Hampshire and Isle of Wight

Prescribing and Medicines Optimisation Guidance

Issue: 93 **Date: 12th December 2023**

Safety guidance

There has been three National Patient Safety Alerts requiring actions in the last few weeks.

1. **NPSA (from MHRA) : Valproate: organisations to prepare for new regulatory measures for oversight of prescribing to new patients and existing female patients (28th Nov 2023)** LINK

MHRA is asking organisations to put a plan in place to implement new regulatory measures for valproate/valproic acid preparations . This follows a comprehensive review of safety data and advice from Commission on Human Medicines (CHM). Required actions to begin as soon as possible and be completed by 31 Jan 2024.

The regulatory change in January 2024, for oral valproate medicines, means that:

- 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.

- At their next annual specialist review, women of childbearing potential and girls should be reviewed using a revised valproate Risk Acknowledgement Form, which will include the need for a second specialist signature if the patient is to continue with valproate and subsequent annual reviews with one specialist unless the patient's situation changes.

The current safety measures for valproate continue to apply, including the valproate pregnancy prevention programme (PPP) for any girls and women of childbearing potential.
Local systems across the ICS will be working together to help co-ordinate this safety alert. Further information will follow.

2. **NPSA (from DHSC): Potential for inappropriate dosing of insulin when switching insulin degludec (Tresiba) products (8th Dec 2023)** LINK

A Medicine Supply Notification issued on 24 May 2023, detailed a shortage of Tresiba® (insulin degludec) FlexTouch® 100units/ml solution for injection 3ml pre-filled pens.

The Medication Safety Officer (MSO) network has highlighted that in response to this shortage, some patients may have been switched to Tresiba® (insulin degludec) FlexTouch® 200units/ml solution for injection 3ml pre-filled pens. Tresiba® FlexTouch® pen delivery devices dial up in unit increments rather than volume.

However, a small number of patients have been incorrectly advised to administer half the number of units. These reports suggest that errors have occurred at the prescribing, dispensing and administration stages of the medicine journey. One case described a patient requiring treatment in hospital for diabetic ketoacidosis because of a reduced insulin dose.
Actions required as soon as possible and no later than 22nd December 2023.

All providers MUST ensure that patients who have been switched to Tresiba® (insulin degludec) FlexTouch® 200units/ml solution for injection 3ml pre-filled pens are:

1. Made aware that Tresiba® FlexTouch® pen delivery devices dial up in unit increments rather than volume and no dose change is necessary.

Primary care providers should:

2. Continue to follow the advice in the Medicine Supply Notification. LINK
3. When prescribing Tresiba® 100units/ml Penfill® cartridges, ensure the patient is also supplied with a compatible Novo Nordisk insulin delivery system and appropriate needles.
4. For a small cohort of patients unable to use Tresiba® 100units/ml Penfill® cartridges a switch to Tresiba® FlexTouch® 200units/ml prefilled pens may be necessary, clinicians should not adjust the dose of insulin.
5. Ensure all patients initiated on a new device are counselled on the change and provided with training on their use, including signposting to training videos, and the potential need for closer monitoring of blood glucose levels. (See reference section of alert for links to patient resources).

Secondary care providers should:

6. Avoid initiating patients on Tresiba® (insulin degludec) FlexTouch® 200units/ml prefilled pens due to supply constraints.
7. If unable to switch to Tresiba 100units/ml Penfill® cartridges, consider initiating a patient on an alternative long-acting insulin.

3. NPSA (from UKHSA) Potential contamination of some carbomer-containing lubricating eye products with Burkholderia cenocepacia - measures to reduce patient risk (7th Dec 23) LINK

UKHSA is investigating an outbreak of Burkholderia cenocepacia involving individuals across the UK. (We have had cases in our ICB area.) This is an emerging issue and, following testing, B. cenocepacia was recovered from some lubricating carbomer eye products.

This alert requires all products specified in the Field Safety Notice (24th Nov) are removed from clinical settings immediately and procurement of these stocks are ceased. Also, all carbomer containing eye products to be avoided in certain patient groups as a precautionary measure.

- individuals with cystic fibrosis
- patients being cared for in critical care settings (e.g., adult, paediatric and neonatal ICU)
- **severely immunocompromised**
- **patients awaiting lung transplantation.**

Where an alternative non carbomer-containing product is not available or not suitable, apply clinical risk assessment as appropriate. To be actioned by 17th December 2023.

4. Emollients and fire risks- Referrals for Safe and Well visits

The ICB and HIOW Fire and Rescue Service have been closely collaborating after multiple instances of fatalities in our ICB area, relating to emollient use and fires. Emollients are not

flammable in themselves. However, when dried onto fabric they act as an accelerant, increasing the speed of ignition and intensity of fire when in contact with a naked flame, such as a cigarette or candle. All emollients carry this risk.

The medicines optimisation team have worked with the local fire service to devise GP clinical system searches that collate the various risk factors (if read-coded) associated with increased fire risk. Practices can then identify the most vulnerable patients, who are ordering emollients regularly, with additional risks.(Smoking, oxygen therapy, living alone, dementia, mobility or sensory impairment or hoarding.)

The fire service would welcome those most at risk in your practices to be contacted and offered a free Safe and Well Fire Service home visit. Referrals to this service may be made via the HIOW Fire and Rescue Service website :LINK

When completing the form, please ensure " general practitioner" referral box is ticked to enable the fire service to monitor the update from primary care.

For those with less risk factors but still regularly ordering emollients, we would encourage, as a minimum, the sharing of the MHRA emollient and fire risk patient leaflet. AccuRx messages have been written to facilitate this. They can also be offered a Safe and Well visit at a further point in time, after those most vulnerable, to stagger the workload for the fire service.

Resources to support this work, including an intervention brief, AccuRx messages, patient letters, MHRA patient leaflets, MHRA 60-second waiting room videos and posters are hosted on the medicines safety pages of the HIOW website, under emollients and fire risks : See LINK

5. **MHRA: Nirmatrelvir, ritonavir (Paxlovid▼): be alert to the risk of drug interactions with ritonavir LINK**

There is a risk of harmful drug interactions with the ritonavir component of the COVID-19 treatment Paxlovid▼ due to its inhibition of the enzyme CYP3A, which metabolises many commonly used drugs. Prescribers should obtain a detailed patient history of current medications before prescribing Paxlovid, checking the Paxlovid product information for known and potential drug interactions.

Local guidance

6. **Local shared care guidelines: Riluzole in adult patients** LINK

The HIOW Prescribing Committee have approved a new shared care guideline for riluzole in adult patients to extend life or the time to mechanical ventilation for patients with amyotrophic lateral sclerosis (ALS). This is available on the HIOW ICB website via link above.

7. **Formulary updates** LINK

- Dapagliflozin is now approved for use in accordance with the NICE TA902: Dapagliflozin for treating chronic heart failure with preserved or mildly reduced ejection fraction. It has been added to the formulary as Amber Recommended (AR) .

- Glucagon (Ogluo®) has been added to the HIOW formulary as Amber Initiated (AI). The Ogluo position statement is available on the link below. Please see under prescribing advice folder :LINK

- Betamethasone valerate 2.25mg (Betesil®) medicated plasters are now Green on the formulary.

Formulary definitions:

GREEN	Suitable for prescribing in primary or secondary care.
AR	Suitable for prescribing in primary care following recommendation by a specialist (Amber Recommended)
AI	Suitable for prescribing in primary care following initiation by a specialist (Amber Initiated).

8. Bumetanide national shortages: Resources to support prescribers LINK

Local guidance for the management of the national shortage of bumetanide 1mg and 5mg tablets have been prepared and are hosted on the HIOW Medicines Optimisation webpages. See link above. Resources include a slide deck summarising the required actions including specialist advice and a patient information leaflet for patients currently prescribed bumetanide.

National guidance

9. SPS: Continuing management of the ADHD medicines shortage LINK

This latest updated guidance from Specialist Pharmacy Services (SPS) is intended to support systems to develop their local action plans as an urgent mitigation in response to shortages of ADHD medication. The ICB website also hosts links to key documents: LINK

NICE guidelines

10. Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer - updated guidance (CG164) LINK

The off-label warning for anastrozole in recommendations 1.7.22 and 1.7.26 on chemoprevention for women at moderate or high risk of breast cancer has been removed in line with the MHRA licence variation.

11. Hypertension in adults: diagnosis and management – updated guidance (NG136) LINK

New recommendations on repeating BP measurements with the patient lying on their back and referring patients for further specialist assessment if BP measurements do not confirm postural hypotension have been added. Recommendations 1.1.5, 1.1.6 and 1.4.16 have also been updated.

12. COVID-19 rapid guideline: managing COVID-19 (update) LINK

Update includes removal of recommendation to consider benzodiazepine for managing anxiety or agitation (support has changed significantly since the guideline was developed) and removal of recommendations on managing acute cough and medicines for end-of-life care.

Other

13. HIOW ICB website resources for pharmacy teams: LINK

A collation of local and national resources has been produced for pharmacy teams and is hosted on the ICB website. This includes an information pack for prescribers. See LINK

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On behalf of Hampshire and Isle of Wight ICB Medicines Optimisation Teams
Local medicines optimisation teams can be contacted via their generic team mailbox: See LINK
Previous bulletins can be found hosted on the ICS website here: link