

Quick reference guide

Alendronate, etidronate, risedronate, raloxifene, strontium ranelate and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women

NOTE: This guidance replaces NICE technology appraisal guidance 87 issued in January 2005.

The review and re-appraisal of alendronate, etidronate, risedronate, raloxifene and teriparatide for secondary prevention of osteoporotic fragility fractures has resulted in changes in the criteria for offering these drugs. In addition, strontium ranelate has also been appraised.

Guidance

This guidance relates only to treatments for the secondary prevention of fragility fractures in postmenopausal women who have osteoporosis and have sustained a clinically apparent osteoporotic fragility fracture. Osteoporosis is defined by a T-score¹ of -2.5 standard deviations (SD) or lower on dual-energy X-ray absorptiometry (DXA) scanning. However, the diagnosis may be assumed in women aged 75 years or older if the responsible clinician considers a DXA scan to be clinically inappropriate or unfeasible.

This guidance assumes that women who receive treatment have an adequate calcium intake and are vitamin D replete. Unless clinicians are confident that women who receive treatment meet these criteria, calcium and/or vitamin D supplementation should be considered.

NICE is developing a clinical guideline on 'Osteoporosis: assessment of fracture risk and the prevention of osteoporotic fractures in individuals at high risk' (see www.nice.org.uk). This technology appraisal guidance should be read in the context of the clinical guideline when it is available.

This guidance does **not** cover the following:

- The use of alendronate, etidronate, risedronate, raloxifene, strontium ranelate or teriparatide for the secondary prevention of osteoporotic fragility fractures in women with normal bone mineral density (BMD) or osteopenia (that is, women with a T-score between -1 and -2.5 SD below peak BMD).
- The use of these drugs for the secondary prevention of osteoporotic fragility fractures in women who are on long-term systemic corticosteroid treatment.

These groups will be covered within future guidance produced by the Institute.

¹ T-score relates to the measurement of bone mineral density (BMD) using central (hip and/or spine) DXA scanning and is expressed as the number of standard deviations (SD) from peak BMD.

NICE technology appraisal guidance 161

The guidance was developed using the NICE multiple technology appraisal process.

NICE technology appraisal guidance is about the use of new and existing medicines and treatments in the NHS in England and Wales.

1 Alendronate is recommended as a treatment option for the secondary prevention of osteoporotic fragility fractures in postmenopausal women who are confirmed to have osteoporosis (that is, a T-score of -2.5 SD or below). In women aged 75 years or older, a DXA scan may not be required if the responsible clinician considers it to be clinically inappropriate or unfeasible.

When the decision has been made to initiate treatment with alendronate, the preparation prescribed should be chosen on the basis of the lowest acquisition cost available.

2 Risedronate and etidronate are recommended as alternative treatment options for the secondary prevention of osteoporotic fragility fractures in postmenopausal women:

- who are unable to comply with the special instructions for the administration of alendronate, or have a contraindication to or are intolerant of alendronate (as defined in section 6) **and**
- who also have a combination of T-score, age and number of independent clinical risk factors for fracture (see section 5) as indicated in the following table.

T-scores (SD) at (or below) which risedronate or etidronate is recommended when alendronate cannot be taken

Number of independent clinical risk factors for fracture (section 5)			
Age (years)	0	1	2
50–54	– ^a	– 3.0	– 2.5
55–59	– 3.0	– 3.0	– 2.5
60–64	– 3.0	– 3.0	– 2.5
65–69	– 3.0	– 2.5	– 2.5
70 or older	– 2.5	– 2.5	– 2.5

^a Treatment with risedronate or etidronate is not recommended.

If a woman aged 75 years or older has not previously had her BMD measured, a DXA scan may not be required if the responsible clinician considers it to be clinically inappropriate or unfeasible.

In deciding between risedronate and etidronate, clinicians and patients need to balance the overall proven effectiveness profile of the drugs against their tolerability and adverse effects in individual patients.

3 Strontium ranelate and raloxifene are recommended as alternative treatment options for the secondary prevention of osteoporotic fragility fractures in postmenopausal women:

- who are unable to comply with the special instructions for the administration of alendronate and either risedronate or etidronate, or have a contraindication to or are intolerant of alendronate and either risedronate or etidronate (as defined in section 6) **and**
- who also have a combination of T-score, age and number of independent clinical risk factors for fracture (see section 5) as indicated in the following table.

T-scores (SD) at (or below) which strontium ranelate or raloxifene is recommended when alendronate and either risedronate or etidronate cannot be taken

Number of independent clinical risk factors for fracture (section 5)			
Age (years)	0	1	2
50–54	– ^a	– 3.5	– 3.5
55–59	– 4.0	– 3.5	– 3.5
60–64	– 4.0	– 3.5	– 3.5
65–69	– 4.0	– 3.5	– 3.0
70–74	– 3.0	– 3.0	– 2.5
75 or older	– 3.0	– 2.5	– 2.5

^a Treatment with raloxifene or strontium ranelate is not recommended.

If a woman aged 75 years or older who has one or more independent clinical risk factors for fracture or indicators of low BMD has not previously had her BMD measured, a DXA scan may not be required if the responsible clinician considers it to be clinically inappropriate or unfeasible.

For the purposes of this guidance, indicators of low BMD are low body mass index (defined as less than 22 kg/m^2), medical conditions such as ankylosing spondylitis, Crohn’s disease, conditions that result in prolonged immobility, and untreated premature menopause².

In deciding between strontium ranelate and raloxifene, clinicians and patients need to balance the overall proven effectiveness profile of these drugs against their tolerability and other effects in individual patients.

² Rheumatoid arthritis is also a medical condition indicative of low BMD.

- 4 Teriparatide is recommended as an alternative treatment option for the secondary prevention of osteoporotic fragility fractures in postmenopausal women:
- who are unable to take alendronate and either risedronate or etidronate, or have a contraindication to or are intolerant of alendronate and either risedronate or etidronate (as defined in section 6), **or** who have a contraindication to, or are intolerant of strontium ranelate (as defined in section 7), **or** who have had an unsatisfactory response (as defined in section 8) to treatment with alendronate, risedronate or etidronate **and**
 - who are 65 years or older and have a T-score of -4.0 SD or below, or a T-score of -3.5 SD or below plus more than two fractures, **or** who are aged 55–64 years and have a T-score of -4 SD or below plus more than two fractures.
- 5 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.
- 6 For the purposes of this guidance, intolerance of alendronate, risedronate or etidronate is defined as persistent upper gastrointestinal disturbance that is sufficiently severe to warrant discontinuation of treatment, and that occurs even though the instructions for administration have been followed correctly.
- 7 For the purposes of this guidance, intolerance of strontium ranelate is defined as persistent nausea or diarrhoea, either of which warrants discontinuation of treatment.
- 8 For the purposes of this guidance, an unsatisfactory response is defined as occurring when a woman has another fragility fracture despite adhering fully to treatment for 1 year and there is evidence of a decline in BMD below her pre-treatment baseline.
- 9 Women who are currently receiving treatment with one of the drugs covered by this guidance, but for whom treatment would not have been recommended according to sections 1 to 4, should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

Implementation tools

NICE has developed tools to help organisations implement this guidance (listed below). These are available on our website (www.nice.org.uk/TA161).

- Slides highlighting key messages for local discussion.
- Costing report and costing template to estimate the savings and costs associated with implementation.
- Audit support for monitoring local practice.

Further information

Ordering information

You can download the following documents from www.nice.org.uk/TA161

- A quick reference guide (this document) – a summary of recommendations for healthcare professionals.
- 'Understanding NICE guidance' – information for patients and carers.
- The full 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:

- N1725 (quick reference guide)
- N1726 ('Understanding NICE guidance').

Related NICE guidance

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

Published

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

Under development

- Osteoporosis: assessment of fracture risk and the prevention of osteoporotic fractures in individuals at high risk. NICE clinical guideline (publication date to be confirmed).

Updating the appraisal

This technology appraisal will be considered for review in July 2010. Information about the progress of a review will be posted on the NICE website (www.nice.org.uk/TA161).

This guidance represents the view of the Institute, 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. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in 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.

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