NHS Forth Valley

Prescriberfile

From the Primary Care Prescribing Group

Topiramate – new MHRA safety review following observational study

The MHRA report in the July Drug Safety Update that they **have initiated a new safety review of topiramate** as a result of an observational study reporting an increased risk of neurodevelopmental disabilities in children whose mothers took topiramate during pregnancy.

As reported previously, topiramate is known to be associated with an increased risk of congenital malformations and effects on foetal growth if used during pregnancy.

Current (evolving) situation with antiepileptic drugs in pregnancy (see MHRA article for full information):

- Of the antiepileptic medicines reviewed for use in pregnancy, lamotrigine and levetiracetam continue to be considered the safer for the baby since they were not associated with an increased risk of birth defects (MHRA advice following safety review of antiepileptic drugs in pregnancy)
- The specific restrictions for **valproate** medicines should continue to be followed (patients of childbearing potential must follow the requirements of the Valproate Pregnancy Prevention Programme)
- Do not prescribe topiramate during pregnancy for migraine prophylaxis.
- Ensure patients of childbearing potential on topiramate are using **highly-effective contraception** (see Prescriberfile Oct/Nov 2021 and June 2022)
- Patients planning a pregnancy or who become pregnant should be referred for specialist advice on antiepileptic treatment from the specialist managing their epilepsy treatment. The Consultant Obstetrician managing the patient during their pregnancy should also be informed by the GP Practice.
- Ensure patients have been given appropriate advice (see MHRA article for details)

Freestyle Libre 1 Sensors are being discontinued

Freestyle Libre 1 Sensors are being discontinued by 31st December 2022.

- Patients will require to be switched to **Freestyle Libre 2 sensor.**
- Patients will need to download and use the new Freestyle Librelink smartphone app.
- Patients who prefer to use a reader should contact Abbot directly to request a new reader compatible with the Libre 2 system via:

https://www.freestylelibre.co.uk/libre/fsl2Replacement.html or Tel: 0800-170-1177

As noted in the June 2021 Prescriberfile, ff a Freestyle Libre 2 device is dislodged or develops a fault, patients should contact Abbott Customer Care for a replacement device. Practices should not issue a further supply of Libre sensors for faulty devices or devices that have been dislodged.

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Please Circulate to All Staff

Inside this issue:

Supply issues

For the latest Supply Issues affecting Primary Care and local associated guidance see here

Key Points of interest:

- New Topiramate safety review and contraception reminder
- Freestyle Libre 1 Discontinuation
- Formulary Updates
- Pay & Report update
- Ensure Nurse Prescribers have Prescriber Code in EMIS
- Status of SIGN vs NICE
- Steroid Emergency Card Update
- Metformin—B12 monitoring advice
- Home Nebulisers—only on Specialist advice

Review Prescribing of Pay and Report Items

Pay and Report status in Scotland is a definition by exclusion - they are items which are commercially available but which are **not** any of the following: medical devices, licensed medicinal products, products on the ACBS list or unlicensed Specials, and are not on the NHS Blacklist

The NHS Forth Valley Area Drug and Therapeutics Committee (ADTC) position is that the supply of these products are generally not supported on the NHS. This decision is in line with the position on these types of products in most Health Boards, as although these products are not blacklisted and in the strictest sense are technically prescribable in Primary Care, these products do not represent best use of scarce NHS resources.

Recent reviews of Pay and Report items have highlighted the following commonly prescribed products which are not supported on prescription:

Pay and Report Product	Alternative	Additional Information
Aveeno Body Wash (£1,854 in 6 months)	Formulary emollients Dermol® 500 Lotion or QV Gentle Wash are formulary choices for soap substitutes.	See FV Formulary for further information on bath and shower emollients
Aveeno Skin Relief Moisturising Lotion (£423 in 6 months)	Formulary emollients.	Only Aveeno Cream is ACBS - but is non-formulary in FV
Forceval Soluble Tablets (£1,732 in 6 months)	Forceval Capsules are a licensed product and are included in the FV Formulary.	

The FV Area Drug and Therapeutics Committee does not support the prescribing of Pay and Report items.

- Practices should review patients on identified Pay and Report items with a view to using licensed products appropriate to the patient's clinical condition.
- Patients are able to purchase Pay and Report items over-the-counter.

Ensure Nurse Prescribers Setup Correctly in EMIS

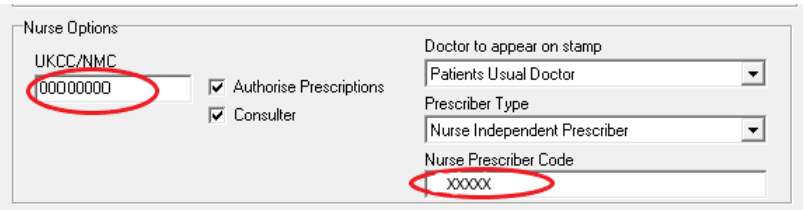
Practitioner Services at NHS National Services Scotland have recently identified an issue of missing Nurse Prescriber Codes with some GP10N Nurse Prescriptions issued from Forth Valley GP Practices. This results in the prescriptions being allocated to a 'Dummy' code and prevents the prescribing and associated costs being allocated correctly in PRISMS prescribing data. It will also impact on any prescribing data used for Nurse appraisals as prescribing data will not be allocated to the individual prescriber.

Practice Managers:

- Please ensure that all Nurse Prescribers have **both** the **UKCC/NMC** fields **and** the **Nurse Prescriber Code** field completed in their user setup in EMIS (see screenshot below).

Nurse Prescribers in GP Practices:

- Please alert the Practice Manager if prescriptions do not print off with your 5 letter prescriber code.



Nurse User Options via User Manager > Edit User > Edit Association

CMO Reminder on Status of SIGN Guidance

The Chief Medical Officer (CMO) wrote to Health Boards recently with a reminder that SIGN clinical guidelines have primacy in NHS Scotland. Other guidelines such as those from NICE should only be used if there is no current up to date SIGN guideline available.

The FV ADTC supports this statement from the CMO. The ADTC notes that there may be some occasions where a SIGN guideline is due for review and a NICE guideline has been more recently updated to take account of more recent clinical evidence. However, in the majority of cases SIGN will take precedence.

Updates to the NHS Forth Valley Formulary

The following changes to the Forth Valley Formulary have been agreed by the New Drugs & Formulary Group. Additions and deletions of medicines are based on formulary submissions, new drug assessment requests or formulary section reviews. ADTC decisions relating to SMC assessments can be accessed here. Relevant messages will be added to *ScriptSwitch*® to support prescribers in primary care.

Liraglutide (Saxenda®) for Weight Management—for recommendation via Weight Management Service

Liraglutide (Saxenda®) has been added to the Formulary for initiation and recommendation by the Weight Management Service (WMS).

- Initially GP Practices will be asked to prescribe, following WMS recommendation—should not be initiated by GPs without WMS recommendation.
- Once WMS have Dietitian Supplementary Prescribers in place - prescribing will be done by the WMS.
- **Must be prescribed by brand name** (Saxenda®) to ensure correct product supplied for weight management (to avoid inadvertent supply of Victoza® which is licensed for Type 2 diabetes)
- Community pharmacists should check indication for use for any generically written prescriptions and issue the appropriate brand.
- **WMS will produce a local treatment pathway to aid GP Practices and the WMS to ensure appropriate prescribing.**
- Patients will be treated for a maximum of 2 years with ongoing review by the WMS to ensure weight targets are reached. Patients will not be allowed to re-trial Saxenda® for a 5 year period.

Patients who have initially been prescribed Saxenda® via private clinics and who wish to receive on the NHS must be referred to the local WMS and will only receive Saxenda® on NHS prescription,if they meet the same criteria as SMC restrictions and meet the ongoing weight loss targets. Otherwise, any prescribing will need to be continued privately. An NHS prescription should only be issued following recommendation from the FV WMS.

Testosterone in women with reduced sexual desire—Formulary Addition Not Supported

Although NICE Menopause guidance and the British Menopause Society suggest the use of testosterone when HRT alone is not effective. The evidence base for the use of testosterone in women is limited. Study data shows that testosterone would give one extra episode of satisfying sexual contact in one month. There is no benefit for any other symptoms.

- Due to the off-label use of testosterone, the limited evidence of benefit and need for ongoing monitoring, testosterone for use in women with reduced sexual desire will **not** be added to the FV Formulary at this stage and it is **not supported for prescribing in Primary Care**. Specialists may prescribe to suitable patients if considered appropriate.
- A factsheet for patients, produced by the British Menopause Society can be used to inform patients on the benefits/risks to the use of testosterone.

Other Changes

- **Skin** (BNF Ch 13): the following have been added to the formulary in line with SMC guidance for **Hospital Specialist Use only**: Bimekizumab (Bimzelx®), Tralokinumab (Adtralza®), Upadacitinib (Rinvoq®), Abrocitinib (Cibinqo®).
- **HRT choices** (BNF Ch 6) have been updated. Novofem®, Zumenon® are no longer formulary choices. Estradot® patches replace Estraderm MX® patches as a formulary choice.
- **Obstetrics & Gynaecology section** (BNF Ch 6) - Danazol, buserelin, bromocriptine and quinagolide are now considered **NON-formulary**.
- A license extension for secukinumab (Cosentyx®) now allows use in children and adolescents with plaque psoriasis (Hospital specialist use only).
- **BNF 5 (Infections)** - following a change in recommendation from the Scottish Antimicrobial Prescribing Group following updated NICE guidance, the 1st line treatment of C. difficile. infection is now oral vancomycin, irrespective of severity. This can now be prescribed by GPs if they identify a patient with C. difficile rather than requiring a recommendation from the microbiology team.
- Febuxostat (BNF Ch 10) Formulary status has changed from specialist initiation to general prescribing in primary care as well. To be used second line after allopurinol.

Reduce harm, waste and unwarranted variation

Steroid Emergency Card—Update

In June 2021 Healthcare Improvement Scotland (HIS) issued advice on the adoption of the new Steroid Emergency Card (SEC) in Scotland. Following this initial communication, some local scoping work has been undertaken by the ADTC to inform the implementation within NHS Forth Valley. A key element of implementing use of the new card will be the identification of existing patients who may benefit from the new SEC. This will be complex, given the range of specialities and medications involved. Work is underway nationally between Health Boards and HIS to identify suitable search strategies using the Scottish Therapeutics Utility (STU) tool. Availability of these searches will be key for all Health Boards in identifying existing patients in GP Practices who should be issued the SEC. We will update prescribers as this work progresses.

In the meantime if clinicians are aware when reviewing a patient, or initiating new steroid therapy that the patient would benefit from the new SEC, this can be issued and a noted in the records (coding of the SEC is under discussion by the national group). Options for printing the cards are also under discussion locally - in the meantime the content of the card can be downloaded from the HIS website.

Drug Safety Updates

Selected highlights from recent Drug Safety Update Bulletins from the MHRA (https://www.gov.uk/drug-safety-update). Click on titles in boxes for links to the full MHRA Drug Safety article.

Prescribers are encouraged to subscribe directly to the Drug Safety Updates Bulletin which is only available by email.
www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/email-signup

Metformin and reduced vitamin B12 levels: new advice for monitoring patients at risk

Decreased vitamin B12 levels, or vitamin B12 deficiency, is now considered to be a common side effect in patients on metformin treatment, especially in those receiving a higher dose or longer treatment duration and in those with existing risk factors.

The June 2022 Drug Safety Update advised that:

- The risk of low vitamin B12 levels increases with higher metformin dose, longer treatment duration, and in patients with risk factors for vitamin B12 deficiency
- Patients being treated with metformin who have symptoms suggestive of vitamin B12 deficiency should have their B12 levels checked.
- Periodic monitoring for patients with risk factors for vitamin B12 deficiency should be considered.
- Patients taking metformin should be advised to seek medical advice if they develop new or worsening symptoms of extreme tiredeness, a sore and red tongue, pins and needles, or pale or yellow skin as these can be signs of low vitamin B12 levels. Patients should not stop taking metformin without discussing with their doctor.

Prescribers are reminded that the FV B12 guidance advises the following regular monitoring for patients currently prescribed metformin:

- Check vitamin B12 levels annually in patients who have been taking metformin for >10 years
- If vitamin B12 <125 ng/l. Give a single dose of IM 1mg hydroxocobalamin injection. Recheck vitamin B12 levels after 12 months. If still <125ng/l inject with a further single dose of vitamin B12 and recheck vitamin B12 levels every 12 months. Treat again if vitamin B12 <125ng/l.
- If vitamin B12 levels >125ng/l. No treatment required. Recheck vitamin B12 levels after 12 months.

Nebulised asthma rescue therapy in children: home use of nebulisers in paediatric asthma should be initiated and managed only by specialists:

- Use of nebulisers without adequate medical supervision can mask deterioration in the underlying disease.
- Only specialists in asthma should initiate and clinically manage use of nebulisers/ nebulised medicines at home
- Independent purchase of nebuliser devices for use at home, outside of medical advice, for the acute treatment of asthma in children and adolescents is not recommended
- Community pharmacists are asked to advise people seeking to purchase a nebuliser for this purpose that such home use of nebulisers is not recommended. The patient/carer should be advised to discuss with their GP or Respiratory Specialist.

See the August Drug Safety Update for more information.

Gina 10 microgram vaginal tablets (estradiol) have recently been reclassified as a pharmacy medicine available without prescription for the treatment of vaginal atrophy due to oestrogen deficiency in postmenopausal women aged 50 years and above, who have not had a period for at least 1 year.

Contact Information:
General Primary Care Prescribing Advice:
Contact your Primary Care Pharmacist; or alternatively
Primary Care Prescribing Support Team on 01324 567937
Email: FV.prescribingsupport@nhs.scot

For Advice Related to Management of Controlled Drugs:
Email FV.cdgovernance@nhs.scot