

## **Shared Care Guidance**

### **Denosumab (Prolia®) for the treatment of Osteoporosis in Adults**

This shared care agreement outlines the way in which the responsibilities for managing the prescribing of denosumab (Prolia®) for the treatment of osteoporosis in adults can be shared between the Secondary Care Specialist and the General Practitioner.

#### **Indication:**

Denosumab (Prolia®) is indicated for the treatment of osteoporosis in postmenopausal women and in men over the age of 75 years or at high risk of fractures when intolerant to oral preparations.

#### **Dose & Administration:**

Denosumab is administered as a 6-monthly 60mg subcutaneous injection, into the thigh, abdomen or upper arm.

No dose adjustment is required in elderly patients or patients with renal impairment.

The first prescription will come from secondary care and the initial drug treatment will be administered within the hospital setting.

#### **Duration of Therapy:**

In accordance with agreed local guidance, denosumab therapy should be continued for a maximum of three years.

#### **Contraindications:**

- Hypocalcaemia
- Hypersensitivity to the active substance or to any of the excipients

#### **Special Precaution: Hypocalcaemia**

It is important to identify patients at risk for hypocalcaemia. Hypocalcaemia must be corrected by adequate intake of calcium and vitamin D before initiating therapy. Clinical monitoring of calcium levels is recommended before each 6-monthly dose and, in patients predisposed to hypocalcaemia within two weeks after the initial dose. If any patient presents with suspected symptoms of hypocalcaemia (e.g. muscle spasms, twitches, cramps, tingling of fingers, toes or around the mouth) during treatment, calcium levels should be measured.

#### **Pregnancy and Breast Feeding:**

Denosumab is not recommended for use in pregnant women.

It is not known whether denosumab is excreted into human milk and so a benefit vs risk decision should be taken if denosumab therapy is required to be used in a breastfeeding patient.

#### **Adverse Effects:**

Common side effects include urinary tract infection, upper respiratory tract infection, cellulitis, sciatica, musculoskeletal pain, constipation, cataracts, rash and pain in the extremity.

A comprehensive list of denosumab-related side effects can be found in the British National Formulary and the Prolia® Summary of Product Characteristics.

#### **Drug Interactions:**

Denosumab has a low potential for drug-drug interactions and no concomitant therapy would contraindicate its use. Refer to the British National Formulary and Electronic Medicines Compendium for more comprehensive detail.

#### **Monitoring Requirements:**

**Author:** Paul Mills. Principal Pharmacist, Clinical Services (CHUFT)

Version 1

**Reviewed by:** Dr Paul Byrne. Consultant Rheumatologist (CHUFT), Dr Shazia Awais. Consultant Orthogeriatrician (CHUFT), Sheila Baldwin. Head of Medicines Management. North East Essex CCG, Carol Sampson. Evidence Base Pharmacist. North East Essex CCG

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**Next review date:** NEEMMC, March 2018

Apart from the need to check calcium levels throughout treatment, there are no specific monitoring requirements associated with denosumab therapy.

The patient's calcium level should be checked:

- Before each dose is administered
- Within two weeks after the initial dose with risk factors for hypocalcaemia (e.g. severe renal impairment)
- If suspected symptoms of hypocalcaemia occur

### **Parameters for Intervention/Withholding Denosumab Treatment:**

After 3 years of treatment, denosumab therapy should be stopped.

Patients experiencing serious denosumab-related adverse effects (e.g. cellulitis) should be reviewed and a decision made as to whether treatment should continue.

Discontinuation of denosumab therapy in patients suspected to have an atypical femur fracture should be considered.

Temporary interruption of denosumab treatment should be considered in patients experiencing osteonecrosis of the jaw.

### **Shared Care Responsibilities:**

#### ***Secondary Care Specialist***

1. Send a letter to the GP with Shared Care Guidelines requesting shared care for the patient.
2. Assess the patient, ensuring the suitability of the patient for denosumab treatment in accordance with local guidance and NICE TA204.
3. Prescribe and administer the first denosumab injection within the secondary care setting.
4. Discuss the treatment with the patient, providing information on benefits and possible adverse effects. Advise the patient to ensure good oral hygiene.
5. Ensure patients are adequately supplemented with calcium and vitamin D.
6. Advise the GP regarding monitoring serum calcium levels prior to subsequent injections.
7. Evaluate any concerns regarding adverse effects from the GP and provide advice when requested.

#### ***Primary Care Practitioner***

1. Communicate with the relevant consultant at Colchester General Hospital their agreement to participate in this shared care guideline (by returning the signed copy attached to this document).
2. Continue prescribing/administering the denosumab treatment as recommended by the specialist.
3. To monitor calcium levels prior to each dose being administered.
4. To identify adverse reactions if the patient presents with any signs; liaising with the hospital specialist where necessary.
5. Promptly treat signs or symptoms of cellulitis as necessary
6. Ensure that the ongoing denosumab therapy is administered within a one month window of the 6-month due date.
7. Continue denosumab therapy for a maximum of three years i.e. five injections, and then stop/therapy.

#### ***Patient (and if appropriate, the carer):***

1. Report to the Secondary Care Specialist or GP if he or she does not have a clear understanding of the prescribed treatment.
2. Share any concerns in relation to treatment with denosumab.
3. Report any adverse effects to the Secondary Care Specialist or GP whilst receiving denosumab therapy.
4. Report symptoms of hypocalcaemia to the Secondary Care Specialist or GP (e.g. muscle spasms, twitches, cramps, tingling of fingers, toes or around the mouth)
5. Report and seek prompt medical attention if signs or symptoms of cellulitis develop
6. Maintain good oral hygiene with regular dental check-ups whilst on treatment with denosumab.

7. Attend the GP surgery when requested to do so for monitoring of serum calcium levels and to receive the six-monthly denosumab injections.
8. Take regularly any calcium and vitamin D supplements if prescribed.
9. Inform their dentist at their next appointment that denosumab therapy has been initiated.

### Contact Numbers for Advice and Support:

Colchester Hospital University NHS Foundation Trust (01206) 747474 (Switchboard)

Colchester Hospital Rheumatology Department (01206) 742165/742279

#### **Consultant Rheumatologist:**

Dr Paul Byrne [paul.byrne@colchesterhospital.nhs.uk](mailto:paul.byrne@colchesterhospital.nhs.uk)

#### **Consultant Orthogeriatrician:**

Dr Shazia Awais [shazia.awais@colchesterhospital.nhs.uk](mailto:shazia.awais@colchesterhospital.nhs.uk)

**CHUFT Pharmacy Department** (01206) 742355

**CHUFT Medicines Information Help Line:** (01206) 742161

### References

- (1) Denosumab (Prolia®) Summary of Product Characteristics - <https://www.medicines.org.uk/emc/medicine/23127>
- (2) Denosumab for the prevention of osteoporotic fractures in postmenopausal women. NICE Technical Appraisal Guidance (TA204) - <https://www.nice.org.uk/guidance/ta204>
- (3) Guidelines for the prevention and treatment of osteoporotic fragility fractures. North East Medicines Management Committee. January 2016.

**Section A (to be completed by Secondary Care Specialist):**

Hospital Number:	
NHS No:	
Date:	
GP Courier No:	
GP Name:	

Name of patient:	
Date of Birth:	
Address:	

Background:

Medications:

Dear GP,  
See attached clinic letter. Please can you sign and return (using the above fax number) to indicate you are in agreement with the Shared Care Guidelines.

Yours sincerely,

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**Section B (to be completed by General Practitioner):**

The above patient (with associated denosumab treatment) has been accepted into our monitoring service.

Accepting GP Name:	
Accepting GP Signature:	
Date:	

Practice Stamp: