

Denosumab Prescribing Information Sheet (for Osteoporosis)

Approved by Basingstoke, Southampton & Winchester District Prescribing Committee

This guidance should be read in conjunction with the BNF, and the latest Summary of Product Characteristics (available at <http://www.medicines.org.uk>).

- Denosumab may be prescribed as an alternative to alendronate if the patient is unable to comply with the special instructions for the administration of alendronate or has a contraindication to, is intolerant of, or has a lack of clinical response to alendronate. (See local DPC approved Osteoporosis guidelines available at West Hampshire CCG's [website](#)).
- **Hypocalcaemia is a contra-indication to denosumab therapy.** Check renal function and serum calcium and correct pre-existing hypocalcaemia before initiation. Recheck renal function and serum calcium before each dose. **In addition**, for patients predisposed to hypocalcaemia [e.g. severe renal impairment (creatinine clearance < 30ml/min; eGFR 15 – 29ml/min/1.73m²) or on dialysis] recheck serum calcium within two weeks and 3 months after each dose or more frequently if clinically indicated. Inform the patient of possible symptoms of hypocalcaemia e.g. paresthesias or muscle stiffness, twitching, spasms and muscle cramps. If a patient presents with suspected symptoms of hypocalcaemia during treatment, serum calcium levels should be measured.
- **Other contra-indications** include hereditary problems of fructose intolerance and hypersensitivity to the active substance or to any of the excipients
- Consider a dental examination prior to starting denosumab in all patients with concomitant risk factors for osteonecrosis of the jaw (ONJ). [Consult Summary of Product Characteristics (available at <http://www.medicines.org.uk>) for list of known risk factors. Give patient the **Denosumab Patient Reminder Card¹ which contains advice about ONJ**. Patients should avoid invasive dental procedures if possible and maintain good oral hygiene and regular dental check-ups while on denosumab treatment. If invasive dental work is undertaken whilst the patient is on denosumab therapy, closer monitoring of the healing process will be necessary.
- Prescribe 60mg denosumab, and administer by subcutaneous injection once every 6 months. No dose adjustment is required in elderly patients or patients with renal impairment. Ensure adequate intake of calcium and vitamin D in all patients and continue calcium and vitamin D supplements if appropriate (link for [dietary calculator](#))². Set up a recall to prompt repeat doses every 6 months. (Guidance is available for all GP software systems from the Medicines Management Team). Add to patient's repeat prescription and remove **other osteoporosis treatments (e.g. bisphosphonates, strontium)**.
- Prescribe on FP10, or set up account for supply to be delivered direct to the practice within 24 hours. (Movianto; Tel. 01234 248500 Fax 01234 248705 email: orders.uk@movianto.com). NB. The denosumab prefilled syringe must be kept in its outer carton, in order to protect from light, and stored in the refrigerator.
- **Adverse events** include hypocalcaemia (see above) and, rarely, cellulitis. Patients must seek prompt medical attention if they develop signs of cellulitis. **New or unusual thigh, hip or groin pain:** may be a symptom of atypical femoral fracture which has been reported very rarely during long-term treatment (≥ 2.5 years). Discontinue denosumab therapy if atypical femur fracture suspected while patient is investigated. Consider referring to orthopaedics if necessary. Report any adverse events to the MHRA.
- Inform patient that more information is available at www.Prolia.co.uk
- **Review** after 5 years treatment, and continue therapy if indicated. Be aware that bone loss is rapid on discontinuation of denosumab therapy; therefore a 'drug holiday' is not appropriate. (See local DPC approved Osteoporosis guidelines available at West Hampshire CCG's [website](#)).

References

1. MHRA Drug Safety Update Volume 8, Issue 12 July 2015 Denosumab (Xygeva ▼, Prolia) ; intravenous bisphosphonates: osteonecrosis of the jaw - further measures to minimise risk.
2. Centre for Genomic + Experimental Medicine (University of Edinburgh) – Calcium Calculator available at <http://www.cgem.ed.ac.uk/research/rheumatological/calcium-calculator>