

# Denosumab (attenuated schedule, oncology use only)

## Indication

Prevention of skeletal related events in bone metastases from solid tumours

## Regimen details

Denosumab 120mg by subcutaneous injection

## Cycle frequency

Every 28 days for the first 2 years (26 cycles) then every 6 months thereafter

## Number of cycles

Given until disease progression

## Administration

Give by subcutaneous injection (slowly) into the thigh, abdomen or upper arm  
Allow the injection to come up to room temperature before use  
Solution may contain traces of white or translucent proteinaceous particles  
Do not inject if solution is cloudy or discoloured

## Pre-medication

None

## Emetogenicity

N/A

## Additional supportive medication

Co-administration of calcium (500mg) and vitamin D (400units) supplements unless hypercalcaemic

## Extravasation

N/A

## Investigations – pre first cycle

Renal function, calcium levels and vitamin D levels  
Pre-existing hypocalcaemia must be corrected before starting treatment

## Investigations –pre subsequent cycles

Check FBC, U&Es and bone profile 14 days after starting treatment  
No routine blood monitoring necessary unless clinically indicated

## Standard limits for administration to go ahead

N/A

## Dose modifications

Do not adjust dose

## Adverse effects –

Diarrhoea, dyspnoea, skin infection including cellulitis, osteonecrosis of the jaw, osteonecrosis of the external auditory canal, atypical fractures of the femur, hypocalcaemia, hypophosphataemia, musculoskeletal pain

Lancashire & South Cumbria Cancer Network  
Systemic Anticancer Treatment Protocol

### Osteonecrosis of the Jaw (ONJ)

ONJ has occurred commonly in patients treated with denosumab. Risk factors include invasive dental procedures, poor oral hygiene or other pre-existing dental disease, infections, older age, concomitant chemotherapy, corticosteroids, angiogenesis inhibitors or radiotherapy, smoking and previous treatment with bisphosphonates.

A dental examination with appropriate preventive dentistry is recommended prior to treatment with denosumab. Denosumab should not be initiated in patients with an active dental or jaw condition requiring surgery or in patients who have not recovered following oral surgery.

All patients should be encouraged to maintain good oral hygiene, receive routine dental check-ups, and immediately report any oral symptoms such as dental mobility, pain or swelling during treatment with denosumab. Patients should be advised to refer to the Patient Information Leaflet for information on symptoms of ONJ.

While on treatment, patients should avoid invasive dental procedures if possible. For patients who develop ONJ while on denosumab therapy, dental surgery may exacerbate the condition. The management plan of individual patients who develop ONJ should be set up in close collaboration between the consultant and a dentist or oral surgeon with expertise in ONJ. Temporary interruption of treatment should be considered until the condition resolves and contributing risk factors are mitigated where possible

### References

NICE guidance TA265 Denosumab for the prevention of skeletal-related events in adults with bone metastases from solid tumours <https://www.nice.org.uk/guidance/ta265>

Xgeva SPC [www.medicines.org.uk/emc/product/4675/smpc](http://www.medicines.org.uk/emc/product/4675/smpc)

A randomised trial of continuing or de-escalating bone modifying agents (BMA) after more than 2 years of treatment in patients with bone metastases from breast or castration-resistant prostate cancer: REaCT-Hold BMA Ng, T.L. et al. *Annals of Oncology*, Volume 36, S1389 - S1390

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**THIS PROTOCOL HAS BEEN DIRECTED BY DR EATON, CONSULTANT ONCOLOGIST**

**RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE**

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