NHS
South Yorkshire
Integrated Care Board

South Yorkshire Integrated Care Board
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Our Ref: DC/NB

3rd December 2024

To: Prescribing Clinicians and Pharmacists within the Barnsley locality

Dear Colleague

Re: Summary of Key Points from the Barnsley Area Prescribing Committee Meetings on 9th October and 13th November 2024.

The main outcomes of the meetings were: -

Prescribing Guidelines

Barnsley Public Health Nursing 0-19 Service Prescribing Formulary [UPDATED]
This guideline has received minor amendments and is available on the BEST website at the following link: health-visitor-formulary.pdf

Barnsley Lipid Management for Primary Prevention of Cardiovascular Disease in Adults [UPDATED] and Barnsley Severe Hyperlipidaemia Pathway [UPDATED]
These guidelines have been updated in line with the summary of national guidance for lipid management of cardiovascular disease which was updated in March 2024 and is available here. The updated guidelines are available on the BEST website:
lipid-management-pathway.pdf
barnsley-severe-hyperlipidaemia-pathway.pdf

Barnsley Emollient Formulary Choices Guidance [MINOR UPDATE]
This guideline has received minor updates in line with the recent MHRA alert. Epimax® ointment and Epimax® paraffin-free ointment should not be applied to the face. Patients should wash their hands and avoid touching their eyes after using these products. The first line ointment choice is now fifty:50 ointment for new patients.

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

Essential Mouth Care Management [UPDATED] and Mouth Care Information for relatives and carers [NEW]
This guideline and leaflet provide information to clinicians and relatives/carers on essential mouth care management in end of life care. The guideline and leaflet are available on the BEST website:
Palliative Care: Essential Mouth Care Management/ Oral Hygiene - BEST

Amber G / Shared Care Guidelines

Ciclosporin 1mg/ml eye drops (Ikervis®), for treatment of severe keratitis in adult patients with dry eye disease, which has not improved despite treatment with tear substitutes Amber-G guidance

The guidance is available on the BEST website at the following link: Ciclosporin Eye Drops - BEST

The guidance notes that response to treatment and examination of the eye(s) should be undertaken every 6 months by the secondary care eye specialist. (Ophthalmic medicinal products, which affect the immune system, including ciclosporin, may affect host defences against local infections and malignancies. Therefore, regular examination of the eye(s) is recommended, e.g., at least every 6 months, when Ikervis® is used for years).

DMARDs Shared Care Guideline for the prescribing of Disease Modifying Antirheumatic Drugs (DMARDs) in rheumatology patients [UPDATED]

This Shared Care Guideline has received a routine update and the updated version will be available on the BEST website in due course.

Shared Care Guideline for Melatonin in Children and Adolescents for sleep disorders [MINOR UPDATE]

This Shared Care Guideline has received minor updates, the main changes are:

- Generic Melatonin 2mg prolonged release tablets have replaced the brand Circadin® 2mg prolonged release tablets as it is more cost-effective to prescribe generically.

- **Ceyesto® melatonin 1mg/ml oral solution has been added for use in children aged 6 years and over** as this is a more cost-effective brand of melatonin 1mg/ml oral solution than the Consilient Health brand. Refer to excipient and shelf-life information in both the guideline and the Barnsley Formulary updates table within this memo. The Consilient Health brand of melatonin 1mg/ml oral solution remains in the shared care guideline, restricted for use in children aged 3 to <6 years. Melatonin oral solution should be reserved for use in patients with enteral feeding tubes or when solid dose formulations are not suitable in line with the shared care guideline and formulary.

The updated Shared Care Guideline will be available on the BEST website in due course.

Heart Failure Diagnosis, Treatment and Services guideline [MINOR UPDATE]

Within this guideline, brain natriuretic peptide (BNP) has been replaced by NT- proBNP in line with NICE CG 106. Updated reference ranges / values have been included as per the latest NHS SYB Pathology: Barnsley & Rotherham Laboratories guidelines.

The updated Heart Failure guideline is available on BEST at the following link: CVS: Heart Failure Pathway (APC Approved) – BEST.

Accessing Guidelines

Prescribing guidelines, shared care and amber G guidelines can be accessed via the BEST website or the Barnsley formulary:

Prescribing guidelines - BEST

Shared care and Amber G guidelines - BEST

The Barnsley Joint Formulary can be accessed at the link below:

http://www.barnsleyformulary.nhs.uk/

Please note that the recent change to the BEST platform resulted in many of the existing links embedded within the formulary and ScriptSwitch to specific guidelines on the BEST website no longer

working. Work is in progress to address this. In the interim please notify deborah.cooke@nhs.net or joanne.howlett2@nhs.net if you identify any links within the formulary or ScriptSwitch which are not working. Guidelines can also continue to be accessed via the BEST website directly using the above links.

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.

Barnsley Formulary Updates

The Committee noted the traffic light classifications recently assigned by the South Yorkshire Integrated Medicines Optimisation Committee (IMOC) and the following formulary positions were agreed by the Committee:

Drug	Formulary Indication	Barnsley Formulary status (including traffic light classification)
Horizon Scanning November IMOC		
Ivermectin 3mg tablets (dual classification)	Human sarcoptic scabies in adults and children weighing ≥15kg	Formulary green New licensed products available
Ivermectin 3mg tablets (dual classification)	Treatment of gastrointestinal strongyloidiasis (anguillulosis) and suspected or diagnosed microfilaraemia in patients with lymphatic filariasis due to Wuchereria bancrofti	Formulary red New licensed products available
TLDL Sub Group List October IMOC		
Bupropion	Nicotine dependence	Formulary green in combination with motivational support in nicotine-dependent patients in line with Barnsley Smoking Cessation guidelines (currently being updated, refer to team member for further information).
NICE TAs		
Vibegron	Overactive bladder syndrome in adults	Formulary green NICE TA999
Latanoprost–netarsudil	Previously treated primary open-angle glaucoma or ocular hypertension	Formulary red NICE TA1009
IMOC approved guidelines		
Alimemazine	Treatment of sleep disorders in children	Formulary amber South Yorkshire ICB Shared Care Protocol It is more cost effective to prescribe alimemazine oral solution as one of the following brands: - Itzenal® (sugar-free solution) - Alfresed® (contains sugar). Both brands available as 7.5mg/5ml and 30mg/5ml formulations.

Ceyesto® melatonin 1mg/ml oral solution	**Restricted** to children/ adolescents who require medication to be administered via a feeding tube (**off label use**) or in exceptional circumstances in other patients where Adaflex®, Melatonin 2mg PR and Slenyto® have been trialled without success (as detailed in the shared care guideline). **Ceyesto® 1mg/ml oral solution is <u>restricted to use in children 6yrs and over.</u>** (The Consilient Health brand of Melatonin 1mg/ml oral solution remains in the Shared Care Guideline, restricted for use in children aged 3 to <6years. Refer to the Shared Care Guideline for further information).	Formulary amber **<u>Excipients:</u>** Propylene glycol 52mg/ml (E1520), benzyl alcohol 6mg/ml, sucralose (E955), sodium ascorbate (1mg/ml), strawberry flavour and purified water. Co-administration with any substrate for alcohol dehydrogenase such as ethanol may induce serious effects in neonates. **<u>Excipients with known effect</u>** Benzyl alcohol may cause allergic reactions and has been linked with the risk of severe side effects including breathing problems (called "gasping syndrome") in young children. The minimum amount of benzyl alcohol at which toxicity may occur is not known. Benzyl alcohol containing products should not be used in pre-term or full-term neonates (up to 4 weeks) unless strictly necessary. Large amounts of benzyl alcohol can build-up in the body and may cause side effects (metabolic acidosis). Large volumes should be used with caution and only if necessary, especially in subjects with liver or kidney impairment or those that are pregnant or breast-feeding. Caution is also advised in young children (under 6 years) due to the risk of accumulation. See dosage and administration section for further information. Shelf life after first opening: 1 month.

MHRA Drug Safety Update

The September and October 2024 MHRA Drug Safety Updates can be accessed at the following links:
Drug Safety Update (publishing.service.gov.uk)
October_2024_DSU.pdf (publishing.service.gov.uk)

Issues relating to primary care:

Valproate use in men: as a precaution, men and their partners should use effective contraception
[Information is in the process of being incorporated into existing valproate shared care guidelines]

A retrospective observational study has indicated a possible association between valproate use by men around the time of conception and an increased risk of neurodevelopmental disorders in their children. Inform male patients who may father children of this possible increased risk and the recommendation to use effective contraception during valproate treatment and for at least 3 months after stopping valproate.
See a previous Drug Safety Update for the introduction of the prescribing requirements in patients under 55 years of age (female and male) – the new advice provided here is in addition to these measures.
No one should stop taking valproate without talking to their healthcare professional.

Information for healthcare professionals:

- findings from a retrospective observational study, combining analyses of electronic medical records in Norway, Denmark and Sweden, indicate a possible increased risk of neurodevelopmental disorders in children born to men treated with valproate in the 3 months prior to conception, compared to those born to men treated with lamotrigine or levetiracetam
- in the study, the cumulative risk of neurodevelopmental disorders ranged from 4.0% to 5.6% in the valproate treated group versus 2.3% to 3.2% in the composite lamotrigine/levetiracetam monotherapy treated group (pooled adjusted hazard ratio 1.50, 95% CI 1.09 to 2.07)
- this potential risk is much lower than the up to 30-40% risk of neurodevelopmental disorders in children born to mothers taking valproate during pregnancy, estimated from several studies
- the study did not include an untreated group and background risk in this patient population is therefore unknown
- an increased risk of neurodevelopmental disorders in children of fathers treated with valproate in the 3 months prior to conception is possible however the causal role of valproate is not confirmed. As such this advice is precautionary

Advice for healthcare professionals:

- inform male patients (of any age) who may father children of the possible risk at initiation of valproate or at their next regular treatment review – this counselling should be given irrespective of the indication for valproate and also after intravenous use of valproate
- as a precaution, recommend that male patients use effective contraception (condoms, plus contraception used by the female sexual partner) throughout the valproate treatment period and for 3 months after stopping valproate, to allow for one completed sperm cycle not exposed to valproate
- at the next regular treatment review, discuss with men on oral valproate treatment whether they are planning a family in the next year and if they are, refer to a specialist to discuss alternative treatment options
- if a female patient reports they are pregnant or planning a pregnancy with a man on valproate (including those undergoing IVF), refer for prenatal counselling
- advise men not to donate sperm during valproate treatment and for 3 months after stopping valproate
- report any suspected adverse drug reactions associated with valproate on a Yellow Card

Information for healthcare professionals to provide to patients:

- if you father a child while you are taking valproate or in the 3 months after stopping valproate, there is a potential small increased risk of the child being diagnosed with a mental or movement related developmental disorder (neurodevelopmental disorder)
- advice will be added to the valproate patient guide; in the meantime see MHRA's Advice for male patients on valproate to use contraception and visual risk of communication diagram to be used by a healthcare professional when counselling the risks

Advice for healthcare professionals to provide to patients:

- it is recommended that you and your female sexual partner should both use effective birth control (condoms and another form of female contraception) as a precaution while you are taking valproate and for at least 3 months after stopping valproate
- allow at least 3 months to pass after stopping valproate before trying to father a child
- you should not donate sperm whilst taking valproate and for 3 months after stopping
- do not stop taking valproate unless you are advised to do so by a healthcare professional
- report any suspected adverse drug reactions associated with valproate on a Yellow Card

GLP-1 receptor agonists: reminder of the potential side effects and to be aware of the potential for misuse

Healthcare professionals are reminded to inform patients about the common and serious side effects associated with glucagon-like peptide-1 receptor agonists (GLP-1RAs).

Advice for healthcare professionals:

- inform patients upon initial prescription and when increasing the dose about the common risk of gastrointestinal side effects which may affect more than 1 in 10 patients. These are usually non-serious, however can sometimes lead to more serious complications such as severe dehydration, resulting in hospitalisation
- be aware that hypoglycaemia can occur in non-diabetic patients using some GLP-1RAs for weight management; ensure patients are aware of the symptoms and signs of hypoglycaemia and know to urgently seek medical advice should they occur
- patients should also be warned of the risk of falsified GLP-1 RA medicines for weight loss if not prescribed by a registered healthcare professional, and be aware that some falsified medicines have been found to contain insulin
- be aware there have been reports of potential misuse of GLP-1RAs for unauthorised indications such as aesthetic weight loss
- report suspected adverse drug reactions to the Yellow Card Scheme

Advice for healthcare professionals to provide to patients:

- GLP-1RAs are prescription-only medicines to be used under medical supervision and should only be prescribed by a registered healthcare professional
- the benefits and risks of using a GLP-1RAs for weight loss outside of the licensed indications have not been studied
- common gastrointestinal side-effects of GLP-1RAs treatment (including nausea, vomiting, diarrhoea and constipation) can persist for several days and may affect more than 1 in 10 patients. This may result in dehydration, which if severe may lead to other serious health complications such as kidney damage resulting in hospitalisation
- throughout treatment stay well hydrated by drinking plenty of fluids (such as water) to avoid dehydration, which can sometimes occur after experiencing gastrointestinal side-effects including vomiting and diarrhoea
- other serious but less common side-effects of GLP-1RAs include acute gallstone disease, pancreatitis, and serious allergic reactions
- if obtaining a private prescription (from a non-NHS prescriber), ensure that this is dispensed from authorised sources, such as registered online pharmacies, to avoid the risk of receiving falsified pens
- carefully read the instructions for use in the Patient Information Leaflet, and use the prescribed dose
- if you are concerned about any side-effects, speak to a healthcare professional

Insulin pumps and continuous glucose monitoring (CGM) equipment: guidance for users on reporting suspected adverse incidents and safety concerns to the MHRA's Yellow Card scheme

The MHRA ask healthcare professionals to support new guidance for users of diabetes management equipment, their families, care givers and representatives. It explains how to report safety concerns to the MHRA using the Yellow Card scheme and describes the information the MHRA need to support their device investigations.

Advice for healthcare professionals:

- insulin pumps and continuous glucose monitoring (CGM) devices are complex devices with the potential to result in serious harm in the event of error. To aid the MHRA in early identification of safety concerns associated with these devices, users of the equipment need to know how to report safety issues to the MHRA
- the MHRA have published guidance to explain to users of all medical devices manufactured for diabetes management how to report safety concerns to the MHRA using the Yellow Card scheme
- this guidance is expected to improve the quality of information the MHRA receives and should the need arise, support a thorough investigation of the relevant equipment
- highlight the guidance to patients using insulin pumps, insulin pens and CGM devices
- remind patients that if they suspect a problem with their device, they should be advised to use an alternative method to manage their diabetes
- the MHRA are also providing a poster with a direct link to the guidance (QR code) which can be printed to display in your clinic waiting room
- healthcare professionals should also speak to their local Medical Device Safety Officer (MDSO) on how you can support the reporting of adverse incidents with these medical devices
- report problems and adverse incidents associated with medical devices used in the management of diabetes on a Yellow Card

Advice for healthcare professionals to provide to patients:

- seek medical advice without delay if you have concerns that your health has been impacted by a potential safety issue relating to your device
- use an alternative device if you suspect your current device is not performing adequately in managing your diabetes. Ensure you have an alternative device available at all times
- it is important to read the guidance being given to you on how to report concerns with the equipment used to manage your diabetes
- it is important that you report safety concerns with your devices to the Yellow Card scheme. Yellow Card reports help the MHRA to identify safety issues and to consider actions to improve the safety and performance of devices used by people living with diabetes
- if you believe there is a safety problem with your equipment, submit a report via the Yellow Card scheme and use the guidance document to help you create a report

Bromocriptine: monitor blood pressure when prescribing bromocriptine for prevention or inhibition of post-partum physiological lactation

A safety review has been conducted by the MHRA following a Yellow Card report concerning a patient who was taking bromocriptine. The review concluded that blood pressure monitoring of patients prescribed with this drug is essential especially during the first days of treatment.

Advice for healthcare professionals:

- bromocriptine should only be prescribed to suppress post-partum physiological lactation, where it is medically indicated such as intrapartum loss, neonatal death, or in some cases of HIV infection of the mother
- bromocriptine should not be used for routine lactation suppression, or for relieving symptoms of postpartum breast pain and engorgement, which can be adequately treated with non-pharmacological interventions (such as firm breast support, ice application) and simple analgesics
- use is contraindicated for patients with uncontrolled hypertension, hypertensive disorders of pregnancy (including eclampsia, pre-eclampsia or pregnancyinduced hypertension), hypertension post-partum and in the puerperium, a history of coronary artery disease or other severe cardiovascular conditions
- particular caution is required in patients who are on concomitant therapy or recent treatment with drugs that can alter blood pressure
- when prescribing bromocriptine for any of its indications, carefully monitor for an increase in blood pressure, especially during the first days of therapy and with any subsequent dose increases
- if patients prescribed bromocriptine present with signs and symptoms of hypertension, treatment should be discontinued, and the patient evaluated promptly by healthcare professionals
- clinical guidance recommends cabergoline as the preferred drug for prevention or inhibition of post-partum physiological lactation, owing to the single dose regime and lower rates of rebound breast activity and adverse events. However, blood pressure monitoring is still necessary when taking cabergoline as both cabergoline and bromocriptine are dopamine agonists and should not be given to women with hypertension or pre-eclampsia
- healthcare professionals are encouraged to read the Summary of Product Characteristics (SmPC) for special warnings and contraindications for the use of bromocriptine and cabergoline
- report suspected adverse drug reactions to bromocriptine or cabergoline to the Yellow Card scheme

Advice for healthcare professionals to provide to patients:

- bromocriptine is used to prevent or stop milk production after childbirth in women who are not breastfeeding only if there are medical reasons for doing so, for example to avoid further distress in women who lose a baby during or just after birth, or in some cases of HIV infection of the mother
- inform your doctor if you had blood pressure problems before or during pregnancy or after giving birth, such as eclampsia, pre-eclampsia, pregnancy-induced high blood pressure or high blood pressure after giving birth
- your doctor will need to check your blood pressure regularly during the first few days of treatment with bromocriptine
- seek urgent medical attention if you experience symptoms of high blood pressure, for example chest pain or unusually severe or persistent headache, with or without vision problems while taking bromocriptine
- report suspected adverse drug reactions to the Yellow Card scheme

Regards

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