**SHARED CARE AGREEMENT**

*Denosumab (Xgeva®) in the prevention of skeletal related events in adults with bone metastases from solid tumours other than prostate (usual dose 120mg monthly)*

NB: Denosumab (Prolia®) for post-menopausal osteoporosis is covered by a separate shared care agreement and the usual dose is 60mg six monthly

Sharing of care assumes communication between the specialist, GP and patient, and other members of the care team including specialist nurses and pharmacists. The intention to share care will be explained to the patient by the specialist initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

If a GP is invited by the specialist to participate in a shared care arrangement, the GP should reply to this request with 10 working days. 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.

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

Denosumab is a fully humanised monoclonal antibody to RANK ligand. It is a potent anti-resorptive agent and is effective in reducing the risk of vertebral and non-vertebral fractures, including hip fracture. Denosumab has demonstrated a statistically significant difference in time to skeletal related events compared to Zoledronic Acid. Denosumab can be given as a subcutaneous dose by a nurse into the upper arm, thigh or abdomen. Site rotation would be advisable. The drug is well tolerated although UHL will retain the care of any patients who have severe renal impairment (CrCl <30ml/min) for closer monitoring due to a lack of data in this patient cohort.

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### Specialist responsibilities

1. Diagnosis of condition and ensure other treatment options have been fully explored. Ensure a dental examination with appropriate preventative dentistry has been undertaken prior to treatment initiation with Denosumab.
2. Check baseline U&Es and calcium levels. Prescribe a supplementation of at least 500 mg calcium and 400 units vitamin D daily, unless hypercalcaemia is present.
3. Initiation of treatment and re-check U&Es and calcium levels within two weeks of initial injection. Review patient 4-6 weeks after first injection and arrange for second dose to be given and monitored by secondary care.
4. Liaison with the GP to share the patient’s care after the first two doses have been administered and the post-treatment U&Es and calcium reviewed and are satisfactory (i.e. creatinine clearance > 30 ml/min and calcium > 2.2 mmol/L) using the *Shared Care Request Form*. Shared care should not be assumed until a written agreement has been received from the GP.
5. Advise GP on monitoring for adverse drug reactions (ADRs) e.g. dyspnoea, diarrhoea, hyperhidrosis.
6. Responding to issues raised by GP.

### GP responsibilities

1. Confirm or decline request to share patient's care as soon as possible, using the shared care request form.
2. Monitor the patient’s overall health and well being and observing patient for evidence of ADRs/abnormalities and raising with secondary care clinician if necessary.
3. Prescription and administration of drug (120mg subcutaneous injection once every month into the thigh, abdomen or upper arm) after the first two doses have been given by secondary care.
4. Prescribe a supplementation of at least 500 mg calcium and 400 units vitamin D daily, unless hypercalcaemia is present.
5. Check U&Es and calcium levels one week before next dose due (i.e. three weeks post previous injection). Confirm creatinine clearance using the Cockcroft Gault equation. Contact specialist for advice if creatinine clearance < 30 ml/min and/or calcium < 2.2 mmol/L.
6. Comply with terms of the Community Based Service and any national advice on denosumab (Xgeva®).
7. Ensuring advice is sought from the secondary care clinician if there is any significant change in the patient's physical health status.
8. Reducing/stopping treatment in line with secondary care clinician’s original request.

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<td>May 14</td>
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<td>June 16</td>
<td>Oct 14</td>
<td>1.2</td>
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### Community pharmacist responsibilities

1. Check that the patient is receiving the medicine as prescribed.
2. Check that the patient is attending for monitoring as outlined above.
3. Report any side effects to the GP.

### Patient responsibilities

1. Do not miss any blood tests or other appointments without first consulting the GP or specialist.
2. Report any adverse effects or warning symptoms to the GP or specialist.

### Further advice and support - this information does not include all prescribing information

Summary of product characteristics via [electronic Medicines Compendium (eMC)](http://www.medicines.org.uk/emc)

British National Formulary via [BNF.org](http://www.bnf.org)

Trent Medicines Information Centre Tel: 0116 258 6491 Fax: 0116 258 5680

e-mail: medicines.info@uhl-tr.nhs.uk

**Denosumab**: updated information to minimise the risk of osteonecrosis of the jaw and hypocalcaemia

Supervising consultant

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<thead>
<tr>
<th>Version</th>
<th>Section</th>
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<tr>
<td>1.1</td>
<td></td>
<td>Minimum calcium level changed to 2.2 in line with the lab's recent change. Note added re Prolia to raise awareness of 2 indications for same drug</td>
<td>July 2014</td>
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<td>1.2</td>
<td>Specialist responsibility</td>
<td>Check calcium within 2 weeks of initial injection as per SPC change, dental exam with appropriate preventative dentistry as per SPC change</td>
<td>Sept 2014</td>
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