NORTHERN IRELAND
MEDICINES MANAGEMENT

Health and Social Care Board

Osteoporosis Supplement

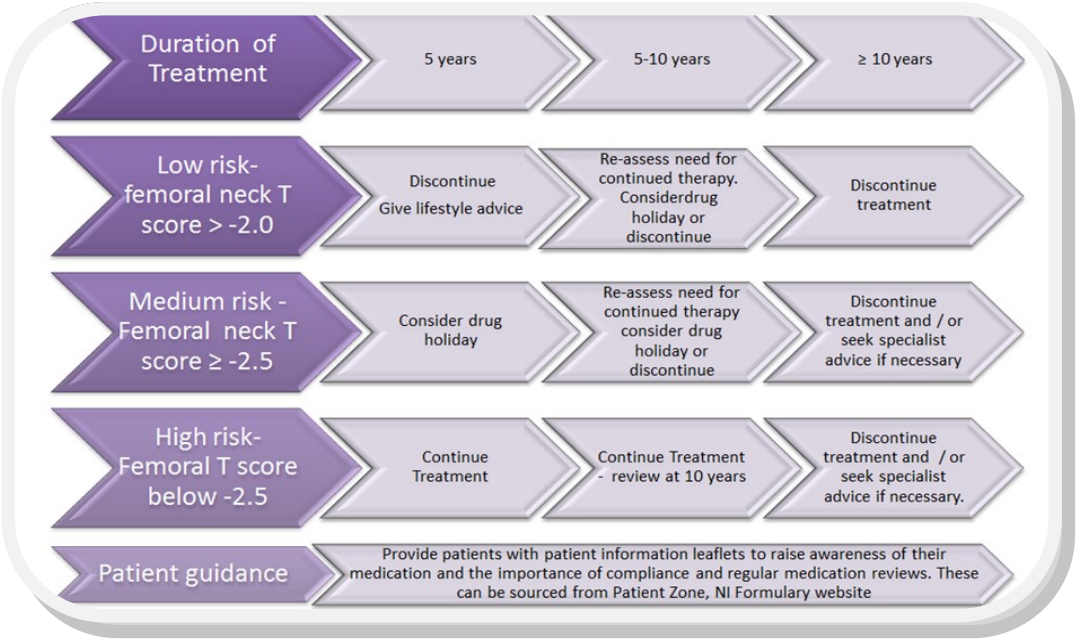
February 2019

Review of Bisphosphonate therapy in the treatment of osteoporosis

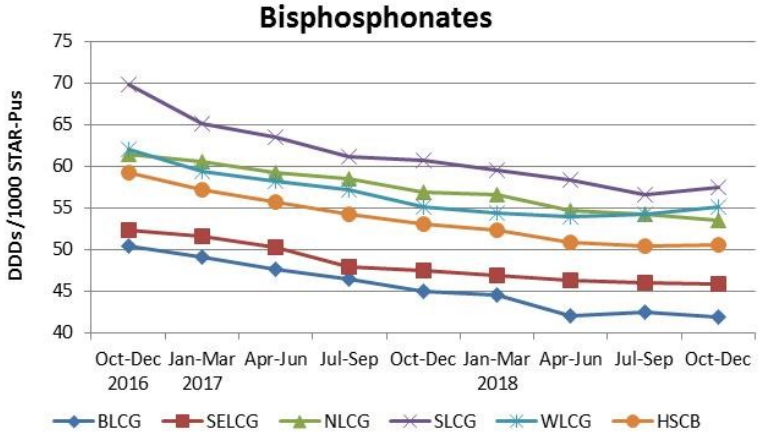
Bisphosphonate medication has shown efficacy in fracture risk reduction over 3 to 5 years of treatment, with the effect lasting for several years after treatment is stopped. However, long term treatment with bisphosphonates has been noted in some cases to have caused atypical femoral fractures. The Medicines 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*.'

Action for GP Practices

Review patients receiving bisphosphonate treatment and assess their risk level using the HSCB Review tool for Oral Bisphosphonates prescribed for Osteoporosis, which takes into consideration the length of time on treatment and the patient fracture risk score. If patients are on a drug holiday, i.e. a break in treatment, reassess their fracture risk after the specified time period, e.g. 2-3 years.



Reviews have been carried out in numerous GP practices throughout Northern Ireland.
Each LCG area has shown a decrease in the volume of bisphosphonate medication prescribed, with an Northern Ireland average reduction of 12%.



DDD/STAR PU is a measurement of the dose based on adult doses and they take into consideration patient profiles.

It is important that GP practices continue to:

- assess patients taking an oral bisphosphonate for the management of osteoporosis
- re-assess fracture risk at a suitable time period after the drug holiday
- if the clinical circumstances change, an earlier review may be required
- place a note 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.

Patient Information Services

In order to raise awareness of their medication and the importance of compliance and regular medication reviews, the following resources have been made available to help support patients with osteoporosis. Copies of these patient information leaflets can be downloaded from the Patient Zone, NI Formulary website.

- **Am I at risk of osteoporosis and fractures?** (National Osteoporosis Society). This covers some of the risk factors that can increase the risk of osteoporosis and what to do if risk factors are present.
- **Drug treatments for osteoporosis** (National Osteoporosis Society). This provides information on the various drug treatment options for patients and advice on how to get the best from the prescribed medicines and how to reduce modifiable risk factors.
- **Bisphosphonate drug holiday in treatment for osteoporosis** (HSCB). This leaflet provides information on the risks associated with taking long-term bisphosphonates and when a drug holiday may be appropriate.

Denosumab Review

Denosumab injection 60mg/ml (Prolia®) is the recommended treatment for post-menopausal osteoporosis where oral bisphosphonates are unsuitable due to contra-indication (e.g. severe GORD), intolerance or compliance issues. Denosumab should be **prescribed by brand name** (see Items unsuitable for generic prescribing). The dose is one injection every 6 months and, because of this, **only one syringe should be prescribed at a time.** Denosumab has to be stored in a fridge and it is important that the patient is aware of this.

Denosumab 120mg/ml (Xgeva®) injection is licensed for the treatment of skeletal related events in adults with bone metastases from solid tumours. This is a RED list drug and supply should come via the Trust.

GP practices should always check the strength of denosumab with secondary care if no strength is indicated on a hospital discharge letter**.**

Prescribing for Women

In Northern Ireland the only licensed indication for denosumab 60mg/ml (Prolia®) that is currently approved is for the treatment of osteoporosis in postmenopausal women at increased risk of fractures (see NICE TA204). For this indication it is an AMBER list drug with share care arrangements. A Shared Care Guideline is available.

Actions for GP Practices

GPs should review their prescribing of denosumab 60mg/ml (Prolia®) in relation to the following points:

- Ensure all denosumab injection 60mg/ml is prescribed as the brand Prolia®.
- Ensure all denosumab injection 60mg/ml issued is for female patients only.
- Ensure all denosumab injections 60mg/ml are issued as one injection every six months.
- Ensure there is a recall system in place to ensure that patients receive their six monthly injection in a timely manner.
- Early requests for prescriptions should be queried.
- Ensure denosumab and a bisphosphonate are not prescribed together unless under the advice of a specialist.

Actions for Community Pharmacists

- Be familiar with the characteristics of denosumab 60mg/ml including dose, administration interval and injection route.
- As part of the clinical check, ensure the quantity and frequency are correct and in line with the SPC. If any issues are identified, contact the prescriber for clarification.
- Support patients to manage treatment, understand dosing interval and administration route.
- Ensure the patient is aware of the special storage required (as denosumab is a fridge item).

Prescribing for Men

When prescribed to male patients, or for any other indication, denosumab is a 'hospital only' drug, thus prescribing responsibility and supply should remain with the Trust specialist.

Actions for GP Practices

- Ensure all denosumab injection 60mg/ml prescribed for men is recorded on the clinical system as a RED list drug and supplied from the local Trust.

Action for Community Pharmacists

- Beware of the RED list status of denosumab when prescribed for a man. Highlight this to the patient's GP if prescribing occurs.

This newsletter has been produced for GPs and pharmacists by the Regional Pharmacy and Medicines Management Team.