Greenwich Clinical Matters

NHS South East London Clinical Commissioning Group

January 2022

MEDICINES MANAGEMENT

MHRA: Dapagliflozin (Forxiga): no longer authorised for treatment of type 1 diabetes mellitus patients

The authorisation holder for dapagliflozin has withdrawn the indication for type 1 diabetes mellitus (T1DM). The removal of the type 1 diabetes indication is not due to any new safety concerns and the other indications of dapagliflozin are unchanged.

Currently the use of dapagliflozin in T1DM is a RED drug and only to be prescribed by a consultant diabetologist so all prescribing should be in secondary care, however there are 9 practices within Greenwich who are identified as currently prescribing dapagliflozin for patients with T1DM.

There are other SGLT2i also being prescribed for T1DM however please be aware that this use is off-label and not approved for use in SEL and so prescribing should remain with specialist only. The SEL Prescribing criteria for SGLT2i is summarised in table below:

SGLT2i	Indication	SEL RAG Rating	Resources
Canagliflozin Dapagliflozin Empagliflozin Ertugliflozin	T2DM	GREEN	MHRA: DKA MHRA: Lower limb Amputation MHRA: Fournier's Gangrene
Dapagliflozin	T1DM	RED	MHRA: License withdrawal
Dapagliflozin	CKD	RED	
Dapagliflozin	HF	AMBER 2	SEL IMOC: Dapagliflozin with HF
Sotagliflozin	T1DM	RED	

Action: Please work with your Prescribing and Pathway Adviser in identifying patients and liaise with initiating specialist over safe repatriation of dapagliflozin to specialist for continued prescribing and monitoring.

Extending the post-thaw expiry of specified batches Comirnaty 30 microgram/dose COVID-19 mRNA vaccine for adults and adolescents

On Monday 17th January, NHS England advised vaccination sites that for specific batches of unpunctured and undamaged Comirnaty 30 microgram/dose COVID-19 mRNA vaccine, the post-thaw expiry date can be extended by 14 days (from 31 days to 45 days) from the date of removal from ultra-low temperature (ULT) storage. The expiry for this stock has been extended in line with national guidance based on information from the manufacturer and MHRA.

Action

For further information please read attachment 1.

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Prescribing update re: Neocate Junior

The prescribing support dietetic service have noted that Neocate Junior is being prescribed more than expected.

Neocate Junior is a high-cost specialist formula. It is not a follow-on formula for Neocate LCP.

Neocate Junior is a 1kcal/ml amino acid supplement indicated only for children with multiple food allergies, growth faltering and/or unable to meet nutritional requirements with an appropriate cow's milk substitute.

Prescriptions should only be requested by a paediatric dietitian following a full nutritional assessment. This prescription should ideally be reviewed every 6 months by a dietitian.

ACTION: If you note that a patient is prescribed this product confirm that they are under active dietetic review. If not please refer to oxl-tr.childrenstherapies@nhs.net . For nutritional prescription advice please contact gst-tr.prescribingsupportdietitians@nhs.net

Shortages of Trulicity (dulaglutide) 3.0mg weekly and 4.5mg weekly injections

Lilly (the manufacturers of dulaglutide (Trulicity®)) have advised that there are currently shortages of the 3.0 mg weekly and 4.5 mg weekly preparations. The shortages are anticipated to be short term, with wholesalers and pharmacies expected to be replenished in April 2022.

Trulicity® 0.75 mg and 1.5 mg doses and other Lilly diabetes medicines are not impacted by this disruption.

The current 2–3-month shortage is due to higher-than-expected demand and not as a result of any quality or regulatory issues.

Action

For patients who are currently prescribed Trulicity 3.0mg weekly and 4.5mg weekly injections:

- Identify patients and contact the initiating team for advice.
- Do not prescribe multiples of the lower Trulicity doses e.g. do not prescribe two 1.5mg weekly injections to make up a 3mg weekly dose. This route of administration is outside of the license and would double the cost of therapy.
- Potential alternatives may include:
    - Temporarily reverting to a lower dose of Trulicity® 1.5 mg weekly, with appropriate glycaemic monitoring. Please consider that additional medication or changes to current medication may be required to maintain glycaemic control
    - Switching patients to an alternative GLP-1 Receptor Agonist.

For queries, Lilly's Medical Information Team can be contacted on 01256 315000 or medinfo_ukhub@lilly.com .

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Learning disability (LD) and autism support for primary care

Trang Dinh and Ashika Patel have recently joined SEL CCG as the LD and Autism Specialist Prescribing Advisors. They can offer clinical advice and support on complex LDA patients including referral facilitation and transfer of care.

Action: Refer to the attachment 2 poster for further support and contact details

MHRA Update

COVID-19 antivirals: reporting to the UK COVID-19 Antivirals Pregnancy Registry

This advice applies to molnupiravir (Lagevrio▼), the combination of PF-07321332 (nirmatrelvir) plus ritonavir (Paxlovid▼), and remdesivir (Veklury▼).

Action: Please report any pregnancies which occur during use of an antiviral, including paternal use, to the UK COVID-19 Antivirals Pregnancy Registry

Gina 10 microgram vaginal tablets (estradiol): consultation on proposal to make available from pharmacies

The MHRA has launched a public consultation which will be open for comments until midday on 23 February 2022. They are seeking views on reclassifying Gina as a pharmacy medicine and ask healthcare professionals to see the consultation page for more information.

Hydroxychloroquine, chloroquine: increased risk of cardiovascular events when used with macrolide antibiotics; reminder of psychiatric reactions

An observational study in patients with rheumatoid arthritis has shown that co-administration of azithromycin with hydroxychloroquine is associated with an increased risk of cardiovascular events and cardiovascular mortality.

Action

Clinicians are to carefully consider the benefits and risks before prescribing systemic azithromycin or other systemic macrolide antibiotics (erythromycin or clarithromycin) to patients being treated with hydroxychloroquine or chloroquine

Benefits of Chloramphenicol eye drops in children outweigh risks

A review of the available toxicological data and a calculation of daily exposure to boron from a typical dosing regimen by MHRA has concluded that the balance between the benefits and risks of chloramphenicol eye drops containing borax or boric acid remains positive for children aged 0 to 2 years. Chloramphenicol eye drops can be safely administered to children aged 0 to 2 years where antibiotic eye drop treatment is indicated.

Action

- A typical regimen of one drop, applied typically 3 to 4 times a day, to both eyes, would result in a daily exposure well below the safety limit for children aged 0 to 2 years
- The product information for affected chloramphenicol products is being updated to reflect the revised advice and remove restrictions for use in infants – in the meantime we ask healthcare professionals to reassure parents and carers that these products can be safely given to children aged 0 to 2 years as prescribed

MEDICINES MANAGEMENT

SEL Integrated Medicines Optimisation Committee (IMOC)

The following IMOC decisions / outputs have been ratified through SEL IMOC and SEL Medicines Optimisation sub-Committee Chair's action and can be accessed via the links:

NEW:

Guidance on the management of gout in primary care has been developed through the SEL IMOC rheumatology subgroup. The guidance aims to better support primary care clinicians in managing this condition and includes information on managing and preventing flares, self-care advice and when to refer.

Formulary inclusion of dapagliflozin as a red medicine (hospital/specialist prescribing and supply only) for the management of chronic kidney disease (CKD). Dapagliflozin is reserved for a specific CKD patient cohort, please refer to the SEL Joint Medicine Formulary for further information.

UPDATED:

- The SEL IMOC shared care agreement process and templates have been updated in line with national guidance from the Regional Medicines Optimisation Committee (RMOC), please refer to the following documents for further detail: Shared care process flowchart , Template for full shared care, Transfer of care template.
- The SEL psoriasis biologic drug treatment pathway and psoriasis pathway outcomes and monitoring framework have been updated through the dermatology sub-group. The main update is the inclusion of bimekizumab in line with NICE guidance.

NICE Update

Updates to managing COVID-19 guideline

NICE have added new recommendations and updated existing recommendations to our rapid guideline on managing COVID-19. These cover

- a new recommendation on the use of ivermectin
- updated recommendations on the use of colchicine.

NICE creates new menu of treatment options for those suffering from depression

The NICE updated draft guideline on the treatment and management of depression in adults explains that patients should make an informed choice on which treatment option is right for them. People with less severe depression could choose counselling, cognitive behavioural therapy, exercise or psychotherapy.

A range of similar psychological interventions, along with the option of antidepressant medication, are also available for more severe depression.

Withdrawal of NICE pathways and Evidence search service closure

NICE Pathways have not been updated after 31 December 2021. This service will be withdrawn in spring 2022.

NICE Evidence search will close on 31 March 2022. This decision has been taken after reviewing the wide range of services currently provided.

Contact Details

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