Guy's and St Thomas' NHS
NHS Foundation Trust

Clinical Guideline

Shared Care Guideline for Denosumab 60mg Injection (Prolia) for secondary prevent of osteoporotic fragility fractures in postmenopausal women

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SHARED CARE PRESCRIBING GUIDELINE

Denosumab 60mg Injection (Prolia®) for the secondary prevention of osteoporotic fragility fractures in postmenopausal women with creatinine clearance > 35mL/min

NOTES to the GP

The information in the shared care guideline has been developed in consultation with Primary Care and it has been agreed that it is suitable for shared care.
This document should provide sufficient information to enable you to make an informed decision regarding the clinical and legal responsibility for prescribing this drug.

The questions below will help you confirm this:

- Is the patient's condition predictable or stable?
- Do you have the relevant knowledge, skills and access to equipment to allow you to monitor treatment as indicated in this shared care prescribing guideline?
- Have you been provided with relevant clinical details including monitoring data?

If you can answer YES to all these questions (after reading this shared care guideline), then it is appropriate for you to accept prescribing responsibility.
If the answer is NO to any of these questions you should contact the requesting consultant or your local CCG medicines management team. It would not normally be expected that shared care prescribing would be declined on the basis of cost.

Prescribing should follow requirements in the South East London Interface Prescribing Policy
The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use. The patient's best interests are always paramount

Date shared care guideline revised: **Approved by:** Kings College Hospital NHS Foundation Trust Rheumatology Clinical Governance 05.11.14 Rheumatology Risk & Quality Meeting (Guy's) 10.12.14 Approved by Lambeth and Southwark Joint Prescribing Committee: 17.04.2015 **Approved by D&T or equivalent Date approved: 14.05.2015** **Review date**: **14.05.2018**	**Prepared by:** **Pharmacists** Scott Mercer GSTT Nicola Torrens KCH **Metabolic Bone** Dr Caje Moniz, KCH Dr Geeta Hampson, GSTT Professor Ignac Fogelman, GSTT Dr Frances Williams, GSTT Professor Tim Spector, GSTT **Elderly Care** Dr Daniel Bailey, KCH Dr Frances Dockery, GSTT **Rheumatology** Dr Terence Gibson, GSTT Dr Sophia Steer, KCH

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Agreement to participate in shared care for Denosumab 60mg Injection (Prolia®) for the secondary prevention of osteoporotic fragility fractures in postmenopausal women with creatinine clearance > 35mL/min

Consultant Name:	**Patient name:**
Consultant signature:	**Patient Hospital Number:**
Date completed:	**Patient Agreement** ☐ **Patient agrees to shared care**
Hospital: ☐ **King's College London** ☐ **Guy's & St Thomas'**	☐ **Patient does not agree to shared care**
GP Name	**Specialist Nurse Name**
GP Signature	**Specialist Nurse Signature**
Date completed:	**Date completed:**

ACTION

1. Consultant Rheumatologist

- Explain shared care to patient and obtain agreement.
- Indicate requesting hospital.
- Complete and sign agreement.
- Email / fax full shared care guideline to GP - fax numbers at **http://www.nhs.uk**.
- Email / fax completed request for shared care to GP for attention and action.
- If using email, the completed request document must be sent via an nhs.net email account.
- The original documents or electronic copies must be filed in the patient's health record.

2. General Practitioner

- If **in agreement** to participate in shared care, please reply to the relevant nhs.net account or fax back to the relevant fax number for the clinic.
- If **not in agreement** to participate in shared care, contact consultant and local CCG medicines management team within 2 weeks of receipt to discuss. If after discussion it is agreed not to undertake shared care for this patient, both the consultant and the local CCG Medicines Management team should be informed.
- Once decision reached file copy in patient's notes.

3. Specialist Nurse

- Once received completed agreement by Consultant and GP, sign to confirm awareness that the patient will be under shared care.
- Take any necessary actions prior to shared care commencing (changing of appointments etc).
- Original to be filed in Patient's clinical record.

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Attach patient addressograph or
Insert patient details
Patient name
Patient ID
Date of Birth

Denosumab 60mg Injection (Prolia®) for the secondary prevention of osteoporotic fragility fractures in postmenopausal women with creatinine clearance >35mL/min

This shared care guideline covers the use of denosumab subcutaneous injection for the secondary prevention of osteoporotic fragility fractures. Practices may be asked to take on prescribing once denosumab has been initiated at King's College Hospital NHS Foundation Trust or Guys and St Thomas' NHS Foundation Trust.

1. CIRCUMSTANCES WHEN SHARED CARE IS APPROPRIATE

- The patient has the first dose prescribed and administered in the hospital clinic
- The patient has not reported adverse effects warranting discontinuation following the first dose
- The consultant and GP agree shared care

2. AREAS OF RESPONSIBILITY

Consultant Responsibilities

- Assess the patient and establish the need for denosumab
- Complete baseline monitoring of U&Es, creatinine, calcium and vitamin D level -confirm if patient is calcium and vitamin D replete
- Review of oral/dental hygiene with patient to ensure no invasive dental procedures (e.g. implant, extraction) planned. If necessary refer to dental clinic or patient's own dentist if required prior to initiation if a dental examination is required prior to initiation of therapy.
- Discuss treatment with patient and ensure they have a clear understanding of it including risks and benefits
    - Explain that the treatment is 6 monthly injections for 5 years
    - Discuss the shared care agreement with the patient and ensure the patient has a clear understanding of the need for their follow up 6 monthly injections at their GP surgery
    - Explain that the hospital will arrange a follow up at 1 year and year 3.
    - Explain that the GP will refer them back for a review at 5 years
    - Advise the patient if they need to take vitamin D or calcium supplements
    - Advise the patient of the importance of good oral/dental hygiene during treatment
    - Advise the patient to seek prompt medical attention if they develop signs symptoms of cellulitis
    - Advise the patient to report any new or unusual thigh, hip or groin pain during treatment.
    - Explain the risk of hypocalcaemia, what symptoms to watch out for and to seek medical advice as soon as possible. Reinforce the need for calcium supplementation if not receiving adequate dietary intake.
- Fax or email a signed shared care guideline with patient details completed to GP for consideration of shared care request with accompanying letter including patient review
- Initiate first denosumab injection

After agreement to shared care

- Inform GP when patient is stable
- Inform GP of abnormal monitoring results and any changes in therapy
- Evaluate adverse events reported by GP or patient
- Report any suspected adverse effects to the MHRA: https://yellowcard.mhra.gov.uk/
- Carry out ongoing monitoring and follow up according to shared care guidelines including continued need for therapy

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General Practitioner Responsibilities

Before agreement to shared care:

- Consider shared care proposal within 2 weeks of receipt of letter from the Consultant
- If named GP is not available over the next week pass request to a GP colleague
- If in agreement to take over on shared care prescribing responsibility, confirmation to the requesting consultant is required within 2 weeks of receipt of shared care request by completing the "Agreement" on page 2 and returning via fax or email
- If not in agreement to share care, discuss with requesting consultant or local CCG medicines management team within 2 weeks of receipt of shared care request

After agreement to shared care:

- Provide ongoing prescriptions for denosumab in line with shared care guideline
- Ensure that denosumab is added to the patient's medication record and any other osteoporosis treatments, such as oral bisphosphonates, strontium, are stopped and removed from the patient's repeat prescription
- Ensure that calcium and vitamin D supplements are continued if appropriate and prescribe the formulation that the patient finds acceptable in order to maximise adherence e.g. chewable tablets, caplets or effervescent tablets
- Monitor general health of patient and check adverse effects as appropriate (see page 7)
- Discuss and inform consultant of any adverse effects during treatment and before any discontinuation of treatment (see page 7)
- Check compatibility interactions when prescribing new or stopping existing medication
- Report any suspected adverse effects to the MHRA: https://yellowcard.mhra.gov.uk/
- Encourage patient adherence with treatment. Discuss with the hospital team if prescriptions are not being collected regularly, particularly if associated with poor or deteriorating health
- Refer patient back to the hospital for a review at 5 years
- Consider asking hospital Bone Health teams to take back prescribing should unmanageable problems (e.g. new fragility fracture, renal function deterioration, dental issues) arise, following discussions with relevant consultant
- Stop treatment on advice of specialist or immediately if urgent need arises

Patient Responsibilities

- Inform Consultant and GP if any invasive dental procedures (e.g. extraction / implant) planned prior to and during treatment with denosumab
- Arrange regular dental check-ups and maintain good oral/dental hygiene – important to prevent complications such as osteonecrosis of the jaw
- Inform dentist of all current prescribed medicines and over the counter medicines being taken, including denosumab
- Take medicines as agreed
- Report any adverse effects to GP and hospital doctor who last administered the injection.
- Do not share medicines
- Attend all hospital, GP and dental appointments
- Inform GP, hospital and dentist of any changes in addresses or telephone contact numbers
- To seek prompt medical attention if any signs or symptoms of cellulitis develop
- To report any new or unusual thigh, hip or groin pain during treatment.
- To continue calcium and vitamin D supplements (if required)

Specialist Nurse Responsibilities

- To ensure that the patient is calcium and vitamin D replete prior to administration of injection.
- To ensure patient meets the criteria for administration of denosumab prior to administration
- To administer the first injection of denosumab
  - To discuss any available patient support programmes
- Advise the patient that other osteoporosis treatments should stop, but if prescribed, calcium and vitamin D supplements should continue
- Check for any adverse effects after the first dose by telephone to patient
- Advise the patient that subsequent injections will be administered at the GP every 6 months. The patient should ensure an appointment is made

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3. COMMUNICATION AND SUPPORT

King's College Hospital switchboard: 0203 299 9000

Metabolic Bone Clinic (Denmark Hill Site) Consultant - Dr Caje Moniz Associate Specialist – Dr Ram Chandra Lead Nurse – Sarah Brannigan	Tel: 0203 299 4181 Fax: 0203 299 3140 Email: cajemoniz@nhs.net
King's Older Persons Assessment Unit / Betty Alexander Suite (KOPAU-BAS) Denmark Hill Site Consultant - Dr Daniel Bailey Lead Nurse – Kathryn O'Donoghue	Tel : 0203 299 6185 Fax : 0203 299 6149 Email : danielbailey2@nhs.net
Immediate general advice	As above
Medication – Prescribing advice, interactions, availability of medicines (Denmark Hill Site) Pharmacist	Pharmacy Department Secretary: 0203 299 3347 Pharmacist Direct: 0203 299 9000 Ext: 35720

Guys and St Thomas' Hospital switchboard: 0207 188 7188

Rheumatology	Tel: 0207 188 5896 - helpline Fax: 0207 407 7532 Email: rheumatologydept@gstt.nhs.uk Geeta.hampson@gstt.nhs.uk Ignac.fogelman@gstt.nhs.uk Frances.williams@gstt.nhs.uk Millicent.stone@gstt.nhs.uk
Older Persons Assessment Unit – Falls & Bone Health Clinic Consultant: Dr Frances Dockery Lead nurse: Edwin Madrazo	Tel : 020 7188 2093 Fax : 020 7188 2095 Email : frances.dockery@gstt.nhs.uk edwin.madrazo@gstt.nhs.uk
Immediate general advice	As above
Medication – Prescribing advice, interactions, availability of medicines	Medicines Information 020 7188 8748

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4. CLINICAL INFORMATION

Indication(s):	Secondary prevention of osteoporotic fragility fractures in postmenopausal women with a creatinine clearance of >35mL/min
Place in Therapy:	Denosumab is recommended as a treatment option for the secondary prevention of osteoporotic fragility fractures only in postmenopausal women at increased risk of fractures who are: ▪ unable to comply with the special instructions for administering alendronate and either risedronate or etidronate, or have an intolerance of, or a contraindication to, those treatments as outlined in NICE Technology Appraisal 204 ▪ unable to comply with the special instructions for administration of, have an intolerance of, or a contraindication to strontium as outlined in MHRA Drug Safety Update Vol6: Iss 9 April 2013
Dose & route of administration:	60mg administered as a subcutaneous injection once every 6 months into the thigh, abdomen or back of arm by an individual who has been adequately trained in injection techniques.
Duration of treatment	5 years with review at 1, 3 and 5 years in secondary care
Criteria for stopping treatment	**Completion of 5 years of treatment** **New fragility fracture after 1 year of therapy** and including review of adherence, DXA scan, FRAX score and patient factors (adherence) by consultant. **Continued bone loss** – after consultant review of clinical factors e.g. adherence, DXA scan, FRAX score.
Monitoring Requirements including frequency:	**Consultant:** ▪ Baseline monitoring of U&Es, creatinine, calcium and vitamin D level - confirm if patient is calcium and vitamin D replete. ▪ Review of therapy at 1, 3 and 5 years including DXA scan, FRAX score and patient factors (adherence). **GP:** ▪ To monitor renal profile and vitamin D levels annually and reinforce need for adherence to supplementation where appropriate. ▪ To monitor calcium levels prior to each dose to ensure patient is not hypocalcaemic. Reinforce need for adherence to supplementation or dietary intake. To monitor patients for signs of hypocalcaemia and to ask patient to seek prompt medical attention if they develop signs or symptoms of hypocalcaemia. ▪ To monitor patients for signs of infections (cellulitis, urinary tract infections, upper respiratory tract infections) and to ask patient to seek prompt medical attention if they develop signs or symptoms of infections.

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Follow up arrangements	**Consultant:** ▪ Review of therapy at 1, 3 and 5 years (including DXA scan, FRAX score, patient factors (adherence). **GP:** ▪ **Administration of injection (once stable) every 6 months.** ▪ **Referral of patient to consultant if unmanageable problems (such as new fragility fracture, renal function deterioration, dental issues) during treatment period.** ▪ **Referral of patient back to hospital following 5 years of therapy.** ▪ **Monitor renal profile annually** ▪ Monitor vitamin D levels annually and ensuring patient is vitamin D replete. ▪ Monitor calcium levels and ensure patient is not hypocalcaemic before each dose.
Practical issues including other relevant advice/information:	**Oral Hygiene & Dental Care** ▪ Patient to arrange regular dental check-ups and maintain good oral/dental hygiene – important to prevent complications such as osteonecrosis of the jaw ▪ Patients must inform their dentist that they are on treatment with denosumab. ▪ If invasive dental treatment is required (e.g. extraction or dental implant), the dose should be delayed until 3 months after invasive dental treatment is completed. **Contraindications** ▪ Hypocalcaemia ▪ Hypersensitivity to the active substance or to any of the excipients. ▪ Concomitant treatment with other denosumab-containing medicinal products **Adverse Effects** ▪ Very common o Pain in extremity o Musculoskeletal pain ▪ Common o Urinary tract o Upper respiratory tract infection o Sciatica o Cataracts o Constipation o Abdominal discomfort o Rash o Eczema ▪ Uncommon o Diverticulitis o Cellulitis o Ear infection ▪ Rare o Osteonecrosis of the jaw o Atypical femoral fractures o Drug hypersensitivity o Anaphylactic reaction o Hypocalcaemia (Patients with CrCl <30ml/min are at

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	higher risk of developing hypocalcaemia in the absence of calcium supplementation**.** **Interactions** Refer to BNF online and Summary of Product Characteristics for relevant interaction studies. ▪ The needle cover of the pre-filled syringe contains dry natural rubber (a derivative of latex) which may cause allergic reactions. ▪ Patients with hereditary problems with fructose intolerance should not use denosumab.
Information provided	Arthritis Research UK: http://www.arthritisresearchuk.org/arthritis-information/drugs/drugs-for-osteoporosis.aspx

Evidence Base for treatment and Key references:	1. Denosumab for the prevention of osteoporotic fractures in postmenopausal women NICE technology appraisal guidance 204. October 2010. (Link updated 11.03.15) http://www.nice.org.uk/guidance/ta204/chapter/1-guidance Update Strontium ranelate (Protelos): risk of serious cardiac disorders – restricted indications, new contraindications, and warnings. MHRA Drug Safety Vol: Issue 9; April 2013. Prolia 60mg solution for injection in a pre-filled syringe Summary of Product Characteristics. Updated 26/08/2014. http://www.medicines.org.uk/emc/medicine/23127 BNF 68 http://www.evidence.nhs.uk/formulary/bnf/current/6-endocrine-system/66-drugs-affecting-bone-metabolism/662-bisphosphonates-and-other-drugs-affecting-bone-metabolism/denosumab/denosumab NHS Lambeth CCG and NHS Southwark CCG Guidance for the management of osteoporosis and fracture prevention in primary Care NHS Lambeth CCG, NHS Southwark CCG, GSTFT and KCH Replacement of low vitamin D in adults including chronic kidney disease, pregnancy and breast feeding guideline Denosumab: updated recommendations. Rare cases of atypical femoral fracture with long-term use. February 2013 https://www.gov.uk/drug-safety-update/denosumab-60-mg-prolia Denosumab Updated Recommendations. Drug Safety Update volume 8 issue 2, September 2014: A2 https://www.gov.uk/drug-safety-update/denosumab-updated-recommendations

NB: for full details of adverse effects and drug interactions refer to latest Summary of Product Characteristics