NHS South Yorkshire Integrated Care Board

Medicines Management Newsletter March 2024

Welcome to the March edition of the Barnsley Place Medicines Management Newsletter. This newsletter is distributed to all practices and pharmacies in the Barnsley area and aims to keep you informed of the latest medicine updates, drug alerts/recalls, and the work currently being completed in GP Practices by the Medicines Management Team.

Updates from the Barnsley Area Prescribing Committee (APC).

Prescribing Guidelines

Possible Alternatives to Unlicensed Specials [UPDATED]

Specials: Unlicensed specials Prescribing guideline

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

Freestyle Libre - Protocol for Adults Shared care guideline

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

Freestyle Libre - Protocol for Children Shared care guideline

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

GI: Oral Nutritional Supplement Prescribing guideline

South Yorkshire ICB Guidance for Continuous Glucose Monitoring (CGM) in Adults and Children with type 1 and type 2 diabetes [NEW]

The South Yorkshire ICB Guidance for Continuous Glucose Monitoring (CGM) in Adults and Children with type 1 and type 2 diabetes has been endorsed by IMOC and is available at the following link:

Diabetes: SY ICB Guidance for Continuous Glucose Monitoring (CGM) in Adults and Children with type 1 and type 2 diabetes Prescribing guideline

A South Yorkshire ICB Guideline to Support the Prescribing of CGM is in development and will include device options and characteristics.

Updates from the Barnsley Area Prescribing Committee (APC) continued.

Barnsley Formulary Updates

Recent formulary changes include:

- **Atogepant,** for the prophylaxis of migraine, has been assigned a **non-formulary grey** classification.
- **Calcifediol**, for the 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, has been assigned a **non-formulary grey** classification.
- **Drospirenone,** progestogen only contraceptive with 24- hour missed pill window, has been assigned a **non-formulary green** classification.
- **Respiratory syncytial virus vaccine**, has been assigned a **non-formulary grey** classification.
- **Hepatitis A vaccine**, has been assigned a **formulary green** classification in line with the Green Book (previously non-formulary grey).
- **Hepatitis B vaccine**, has been assigned a **formulary green** classification in line with the Green Book (previously non-formulary grey).
- **Dexcom One** (CGM), has been assigned a **formulary amber** classification. Note that both the sensors and transmitters are now included in the Drug Tariff and can be prescribed.
- **Famotidine,** H2-receptor antagonist, has been assigned a **formulary green** classification.
- **Altraplen® Compact Daily**, a milk- based ready to drink ONS, has been assigned a **formulary amber-G** classification. 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**, a long acting dual GIP and GLP-1 receptor agonist for type 2 diabetes, has been assigned a **formulary amber-G** classification.
- **Fentanyl (Immediate release),** for patients undergoing palliative care treatment as per NHSE guidance, has been assigned a **non-formulary amber-G** classification.
- **Fentanyl (Immediate release),** for patients **not** undergoing palliative care treatment as per NHSE guidance, has been assigned a **non-formulary grey** classification.
- **Reboxetine**, for the treatment of depression, has been assigned a **non-formulary amber-G** classification.
- **Rupatadine**, a non-sedating antihistamine, has been assigned a **non-formulary grey** classification.
- **Simple eye ointment**, has been assigned a **non-formulary grey** classification.
- **Sun protection cream**, has been assigned a **formulary grey** classification (previously formulary green)**.** South Yorkshire Self-Care guidance applies unless the patient has an ACBS approved indication.
- **Daridorexant,** for treatment of adult patients with insomnia, has been assigned an interim **grey** classification by SY IMOC and a supporting pathway and prescribing guideline are currently in development. The classification will be reviewed by IMOC in due course, refer to IMOC TLDL for the latest information.

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.

MHRA Drug Safety Update (continued)

- 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.

MHRA Drug Safety Update (continued)

- 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.

MHRA Drug Safety Update (continued)

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.

Support to Community Pharmacies

As part of the continued effort to support community pharmacies, we encourage pharmacies to contact us with any concerns or issues they may be facing, and we will endeavour to help wherever we can.

Pharmacies are advised to flag any significant issues or concerns as soon as possible.

Discharge Medication Service

If a pharmacy needs to query any discrepancies as part of the Discharge Medication Service, could you please cc the respective clinical pharmacist within the GP practice.

Disruptions to communication methods (phone lines/email)

Should any community pharmacies experience disruption to their lines of communication can they please bring these to our attention, wherever possible.

The team can be contacted by email:

Shoaib Ashfaq, Primary Care Network Clinical Pharmacist – s.ashfaq@nhs.net
Mir Khan, Primary Care Network Clinical Pharmacist – mir.khan1@nhs.net
Shauna Kemp, Primary Care Network Technician – shauna.kemp@nhs.net

If you have any queries regarding medication or require support in identifying patients affected by any of the issues discussed in this newsletter, please contact the Medicines Management Pharmacist and/or Technician working in your practice.

Alternatively contact the Medicines Management Team on 01226 433669 or 433798.

We would welcome any feedback you have to give on this newsletter, as well as any suggestions for future articles.

Please send ideas and comments to Jody Musgrave or Claire Taylor via email addresses jody.musgrave@nhs.net or claire.taylor18@nhs.net

Many Thanks