will equate to no more than £27k per Place so within the £100k delegated authority of this committee.

Availability of PAS and details (if appropriate): No

Availability of homecare service (if appropriate): No

*NICE funding requirements are based on Quality Adjusted Life Years (QALY) threshold. If there is evidence that the incremental cost rises above this threshold in the future, the APC may reconsider the commissioning status.

Alternative treatments and cost per patient (per year / per month as appropriate)

Other NICE recommended products:

none

Options not reviewed by NICE but used in standard practice:

Treatment includes off-label proton pump inhibitors (such as omeprazole or lansoprazole) and corticosteroids (off-label fluticasone and unlicensed budesonide). People can also try elimination diets such as the 6-food elimination diet (SFED), which involves eliminating the known allergens milk, eggs, nuts, wheat, soy and seafood.

Impact to patients

Access to treatment is currently variable and not always effective.

Dosing and delivery of off-label corticosteroids is difficult and imprecise because it involves swallowing formulations originally designed for inhalation, which is counterintuitive and poorly understood by patients and clinicians.

Dietary interventions are hugely challenging and professional support is often difficult to access. Specialist diets can be expensive, so they are not affordable for many people. NICE concluded there was an unmet need for a licensed, effective treatment for eosinophilic oesophagitis.

Impact to primary care prescribers

For induction of remission only it is unlikely to impact primary care prescribing.

Impact to secondary care

Likely to be prescribed in secondary care as uncommon and short duration of therapy.

Impact to CCGs

None anticipated

Implementation

Addition to PAD and formularies with place in therapy as in NICE guideline

Recommendation to APC

PbRe: N



Recommended traffic light status (see attached guidelines): RED – Gastroenterology prescriber only

Local formulary status:

St Georges Hospital – On formulary RED drug Kingston Hospital – On formulary RED drug Epsom and St Helier – On formulary Gastroenterologists only Royal Surrey County Hospital – Not on formulary Ashford and St Peter's– Not on formulary Surrey and Sussex– Not on formulary

References:

1 Budesonide orodispersible tablet for inducing remission of eosinophilic oesophagitis Technology appraisal guidance [TA708]Published: 23 June 2021

https://www.nice.org.uk/guidance/ta708

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