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. **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 Card 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).

  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-calcculator