**South Yorkshire Integrated Care Board**
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Our Ref: DC/NB

9th October 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 September 2023**

The main outcomes of the meeting were: -

## Prescribing Guidelines

The following guideline was approved by the Committee:

**Hormone Replacement Therapy Formulary Treatment Options [NEW]**
This new guideline outlines the oral, transdermal and topical formulary treatment options for HRT. Additional information includes; information on treatments for older women (60 years plus), choice of HRT, information on topical testosterone therapy in post-menopausal women – unlicenced use *(this should be initiated by a specialist in line with the Shared Care Guideline*), risks of HRT, information on review and duration of treatment, and when to refer. Refer to the table below for information on formulary changes*.

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

## Amber G / Shared Care Guidelines

There were no amber-G / shared care guideline 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

## Other

**Methenamine Hippurate**

It was noted that generic methenamine is now less expensive than the Hiprex® brand and it was therefore agreed to remove recommendations to prescribe as the brand Hiprex® from the Barnsley Formulary and the 'Barnsley Primary Care Antimicrobial Prescribing Guidance Supporting Information'.

**Barnsley Guidance on alternatives to vitamin B12 injections (hydroxocobalamin) during the COVID-19 pandemic**

It was agreed that this guidance will be removed from the BEST website and the Barnsley Formulary as the information on which it was based is no longer available on the British Society Haematology (BSH) website.

## Barnsley Formulary Updates

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

| Drug | Formulary Indication | Formulary status (including traffic light classification) |
|---|---|---|
| **September 2023 IMOC TLDL Sub-group list** | | |
| **Dequalinium chloride 10mg vaginal tablets** | Bacterial vaginosis | Non-formulary red (previously non-formulary provisional grey) |
| **Dexamethasone and levofloxacin 1mg/5mg in 1mL eye drops (Ducressa®)** | Prevention of infection associated with cataract surgery in adults | Non-formulary red (previously non-formulary provisional grey) |
| **Duloxetine** | Stress Urinary Incontinence | Non-formulary amber-G (previously non-formulary grey) |
| **Eyelid hygiene preparations (e.g. Blephasol® wipes and lotion)** | Eyelid hygiene | Non-formulary grey |
| **Fampridine** | Multiple sclerosis | Non-formulary grey |
| **Fluoride tablets** | Dental indications | Non-formulary red |
| **Freestyle Libre®** | Flash glucose monitoring system | Formulary amber-G (previously formulary amber) |
| **Glucosamine and chondroitin** | Pain associated with osteoarthritis | Non-formulary grey.<br><br>Glucosamine and chondroitin are included in the NHS England guidance 'Items which should not routinely be prescribed in Primary Care'<br>NHS England » Items which should not routinely be prescribed in primary care: policy guidance |

| September 2023 IMOC Horizon Scanning | | |
|---|---|---|
| **Cholera vaccine (Vaxchora®)** | Immunisation | Non-formulary grey.<br>Vaxchora® not yet included in the Green Book. |
| **Hepatitis A vaccine (Avaxim Junior®)** | Immunisation | Non-formulary grey.<br>Avaxim Junior® not yet included in the Green Book. |
| **Hepatitis B vaccine 10microgram vial (PreHevbri®)** | Immunisation | Non-formulary grey.<br>PreHevbri® not yet included in the Green Book. |
| **Naloxone 1.26mg in 0.1mL single-dose nasal spray** | Emergency therapy for known or suspected opioid overdose | Non-formulary |
| **Netarsudil + latanoprost 50micrograms/200 micrograms in 1mL eye drops (Roclanda®)** | Primary open-angle glaucoma or ocular hypertension | Non-formulary grey |
| **Tozinameran 10 dose multi-dose vial (Comirnaty® 3micrograms/ dose)** | COVID-19 vaccine - infants and children aged 6 months to 4 years | Formulary green.<br>Information for healthcare professionals can be found here |
| ***HRT formulary section will be updated with the information below in line with the HRT Guideline:** | | |
| **Zumenon® tablets** | First line oral 'oestrogen only' HRT preparation | Formulary green |
| **Elleste Solo® tablets** | Alternative first line oral 'Oestrogen only' HRT preparation | Formulary green |
| **Premarin® tablets** | 0.625mg or 1.25mg conjugated oestrogen - second line oral 'oestrogen only' HRT preparation.<br><br>300mcg conjugated oestrogen - Low dose oral 'oestrogen only' HRT preparation- suitable for older women (60 years and over). | Formulary green |
| **Premique® tablets** | Low dose oral 'continuous combined' HRT preparation for women over 60 years | Formulary green |
| **Kliovance® tablets** | Alternative low dose oral 'continuous combined' HRT preparation for women over 60 years | Formulary green |
| **Novofem® tablets** | First line oral 'sequential combined' HRT preparation | Formulary green |
| **Elleste Duet® tablets** | Alternative first line oral 'sequential combined' HRT preparation | Formulary green |
| **Femoston® tablets** | Second line oral 'sequential combined' HRT preparation | Formulary green |
| **Tridestra® tablets** | Alternative second line oral 'sequential combined' HRT preparation | Formulary green |
| **Kliofem® tablets** | First line oral 'continuous combined' HRT preparation | Formulary green |
| **Elleste Duet Conti® tablets** | First line oral 'continuous combined' HRT preparation | Formulary green |
| **Femoston Conti® tablets** | Second line oral 'continuous combined' HRT preparation | Formulary green |
| **Indivina® tablets** | Second line oral 'continuous combined' HRT preparation | Formulary green |
| **Bijuve® capsules** | Second line oral 'continuous combined' HRT preparation | Formulary green |
| **Evorel® patch** | First line transdermal 'oestrogen only' HRT preparation | Formulary green |
| **Estradot® patch** | Second line transdermal 'oestrogen only' HRT preparation | Formulary green |
| **Estraderm MX® patch** | Second line transdermal 'oestrogen only' HRT preparation | Formulary green |
| **Evorel Sequi® patch** | First line transdermal 'sequential combined' HRT preparation | Formulary green |

| | | |
|---|---|---|
| **FemSeven Sequi® patch** | Second line transdermal 'sequential combined' HRT preparation | Formulary green |
| **Evorel Conti® patch** | First line transdermal 'continuous combined' HRT preparation | Formulary green |
| **FemSeven Conti® patch** | Second line transdermal 'continuous combined' HRT preparation | Formulary green |
| **Oestrogel® gel** | Alternative to patch, transdermal 'oestrogen only' HRT preparation | Formulary green |
| **Sandrena® gel** | Alternative non-patch transdermal 'oestrogen only' HRT preparation | Formulary green |
| **Utrogestan® (micronised progesterone) capsules** | 'Oestrogen only' transdermal therapy can be used with micronised progesterone (Utrogestan®). Refer to the HRT guidance for further information. | Formulary green |
| **Ovestin® cream** | First line topical oestrogen treatment option. | Formulary green |
| **Vagirux® vaginal tablet** | Second line topical oestrogen treatment option. | Formulary green |
| **Estring® vaginal delivery system** | Third line topical oestrogen treatment option. Reserved for women with dexterity issues or allergies which prevent use of cream or vaginal tablets. | Formulary green |
| **Other** | | |
| **Morphine sulphate orodispersible immediate release tablets (Actimorph®)** | Opioid analgesic | Formulary green. Different strengths available.<br><br>Morphine sulphate oral solution **10mg/5ml** will also remain formulary green. |
| **Lurasidone** | Antipsychotic | Non-formulary provisional red (Previously non-formulary provisional amber) |

## MHRA Drug Safety Update

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

Issues relating to primary care:

| **Fluoroquinolone antibiotics: reminder of the risk of disabling and potentially long-lasting or irreversible side effects** |
|---|
| Healthcare professionals prescribing fluoroquinolone antibiotics (ciprofloxacin, delafloxacin, levofloxacin, moxifloxacin, ofloxacin) are reminded to be alert to the risk of disabling and potentially long-lasting or irreversible side effects. Do not prescribe fluoroquinolones for non-severe or self-limiting infections, or for mild to moderate infections (such as in acute exacerbation of chronic bronchitis and chronic obstructive pulmonary disease) unless other antibiotics that are commonly recommended for these infections are considered inappropriate. Fluoroquinolone treatment should be discontinued at the first signs of a serious adverse reaction, including tendon pain or inflammation. |
| **Advice for healthcare professionals:**<br>• 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 systems, organ classes, and senses<br>• despite new restrictions and precautions introduced in 2019, a new study has shown no evidence of a change in fluoroquinolone prescribing patterns in the UK, and the MHRA has continued to receive Yellow Card reports of these side effects<br>• advise patients to stop 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 for further advice – sheet for patients |

- do not prescribe fluoroquinolones:
    - for non-severe or self-limiting infections, or non-bacterial conditions, for example non-bacterial (chronic) prostatitis
    - for mild to moderate infections (such as in acute exacerbation of chronic bronchitis and chronic obstructive pulmonary disease) unless other antibiotics that are commonly recommended for these infections are consider inappropriate (see the full MHRA alert)
- do not prescribe ciprofloxacin or levofloxacin for uncomplicated cystitis unless other antibiotics that are commonly recommended are considered inappropriate (see the full MHRA alert)
- 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 use of a corticosteroid with a fluoroquinolone since coadministration 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, parents and carers:**

- fluoroquinolone antibiotics are a group of antibiotics that include ciprofloxacin, delafloxacin, levofloxacin, moxifloxacin, and ofloxacin – sometimes 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 your shoulders, arms, or legs
    - abnormal pain or sensations (such as persistent pins and needles, tingling, tickling, numbness, or burning), weakness in your body, especially in the legs or arms, or difficulty walking
    - severe tiredness, depressed mood, anxiety, or 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 during or shortly after taking a fluoroquinolone – this means you should avoid them in the future

**Methotrexate: advise patients to take precautions in the sun to avoid photosensitivity reactions**

Photosensitivity reactions are known side effects of methotrexate treatment and can be severe. Patients should be advised to take precautions to protect their skin in the sun.

**Advice for healthcare professionals:**

- photosensitivity reactions (which include phototoxicity, where a drug is activated by exposure to UV light and causes damage to the skin that can look and feel like a sunburn or a rash) are known side effects of methotrexate treatment and can occur with both low-dose and high-dose treatment
- reactions manifest as severe sunburn such as rashes with papules or blistering, with some patients reporting swelling; rarely, photosensitivity reactions have contributed to deaths from secondary infections
- healthcare professionals, including those prescribing and dispensing methotrexate, should remind patients to take precautions to protect themselves from the sun and UV rays
- report suspected adverse drug reactions associated with methotrexate on a Yellow Card

**Advice for healthcare professionals to provide to patients and caregivers:**

- methotrexate treatment may make your skin more sensitive to the sun
- sun exposure during methotrexate treatment could cause very severe reactions that look and feel like sunburn
- avoid exposure to intense sunlight (especially between 11 am and 3 pm) or to UV rays (for example, using sunbeds or tanning equipment) while taking methotrexate
- use a sun protection product with a high protection factor when exposed to the sun
- wear a hat and clothes that cover your arms and legs when in the sun
- talk to a healthcare professional if you are worried about a skin reaction you have had while taking methotrexate

**Valproate: re-analysis of study on risks in children of men taking valproate**

The MHRA are providing an update on a retrospective observational study on the risk to children born to men who took valproate in the 3 months before conception and on the need for the re-analysis of the data from this study before conclusions can be drawn. No action is needed from patients.

It is vitally important that patients do not stop taking valproate unless they are advised by their specialist to do so.

For female patients, healthcare professionals should continue to follow the existing strict precautions related to preventing the use of valproate in pregnancy (Valproate Pregnancy Prevention Programme).

**Advice for healthcare professionals:**

- the MHRA continue to rigorously review all emerging data on valproate-containing medicines including findings from a retrospective observational study suggesting an increased risk of neurodevelopmental disorders in children whose fathers took valproate in the 3 months before conception, compared to those whose fathers took lamotrigine or levetiracetam
- however errors have been subsequently identified in the study that may impact on the results; a full re-analysis is required before conclusions can be drawn
- as soon as the revised study analysis is available, it will be carefully re-assessed by the MHRA, and any further guidance will be communicated to patients and healthcare professionals as soon as possible
- for female patients, continue to follow the existing strict precautions related to the known and significant harms of valproate in pregnancy (Valproate Pregnancy Prevention Programme, see page 11 of the full MHRA alert)
- GPs and pharmacists should continue to provide repeat prescriptions for valproate; patients currently taking valproate must be advised not to stop taking it unless they are advised by a specialist to do so
- report any suspected adverse drug reactions associated with valproate on a Yellow Card

**Advice for healthcare professionals to provide to patients**:

- valproate is a medicine for epilepsy and bipolar disorder; brand names of valproate include Convulex, Depakote, Epilim, Epilim Chrono or Chronosphere, Episenta, Epival, and Syonell
- do not stop taking valproate or alter your dose without checking with your specialist first; if you stop taking valproate without your specialist's advice your condition may get worse
- valproate is associated with a significant risk of birth defects and neurodevelopmental disorders in children born to women who take valproate during pregnancy – see the existing advice to women and girls
- findings of a study submitted to the MHRA have suggested that there may be an increased risk of neurodevelopmental disorders in children of men who took valproate in the 3 months before conception in comparison to children born to men taking lamotrigine or levetiracetam
- however, errors have been identified in the study that may impact on the results; these mean a full re-analysis is being done before conclusions can be drawn

- as soon as the revised study analysis is available, it will be carefully re-assessed by the MHRA and any further guidance will be communicated to patients as soon as possible
- it is vitally important that you do not stop taking valproate unless a specialist tells you to; talk to a healthcare professional if you are concerned about your medicine or your or your child's health

Regards

Deborah Cooke
Lead Pharmacist

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