

SHARED CARE GUIDELINE

Denosumab for the treatment of osteoporosis

Implementation Date: December 2016

Review Date: December 2018

This guidance has been prepared and approved for use within Sunderland in consultation within the CCG, and Secondary Care Trusts.

The guideline sets out the details of the transfer of prescribing and respective responsibilities of GPs and specialist services within shared care prescribing arrangements. It is intended to provide sufficient information to allow GPs to prescribe this treatment within a shared care setting

Approved by:

Committee	Date
Joint Formulary Committee	November 2016
Medicines optimisation and guidelines group	December 2016

Instructions for completion:

- | |
|---|
| <input type="checkbox"/> Consultant to counsel patient on medication and ensure patient has been provided with information leaflet
<input type="checkbox"/> Consultant to ensure all clinical details completed on this document
<input type="checkbox"/> Consultant to ensure patient understands proposed monitoring and prescribing arrangements if a shared care agreement is entered into
<input type="checkbox"/> GP to complete final section of form and return to specialist prescriber within 28 days
<input type="checkbox"/> GP to retain copy of document on patient record within surgery |
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Clinical details:

SHARED CARE GUIDELINE					
Non-proprietary name	Denosumab	Brand name	Prolia	Licensed Y/N?	Y
Dosage form and strength	60mg solution for injection in a prefilled syringe 60mg solution for injection			BNF class	6.6.2
Indication	<ul style="list-style-type: none"> Treatment of osteoporosis in postmenopausal women Treatment of men at increased risk of fractures (both primary and secondary prevention) 				
Dosage and Administration	60 mg administered as a single subcutaneous injection once every 6 months into the thigh, abdomen or upper arm. Injection must be administered by an individual who is adequately trained in injection techniques. Duration of treatment is usually 3 years. Patients are then followed up with a DEXA scan and specialist review				
Eligibility criteria for shared care	<ul style="list-style-type: none"> Patients must be under the care of the CHS specialist rheumatology/ endocrinology team via the bone clinic Patients must have been treated according to the 'Osteoporosis management guidelines in adults' guideline Patients must have been intolerant or had inadequate response to an oral bisphosphonate Adult patients only 				
Excluded patients	<p>HYPOCALCAEMIA: Patients with hypocalcemia cannot be administered denosumab. Hypocalcemia & Vitamin D deficiency must be corrected prior to initiation of therapy (baseline Vitamin D levels are necessary – see specialist responsibilities, below). Calcium levels should be checked for any patient who presents with suspected hypocalcemia throughout treatment. Signs of hypocalcemia can include muscle spasms, twitches, cramps, numbness of fingers, toes or around the mouth.</p> <p>RENAL IMPAIRMENT: Patients with CrCl <30ml/min.</p>				
Initiation	Patients will be administered the first dose of denosumab by secondary care before requesting (in writing) that prescribing responsibility be transferred to the patient's				

	GP. Requests must be accompanied by a signed shared care agreement.
Specialist Responsibilities	<ul style="list-style-type: none"> • Establish diagnosis and follow osteoporosis management guideline • Ensure adequate counselling of patient • Provide patients with information on how to identify suspected hypocalcemia so know when to get reviewed inbetween injections • Check renal function, bone profile, PTH and vitamin D prior to initiation • Ensure calcium and vitamin D replaced prior to initiation where necessary • Administer initial injection of denosumab • Request that GP participate in shared care in writing and provide completed copy of shared care guideline • Offer advice, where needed, if patient's condition changes • Arrange annual follow up appointment. Note; follow up can be extended to between 18-24 months for bone clinic review if appropriate
GP Responsibilities	<ul style="list-style-type: none"> • Promptly confirm acceptance or refusal of shared care • Prescribe and arrange administration of six monthly denosumab • Screen patients for any contraindications prior to injection • Monitor calcium levels prior to each injection (every 6 months) and if hypocalcaemia is suspected • Check bone panel and U&Es in patients susceptible to hypocalcemia • Check bone panel, vitamin D levels and U&Es are within standard range prior to each injection • Refer patients with low calcium/vitamin D back to secondary care • Check for drug interactions when prescribing new medications • Monitor for any side effects and report to specialist. GPs must also appropriately report via www.yellowcard.mhra.gov.uk if required • Seek advice of consultant if necessary
Adverse Effects, Precautions and Contraindications	<p>Rarely, osteonecrosis of the jaw has been reported in patient receiving denosumab. Patients should be encouraged to maintain good oral hygiene and report any oral symptoms immediately.</p> <p>Atypical femoral fractures have been reported in patients receiving denosumab. Patients should report any new or unusual thigh, hip or groin pain.</p> <p>Contraindicated in hypocalcaemia.</p> <p>Contraindication if patient has hypersensitivity to denosumab or any excipient.</p>
Common Drug Interactions	There are no clinical data on the co-administration of denosumab and hormone replacement therapy (oestrogen), however the potential for a pharmacodynamic interaction is considered to be low.
Communication/ Contact Details	<p>Louise West Osteoporosis- Specialist Nurse David Wright-Consultant Rheumatologist Ashwin Joshi- Consultant Endocrinologist Available via: 0191 5656256 Secretary extension: 42160</p>

This information is not inclusive of all prescribing information and potential adverse effects. Please refer to full prescribing data in the SPC or the BNF.

Shared Care Request/Confirmation

Private and Confidential

Patient information:

To be completed by specialist prescriber:

<p>Consultant</p> <p>Department</p> <p>Hospital</p>	<p>Patient details (use hospital label if preferred)</p> <p>Name</p> <p>Address</p> <p>.....</p> <p>Postcode Sex</p> <p>NHS or Hosp. Reg. No. DoB</p>
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Treatment Requested for Prescribing in Accordance with Shared Care Arrangement:

To be completed by specialist prescriber:

Drug name	
Dose	
Frequency	
Indication	
Other information	

Name (print)..... Signature (of specialist prescriber)..... Date.....

Acceptance/rejection of treatment under Shared Care Agreement:

To be completed by GP:

Please tick one box

I ACCEPT the proposed shared care arrangement for this patient

or

I ACCEPT the proposed shared care arrangement with the caveats below

or

I DO NOT ACCEPT the proposed shared care arrangement for this patient

My caveats / reason(s) for not accepting include:

Name (print)..... Signature (of GP)..... Date.....

N.B. Participation in this shared care arrangement implies that prescribing responsibility is shared between the specialist prescriber and the patient's GP