Lincolnshire Prescribing and Clinical Effectiveness 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

Table of contents –

Drug Assessments

Product	Summary	Decision
Fenofibrate tablets and capsules	**Introduction:** Fenofibrate tablets 160mg and 67mg, 200mg and 267mg capsules. Fenofibrate as an adjunct to diet and other non - pharmacological treatment (e.g. exercise, weight reduction) for the following: - Treatment of severe hypertriglyceridaemia with or without low HDL cholesterol. - Mixed hyperlipidaemia when a statin is contraindicated or not tolerated. - Mixed hyperlipidaemia in patients at high cardiovascular risk in addition to a statin when triglycerides and HDL cholesterol are not adequately controlled. **Further relevant information:** Request received from ULHT endocrinology department to include a fibrate onto the formulary which can be used in combination with a HMG-COA reductase inhibitor or other fibrates. Fenofibrate is also significantly cheaper than the current formulary product gemfibrozil. PACEF approved fenofibrate for inclusion not the formulary and agreed to remove genfibrozil classing it as RED/RED for new patients. Bezafibrate is also approved for use as an alternative fibrate.	Fenofibrate is approved for inclusion onto the formulary as first-line fibrate. Bezafibrate is approved as second line alternative fibrate. Both are classed as GREEN. Gemfibrozil is removed from the formulary and classed as RED/RED for new patients. Patients currently receiving gemfibrozil can continue on this therapy until they and their clinician consider it appropriate to stop.
Glycopyrronium 320mcg in 1ml oral solution (Sialanar®)	**Introduction:** Sialanar is licensed for the symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders. **Product Information/Active Ingredients:** Each ml contains 400 micrograms glycopyrronium bromide equivalent to 320 micrograms of glycopyrronium base. The dosing schedule for glycopyrronium is based on the weight of the child, starting with approximately 12.8 micrograms/kg per dose (equivalent to 16 micrograms/kg per dose glycopyrronium bromide), three times per day. Detailed dosing schedule included with product summary of product characteristics (SPC) **Further relevant information:** Sialanar is the only product which is licensed for the treatment of sialorrhoea in children. Previously the only formulation of glycopyrronium available was an unlicensed glycopyrronium oral solution. Hyoscine patches were also used off licensed to treat this condition in children. The licensed product Sialanar is twice the strength, of the unlicensed solution containing the equivalent of 400mcg glycopyrronium bromide per ml compared to 200mcg per ml. To avoid confusion Sialanar should be prescribed by brand. PACEF has advised that patients currently receiving treatment with the unlicensed solution should only be switched to the	Approved as Amber 2 PACEF has advised that patients currently receiving treatment with the unlicensed solution should only be switched to the licensed product following review by or on the advice of a specialist.

	licensed product following review by or on the advice of a specialist.	
Oxeltra® – prolonged release oxycodone	**Introduction** Lower cost brand of prolonged release oxycodone. Oxycodone is included on the formulary as a second line opioid when morphine sulphate is not an appropriate choice. **Further relevant information** Available in a range of strengths 5mg, 10mg, 15mg, 20mg, 30mg, 40mg, 60mg and 80mg. Oxeltra is significantly lower cost compared to alternative formulary approved products Abtard/Longtec and Reltebon. To be used as first line lower cost oxycodone prolonged release product. Patients currently receiving alternative brands of oxycodone prolonged release should be reviewed and switched to Oxeltra where possible.	Approved for inclusion onto the formulary as GREEN. To maximise potential savings prescribe by brand.
Yaltormin® sustained release metformin	**Introduction** Lower cost brand of sustained release metformin. **Further relevant information** Available in three strengths 500mg, 750mg, Yaltormin is currently lower cost than Sukkarto the other formulary approved sustained release brand of metformin. Patients currently receiving generic metformin or one of the non-formulary brands should be reviewed and switched to Yaltormin or Sukkarto.	Approved for inclusion onto the formulary as GREEN. Sukkarto is an alternative lower cost option. To maximise potential savings prescribe by brand.

Sodium Chloride 5% eye drops

The Optum Medicine Management Team have recently received a number of enquiries from practices citing difficulty in prescribing the recommended first line product. Full details of PACEF advice regarding sodium chloride 5% eye drops can be found in PACE Bulletin Vol 8 No 13 issued in July 2014.

In summary PF sodium chloride 5% preservative free eye drops are the preferred first-line product on grounds of cost and are classed as AMBER 2 on the Lincolnshire Joint formulary.
NaCl 5% single use eye drops (Essential Pharmaceuticals) should only be prescribed if PF drops are unavailable.

A number of people have cited problems with finding the product PF drops listed on SystmOne. To find the product you need to type the words “sodium chloride drops” or “PF drops” in the free text search box and then the product will appear in the drop down menu.

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

Valproate pregnancy prevention programme: actions required now from GPs, specialists and dispensers

Valproate medicines must not be used in women of childbearing potential unless the Pregnancy [prevention programme is in place.

The MHRA have a reminder of actions for healthcare professionals:
Actions for GPs:

- Identify and recall all women and girls on valproate who may be of child bearing potential.
- Provide the patient guide to the patient (or her parents or responsible person as necessary).
- Check they have been reviewed by a specialist in the last year (i.e. they have an in date Risk Acknowledgement form) and are on highly effective contraception.

Actions for specialists:

- Book in review appointments at least annually with women and girls under the pregnancy prevention programme and re-evaluate treatment as necessary.
- Explain clearly the conditions as outlines in the supporting materials.
- Compete and sign with the patient or their responsible person the risk Acknowledgment form- copies of the form must be given to the patient or responsible person and sent to their GP.

Actions for dispensers:

- Valproate medicines must always be dispensed with the accompanying patient information leaflet.
- Dispense whole packs whenever possible, and ensure there is a warning label either on the carton or added via a sticker.
- Discuss risks in pregnancy with female patients each time you dispense valproate medicines and ensure they have the patient guide and have seen their GP or specialist to discuss their treatment and the need for contraception.
- Ensure new packs of valproate information materials are placed in a designated place accessible to all dispensary staff and dispose of any old materials related to valproate medicines.

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

Rivaroxaban (Xarelto) after transcatheter aortic valve replacement: increase in all cause mortality, thromboembolic and bleeding events in patients in a clinical trial.
Rivaroxaban treatment in patients who undergo transcatheter aortic valve replacement (TAVR) should be stopped and switched to standard care.

MHRA have issued the following advice for healthcare professionals:

- Preliminary analysis of a phase 3 clinical trial show risks of all cause death and bleeding post TAVR were approximately doubled in patients assigned to a rivaroxaban – based anticoagulation strategy compared with those assigned to receive an antiplatelet based strategy & clopidogrel and aspirin).
- Rivaroxaban is not authorised for thromboprophylaxis in patients with prosthetic heart valves, including patients who have undergone TAVR, and should not be used in such patients.
- Rivaroxaban treatment in patients who undergo TAVR should be stopped and switched to standard care.
- The direct acting oral anticoagulants apixaban and edoxaban have not been studied in patients with prosthetic heart valves and their use is also not recommended in these patients; the use if dabigatran is contraindicated in patients with prosthetic heart valves requiring anticoagulant treatment.
- Report any suspected adverse reactions to rivaroxaban on a yellow card.

Ritonavir containing products: reports of interaction with levothyroxine leading to reduced thyroxine levels.

Monitor thyroid stimulating hormone (TSH) in patients treated with levothyroxine for at least a month after starting and ending ritonavir treatment.

MHRA have issued the following advice for healthcare professionals:

- Reduced thyroxine levels have been reported in patients concomitantly taking ritonavir-containing products and levothyroxine
- Monitor thyroid – stimulating hormone (TSH) in patients treated with levothyroxine for at least the first month after the start and end of ritonavir treatment.
- Report any suspected adverse drug reactions on a yellow card.

Transdermal fentanyl patches: life threatening and fatal opioid toxicity from accidental exposure, particularly in children.

MHRA have continued to receive reports of unintentional opioid toxicity and overdose of fentanyl due to accidental exposure to patches.

MHRA have issued the following advice for healthcare professionals:

- Always fully inform patients and their caregivers about directions for safe use of fentanyl patches, including the importance of
    - Not exceeding the prescribed dose
    - Following the correct frequency of patch application, avoiding touching the adhesive side of patches and washing hands after application.
    - Not cutting patches and avoiding exposure of patches to heat including hot water (bath,shower)
    - Ensuring that old patches are removed before applying the new one
    - Following instructions for safe storage and properly disposing of used patches or those which are not needed.
- Ensure that patients and caregivers are aware of the signs and symptoms of fentanyl overdose and advise them to seek medical attention immediately (by dialling 999 and requesting an ambulance) if overdose is suspected.
- In patients who experience serious adverse events, remove patches immediately and monitor for up to 24 hours after patch removal.
- Report any cases of accidental exposure where harm has occurred or suspected side effects via yellow card scheme.

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