BNSSG Shared Care Guidance
Please complete all sections

Section 1: Heading

Drug	Budesonide Oro-dispersible tablets "Jorveza"
Amber ***three months***	
Indication	Eosinophilic oesophagitis in adults (≥18 years old) Maintenance treatment (following 12 week induction period)

Section 2: Treatment Schedule

Usual dose and frequency of administration *(Please indicate if this is licensed or unlicensed and any relevant dosing information)*	0.5mg - 1mg twice daily. Higher dose of 1mg twice daily is recommended for patients with long standing disease history and/or high extent of oesophageal inflammation in their acute disease state. This SCP is for maintenance treatment after up to 12 weeks of induction treatment (TLS Red). Prescribing responsibility for maintenance treatment can be transferred to primary care immediately after the 12 weeks of induction treatment has been completed if a specialist review has confirmed that maintenance treatment is required. The first three months of maintenance treatment does not need to be prescribed by the specialist if 12 weeks of induction treatment has already been supplied by them.
Route and formulation	Oral – oro-dispersible tablet placed on tip of the tongue and gently pressed against the roof of the mouth and allowed to dissolve. Swallow with saliva. Take 30 minutes after food.
Duration of treatment	12 month total treatment course (including 12 weeks induction treatment) i.e. 3 months induction treatment from specialist and up to 9 months maintenance treatment from primary care. To be reviewed by the specialist team before end of 12 month treatment course.

Section 3: Monitoring

Please give details of any tests that are required before or during treatment, including frequency, responsibilities (please state whether they will be undertaken in primary or secondary care), cause for adjustment and when it is required to refer back to the specialist.

Baseline tests – where appropriate
Index OGD with biopsy proven eosinophilic oesophagitis (EoE) (> 15 eosinophils/hpf)
Subsequent tests – where appropriate *(Please indicate who takes responsibility for taking bloods and interpreting results)*

Test	Frequency	Who by	Action/management
Outpatient dysphagia assessment	3 – 6 monthly	Specialist health care professional with an interest in EoE	Repeat OGD +/- biopsies if appropriate
OGD +/- dilatation	As required if symptoms severe	Endoscopist	

Section 4: Side Effects

Please list only the most pertinent side effects and management. Please provide guidance on when the GP should refer back to the specialist. For everything else, please see BNF or SPC.

Side effects and management	<table><tr><th>Side effect</th><th>Frequency/severity</th><th>Action/management</th></tr><tr><td>Oral or oesophageal candida</td><td>High frequency but low severity</td><td>Treatment with topical or systemic anti-fungal (Jorveza can be continued during treatment)</td></tr></table>
Referral back to specialist	Hepatic impairment

Section 5: Other Issues

(e.g. Drug Interactions, Contra-indications, Cautions, Special Recommendations)

Please list only the most pertinent action for GP to take (For full list please see BNF or SPC)

Issues	**Contraindications** Hypersensitivity to budesonide or any of the excipients **Cautions** Renal impairment – use in caution in mild-moderate renal impairment. Budesonide is not recommended in severe renal impairment. Hepatic impairment – not recommended in hepatic impairment due to increased risk of corticosteroid side effects. **Infections and vaccination** Increased susceptibility to infections. Chickenpox, herpes zoster and measles may be more serious in patients treated with budesonide. Check vaccination status – care should be taken to avoid exposure. The co-administration of live vaccines should be avoided as the immune response is likely to be reduced. The antibody response to other vaccines may be diminished. **Pregnancy**: Administration during pregnancy should be avoided unless there are compelling reasons for therapy with Jorveza. Although data on the use of inhaled budesonide in a large number of exposed pregnancies indicate no adverse effect, the maximal concentration of budesonide in plasma has to be expected to be higher in the treatment with Jorveza compared to inhaled budesonide. **Breast-feeding** Budesonide is excreted in human milk (data on excretion after inhalative use is available). However, only minor effects on the breast-fed child are anticipated after oral use of Jorveza within the therapeutic range. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from budesonide therapy taking into account the

	benefit of breast-feeding for the child and the benefit of therapy for the woman. **Interactions** CYP3A4 inhibitors Co-treatment with potent CYP3A inhibitors such as ketoconazole, ritonavir, itraconazole, clarithromycin, cobicistat and grapefruit juice may cause a marked increase of the plasma concentration of budesonide and is expected to increase the risk of systemic adverse reactions. Therefore, concomitant use should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid adverse reactions, in which case patients should be monitored for systemic corticosteroid adverse reactions. Ketoconazole 200 mg once daily orally increased the plasma concentration of budesonide (3 mg single dose) approximately 6-fold during concomitant administration. When ketoconazole was administered approximately 12 hours after budesonide, the plasma concentration of budesonide increased approximately 3-fold. ACTH stimulation test for diagnosing pituitary insufficiency might show false results (low values) for patients on budesonide. Cardiac glycosides The action of glycoside can be potentiated by potassium deficiency which is a potential and known adverse reaction of glucocorticoids. Saluretics Concomitant use of glucocorticoids may result in enhanced potassium excretion and aggravated hypokalaemia.
Reminder to ask patient about specific problems	Advise patient regarding interaction with CYP3A4 inhibitors such as ketoconazole, ritonavir, itraconazole, clarithromycin, cobicistat and grapefruit juice.

Section 6: Advice to the patient

Advice for prescribing clinician to inform patient

1. Oro-dispersible tablet should be placed on the tip of the tongue and gently pressed against the roof of the mouth and allowed to dissolve. This usually takes at least 2 minutes but can take up to 20 minutes. Swallow with saliva. Take 30 minutes after food. The oro-dispersible tablet should be taken immediately once removed from the blister package.
2. Jorveza should be taken at least 30 minutes before food, drink or performing oral hygiene. Oral solutions, sprays or chewable tablets should be avoided for at least 30 minutes before and after taking the tablet.
3. This medication needs to be taken regularly. Maintain a soft, easy to swallow diet until dysphagia resolved.
4. Supply Steroid Emergency Cards for patients on doses of 1.5mg or more per day. See BNSSG Guidance on issuing the Steroid Emergency Card in adults

Section 7: Generic principles of shared care for SECONDARY CARE

Please do not amend.

Core responsibilities

1. Initiating treatment and prescribing for the length of time specified in **section 1.**
2. Undertaking the clinical assessment and monitoring for the length of time specified in **section 1** and thereafter undertaking any ongoing monitoring as detailed in **section 3.**
3. Communicate details of the above in 1 and 2 to GP within the first month of treatment. This information should be transferred in a timely manner.
4. Refer patients to GP and provide information of further action where appropriate e.g. if blood test is due.

5. To provide advice to primary care when appropriate.
6. Review concurrent medications for potential interaction prior to initiation of drug specified in **section 1.**
7. Stopping treatment where appropriate or providing advice on when to stop.
8. Reporting adverse events to the MHRA.
9. Reminder to ask patients about particular problems see **section 5.**

Section 8: Generic principles of shared care for PRIMARY CARE

Please do not amend.

Core responsibilities

1. Responsible for taking over prescribing after the length of time specified in **section 1.**
2. Responsible for any clinical assessment and monitoring if detailed in **section 3** after the length of time specified in **section 1.**
3. Review of any new concurrent medications for potential interactions.
4. Reporting adverse events to the MHRA.
5. Refer for advice to specialist where appropriate.
6. Reminder to ask patients about particular problems see **section 5.**

Section 9: Contact Details

Name	Organisation	Telephone Number	E mail address
Dr Amanda Beale	UHBW	0117 342 7208	GastroHepSecs@UHBW.nhs.uk
Cara Leung/ Rebecca Chalker (Gastro specialist pharmacists)	NBT	0117 4142255	gastropharmacists@nbt.nhs.uk
NBT Gastroenterology consultants	NBT	Click here to enter details	gastroenterologyandhepatologysecretaries@nbt.nhs.uk

Section 10: Document Details

Date prepared	April 2022, reviewed April 2024
Prepared by	Dr Amanda Beale and Consultant Nurse Trudy Reed
Date approved by JFG	03/09/2024
Date of review	September 2027
Document Identification: Version	V2

Section 11: Collaboration

All shared care protocols should be BNSSG wide where possible. Specialists in any one discipline are encouraged to collaborate across the health community in preparing shared care guidance. Please give details

1. NBT gastroenterology team

Section 12: References

Please list references

1. Dr Falk Pharma UK Ltd, 2020. Jorveza 1mg orodispersible tablets; SPC. Available from: https://www.medicines.org.uk/emc/product/9446/smpc [Accessed 15.03.2022]

BNSSG Shared Care Guidance

Moderate-Severe Eosinophilic Oesophagitis (EoE) Treatment Pathway (EoE diagnosed at Endoscopy by biopsy from 2 biopsy sites showing greater than 15 eosinophils per hpf)

Timeline	Diagnosis	Plan
0	Confirmed EoE	• Patient seen in clinic or telephoned and diagnosis explained and treatment options discussed * • If appropriate start topical steroid
12 weeks	Re-assessment Confirms full response Partial response ** No change in symptoms or symptoms worsen	• Stop treatment with open follow up if symptoms return • Consider continuing topical steroid (up to 12 month total depending upon symptoms) • Consider referral to dietician to offer food exclusion diet • Telephone follow up in 3 months • Discuss treatment compliance, reiterate importance of daily use • Urgent referral to dietician to offer food exclusion diet • Consider continuing topical steroid treatment if index OGD showed severe*** fibrosis

		• Urgent OGD and biopsy (+/- dilatation if appropriate) • Consider barium swallow or referral to GI Physiology • Outpatient follow up once OGD +/- Barium Swallow complete
12 weeks +	Symptoms return after break in topical steroid treatment.	• Discuss severity of symptoms in clinic (if not already completed consider barium swallow or repeat OGD & biopsies) • ****Discuss option of extended course of steroid treatment • Discuss OGD + dilatation if dysphagia causing significant problems with swallowing (unable to maintain nutrition) • Re-commence initial 4–6-week course of topical steroid treatment. Contact GP detailing the plan and requesting continuation of topical steroid medication for up to 12 months treatment in total. • Request outpatient follow up/ review (to be completed prior to completion of 12 months treatment)

		• Ensure patient is aware of the plan and is aware of how to contact the hospital if symptoms change.
12 months if steroid treatment continued	Re-assessment	• Review patient before completion of 12 months of topical steroid and review symptoms/response to treatment • Discuss regular dilatation for ongoing symptom control if necessary • If no response to topical steroid treatment then request repeat OGD +/-biopsy if patient has not been re-scoped & biopsied as part of ongoing symptom treatment with dilatation.

*vast majority of patients have received at least 1 course of PPI treatment prior to OGD for dysphagia (as per NICE guidance for reflux type symptoms). Continued use/value of PPI will depend upon symptom benefit, clinical picture and histopathology

** it is hard to quantify how many patients will respond fully in 3 months. This will depend upon the severity of the eosinophilic degradation and fibrotic damage. The index OGD will provide information on the level of mucosal damage and fibrosis, this coupled with the length of time symptoms have been present and the level of symptoms will provide an indication of severity. The more severe the EoE damage the more likely a lengthy course of topical steroids will be required to reverse the damage.

*** severe – some stricturing already present, heavy white plaques (abscesses that form when eosinophils burst in clumps atop the mucosa), crepe paper oesophagus (white, indurated sub mucosa with a friable surface mucosa that tears easily as you advance the scope) +/- admission with food bolus

**** For every year EoE goes untreated the risk of stricture formation increases by 9% (*Warners MJ et al. Am J Gastroenterology 2018; 113(6): 836-44*.)