

Denosumab Prescribing in the Treatment of Osteoporosis and Fracture Prevention

- Denosumab 60mg subcutaneous injection every 6 months.
- Can be initiated by primary or secondary care and option of self-injection in appropriate patients.
- Treatment for secondary prevention of osteoporosis fragility fractures in post- menopausal women and men who are intolerant of other treatment options.
- Treatment for primary prevention of fragility fractures in post-menopausal women with low T-scores and other risk factors for fractures – parental history of hip fracture, alcohol intake > 4 units/day, rheumatoid arthritis.

Age	T-score cut off with number of risk factors		
	0	1	2
65-69 years	Not recommended	-4.5	-4.0
70-74 years	-4.5	-4.0	-3.5
>75 years	-4.0	-4.0	-3.0

- Before each injection, a blood test for calcium, vitamin D and renal function needs to be carried out in the preceding 2 weeks.
- Patient groups who may be unsuitable for denosumab include those less than 70 years old, history of hypocalcaemia, inability to comply with treatment, creatinine clearance < 30ml/min, current extensive dental problems.
- Denosumab should not be stopped abruptly or discontinued for a ‘drug holiday’ due to rapid rebound loss of bone density and increased risk of vertebral fractures.
- If patients need to discontinue denosumab due to falling renal function (e.g. below a creatinine clearance of 25ml/min) or other reasons, this should be discussed with secondary care (who may advise on alternative appropriate treatments). It is acceptable to stop after the initial injection if patient unable to tolerate. Any delay in 6 monthly injections should be by no longer than 1 month.
- Current guidance is that treatment should be reviewed, if a patient has a new fractures or after five years.
- At the five-year review, please check adherence to denosumab, side effects, fractures on treatment, tolerability to calcium / vitamin D supplements and falls risk. Consider a bone density scan as part of this review. Secondary care should be consulted if discontinuation is considered.
- Current UK pilot of Prolia Proactive online system for patient recall compatible with all GP clinical systems. Further details from your local Medicines Optimisation team or Oberoi Consulting (admin@oberoi-consulting.com or 01332 546 956)

Resources:

1. SIGN 142. Management of osteoporosis and the prevention of fragility fractures.
<https://www.sign.ac.uk/media/1741/sign142.pdf>
2. NICE TA 204. Denosumab for the prevention of osteoporotic fractures in postmenopausal women. <https://www.nice.org.uk/guidance/TA204>
3. Royal Osteoporosis Society. Denosumab treatment and the Covid 19 pandemic.
<http://theros.org.uk/healthcare-professionals/covid-19-hub/denosumab-prolia-treatment-and-the-covid-19-pandemic/>
4. Summary of product characteristics. Prolia 60mg solution for injection in pre-filled syringe
<https://www.medicines.org.uk/emc/product/568>