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## MHRA Drug Safety Update (Click [here](#) for full alerts)

### Valproate use in men

The MHRA previously introduced new prescribing requirements for both male and female patients under 55 years of age—[see here](#). In addition to these new requirements, the MHRA has now issued further safety information relating to the use of valproate in male patients.

A retrospective observational study has indicated a possible association between valproate use by men around the time of conception and an increased risk of neurodevelopmental disorders in their children.

The MHRA has issued the following advice for healthcare professionals:

- inform male patients (of any age) who may father children of the possible risk at initiation of valproate or at their next regular treatment review – this counselling should be given irrespective of the indication for valproate and also after intravenous use of valproate
- as a precaution, recommend that male patients use effective contraception (condoms, plus contraception used by the female sexual partner) throughout the valproate treatment period and for 3 months after stopping valproate, to allow for one completed sperm cycle not exposed to valproate
- at the next regular treatment review, discuss with men on oral valproate treatment whether they are planning a family in the next year and if they are, refer to a specialist to discuss alternative treatment options
- if a female patient reports they are pregnant or planning a pregnancy with a man on valproate (including those undergoing IVF), refer for prenatal counselling
- advise men not to donate sperm during valproate treatment and for 3 months after stopping valproate
- report any suspected adverse drug reactions associated with valproate on a [Yellow Card](#)

Further information on the above can be found [here](#).

### Reminder on the use of Pregabalin in Pregnancy

In April 2022 the MHRA issued updated information on the safety of using pregabalin during pregnancy. The MHRA concluded that pregabalin use during the first trimester of pregnancy may cause a slightly increased risk of major congenital malformations in the unborn child.

The advice for healthcare professionals is that:

- Women of childbearing potential prescribed pregabalin must have effective contraception during treatment
- Clinicians should continue to avoid use of pregabalin during pregnancy unless clearly necessary and only if the benefit to the patient clearly outweighs the potential risk to the fetus – ensuring that the patient has a full understanding of the benefits, risks, and alternatives, and is part of the decision-making process
- Clinicians should advise patients planning a pregnancy or who become pregnant during treatment to make an appointment to discuss their health condition and any medicines they are taking
- In cases where the benefit outweighs the risk, and it is clearly necessary that pregabalin should be used during pregnancy, it is recommended to:
  - use the lowest effective dose
  - report any suspected adverse drug reactions, including for the baby, via the [Yellow Card scheme](#)

Further information on the above can be found [here](#).

## Forth Valley Prescribing Advice

### Tena and Robinson Procedure Pads

The use of procedure pads (Tena and Robinson pads) for incontinence is not supported within Forth Valley. The inappropriate use of these procedure pads as incontinence appliances is associated with a multitude of risks, as per examples listed below:

- Procedure pads become displaced, folded and creased which inhibits both the performance and comfort and increases the risk of tissue damage and pressure ulceration
- Procedure pads increase the risk of pressure ulceration due to reduced skin integrity
- Procedure pads increase the risk of a fungal infection of the skin if an area on the body which is naturally warm and moist, is not cleaned and the moisture is not well managed
- Procedure pads do not have the absorbent capacity required in high volume leakage bursts of urine
- Procedure pads do not have the absorbent capacity required alongside breathability, for instance for loose faecal incontinence

The NHS Forth Valley Tissue Viability Service, the Forth Valley Bladder and Bowel Service, and the Forth Valley Primary Care Prescribing Group do not support the prescribing or the use of these products as incontinence appliances. These products should NOT be prescribed or recommended to patients for the management of continence issues.

Primary Care clinicians are asked not to prescribe or recommend Tena or Robinson procedure pads for incontinence. Further information regarding the management of this patient group will be issued to practices in due course.

### Five day Antibiotic Course Lengths

Since 2019 NICE have recommended 5-day courses of antibiotics for a range of common infections, reducing from the conventional 7-14 day courses, often chosen simply due to there being 7 days in the week.

A large body of evidence from Scotland and internationally now exists supporting the recommendation that 5-day courses are as safe and effective for treating many common infections in Primary Care including; infective exacerbation of COPD and community acquired pneumonia.

Additionally, while often not required, when antibiotics are indicated for sore throat, acute cough and acute sinusitis, 5 days is usually enough.

NHS Forth Valley Primary Care guidelines will reflect these course lengths, contributing to our target to reduce antibiotic prescribing across the health board, helping to reduce the development and spread of antibiotic resistance.

Over the next 5 years NHS Forth Valley must reduce our antibiotic use by 5% from our 2019 levels. Recognising when antibiotics are not needed, and prescribing appropriate course lengths will help us reach that goal across the Board.

As part of this change in practice, the default doses on EMIS PCS for amoxicillin 500mg capsules, clarithromycin 250mg & 500mg tablets, and doxycycline 100mg capsules, have been set to a default course length of 5 days.

### Maternity/Obstetrics - Prescribing based on Microbiology Results - Change in Process

A new process has been put in place across all maternity patients in Forth Valley to enable prescribing based on microbiology results to be actioned by maternity/obstetrics. The Midwife taking the sample will follow up the result and arrange a prescription to be sent directly to the women's preferred Community Pharmacy. **This process ONLY covers prescriptions required based on microbiology results (e.g. antibiotics, antifungals).** GPs will still receive requests for routine prescribing of iron, folic acid, and aspirin.

## Access to Medicines

### Peer Approved Clinical System (PACS) Tier 2 and Individual Patient Treatment Requests (IPTR) - What's the difference?

The PACS 2 process provides an opportunity for senior clinicians, on a case-by-case basis for individual patients, to request use of a licensed medicine (other than ultra-orphan) for a licensed indication where the medicine:

- has not been recommended by the SMC following their appraisal of clinical and cost-effectiveness
- **OR** the medicine is being used out with the SMC restrictions
- **OR** the SMC is yet to issue advice for the medicine and indication (**medicine on the SMC workplan**)

For medicines where the SMC has either issued 'not recommended' advice following a non-submission or where no SMC submission has been made yet, an Individual Patient Treatment Request (IPTR) would be required. The IPTR process should also be used for licensed medicines being used for unlicensed indications (off label) where the cost is more than £5,000 per annum.

Please see relevant policies on intranet for further information relating to the PACS 2 and IPTR process within Forth Valley. For any queries relating to PACS 2 and IPTRs, please email [fv.fviptr@nhs.scot](mailto:fv.fviptr@nhs.scot).

## Prescribing Improvement Initiative (PII) Update

### Edoxaban to Apixaban Switch

The 2024/25 PII project commenced on 5th August. For August and September, a total of 678 reviews have been undertaken across Forth Valley and 579 patients have been switched to Apixaban—this equates to a switch rate of 85%. At present 13 practices out of the 45 practices that signed up to the project have submitted claims.

### Other Switches

For the other PII projects (e.g. controlled drug changes etc.), for the period August and September, a total of 238 reviews have been undertaken across Forth Valley and 192 patients have been switched to the preferred product, this equates to a switch rate of 81%.

## Forth Valley Formulary Updates

### Empagliflozin (Jardiance®)

Empagliflozin has been added to the Forth Valley formulary for adults for the treatment of chronic kidney disease. Its use is restricted to patients having individually optimised standard care (including angiotensin converting enzyme inhibitors or angiotensin II receptor blockers, unless these are contraindicated or not tolerated), and either, at the start of treatment: an estimated glomerular filtration rate (eGFR) of 20 mL/min/1.73m<sup>2</sup> up to 45 mL/min/1.73m<sup>2</sup>, or an eGFR of 45 mL/min/1.73m<sup>2</sup> up to 90 mL/min/1.73m<sup>2</sup> and either: A urine albumin-to-creatinine ratio (uACR) of 22.6 mg/mmol or more, or Type 2 Diabetes Mellitus (T2DM). This can be initiated in either Primary or Secondary Care.

### Tirzepatide (Mounjaro®)

Tirzepatide has been added to the Forth Valley formulary for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise in addition to other oral anti-diabetic medicines as an option when glucagon-like peptide-1 (GLP-1) receptor agonists would be considered. Tirzepatide will be initiated in Secondary Care, but may be continued in Primary Care.

### Budesonide/formoterol (Symbicort Turbohaler®) 200/6 micrograms/inhalation

Symbicort Turbohaler® 200/6 micrograms/inhalation has been added to the Forth Valley formulary **as reliever therapy** for adults and adolescents (12 years and older) with mild asthma in patients **who would otherwise** receive low dose inhaled corticosteroid (ICS) maintenance therapy plus short-acting beta-2 adrenoceptor agonist (SABA) as needed. This can be initiated in either Primary or Secondary Care.

## **Forth Valley Guideline Updates**

### **Adult Chronic Kidney Disease Diagnosis and Management**

This is a new guideline to support the diagnosis and management of Chronic Kidney Disease (CKD) in Primary Care.

### **Vitamin D Deficiency in Adults**

This is an updated version of the 'Investigation and Treatment of Vitamin D in Adults' guideline.

### **Rabies Post-Exposure Prophylaxis Protocol**

This is an updated version of existing guidance. The 'Rabies Post-Exposure Prophylaxis' document has been produced for healthcare professionals and pharmacy staff in NHS Forth Valley who may be involved in the assessment and delivery of post-exposure prophylaxis for individuals who have been exposed, or have potential exposure, to rabies. The document applies to but is not limited to doctors and nurses working in community settings such as Primary Care or community clinics, out-of-hours services, emergency departments and infectious diseases units.

### **Community Pharmacy guideline for Dispensing and Supervision of Opioid Substitution Treatment (OST)**

This is an updated version of existing guidance. This guideline covers OST prescription requirements, good dispensing practices, controlled drug collection, dispensing and supervised self-administration of medication (SSAM), when to contact the prescriber and/or withhold a dose, pharmaceutical care planning, arrangements for patients in police custody, and child protection.

### **Guidance on Alcohol Dependence: Maintenance of Abstinence**

This is an updated version of existing guidance. This document is to guide secondary care clinicians in the management of relapse prevention after successful treatment of acute alcohol withdrawal syndrome. It applies to specialist services for substance use, such as the Community Alcohol and Drug Service (CADS) and Change Grow Live (CGL).

For other clinicians, including GPs, this guidance is for information to allow the ongoing prescription in Primary Care whilst the psychosocial support of the patients remains under specialist services.

### **Multiple Sclerosis Service Management of MS Relapses**

This is an updated version of existing guidance. This guideline covers management of MS relapses, treatment of MS relapses, and what to do if a patient has symptoms suggestive of MS relapse.