

## DENOSUMAB (PROLIA®)

Denosumab (Prolia®) is a monoclonal antibody drug indicated for the treatment of osteoporosis in men and postmenopausal women at increased risk of fractures, administered as a six-monthly subcutaneous injection.

**All patients** being considered for Denosumab (Prolia®) should be discussed with the Bone Team of the Rheumatology department **before** treatment is initiated.

General Practitioners can claim for this item of service under the Minor Surgery enhanced service contract.

## Denosumab (Prolia) - Osteoporosis

### PATIENT COUNSELLING

#### Skin Rashes

Skin rash is the most common undesirable effect.

#### Hypocalcaemia

Hypocalcaemia is both a specific contraindication to treatment **and** a risk associated with treatment.

The risk of hypocalcaemia during treatment increases with the degree of renal impairment; patients with severe renal impairment (eGFR < 30 mL/min) or receiving dialysis are at greater risk of developing hypocalcaemia and we do not recommend denosumab in patients receiving dialysis.

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).

#### Osteonecrosis of the Jaw

Check for osteonecrosis of the jaw risk factors before starting Denosumab (Prolia®):

- Smoking
- Old age
- Poor oral hygiene
- Invasive dental procedures (e.g. tooth extractions, dental implants, oral surgery)
- Comorbidity (e.g. dental disease, anaemia, coagulopathy, infection)
- Advanced cancer
- Previous treatment with bisphosphonates
- Concomitant treatments (e.g. chemotherapy, antiangiogenic biologics, corticosteroids, radiotherapy to head and neck)

Tell **all patients** to maintain good oral hygiene, receive routine dental check-ups, and immediately report any oral symptoms such as dental mobility, pain, or swelling to a doctor and dentist.

### MONITORING

#### Prior to first injection

Check the following blood tests:

- U+Es, calcium and vitamin D levels

Vitamin D needs to be  $\geq 50$  nmol/l.

If not, then replace with appropriate calcium and vitamin D supplements for at least 6 weeks prior to giving first injection.

Patients with eGFR < 30 mL/min should be discussed with the Bone Team of Rheumatology.

#### Regular monitoring

Check calcium levels:

- 2 weeks before each dose
- Within two weeks after the initial dose in patients with risk factors for hypocalcaemia (e.g. severe renal impairment, eGFR <30 mL/min)
- If suspected symptoms of hypocalcaemia occur

Treatment should not be given if patient has hypocalcaemia – discuss with Bone Team of Rheumatology.

It is essential that patient remains on calcium and vitamin D supplements throughout the whole treatment course and that prior to each injection it is checked that patient is taking their supplements.

**Lengthy injection delays or stopping Denosumab, without an alternative treatment, can increase spinal fracture risk.**

### FURTHER INFORMATION

Further information is available from the Royal Osteoporosis Society:  
[www.theros.org.uk](http://www.theros.org.uk)