DENOSUMAB (PROLIA®)

ESCA: For the treatment of osteoporosis in postmenopausal women.

SECONDARY CARE SECTION TO BE COMPLETED BY INITIATING DOCTOR

Patients name……Date treatment commenced……

	Tick box
One copy of agreement sent to general practitioner (One copy filed in patients notes)	☐
One copy of information leaflet given to patient	☐

Name of initiating doctor…….

Consultant…….

Speciality……

Fax Number: 01902 …….

PRIMARY CARE SECTION TO BE COMPLETED BY GENERAL PRACTITIONER

I agree*/don't agree* to enter into a shared care arrangement for the treatment of the above patient with this medicine (*delete as appropriate)

G.P. Name……

Signature…….. Date…….

Once signed please detach this sheet and fax to the number shown above.

AREAS OF RESPONSIBILITY FOR THE SHARING OF CARE

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of denosumab in patients with osteoporosis can be shared between the specialist and general practitioner (GP). GPs are **invited** to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. **If a specialist asks the GP to prescribe this drug, the GP should reply to this request as soon as practicable.**

Sharing of care assumes communication between the specialist, GP and patient. The intention to share care is usually explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use.

RESPONSIBILITIES and ROLES

Specialist responsibilities
1 Assess patient suitability for Denosumab in line with NICE TA 204.
2 Discuss the potential risks, benefits and side effects of treatment with the patient, and advise of shared care process
3 Arrange for appropriate haematology/biochemistry.
4 Initiate treatment with Denosumab if not contraindicated.
5 Confirm that the GP is willing to participate in shared care.
6 Advise the GP on when to stop treatment, or consult with the specialist.
7 Report adverse events to the CSM, MHRA and GP.
8 Ensure that clear backup arrangements exist for GPs to obtain advice and support.

General Practitioner responsibilities
1 Reply to the request for shared care as soon as practicable. 2 Prescribe denosumab at the dose recommended. 3 Ensure practice system is set up to recall patient after six month interval 4 Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment
5 Refer back to specialist if the patient's condition deteriorates, as advised.
6 Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
7 Report adverse events to the specialist and CSM and MHRA.

Patient's role
1 Report to the specialist or GP if she does not have a clear understanding of the treatment. 2 Attend as arranged for the administration of the injection 3 Adhere to any calcium and vitamin D supplementation 4 Share any concerns in relation to treatment with denosumab.
5 Inform specialist or GP of any other medication being taken, including over-the-counter products.
6 Report any other adverse effects or warning symptoms to the specialist or GP whilst receiving denosumab.

BACK-UP ADVICE AND SUPPORT

Contact details	**Telephone No.**	**Bleep:**	**Fax:**	**Email address:**
Specialist: Dr J Dixey	5492			josh.dixey@nhs.net
Specialist: Dr P Newton	8020			paulnewton1@nhs.net
Specialist: Dr Al-Allaf	8021			wahab.al-allaf@nhs.net
Specialist: Dr Barkham	8028			nickbarkham@nhs.net
Hospital Pharmacy Dept: Sue Reed	5136			Susan.reed@nhs.net
Other:				

SUPPORTING INFORMATION (see SPC for complete details)

Licensed indications
Treatment of osteoporosis in postmenopausal women at increased risk of fractures.

Dosage and Administration
The recommended dose of denosumab is 60mg administered as a single subcutaneous injection once every 6 months into the thigh, abdomen or back of arm.

Patients must be adequately supplemented with calcium and vitamin D.
No dose adjustment is needed in patients with renal impairment
The safety and efficacy of denosumab has not been studied in patients with hepatic impairment
No dose adjustment is required in elderly patients.

Contraindications and cautions for use
Denosumab is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients.
Denosumab is contraindicated in patients with hypocalcaemia.

Precautions for use

Calcium & Vitamin D Supplementation Adequate intake of calcium and vitamin D is important in all patients.
Hypocalcaemia Hypocalcaemia must be corrected before initiating therapy. Patients with severe renal function or receiving dialysis are at greater risk of developing hypocalcaemia. Clinical monitoring of calcium levels is recommended for patients predisposed to hypocalcaemia.
Skin Infections Patients should seek prompt medical attention if they develop signs or symptoms of cellulitis.
Osteonecrosis of the Jaw (ONJ) ONJ has been reported in patients receiving denosumab. A dental examination with appropriate preventive dentistry should be considered before commencement of treatment. Good oral hygiene measures should be maintained during treatment.

Allergy The needle cover of the pre-filled syringe contains dry natural rubber (a latex derivative).

Monitoring
There is no specific monitoring required for Denosumab.

Drug Interactions
There is a low potential for drug-drug interactions.

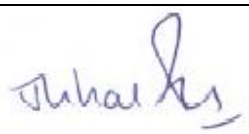
Side Effects

Infections and infestations	Common	Urinary tract infection
	Common	Upper respiratory tract infection
Metabolism and nutrition disorders	Very rare	Hypocalcaemia[1]
Nervous system disorders	Common	Sciatica
Eye disorders	Common	Cataracts[1]
Gastrointestinal disorders	Common	Constipation
Skin and subcutaneous tissue disorders	Common	Rash
Musculoskeletal and connective tissue disorders	Common	Pain in extremity

Denosumab was launched in 2010 and has black triangle (▼) status. ***All*** *suspected reactions (including those considered not to be serious and even where the causal link is uncertain) should be reported to the CSM and MHRA.*

Cost
A year's treatment with DENOSUMAB costs £366(Basic cost used in pricing NHS prescription).

References.
Amgen. Denosumab. *Summary of Product Characteristics* 08.06.2010.

This shared care agreement has been approved for use in Wolverhampton by:		**Signature**	**Date**
RWHT Medicines Management Committee Chairman	Dr. I. Perry		4.5.11
Wolverhampton City PCT Prescribing Board Chairman	Dr. J. Parkes		4.5.11