ESCA: Denosumab for the treatment of osteoporosis in postmenopausal women.

Specialist details Name Tel:	Patient identifier

This effective shared care agreement (ESCA) sets out details for the sharing of care for patients given subcutaneous denosumab. It should be read in conjunction with the Summary of Products Characteristics (SPC; datasheet).
The purpose of this document is to assist the provision of denosumab. Initiation of treatment should be the responsibility of a specialist, or a general practitioner who has a specialist interest. Once the patient is stabilised on treatment, it is then appropriate for GP's without a special interest to prescribe this drug over the longer term within the guidance of an ESCA. This document sets out the responsibilities of the hospital and the General Practitioner in the provision of shared care.

Areas of care for which the hospital will be responsible
1 Assess patient suitability for denosumab in line with NICE TA 204.
2 Discuss the potential risks, benefits and side effects of treatment with the patient, and advise of shared care process
3 Arrange for appropriate haematology/biochemistry.
4 Initiate the first dose of treatment with denosumab if not contraindicated.
5 Confirm that the GP is willing to participate in shared care.
6 Advise the GP on when to stop treatment, or consult with the specialist.
7 Report adverse events to the CSM, MHRA and GP.
8 Ensure that clear backup arrangements exist for GPs to obtain advice and support.

Areas of care for which the GP will be responsible
1. Reply to the request for shared care as soon as practicable.
2 Prescribe and administer the second and subsequent treatment with denosumab at the dose recommended.
3 Ensure practice system is set up to recall patient after six month interval
4 Report to and seek advice from the specialist on any aspect of patient care that is of concern to the GP and may affect treatment
5 Refer back to specialist if the patient's condition deteriorates, as advised.
6 Stop treatment on the advice of the specialist or immediately if an urgent need to stop treatment arises.
7 Report adverse events to the specialist and CSM and MHRA.

Patients' Role
1 Report to the specialist or GP if she does not have a clear understanding of the treatment.
2 Attend as arranged for the administration of the injection
3 Adhere to any calcium and vitamin D supplementation
4 Share any concerns in relation to treatment with denosumab.
5 Inform specialist or GP of any other medication being taken, including over-the-counter products.
6 Report any other adverse effects or warning symptoms to the specialist or GP whilst receiving denosumab.

Therapeutic Uses and Licensed indications
Treatment of osteoporosis in postmenopausal women at increased risk of fractures.

Posology and Administration
The recommended dose of denosumab is 60mg administered as a single subcutaneous injection once every 6 months into the thigh, abdomen or back of arm.
Patients must be adequately supplemented with calcium and vitamin D.
No dose adjustment is needed in patients with renal impairment
The safety and efficacy of denosumab has not been studied in patients with hepatic impairment
No dose adjustment is required in elderly patients.

Adverse effects, precautions and contraindications
Side Effects

Infections	Common	Urinary tract infection
	Common	Upper respiratory tract infection
	Uncommon	Diverticulitis[1]
	Uncommon	Cellulitis[1]
	Uncommon	Ear infection
Metabolism and nutrition disorders	Very rare	Hypocalcaemia[1]
Nervous system disorders	Common	Sciatica
Eye disorders	Common	Cataracts[1]
Gastrointestinal disorders	Common	Constipation
Skin and subcutaneous tissue disorders	Common	Rash
	Uncommon	Eczema
Musculoskeletal and connective tissue disorders	Common	Pain in extremity

The following convention has been used for the classification of the adverse reactions reported in these phase II and III clinical studies - very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to < 1/1,000) and very rare (< 1/10,000) based on 1-year event rates. Within each frequency grouping and system organ class, undesirable effects are presented in order of decreasing seriousness.

Precautions for use

Calcium & Vitamin D Supplementation Adequate intake of calcium and vitamin D is important in all patients.

Hypocalcaemia Hypocalcaemia must be corrected before initiating therapy. Patients with severe renal function or receiving dialysis are at greater risk of developing hypocalcaemia. Clinical monitoring of calcium levels is recommended for patients predisposed to hypocalcaemia. A blood test every six months two weeks prior to treatment is good practice.

Skin Infections Patients should seek prompt medical attention if they develop signs or symptoms of cellulitis.

Osteonecrosis of the Jaw (ONJ) ONJ has been reported in patients receiving denosumab. A dental examination with appropriate preventive dentistry should be considered before commencement of treatment. Good oral hygiene measures should be maintained during treatment.

Allergy The needle cover of the pre-filled syringe contains dry natural rubber (a latex derivative).

Contraindications and cautions for use

Denosumab is contraindicated in patients with hypersensitivity to the active substance or to any of the excipients.

Denosumab is contraindicated in patients with hypocalcaemia.

Drug and Other forms of Interaction

Drug Interactions

There is a low potential for drug-drug interactions.

Presentations

Prolia®▼ 60 mg solution for injection in a pre-filled syringe. Store in a refrigerator (2°C – 8°C). Do not freeze. Keep the pre-filled syringe in the outer carton in order to protect from light. Do not shake excessively.

References

NHS Wolverhampton – Denosumab ESCA – 2011.
Summary of Product Characteristics. http://www.medicines.org.uk.
Keele Medicines Management ESCA toolkit. http://www.esca-keele.co.uk/denosumab.

Contacts

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