

## Denosumab biosimilar 60mg Injection - Prescribing Support Information

This document provides prescribing and monitoring guidance for denosumab 60mg biosimilar therapy to support primary care clinicians in the BLMK area who are prescribing denosumab for the management of osteoporosis. It should be read in conjunction with the transfer of care letter from the specialist, the Summary of Product Characteristics (SPC) and the electronic BNF.

<b>Category</b>	Denosumab is a human monoclonal IgG2 antibody that binds to RANKL, inhibits osteoclast formation, function, and survival, thereby decreasing bone resorption.
<b>Therapeutic indications</b>	<p>Use of denosumab in accordance with the criteria outlined in the <a href="#">BLMK osteoporosis guideline</a> and the <a href="#">BLMK glucocorticoid-induced osteoporosis guideline</a>:</p> <ul style="list-style-type: none"> <li>• Management of osteoporosis in post-menopausal women (both primary and secondary prevention of osteoporotic fragility fractures) (<a href="#">NICE TA204</a>)</li> <li>• Management of osteoporosis in men (age ≥ 50 years; both primary and secondary prevention of osteoporotic fragility fractures).</li> <li>• Prevention and treatment of glucocorticoid-induced osteoporosis in post-menopausal women and men (age ≥ 50 years).</li> </ul>
<b>Place in therapy</b>	<ul style="list-style-type: none"> <li>• As an alternative to the use of oral / IV bisphosphonate if bisphosphonates are contraindicated or not tolerated.</li> <li>• As a joint third line treatment option (NB:- either denosumab 60mg s/c or IV zoledronic acid or IV ibandronic acid can be used as a third line treatment option following the use of a first- or second-line oral bisphosphonate.)</li> <li>• As the first line treatment choice in patients with severe renal impairment (as oral and IV bisphosphonates should be avoided in severe renal impairment). NB: When denosumab is used in these patients the responsibility for prescribing and monitoring patients should remain with secondary care specialists (<b>no primary care prescribing</b>). In addition, any patient who subsequently develops severe renal impairment should be transferred back to the specialist team.</li> <li>• Denosumab may also be recommended and initiated by the specialist team in patients who have completed a course of anabolic treatment.</li> </ul>
<b>Pharmaceutical form</b>	<p>60mg in 1ml pre-filled syringe</p> <p>A range of biosimilar products are now available. Clinicians should refer to the relevant local formularies (depends on the location of the specialist team who initiated treatment) for details of which <b>specific brand</b> to prescribe. <b>Denosumab biosimilar 60mg must be prescribed by brand name.</b></p> <p><b>Please note this may be a different brand to the one initiated in hospital.</b></p> <ul style="list-style-type: none"> <li>- The patient should be informed, and it should be recorded in the patients notes, that the brand used in primary care may be different from that given in secondary care.</li> </ul> <p><b>Links to local formularies</b></p> <p><a href="#">Bedfordshire and Luton Joint Formulary</a>; <a href="#">Milton Keynes Joint Formulary</a>).</p>

This information does not replace the Summary of Product Characteristics (SPC) and should be read in conjunction with it. Please see [BNF](#) & [SPC](#) for comprehensive information.

The following organisations contribute to and participate in the BLMK APC – Bedfordshire, Luton and Milton Keynes Integrated Care Board; Bedfordshire Hospitals NHS Foundation Trust; Cambridgeshire Community Services NHS Trust; Central and North West London NHS Foundation Trust; East London NHS Foundation Trust; Milton Keynes University Hospital NHS Foundation Trust

<p><b>Formulary status</b></p>	<p><b>SpIS</b> specialist initiation and stabilisation (specialist to initiate treatment and administer first injection prior to continuation in primary care).</p>
<p><b>Responsibilities</b></p>	<p>The initial injection of denosumab should be prescribed and administered by a secondary care specialist. If the patient is subsequently stable and free from adverse reactions, the ongoing prescribing and monitoring can be transferred to the primary care clinician for the second and subsequent injections at 6 monthly intervals.</p> <p>NB Denosumab should be administered by a trained healthcare professional</p> <p><b><u>Specialist Responsibilities :</u></b></p> <ul style="list-style-type: none"> <li>• To discuss treatment options with the patient and ensure that the patient is suitable for treatment with denosumab according to NICE guideline and local agreement.</li> <li>• To identify patients with <b>risk factors for developing hypocalcaemia</b> such as :-             <ul style="list-style-type: none"> <li>- Vitamin D deficiency</li> <li>- Severe renal impairment (creatinine clearance &lt; 30ml/min) or Chronic kidney disease or dialysis</li> <li>- Diuretic use</li> <li>- Elevated parathyroid hormone</li> </ul> </li> <li>• <b>Carry out baseline blood tests</b> to check renal function, serum adjusted calcium levels, and vitamin D levels <b>before</b> starting therapy</li> <li>• <b>Prior to initiating therapy</b>, confirm the <b>absence</b> of:-             <ul style="list-style-type: none"> <li>○ <b>Hypocalcaemia</b> <ul style="list-style-type: none"> <li>▪ must be corrected by ensuring adequate intake of calcium and vitamin D (serum 25-OH vitamin D level of greater than 50nmol/L) before initiating therapy.</li> </ul> </li> <li>○ <b>Hypersensitivity</b> to the active substance or to any of its excipients e.g., sorbitol, polysorbate</li> <li>○ <b>Allergy to latex</b> (check individual SPCs for suitable products as may vary between products)</li> <li>○ <b>Pregnancy, lactation</b></li> <li>○ <b>Severe renal impairment</b> (creatinine clearance &lt;30ml/min). No dose adjustment is required in patients with renal impairment however patients may be more at risk of developing hypocalcaemia – <b>Primary care prescribing is NOT appropriate for patients with severe renal impairment – patients should remain under the care of the specialist).</b></li> </ul> </li> <li>• <b>Monitor calcium levels</b> <ul style="list-style-type: none"> <li>- check the patient's calcium level <b>before</b> initiating therapy.</li> <li>- <b>Repeat calcium level monitoring within two weeks after the initial dose of denosumab is given in patients who are <u>predisposed to hypocalcaemia</u></b></li> <li>- <b>Repeat calcium level</b> within two weeks after each <u>subsequent dose</u> in patients with severe renal impairment ( these patients remain under the care of the specialist team)</li> <li>- Check calcium levels in any patient who presents with suspected symptoms of hypocalcaemia during treatment</li> </ul> </li> <li>• Check <b>calcium and vitamin D</b> intake</li> <li>• <b>Oral Hygiene.</b> Specialist to assess the patient to ensure that they have good oral hygiene and to use clinical judgement to determine if a dental examination is required prior to initiating denosumab.</li> </ul>

- Ensure the patient understands the importance of compliance with the 6-monthly denosumab treatment regimen and advise that treatment should **not** be stopped without specialist review
- Advise patient to report symptoms of hypocalcaemia to their doctor (eg muscle spasms , twitches , or cramps , numbness or tingling in the fingers , toes or around the mouth.
- Advise patient to report any ear pain , discharge from the ear or an ear infection during denosumab treatment
- Provide the patient with the patient information leaflet (from the manufacturer) and a denosumab patient reminder card.
- Inform the patient that subsequent doses given in primary care may be a different biosimilar brand to the one administer in the hospital setting and note this in the patient's record.
- Administer the first dose in the hospital and monitor the patient's response.
- Review patient at 3-5 years to assess the need to continue treatment, or sooner if primary care clinician has concerns.
- Notify the patient's primary care clinician that the initial dose has been given in secondary care and provide details of the name of the biosimilar brand used in the hospital setting.

**Primary care responsibilities:**

- Reinforce the importance of compliance with the treatment regimen and maintaining adequate intake of calcium and vitamin D.
- Provide patient with relevant information – see [counselling points](#) section
- **Add the relevant** denosumab 60mg biosimilar (see local formulary for details) to be given every 6 months to the patient record. (Please note that the biosimilar brand given in the hospital setting may be different from the brand used in primary care –in primary care, the **same** brand should be used each time).
- Denosumab 60mg biosimilar **must be prescribed by specific brand name**)
- Ensure that any prescriptions for other osteoporosis treatments such as bisphosphonates are stopped, and that calcium and vitamin D tablets remain on repeat if they were advised by the specialist.
- **Ensure that the relevant blood test results are requested AND checked before the next dose is due** (see [blood test monitoring requirements](#) below for details)
- Practices are advised to set up a robust recall system to ensure patients receive timely treatment at six-monthly (+/- 2 weeks) intervals
- Practises are advised to set up a robust recall system to ensure that patients receive the relevant blood test forms (to be **issued 4 weeks** before next dose is due). (see blood test monitoring requirements below)
- Add to the patient record that the patient will needs to be reviewed by the specialist team in 3-5 years after the first injection was given.
- Practice arrangements to be made to ensure that denosumab is stored in a vaccine refrigerator and the temperature monitored daily.

	<p><b><u>Patient Responsibilities</u></b></p> <ul style="list-style-type: none"> <li>To follow the advice provided by specialist / GP (as detailed in the <a href="#">counselling points</a> section)</li> </ul> <p><b><u>Important Practical Points for patients</u></b></p> <ul style="list-style-type: none"> <li>Contact the GP surgery to request a blood test form <b>and</b> to arrange an appointment for a blood test <b>4 weeks before the next denosumab injection is due</b> (The blood test form should be to check calcium, renal function, and vitamin D),</li> <li>Contact the GP surgery to make an an appointment to receive the next 6 monthly injection <b>NB The timing of the injections is very important and the doses should be given 6 months apart</b> (plus or minus 2 weeks) as any delay in treatment increases the risk of developing an osteoporotic fracture.</li> <li><b>Do not stop treatment without a specialist review / seeking medical advice</b></li> </ul>
<p><b>Blood test monitoring requirements</b></p>	<p><b><u>Blood test monitoring – Primary care clinician’s Responsibilities</u></b></p> <p><b><u>Calcium monitoring</u></b></p> <p>It is important to check if patient develops any <a href="#">risk factors for developing hypocalcaemia</a></p> <p>It is important to monitor calcium levels <b>prior to every dose</b> of denosumab.</p> <p><u>post denosumab dose</u> - clinical monitoring of calcium levels within 2 weeks of denosumab is only recommended for patients pre-disposed to hypocalcaemia and those with severe renal impairment (creatinine clearance &lt; 30ml/min). Chronic kidney disease or receiving dialysis. (These types of patients are not suitable for management in primary care , and should remain under the care of the specialist team)</p> <ul style="list-style-type: none"> <li>Order the following blood tests before the next dose of denosumab is due <ul style="list-style-type: none"> <li><b>Adjusted serum calcium level</b></li> <li><b>25OH vitamin D level</b></li> <li><b>Renal function (creatinine clearance)*</b></li> </ul> </li> <li>Check the results of all the above blood tests <b>before each dose of denosumab is given</b></li> <li>if a patient’s blood test indicate hypocalcaemia or if the patient presents with symptoms of <a href="#">suspected hypocalcaemia</a> , <b>withhold the next dose and contact the specialist team for advice as soon as possible</b></li> <li>check calcium levels at any time if patient has any <a href="#">suspected signs of hypocalcaemia</a></li> </ul> <p><b><u>Renal function monitoring</u></b></p> <ul style="list-style-type: none"> <li>If the patient develops severe renal impairment (creatinine clearance# &lt;30ml/min), chronic kidney disease, dialysis the next dose of denosumab should <b>not</b> be administered in primary care and urgent advise should be sought from the specialist team.</li> </ul>

	<ul style="list-style-type: none"> <li>In patients who are referred back to the specialist team, advise secondary care of the specific brand that the patient has been receiving in primary care as this may be different to the brand used in secondary care.</li> </ul> <p># The Creatinine Clearance calculator in SystmOne or an online may be used to determine the patient's creatinine clearance.</p>
<b>Dosing Advice</b>	60mg administered as a single subcutaneous injection once every 6 months into the thigh, abdomen or upper arm. Patients must be adequately supplemented with calcium and vitamin D.
<b>Calcium and Vitamin D</b>	<p>Adequate intake of calcium and vitamin D is important in all patients receiving denosumab 60mg.</p> <ul style="list-style-type: none"> <li>Prior to initiating therapy, the specialist should check dietary calcium intake and check vitamin D levels; start calcium 1-1.2g plus colecalciferol 20mcg (800 IU) daily if deemed necessary, explaining the importance of taking these to the patient, and the potential detriment of non-compliance.</li> <li>If dietary calcium intake is adequate, then vitamin D supplementation alone may suffice.</li> <li><a href="#">Click here</a> to view further information around dietary intake of calcium and to access a <a href="#">calcium intake calculator</a>.</li> <li>The patient should be asked about their dietary calcium intake and whether they are taking calcium and / or vitamin D supplements <b>at each clinic visit prior to receiving their next dose.</b></li> </ul>
<b>Missed doses</b>	<p>Missing an injection by more than 2 weeks (after the 6-month target date) can lead to increased risk of osteoporotic fracture. Due to the potential reduction in bone mineral density (BMD) with cessation of denosumab, the dosing frequency of every six months plus or minus two weeks <b>must be</b> maintained. Treatment effect reverses rapidly, so denosumab is <b>NOT</b> suitable for 'drug holidays' as can be considered for bisphosphonate treatment.</p> <p><b>If a patient misses their next dose by more than 2 weeks – contact the specialist team for advice</b></p>
<b>Duration of therapy review / Stopping treatment</b>	<p><b>Primary care clinicians should request a DXA after 3-5 years of treatment</b>, specifying duration of treatment so far, and any changes in risk factors since treatment started. Specialist advice regarding duration of treatment will be provided in the DXA report or alternatively advice is available via 'Advice and Guidance'</p> <p>In line with <a href="#">MHRA advice</a> (August 2020), denosumab <b>should not be stopped or ongoing treatment delalist review</b> (due to increased risk of multiple vertebral fractures reported).</p> <p>If a primary care clinician has any concerns regarding denosumab treatment at any time , they should seek advice from the specialist team via advice and guidance</p>
<b>Special patient populations</b>	<p><b>Elderly (age ≥ 65)</b> No dose adjustment is required in elderly patients.</p> <p><b>Renal impairment</b> No dose adjustment is required in patients with renal impairment.</p>

	<p>Patients with severe renal impairment (creatinine clearance &lt;30 ml/min) or receiving dialysis are at greater risk of developing hypocalcaemia. The risks of developing hypocalcaemia and accompanying parathyroid hormone elevations increase with increasing degree of renal impairment. Adequate intake of calcium, vitamin D and regular monitoring of calcium is especially important in these patients.</p> <p>No data is available in patients with long-term systemic glucocorticoid therapy and severe renal impairment (creatinine clearance &lt;30 ml/min).</p> <p><b>NB: It has been agreed locally that primary care clinicians should not prescribe denosumab for patients with severe renal impairment (see <a href="#">Osteoporosis guidelines</a>) and that the care of these patients should remain with the Specialist team. Any patient who subsequently develops severe renal impairment should be transferred back to the specialist team for ongoing care.</b></p> <p><b>Hepatic impairment</b> The safety and efficacy of denosumab have not been studied in this population.</p> <p><b>Children and adolescents aged &lt;18 years</b> Denosumab should not be used because of safety concerns of serious hypercalcaemia, and potential inhibition of bone growth and lack of tooth eruption.</p>
<p><b>Contra- indications</b></p>	<ul style="list-style-type: none"> <li>• Hypersensitivity to the active substance or to any of the excipients</li> <li>• Hypocalcaemia</li> </ul>
<p><b>Cautions</b> (see <a href="#">SPC</a> for full details) and <a href="#">MHRA Drug Safety Update information</a> (see also <a href="#">references</a>)</p>	<p><b>Hypocalcaemia</b> must be corrected by adequate intake of calcium and vitamin D <b>before</b> initiating therapy.</p> <p>Clinical monitoring of calcium levels is required <b>before each dose</b> and, <b>in patients predisposed to hypocalcaemia</b>, within two weeks after the initial dose. Patients should be advised to report symptoms indicative of hypocalcaemia.</p> <p><b>Symptoms of hypocalcaemia</b></p> <ul style="list-style-type: none"> <li>- muscle spasms, twitches, cramps, numbness or tingling in the fingers, toes, or around the mouth</li> </ul> <p><b>Skin infections:</b> Patients receiving denosumab may develop skin infections (predominantly cellulitis) leading to hospitalisation. Patients should be advised to seek prompt medical attention if they develop signs or symptoms of cellulitis.</p> <p><b>Osteonecrosis of the jaw (ONJ)</b> has been reported rarely in patients receiving denosumab for osteoporosis. The risk of ONJ increases with increasing duration of treatment.</p> <p>A dental examination with appropriate preventive dentistry should be considered <b>prior to</b> treatment with denosumab in patients with concomitant risk factors (see SPC). Whilst on treatment, patients should be advised to inform their dentist that they are receiving denosumab treatment and that they should avoid invasive dental procedures unless necessary. All patients should be advised to maintain good oral hygiene practices during treatment, receive routine dental check-ups, and report any oral symptoms such as dental mobility, pain or swelling, or non-healing of sores or discharge.</p> <p>For patients who develop ONJ while on denosumab therapy, dental surgery may exacerbate the condition. If ONJ occurs during treatment with denosumab, refer to secondary care specialist.</p> <p><b>Osteonecrosis of the external ear canal.</b> The possibility of osteonecrosis of the external auditory canal should be considered in patients receiving denosumab who present with</p>

	<p>ear symptoms including chronic ear infections or in those with suspected cholesteatoma. Possible risk factors include steroid use and chemotherapy, with or without local risk factors such as infection or trauma. Advise patients to report any ear pain, discharge from the ear, or an ear infection during denosumab treatment.</p> <p><b>Atypical femoral fractures</b> have been reported in patients receiving denosumab. They may occur with little or no trauma in the subtrochanteric and diaphyseal regions of the femur. Patients should be advised to report new or unusual thigh, hip, or groin pain. Patients presenting with such symptoms should be evaluated for an incomplete femoral fracture.</p> <p><b>Long-term antiresorptive treatment</b> (including both denosumab and bisphosphonates) may contribute to an increased risk for adverse outcomes such as osteonecrosis of the jaw and atypical femur fractures due to significant suppression of bone remodelling.</p> <p><b>Increased risk of multiple vertebral fractures after stopping or delaying ongoing treatment.</b> An increased risk of multiple vertebral fractures has been reported in patients within 18 months of stopping or delaying ongoing denosumab. Patients should not stop treatment without a specialist review.</p>
<p><b>Adverse effects</b> (see <a href="#">SPC</a> for full details)</p> <p>Report suspected adverse effects to the <a href="#">MHRA</a></p>	<ul style="list-style-type: none"> <li>• The most common side effects (seen in more than one patient in ten) are musculoskeletal pain and pain in the extremity.</li> <li>• Other commonly reported side effects include UTI, upper respiratory tract infections, sciatica, constipation, abdominal discomfort, rash, and eczema.</li> <li>• Uncommon cases of ear infection, cellulitis, and diverticulitis; rare cases of hypocalcaemia, hypersensitivity, osteonecrosis of the jaw, atypical femoral fractures, and osteonecrosis of the external auditory canal have been observed in patients taking denosumab 60mg.</li> </ul> <p><b>NB:</b> Tell all patients to report symptoms of hypocalcaemia to their doctor (e.g., muscle spasms, twitches, or cramps; numbness or tingling in the fingers, toes, or around the mouth).</p>
<p><b>Pregnancy, lactation and fertility</b> (see <a href="#">SPC</a> for full details)</p> <p><b>NB: only recommended for use in post-menopausal women</b></p>	<p><b>Pregnancy</b></p> <p>Denosumab is not recommended for use in pregnant women and women of child-bearing potential not using contraception. Women should be advised not to become pregnant during and for at least 5 months after treatment with denosumab.</p> <p><b>Lactation</b></p> <p>It is unknown whether denosumab is excreted in human milk. A decision on whether to abstain from breast-feeding or to abstain from therapy with denosumab should be made, taking into account the benefit of breast-feeding to the newborn/infant and the benefit of denosumab therapy to the woman.</p> <p><b>Fertility</b></p> <p>No data are available on the effect of denosumab on human fertility. Animal studies do not indicate direct or indirect harmful effects with respect to fertility.</p>
<p><b>Interactions</b> (see <a href="#">SPC</a> for full details)</p>	<p>No known significant 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.</p>

**Counselling  
points**

Ensure the patient understands the importance of:

- Compliance with denosumab treatment. Explain that it is very important that denosumab injections are given every 6 months (plus or minus 2 weeks) as any delay in treatment increases the risk of developing an osteoporotic fracture.
- Attendance for blood tests prior to each dose of denosumab : – **inform the patient to make an appointment with their GP practice for blood tests 4 weeks before the next denosumab injection is due (to check calcium, kidney function, and vitamin D), AND an appointment to receive the 6 monthly injection.**
- Maintaining adequate [calcium and vitamin D](#) intake through a healthy diet and taking any supplements if required, as advised by the specialist / primary care clinician.
- Maintaining good oral hygiene:
  - Advise patient to inform their dentist that they are receiving denosumab treatment and to attend regular dental appointments.
  - Advise patient to inform their GP if they do not receive routine dental care or are planning to undergo dental surgery.

**Counsel patient** to inform GP or secondary care specialist if they:

- Have ever had severe kidney problems, kidney failure or has needed dialysis.
- Have cancer, are undergoing chemotherapy or radiotherapy.
- Are taking steroids
- Are pregnant, think they may be pregnant, or are planning a pregnancy; if they are breast-feeding or planning to do so.
- Patient to tell GP and their dentist that they are receiving denosumab if currently having dental treatment or planning to undergo dental surgery.
- Patient to immediately report any adverse events to the GP or hospital doctor, whoever last administered denosumab, particularly if patient develops a swollen, red area of skin, most commonly in the lower leg, that feels hot and tender (cellulitis), symptoms of fever, muscle aches, dizziness, and any dental problems.
- **Have symptoms of hypocalcaemia** (e.g., muscle spasms, twitches, cramps, numbness or tingling in the fingers, toes, or around the mouth).
- Experience ear symptoms including chronic ear infections, ear pain, or discharge from the ear.
- Have any new or unusual thigh, hip, or groin pain.

**References**

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3. Bedfordshire, Luton & Milton Keynes ICS Glucocorticosteroid induced Osteoporosis Guidelines, updated July 2025. Accessible via: [Prevention and Treatment of Glucocorticoid induced Osteoporosis in Post-menopausal Women & Men \(age ≥ 50 years\) in the Primary Care Setting – BLMKICB Medicines Optimisation](#)
4. Denosumab for the prevention of osteoporotic fractures in postmenopausal women, NICE TA204, issued October 2010 (last updated March 2014). Accessible via: <https://www.nice.org.uk/guidance/ta204>.
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9. MHRA Drug Safety Update. Denosumab (Xgeva ▼, Prolia); intravenous bisphosphonates: osteonecrosis of the jaw—further measures to minimise risk, July 2015. Accessible via: <https://www.gov.uk/drug-safety-update/denosumab-xgeva-prolia-intravenous-bisphosphonates-osteonecrosis-of-the-jaw-further-measures-to-minimise-risk>.
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11. MHRA Drug Safety Update. Denosumab 60mg (Prolia): increased risk of multiple vertebral fractures after stopping or delaying ongoing treatment, August 2020. Accessible via: <https://www.gov.uk/drug-safety-update/denosumab-60mg-prolia-increased-risk-of-multiple-vertebral-fractures-after-stopping-or-delaying-ongoing-treatment>.
12. MHRA Drug Safety Update. Denosumab 60mg (Prolia): should not be used in patients under 18 years due to the risk of serious hypercalcaemia, May 2022. Accessible via: <https://www.gov.uk/drug-safety-update/denosumab-60mg-prolia-should-not-be-used-in-patients-under-18-years-due-to-the-risk-of-serious-hypercalcaemia>.

Version	Author	Purpose/Change	Date
1.0	Medicines Optimisation Team	New document (supersedes BLMK shared care guideline)	4 <sup>th</sup> March 2026