Lincolnshire Prescribing and Clinical Effectiveness Bulletin

Volume 12 No 7, August 2018

Optum in association with Lincolnshire Clinical Commissioning Groups, Lincolnshire Community Health Services, United Lincolnshire Hospitals Trust and Lincolnshire Partnership Foundation Trust

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New Drug Assessments

Product	Summary	Decision
Trelegy Ellipta®	**Introduction:** Licensed for the maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of an inhaled corticosteroid (ICS) and a long acting beta-2 agonist (LABA). **Active ingredients** Contains a steroid (fluticasone furoate 92mcg), a LABA (vilanterol 22mcg) and a LAMA umeclidinium 55mcg. **Further relevant information:** The recommended and maximum dose is one inhalation of Trelegy Ellipta 92/55/22 micrograms once daily, at the same time each day. Trelegy Elipta and the other licensed triple therapy Trimbow are the same cost (£44.50 for a 30 days treatment) and offer significant cost savings compared to triple therapy delivered through 2 or more devices.	Approved as Green on the formulary. To be used as an option for treatment of COPD within licensed indication. This is the second combination inhaler licensed for maintenance treatment of COPD which delivers triple therapy (ICS/LABA & LAMA) in a single device. Lincolnshire guidance on COPD is being amended to include use of this device. The inhaler should be prescribed by brand name.
Anoro Ellipta®	**Introduction:** Licensed for maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. **Active Ingredient:** Each single inhalation provides a delivered dose (dose leaving the mouthpiece) of 65 micrograms umeclidinium bromide equivalent to 55 micrograms of umeclidinium and 22 micrograms of vilanterol (as trifenatate). **Further relevant information:** There are three other LABA/LAMA combinations all listed as GREEN on Lincolnshire fomulary. Duaklir Genuair: Formeterol 12mcg/Aclidinium 340mcg Ultibro Breezhaler: Indacaterol/glycopyrronium Spiolto Respimat: Olodaterol 2.5mcg/Tiotropium 2.5mg All LAMA/LABA combinations, cost £32.50 for30 day's treatment.	Approved as Green on the formulary. To be used as an option for treatment of COPD within licensed indication when dual therapy with a LABA & a LAMA is indicated. Lincolnshire guidance on COPD is being amended to include use of this device. The inhaler should be prescribed by brand name.

Product	Summary	Decision
Incruse Ellipta®	**Introduction:** Licensed as maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. **Active Ingredient:** Each inhalation provides a delivered dose (dose leaving the mouthpiece) of 65 micrograms umeclidinium bromide equivalent to 55 micrograms of umeclidinium **Further relevant information:** There are three other LAMAS approved on the Lincolnshire formulary. Tiotropium as either Braltus or Spriva Respimat are the lowest cost LAMA's (£25.80 & £23.00 per month respectively). Umeclidinium (Incruse Ellipta) is priced the same as glycopyrronium £27.50 per month. Aclidinium (Ekilira Genuair) costs £28.60 per month. Consideration needs to be given to dosing regimen and choice of device when selecting which treatment option to use.	Approved as Green on the formulary. To be used as an option for treatment of COPD within licensed indication when a LAMA is indicated. Lincolnshire guidance on COPD is being amended to include use of this device. The inhaler should be prescribed by brand name
Relvar Ellipta®	**Introduction:** Relver Ellipta 92/22 (92mcg fluticasone furoate /22mcg vilanterol) is licensed for symptomatic treatment of adults with COPD with a FEV_1<70% predicted norm with an exacerbation history despite regular bronchodilator therapy. It is also indicated for treatment of asthma in adults and adolescents over 12 years and older when a combination product containing a LABA & ICS is considered appropriate. Relvar Ellipta 184/22 (184mcg fluticasone furoate /22mcg vilanterol) is indicated for treatment of asthma in adults and adolescents over 12 years and older when a combination product containing a LABA & ICS is considered appropriate. **Further relevant information:** There are a number of LABA/ICS combinations included on the formulary. Consideration needs to be given to previous and concurrent therapies and type of device previously used when selecting which combination product to use.	Approved as Green on the formulary. To be used as an option for treatment of COPD and asthma within licensed indication when an ICS/LABA combination is indicated. Lincolnshire guidance on COPD and asthma is being amended to include use of this device. The inhaler should be prescribed by brand name.

Ferric Maltol 30mg capsules (Feraccru®)	**Introduction:** This is indicated for treatment of iron deficiency in adults. **Further relevant information:** Ferric maltol (Feraccru®) has been requested by gastroenterology for 30 patients per month with inflammatory bowel disease (IBD) with mild to moderate iron deficiency. It would be used in patients who are intolerant of standard oral iron preparations, prior to commencement of intravenous iron.	PACEF approved Ferracru as AMBER 2 for treatment of iron deficiency use in patients with Inflammatory Bowel Disease who have failed to tolerate treatment with two oral iron preparations.
Pentoxifylline 400mg tablets	**Introduction** Pentoxifylline is licensed for treatment of peripheral vascular disease. This request covered its unlicensed use in the treatment of Behcet's disease **Further relevant information:** Behcet's Syndrome is a rare inflammatory multi-system disorder of unknown cause, typically characterised by recurrent oral aphthous ulcers, genital ulcers, uveitis and skin lesions. Disease management is tailored to • Affected organ(s) • Extent and severity of involvement • Age and gender of the patient Pentoxifylline provides an alternative treatment option when other first-line treatments (e.g. colchicine, corticosteroids and immunosuppressants) are not appropriate, not tolerated or ineffective.	PACEF approved pentoxifylline for its unlicensed use in treatment of Behcet's disease. To be classed as AMBER 2 on formulary.
Levosert® 20mcg/24 hours IDS	**Introduction** Levosert is an intrauterine device containing 52mg of levonorgestrel. Previously not approved for inclusion onto formulary. Licensed duration of efficacy for contraception now extended to four years. **Further relevant information:** Based on cost price Levosert is now the most cost effective option particularly in those women whose use would be ≤4 years. The alternative intrauterine device containing 52mg of levonorgestrel (Mirena) is licensed for use up to 5 years and remains on the formulary for those who have previously used the Mirena coil and who are likely to use it for a period of four or more years. For those women who have yet to try a levonorgesterel device then Levosert should be considered a first choice.	PACEF approved Levosert for inclusion onto the formulary as GREEN for contraceptive use only

Safinamide Tablets (Xadago®)	**Introduction** Safinamide is a non-competitive, reversible inhibitor of the MAO-B enzyme, which breaks down dopamine in the central nervous system. It is third of class. Two other MOA-B inhibitors on formulary selegiline and rasagiline. **Active ingredient** Available in two strengths 50mg & 100mg. Initial dose 50 mg per day and may be increased to 100 mg/day on the basis of individual clinical need. **Further relevant information** Safinamide is indicated for the treatment of adult patients with idiopathic Parkinson's disease (PD) as add-on therapy to a stable dose of Levodopa (L-dopa) alone or in combination with other PD medicinal products in mid-to late-stage fluctuating patients. ULHT clinicians have requested that Sulfinamide be used as a third line MAOB inhibitor for patients who suffer increased off periods in PD treatment.	PACEF approved Safinamide tablets for inclusion onto the formulary as AMBER 2. Treatment to be initiated on or at the request of specialist. Safinamide significantly more expensive that other MAOBs and therefore should only be used third line in patients already receiving treatment with a MAOB inhibitor who suffer increased off periods in PD treatment.
Benzbromarone tablets	**Introduction** ULHT rheumatologists have requested benzbromarone is included onto the formulary for the treatment of gout as a third line agent when allopurinol & febuxostat have failed. Dose range 50mg – 200mg daily The usual dose of Benzbromarone is 100mg per day **Further relevant information** Benzbromarone, is a potent uricosuric drug, introduced in the 1970s. However in 2003, the drug was withdrawn by Sanofi-Synthélabo, after reports of serious hepatotoxicity, although it is still marketed in several countries by other drug companies. NICE and BSR guidelines for the treatment of gout recommend benzbromarone as a third line treatment option in patients (with mild to moderate renal insufficiency) who are resistant to, or intolerant of, xanthine oxidase inhibitors. Specialist service have confirmed that the side effect profile with be discussed with patients, and will include regular monitoring of side effects. Liver function tests will be done every 3 months for the first year and after that every 6 months for one year.	PACEF ratified ULHT DTC's decision to approve this drug onto the formulary as a RED Hospital only drug. All prescribing, supply and monitoring will remain the responsibility of the specialist.

Pipexus® – sustained release pramipexole formulation	**Introduction** Lower cost brand of sustained release prampexiole indicated for treatment of Parkinson's Disease. **Further relevant information** Available in a range of strengths. To be used as a lower cost alternative to Mirapexin®	PACEF approved Pipexus tablets for inclusion onto the formulary as AMBER 2.
Brancico XL® modified release quetiapine	**Introduction** Lower cost brand of modified release quetiapine. **Further relevant information** Brancico XL comes in a range of strengths and is available from main wholesalers and some short line wholesalers. This is currently the second lower cost formulation.	PACEF approved Brancico XL modified release Quetiapine onto the formulary as GREEN. Sondate XL & Brancico XL are lowest cost options. Biquelle, Mintreleq and Zaluron remain included as lower cost alternatives to higher cost brands or generic prescribing.

MEDICINES AND HEALTHCARE REGULATORY AGENCY (MHRA): DRUG SAFETY UPDATE (May 2018)

Braltus (tiotropium): risk of inhalation of capsule if placed in mouthpiece of the inhaler.

The MHRA have received two Yellow Card reports that patients have inhaled a Braltus capsule from the mouthpiece into the back of the throat, resulting in coughing and risking aspiration or airway obstruction.

Braltus is currently approved for use on Lincolnshire Joint Formulary as a GREEN drug,

MHRA have issued the following advice for healthcare professionals:

- Train patients in the correct use of their inhaler; a placebo device is available for training purposes and instructions for patients are provided in the patient information leaflet and on the carton.
- Tell patients to store capsules in the screw-cap bottle provided (never in the inhaler) and to always check the mouthpiece is clear before inhaling.
- Pharmacists dispensing Braltus capsules should remind patients always to read the instructions for use in the package leaflet and that they must never place a capsule directly into the mouthpiece.
- Please continue to report adverse incidents during use of the inhaler as well as suspected adverse reactions to the medicine on a yellow card.

MEDICINES AND HEALTHCARE REGULATORY AGENCY (MHRA): DRUG SAFETY UPDATE (July 2018)

Pressurised metered dose inhalers (pMDI): risk of airway obstruction from aspiration of loose objects.

The MHRA have received reports of patients who have inhaled objects into the back of the throat, resulting in coughing. In some cases the objects were aspirated, causing airway obstruction.

MHRA have issued the following advice for healthcare professionals:

- Train patients in the correct use of their inhaler; instructions for patients are provided in the patient information leaflet.
- Tell patients to move the mouthpiece cover fully, shake the inhaler to remove loose objects that may be visible, check the inside and outside of the mouthpiece are clear before inhaling a dose.
- To prevent objects entering the mouthpiece during storage, remind patients to replace the cover immediately after use, ensuring it clicks in place.
- Pharmacists dispensing a pMDI should emphasise to patients the need to clean the device regularly by following the instructions in the patient leaflet and to inspect the device for signs of damage; devices that are damaged should be replaced immediately.
- Please continue to report adverse incidents during use of the inhaler as well as suspected adverse reactions to the medicine on a yellow card.

Produced by
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August 2018

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