NORTHERN IRELAND MEDICINES MANAGEMENT

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Health and Social Care Board

NEWSLETTER

In This Issue

Revised Shared care Guideline for Denosumab injection (Prolia®)

The Shared Care Guideline (SCG) for denosumab injection (Prolia®) has been updated.
Note: denosumab (Prolia®) is still only approved for use in NI for the treatment of osteoporosis in post-menopausal women at increased risk of fracture.

Changes to the SCG include:

- Corrected calcium levels should be checked and confirmed to be within normal limits of lab before each dose (e.g. one to three weeks before each dose is given). *[This is different from previous version of SCG which specified two weeks]*
- A number of different Pathways for prescribing and administration (with agreement between GP and Hospital Specialist) are now included
- Update to Adverse effects, precautions and contraindications section.

◊ **Pathway 1:** First dose in secondary care with ongoing prescribing and administration in primary care
◊ **Pathway 2:** First dose in secondary care with ongoing prescribing in primary care – patient to self-administer
◊ **Pathway 3:** First dose in primary care with subsequent prescribing and administration in primary care.

Amended Hospital specialist responsibilities:

- Arrange shared care with GP and decide which Pathway best suits patient
- Continue to review the patient at agreed specified intervals to monitor disease response to treatment and need to continue therapy. The optimal duration of denosumab treatment for osteoporosis has not been established; re-evaluate the need for continued treatment periodically based on the expected benefits and potential risks of denosumab on an individual patient basis, particularly after 5 or more years of use. *[Previously only stated review every two years]*

Reminder
The dose of denosumab (Prolia®) is one injection every 6 months –
only one syringe should be prescribed at a time.

The GP responsibilities now include the following points:

- Ensure practice systems are in place for prescribing (and administration if needed) every six months and inform initiating specialist if any missed treatments are identified. The Prolia® ProActive service can support clinicians in primary care with this and is available at www.prolia.co.uk
- Prescribe a sharps box where needed
- Patients should not stop denosumab without specialist review
- Ensure corrected calcium levels and renal function are checked before every dose (e.g. one to three weeks before each dose is administered). These should also be checked two weeks after each dose for those patients who require it as advised by specialist. If any results are abnormal or if any concerns, withhold denosumab and contact initiating specialist for advice
- Ensure calcium and vitamin D preparations are prescribed as advised by specialist (see NI Formulary)
- Ensure other anti-resorptives (e.g. bisphosphonates) are discontinued prior to starting denosumab.

MST sachets — Choosing a suitable alternative for patients

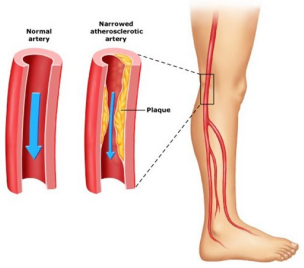
MST Continus® sachets (morphine prolonged release granules for suspension) were discontinued by the manufacturer in February 2021. Identifying a suitable alternative requires consideration of a patient's ability to swallow, especially for those who are approaching end of life.

The Northern Ireland Palliative Care Pharmacy Group has developed a resource to be used as a reference for clinical staff when selecting an alternative to MST Continus® sachets. It includes an algorithm and a table comparing the different alternatives, their advantages, any concerns regarding administration and recommendations for certain patients either at home or in a hospital or hospice.

This resource may be accessed via the Primary Care intranet.

Deprescribing: Naftidrofuryl

Peripheral vascular disease occurs as a result of slowly progressing arteriosclerosis, with intermittent claudication (defined as 'cramping discomfort in the calf clearly provoked by exercise and relieved by some minutes rest').



Several agents, including naftidrofuryl (or Praxilene®) and oxpentifylline (or Trental®), are marketed for the treatment of intermittent claudication.

As per the NI Formulary, there is currently insufficient evidence to recommend the routine use of peripheral vasodilators. Symptoms in patients with intermittent claudication are often improved through the use of treatments and lifestyle interventions to reduce cardiovascular risk. Those remaining symptomatic may be considered for treatment with naftidrofuryl, however this is recommended to be discontinued if no symptomatic benefit is seen after 3 to 6 months.

Despite this, nearly £80,000 was spent on naftidrofuryl in the last year in NI.

Actions for GP practices

Offer all people with peripheral arterial disease oral and written information about their condition. Discuss it with them so they can share decision-making, and understand the course of the disease and what they can do to help prevent disease progression.

Information should include:

- The causes of their symptoms and the severity of their disease
- The risks of limb loss and/or cardiovascular events associated with peripheral arterial disease
- The key modifiable risk factors, such as smoking (see NI Formulary website for resources on smoking cessation advice), control of diabetes, hyperlipidaemia, diet, body weight and exercise
- Review all patients prescribed naftidrofuryl capsules who have received therapy for six months or more. Discontinue therapy if no symptomatic benefit has been shown, provided it is clinically appropriate to do so
- Communicate planned review with local community pharmacies in advance, to allow consistent management of patient queries.

More information can be found at NICE CG147 and the NI Formulary.

Consider the following:

- Clinical effectiveness not established.
- Do the known possible adverse drug reactions outweigh the possible benefits?

Adverse effects: include diarrhoea, nausea, vomiting, epigastric pain, skin rashes, oesophagitis (if capsules are taken with insufficient liquid and become stuck in the throat), and calcium oxalate kidney stones (very rare). Rarely following treatment with naftidrofuryl oxalate, symptoms of liver damage have been reported, and require discontinuation of treatment.

Benefits: oral naftidrofuryl has a statistically significant and clinically meaningful, although moderate, effect of improving walking distance in the six months after initiation of therapy for people with intermittent claudication.

- Rarely indicated for long term treatment.

NICE GUIDANCE — RECENTLY PUBLISHED

NICE TA729 — Sapropterin for treating hyperphenylalaninaemia in phenylketonuria
NICE TA734 — Secukinumab for treating moderate to severe plaque psoriasis in children and young people
NICE TA735 - Tofacitinib for treating juvenile idiopathic arthritis
NICE TA736 — Nivolumab for treating recurrent or metastatic squamous cell carcinoma of the head and neck after platinum-based chemotherapy (review of TA490)
NICE TA737 — Pembrolizumab with platinum- and fluoropyrimidine-based chemotherapy for untreated advanced oesophageal and gastro-oesophageal junction cancer
NICE TA738 — Berotralstat for preventing recurrent attacks of hereditary angioedema
NICE TA739 — Atezolizumab for untreated PD-L1-positive advanced urothelial cancer when cisplatin is unsuitable (review of TA492)

MANAGED ENTRY DECISIONS

- Mercaptamine bitartrate (Procysbi®)
- Amikacin, liposomal (Arikayce®)
- Pembrolizumab (Keytruda®)
- Abemaciclib (Verzenios®)
- Berotralstat (Orladeyo®)
- Tofacitinib (Xeljanz®)
- Apalutamide (Erleada®) x 2 decisions
- Secukinumab (Cosentyx®)
- Chloroprocaine (Ampres®)
- Midazolam 2mg/ml oral solution in single-dose container (Ozalin®)
- Vericiguat (Verquvo®)

For full details see Managed Entry section of NI Formulary

This newsletter has been produced for GPs and pharmacists by the Regional Pharmacy and Medicines Management Team. If you have any queries or require further information on the contents of this newsletter, please contact one of the Pharmacy Advisors in your local HSCB office:

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