

Prescribing and Medicines Optimisation Guidance

Issue: 91

Date: 22nd November 2023

Safety guidance

1. MHRA: Isotretinoin (Roaccutane ▼): introduction of new safety measures, including additional oversight of the initiation of treatment for patients under 18 years of age [LINK](#)

MHRA have strengthened the safe use of isotretinoin through the introduction of additional oversight of the initiation of isotretinoin in patients under 18 years and through improved assessment and monitoring of mental health and sexual function issues. We ask healthcare professionals to review these new measures and supporting materials and integrate them into their clinical practice when referring patients and when prescribing or dispensing isotretinoin.

Summary of measures:

- Two independent prescribers need to agree the initiation of isotretinoin in patients under 18 years
- New counselling requirements about potential mental health and sexual function side effects
- Assessment of mental health and sexual function before starting treatment and monitoring of mental health and sexual function during treatment
- New roles and responsibilities for healthcare professionals
- New regulatory risk minimisation materials : [Acknowledgement of Risk Form](#), [Patient Reminder Card](#), [Pharmacist Checklist](#)

Isotretinoin (oral) is a red drug (hospital/specialist prescribing only) on the local formulary [LINK](#) MHRA asks the referrer (usually the GP) to provide information about isotretinoin to the patient and provide counselling (where possible) regarding the benefits and risks of isotretinoin treatment.

2. MHRA warns of unsafe fake weight loss pens [LINK](#)

The MHRA has warned the public not to buy pre-filled pens claiming to contain semaglutide or liraglutide. They have seized 369 potentially fake semaglutide pens and received reports of fake liraglutide pens that have been obtained through non-legitimate routes this year. The MHRA has received reports of a very small number of people who have been hospitalised after using potentially fake weight-loss pens. It is thought that they contained insulin.

Saxenda (liraglutide), is authorised in the UK for weight loss, with diet and exercise. Ozempic (semaglutide) has been authorised for the treatment of adults with type 2 diabetes, also with diet and exercise. It is not authorised for weight loss, but it is commonly used off-label for that purpose. Both are prescription only medications.

3. Direct healthcare professional communication: Azathioprine 75 mg & 100 mg tablets - risk of overdose if wrong dose prescribed or dispensed [LINK](#)

Two new strengths of azathioprine have been launched in the UK: 75mg and 100mg. As these strengths have not previously been available, caution is required when prescribing and dispensing this product range to ensure that the patient receives the dose intended.

4. MHRA :Yellow card scheme [LINK](#)

With Medicines Safety week falling in November, it provides an annual reminder of the importance of reporting suspected side effects to medicines, vaccines, e-cigarettes, medical device incidents, defective or falsified (fake) products to the MHRA to ensure safe and effective use.

Local guidance

5. Injectable therapies to support weight management.

- **Liraglutide (Saxenda):** There are limited and intermittent supplies of all GLP1-RAs including liraglutide for weight loss and it is unavailable until mid-2024. Therefore, this is not available to patients and not provided by the Tier 3 Specialist Weight Management service. See National Patient Safety Alert [LINK](#)
- **Semaglutide (Wegovy):** On 4th September, the DHSC announced the launch of semaglutide as an option for weight management, in line with NICE guidance. However, HIOW ICB are still considering the introduction of this new pathway within the Tier 3 service. Once semaglutide is available, Primary Care will be provided with information on how to refer patients. In the meantime, please do not refer patients to the Tier 3 service for semaglutide.

Referrals can still be made to specialist services for those who meet the service criteria. Across HIOW ICB there are two Tier 3 specialist services:

1. Tier 3 Specialist Weight Management Service 'The Weigh Ahead' provided by Spire Healthcare.

The service would like to make GP referrers aware of the significant increase in referrals into the service since the media coverage in March 2023 and September 2023 regarding injectable weight loss interventions. Spire Healthcare have asked that you please ensure that all required elements of the referral form are complete including recent bloods and uploaded to the E-referral system.

2. Integrated Complex Obesity Service (ICOS) provided by Portsmouth Hospital University NHS Trust.

ICOS is a specialist Tier 3 weight management service, which is available to people registered at GP practices in Portsmouth City. It is multi-professional service that provides clinical assessment and treatment of pre-bariatric surgery patients in preparation for surgical intervention and treatment for those not wishing / unsuitable for surgery who have complex obesity, with medically diagnosed co-morbidities that have a significant impact on their life. Access to the service is available through a GP referral or the Tier 2 Portsmouth Weight Management Hub.

6. Biosimilar medicines position statement and guidance [LINK](#)

This document provides a position statement and guidance outlining the aim for early adoption of biosimilar medicines within the locality of the Hampshire and Isle of Wight Integrated Care System (HIOW ICS).

National guidance

7. NHSE: Recommended blood glucose and ketone meters, testing strips and lancets - update [LINK](#)

The NHSE recommended meters, strips and lancets have passed a rigorous evaluation process ensuring that only the best of the highest quality and, cost-effective devices are approved. See page 6 for a useful summary table of NHSE recommendations. Recently updated with minor amendments.

An intervention brief has been written by the Medicines Optimisation team to help facilitate the switching to NHSE recommended meters and strips [LINK](#)

However, please note that *Accu-Chek Instant* and *Accu-Chek Performa* testing strips have seen a recent price reduction since this update. Therefore, as with other lower cost testing strips, patients already on these strips should be excluded from the switch work.

8. MHRA: Full pack dispensing of valproate-containing medicines - guidance [LINK](#)

Legal changes have come into force for the dispensing of valproate-containing medicines in the manufacturer's original full pack. This ensures women always receive the manufacturer's patient card and information leaflet, containing details about the harms of valproate during pregnancy.

This new legislative amendment is a further measure to ensure that patients taking valproate-containing medicines have access to information setting out the risks and need for patients of childbearing potential to fulfil the conditions of the Pregnancy Prevention Programme before taking valproate-containing medicine.

Based on an individual risk assessment, which assesses the needs of patients, pharmacists can make exceptions to these rules and supply medicines containing valproate in different packaging (for example in a monitored dosage system), provided processes are in place to ensure a PIL is supplied.

9. Press release: MHRA authorises anastrozole to prevent breast cancer in post-menopausal women [LINK](#)

Approval for prevention in post-menopausal women at moderate/high risk of developing the disease was based on the IBIS-II study which showed fewer women developed breast cancer in the anastrozole group compared to the placebo group. It is dosed as 1mg daily for 5 years. Further information can be found here: [LINK](#)

The NICE guideline on familial breast cancer has recommended anastrozole as a preventative treatment for postmenopausal women at increased risk since 2017. It has now been updated to reflect that the preventative use of anastrozole is now licensed [LINK](#)

10. SPS launches new refrigerated medicines stability tool [LINK](#)

Specialist Pharmacy Service's new tool provides advice on whether refrigerated medicines can be used after exposure to out-of-range temperatures. The fridge database has been reformatted to make it clearer and more concise for the user.

NICE guidelines

11. Suspected acute respiratory infection in over 16s: assessment at first presentation and initial management - guidance (NG237) [LINK](#)

Guideline covers assessment & treatment of people with symptoms and signs of acute bacterial/viral respiratory infection at first remote or in-person contact with NHS services to ensure treatment follows best care pathway.

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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](#)