South West Yorkshire Area Prescribing Committee

Denosumab (*Prolia*®) for Osteoporosis Shared Care Guideline

Introduction	
General statements	• The patient will receive supplies of the drug from the hospital until the transfer of shared care is agreed between consultant and primary care prescriber. • The primary care prescriber must reply in writing to the request for shared care within two weeks if unwilling to participate. • The responsibility for prescribing and monitoring must be documented clearly in the patient's hospital and general practice notes. • Shared care should only be considered when the patient's clinical condition is stable or predictable. The full summary of product characteristics (SPC) should be read before prescribing.
Indication	Denosumab may be used under this guideline within its licensed indication, in accordance with NICE technology appraisal 204. Denosumab is an option for: • **Primary prevention** of osteoporotic fragility fractures in postmenopausal women and in men at increased risk of fractures who o are unable to comply with special instructions for administering alendronate or risedronate, or have an intolerance of, or contraindications to these treatments **and** o fulfil the criteria based on BMD measurement, age & risk factors for fracture as per TA204. **Secondary prevention of** osteoporotic fragility fractures only in postmenopausal women at increased risk of fractures who o are unable to comply with special instructions for administering alendronate or risedronate, or have an intolerance of, or contraindications to these treatments • Treatment of bone loss associated with hormone avlation in men with prostate cancer at increased risk of fractures. ➢ Occasionally primary care may be asked to prescribe denosumab outside of the licensed indication on expert opinion from secondary care

Individual's Responsibilities	
Hospital specialist's responsibilities	• To initiate denosumab in appropriate patients. • To obtain informed consent. This is particularly important if treatment is administered outside licensed indications.

	• To undertake baseline monitoring to ensure patient is calcium and vitamin D replete. • In most cases advice will be given to provide supplementation with calcium and vitamin D at a daily dosage of calcium 1g and colecalciferol 800 units. This is particularly important in patients with eGFR < 30ml/min/1.73m^2 or CrCl <30ml/min. • To discuss the benefits and side effects of treatment with the patient/carer, including advice to register for the 'Prolia patient support program - reminder service'. • Consider need for a dental examination prior to treatment in patients at risk of osteonecrosis of the jaw. • To be aware of specific safety concerns, notably the risk of osteonecrosis of the jaw click here , and osteonecrosis of the external auditory canal click here (believed to be more likely with concurrent use of steroids, or chemotherapy) • To prescribe and administer the **initial dose** of denosumab. • To assess the efficacy and tolerability of treatment in the individual and need to continue treatment. • To contact patient's GP practice to ask them to prescribe under shared care. • To advise the primary care prescriber regarding continuation of treatment, including the length of treatment and follow-up. • To discuss any concerns with the primary care prescriber regarding the patient's therapy. • To undertake a 5 year review of treatment following re-referral by the primary care prescriber.
Primary care prescriber's responsibilities	• To agree to prescribe denosumab from 6 months onwards in accordance with the SCG/advice from the consultant. Reply in writing to the request for shared care within two weeks if unwilling to participate. • To undertake monitoring as per SCG. • To check for drug interactions for newly prescribed drugs. • To ensure that denosumab is pre-ordered/prescribed within reasonable time and determine who will be responsible for administration to the patient. • To be aware of specific safety concerns, notably the risk of osteonecrosis of the jaw click here , and osteonecrosis of the external auditory canal click here (believed to be more likely with concurrent use of steroids, or chemotherapy) • To report any adverse reactions to the CHM (MHRA) and the referring consultant. • To seek the advice of the consultant if there are any concerns with the patient's therapy and refer appropriate patients to secondary care for assessment. • To inform the consultant if the patient discontinues treatment for any

	reason. • To conduct an annual (or more frequent if required), medication review. • To check if the patient is continuing calcium and vitamin D treatment if recommended. If treatment has been stopped, check the patient is not hypocalcaemic prior to further doses of denosumab. • To prescribe and administer 6 monthly denosumab SC injection via GP practice. Treatment should be administered within a one month window around each 6-monthly time-point, thus ensure a system to recall patients after 6 months. • Refer the patient for a 5 year review by a hospital specialist.
Timeline Summary	**Baseline – Hospital Clinic:** • Ensure the patient is calcium and vitamin D replete. • Administer the first injection. • Give patient information including advice to register for the 'Prolia patient support program - reminder service'. • Seek agreement from GP practice to continue treatment. **6 months onwards – GP practice:** • Check continuing calcium and vitamin D treatment if recommended- if the patient has stopped supplements, check they are not hypocalcaemia prior to treatment. • 6 monthly SC injections administered via GP practice. • Treatment should be administered within a 1 month window around each 6-monthly time-point. • Primary care prescriber to refer for a review at 5 years. **5 years – Hospital:** • Undertake fracture risk assessment. • Discharge for continued treatment via GP practice if response is satisfactory. • Management plan - this may recommend reassessment (re-referral) after further 5 years of treatment or may recommend stopping treatment.
Monitoring required	**Prior to initiation of therapy (Hospital specialist) :** • Check calcium and vitamin D levels. Vitamin D deficiency and hypocalcaemia must be corrected before initiation of therapy. • A dental examination should be considered prior to treatment in patients at risk of osteonecrosis of the jaw. **Subsequent monitoring (usually primary care prescriber's**

	responsibility) : • Monitoring of calcium and vitamin D levels prior to each injection is recommended for patients predisposed to hypocalcaemia (eg. eGFR < 30ml/min/1.73m^2 or CrCl <30ml/min). • Check patient is taking calcium and vitamin D if advised at baseline. • Patients receiving denosumab may develop skin infections (predominantly cellulitis) leading to hospitalisation. Patients should be advised to seek prompt medical attention if they develop signs or symptoms of cellulitis. • While on treatment, patients should delay invasive dental procedures if possible until just prior to their next 6 monthly injection but these procedures are not contra-indicated and should go ahead if urgent.
When and how to discontinue treatment	• If there are concerns about side effects or inefficacy (e.g. new fractures) refer to secondary care consultant at any time. • Re-referral of patient to secondary care to assess the efficacy and tolerability of treatment in the individual, and the need to continue treatment beyond 5 years.
Information given to the patient	• Report to the specialist or primary care prescriber if they do not have a clear understanding of their treatment and share any concerns in relation to treatment with denosumab. • Register with the manufacturer's 'Prolia® patient support program' to receive a reminder when their next treatment is due. • To attend GP practice every 6 months for denosumab injections and for any blood tests required. • Report any adverse reactions to the primary care prescriber or specialist whilst receiving treatment with denosumab. • Patients receiving denosumab may develop skin infections (predominantly cellulitis) requiring hospitalisation. If symptoms develop, patients should contact a health care professional immediately. • To seek medical attention if they develop signs of hypocalcaemia. • To report any new or unusual thigh, hip or groin pain as this may be an early indication of atypical fracture of femur (thigh bone). • Good oral hygiene practices should be maintained during treatment with denosumab. • Report any ear pain, discharge from the ear or ear infection to the GP immediately. This could be the first sign of osteonecrosis. • To inform their dentist they have been initiated on denosumab at the next routine appointment. • Avoid invasive dental procedures if possible and to inform the primary care prescriber or specialist before considering any invasive dental treatment. • To continue taking calcium and vitamin D supplements if prescribed.

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Contact details	Documented in letter from specialist to GP practice.

Product Information	
The information in this Shared Care Guideline should be used in conjunction with the latest edition of the BNF and SPC	
Dosage and administration	• **Denosumab 60 mg** in 1ml pre-filled syringe administered as a **subcutaneous injection** once **every 6 months** into the thigh, abdomen or upper arm. • Patients must be calcium and vitamin D replete. Supplementation with calcium 1g and colecalciferol 800 units daily may be given if required.
Adverse effects	Refer to the current BNF and www.medicines.org.uk/emc/ The MHRA has issued advice on minimising the risk of osteonecrosis of the jaw and monitoring for hypocalcaemia. It has also issued advice about osteonecrosis of the external auditory canal.
Precautions and contra-indications	Refer to the current BNF and www.medicines.org.uk/emc/
Clinically relevant drug Interactions and their management	Refer to the current BNF and www.medicines.org.uk/emc/