

Statement of Advice:

denosumab (Prolia[®]) 60 mg solution for injection in a pre-filled syringe (No: 1013/14) Amgen Ltd

10 October 2014

ADVICE: in the absence of a submission from the holder of the marketing authorisation

denosumab (Prolia[®]) is not recommended for use within NHS Scotland.

Indication under review: osteoporosis in men at increased risk of fractures

The holder of the marketing authorisation has not made a submission to SMC regarding this product in this indication. As a result we cannot recommend its use within NHSScotland.

NICE (National Institute for Health and Clinical Excellence) is currently undertaking a multiple technology appraisal (MTA) that includes the use of denosumab in this indication. However, due to the significant time interval between product availability and the expected date of NICE guidance, not recommended advice has been issued.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

**Chairman,
Scottish Medicines Consortium**