Shared Care Guideline: Denosumab (Prolia®) for osteoporosis	
Licensed indication	Denosumab is licensed for the treatment of osteoporosis in postmenopausal women at increased risk of fractures.
Patient Pathway and selection criteria	Denosumab will be initiated and the first dose administered by secondary care. Thereafter, prescribing and administration can be undertaken in primary care under the shared care guideline. Denosumab should be used in accordance with NICE TA204 restrictions apply with regards to T score and previous drug treatment*.
Normal dose and administration	Denosumab 60mg administered as a subcutaneous injection once every 6 months into the thigh, abdomen or upper arm. No dose adjustment is required in patients with renal impairment, or in elderly patients. Patients must be adequately supplemented with calcium and vitamin D.
Contra-indications	• Hypocalcaemia • Hypersensitivity to the active substance or any of the excipients
Cautions	• **Hypocalcaemia:** Hypocalcaemia must be corrected by adequate intake of calcium and vitamin D before initiating therapy. Patients with severe renal impairment (creatinine clearance <30 ml/min) or receiving dialysis are at greatest risk of developing hypocalcaemia. Signs and symptoms of hypocalcaemia include altered mental status, tetany, seizures and QTc prolongation. Hypocalcaemia with denosumab most commonly occurs within the first 6 months of treatment, but it can occur at any time during treatment. • **Skin Infections:** Patients receiving denosumab may develop skin infections (predominantly cellulitis). Patients should be advised to seek prompt medical attention if they develop signs or symptoms of cellulitis. • **Osteonecrosis of the Jaw (ONJ):** ONJ has been rarely reported in patients treated with denosumab. Most, but not all, cases have been in cancer patients • **Atypical fractures of the femur:** Atypical femoral fractures (rare) have been reported. Patients should be advised to report new or unusual thigh, hip, or groin pain. Patients presenting with such symptoms should be evaluated (bilaterally) for an incomplete femoral fracture. • **Allergy to dry natural rubber:** The needle cover of the pre-filled syringe contains dry natural rubber (a derivative of latex), which may cause allergic reactions. • **Fructose intolerance;** Patients with rare hereditary problems of fructose intolerance should not use denosumab.
Specialist responsibility	• Check suitability of patient for Denosumab against guidelines and individual patient factors • Ensure that the patient/carer is an informed recipient of

	denosumab, and discuss the benefits and side effects of treatment with the patient and their responsibilities as listed below • Check serum calcium and vitamin D levels, and correct pre-existing hypocalcaemia and vitamin D deficiency before initiating denosumab. • Consider referring for a dental examination prior to treatment in patients with concomitant risk factors for ONJ. Any preventative dental work should be completed in these patients prior to treatment and whilst on treatment invasive dental treatment should be avoided where possible. • Advise on importance of good oral hygiene whilst on denosumab treatment • Advise fully on potential side effects and action to be taken if these develop. • Inform GP of treatment start date and any other relevant clinical information e.g. baseline bloods. Provide shared care template and obtain GP agreement for on going management. • Advise length of course and stopping criteria as necessary (treatment holiday may be considered after X years) • Administer the first dose of denosumab before transferring care to the GP • Provide support and information to GP as may be required in the future to facilitate patient care
Adverse effects (consult BNF or SPC for a comprehensive list)	• Common adverse effects: urinary tract infection, upper respiratory tract infection, cataracts, constipation, sciatica, rash, eczema, and pain in extremity (very common) • Uncommon adverse effects: Skin infections predominantly cellulitis, diverticulitis • Rare adverse effects: hypocalcaemia, osteonecrosis of the jaw, atypical femoral fractures
Pregnancy	Denosumab is not recommended for use in pregnant women.
Pharmaceutical aspects	Store in a refrigerator (2-8°C), do not freeze. Keep the pre-filled syringe in the outer carton to protect from light. Do not shake excessively. Denosumab may be stored at room temperature (up to 25°C) for up to 30 days in the original container. Once removed from the refrigerator, denosumab must be used within this 30 day period.
N.B. The doctor who prescribes the medicine has the clinical responsibility for the drug and the consequence of its use. **Denosumab, when used in accordance with NICE, would normally be used for three years only after which treatment is stopped.**	
General practitioner responsibilities	1. To respond to the request for shared care as soon as is practicable. 2. To ensure that denosumab is added to the patient's drug record. To prescribe and administer denosumab injection every 6 months following initial dose, for the time period specified by the consultant. 3. To ensure that other osteoporosis treatments (e.g. alendronate, strontium) are stopped and removed from the patient's repeat prescription. 4. To ensure that calcium and vitamin D supplements are continued if

	appropriate. 5. Reinforce the patient's understanding of the nature, effect and potential side effects of denosumab before prescribing it as part of the shared care programme and contact the specialist for clarification where appropriate. Monitor patient's overall health and well-being. 6. Monitor calcium levels annually if the patient is at risk of hypocalcaemia. 7. To report any adverse events to the consultant, where appropriate. 8. To report any adverse events to the MHRA, where appropriate. 9. Monitor the progression of disease.
CCG responsibilities	1. To provide feedback to trusts via Trust Medicines Committee. 2. To support GPs in decision making and facilitate appropriate use and monitoring of denosumab. 3. To support trusts in resolving issues that may arise as a result of shared care.
Patient/carer responsibilities	1. To ensure that they have a clear understanding of their treatment (denosumab). 2. To report any adverse effects to their GP and/or specialist, including any new or unusual thigh, hip or groin pain , or signs/ symptoms suggestive of cellulitis. 3. To report any changes in disease symptoms to GP and/or specialist. 4. To alert GP and/or specialist of any changes of circumstance which could affect management of disease. 5. To avoid (where possible) invasive dental procedures and maintain good oral hygiene whilst on denosumab treatment. (If dental procedures cannot be avoided these should, where possible, be undertaken towards the end of the 6 month treatment period.) 6. To attend hospital and GP clinic appointments. 7. To attend the GP surgery to have denosumab administered as prescribed every 6 months.

* Intolerance of bisphosphonates is defined as oesophageal ulceration, erosion or stricture, or severe lower GI symptoms any of which warrants discontinuation of treatment.

Contact details

Initial contact should be made with the initiating consultant.

Initiating consultant at BTUH Name (please print):	Please insert contact details:

Ref; NICE TA204
Summary of product characteristics for Prolia®

Denosumab shared care agreement letter: consultant request

Name of Trust: Basildon and Thurrock University Hospital NHS FT

Name of GP:
Address:

Dear GP,

Re: Patient's Name:
Date of Birth:
NHS Number:
Hospital Number:

This patient is suitable for treatment with denosumab (Prolia®) for the treatment of osteoporosis in postmenopausal women/treatment of bone loss associated with hormone ablation in men with prostate cancer.

I am requesting your agreement to share the care of this patient. Enclosed is a copy of the shared care guidelines for denosumab to be retained in the patient's notes. Should you agree to shared care, we will send a letter containing the details of the patient's treatment plan, and all relevant blood results.

Treatment was started on (insert date denosumab administered). If you are in agreement, please undertake monitoring and treatment. The next dose will be due on (insert date in 6 months).

Please sign below and return this letter to the Hospital Specialist if you agree to the shared care arrangements for this patient.

Many thanks

Hospital Specialist	GP
Signature:	Signature:
Name:	Name:
Date:	Date:

If you are not taking on shared care for this patient please state the reason why and return this letter to the Hospital Specialist: