NHS National Institute for Health and Clinical Excellence

Quick reference guide

Denosumab for the prevention of osteoporotic fractures in postmenopausal women

Guidance

- 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-score¹, age and number of independent clinical risk factors for fracture (see section 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

| | Number of independent clinical risk factors for fracture | | |
|-------------|--|------|------|
| Age (years) | 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 |

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

- 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.
- 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.
- People currently receiving denosumab for the primary or secondary prevention of osteoporotic fragility fractures who do not meet the criteria specified in recommendations 1 or 2 should have the option to continue treatment until they and their clinician consider it appropriate to stop.

Implementation tools

NICE has developed tools to help organisations put this guidance into practice (listed below). These are available on our website (**www.nice.org.uk/guidance/TA204**).

- A costing statement explaining the resource impact of this guidance.
- Audit support for monitoring local practice.



^a Treatment with denosumab is not recommended.

Further information

Ordering information

You can download the following documents from www.nice.org.uk/quidance/TA204

- A quick reference guide (this document) the recommendations.
- 'Understanding NICE guidance' a summary for patients and carers.
- The NICE guidance.
- Details of all the evidence that was looked at and other background information.

For printed copies of the quick reference guide or 'Understanding NICE guidance', phone NICE publications on 0845 003 7783 or email publications@nice.org.uk and quote:

- N2338 (guick reference guide)
- N2339 ('Understanding NICE guidance').

Related NICE guidance

For information about NICE guidance that has been issued or is in development, see **www.nice.org.uk**

Published

- Alendronate, etidronate, risedronate, raloxifene and strontium ranelate for the primary prevention of osteoporotic fragility fractures in postmenopausal women (amended). NICE technology appraisal guidance 160 (2008; amended 2010). Available from www.nice.org.uk/guidance/TA160
- Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women (amended). NICE technology appraisal guidance 161 (2008; amended 2010).
 Available from www.nice.org.uk/guidance/TA161

Updating the appraisal

This technology appraisal will be considered for review at the same time that NICE technology appraisal guidance 160 and 161 (2008; amended 2010) are considered for review. Information about the progress of a review will be available at www.nice.org.uk/guidance/TA204

This guidance represents the view of NICE, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. However, the guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

© National Institute for Health and Clinical Excellence, 2010. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the express written permission of NICE.