AWTTC
All Wales Therapeutics & Toxicology Centre
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

Enclosure No:	4/AWMSG/0526
Agenda Item No:	8 – Budesonide (Jorveza®) for maintaining remission of eosinophilic oesophagitis in adults (4507)
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Action for AWMSG:
Members are asked to consider the decision rationale and endorse the recommendation made by the Licensed One Wales Medicines Assessment Group (LOWMAG) to confirm that the decision-making process has been completed robustly and consistently.

Purpose:
Licensed medicines may be assessed by the AWMSG limited assessment route if the AWMSG Scrutiny Panel determine that specific criteria have been met which justify that the review of clinical evidence (if appropriate), budget impact, equity of access and wider societal issues is sufficient to make a robust recommendation on access to the medicine in NHS Wales. LOWMAG has considered and discussed the evidence presented in an Evidence Summary Report (ESR) compiled by AWTTC, the views of clinicians and patients, and comments from the Marketing Authorisation holder, and has provided a recommendation with rationale to the All Wales Medicines Strategy Group (AWMSG). AWMSG is being asked to endorse the LOWMAG recommendation which will then be forwarded to Welsh Government for ratification.

Overview:
The AWMSG Scrutiny Panel decided that budesonide (Jorveza®) orodispersible tablets was suitable for a limited assessment via the Licensed One Wales Medicines Assessment Group (LOWMAG) as the medicine is recommended for maintaining remission EoE in a joint consensus guideline by the British Society of Gastroenterology and the British Society of Paediatric Gastroenterology, Hepatology and Nutrition, and the budget impact is likely to be low as the treatment is already being prescribed to patients across NHS Wales. As the treatment isn't included in a NICE guideline, the AWMSG Scrutiny Panel agreed that the limited assessment should consider the evidence for clinical effectiveness.

Attached is the LOWMAG recommendation and accompanying rationale for:

Budesonide (Jorveza®) orodispersible tablets for maintaining remission of eosinophilic oesophagitis in adults.

The ESR has been provided separately for information.

If you have any questions regarding the ESR, LOWMAG recommendation or decision rationale, please email awttc@wales.nhs.uk by 13th of May 2026.

The assessment lead will respond to your query by email ahead of the meeting and will also provide a verbal summary at the meeting of any significant issues raised. It is anticipated that there will be no discussion required on the day, however, there will be opportunity to clarify any outstanding issues.

Once the LOWMAG recommendation has been endorsed by AWMSG, it will be forwarded to Welsh Government for ratification. In exceptional circumstances, where AWMSG is unable to endorse the recommendation by LOWMAG, the reasons for non-endorsement must be fully justified and will be raised with LOWMAG for further consideration. This will allow for recommendations to be re-considered by AWMSG subject to further information being supplied by LOWMAG.

Licensed One Wales Medicines Assessment Group Recommendation
Budesonide (Jorveza®) orodispersible tablets

Date of advice: April 2026
AWTTC reference number: 4507

Recommendation to the All Wales Medicines Strategy Group (AWMSG)

Budesonide (Jorveza ®) orodispersible tablets are recommended for use in NHS Wales for maintaining remission of eosinophilic oesophagitis in adults.

This recommendation is interim to the publication of NICE Technology Appraisal GID-TA11623.

This recommendation will be reviewed if there is new evidence that is likely to change it.

Licensed One Wales Medicine Assessment Group summary of decision rationale

Medicine: **Budesonide (Jorveza®) orodispersible tablets**
Assessment type: **Limited**
Indication: **Maintaining remission of eosinophilic oesophagitis in adults**

Meeting date: **15 April 2026**

Criteria	LOWMAG opinion
Clinical effectiveness	LOWMAG considered the evidence provided by the BUL-2 study, which is deemed the most relevant source of evidence pertinent to the assessment. The group noted the favourable remission rates in adult patients with eosinophilic oesophagitis (EoE) who received orodispersible budesonide at a dose of 0.5 mg twice daily and 1 mg twice daily, versus those who received placebo (73.5%, 75% and 4.4% respectively). The group recognised that the median time to relapse in the placebo group was 87 days; 50% of patients in the placebo group relapsed within 3 months. LOWMAG considered evidence from a 96-week open-label extension (OLE) study of BUL-2, where the high rates of clinical remission reported in the BUL-2 study were maintained. At 96 weeks, 81.9% of patients were in clinical remission versus 77.7% at OLE baseline, and 80.1% patients were in histological remission versus 91.8% at OLE baseline. LOWMAG considered the safety profile of orodispersible budesonide when used to maintain remission of EoE in adults. The most frequently reported adverse effects were acknowledged, which were localised candidiasis and low cortisol levels. These were comparable to the expected safety profile for the medicine. LOWMAG asked the clinical expert to share their experience of managing candidiasis in their patients. The clinical expert noted that usually, one course of nystatin is sufficient to treat the infection. They noted that, for patients experiencing recurrent episodes of candidiasis, reducing the dose of orodispersible budesonide from twice daily to once daily (off-label dose) has helped to address this. LOWMAG concluded that the favourable remission rates reported in the BUL-2 study and the subsequent OLE study suggests that orodispersible budesonide is a clinically effective treatment for maintaining remission of EoE in adults. LOWMAG also concluded that the adverse events reported in the clinical studies and the summary of product

	characteristics suggests that the treatment is a tolerable regimen.
Cost-effectiveness	As this is a limited assessment cost effectiveness is not considered.
Budget impact	LOWMAG considered the company's estimated patient uptake to be an overestimate as it assumes that all prevalent patients would be eligible for treatment. LOWMAG acknowledged AWTTC's lower estimate of patient uptake which is based on linear extrapolation of NHS Wales prescribing data. LOWMAG concluded that the true patient uptake is challenging to estimate, but the estimate from AWTTC is likely to more closely reflect practice. LOWMAG agree that the annual re-induction with orodispersible budesonide is an appropriate comparator, which was reflected in AWTTC's budget impact. However, LOWMAG acknowledged that, as orodispersible budesonide is currently used across NHS Wales to maintain remission of EoE, the comparators used in both the company and AWTTC budget impact model do not accurately represent current practice. LOWMAG considered the cost-savings afforded by orodispersible budesonide through avoidance of elective procedures, emergency admissions, and GP visits. LOWMAG acknowledge that the extent of this cost-saving is challenging to quantify due to paucity of NHS Wales-specific data. LOWMAG acknowledged that, in practice, some NHS Wales clinicians prescribe orodispersible budesonide at the licensed doses for maintenance treatment, whereas others prescribe an off-label dose of 1 mg once daily. LOWMAG acknowledged that although this assessment relates to the licensed posology of orodispersible budesonide, the off-label prescribing practice of some NHS Wales clinicians is considered in AWTTC's budget impact to reflect real-word prescribing. LOWMAG acknowledge that prescribing the off-label dose of orodispersible budesonide is associated with a lower budget impact than the licensed doses. LOWMAG acknowledges that there is already uptake and NHS Wales spend on orodispersible budesonide from all health boards in Wales. Therefore, LOWMAG considers that the additional acquisition cost of making orodispersible budesonide routinely available to all eligible patients throughout Wales to be low.
Resource use	LOWMAG concluded that maintenance treatment of EoE with orodispersible budesonide is anticipated to reduce the

	amount of clinic time for secondary care clinicians, the requirements for elective oesophagogastro duodenoscopy (OGD), and the number of emergency admissions for the management of food bolus obstruction compared to comparator treatments. The patient organisation representative highlighted that the requirement for re-induction(s) with orodispersible budesonide treatment to manage relapses adds to service workload and costs, as patients require appointments with GPs and secondary care specialists to manage their symptoms and achieve remission.
Other factors	LOWMAG recognised that orodispersible budesonide is the only UK-licenced oral treatment option for maintaining remission of EoE in adults. LOWMAG noted that an AWMSG statement of advice was issued in 2020, indicating that the use of orodispersible budesonide to maintain remission of EoE in adults could not be endorsed. LOWMAG acknowledged that, despite this statement of advice and the non-formulary status of orodispersible budesonide in the majority of health boards across Wales, several clinicians continue to prescribe the treatment. LOWMAG noted that NICE have guidance awaiting development for orodispersible budesonide for maintaining remission of EoE in people aged 2 years and over (GID-TA11623). LOWMAG acknowledged that the recommendation made by LOWMAG will be interim to the publication of NICE Technology Appraisal GID-TA11623. LOWMAG acknowledged the testimony of a clinical expert who stated that EoE can significantly impact a patient's quality of life and can lead to food bolus obstruction requiring emergency endoscopy. They noted that they currently prescribe orodispersible budesonide to maintain remission of EoE at both the licensed dose, and an off-label dose of 1 mg once daily, which they have found to be effective. The clinical expert highlighted the resource burden associated with relapses of EoE by sharing local audit data. They noted that 10% of their patients in non-remission required an urgent endoscopy and dilatation procedure due to significant symptoms. The expert noted that, of those patients in non-remission, the majority were managed via either proton pump inhibitor therapy or dietary elimination or had stopped orodispersible budesonide treatment.

	LOWMAG noted the testimony of a patient organisation representative who stated that orodispersible budesonide is an important treatment option for maintaining remission of EoE. The patient organisation representative highlighted that there is inequity of access to orodispersible budesonide for maintenance treatment across the UK. LOWMAG acknowledged that, without effective maintenance treatment, patients often relapse placing a significant burden on patients and primary and secondary care resources. LOWMAG acknowledged the view of the company, who noted that in areas where orodispersible budesonide treatment is limited to induction, the rate of complications and emergency admissions is high, resulting in additional service burden.
Final recommendation	LOWMAG recommends the use of budesonide (Jorveza®) orodispersible tablets for use in NHS Wales for maintaining remission of eosinophilic oesophagitis in adults.
Summary of rationale	LOWMAG recognises that orodispersible budesonide is recommended for maintaining remission of EoE in adults in the 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 (2022), and data from the BUL-2 and subsequent OLE study provides evidence for its clinical effectiveness in this indication. LOWMAG acknowledge that there is a risk of inequity of access to orodispersible budesonide for maintaining remission of EoE between Wales and some other areas of the UK, as some Integrated Care Boards in England have made the treatment available to patients. LOWMAG recognises that the use of orodispersible budesonide to maintain remission of EoE may reduce the resource burden associated with managing EoE due to the need for fewer OGD interventions and emergency admissions. LOWMAG consider that making orodispersible budesonide routinely available throughout NHS Wales will have a low service impact. LOWMAG consider the additional acquisition cost of making orodispersible budesonide routinely available to all eligible patients throughout Wales to be low, as clinicians are already prescribing the treatment to patients across NHS Wales.