Lincolnshire Prescribing and Clinical Effectiveness (PACE) Bulletin

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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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DRUG ASSESSMENT SUMMARY

Product	Summary	Decision
Gabapentin 6% gel	**Introduction:** Topical gabapentin 6% w/w gel is an unlicensed product. This has been requested by ULHT based clinicians to be used as a topical treatment of neuropathic pain associated with vulval pain syndrome. Its use will be restricted to women who have not responded to, or are intolerant to licensed pharmacological options and or physical or psychological interventions **Further relevant information:** This has been approved for specialist use only and all prescribing will be retained by hospital based specialists. The number of patients receiving this treatment is expected to be very low.	Approved for inclusion on the formulary as RED.
Invicorp® (Solution for injection Aviptadil 25micrograms / Phentolamine 2mg	**Introduction:** Invicorp® is indicated for the symptomatic treatment of erectile dysfunction (ED) in adult males due to neurogenic, vasculogenic, psychogenic, or mixed aetiology. Intended dosage is one injection for the treatment of erectile dysfunction before each intercourse. Frequency of injection should not exceed once daily or three times weekly. Duration of erection should not exceed one hour. **Further relevant information:** Request received from ULHT urology to add to the formulary as an alternative to alprostadil (Caverject®) injection. There have recently been disruptions to supply of alprostadil injection, and therefore an alternative injectable therapy is required. Evidence from clinical studies demonstrate similar efficacy as Caverject®. Ivicorp® is a similar cost per injection as Caverject®, costing £9.50 per injection compared to £9.24-£11.94 depending on dose of alprostadil required. Initiation of treatment and training of patient to self- inject will remain responsibility of hospital based services.	Approved for inclusion on the Formulary as AMBER 2.
Ciprofloxacin 2mg/ml(0.2%) ear drops (Cetraxal®)	**Introduction:** Ciprofloxacin 0.2% ear drops in a unit dose presentation is a licensed product for the treatment of acute otitis externa in adults and children over 1 year, with an intact tympanic membrane, caused by ciprofloxacin susceptible bacteria. Ciprofloxacin is used as an alternative to gentamicin-containing products where there may be concern over ototoxicity. In addition, topical ciprofloxacin avoids the need for systemic treatment which is associated with serious and prolonged side effects. **Further relevant information:** Ciprofloxacin 0.2% ear drops are indicated where previously Ciprofloxacin 0.3% eye drops have been used off-license in the ears. Ciprofloxacin ear drops are well-tolerated with an incidence similar to comparator drops. The licensed dose of the ear drops is instil the contents of a single use ampoule into the affect ted ear twice daily for seven days.	Approved for inclusion on the Joint Formulary as GREEN.

UPDATES

Clozapine – ensure it is included on the primary care record.

Clozapine is an antipsychotic medicine that is prescribed by psychiatrists when other antipsychotic medicines have failed to adequately control the symptoms of schizophrenia. Clozapine is classed as RED on Lincolnshire Joint Formulary and all prescribing and monitoring of patients remain the responsibility of the Lincolnshire partnership Foundation trust (LPFT).
Clozapine is associated with potentially serious side effects including agranulocytosis, myocarditis, seizures and life-threatening constipation.
All people prescribed clozapine are registered with a clozapine monitoring service which ensures that the necessary blood checks have been completed prior to further supplies of clozapine being issued.
Whilst there should be no prescribing of clozapine by GPs as it is a RED drug and should only be prescribed by LPFT, it is important that clozapine is included onto the primary care record. This is to ensure that any clinician needing to access a person's medication history is made aware that the patient is currently receiving treatment with clozapine. It is also to inform clinicians should the patient complain of any clozapine related side effects or if another medication was to be prescribed which may interact with Clozapine.
LPFT have advised that clozapine should be entered onto the primary care record as a repeat medication prescribed elsewhere, or as hospital only drugs. This therefore enables the information to be extracted onto the Summary Care Record (SCR). Letters were sent out by LPFT to each patient's GP surgery with the current dose, so please ensure you refer to these when entering onto the primary care record.
LPFT are contacting all GPs whose patients are currently taking clozapine to ensure the necessary record entries are made for those that haven't yet added it on following the letters.

MHRA (MEDICINES & HEALTHCARE PRODUCTS REGULATORY AGENCY): DRUG SAFETY UPDATE (March 2019)

GLP-1 receptor agonists: reports of diabetic ketoacidosis when concomitant insulin was rapidly reduced or discontinued.

MHRA have received reports of diabetic ketoacidosis in patients with type 2 diabetes on a combination of a GLP-1 receptor agonist and insulin who had doses of concomitant insulin rapidly reduced or discontinued.
A number of GLP-1 agonists are approved for use and classed as GREEN on the Lincolnshire Joint Formulary: dulaglutide (Trulicity), exenatide (Byetta) & exenatide prolonged release (Bydureon), liraglutide (Victoza), lixisenatide (Lyxumia) & semaglutide (Ozempic)
Lixisenatide and semaglutide were not subject to the EU review. The MHRA have stated they have not (at the time of publication of the June 2019 Drug Safety Update) received any UK reports of diabetic ketoacidosis in association with these two products. However the theoretical risk of diabetic ketoacidosis when changes are made to insulin dose cannot be excluded.

The MHRA have issued the following advice to healthcare professionals

- Serious and life threatening cases of diabetic ketoacidosis have been reported in association with exenatide, liraglutide and duraglutide, particularly after discontinuation or reduction of concomitant insulin.
- Blood glucose self-monitoring is necessary when adjusting the dose of insulin, particularly when GLP-1 receptor agonist therapy is initiated and insulin reduced.
- If the insulin dose is to be reduced, a stepwise approach is recommended.
- Discuss with the patient the risk factors and signs and symptoms of diabetic ketoacidosis and advise then to seek immediate medical advice if these develop.
  Report suspected drug reactions using Yellow card scheme.

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