NORTHERN IRELAND MEDICINES MANAGEMENT
Newsletter
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Isotretinoin (Roaccutane®): introduction of new safety measures

The Medicines and Healthcare products Regulatory Agency (MHRA) released a Drug Safety Update in October 2023 detailing new safety measures, including additional oversight of the initiation of treatment for patients under 18 years of age for isotretinoin. These measures are mandatory since 31st October 2023.


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Isotretinoin (Roaccutane▼): introduction of new safety measures, including additional oversight of the initiation of treatment for patients under 18 years of age

We 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

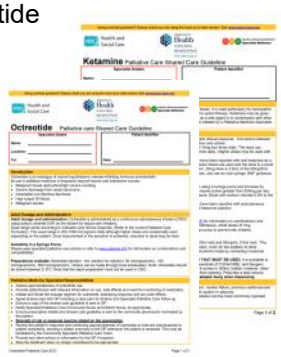
1. 2 independent prescribers need to agree the initiation of isotretinoin in patients under 18 years
2. New counselling requirements about potential mental health and sexual function side effects
3. Assessment of mental health and sexual function before starting treatment and monitoring of mental health and sexual function during treatment
4. New roles and responsibilities for healthcare professionals
5. New regulatory risk minimisation materials

The responsibility for prescribing in Northern Ireland remains with the consultant or specialist clinician ('red list'). It is recommended that the supply of these specialist medicines should be organised via the hospital pharmacy however if the patient has presented to the pharmacy with a private prescription these new mandatory requirements for dispensing apply.

The British Association of Dermatologists (BAD) have provided a range of support materials, including material for primary care who are referring to secondary care.

Ketamine and octreotide in palliative care

The Shared Care Guidelines (SCG) for ketamine and octreotide in palliative care were updated in August 2023 — see NI Specialist Medicines website.


Ketamine Palliative Care Shared Care Guideline

Octreotide Palliative care Shared Care Guideline

Ketamine

Ketamine is a schedule 2 (part 1) controlled drug.
Ketamine is an 'amber' list medicine when used in palliative care and should only be initiated by a palliative medicine specialist. Ketamine may be administered orally or by continuous subcutaneous infusion (CSCI) via a syringe pump.
Details of how to order can be found in the SCG.

Points to note with ketamine oral solution:

- must be prescribed as the **standard strength of 50mg/5ml**
- a total volume proportionate to the daily prescribed dose should be prescribed
- preparations expire 28 days from opening

Octreotide

Octreotide is frequently used beyond licence in palliative medicine, e.g. malignant bowel obstruction/high volume vomiting; severe discharge from rectal carcinoma; intractable non-infective diarrhoea; high output GI fistula and malignant ascites.

Points to note with octreotide:

- octreotide is administered as a CSCI using sodium chloride 0.9% as the diluent.
- dose range varies according to indication and clinical response. The usual range is 200-1500 micrograms daily, although higher doses are occasionally used
- it is available as 1ml solution for injection: 50 micrograms/ml, 100 micrograms/ml, 500 micrograms/ml
- orders can be made through local wholesalers
- the depot preparation must not be used in CSCI.

Patient monitoring for both ketamine and octreotide should be performed as agreed with the specialist palliative care team.

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NICE Guidance

Recently published:

NICE TA947 — Loncastuximab tesirine for treating relapsed or refractory diffuse large B-cell lymphoma and high-grade B-cell lymphoma after 2 or more systemic treatments
NICE TA949 — Belumosudil for treating chronic graft-versus-host disease after 2 or more systemic treatments in people 12 years and over
NICE TA950 — Nivolumab–relatlimab for untreated unresectable or metastatic melanoma in people 12 years and over
NICE TA951 — Olaparib with abiraterone for untreated hormone-relapsed metastatic prostate cancer
NICE TA952 — Talazoparib for treating HER2-negative advanced breast cancer with germline BRCA mutations

Recently withdrawn:

NICE TA855 — Mobocertinib for treating EGFR exon 20 insertion mutation-positive advanced non-small-cell lung cancer after platinum-based chemotherapy

Managed Entry Decisions

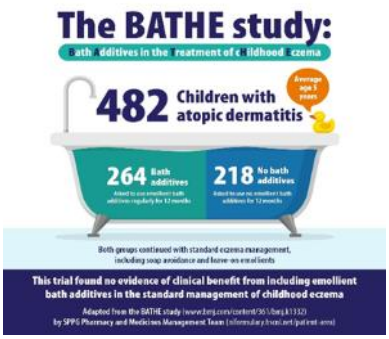
Full details here

- Trastuzumab deruxtecan (Enhertu®)
- Tirzepatide (Mounjaro®)
- Budesonide (Kinpeygo®)
- Durvalumab (Imfinzi®)
- Olaparib (Lynparza®)
- Talazoparib (Talzenna®)
- Loncastuximab tesirine (Zynlonta®)
- Belantamab mafodotin (Blenrep®)
- Lutetium (177Lu) vipivotide tetraxetan (Pluvicto®)

Reminder – Bath and shower emollients removed from NI Formulary

Emollient bath and shower preparations are not routinely recommended for use in dry and pruritic skin conditions due to a lack of robust evidence of clinical effectiveness. The BATHE study found no benefit from the addition of emollient bath additives to the standard management of childhood eczema. The Northern Ireland Formulary has been updated and all emollient bath and shower preparations have been removed.

As an alternative, suitable **leave-on** emollients may be recommended (and where clinically indicated prescribed) for use as a soap substitute, body wash or bath additive if required. A resource page to support this is now available here. A patient guide is included on this resource page and can be downloaded and printed.



Deprescribing

This month the focus of deprescribing is oral nutritional supplements. Refer also to Deprescribing section on the NI Formulary website for resources to support deprescribing.

Deprescribe: Oral nutritional supplements

£8.8 million was spent on adult oral nutritional supplements (ONS) in 2022/23 in primary care in Northern Ireland, significantly higher than other regions of the UK.
There are 7 suggested steps to ensure appropriate prescribing of adult ONS in primary care. Please refer to 7 steps guidance within the NI Formulary or the recent ONS newsletter supplement for more detailed information.

Note: before considering ONS (Step 5), discuss 'Food First' and food fortification dietary advice (Step 4):

Step 4 – Discuss 'Food First' and Food Fortification Dietary Advice

Encourage daily:

One pint of fortified milk (add 2-4 heaped tablespoons of dried skimmed milk powder to 1 pint full cream milk)
Two nourishing snacks
Three fortified meals (add butter, margarine, etc to potatoes, serve meals with creamy sauces, add cream or evaporated milk to puddings
Four-week review if MUST>2, 2-3 months if MUST=1*

* Nursing and residential homes should follow regional guidance with regards to MUST scores.

Example of the impact of Food Fortification:

Scrambled egg with whole milk (120g)

Before fortification: 308kcal and 13.1g protein

Add 1 tsp butter, 2 tsp dried skimmed milk powder and 45g cream cheese.

Image by Freepik

After fortification: 603kcal and 15.8g protein

*Note: An ONS 1.5kcal/ml milkshake style ONS such as Ensure Plus®/ Fortisip®/Aymes Complete® contains approximately **300kcal and 12g/13g of protein**.*
*A powdered ONS (made up with 200ml of whole milk) such as Aymes shake® contains approximately **380kcal and 19g of protein.***

Actions for GP Practices

- Include ONS in all medication reviews
- Review any correspondence from Dietetics to determine if targets/goals have been met
- Review patients prescribed ONS with non-ACBS listed indication (see NI Formulary for ACBS indications)
- Review patients prescribed one supplement daily which has not been recommended by a dietitian (300-330kcal can be easily met with 'food first' advice)
- If pattern reflects requesting on an 'ad hoc' basis, take off repeat, review to establish how patient is taking their ONS and if further use is clinically appropriate
- Discuss with patient a switch to cost effective ONS products, where appropriate.
    - **Powdered ONS is the cost effective choice in primary care** (not suitable for all patients)
- Signpost to making the most of your food/watch out for weight loss advice resources and oral nutrition support resources, where appropriate.