South Yorkshire Integrated Care Board

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Our Ref: DC/NB

7th March 2024

To: Prescribing Clinicians and Pharmacists within the Barnsley locality

Dear Colleague

Re: Summary of Key Points from the Barnsley Area Prescribing Committee Meeting on 14th February 2024.

The following guidelines were approved by the Committee and will be made available on the BEST website in due course:

Rubefacients, benzydamine cream, mucopolysaccharide and cooling products (excluding topical NSAIDS and Capsaicin) Area Prescribing Committee Position Statement [UPDATED]
This position statement has been updated in line with the updated NHS England guidance 'Items which should not routinely be prescribed in primary care' and the updated NICE guidance NG226 Osteoarthritis in over 16s: diagnosis and management.

Inclisiran 284mg injection (Leqvio®) shared care guideline for treating primary hypercholesterolaemia or mixed dyslipidaemia [NEW]
This shared care guideline has been developed to enable the continuation of care by primary care clinicians of patients initiated on inclisiran by a specialist lipid service, where this is appropriate and in the patient's best interests.

Amber-G guidelines [UPDATED]

- **Vortioxetine (Brintellix®)**
  Updated with minor amendments.

- **Pregabalin for Generalised Anxiety Disorder**
  Reviewed in line with the updated NICE CKS.

- **Acamprosate calcium**
  Updated with minor amendments.

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/

Other

Generic Apixaban is the First Line DOAC for Non-Valvular AF

The Committee received the updated national commissioning recommendations for DOACs, which following the apixaban patent expiry and the subsequent availability of generic apixaban, highlight that generic apixaban is now the best value DOAC. In the absence of a specific clinical reason to select a particular DOAC, generic apixaban is now the first line DOAC for new patients with non-valvular AF. Apixaban is a twice a day treatment. Edoxaban is the second best value DOAC overall and the lowest cost once a day treatment option.

The Barnsley formulary and local DOAC guidelines are in the process of being updated.

SYICB Position Statement on the Prescribing of Gabapentinoids

The SYICB position statement, which relates to patients prescribed pregabalin or gabapentin to manage neuropathic pain, highlights some of the risks associated with these drugs and includes key recommendations to ensure/improve patient safety.

The position statement was recently approved by the South Yorkshire Integrated Medicines Optimisation Committee (SY IMOC) and can be accessed via the SY IMOC website: SYICB Position Statement on the Prescribing of Gabapentinoids V1.0.pdf. A link will also be added to the BEST website and the Barnsley formulary in due course.

The Barnsley pregabalin guideline for neuropathic pain and neuropathic pain drug management guideline also remain available on the BEST website:
Pregabalin Guidelines for Neuropathic Pain (APC Approved)

Practice level review work around pregabalin has been undertaken as part of the 2023-24 Medicines Optimisation Scheme. Please liaise with the Clinical Pharmacist or Technician supporting your practice for further information.

Barnsley Formulary Updates

The Committee noted 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)
Other		
Empagliflozin	Chronic Kidney Disease	Formulary green NICE TA942
Aerobika® device	Oscillating positive Expiratory pressure (OPEP) device	Formulary Amber-G The prescribing Oscillating Positive Expiratory Pressure (OPEP) Devices (Barnsley) guidance will be available on the BEST website in due course.

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

MHRA Drug Safety Update

The January 2024 MHRA Drug Safety Update can be accessed at the following link:
https://assets.publishing.service.gov.uk/media/65ae8f33fd784b0010e0c688/January_DSU_PDF.pdf

Issues relating to primary care:

Valproate (Belvo, Convulex, Depakote, Dyzantil, Epilim, Epilim Chrono or Chronosphere, Episenta, Epival, and Syonell▼): new safety and educational materials to support regulatory measures in men and women under 55 years of age

New safety and educational materials have been introduced for men and women and healthcare professionals to reduce the harms from valproate, including the significant risk of serious harm to the baby if taken during pregnancy and the risk of impaired fertility in males. These safety and educational materials support the new regulatory measures announced in the National Patient Safety Alert. Healthcare professionals should review the new measures and materials and integrate them into their clinical practice when referring patients and when prescribing or dispensing valproate.
The MHRA are also reviewing data highlighted in Drug Safety Update August 2023, which may suggest an increased risk of neurodevelopmental disorders in children whose fathers took valproate in the 3 months before conception. As a precaution we advise male patients who are planning a family within the next year, to discuss treatment options with a healthcare professional.

Advice for healthcare professionals:

- valproate must not be started in new patients (male or female) younger than 55 years, unless two specialists independently consider and document that there is no other effective or tolerated treatment, or there are compelling reasons that the reproductive risks do not apply. For the majority of patients, other effective treatment options are available
- at their next annual specialist review, women of childbearing potential and girls receiving valproate should be reviewed using the revised valproate Annual Risk Acknowledgement Form. A second specialist signature will be needed if the patient is to continue on valproate, however subsequent annual reviews will only require one specialist
- general practice and pharmacy teams should continue to prescribe and dispense valproate and if required offer patients a referral to a specialist to discuss their treatment options. Valproate should be dispensed in the manufacturer's original full pack
- report suspected adverse drug reactions associated with valproate on a Yellow Card

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

- do not stop taking valproate without advice from a specialist. This is because epilepsy or bipolar disorder may worsen without treatment
- if you are on valproate, please attend any offered appointments to discuss your treatment plan and talk to a healthcare professional if you are concerned
- consult the Patient Information Leaflet and new Patient Guide for information about the risks of valproate – see also the MHRA information page for resources
- as a precaution, male patients who are planning a family within the next year should speak to a healthcare professional about their treatment options

Fluoroquinolone antibiotics: must now only be prescribed when other commonly recommended antibiotics are inappropriate

Systemic fluoroquinolones must now only be prescribed when other commonly recommended antibiotics are inappropriate. This follows a review by the MHRA which looked at the effectiveness of current measures to reduce the identified risk of disabling and potentially long-lasting or irreversible side effects.

Advice for healthcare professionals:

- systemic (by mouth, injection, or inhalation) fluoroquinolones can cause long-lasting (up to months or years), disabling and potentially irreversible side effects, sometimes affecting multiple body systems and senses
- the UK indications for systemic fluoroquinolones have been updated so they must only be used in situations when other antibiotics, that are commonly recommended for the infection, are inappropriate
- situations in which other antibiotics are considered to be inappropriate and where a fluoroquinolone may be indicated are where:
    - there is resistance to other first-line antibiotics recommended for the infection
    - other first-line antibiotics are contraindicated in an individual patient
    - other first-line antibiotics have caused side effects in the patient requiring treatment to be stopped
    - treatment with other first-line antibiotics has failed
- this goes further than previous measures which set out that fluoroquinolones should not be prescribed for non-severe or self-limiting infections, or non-bacterial conditions, for example non-bacterial (chronic) prostatitis. These measures are still in place.
- as a reminder, patients should be advised to stop fluoroquinolone treatment at the first signs of a serious adverse reaction, such as tendinitis or tendon rupture, muscle pain, muscle weakness, joint pain, joint swelling, peripheral neuropathy and central nervous system effects, and to contact their doctor immediately
- refer to MHRA's sheet for patients (regular print or large print) for further advice
- remain alert to the risk of suicidal thoughts and behaviours with use of fluoroquinolone antibiotics. A reminder about these risks was published in the September 2023 issue of Drug Safety Update.
- as a reminder of advice published in our August 2023 issue of Drug Safety Update:
    - avoid fluoroquinolone use in patients who have previously had serious adverse reactions with a quinolone antibiotic (for example, nalidixic acid) or a fluoroquinolone antibiotic
    - prescribe fluoroquinolones with special caution for people older than 60 years and for those with renal impairment or solid-organ transplants, because they are at a higher risk of tendon injury
    - avoid coadministration of a corticosteroid with a fluoroquinolone since this could exacerbate fluoroquinolone-induced tendinitis and tendon rupture
- report suspected adverse drug reactions to fluoroquinolone antibiotics on the Yellow Card website or via the Yellow Card app (download it from the Apple App Store, or Google Play Store)

Advice for healthcare professionals to provide to patients:

- fluoroquinolones are a class of antibiotics that include ciprofloxacin, delafloxacin, levofloxacin, moxifloxacin, and ofloxacin – these medicines may also have a brand name so patients should check the details of all antibiotics prescribed to them
- fluoroquinolone antibiotics have been reported to cause serious side effects involving tendons, muscles, joints, nerves, or mental health – in some patients, these side effects have caused long-lasting or permanent disability
- stop taking your fluoroquinolone antibiotic and contact your doctor immediately if you have any of the following signs of a side effect:
    - tendon pain or swelling – if this happens, rest the painful area until you can see your doctor
    - pain in your joints or swelling in joints such as in the shoulders, arms, or legs
    - abnormal pain or sensations (such as persistent pins and needles, tingling, tickling, numbness, or burning), weakness in the legs or arms, or difficulty walking
    - severe tiredness, depressed mood, anxiety, problems with your memory or severe problems sleeping
    - changes in your vision, taste, smell or hearing

Tell your doctor if you have had any of the above effects at any point while taking a fluoroquinolone – this means you should avoid them in the future

Omega-3-acid ethyl ester medicines (Omacor/Teromeg 1000mg capsules): dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or cardiovascular risk factors
Systematic reviews and meta-analyses of randomised controlled trials have highlighted a dose-dependent increased risk of atrial fibrillation in patients with established cardiovascular diseases or cardiovascular risk factors treated with omega-3-acid ethyl ester medicines compared to placebo.
Advice for healthcare professionals: • atrial fibrillation is now listed as an adverse drug reaction with a "common" frequency (may affect up to 1 in 10 people) for medicines containing omega-3-acid ethyl esters licensed for the treatment of hypertriglyceridaemia • the observed risk was found to be highest with a dose of 4 g/day • advise patients taking omega-3-acid ethyl ester medicines for the treatment of hypertriglyceridaemia to seek medical attention if they develop symptoms of atrial fibrillation • if a patient develops atrial fibrillation whilst taking these medicines for the treatment of hypertriglyceridaemia then the medicine should be discontinued permanently • report suspected adverse drug reactions associated with omega-3-acid ethyl ester medicines on a Yellow Card **Advice for healthcare professionals to provide to patients:** • medicinal products containing omega-3 ethyl esters are licensed for the reduction of high triglyceride levels (hypertriglyceridaemia) after changes to diet have not worked • very high levels of triglycerides in the blood can cause problems such as increasing the risk of coronary heart disease and causing inflammation of the pancreas (pancreatitis) • before taking an omega-3-acid ethyl ester medicine, inform your doctor or pharmacist if you are currently experiencing heart problems or have a history of heart problems • talk to your doctor if you experience palpitations, dizziness, shortness of breath and tiredness as these may be symptoms of an irregular and often very rapid heart rhythm (atrial fibrillation) • do not stop your hypertriglyceridaemia treatment without first discussing this with your doctor

Kind Regards

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Lead Pharmacist

cc: Medicines Management Team
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