Rationale for Initiation, Continuation and Discontinuation (RICaD)

Denosumab (PROLIA®) for the treatment of osteoporosis in postmenopausal women

This document is recommended by the South Staffordshire Area Prescribing Group for selected medicines that do not require an Effective Shared Care Arrangement but where GPs may wish for reassurance that certain guidance (usually NICE) is being followed. It is intended for completion by specialists in order to give Primary Care prescribers a clear indication of the reason for recommending the medication together with suggested criteria for its subsequent continuation or discontinuation. This RICaD should be provided as a supplement to the specialist's clinical letter

NHS no.		**Name**	
DOB		**Patient address**	

GP	**Dr**	**GP address**	

Rationale for Choice – to be completed by the specialist and sent to the GP with clinic letter.

	Specialists please complete all shaded areas as appropriate
Relevant Diagnosis:	Osteoporosis in postmenopausal women
Agreed Indication(s) for inclusion in the Interface Formulary:	NICE TA204: Denosumab for the prevention of osteoporotic fractures in postmenopausal women October 2010. Denosumab is recommended as a treatment option for the primary 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 *and* • who have a combination of T-score[1], age and number of independent clinical risk factors for fracture (see section 1.3) as indicated in NICE guidance

Reason why denosumab is appropriate:	☐ Patient is unable to comply with the special instructions for administering alendronate, risedronate or etidronate, or has an intolerance of, or a contraindication to, those treatments. Details: _____ _____ _____ _____ _____ _____ *and* ☐ Patient has T-score to indicate denosumab treatment appropriate T-score: _____
Specialist responsibilities ***(tick once complete)***	☐ Assess patient in accordance with NICE TA204 ☐ Undertake baseline bloods (renal function, calcium and vitamin D) ☐ Correct hypocalcaemia, if present ☐ Advise patient to undergo regular dental checks and to advise dentist they are receiving denosumab therapy due to potential osteonecrosis of the jaw ☐ Advise patient to report any ear pain, discharge from the ear or an ear infection whilst on denosumab ☐ Administer 1st dose of denosumab
Date denosumab treatment commenced:	**____ / ____ / ____**
Date next DEXA scan due:	To be performed every 3 years whilst on treatment **____ / ____ / ____**
I confirm that this patient is eligible to receive denosumab 60mg/mL in accordance with NICE guidance and is suitable for prescribing and administration within primary care.	
Specialist (please print and sign)	
Contact details and date	

Guidance on initiation and titration

Initiation dose:	The recommended dose of Prolia® is 60 mg administered as a single subcutaneous injection once every 6 months into the thigh, abdomen or upper arm. The first dose will be administered by specialist service/secondary Care. Prescribing and administration may be then transferred to primary care (where services are available).
Additional info:	SPC can be accessed at http://emc.medicines.org.uk

Criteria for Assessment and Continuation

Assessment of Efficacy	
Date	6 monthly
Location	GP practice (where services are available)
Method	Prior to each injection: ☐ Check renal function ☐ Check calcium levels ☐ Review of side-effects – specifically signs or symptoms of cellulitis, dental problems, ear problems, swelling or non-healing of tissues and any unusual groin, hip or thigh pain If patients develop symptoms suggestive of hypocalcaemia to check calcium level (at any time during treatment).
Continuation Criteria	No significant side-effects reported. Calcium and vitamin D supplement is continued and no hypocalcaemia or vitamin D deficiency suspected. eGFR >30mL/min^2. Treatment duration is <3years. Treatment >3years should only continue after DEXA scan performed and denosumab has been recommended for a further 3 years.
Discontinuation Criteria	Denosumab should be withheld and patient referred back to the specialist in the event that the patient has hypocalcaemia (serum calcium <2.2mmol/L or below testing laboratory normal range) or vitamin D deficiency (Serum 25-hydroxy Vitamin D <30nmol/L) that cannot be corrected with appropriate supplementation or if the eGFR is <30ml/min^2. Treatment should be withheld pending specialist review if the patient suffers an atypical fracture or significant side-effects whilst on

	treatment. After the patient has received a total of 3 years denosumab treatment a further DEXA scan should be performed and an opinion as to whether denosumab should continue for a further 3 years.
Follow up action	Advise patient next denosumab dose due in 6 months. Ensure recall procedure in place for next administration. Advise patient to undergo regular dental checks and for the patient to advise their dentist they are receiving denosumab therapy. Denosumab was launched in 2010 and still has black triangle status (▼). All suspected reactions (including those not to be serious and even where the causal link is uncertain) should be reported to the MHRA.