Bath Clinical Area Partnership
Prescribing and Therapeutics Committee

http://nww.banes-pct.nhs.uk/GPsDentistsPharmacists/BCAPPrescribingandTherapeutics/Pages/default.aspx

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Denosumab (Prolia®) for the treatment of osteoporosis

Product Information

- Denosumab is a human monoclonal antibody licensed for the treatment of osteoporosis in postmenopausal women at risk of fractures.
- Denosumab significantly reduces the risk of vertebral, non vertebral and hip fracture
- Denosumab is available in a prefilled syringe of 60mg in 1ml
- Denosumab should be administered twice a year by sub-cutaneous injection by an individual who has been adequately trained in sub-cutaneous injection technique
- Denosumab is ordered via Movianto and should be stored in a fridge (2-8°). It may be exposed to room temp for a maximum period of 30 days

Place in therapy

NICE (http://www.nice.org.uk/nicemedia/live/13251/51293/51293.pdf)approved the use of Denosumab in October 2010 for

Secondary Prevention: Of osteoporotic fragility fractures in postmenopausal women at increase risk of fracture and who are unable to comply with or tolerate or who are contraindicated to alendronate, risedronate or etidronate (i.e. second line – see BCAP guideline)

Primary Prevention: As above and in line with particular T score value, risk and associated age (see BCAP guideline)

BCAP

Has assigned Denosumab an **'amber with shared care'** traffic light status (to be reviewed within 1 year). The first dose will be administered by the RNHRD within the osteoporosis service, the patient will be reviewed 3 months later and the GP approached to take part in shared care (see shared care guideline). The RUH (Dr Hicks) will also be initiating treatment with denosumab.

Other important product information:

- Contraindication: Hypocalcaemia, hypersensitivity to the active substance or any of the excipients
- Hypocalcaemia **must** be corrected by calcium and vitamin D before Denosumab is administered (see Appendix 4)
- Denosumab has a low potential for drug –drug interactions
- Patients receiving denosumab may develop skin infections (predominantly cellulitis) leading to hospitalisation.

Monitoring:

Clinical monitoring of calcium levels is recommended for patients predisposed to hypocalcaemia (patients with severe renal impairment creatinine clearance<30ml/min) or receiving dialysis are at greater risk of developing hypocalcaemia.

Cost

Denosumab costs £183 per injection. (£366 per annum) (Excluding VAT)

See:

Appendix 1 - BCAP Primary and Secondary Prevention of osteoporotic fragility fractures in postmenopausal women

Appendix 2 – Share care guideline for denosumab

Appendix 3 – Protocol for primary care management of patients prescribing Prolia (denosumab) for prevention of fractures.

Appendix 4 – Vitamin D deficiency and insufficiency – using appropriate available products

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