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DRUG ASSESSMENT SUMMARY

Product	Summary	Decision
Budesonide orodispersible 1mg tablets (Jorveza®)	**Introduction:** Budesonide 1mg orodispersible tablets (Jorveza®) have been requested to be included onto the formulary, for its licensed indication of the treatment of eosinophilic oesophagitis. The treatment is a 6 week course of 1mg twice daily. If the patient responds to treatment but symptoms not fully resolved a further 6 week course can be prescribed. The tablet should be dissolved against the roof of the mouth through frequent swallowing the dispersed material provides topical application to the oesophagus. Food, drink or any oral medication must be avoided for at least 30 minutes after the tablet has fully dispersed. PACEF recommended that treatment should be classed as AMBER 2. Therefore it will be appropriate for the initial treatment and subsequent 6 week course to be prescribed in primary care on the advice of a specialist. **Further relevant information:** Eosinophilic oesophagitis is a chronic immune-mediated, inflammatory disease of the oesophagus. It is characterised by oesophageal dysfunction: dysphagia, bolus obstruction, chest pain associated with inflammation, potentially progressing to oesophageal remodelling and stricture formation; and histological changes. In severe acute cases, emergency admission may be necessary. Patients may suffer social embarrassment and isolation as a result of symptoms. This condition is rare and it is anticipated that only 20 patients per year may be diagnosed with eosinophilic oesophagitis in Lincolnshire, Until this product was launched there have been no licensed therapies to treat this condition. Current management options have been either the unlicensed use of proton pump inhibitors(PPI's) or the use of a corticosteroid containing inhaler such as fluticasone , or a nebuliser solution of a corticosteroid prepared as a viscous slurry mixture which can be swallowed. There are no licensed or recommended doses for using the corticosteroid inhalers or nebuliser solutions. There are currently no NICE guidelines covering the management of this condition although a NICE technology appraisal for budesonide orodispersible tablets is anticipated in July 2020.	Approved for inclusion on the formulary as AMBER 2.
Fixapost eye drops (latanoprost 50mcg and timolol 5mg per 1ml)	**Introduction:** Fixapost® is a new combination preservative free eye drops, licensed for the reduction of intraocular pressure (IOP) in patients with open angle glaucoma and ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues. Fixapost eye drops are preservative free single unit dose vials. Each vial is 0.2ml, with 1ml containing latanoprost 50 micrograms and timolol maleate equivalent to 5 mg timolol. One drop contains approximately 1.5 micrograms of latanoprost and 0.15 mg of timolol.	Approved for inclusion on the formulary as first line when a preservative free combination of latanoprost and timolol is required. Classed as AMBER 2.

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	Further relevant information: Current UK guidelines suggest using combination products containing a prostaglandin plus beta-blocker when required during stepping up in treatment of glaucoma. While Fixapost costs more than the preservative containing generic latanoprost/timolol eye drops, it is significantly lower cost than if two separate preservative free preparations containing timolol and latantoprost are used. **Please note – Preservative free formulations should only be used in genuine cases of hypersensitivity to the preservative or following corneal transplant surgery.**	
Ketotifen tablets 1mg or Ketotifen sugar free elixir 1mg/5ml.	**Introduction:** ULHT based specialist has requested the addition of ketotifen to the formulary for the management of symptoms associated with mast cell activation disease. This use will be off-label. Ketotifen is a sedative antihistamine, licensed for the treatment of allergic rhinitis. It is currently classed as RED/RED non-formulary. **Further relevant information:** Mast Cell Diseases is an umbrella term to describe the family of conditions that affect the number and functioning of mast cells in the body including, the various forms of mastocytosis, mast cell activation syndrome (MCAS), and familial alpha-tryptasemia. The main stay of treatment is avoidance of triggers and initially treatment options include the use of H1 and H2 antihistamines. There are no licensed therapies. Ketotifen has a role in management of condition both as an antihistamine and also due to its mast cell stabilising properties. Published evidence is very limited due to absence of clinical trials. Evidence mainly from case studies. Evidence available does seem to indicate that ketotifen does have a role in the management of symptoms associated with this condition. The cost of treatment with ketotifen is not high based on a dose of 2mg twice daily, cost of a year's treatment would be £182.73.	Approved for inclusion on the formulary restricted for unlicensed use in the management of mast cell activation disease as AMBER 2.
Alimemazine tablets and solution	**Introduction:** Alimemazine has been included on the Lincolnshire Formulary, classed as GREEN as a treatment option when a sedating antihistamine is required. The cost of alimemazine products had increased significantly since October 2017 and PACEF had received a request to review its formulary position. **Further relevant information:** Alimemazine is most often used at the request of the community paediatric service in the management of sleep disorders in children and adolescents with diagnosed neurodevelopment disorders. All children/adolescents would be seen within the specialist sleep clinic and they and their families would be supported with non -pharmacological sleep management strategies. Those who continue to have sleep difficulties despite	Alimemazine reclassified as AMBER 2 reserved for those children and adolescents with proven sleep disorders that have not responded to pharmacological management, nor treatment with melatonin.

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	interventions are referred to the community paediatrician for a trial of melatonin. A small number may fail to respond adequately to treatment with melatonin and therefore require treatment with Alimemazine. PACEF therefore considered that as treatment options for this group are limited Alimemazine should remain on the formulary for this indication. It was agreed that as treatment would only be as a result of specialist assessment and review it should be reclassified as AMBER 2.	
DesmoMelt 120mcg and 240mcg (desmopressin acetate) oral lyophillisate sugar free tablets.	**Introduction:** DesmoMelt are indicated for the treatment of primary nocturnal enuresis, administered as a single daily dose at night. ULHT paediatricians have requested that these are added to the formulary as an alternative desmopressin formulation. **Further relevant information:** NICE Clinical Guideline111, Bedwetting in under 19s; Published: October 2010 recommends the use of DesmoMelts for children and young people who are requiring treatment with desmopressin who are not able to take a standard tablet. ULHT paediatricians have requested that the formulary is updated in line with national Guidance. ULHT DTC approved the request and classed DesmoMelts as GREEN in line with the classification for other desmopressin formulations.	DesmoMelt – oral lyophillisate desmopressin acetate is approved for inclusion on the formulary classed as GREEN.

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