



National Institute for Health and Clinical Excellence

Tel: 0845 003 7782
www.nice.org.uk

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PRESS RELEASE

NICE recommends new treatment option for women at increased risk of osteoporotic fractures

NICE today (27 October) recommends denosumab (Prolia) as a treatment option for certain postmenopausal women¹ who are at increased risk of primary and secondary osteoporotic fractures if other treatments available on the NHS are unsuitable.

NICE currently recommends a range of treatment options for reducing the risk of postmenopausal women suffering either a first osteoporotic fracture or a further fracture. Most women are prescribed alendronate in the first instance before being prescribed risedronate or etidronate, but for some, these drugs (classed as oral bisphosphonates) may be unsuitable. For example, some postmenopausal women may not be able to comply with the special instructions for administration of oral bisphosphonates, or they may have a contraindication to, or intolerance of, oral bisphosphonates. For certain women at increased risk of fractures who can't take alendronate, nor either risedronate or etidronate, denosumab is now one of the possible treatment options.

Dr Carole Longson, Health Technology Evaluation Centre Director at NICE said:

“We are pleased to be able to recommend denosumab to help prevent osteoporotic fractures in postmenopausal women at increased risk of fracture who are unable to take oral bisphosphonates. Denosumab joins the range of treatments that NICE has already advised should be available on the NHS, to help stop a fracture from occurring in the first place, or to help women who have previously had a fracture. This new guidance is good news for postmenopausal women at increased risk of

¹Defined for primary prevention by a combination of low bone mineral density, age and a number of other clinical risk factors such as parental history of hip fracture, high alcohol intake and rheumatoid arthritis.

fracture as it means that they now have a further treatment option to help them avoid suffering an osteoporotic fracture.”

ENDS

Notes to Editors:

About the guidance

1. The guidance is available at <http://guidance.nice.org.uk/TA204> from Wednesday 27 October 2010.
2. Denosumab (Prolia, Amgen) is a monoclonal antibody that reduces osteoclast activity, and so reduces bone breakdown. Denosumab has a UK marketing authorisation for the treatment of osteoporosis in postmenopausal women at increased risk of fractures.
3. The guidance recommendations are:
 - i. 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-score², age and number of independent clinical risk factors for fracture (see section 1.3) as indicated in the following table.

T-scores (SD) at (or below) which denosumab is recommended when alendronate and either risedronate or etidronate are unsuitable

Age (years)	Number of independent clinical risk factors for fracture		
	0	1	2
65–69	– ^a	–4.5	–4.0
70–74	–4.5	–4.0	–3.5
75 or older	–4.0	–4.0	–3.0

^a Treatment with denosumab is not recommended.

- ii. 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.
- iii. For the purposes of this guidance, independent clinical risk factors for fracture are parental history of hip fracture, alcohol intake of 4 or more units per day, and rheumatoid arthritis.
- iv. People currently receiving denosumab for the primary or secondary prevention of osteoporotic fragility fractures who do not meet the criteria specified in

² T-score measures bone mineral density using central (hip and/or spine) double-energy X-ray (DXA) scanning, and is expressed as the number of standard deviations (SD) below peak bone mineral density.

recommendations i or ii should have the option to continue treatment until they and their clinician consider it appropriate to stop.

4. Denosumab is administered as a single subcutaneous injection into the thigh, abdomen or the back of the arm. The recommended dosage is 60mg once every six months. Each dose costs £183, which means that the annual cost of treatment with denosumab is £366. Costs may vary in different settings because of negotiated procurement discounts.
5. Further NICE guidance on primary and secondary prevention of osteoporotic fractures is at www.nice.org.uk/TA160 and www.nice.org.uk/TA161.

About NICE

6. The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance and standards on the promotion of good health and the prevention and treatment of ill health.
7. NICE produces guidance in three areas of health:
 - **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
 - **health technologies** – guidance on the use of new and existing medicines, treatments, medical technologies (including devices and diagnostics) and procedures within the NHS
 - **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.
8. NICE produces standards for patient care:
 - **quality standards** – these reflect the very best in high quality patient care, to help healthcare practitioners and commissioners of care deliver excellent services
 - **Quality and Outcomes Framework** – NICE develops the clinical and health improvement indicators in the QOF, the Department of Health scheme which rewards GPs for how well they care for patients.
9. NICE provides advice and support on putting NICE guidance and standards into practice through its **implementation programme**, and it collates and accredits high quality health guidance, research and information to help health professionals deliver the best patient care through **NHS Evidence**.