Denosumab (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

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
If blood results not within range, authorisation to administer **must** be given by prescriber/ consultant.

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

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 - accessed 15/07/2020

Xgeva SPC www.medicines.org.uk/emc/product/4675/smpc - accessed 15/07/2020

THIS PROTOCOL HAS BEEN DIRECTED BY DR EATON, CONSULTANT ONCOLOGIST

RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE

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