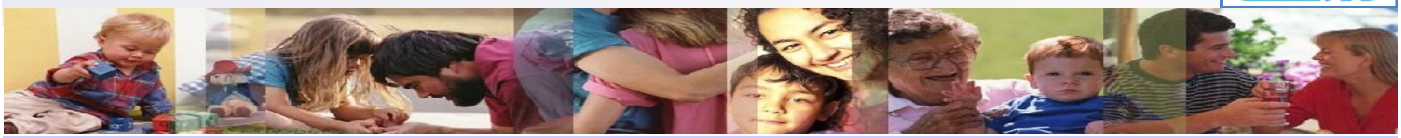
NORTHERN IRELAND MEDICINES MANAGEMENT



Newsletter Supplement: Prescribing for Osteoporosis

September 2017

Background

Bisphosphonate medication has shown efficacy in fracture risk reduction over 3 to 5 years of treatment. It acts by binding to bone mineral and inhibits bone turnover. The effect lasts for several years after treatment is stopped.

First line choices from the NI Formulary are:

- Risedronate 35mg weekly plus calcium and vitamin D

OR

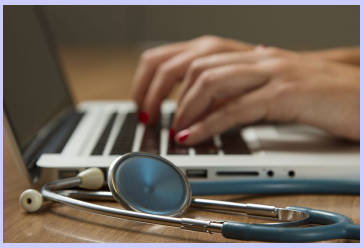
- Alendronic Acid 70mg weekly plus calcium and vitamin D

Long-term treatment with bisphosphonates may increase bone fragility by suppressing normal bone remodelling — a process essential for repair of skeletal micro-damage. Atypical femoral fractures have been reported (rarely) with bisphosphonate therapy, mainly in patients receiving long-term treatment for osteoporosis. The Medicines and Healthcare Products Regulatory Agency (MHRA) subsequently issued a warning of the risk of atypical femoral fractures with long term bisphosphonate use: '*The need for continued treatment should be re-evaluated periodically based on the benefits and potential risks of bisphosphonate therapy for individual patients, particularly after 5 or more years of use*.'

Because the effects of bisphosphonates lasts for several years after the bisphosphonate has been stopped, it is reasonable to consider a treatment break ('drug holiday').

Review Tool for Oral Bisphosphonates Prescribed for Osteoporosis

HSCB has produced a review tool: '*Review tool for Oral Bisphosphonates prescribed for Osteoporosis',* which can be accessed via the primary care intranet http://primarycare.hscni.net/pharmacy-and-medicines-management/resources/osteoporosis/.



The review covers the primary care treatment of patients with osteoporosis receiving oral bisphosphonates and prophylaxis in patients with the potential to develop osteoporosis in order to:

- Ensure the product and dose is appropriate for the indication
- Consider a "drug holiday" for those on therapy for 5 years or more if at moderate risk of an osteoporotic fracture
- Identify patients prescribed therapy for more than 10 years, so that therapy can be discontinued and if necessary specialist advice sought about ongoing management
- Consider discontinuation of therapy for low risk patients
- Ensure that where treatment is to be continued or to be restarted after an appropriate drug holiday, the choice of therapy is in line with the NI Formulary.

Bisphosphonate prescribing for all patients should be reviewed to ensure that the most appropriate, cost effective preparation is prescribed.

Bisphosphonate Review: A Local Example

A review was carried out in six local GP practices. A total of 627 patients were identified as having a current prescription for a bisphosphonate. The results of the review were as follows:

Prescribing for > 10 years

- 13% of patients were identified as having been prescribed a bisphosphonate for >10 years
- Of these, 79% had their medicine subsequently discontinued by the GP
- 19% of patients in this group were referred to secondary care for review

Prescribing between 5 to 10 years

- 29% of patients were identified as having been prescribed a bisphosphonate for between 5 to 10 years
- Of these, 21% had their medication subsequently discontinued by the GP
- 24% were allocated a drug holiday for between 1 to 3 years, depending on the bisphosphonate prescribed.
- 28% of patients in this group were referred to secondary care for review

Summary of the bisphosphonate review

This review has shown that, on average for a practice, potentially 17% of the total number of patients prescribed a bisphosphonate could have their medicine discontinued, while a drug holiday could be appropriate for a further 7% of patients.

Actions:

- GP practices should use the *Review tool for Oral Bisphosphonates prescribed for Osteoporosis* for patients who are taking an oral bisphosphonate for the management of osteoporosis.
- Re-assess fracture risk at a suitable time period after the drug holiday, unless clinical circumstances suggest an earlier review. A note should be placed in the patient record to identify a re-assessment date.
- Community pharmacists have an important role in supporting adherence and in reinforcing the advantages of the 'drug holiday' from oral bisphosphonate medication.

Denosumab Prescribing

Denosumab injections are available in two strengths:

- 60mg/ml (**Prolia**®) which is licensed for treatment of osteoporosis in post-menopausal women at increased risk of fractures and for men with prostate cancer to treat bone loss associated with hormone ablation

- 120mg/1.7ml (**Xgeva**®) which is licensed for the treatment of skeletal related events in adults with bone metastases from solid tumours. This is a RED drug and supply should come via the TRUST.

The only licensed indication for denosumab that is currently approved for use in Northern Ireland is for the treatment of osteoporosis in postmenopausal women at increased risk of fractures. **Prescribing for men is not commissioned in primary care, therefore HS21 prescriptions should not be issued**. Supply should come from the initiating Trust via the Interface Pharmacist Network Specialist Medicines (IPNSM) http://www.ipnsm.hscni.net/. Practices should identify any male patients receiving Prolia® injections and contact IPNSM to arrange supply. Denosumab 60mg/ml (Prolia®) should be **prescribed by brand** (see items unsuitable for generic prescribing) and, as the dose is one injection every 6 months, **only one syringe should be prescribed at a time.**

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.

Previous editions of the newsletter can be found in the Newsletters section of the Northern Ireland Formulary website: http://niformulary.hscni.net/PrescribingNewsletters/Pages/default.aspx.