

**South East London Integrated Medicines Optimisation Committee
Formulary recommendation**

Reference:	141
Intervention:	Budesonide (Jorveza™) orodispersible tablets for maintenance treatment of eosinophilic oesophagitis <small>(Budesonide is a glucocorticoid steroid, which exerts local anti-inflammatory effects)</small>
Date of Decision:	October 2022
Date of Issue:	March 2023 (time limited approval for 12 months)
Recommendation:	Amber 2 – initiation and 12 week induction course prescribed and supplied by the specialist gastroenterology team after which prescribing may be transferred to primary care
Further Information	<ul style="list-style-type: none"> • Budesonide (Jorveza™) orodispersible tablets is accepted for use in South East London for inducing and maintaining remission of eosinophilic oesophagitis (EoE). • Jorveza™ is licensed for both inducing and maintaining remission of EoE and recommended for inducing remission of EoE in line with NICE TA 708. • The initiation of Jorveza™ is restricted to the specialist gastroenterology team, who will prescribe for the initial 12 week induction period. • Some patients may benefit from alternative treatment options for the management of EoE before Jorveza™ based on patient factors and preference; this includes treatment with a proton pump inhibitor, or implementing a food elimination diet. • After induction of remission, some patients may require on-going maintenance treatment. Maintenance treatment can be transferred to primary care under the “Amber 2” arrangements, see the primary care information sheet for Jorveza™ for more information. • The recommended dose of Jorveza™ for induction treatment is 1mg twice a day and 1mg or 0.5mg twice a day for maintenance treatment. • The formulary applicant confirmed to the Committee that, in practice, a 12-week induction period is used in all patients suitable for Jorveza™. • The on-going need for maintenance treatment with Jorveza™ and duration of treatment should be regularly reviewed and guided by the specialist gastroenterology team based on symptomatic and endoscopic response. • Gastroprotection is not routinely recommended for patients on Jorveza™ but should be considered for patients at high risk of gastrointestinal bleeding or dyspepsia • Patients treated with Jorveza™ should be counselled on steroid sick day rules and be provided with a steroid treatment card by the initiating specialist. See the Steroid Emergency Card Guidance for Primary Care and the primary care information sheet for Jorveza™ for further information. • This approval is time limited to one year to enable experience of use with Jorveza™ for maintaining remission of EoE. A report summarising outcomes with Jorveza™ over this period will be presented back to the Committee after 1 year. This report will be coordinated across all Trusts in SEL by the original formulary applicant and will include: <ul style="list-style-type: none"> - The total number of patients initiated on Jorveza™ for maintenance treatment across SEL for the management of eosinophilic oesophagitis - Whether use of Jorveza™ is in line with this recommendation and the rationale for any deviation - Patient related outcomes, including: <ul style="list-style-type: none"> (i) Response to treatment (ii) Adverse effects (iii) Number of patients switching from Jorveza™ to alternative treatments
Shared Care/ Transfer of care required:	N/A Practices should be signposted to the Primary Care Information sheet for Jorveza™

Cost Impact for agreed patient group	<ul style="list-style-type: none"> • Due the rarity of the disease and novelty of the treatment the cost of the treatment is higher, with overall maintenance around £2,600 per patient per annum. • Local experts estimate there will be approximately 105 patients eligible for treatment with Jorveza™ per annum, of which 80 – 100% (91 patients) will be SEL • For SEL, assuming 75% of patients require maintenance treatment and 25% require 2 induction courses for 12 weeks per annum, the cost of Jorveza™ would be ~ £193,000 per annum (~£10,000 per 100,000 population). If 100% of SEL patients received maintenance treatment, the cost impact would be ~£238,000 per annum (or ~£12,500 per 100,000 population).
Usage Monitoring & Impact Assessment	<p>Acute Trusts:</p> <ul style="list-style-type: none"> • Monitor and audit usage of Jorveza™ as agreed and report back to the Committee in 12 months (data to be collated and presented no later than March 2024). <p>SEL Borough Medicines Teams</p> <ul style="list-style-type: none"> • Monitor ePACT2 prescribing data. • Exception reports from GPs if inappropriate prescribing requests are made to primary care.
Evidence reviewed	<p>References (from evidence evaluation)</p> <ol style="list-style-type: none"> 1. Miehke S, Lucendo A, Straumann A et al. Orodispersible budesonide tablets for the treatment of eosinophilic esophagitis: a review of the latest evidence. <i>Therapeutics Advances in Gastroenterology</i> 2020 13 p1-15. 2. Greuter T, Bussmann C, Safroneeva E, et al. long-term treatment of eosinophilic esophagitis with swallowed topical corticosteroids: development and evaluation of a therapeutic concept. <i>Am J Gastroenterol</i> 2017; 112:1527–1535. 3. Public Assessment Report – Jorveza. European Medicines Agency 2018. 4. Dhar A, Haboubi H, Attwood S. British Society of Gastroenterology (BSG) and British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPGHAN) joint consensus guidelines on the diagnosis and management of eosinophilic oesophagitis in children and adults. <i>Gut</i> 2022 71 p1459–1487. 5. Lucendo A, Molina-Infante J, Areas A et al. Guidelines on eosinophilic esophagitis: evidence-based statements and recommendations for diagnosis and management in children and adults. <i>United European Gastroenterology Journal</i> 2017, Vol. 5(3) 335–358. 6. Hirano I, Chan E, Rank M. AGA Institute and the Joint Task Force on Allergy-Immunology 7. Practice Parameters Clinical Guidelines for the Management of Eosinophilic Esophagitis. <i>Gastroenterology</i> 2020 158 p1776–1786. 8. Jorveza (budesonide orodispersible tablets), Summary of Product Characteristics. Available here [Accessed 22/08/2022] 9. Public Assessment Report – variation. Jorveza – maintenance use. EMA 2020. Available here [Accessed 22/08/2022] 10. Budesonide orodispersible tablet for inducing remission of eosinophilic oesophagitis. NICE TA708 June 2021. 11. Strauman A, Lucendo A, Miehke S et al. Budesonide Orodispersible Tablets Maintain Remission in a Randomized, Placebo-Controlled Trial of Patients With Eosinophilic Esophagitis. <i>Gastroenterology</i> 2020 159 p1672–1685. 12. Lucendo A, Miehke S, Schlag C et al. Efficacy of budesonide orodispersible tablets as induction therapy for eosinophilic esophagitis in a randomised placebo-controlled trial. <i>Gastroenterology</i> 2019 157 p74-86. 13. Personal communication with Dr. Falk Pharma August 2022.

NOTES:

- a) SEL IMOC recommendations and minutes are available via the [website](#)
- b) This SEL IMOC recommendation has been made on the cost effectiveness, patient outcome and safety data available at the time. The recommendation will be subject to review if new data becomes available, costs are higher than expected or new NICE guidelines or technology appraisals are issued.
- c) **Not to be used for commercial or marketing purposes. Strictly for use within the NHS.**