Indication	Prevention of skeletal-related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with bone metastases from breast cancer and from solid tumours other than prostate if bisphosphonates would otherwise be prescribed and the manufacturer provides denosumab with the discount agreed in the patient access scheme. This schedule of denosumab, given every 12 weeks, should usually only commence after initial monthly denosumab, and at the clinicians discretion once bone metastases are under control and sclerosing – and especially after 3 years when the risk of side effects from monthly dosing is likely to increase.
Treatment Intent	Palliative
Frequency and number of cycles	To be given every 12 weeks. Continue for as long as required or until unacceptable toxicity.
Monitoring parameters pre-treatment	• Pre-existing hypocalcaemia must be corrected prior to initiating therapy with denosumab. • Patients should have U&Es, bone profile, LFTs and FBC taken within 1 week prior to each cycle. Patients at risk of hypocalcaemia should be monitored more frequently as necessary or if suspected symptoms of hypocalcaemia occur. • **Renal impairment:** no dose adjustment necessary, however, use with caution in patients with CrCl ≤30 ml/min or receiving dialysis as these patients are at greater risk of developing hypocalcaemia. • **Hepatic impairment:** no data available. • Patients should be advised to seek prompt medical attention if they develop signs or symptoms of cellulitis. • Denosumab is not recommended for use in pregnant women and women of childbearing potential not using contraception. Osteonecrosis of the jaw • A dental examination with appropriate preventive dentistry is recommended for all patients prior to the start of denosumab treatment. • Patients should be encouraged to have regular dental check-ups whilst on treatment. • Do not start treatment in patients with an active dental or jaw condition requiring surgery or in patients who have not completely recovered following oral surgery. • While on treatment avoid dental procedures if possible. • If patients require **invasive** dental procedures (ie: dental extraction, or root planing /deep scaling/root canal therapy) then the patient should stop treatment 8 weeks prior, and recommence treatment when there is healing as assessed by a dental professional. NB Superficial dental fillings, normal hygiene appointments and the provision of dentures are not invasive dental procedures and therefore there is no indication to stop denosumab for these. • Patients who develop osteonecrosis of the jaw should be referred to a maxillofacial surgeon. • Caution is advised when denosumab is administered with anti-angiogenic drugs (eg bevacizumab, sunitinib, pazopanib), as an increase in the incidence of ONJ has been observed in patients treated concomitantly with these medicinal products. • Osteonecrosis of the external auditory canal should be considered in patients who present with ear symptoms including chronic ear infections. • During treatment patients should be advised to report any thigh, hip or groin pain and any patient presenting with such symptoms should be evaluated for an incomplete femur fracture.
Reference(s)	SPC accessed on line 12/11/2019

NB For funding information, refer to CDF and NICE Drugs Funding List

Repeat every 12 weeks

Drug	Dose	Route	Directions
Denosumab Xgeva®	**120mg**	**sub-cutaneous**	**injection into the thigh, abdomen or upper arm**
TTO Drug	Dose	Route	Directions
Calcium 600mg & colecalciferol 400iu tablets (**Adcal D3**)	1 tablet	PO	Once daily, chewed or sucked before swallowing.