Eosinophilic oesophagitis (EoE) causing food bolus obstruction in adults: an integrated pathway

For patients aged 18+ years

ENTER

Development of this optimal pathway was supported by Wilmington Healthcare, funded by an educational grant from Dr Falk.

February 2024 - WHCB17414

Foreword

Failure to diagnose eosinophilic oesophagitis (EoE) is a serious barrier to optimal patient care, resulting in a cycle of persistent episodes of food bolus obstruction (FBO), sometimes leading to repeat attendances at accident and emergency (A&E) departments and delays before appropriate treatment. Even once the condition is diagnosed, delays in starting licensed treatment and logistical issues with repeat prescribing can impact on the patient's management. A clear integrated pathway is needed to optimise the management of the increasing number of patients with this chronic condition.

EoE is a chronic condition in which eosinophils infiltrate the oesophageal epithelium and fibrosis develops in the submucosa.[1-7] It is characterised clinically by symptoms related to oesophageal dysfunction, such as solid-food dysphagia, food impaction, and non-swallowing-/swallowing-related chest pain and histologically by eosinophil-predominant inflammation.[1,2,8–10]

Patients with EoE typically have the condition for many years and become used to being aware of food travelling down their oesophagus.[8,10] They may adapt their eating in order to avoid these sensations – for example, drinking large amounts of water or only eating foods that are known to travel smoothly down the oesophagus.[10] They are prolonged chewers, slow to eat and the last to finish a meal,[8] so they often avoid eating out and become socially isolated.

Rarely detected 30 years ago, EoE is becoming common. Pooled estimates of global annual incidence and prevalence are 5.3 and 40/100,000 population, respectively,[7] but US and European prevalence rates are much higher at 79-118/100,000.[4,6]

The observed increase is a real increase in disease frequency, as it is mirrored by an increase in the frequency of FBO presenting to A&E departments. Indeed, FBO is now one of the most common gastrointestinal emergency admissions.

Guidelines developed by the British Society of Gastroenterology (BSG) and British Society of Paediatric Gastroenterology and Nutrition (BSPGHAN)[11] give clear guidance on what should be done for these patients. If these guidelines could be followed, the quality of patient care would be dramatically improved, providing clear diagnosis, effective treatment, and cost efficiency for both the health service and the patient.

Professor Stephen E Attwood
Honorary Professor, Health Services Research, Durham University, UK

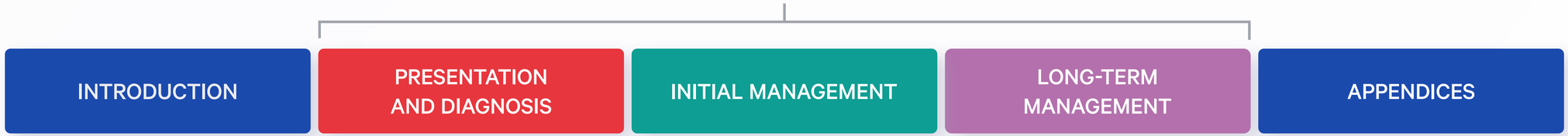
This document sets out an optimal pathway based on recommended best practice for the management of EoE. It has been developed based on consensus of expert groups combined with insights from interviews with stakeholders involved at all stages of the pathway. It behoves clinicians in primary care and each hospital trust to put this into practice – the sooner the better, given how quickly the incidence of EoE is rising.[2]

A&E, accident and emergency; BSG, British Society of Gastroenterology; BSPGHAN, British Society of Paediatric Gastroenterology, Hepatology and Nutrition; EoE, eosinophilic oesophagitis; FBO, food bolus obstruction.

How to use this document

The integrated care pathway is used as a menu system for this interactive document.

The pathway is divided into three sections, with an algorithm and bulleted list of actions for each stage of the pathway. The sections are colour coded throughout the document:

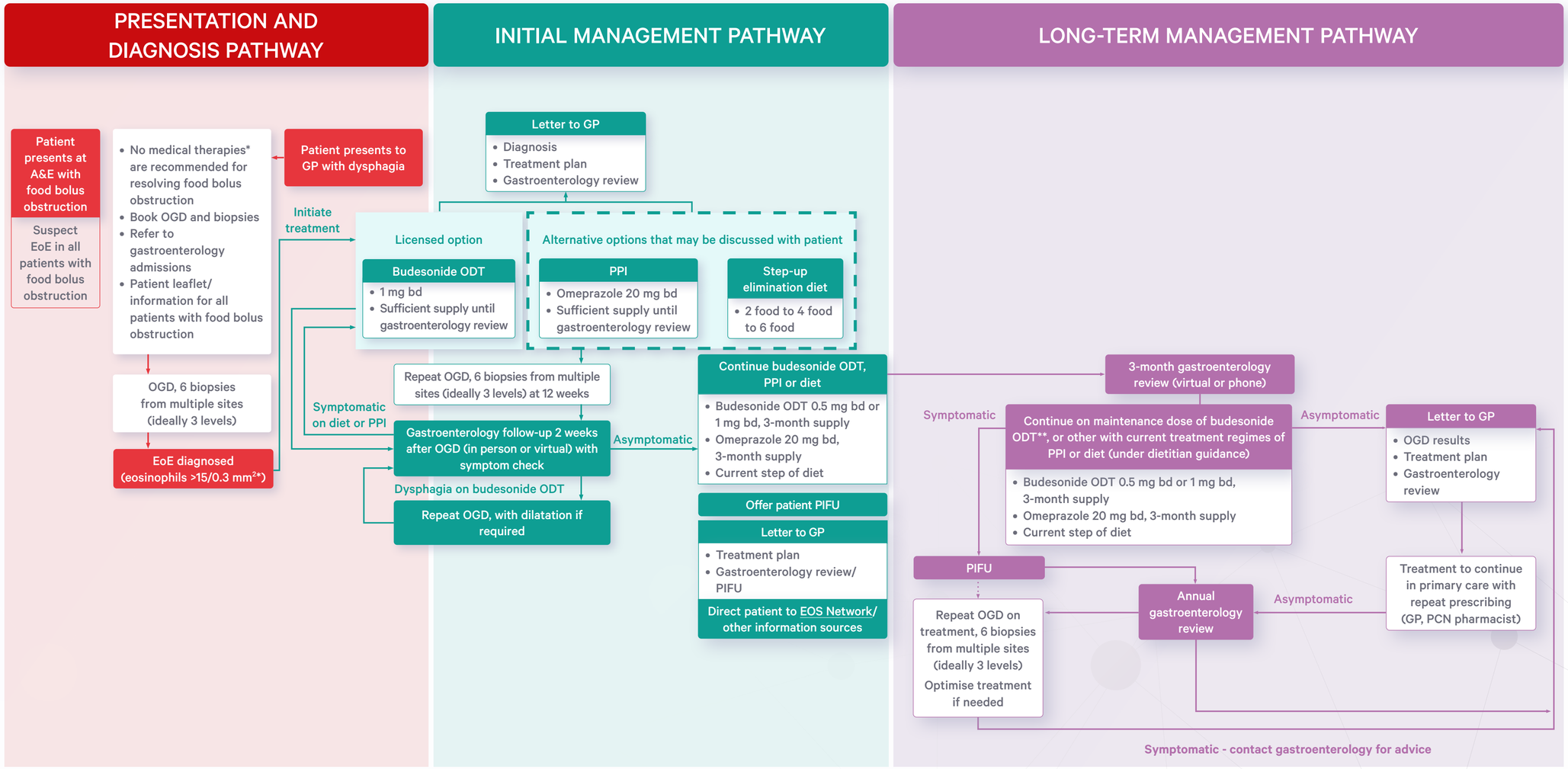


CLICK ON THE ICONS

- Information button for more detail
- Forward button to move to the next page
- Back button to move to the previous page
- Close button to return to the pathway
- Home button to return to the full pathway

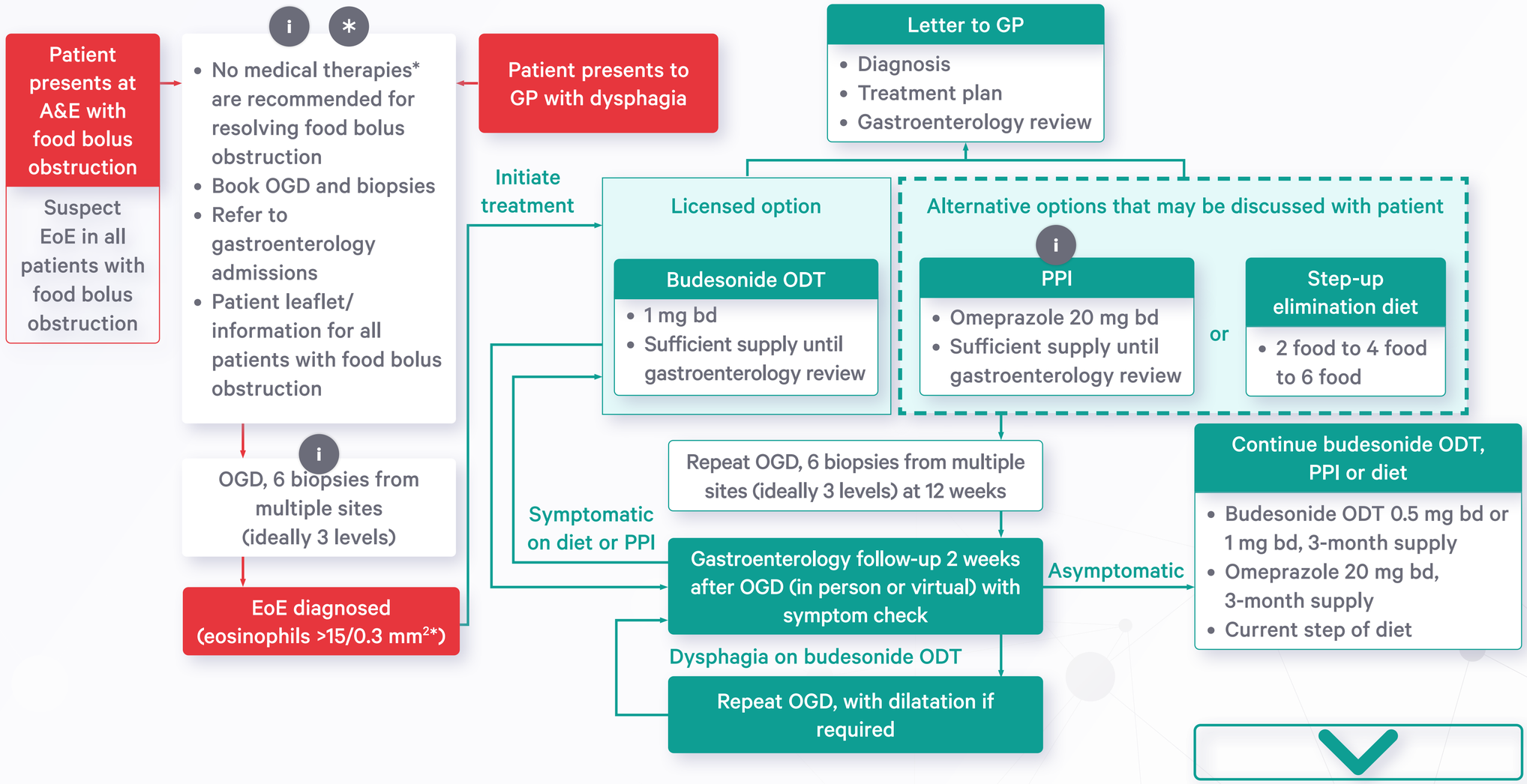
Appendix 1 contains a list of references used in this document, which can be accessed through the button on each page.

Overview of the pathway



*Formerly per high-power field. ** Ensure appropriate maintenance shared care treatment plan is in place.
A&E, accident and emergency; EoE, eosinophilic oesophagitis; GP, general practitioner; ODT, oral dispersible tablet; OGD, oesophago-gastro-duodenoscopy; PCN, primary care network; PIFU, patient-initiated follow-up; PPI, proton pump inhibitor.

Integrated care pathway for EoE (1)



*Formerly per high-power field. ** Ensure appropriate maintenance shared care treatment plan is in place.
A&E, accident and emergency; bd, twice daily; ENT, ear, nose and throat; EoE, eosinophilic oesophagitis; GP, general practitioner; ODT, oral dispersible tablet; OGD, oesophago-gastro-duodenoscopy; PCN, primary care network; PIFU, patient-initiated follow-up; PPI, proton pump inhibitor

Pathway

Presentation

Presentation in A&E

Presentation in A&E – referral, OGD and patient information

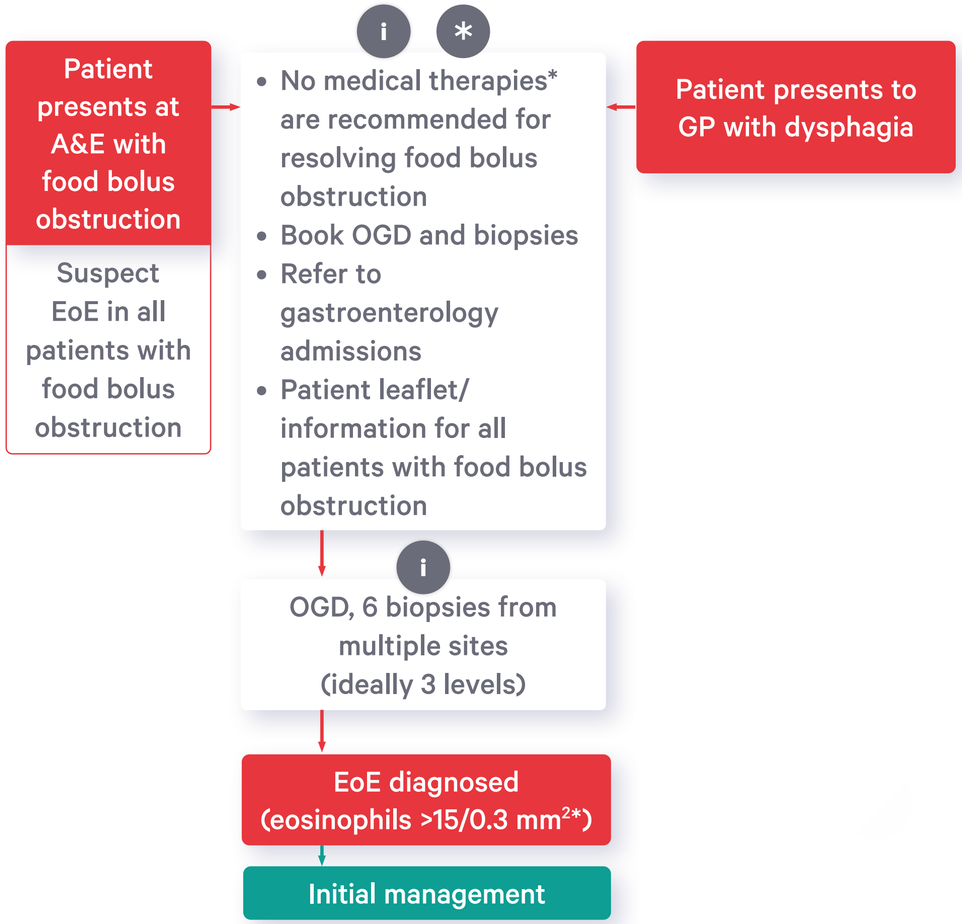
Presentation in primary care

OGDs

Six biopsies at 3 levels

Eosinophils in oesophageal epithelium

Presentation and diagnosis pathway

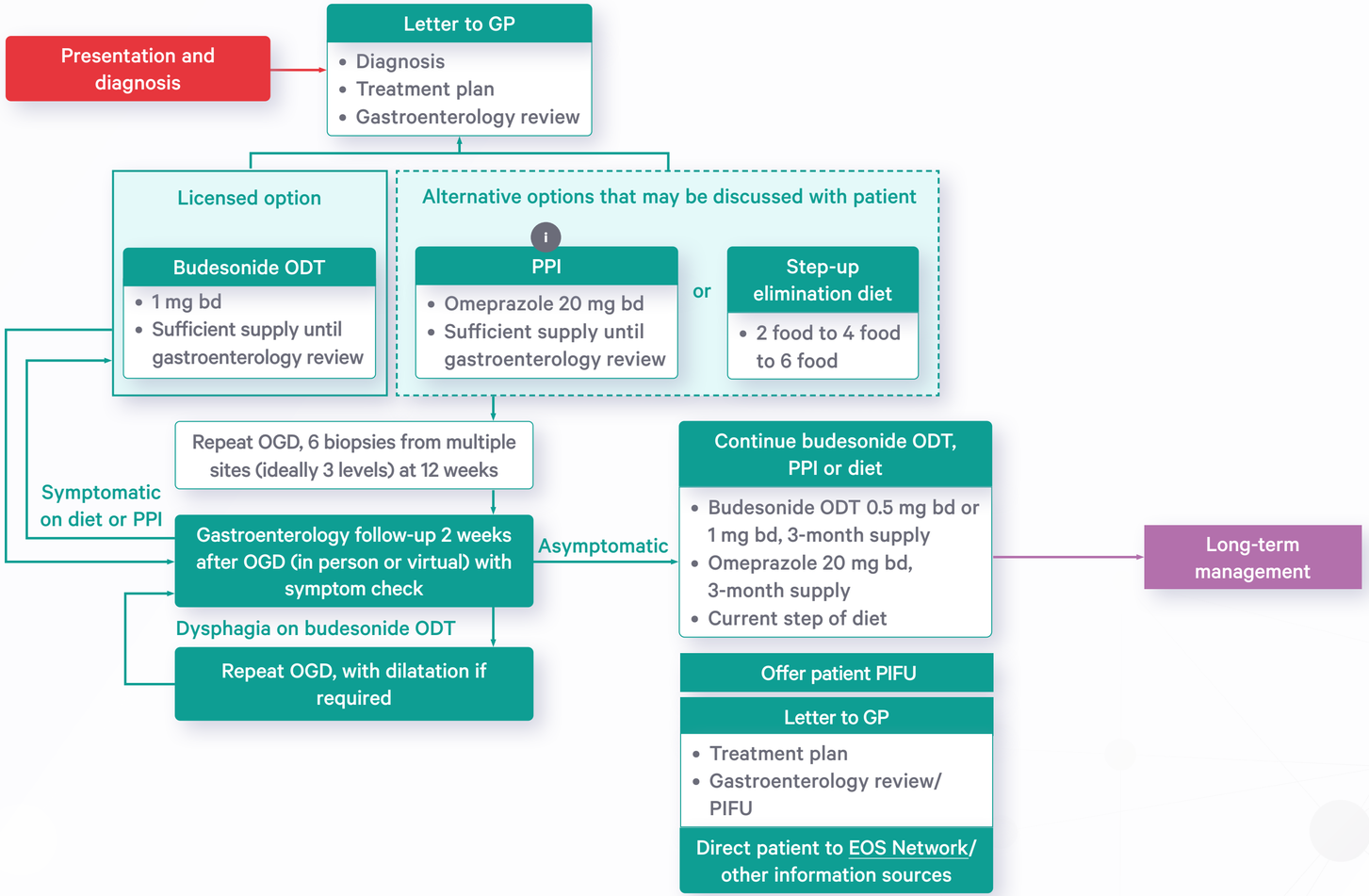


- In adults, food bolus obstruction and dysphagia are strongly associated with a diagnosis of EoE, which rarely resolves spontaneously.[11]
- Initial treatment:[11]
  - Remove food bolus obstruction
  - Perform immediate dilatation if indicated
  - Chest X-ray if a patient with food bolus obstruction has clinical distress or signs of surgical emphysema to assess for mediastinal air before urgent endoscopy[11,22]
  - Do not start a PPI or try other conservative treatments.
- Refer urgently to gastroenterology.
- Book OGD with biopsies before the patient leaves:
  - OGD within 6 hours if the patient is distressed
  - OGD within 24 hours if acute food bolus obstruction/or patient cannot swallow own saliva with high risk of aspiration
  - OGD within 2–4 weeks if food bolus obstruction resolves to ensure EoE can be diagnosed before another food bolus obstruction event.
- Provide patient leaflet/information for all patients.
- Diagnosis of EoE requires OGD with biopsies:
  - Biopsies should be taken even if the oesophagus looks normal[8]
  - At least six biopsies should be taken from three sites[9,14] (two from each of top, middle and lower oesophagus)
  - EoE is confirmed when >15 eosinophils per 0.3 mm^2 of oesophageal epithelium.[9]*

*Formerly per high-power field.
A&E, accident and emergency; ENT, ear, nose and throat; EoE, eosinophilic oesophagitis; GP, general practitioner; OGD, oesophago-gastro-duodenoscopy; ODT, oral dispersible tablet; PPI, proton pump inhibitor.

Pathway
Treatment summary
Diet and unlicensed drugs
Diets are variably effective
PPIs
Corticosteroids
Licensed for treatment of EoE in adults
Indicated for induction of remission in EoE
Effective at inducing remission in EoE

Initial management



- Discuss treatment options with patient once diagnosis is confirmed:
  - Budesonide ODT: provide 4-month supply of 1 mg bd
  - PPI: provide 4-month supply of 20 mg bd
  - With the guidance of a dietitian: step-up elimination diet – 2 food to 4 food to 6 food
- Book OGD with biopsies at 12 weeks for patients opting for diet/PPI
- Arrange gastroenterology follow-up (in person or virtual) at 14 weeks
- Send letter to GP:
  - Confirm diagnosis, treatment plan and timing of next gastroenterology review
- 3-month gastroenterology follow-up, including symptom check:
  - If patient is asymptomatic,

Read more

bd, twice daily; EoE, eosinophilic oesophagitis; GP, general practitioner; ODT, oral dispersible tablet; OGD, oesophago-gastro-duodenoscopy; PIFU, patient-initiated follow-up; PPI, proton pump inhibitor.

Pathway

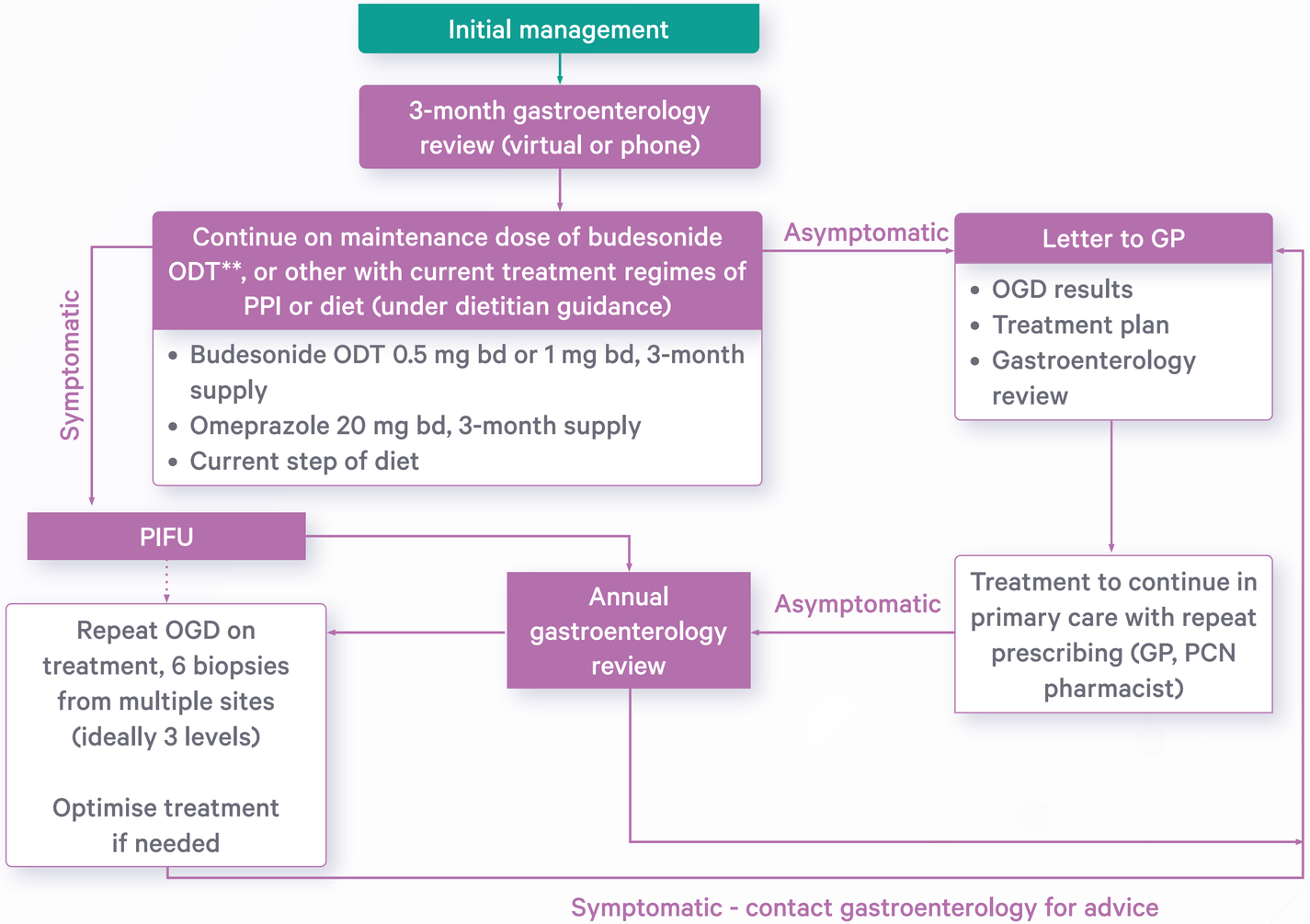
Relapse

Maintains remission in EoE

Indicated for maintenance in EoE

Ensuring continued access

Long-term management



- Gastroenterology symptom check at 3 months (virtual or phone)
  - Continue budesonide ODT, PPI or diet
    - Budesonide ODT 0.5 mg bd or 1 mg bd, 3-month supply
    - Omeprazole 20 mg bd, 3-month supply
    - Current step of diet under guidance of dietitian
  - Letter to GP
    - Confirm OGD results, treatment plan, PIFU is in place and timing of next gastroenterology review.
- Repeat prescribing:
  - Budesonide ODT by GP if possible or via gastroenterology secretary if not
  - PPI via GP
- Annual gastroenterology follow-up:
  - Continue budesonide ODT, PPI or diet if patient is asymptomatic
    - Budesonide ODT 0.5 mg bd or 1 mg bd, 3-month supply
    - Omeprazole 20 mg bd, 3-month supply

Read more

**Ensure appropriate maintenance shared care treatment plan is in place.
GP, general practitioner; ODT, oral dispersible tablet; OGD, oesophago-gastro-duodenoscopy; PCN, primary care network; PIFU, patient-initiated follow up; PPI, proton pump inhibitor.

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Contributors

The optimal pathway described in this document has been developed based on consensus of an expert group combined with insights from interviews with stakeholders involved at all stage of the pathway.

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Development of this optimal pathway was supported by Wilmington Healthcare, funded by an educational grant from Dr Falk.

Supporting information

Adverse events should be reported. In the UK visit www.mhra.gov.uk/yellowcard. In Ireland: https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form.

Adverse events should also be reported to Dr Falk Pharma UK Ltd on pv@drfalkpharma.co.uk or 0044 (0)1628 536600.

Prescribing Information (refer to full SmPC before prescribing).

Presentations: Jorveza 1 mg and 0.5 mg orodispersible tablets containing 1 mg or 0.5 mg of budesonide. Indications: treatment of eosinophilic esophagitis (EoE) in adults (older than 18 years of age). Dosage: Induction of remission: one 1 mg tablet taken twice daily (morning and evening) after a meal and immediately after removal of the tablet from the blister pack. Usual duration of induction treatment is 6 weeks. Extend up to 12 weeks for non-responding patients. Maintenance of remission: 0.5 mg twice daily or 1 mg twice daily depending on clinical need. A maintenance dose of 1 mg twice daily is recommended for patients with long-standing disease history and/or high extent of esophageal inflammation in the acute disease state. Duration of maintenance treatment - to be determined by the treating physician. Administration: tablet is placed on tip of tongue and pressed to top of mouth then swallowed slowly without liquid or food and without chewing or swallowing undisintegrated. May take 2 to 20 minutes to disintegrate and swallow completely. Wait at least 30 minutes before eating, drinking or performing oral hygiene. Contra-indications: hypersensitivity to budesonide or any ingredient of the tablets. Warnings/precautions: infections - Suppression of inflammatory response and immune function increases susceptibility to infections and their severity which can be atypical or masked. Oral, oropharyngeal and esophageal candida infections occur at high frequency. Treat symptoms with topical or systemic anti-fungals. Jorveza treatment can continue. Chickenpox, herpes zoster and measles - can be more serious in patients treated with glucorticosteroids. Check vaccination status. Avoid exposure. Vaccines - avoid co-administration of live vaccines and glucocorticosteroids. The antibody response to other vaccines may be diminished. Special populations - monitor patients with tuberculosis, hypertension, diabetes mellitus, osteoporosis, peptic ulcer, glaucoma, cataract, family history of diabetes, family history of glaucoma. Systemic effects of glucocorticosteroids may occur, depending on duration of treatment, concomitant and previous glucocorticosteroid treatment and individual sensitivity. Patients with reduced liver function - an increased systemic availability of budesonide may be expected, with increased risk of adverse reactions.

Patients with hepatic impairment should not be treated. Not recommended for use in patients with severe renal impairment. Angioedema - treatment should be stopped if signs of angioedema are observed. Visual disturbance - patients with blurred vision or other visual disturbances should be considered for referral to an ophthalmologist. Causes may include cataract, glaucoma or central serous chorioretinopathy resulting from corticosteroid use. Others - glucocorticosteroids may cause suppression of the hypothalamic–pituitary–adrenal (HPA) axis and reduce the stress response. When patients are subject to surgery or other stresses, supplementary systemic glucocorticosteroid treatment is therefore recommended. Concomitant treatment with ketoconazole or other CYP3A4 inhibitors should be avoided. Serological testing - adrenal function may be suppressed by budesonide so an ACTH stimulation test for diagnosing pituitary insufficiency might show false (low) results. Sodium - contains 52 mg of sodium per daily dose. Interactions: CYP3A4 inhibitors - concomitant treatment with ketoconazole or other potent CYP3A inhibitors including grapefruit juice should be avoided to reduce the risk of systemic side effects unless the benefit outweighs the risk. Such treatment should be monitored.

Oestrogens, oral contraceptives - may elevate plasma concentrations and enhance effects of glucocorticosteroids. Concomitant intake of low-dose combination oral contraceptives has not shown this effect. Cardiac glycosides - action of glycoside can be potentiated by potassium deficiency - a potential and known adverse reaction of glucocorticoids. Saluretics - potassium excretion can be enhanced and hypolalaemia aggravated. Use in pregnancy should be avoided unless there are compelling reasons for therapy. Breast-feeding - budesonide is excreted in human milk. The benefit of breast feeding for the child and the benefit of therapy for the woman should be assessed. Fertility - there are no data on the effect of budesonide on human fertility. Undesirable effects: fungal infections in the mouth, pharynx and the oesophagus were the most frequently observed adverse reactions in clinical studies. Long term treatment did not increase the rate. Adverse reactions and frequencies: Very common: esophageal candidiasis, oral and/or oropharyngeal candidiasis,

Common: sleep disorder, headache, dysgeusia, dry eyes, gastroesophageal reflux disease, nausea, oral paraesthesia, dyspepsia, upper abdominal pain, dry mouth, glossodynia, tongue disorder, oral herpes, fatigue, blood cortisol decreased. Uncommon: nasopharyngitis, pharyngitis, angioedema, , anxiety, agitation, dizziness, , hypertension, cough, dry throat, oropharyngeal pain, abdominal pain, abdominal distension, , dysphagia, erosive gastritis, gastric ulcer, lip edema, gingival pain, rash, urticaria, sensation of foreign body, osteocalcin decreased, weight increased. . Other (class) effects with unknown frequency that may occur: increased risk of infection, Cushing's syndrome, adrenal suppression, growth retardation in children, hypokalaemia, hyperglycaemia, depression, irritability, euphoria, psychomotor hyperactivity, aggression, pseudotumor cerebri including papilloedema in adolescents, glaucoma, cataract (including subcapsular cataract), blurred vision, central serous chorioretinopathy (CSCR), increased risk of thrombosis, vasculitis (withdrawal syndrome after long-term therapy), duodenal ulcers, pancreatitis, constipation, allergic exanthema, petechiae, delayed wound healing, contact dermatitis, ecchymosis, muscle and joint pain, muscle weakness and twitching, osteoporosis, osteonecrosis, malaise.

Legal category: POM. **Cost:** 1 mg - pack of 90 - £323; 0.5 mg - pack of 60 - £214.80. Not currently available in Ireland. **Product licence holder:** Dr. Falk Pharma GmbH. **Product licence number:** IE/NI: 1 mg: EU/1/17/1254/004, 0.5 mg: EU/1/17/1254/008. GB: 1 mg: PLGB08637/0030; 0.5 mg: PLGB08637/0032. **Date of preparation:** February 2023.

Further information is available on request.

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Date of Preparation: February 2024. UK2400014.