CHEMOTHERAPY PROTOCOL

Systemic Anti-Cancer Treatment At Home Nurse Handbook

DENOSUMAB PROTOCOL

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Date	Version	Author name and designation	Summary of main changes
Jan 2016	1.0	Frances Lawton - Project Manager; Chemotherapy Directorate	*First version.*
Jan 2019	1.1	Dorothy Probert- Manager Clatterbridge in The Community	No changes made

Approved for use in

Denosumab is recommended in adults with bone metastases from solid tumours including breast cancer.

Dosage

Drug	Dosage	Frequency
Denosumab	120mg	Every 28 days
Calcium	600mg	Daily
Vitamin D	400iu	Daily

- Vitamin D level should be checked prior to starting treatment
- At least 600 mg calcium and 400 IU vitamin D daily is required in all patients, unless hypercalcaemia is present.
- Pre-existing hypocalcaemia must be corrected prior to initiating therapy.
- Absolute contra-indications are hypercalcaemia resulting for example from myeloma, bone metastases or other malignant bone disease, sarcoidosis; primary hyperparathyroidism and vitamin D overdosage. Severe renal failure.
- Patients with mild to moderate renal failure or mild hypercalciuria should be supervised carefully including periodic checks of plasma calcium
- A dental examination with appropriate preventive dentistry is recommended prior to treatment.

Supportive Treatments

None (mildly emetogenic) / hypersensitivy reaction / anaphylaxis

Extravasation risk

None as given subcutaneously

Administration

Day	Drug	Dose	Route
1	Denosumab	120mg	Sub-cutaneous injection in thigh, abdomen or upper arm
1-28	Calcium Vitamin D	600mg 400iu	PO (please note patients may be receiving supply from GP)

Considerations

- Formulation is 120mg vial of Denosumab in 1.7ml of solution, do not shake excessively.
- Allow vial to reach room temperature before administration to avoid discomfort at injection site.
- Visually inspect vial prior to administration, do not use if cloudy or discoloured
- A 27 gauge needle is recommended for the administration of denosumab.
- Treatment is continuous as long as patient is receiving benefit.
- Calcium and vitamin D may be increased or stopped based on clinical need.
- Patients with rare hereditary problems of fructose intolerance should not use denosumab.

Main Toxicities

Denosumab
Dyspnoea, hypocalcaemia (muscle spasms, twitches, cramps, and/or numbness in fingers, toes or around the mouth), hypophosphataemia, diarrhoea, muscular skeletal pain, hyperhidrosis, osteonecrosis of the jaw, cellulitis, fever, chills
Calcium and vitamin D
Gastro-intestinal disturbance, hypercalciuria, hypercalcaemia

Investigations

Biochemistry prior to each dose, including serum calcium and within 2 weeks of the initial dose

Medical review

3 monthly medical review.

Nurse led review

PS 0-2, on cycles when not seen by clinician. Nurse review at each cycle including completion of the metastatic checklist for patients with advanced disease. If unacceptable toxicity, decline in performance status during treatment or intercurrent problems occur (in particular deranged electrolytes or symptoms on osteonecrosis of the jaw) do not give the medicine before obtaining medical advice and refer back for medical review.

Refer back to medical team if patient has deranged electrolytes or dental or oral problems or symptoms as these may be indicative of osteonecrosis of the jaw.

Dose Modification

Dose reduction schedule
Dose reductions of denosumab are not used to manage toxicity. Calcium and vitamin D doses can be adjusted according to plasma calcium levels

Hypercalcaemia

Denosumab
Calcium and vitamin D
Consider dose reduction

Hypocalcaemia

Denosumab
Hold denosumab. No dose adjustment. Hypocalcaemia can occur at any time during therapy and most commonly occurs during the first 6 months of dosing. If hypocalcaemia occurs check vitamin D levels and then consider additional calcium supplementation.

Calcium and vitamin D
Consider increasing Calcium and vitamin D to 2 tablets in patient is hypocalcaemia in consultation with managing Clinician

Renal Impairment

Denosumab
No dose adjustment is required for patients with renal impairment although experience with severe renal impairment (CrCl <30ml/min) is limited. Patients with mild to moderate renal failure or mild hypercalciuria should be supervised carefully including periodic checks of plasma calcium levels and urinary calcium excretion.
Calcium and vitamin D

Osteonecrosis of the jaw (ONJ)

Denosumab
The management plan of individual patients who develop ONJ should be set up in close collaboration between the treating physician and a dentist or oral surgeon with expertise in ONJ

References:

BNF

Denosumab SPC