South Yorkshire Integrated Care Board

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Our Ref: DC/NB

22nd December 2023

To: Prescribing Clinicians and Pharmacists within the Barnsley locality

Dear Colleague

Re: Summary of Key Points from the Barnsley Area Prescribing Committee Meeting on 13th December 2023.

The main outcomes of the meeting were: -

Prescribing Guidelines

The following prescribing guidelines were approved by the Committee:

Possible Alternatives to Unlicensed Specials [UPDATED]
This is an interim update due to the volume of new Drug Tariff unlicensed specials. The updated guideline will be available on the BEST website in due course.

Protocol for initiating Freestyle Libre® 2 for glucose monitoring in ADULTS and Freestyle Libre® 2 contract/agreement for adults [UPDATED]

Protocol for initiating Freestyle Libre® 2 for glucose monitoring in CHILDREN and Freestyle Libre® 2 contract/agreement for children and young people [UPDATED]

Summary of the main changes:

- Information regarding the discontinuation of Freestyle Libre (FSL) 1 in January 2023 has been added. Only FSL2 is now available, specific information applicable only to FSL1 has been removed.
- The adult guideline has been updated in line with NICE NG17 for type 1 diabetes (ALL type 1 diabetes patients are eligible for flash glucose monitoring). DVLA requirements have also been updated.
- The children's protocol has been updated in line with NICE NG18 (ALL type 1 diabetes paediatric patients aged 4 and over are eligible flash monitoring if real time CGM is unsuitable or the patient has a specific preference for flash monitoring).
- Criteria for initiating flash monitoring in type 2 diabetics has been added to the adult protocol as per NICE NG28.
- Information that type 2 diabetes patients may be discharged from the specialist service as appropriate has been added to the adult protocol (i.e. patients will not receive an annual review by the BIDS/hospital team unless clinically indicated. The initial 3 months of FSL prescribing, usage, and monitoring of outcomes will still be carried out by the specialist team). Note that paediatric patients in general, will remain under specialist care longer-term.
- Information has been added about what to do in the event of a reader being faulty or a sensor falling off:

- Patients who report that their reader is faulty or that their sensor has fallen off should contact the company (contact details are included within the guideline). Faulty readers or detached sensors should be retained until the issue has been discussed with the company.
- Patients do not need to contact their GP or specialist team in these circumstances unless their sensors detach regularly, in which case a clinical review may be appropriate.
- Patients should use their supply of capillary blood glucose testing equipment until a new sensor/reader is applied/received.

The updated protocols will be available on the BEST website in due course.

Oral Nutritional Supplements (ONS) Prescribing Guidelines in Primary Care: Adults aged 18 years and over [UPDATED]

Summary of the main changes:

- Altraplen® Compact Daily has been added to the guideline (milk-based ready-to-drink ONS). This is identical to Aymes Actagain® 600 in terms of volume, nutritional content and cost but has been added as an alternative option.
- Aymes® Shake Compact/Ensure® Shake (made compact) remain the first line products (both powder formulations) in primary care.
- Aymes Actagain® 600 and Altraplen® Compact Daily are the preferred choice if the above powders are unsuitable/contraindicated.
- There is an important note regarding dosage as one bottle/carton of Aymes Actagain® 600/Altraplen® Compact Daily is the nutritional equivalent of two bottles of most other compact ONS. This detailed on the switching algorithm (Appendix 4).

The updated guideline will be available on the BEST website in due course.

Amber G / Shared Care Guidelines

There were no amber-G / shared care guidelines approved by the Committee this month.

Prescribing guidelines are available on the BEST website:
http://best.barnsleyccg.nhs.uk/clinical-support/medicines/prescribing-guidelines/

Shared Care and Amber-G guidelines are available on the BEST website:
http://best.barnsleyccg.nhs.uk/clinical-support/medicines/shared-care-guidelines/.

The Barnsley Joint Formulary can be accessed at the link below:
http://www.barnsleyformulary.nhs.uk/

Healthcare professionals (including primary and secondary care clinicians and community pharmacists) are encouraged to report any medicines related interface issues (examples include shared care, prescribing guideline, formulary or discharge related issues), particularly where guidelines are not being complied with, to the following email address: BarnsleyAPCReport@nhs.net.

The Barnsley Interface Issues Form available on the BEST website should be used to report the issue: link

Barnsley Formulary Updates

The Committee noted the traffic light classifications recently assigned by the SY IMOC and the following formulary positions were agreed by the Committee:

Drug	Formulary Indication	Formulary status (including traffic light classification)
December 2023 IMOC Horizon Scanning		
Atogepant	Prophylaxis of migraine	Non-formulary grey

Calcifediol	Treatment of vitamin D deficiency in adults, prevention of vitamin D deficiency in adults with identified risks, and as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.	Non-formulary grey
Drospirenone	Contraception	Non-formulary green Progestogen only contraceptive with 24- hour missed pill window FSRH Clinical Guideline: Progestogen Only Pills
Respiratory syncytial virus vaccine	Active immunisation for the prevention of lower respiratory tract disease caused by respiratory syncytial virus in adults aged ≥60 years	Non-formulary grey Not yet included in the Green Book
TLDL Sub Group list November 2023		
Hepatitis A vaccine	Immunisation	Formulary green in line with the Green Book (previously non-formulary grey)
Hepatitis B vaccine	Immunisation	Formulary green in line with the Green Book (previously non-formulary grey)
Other		
Dexcom One	CGM	Formulary amber Note that both the sensors and transmitters are now included in the Drug Tariff and can be prescribed. SY CGM guidance currently in development. Doncaster and Sheffield Dexcom One Position Statements are available for information: Dexcom One Sheffield position statement Dexcom One Doncaster position statement
Famotidine	H2-receptor antagonist	Formulary green
Altraplen® Compact Daily	Milk- based ready to drink ONS	Formulary amber-G To be initiated by dietitian ONLY. Note that Altrapen® Compact daily is a once daily product. If a 'compact' ONS is required in primary care, please consider Aymes® Shake Compact.
Tirzepatide	Type 2 diabetes	Formulary amber-G for type 2 diabetes in line with NICE TA 294: NICE TA924 Tirzepatide for treating type 2 diabetes Tirzepatide is a long acting dual GIP and GLP-1 receptor agonist.

Empagliflozin	Chronic heart failure with preserved or mildly reduced ejection fraction	Formulary amber -G NICE TA929 Empagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction The SGLT2 inhibitors for Heart Failure Amber-G guideline will be updated in due course.

MHRA Drug Safety Update

The November 2023 MHRA Drug Safety Update can be accessed at the following link:
Drug Safety Update (publishing.service.gov.uk)

Issues relating to primary care:

Ozempic▼(semaglutide) and Saxenda (liraglutide): vigilance required due to potentially harmful falsified products

Falsified, potentially harmful Ozempic▼ and Saxenda products have been found in the UK. The MHRA ask healthcare professionals to remind patients using these products to always obtain prescription medicines from a qualified healthcare provider and not to use products they suspect are falsified as this may lead to serious health consequences. We also ask healthcare professionals to remain vigilant for symptoms linked to hypoglycaemia in patients who may have obtained a falsified product containing insulin

Advice for healthcare professionals:

- be aware that falsified Ozempic and Saxenda products have been found in the UK, including falsified pens containing insulin, which may lead to patient harm
- remain vigilant for symptoms linked to hypoglycaemia in patients who may have obtained a falsified product and provide appropriate treatment for any patient who may have inadvertently administered insulin via these products
- if you encounter a suspected falsified product, quarantine it and report to the Yellow Card scheme
- advise patients who are concerned that the pens they have purchased might be falsified that they should not use the pens and report as mentioned above
- Ozempic and Saxenda from legitimate supply chains are unaffected

Advice for healthcare professionals to give to patients and the public:

- you must not use Ozempic and Saxenda products or pens that you suspect are falsified as this may lead to serious health consequences
- check the Patient Information Leaflet for Ozempic and Patient Information Leaflet for Saxenda to clarify what the genuine pens look like. Do not use any products that appear suspicious – an example image of a fake Ozempic pen is available in the MHRA's advice to the public
- falsified Ozempic and Saxenda pens may contain insulin – seek urgent medical attention if you experience symptoms of low blood sugar, which includes feeling dizzy, sweating or blurred vision; take the suspected fake medicine with you so your doctors know what may have caused this
- if more severe symptoms of low blood sugar occur, such as seizures (fits) and loss of consciousness, call 999 immediately
- if obtaining a private prescription (from a non-NHS prescriber), ensure that this is from authorised sources, such as registered online pharmacies, to avoid the risk of receiving falsified pens or products
- report suspected falsified Saxenda or Ozempic products to the MHRA's Yellow Card scheme

Nirmatrelvir, ritonavir (Paxlovid▼): be alert to the risk of drug interactions with ritonavir

There is a risk of harmful drug interactions with the ritonavir component of the COVID-19 treatment Paxlovid▼ due to its inhibition of the enzyme CYP3A, which metabolises many commonly used

drugs. Prescribers should obtain a detailed patient history of current medications before prescribing Paxlovid, checking the Paxlovid product information for known and potential drug interactions.

Advice for healthcare professionals:

- there is a risk of potentially serious drug interactions with the ritonavir component of Paxlovid leading to increased toxicity from, or reduced effectiveness of concomitant medications
- ritonavir is a potent CYP3A4 inhibitor that acts to boost the plasma levels of the nirmatrelvir component of Paxlovid by preventing its degradation; as many commonly used drugs are metabolised by CYP3A4, the risk of harmful drug interactions with Paxlovid is significant
- drug interactions may also reduce the effectiveness of Paxlovid, in the treatment of COVID-19
- obtain a thorough history of patients' current medications, including over the counter (OTC) medications, herbal remedies and illicit or recreational drug use
- refer to the Paxlovid Summary of Product Characteristics (SmPC) (especially sections 4.3, 4.4 and 4.5) before prescribing Paxlovid to check for contraindications and potential interactions – links to other resources to assist with this are available**
- remind patients to read the Patient Information Leaflet (PIL) and to be vigilant for any adverse reactions, seeking medical advice when required
- report suspected adverse drug reactions associated with Paxlovid on a Yellow Card

Advice for healthcare professionals to provide to patients:

- Paxlovid is used to treat COVID-19 infection in patients at risk of developing severe disease
- Paxlovid is an antiviral medicine composed of 2 drugs called ritonavir and nirmatrelvir
- ritonavir can affect how other medicines work, potentially leading to harmful effects
- because of this risk, your doctor or healthcare provider should ask you detailed questions about which medicines you are currently taking before prescribing Paxlovid and it is important that you mention all medicines that you use, including over the counter (without prescription) medicines, herbal remedies and any recreational drug use
- it is important not to change or stop taking any medications before discussing this with a healthcare professional
- please read the leaflet that accompanies your medicine and be vigilant for any side effects
- if you are concerned about a potential side effect after taking Paxlovid or any other medication, seek advice from a healthcare professional and submit a Yellow Card

****Resources to assist prescribers of Paxlovid**

There are several online resources available to aid in the safe prescribing of Paxlovid:

Specialist Pharmacy Service (SPS): Using nirmatrelvir and ritonavir (Paxlovid) in practice sets out comprehensive information on checking interacting medicines as well as other safety-related issues. This guidance also includes links to specific patient information, including:

- NHS.UK Medicines A-Z: has a monograph for Paxlovid that includes a section on 'Taking Paxlovid with other medicines and herbal supplements'.

The SPS clinical enquiry answering service supports primary care healthcare professionals in England with questions about Paxlovid. Contact details can be found via Medicines Advice contact details – SPS - Specialist Pharmacy Service – The first stop for professional medicines advice.

In addition, the University of Liverpool hosts several online resources which provide information about the safe prescribing of Paxlovid, such as the Liverpool COVID-19 Interaction Checker. The University has also created a flowchart to aid prescribers in the identification of potential unsafe prescribing regarding patient concomitant medications. You can access the flowchart by selecting the first link under the heading 'Resources for nirmatrelvir/ritonavir (Paxlovid; 5 day administration)' available on this page: Liverpool COVID-19 Interactions (covid19-druginteractions.org).

E-cigarette use or vaping: reminder to remain vigilant for suspected adverse reactions and safety concerns and report them to the Yellow Card scheme

Healthcare professionals should be vigilant for suspected adverse reactions and safety concerns associated with e-cigarettes and e-liquids, commonly known as vapes. Please report adverse reactions to the Yellow Card scheme and promote vigilance among patients. The MHRA is responsible for assessing whether the manufacturer or submitter has met the requirements in their notification for nicotine-containing e-cigarettes and e-liquids before the product comes to market. Trading Standards are responsible for enforcing the safety and quality of nicotine-containing e-cigarettes and e-liquids once they have been supplied to the UK market. The MHRA is also responsible for collecting and monitoring information about safety concerns related to these products through the Yellow Card Scheme.

Advice for healthcare professionals:

- document use of e-cigarette products, commonly referred to as 'vapes' and 'vaping' in the medical records for all patients when taking a medical history (see "Document e-cigarette use in medical records")
- advise patients to be vigilant about suspected adverse reactions that occur after the use of e-cigarettes and e-liquids
- advise patients to purchase and use legally compliant e-cigarette and e-liquid products
- report any suspected adverse reactions or safety concerns to the Yellow Card Scheme and include as many details as possible to ensure the MHRA can continue to perform safety vigilance

Advice for healthcare professionals to provide to patients:

- continuous reviews by the Office for Health Improvement and Disparities (OHID) have found that whilst not risk-free, vaping (e-cigarette use) is significantly less harmful than smoking and is one of the most effective tools to help adults quit smoking
- only purchase and use 'notified' products from reputable retailers; check if a product has been notified to the MHRA and meets the minimum requirements for supply in the UK by verifying if the product is present in the MHRA ECIG Publications List (see "Advice for consumers")
- talk to your doctor, a stop-smoking advisor or another healthcare professional if you experience any side effects or have any concerns about the product you are using
- report any side effects or safety concerns that you have to the Yellow Card Scheme and provide as much information as possible to help the MHRA assess your report

Regards

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cc: Medicines Management Team
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