TRANSFER OF CARE - MONITORING & GUIDANCE DOCUMENT FOR DENOSUMAB BIOSIMILAR (OSVYRTI®) FOR OSTEOPOROSIS IN POST MENOPAUSAL WOMEN

Denosumab biosimilar (Osvyrti®) is indicated for the treatment of osteoporosis in postmenopausal women at increased risk of fractures, administered as a six-monthly subcutaneous injection. It significantly reduces the risk of vertebral, non-vertebral and hip fractures. This document provides guidance for GPs to monitor patients on Osvyrti®, who had their first dose at the hospital and have now been transferred to your care for continuation of treatment. This also contains general prescribing information on denosumab biosimilar (Osvyrti®). 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 (FLS).

PRESCRIBING INFORMATION

DRUG, DOSE, ROUTE & ADMINISTERED FREQUENCY	Denosumab biosimilar (Osvyrti®) 60mg Subcutaneous Injection every 6 months	See BNF and Summary of Product Characteristics for full prescribing information

MONITORING & FOLLOW UP

PARAMETER	MONITOR	FREQUENCY	ACTION REQUIRED	RESPONSIBLE
Pre-treatment Assessment	• Renal Function • Calcium levels • Vitamin D level • Signs or symptoms of cellulitis • Patient Information	Pre-treatment	• Aim for normal target range for Vitamin D and Calcium. • If hypocalcaemia , ensure patient is asymptomatic, increase calcium supplementation if indicated and recheck 2 weeks later. (Replete calcium and vitamin D) • Check vitamin D level within last 6 months. Correct if any deficiency. • 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 mild hypocalcaemia (adjusted. Ca2+ 2.0 – 2.19mmol/L), ensure patient is asymptomatic, increase calcium supplementation if indicated and recheck 2 weeks later. (Replete calcium and vitamin D).	GP

			• If moderate or severe hypocalcaemia (<1.99 mmol/L OR symptomatic, contact medical team via switchboard. • Provide patient with patient information leaflet	
After 5 years treatment			• Contact FLS for review • Continue Osvyrti® until advised. Do not withhold as delayed or missed doses may result in rebound fragility fractures	GP
After 10 years treatment			• Contact FLS for review	GP

DENOSUMAB BIOSIMILAR (OSVYRTI®) 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 • 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) • 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	• Correct with calcium and Vitamin D supplementation • Treat with antibiotics/ refer to on call medical team if IV treatment required

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	020 8970 8408
NEL ICB Medicines Optimisation Team	020 3182 3133

REFERENCES

1. NICE TA204 'Denosumab for the prevention of Osteoporotic fractures in postmenopausal women' https://www.nice.org.uk/guidance/ta204/chapter/1-Recommendations (accessed 19/12/2025)
3. MHRA December 2014: Drug Safety Update. 'Denosumab: minimising the risk of osteonecrosis of the jaw; monitoring for hypocalcaemia' https://www.gov.uk/drug-safety-update/denosumab-updated-recommendations (accessed 19/12/2025)
4. MHRA July 2015: Drug Safety Update. Drug Safety Update. 'Denosumab (Xgeva▼ , Prolia); intravenous bisphosphonates: osteonecrosis of the jaw – further measures to minimize risk' https://www.gov.uk/drug-safety-update/denosumab-xgeva-prolia-intravenous-bisphosphonates-osteonecrosis-of-the-jaw-further-measures-to-minimise-risk (accessed 19/12/2025)
5. MHRA December 2014: Drug Safety update. 'Denosumab: Rare cases of atypical femoral fracture with long-term use' https://www.gov.uk/drug-safety-update/denosumab-60-mg-prolia (accessed 19/12/2025)
6. MHRA August 2020: Drug Safety Update. 'Denosumab (Prolia): increased risk of multiple vertebral fractures after stopping or delaying ongoing treatment' https://www.gov.uk/drug-safety-update/denosumab-60mg-prolia-increased-risk-of-multiple-vertebral-fractures-after-stopping-or-delaying-ongoing-treatment (accessed 19/12/2025)

7. Prolia® SPC. Electronic Medicines Compendium. https://www.medicines.org.uk/emc/product/568/smpc (accessed 19/12/2025)
8. Denosumab. BNF. https://bnf.nice.org.uk/drugs/denosumab/ (accessed 19/12/2025)
9. Osvyrti® PIL (22/01/2026)