Denosumab for the treatment of osteoporosis in postmenopausal women at increased risk of fractures - prescribing information

This information sheet does not replace the SPC, which should be read in conjunction with this guidance. Prescribers should also refer to the appropriate paragraph in the current edition of the BNF.

Link to the relevant SPC website: http://www.emc.medicines.org.uk Licence: treatment of osteoporosis in postmenopausal women at increased risk of fractures.

Criteria for Use: Denosumab has been approved by NICE (http://publications.nice.org.uk/denosumab-for-the-prevention-of-osteoporotic-fractures-in-postmenopausal-women-ta204).

Primary Prevention
Denosumab is recommended as a treatment option for the primary prevention of osteoporotic fragility fractures only in postmenopausal women at increased risk of fractures
  • who are unable to comply with the special instructions for administering alendronate and either risedronate or etidronate, or have an intolerance of, or a contraindication to, those treatments and
  • who have a combination of T-score, age and number of independent clinical risk factors for fracture (Independent clinical risk factors for fractures are parental history of hip fracture, alcohol intake of 4 units or more per day, and rheumatoid arthritis).

Secondary Prevention
Denosumab is recommended as a treatment option for the secondary prevention of osteoporotic fragility fractures only in postmenopausal women at increased risk of fractures who are unable to comply with the special instructions for administering alendronate and either risedronate or etidronate, or have an intolerance of, or a contraindication to, those treatments.

Dose
The recommended dose of denosumab is 60mg administered as a single subcutaneous injection once every 6 months into the thigh, abdomen or back of the arm. Patients must be adequately supplemented with calcium and vitamin D.

Surrey Osteoporosis pathway (http://pad.res360.net)
Denosumab is recommended as a treatment option following the use of bisphosphonates.

Cautions (see BNF or SPC)
  • Hypocalcaemia must be corrected by adequate intake of calcium and vitamin D before initiating therapy.
  • Patients receiving denosumab may develop skin infections (predominantly cellulitis). Patients must seek prompt medical attention if they develop signs of cellulitis.
  • Osteonecrosis of the jaw (ONJ) has been reported (rare).
  • A dental examination with appropriate preventive dentistry should be considered prior to starting denosumab in patients with concomitant risk factors (a diagnosis of cancer with bone lesions, concomitant therapies {chemotherapy, corticosteroids, antiangiogenic biologics, radiotherapy to head and neck}, poor oral hygiene, dental extractions, and co-morbid disorders {pre-existing dental disease, anaemia, coagulopathy, infection} and previous treatment with bisphosphonates).
  • While on denosumab treatment patients should avoid invasive dental procedures and maintain good oral hygiene. Dental procedures should be considered prior to the next dose.
  • The needle cover of the prefilled syringe contains dry natural rubber (a derivative of latex), which may cause allergic reactions.
  • Patients with rare hereditary problems of fructose intolerance should not use denosumab.

Contraindications (see BNF or SPC)
  • Hypocalcaemia
  • Hypersensitivity to the active substance or to any of the excipients

Produced by: Linda Honey, Head of Medicines Management, NW Surrey CCG with input from Dr Sian Griffiths, Surrey & Sussex healthcare NHS Trust
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Side effects (see BNF or SPC)

- Mild, transient decreases in serum calcium
- Skin infections predominantly cellulitis. Please monitor carefully if patients are on immunosuppressants particularly anti-TNF
- Other common undesirable effects (incidence of 1-10%) were urinary tract infection, upper respiratory tract infection, cataracts, constipation, sciatica, rash, pain in extremity.
- There have been no reports of anaphylaxis with the injection of denosumab to date.

Interactions (see BNF or SPC)

- No interaction studies have been performed.

Check list for initiation of denosumab:

- Assess the suitability of the patient for denosumab including does the patient meets the NICE criteria / Surrey osteoporosis pathway guidelines. **NOTE:** denosumab is not licensed for use in men and therefore is not supported by NICE / Surrey guidelines (please see guidelines for alternative treatment options for men).
- Denosumab treatment for renal patients with a CKD of 4 & 5 OR patients with a T-score of ≤ 4.5 should remain under specialist care and a GP should **not** initiate treatment or be approached to enter into a shared care agreement
- Assess the patient to ensure he/she has good oral hygiene and use clinical judgement to determine if dental examination is required prior to initiating therapy.
- Ensure that the patient does not have a latex allergy, the needle cover of the prefilled syringe contains dry natural rubber (a derivative of latex), which may cause allergic reactions.
- Check that the patient is calcium and vitamin D replete prior to each injection. Hypocalcaemia must be corrected by adequate intake of calcium and vitamin D before initiating therapy (there are no other specific monitoring requirements for denosumab)
- Ensure that the patient is taking calcium and vitamin D supplements.
- Ensure that other osteoporosis treatments (eg, alendronate, strontium) are stopped and removed from the patient's repeat prescription.
- Discuss the benefits and side effects of treatment with the patient, explaining to the patient that the treatment is 6 monthly injections for up to 5 years
- Advise patients to:
  - To seek prompt medical attention if they develop signs or symptoms of cellulitis.
  - To avoid invasive dental procedures if possible (extractions, implants) and maintain good oral hygiene whilst on denosumab treatment. If treatments are considered necessary then patients are advised to seek advice from the prescribing consultant.
  - To continue the calcium and vitamin D supplement.
  - To attend the GP surgery every 6 months for the denosumab injection
  - To report any adverse events to the doctor who administered the injection.
- Ensure an account is set up to order denosumab and determine if it will come direct to the practice (more straightforward scenario for the patient). Denosumab can be delivered direct to the practice within 24 hours (Movianto; 01234 248631 - product code 900320). **NB.** The denosumab prefilled syringe must be kept in its outer carton, in order to protect from light, and stored in a refrigerator. Alternatively, if the patient will need to collect their prescription from the pharmacy ensure an FP10 is written.
- Report any adverse events to the MHRA and discuss with a specialist if action is uncertain.
- Refer patient to secondary care for review on completion of the treatment course at 5 years or sooner if any concerns.