NICE National Institute for Health and Care Excellence

NICE Pathways

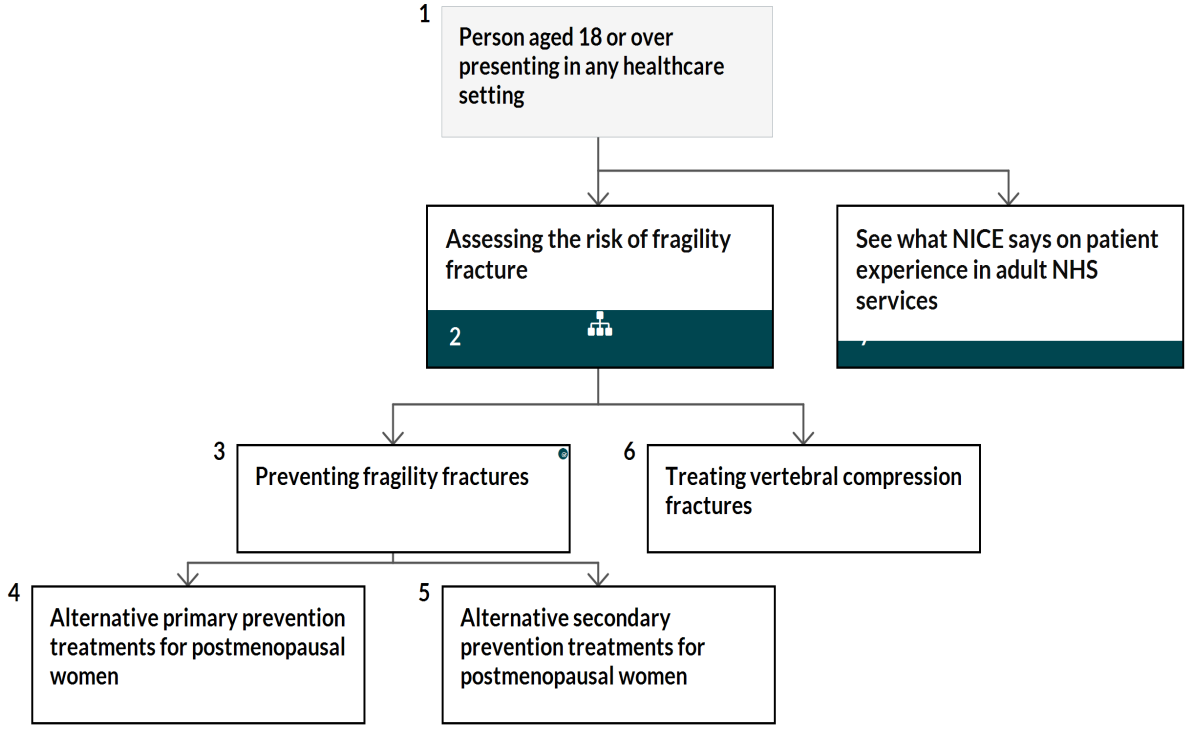
Osteoporosis overview

NICE Pathways bring together everything NICE says on a topic in an interactive flowchart. NICE Pathways are interactive and designed to be used online.

They are updated regularly as new NICE guidance is published. To view the latest version of this NICE Pathway see:

http://pathways.nice.org.uk/pathways/osteoporosis
NICE Pathway last updated: 20 August 2019

This document contains a single flowchart and uses numbering to link the boxes to the associated recommendations.



1 Person aged 18 or over presenting in any healthcare setting

No additional information

2 Assessing the risk of fragility fracture

See Osteoporosis / Osteoporosis: assessing the risk of fragility fracture

3 Preventing fragility fractures

Bisphosphonates

The following recommendations are from NICE technology appraisal guidance on bisphosphonates for treating osteoporosis.

The purpose of this technology appraisal was to establish at what level of absolute fracture risk bisphosphonates are cost-effective. Please note that because of the reduction in prices for oral bisphosphonates over the last few years, the absolute risk level at which these drugs are cost-effective is now very low. The absolute risk level at which oral bisphosphonates are recommended as treatment options in this guidance are therefore not clinical intervention thresholds.

In February 2018, NICE issued a clarification statement on implementation of this appraisal.

Oral bisphosphonates (alendronic acid, ibandronic acid and risedronate sodium) are recommended as options for treating osteoporosis in adults only if:

- the person is eligible for risk assessment as defined in when to assess a person depending on age and sex and
- the 10-year probability of osteoporotic fragility fracture is at least 1%.

Intravenous bisphosphonates (ibandronic acid and zoledronic acid) are recommended as options for treating osteoporosis in adults only if:

- the person is eligible for risk assessment as defined in when to assess a person depending on age and sex and
- the 10-year probability of osteoporotic fragility fracture is at least 10% or
- the 10-year probability of osteoporotic fragility fracture is at least 1% and the person has

- difficulty taking oral bisphosphonates (alendronic acid, ibandronic acid or risedronate sodium) or these drugs are contraindicated or not tolerated.

Estimate the 10-year probability of fragility fracture using the FRAX or QFracture risk tools, in line with recommendations on estimating absolute risk.

The choice of treatment should be made on an individual basis after discussion between the responsible clinician and the patient, or their carers, about the advantages and disadvantages of the treatments available. If several generic products are available, start treatment with the least expensive formulation, taking into account administration costs, the dose needed and the cost per dose.

These recommendations are not intended to affect treatment with alendronic acid, ibandronic acid, risedronate sodium and zoledronic acid that was started in the NHS before this guidance was published. Adults having treatment outside these recommendations may continue without change to the funding arrangements in place for them before this guidance was published, until they and their NHS clinician consider it appropriate to stop.

See why we made the recommendations on bisphosphonates [See page 12].

NICE has published information for the public on bisphosphonates.

Discuss stopping bisphosphonate treatment after 3 years

Tell a person who has been taking bisphosphonate for osteoporosis for at least 3 years that there is no consistent evidence of:

- further benefit from continuing bisphosphonate for another 3 years
- harms from stopping bisphosphonate after 3 years of treatment.

Discuss stopping bisphosphonate after 3 years and include patient choice, fracture risk and life expectancy in the discussion.

Quality standards

The following quality statements are relevant to this part of the interactive flowchart.

2. Starting drug treatment

3. Adverse effects and adherence to treatment

4. Long-term follow-up

4 Alternative primary prevention treatments for postmenopausal women

Denosumab

The following recommendations are an extract from NICE technology appraisal guidance on denosumab for the prevention of osteoporotic fractures in postmenopausal women.

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-score, age and number of independent clinical risk factors for fracture (see below) 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
[a] Treatment with denosumab is not recommended.			

Independent clinical risk factors

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.

Women currently receiving treatment

Women currently receiving denosumab for the primary prevention of osteoporotic fragility fractures who do not meet the criteria specified above should have the option to continue treatment until they and their clinician consider it appropriate to stop.

NICE has written information for the public on denosumab.

Raloxifene

The following recommendations are from NICE technology appraisal guidance on raloxifene for the primary prevention of osteoporotic fragility fractures in postmenopausal women.

Raloxifene is not recommended as a treatment option for the primary prevention of osteoporotic fragility fractures in postmenopausal women.

This guidance relates only to treatments for the primary prevention of fragility fractures in postmenopausal women who have osteoporosis. Osteoporosis is defined by a T-score of −2.5 SD or below on 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.

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

- The treatment of women who have sustained a clinically apparent osteoporotic fragility fracture (for recommendations for the treatment of women with a prior osteoporotic fragility fracture, see alternative secondary prevention treatments for postmenopausal women [See page 7]).
- The use of raloxifene for the primary prevention of osteoporotic fragility fractures in women with normal BMD or osteopenia (that is, women with a T-score between −1 and −2.5 SD below peak BMD).
- The use of this drug for the primary prevention of osteoporotic fragility fractures in women

- who are on long-term systemic corticosteroid treatment.

Independent clinical risk factors

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.

Primary prevention

For the purposes of this guidance, primary prevention refers to opportunistic identification, during visits to a healthcare professional for any reason, of postmenopausal women who are at risk of osteoporotic fragility fractures and who could benefit from drug treatment. It does not imply a dedicated screening programme.

Women currently receiving treatment

Women who are currently receiving treatment but for whom treatment would not have been recommended according to this guidance, should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

For further information, see what NICE says on medicines optimisation.

5 Alternative secondary prevention treatments for postmenopausal women

Raloxifene and teriparatide

The following recommendations are from NICE technology appraisal guidance on raloxifene and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women.

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-score of –2.5 SD or below on 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.

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

- The use of raloxifene or teriparatide for the secondary prevention of osteoporotic fragility fractures in women with normal 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.

Raloxifene is recommended as an alternative treatment option 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 risedronate, or have a contraindication to or are intolerant of alendronate and either risedronate (as defined in intolerance below) **and**
- who also have a combination of T-score, age and number of independent clinical risk factors for fracture (see independent clinical risk factors below) as indicated in the following table.

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

	Number of independent clinical risk factors for fracture		
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 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 menopause. Rheumatoid arthritis is also a medical condition indicative of low BMD.

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 risedronate, or have a contraindication to or are intolerant of alendronate and either risedronate or etidronate (as defined in intolerance below), **or** who have had an unsatisfactory response (as defined in unsatisfactory response below) to treatment with alendronate or risedronate **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.

Independent clinical risk factors

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.

Intolerance

For the purposes of this guidance, intolerance of alendronate or risedronate 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.

Unsatisfactory response

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.

Women currently receiving treatment

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 this guidance, should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

Denosumab

The following recommendations are an extract from NICE technology appraisal guidance on denosumab for the prevention of osteoporotic fractures in postmenopausal women.

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.

Women currently receiving denosumab for the secondary prevention of osteoporotic fragility fractures who do not meet the criteria specified should have the option to continue treatment until they and their clinician consider it appropriate to stop.

NICE has written information for the public on denosumab.

For further information, see what NICE says on medicines optimisation.

6 Treating vertebral compression fractures

The following recommendations are from NICE technology appraisal guidance on percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures.

Percutaneous vertebroplasty, and percutaneous balloon kyphoplasty without stenting, are

recommended as options for treating osteoporotic vertebral compression fractures only in people:

- who have severe ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management **and**
- in whom the pain has been confirmed to be at the level of the fracture by physical examination and imaging.

NICE has written information for the public on percutaneous vertebroplasty and percutaneous balloon kyphoplasty.

7 See what NICE says on patient experience in adult NHS services

See Patient experience in adult NHS services

Why we made the recommendations on bisphosphonates

Alendronic acid, ibandronic acid, risedronate sodium and zoledronic acid are bisphosphonates, licensed for treating osteoporosis. Currently clinicians offer bisphosphonates to people with osteoporosis who are eligible for risk assessment and who have a high fracture risk.

To simplify the criteria for treatment and bring the guidance into line with NICE's guideline on osteoporosis (NICE guideline CG146), the evidence on bisphosphonates has been reviewed. A new network meta-analysis confirms that bisphosphonates are more effective at reducing the risk of fracture than placebo.

Risk assessment tools are used in clinical practice (FRAX and QFracture), in line with NICE's guideline on osteoporosis. These tools measure risk differently and can give different levels of risk in the same person.

Oral bisphosphonates are recommended because new analyses show they are cost effective for people with at least a 1% risk of osteoporotic fragility fracture, irrespective of the assessment tool used. Similarly, intravenous bisphosphonates are recommended because they are cost effective for people with at least a 10% risk of osteoporotic fragility fracture, irrespective of the risk assessment tool used.

For some people with a 1% risk of osteoporotic fragility fracture, oral bisphosphonates may be contraindicated or not tolerated, or taking them might be difficult or impossible. For these people intravenous bisphosphonates are recommended.

For more information see the committee discussion in the NICE technology appraisal on bisphosphonates for treating osteoporosis.

Glossary

BMD

bone mineral density

DXA

dual-energy X-ray absorptiometry

Intervention threshold

the level of risk at which an intervention is recommended; people whose risk is in the region from just below to just above the threshold may be reclassified if BMD is added to assessment (it was out of the scope of the osteoporosis: fragility fracture risk clinical guideline to recommend intervention thresholds; healthcare professionals should follow local protocols or other national guidelines for advice on intervention thresholds)

SD

standard deviations

T-score

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

Sources

Multimorbidity: clinical assessment and management (2016) NICE guideline NG56

Bisphosphonates for treating osteoporosis (2017 updated 2018) NICE technology appraisal guidance 464

Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures (2013) NICE technology appraisal guidance 279

Denosumab for the prevention of osteoporotic fractures in postmenopausal women (2010) NICE technology appraisal guidance 204

Raloxifene and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women (2011 updated 2018) NICE technology appraisal guidance 161

Raloxifene for the primary prevention of osteoporotic fragility fractures in postmenopausal women (2011 updated 2018) NICE technology appraisal guidance 160

Your responsibility

Guidelines

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Technology appraisals

The recommendations in this interactive flowchart represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, health professionals are expected to take these recommendations fully into account, alongside the individual needs, preferences and values of their patients. The application of the recommendations in this interactive flowchart is at the discretion of health professionals and their individual patients and do not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

Commissioners and/or providers have a responsibility to provide the funding required to enable the recommendations to be applied when individual health professionals and their patients wish to use it, in accordance with the NHS Constitution. They should do so in light of their duties to

have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Medical technologies guidance, diagnostics guidance and interventional procedures guidance

The recommendations in this interactive flowchart represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take these recommendations fully into account. However, the interactive flowchart 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.

Commissioners and/or providers have a responsibility to implement the recommendations, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this interactive flowchart should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.