Barking and Dagenham, Havering and Redbridge Clinical Commissioning Groups

Barking, Havering and Redbridge University Hospitals NHS Trust

TAKING PRIDE IN OUR CARE TOGETHER

TRANSFER OF CARE MONITORING & GUIDANCE DOCUMENT FOR DENOSUMAB (PROLIA®) IN POST MENOPAUSAL WOMEN WITH OSTEOPOROSIS

Denosumab (Prolia®) is licensed for the treatment of osteoporosis in postmenopausal women at increased risk of fractures. It significantly reduces the risk of vertebral, non-vertebral and hip fractures. Denosumab has been approved by NICE (TA 204). This document provides guidance for GPs to monitor patients on denosumab, who had their first dose at the hospital and have now been transferred to your care for continuation of treatment (Click here for BHR CCGs and BHRUT osteoporosis pathway). This also contains general prescribing information on denosumab. You will have also been provided with a transfer of care letter, detailing when the dose had been administered at the hospital. The patient information leaflet is available on the electronic medicines compendium (EMC). If you require any further information, please contact the Fracture Liaison Service.

PRESCRIBING INFORMATION

DRUG, DOSE , ROUTE & ADMINISTERED FREQUENCY,	Denosumab 60mg Subcutaneous Injection every 6 months	Please refer to the up to date Summary of Product Characteristics (SmPC)

MONITORING & FOLLOW UP

PARAMETER	MONITOR	FREQUENCY	ACTION REQUIRED	RESPONSIBLE
Pre-treatment Assessment	• Calcium levels • Signs or symptoms of cellulitis • Patient Information	Pre-treatment	• Aim for normal target range. • If hypocalcaemia , ensure patient is asymptomatic, increase calcium supplementation if indicated and recheck 2 weeks later.(Replete calcium and vitamin D) • Provide patient with patient information leaflet	Trust/ GP
During treatment	• Calcium levels • Patient Information	For all patients: 2- 4 weeks before each injection For patients predisposed to hypocalcaemia - (e.g. severe renal impairment, creatinine clearance less than 30ml/min): repeat 2 weeks after injection • Before administration	• Aim for normal target range. • If hypocalcaemia , ensure patient is asymptomatic, increase calcium supplementation if indicated and recheck 2 weeks later. (Replete calcium and vitamin D). • If any concerns, refer to the Fracture Liaison Service at Queens hospital • Provide patient with patient information leaflet	GP
Post 3 years treatment	• DXA scan	After patient receives 6th injection refer for DXA scan	• If any concerns, refer to the Fracture Liaison Service at Queens hospital	GP

Developed by: Uma Horton, Pharmacy Clinical Business Manager
Reviewed by: Dinesh Gupta, Assistant Chief Pharmacist & Dr Thushani Wickramaratne, Lead Consultant for Osteoporosis January 2019
Approved by: BHRUT Medicines Optimisation Group Date approved: February 2019 Review Date: February 2022
BHR CCGs Area Prescribing sub-Committees Date approved: April 2019

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DENOSUMAB (PROLIA®) PRESCRIBING INFORMATION

(This information is not exhaustive; please refer to the current BNF and SmPC for further information)

PARAMETER	INFORMATION	ACTION REQUIRED
Dose administration	• 60mg by subcutaneous injection every 6 months into the thigh, abdomen or back of arm.	• Administration required 6 months after initial dose at the Trust by GP Practice
Contraindications (List is not exhaustive)	• Hypocalcaemia • Hypersensitivity to the active substance or to any of the excipients • Latex allergy. Needle cover contains dry natural rubber • Fructose intolerance	• Hypocalcaemia must be corrected by adequate intake of calcium and vitamin D before initiating therapy • Refer to the SmPC for excipients • Check allergy status • Check intolerance
Cautions (List is not exhaustive)	• Hypocalcaemia • Develop skin infections (predominantly cellulitis) • Rare reports of Osteonecrosis of the jaw (ONJ) • Osteonecrosis of external auditory canal	• Monitor calcium and vitamin D levels • Patients with severe renal impairment (creatinine clearance < 30 mL/min) or receiving dialysis are at greater risk of developing hypocalcaemia • Patient to seek prompt medical attention if they develop signs of cellulitis. ▪ Dental examination with appropriate preventive dentistry should be considered ▪ Monitor those who present with ear symptoms including chronic ear infections
Interactions	• No interaction studies have been performed	• Refer to current SmPC
Renal impairment	• No dose adjustment required	• Patients with Stage 5 CKD may not be suitable for transfer of care
Elderly ((age ≥ 65)	• No dose adjustment required	
Hepatic impairment	• Safety and efficacy not studied in hepatic impairment	
Pregnancy	• Not recommended	
Breastfeeding	• Unknown	
Adverse effects (List is not exhaustive)	• Mild, transient decreases in serum calcium. • Skin infections (predominantly cellulitis)	• Correct with calcium and Vitamin D supplementation • Treat with antibiotics/ refer to on call medical team if IV treatment required

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	• Other common undesirable effects (incidence of 1-10%) were urinary tract infection, upper respiratory tract infection, cataracts, constipation, abdominal discomfort, sciatica, rash, eczema, pain in extremity, muscular skeletal pain	

CONTACT INFORMATION

BHRUT NHS TRUST	CONTACT NUMBER
Osteoporosis Nurse Specialist (Fracture Liaison Clinic)	01708 435 000 Ext. 3219
Consultant Rheumatologists	Contact via specialist Rheumatology or Osteoporosis nurse 01708 435000 ext. 2721/2722
General Medical Registrar on-call (out of hours)	Air call via switchboard 01708 435 000
Rheumatology Nurse Specialist	Queens Hospital- 01708 435 000 ext. 4821 King George Hospital- 01708 435 000 ext. 8408
BHR CCGs Medicines Management Team	0203 182 3133

REFERENCES

1. BHR CCG's/BHRUT Denosumab Shared Care Guideline V1, February 2014
2. Nice Guidance TA 204 http://publications.nice.org.uk/denosumab-for-the-prevention-of-osteoporotic-fractures-in-postmenopausal-women-ta204
3. BNF Edition 76, September 2018
4. Electronic Medicines Compendium (accessed 30/01/2019)
5. BHR CCGs & BHRUT Pathway for initiating treatment for osteoporosis in postmenopausal women August 2017

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