

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Guideline scope

### Osteoporosis: risk assessment, treatment and prevention of fragility fractures (update)

This guideline will update and replace the NICE guideline on assessing the risk of fragility fracture in osteoporosis (CG146).

The guideline will be developed using the methods and processes outlined in [developing NICE guidelines: the manual](#).

This guideline will also be used to update the [NICE quality standard for osteoporosis](#).

## 1 Why the guideline is needed

Osteoporosis is a condition that reduces bone strength and increases the risk of fractures. It causes 500,000 fractures a year in the UK, at an estimated cost to the NHS of £4.5 billion.

Fractures associated with osteoporosis, often described as 'fragility' fractures. They are typically caused by low impact injuries that would not normally cause a fracture (such as a fall from standing height). Fragility fractures can occur spontaneously, in people with no history of injury. Most vertebral fragility fractures are not caused by falls, instead happening after activities involving lifting, twisting or bending.

Fragility fractures most commonly affect the vertebral body, hip, proximal humerus and distal forearm. However, fragility fractures can happen in any bone, and some fractures (for example pelvis and rib fractures) are just as

strongly associated with reduced bone strength as the most common fragility fractures.

Traditionally, osteoporosis has been diagnosed based on bone mineral density measurements. However, bone mineral density is just one of many factors that influence bone strength and fracture risk, and most fragility fractures occur in people with bone mineral density higher than the standard threshold. Independent factors also need to be considered, such as age, previous fragility fracture, use of glucocorticoids, and parental history of hip fracture.

Fracture risk is assessed using risk factor assessment tools, which estimate fracture risk based on a person's individual risk profile. There are a variety of different tools, each with different potential benefits and limitations.

An additional challenge is re-assessing risk for people who are taking treatment to protect their bone health, or who have risk factors for accelerated bone loss. Re-assessment can improve adherence to treatment, and help inform decisions to stop, continue or switch treatment.

There are a range of treatments that effectively reduce fracture risk. However, many people with previous fragility fractures or known risk factors do not receive appropriate assessment and treatment. Better assessment would help people to make informed decisions about treatments to reduce fracture risk, and reduce the costs associated with osteoporosis.

This guideline update is needed to take account of new research on how to target and conduct risk assessment. In addition, the current guideline only covers risk assessment, and the update will also cover treatment to reduce primary and secondary fracture risk.

## **2 Who the guideline is for**

This guideline is for:

- Health and social care professionals providing NHS-commissioned services

- Commissioners of health and social care services
- People using services, their families and carers and the public.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the [Welsh Government](#), [Scottish Government](#), and [Northern Ireland Executive](#).

### ***Equality considerations***

NICE has carried out [an equality impact assessment](#) during scoping. The assessment:

- lists equality issues identified, and how they have been addressed
- explains why any groups are excluded from the scope.

The guideline will look at inequalities relating to age, disability, pregnancy and maternity, race and sex.

## **3 What the guideline will cover**

### ***3.1 Who is the focus?***

#### **Groups that will be covered**

Adults (18 years and older)

### ***3.2 Settings***

#### **Settings that will be covered**

All settings where NHS-funded care or social care is provided or commissioned.

### ***3.3 Activities, services or aspects of care***

#### **Key areas that will be covered**

We will look at evidence in the areas below when developing the guideline, but it may not be possible to make recommendations in all the areas.

- 1 Information and support needs for adults with suspected or known risk of fragility fracture and their families and carers.
- 2 Identifying adults who should be assessed for fragility fracture risk
  - risk factors for fragility fracture
  - use of electronic health and social care records (including GP practice lists).
- 3 Methods of risk assessment
  - bone density assessment
  - risk prediction tools, including FRAX (with or without trabecular bone score) and QFracture.
- 4 Identifying vertebral fragility fractures
  - use of risk prediction tools such as the vertebral fracture clinical decision tool (VFRAC)
  - imaging
  - automated imaging algorithms and computer-based diagnostics.
- 5 Treatments to reduce fracture risk
  - bisphosphonate medicines
  - non-bisphosphonate medicines (anabolic and antiresorptive therapies)
  - hormone replacement therapy - (we may cross-refer to the [NICE guideline on menopause](#) if the recommendations in that guideline are relevant)
  - exercise.
- 6 Repeat risk assessment (timing and methods) for people not receiving treatment, including
  - re-assessment of bone density
  - risk prediction tools, including FRAX and QFracture.
- 7 Treatment monitoring and review (timing and methods), including
  - re-assessment of bone density
  - bone turnover markers
  - risk prediction tools, including FRAX and QFracture
  - actions after the review
  - timing and duration of bisphosphonate treatment pauses, if needed.

Note that guideline recommendations for medicines will normally fall within licensed indications. Exceptionally, and only if clearly supported by evidence, use outside a licensed indication may be recommended. The guideline will assume that prescribers will use a medicine's summary of product characteristics to inform decisions made with individual patients.

### **Areas that will not be covered**

- 1 Public health measures (other than exercise) to reduce osteoporosis and fragility fracture.
- 2 Preventing falls.
- 3 Managing fractures.

### **Related NICE guidance**

#### ***Published***

- [Hyperparathyroidism \(primary\): diagnosis, assessment and initial management](#) (2019) NICE guideline NG132
- [Prostate cancer: diagnosis and management](#) (2019, last updated 2021) NICE guideline NG131
- [Ulcerative colitis: management](#) (2019) NICE guideline NG130
- [Crohn's disease: management](#) (2019) NICE guideline NG129
- [Decision making and mental capacity](#) (2018) NICE guideline NG108
- [Eating disorders: recognition and treatment](#) (2017, last updated 2020) NICE guideline NG69
- [Parkinson's disease in adults](#) (2017) NICE guideline NG71
- [Spondyloarthritis in over 16s: diagnosis and management](#) (2017) NICE guideline NG65
- [Multimorbidity: clinical assessment and management](#) (2016) NICE guideline NG56
- [Menopause: diagnosis and management](#) (2015, last updated 2019) NICE guideline NG23

- [Coeliac disease: recognition, assessment and management](#) (2015) NICE guideline NG20
- [Hip fracture: management](#) (2011, last updated 2017) NICE guideline CG124
- [Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures](#) (2013) NICE technology appraisal guidance TA279
- [Falls in older people: assessing risk and prevention](#) (2013) NICE guideline CG161

### ***In development***

- [Hip fracture: management \(update\)](#). NICE guideline. Publication expected January 2023.
- [Falls: assessment and prevention in older people and people 50 and over at higher risk \(update\)](#). NICE guideline. Publication expected June 2024.

### ***NICE Technology Appraisals***

In reviewing the different treatment options, NICE will undertake a comparative analysis that includes the treatments listed in the following technology appraisals (TA791, TA464, TA204, TA161 and TA160). These treatments will be ordered in a care pathway.

NICE is currently exploring how to integrate existing NICE Technology Appraisals into NICE Guidelines. NICE will engage with stakeholders on decisions regarding individual TAs and any resulting implications.

- [Romosozumab for treating severe osteoporosis](#) (2022) NICE technology appraisal guidance TA791
- [Bisphosphonates for treating osteoporosis](#) (2017, last updated 2019) NICE technology appraisal guidance TA464
- [Denosumab for the prevention of osteoporotic fractures in postmenopausal women](#) (2010) NICE technology appraisal guidance TA204
- [Raloxifene and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women](#) (2008, last updated 2018) NICE technology appraisal guidance TA161

- [Raloxifene for the primary prevention of osteoporotic fragility fractures in postmenopausal women](#) (2008, last updated 2018) NICE technology appraisal guidance TA160
- [Abaloparatide for treating idiopathic or hypogonadal osteoporosis in men](#). NICE technology appraisal guidance. Publication date to be confirmed

### ***NICE guidance about the experience of people using NHS and social care services***

NICE has produced the following guidance on the experience of people using the NHS and social care. This guideline will not include additional recommendations on these topics unless there are specific issues related to Osteoporosis: assessing the risk of fragility fracture:

- [People's experience in adult social care services](#) (2018) NICE guideline NG86
- [Medicines optimisation](#) (2015) NICE guideline NG5
- [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- [Medicines adherence](#) (2009) NICE guideline CG76

### **3.4 *Economic aspects***

We will take economic aspects into account when making recommendations. We will develop an economic plan that states for each review question (or key area in the scope) whether economic considerations are relevant, and if so whether this is an area that should be prioritised for economic modelling and analysis. We will review the economic evidence and carry out economic analyses, using an NHS and personal social services (PSS) perspective, as appropriate.

### **3.5 *Key issues and draft questions***

While writing this scope, we have identified the following key issues and draft review questions related to them:

- 1 Information and support needs for adults with suspected or known risk of fragility fracture and their families and carers

- 1.1 What are the information and support needs of adults having risk assessment for fragility fractures and their families and carers?
  - 1.2 What are the information and support needs of adults who are at risk of fragility fractures or who have osteoporosis and their families and carers?
  - 1.3 What are the information and support needs of adults, and their families and carers, who are at risk of fragility fractures or who have osteoporosis and cognitive impairment, learning disabilities or autism?
- 2 Identifying adults who should be assessed for fragility fracture risk
    - 2.1 What are the indications for identifying adults who should be assessed for fragility fracture risk?
    - 2.2 How accurate are electronic health and social care records (including GP practice lists) for identifying adults who should be assessed for fragility fracture risk?
- 3 Methods of risk assessment
    - 3.1 What is the accuracy of risk assessment tools (including FRAX [with or without trabecular bone score] and QFracture) for predicting the risk of fragility fracture in adults, including those who have had a previous fragility fracture?
    - 3.2 What is the clinical and cost effectiveness of risk assessment tools (including FRAX [with or without trabecular bone score] and QFracture) for predicting the risk of fragility fracture in adults, including those who have had a previous fragility fracture?
    - 3.3 What is the accuracy of bone density assessment techniques such as DXA, DXA with trabecular bone score, DXA with VFA, ultrasound (for example Bindex) and CT scans?
    - 3.4 What is the clinical and cost effectiveness of bone density assessment techniques such as DXA, DXA with trabecular bone score, DXA with VFA, ultrasound (for example Bindex) and CT scans?
- 4 Identifying vertebral fragility fractures



- 4.1 What is the diagnostic accuracy of methods of identifying vertebral fracture, including vertebral fracture assessment (VFA) by DXA, VFRAC, spinal x-ray, MRI, CT, automated imaging algorithms and computer-based diagnostics?
- 4.2 What is the clinical and cost effectiveness of methods of identifying vertebral fracture, including vertebral fracture assessment (VFA) by DXA, VFRAC, spinal x-ray, MRI, CT, automated imaging algorithms and computer-based diagnostics?
- 5 Treatments to reduce fracture risk
- 5.1 What is the clinical and cost effectiveness of treatment for preventing fragility fractures? Treatments include:
- bisphosphonates (alendronate, ibandronate, risedronate and zoledronate)
  - non-bisphosphonates (abaloparatide, denosumab, raloxifene, romosozumab, teriparatide, and strontium ranelate)
  - hormone replacement therapy
- 5.2 What is the clinical and cost effectiveness of calcium or vitamin D in addition to other pharmacological treatments for preventing fragility fractures?
- 5.3 What is the clinical and cost effectiveness of exercise for treating osteoporosis?
- 6 Repeat risk assessment (timing and methods) for people not receiving treatment
- 6.1 What is the most clinically and cost-effective strategy for monitoring adults at risk of fragility fracture, including repeating the risk assessment and bone mineral density techniques?
- 7 Treatment monitoring and review (timing and methods)
- 7.1 What is the most clinically and cost-effective strategy for monitoring adults who are having treatment?

7.2 Which risk assessment tools (including FRAX [with or without trabecular bone score] and QFracture) are the most accurate for predicting the risk of fragility fracture in adults having treatment?

7.3 What is the most effective timing and duration of treatment pauses for adults on bisphosphonates?

See the section on [NICE Technology Appraisals](#).

The key issues and draft questions will be used to develop more detailed review questions, which guide the systematic review of the literature.

### **3.6 Main outcomes**

The main outcomes that may be considered when searching for and assessing the evidence are:

- health-related quality of life
- mortality after fracture
- fragility fracture (including hip and vertebral fractures)
- bone mineral density
- adverse effects of treatment
- adherence
- healthcare resource use, for example hospitalisation and entry into long-term residential care.

## **4 NICE quality standards**

**NICE quality standards that may need to be revised or updated when this guideline is published**

- [Osteoporosis](#) (2017) NICE quality standard QS149

## **5 Further information**

The guideline is expected to be published in January 2025.
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You can follow progress of the [guideline](#). Our website has information about how [NICE guidelines](#) are developed.

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