South Yorkshire Integrated Care Board

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Barnsley Office: Hillder House
49-51 Gawber Road
Barnsley
S75 2PY
01226 433798

Our Ref: DC/NB

3rd March 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 8th February 2023

The main outcomes of the meeting were: -

Prescribing Guidelines

The Committee endorsed the following Barnsley prescribing guidelines:

Edoxaban is to be used first line for patients with NVAF unless there is a specific clinical reason not to do so [NEW]

Edoxaban is the first line DOAC for NVAF in line with the APC Position Statement. This guidance has been produced to support work on the NHSE Investment and Impact Fund (IIF) indicators for PCNs which focus on DOAC prescribing in Atrial Fibrillation. The guidance aims to ensure that any changes to medication, as part of work towards the indicators, are undertaken appropriately in a safe and effective manner.

The guidance outlines factors which should be taken into consideration if a switch to edoxaban is being considered and includes information on circumstances when a switch to edoxaban (from another DOAC) must **NOT** be undertaken. It should be noted that whilst the information aims to mitigate risk, it is not considered to be exhaustive and should be used in conjunction with other resources including the SPC (including contraindications and cautions), the Anticoagulation for stroke prevention in NVAF guidance and the NICE Technology Appraisal.

The guidance is available on the BEST website at the following link:
CVS: Edoxaban is to be used first line for patients with NVAF unless there is a specific clinical reason not to do so - Prescribing guideline (barnsleyccg.nhs.uk)

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

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

Shared Care Guidelines

Bempedoic acid with ezetimibe for primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia Amber-G guideline [NEW]

This Amber-G guidance applies to the use of bempedoic acid with ezetimibe in line with TA694 and the Barnsley Lipid Management for Primary Prevention guidance/ Barnsley Lipid Management for Secondary Prevention guidance (currently in development).

Bempedoic acid with ezetimibe is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet in adults:

• in patients who are either statin-intolerant or for whom a statin is contraindicated, **and** are unable to reach non-HDL-C goals with ezetimibe alone.

Note: Use of bempedoic acid without ezetimibe, or in combination with a statin is outside the scope of this guidance.

Bempedoic acid with ezetimibe can be prescribed and monitored in primary care following recommendation or initiation by a specialist via the lipid clinic or 'advice and guidance'. Alternatively, bempedoic acid with ezetimibe can be initiated by primary care clinicians with the appropriate knowledge and competencies in line with Barnsley Lipid Management guidance.

Note: It is more cost-effective to prescribe bempedoic acid 180mg/ ezetimibe 10mg tablets combination product than bempedoic acid and ezetimibe as two separate products.

The Amber-G guidance will be available on the BEST website in due course.

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

Prescribers (including secondary care clinicians) are encouraged to report any problems they experience with shared care or other medicines related issues, particularly where guidelines are not being complied with, to the following email address: BarnsleyAPCReport@nhs.net.

The Barnsley Interface Issues Form should be used to report such problems:
http://www.barnsleyccg.nhs.uk/members-professionals/area-prescribing-committee.htm

Other

Freestyle Libre 2

Following requests received in primary care relating to the initiation of Freestyle Libre 2 in patients with Type 2 Diabetes, the Committee were asked to agree an interim local position whilst the local guideline is in the process of being updated to bring it in line with current NICE guidance.

It was agreed that whilst the local guideline is in the process of being updated, if the specialist service choose to initiate Freestyle Libre 2 in patients with Type 2 Diabetes who meet the NICE criteria, the same process which is currently in place for initiation in patients with Type 1 Diabetes should be followed i.e. the specialist service should initiate and retain the prescribing for the first 3 months.

Traffic Light Classifications

The Committee assigned the following classifications to the products included in the following table:

Drug	Formulary Indication	Traffic light status (Drugs with a provisional classification are not currently included on the Barnsley formulary)
SPS New Medicines Newsletter December 2022		
Hydrocortisone (*Hisone*®) 5mg, 10mg and 20mg dispersible tablets	Glucocorticoid therapy	Non formulary provisional green
Smallpox vaccine (*Imvanex*®)	Active immunisation against smallpox, monkeypox and disease caused by vaccinia virus in adults	Formulary green
Other		
Dapagliflozin	Chronic Kidney Disease	Formulary green (previously formulary amber-G)

MHRA Drug Safety Update

The January 2023 MHRA Drug Safety Updates can be accessed at the following link:
Jan-2023-DSU-PDF.pdf (publishing.service.gov.uk)

Issues relating to primary care:

Xaqua® (metolazone) 5mg tablets: exercise caution when switching patients between metolazone preparations

Prescribers and dispensers should use caution if switching patients between different metolazone preparations as the rate and extent of absorption of metolazone are formulation dependent. This can impact the bioavailability of the product. The MHRA suggest following good practice in prescribing medicines by considering the licensed formulation (Xaqua®) in preference to unlicensed imported metolazone preparations in new patients. The product information for Xaqua® has been updated to clarify that references to comparative bioavailability with other metolazone products relate specifically to Metenix® and not to any other metolazone preparations.

Advice for healthcare professionals, and patients and carers can be found in the MHRA drug safety update (link above)

Please note that any necessary amendments to the Barnsley metolazone Amber G guideline will be made in due course following discussion with local specialists.

Topical testosterone (Testogel®): risk of harm to children following accidental exposure

Premature puberty and genital enlargement have been reported in children who were in close physical contact with an adult using topical testosterone and who were repeatedly accidentally exposed to this medicine. To reduce these risks, advise patients to wash their hands after application of topical testosterone, cover the application site with clothing once the product has dried, and wash the application site before physical contact with another adult or child.

Advice for healthcare professionals:

- when prescribing topical testosterone, inform patients of the potential consequences if it is accidentally transferred to other people
- inform patients that accidental transfer can lead to increased blood testosterone levels in the other person
- advise patients of the possible effects should accidental exposure occur in adult women (facial and/or body hair growth, deepening of voice, changes in menstrual cycle) or children (genital enlargement and premature puberty, including development of pubic hair)
- counsel patients on methods to reduce the risks of accidental exposure, including washing their hands with soap and water after application, covering the application site with clean clothing (such as a t-shirt) once the gel has dried, and washing the application area with soap and water before physical contact with another person

- encourage patients to be vigilant about implementing measures to minimise risk, to be alert for signs of accidental exposure, and to seek medical advice if accidental exposure is suspected
- report suspected adverse drug reactions associated with topical testosterone on a Yellow Card

Advice for healthcare professionals to provide to patients:

- topical testosterone products are used for testosterone replacement. When using these products on your skin, you must take care that the testosterone product is not accidentally transferred onto the skin of someone else
- if the testosterone in the product is accidentally transferred to someone else through physical contact, it can lead to increased blood testosterone levels in the other person. It can cause facial and body hair growth, deepening of voice and changes in the menstrual cycle of women, or accelerated height, genital enlargement, and early puberty (including development of pubic hair) in children
- the following precautions can reduce the risk of accidentally transferring testosterone from the patient's skin to another person:
    - after applying the product, wash your hands with soap and water
    - once the product has dried, cover the application site with clean clothing (such as a t-shirt)
    - before physical contact with another person (adult or child), wash the application site with soap and water after the recommended time period following application has passed

Electronic Prescribing and Medicines Administration Systems: report adverse incidents on a Yellow Card

The MHRA ask healthcare professionals to be vigilant to adverse incidents involving software, apps, and artificial intelligence (AI) as medical devices and to report incidents to the MHRA via the Yellow Card scheme.

Advice for healthcare professionals:

- be alert for potential errors occurring when using Electronic Prescribing and Medicines Administration Systems (ePMAS) which may lead to patient harm, especially errors involving the dosing of medicines or vaccines
- ePMAS and other software, apps and artificial intelligence intended to be used for a medical purpose are likely to be medical devices and any adverse incidents involving these devices should be reported to the MHRA's Yellow Card scheme
- use the new digital Yellow Card report form to inform the MHRA about adverse incidents involving software as a medical device

Regards

Deborah Cooke
Lead Pharmacist

cc: Medicines Management Team
Rebecca Hoskins, BHNFT
Mike Smith, BHNFT
Sarah Hudson, SWYPFT
Area Prescribing Committee Members (Secretary to the APC to circulate)
Local Medical Committee (Secretary to the LMC to circulate)
Alex Molyneux, Chief Pharmacy Officer, South Yorkshire ICB
Gary Barnfield, South Yorkshire ICB (Sheffield)
Charlotte McMurray, South Yorkshire ICB (Doncaster)
Stuart Lakin, South Yorkshire ICB (Rotherham)