DENOSUMAB - local funding required

INDICATION (ICD10) D48.1
1. Neoadjuvant and maintenance single agent in giant cell tumours of the bone

REGIMEN
Cycle 1
Days 1, 8 and 15 DENOSUMAB 120mg SC once daily

Cycle 2 onwards
Day 1 DENOSUMAB 120mg SC once daily

CYCLE FREQUENCY AND NUMBER OF CYCLES
Every 28 days

ANTI-EMETICS
None required

CONCURRENT MEDICATION REQUIRED

Denosumab	Vitamin D. Adequate intake of calcium

INVESTIGATIONS
Blood results required before SACT administration
FBC, U&E, Ca^{++} and LFTs every cycle
Bone profile including Vitamin D, PTH) PINP every cycle
Neutrophils x 10^9/L ≥1.5
Platelets x 10^9/L ≥100
Serum creatinine every cycle
Baseline weight and every cycle

MAIN TOXICITES AND ADVERSE REACTIONS

Denosumab	Osteonecrosis of jaw/auditory canal, suspend treatment if invasive dental work needed. Hypocalcaemia must be corrected by adequate intake of calcium and vitamin D before initiating therapy. Patients with severe renal impairment (CrCl <30ml/min) or receiving dialysis are at greater risk of developing hypocalcaemia. Infections and infestations - UTI, respiratory, diverticulitis, cellulitis and ear infections Sciatica Cataracts Constipation Skin - rash and eczema Pain

INTERACTIONS WHICH MAY REQUIRE DOSE MODIFICATIONS (not exhaustive list check SPC/BNF/Stockleys)

Denosumab	-

DOSE MODIFICATIONS

Hepatic impairment

Not studied

Renal impairment

No dose adjustment required

REFERENCES

1. Thomas D et al Denosumab in patients with giant-cell tumour of bone; an open label phase 2 study. Lancet Oncology vol11 March 2010; 275-280