DENOSUMAB (Prolia®) **60mg sc twice yearly for osteoporosis in men and women**[1]

Information for Treatment of Adults in Primary Care

Formulary Approved Indication

- Green+ - Requires initiation by specialist
- Specialist responsibilities: Initiation, including monitoring before starting treatment and administration of first dose
- GP responsibilities: Prescribing, administration and monitoring following initiation by specialist

Dose

- 60mg by subcutaneous injection every six months.
- No dosage adjustment is required in the elderly or in patients with renal impairment.

Cautions

- Adequate intake of calcium and vitamin D is important during treatment.
- The needle cover contains a derivative of latex which may potentially cause allergic reactions.

Side-effects

- Hypocalcaemia
- Osteonecrosis of the jaw
- Atypical femoral fractures[2]

Routine Monitoring of Denosumab (Prolia®)

- Calcium levels
    - prior to each dose of denosumab
    - symptoms of hypocalcaemia occur or if otherwise indicated based on the clinical condition of the patient
- When on denosumab therapy patients should be encouraged to maintain good dental hygiene, receive routine dental check-ups and report any oral symptoms[3].
- Patients should also be advised to report symptoms of hypocalcaemia (paraesthesiae, cramps, muscle twitching, spasms) or of atypical femoral fracture (new, unusual hip or groin pain) during treatment.
- Adequate intake of calcium and vitamin D during treatment should be maintained through supplementation or diet. Assessment of intake should be documented if supplementation not felt to be necessary. Risk of hypocalcaemia is increased further in patients with severe renal failure (eGFR <30 mL/minute) or on dialysis.
- Review need for ongoing treatment every 3 years

References

[1] NICE TA204: Denosumab for the prevention of osteoporotic fractures in postmenopausal women (October 2010). Available from https://www.nice.org.uk/guidance/ta204

[2] Denosumab 60 mg (Prolia®): rare cases of atypical femoral fracture with long-term use : MHRA Feb 2013 Drug Safety update volume 6 Issue7

[3] Denosumab: minimising the risk of osteonecrosis of the jaw; monitoring for hypocalcaemia. MHRA 25/9/2014, accessible from https://www.gov.uk/drug-safety-update/denosumab-updated-recommendations