NICE National Institute for Health and Care Excellence

NICE quality standard

Osteoporosis

Quality standard

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www.nice.org.uk/guidance/qs149

Contents

This standard is based on CG146, CG76, NG5 and NG56.

This standard should be read in conjunction with QS143, QS86, QS16 and QS81.

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Statement 1 Adults who have had a fragility fracture or use systemic glucocorticoids or have a history of falls have an assessment of their fracture risk.

Statement 2 Adults at high risk of fragility fracture are offered drug treatment to reduce fracture risk.

Statement 3 Adults prescribed drug treatment to reduce fracture risk are asked about adverse effects and adherence to treatment at each medication review.

Statement 4 Adults having long-term bisphosphonate therapy have a review of the need for continuing treatment.

NICE has developed guidance and a quality standard on patient experience in adult NHS services (see the NICE pathway on patient experience in adult NHS services), which should be considered alongside these quality statements.

Other quality standards that should be considered when commissioning or providing osteoporosis services include:

- Menopause (2017) NICE quality standard 143
- Falls in older people (2015, updated 2017) NICE quality standard 86
- Hip fracture in adults (2012, updated 2016) NICE quality standard 16.

A full list of NICE quality standards is available from the quality standards topic library.

Quality statement 1: Assessment of fragility fracture risk

Quality statement

Adults who have had a fragility fracture or use systemic glucocorticoids or have a history of falls have an assessment of their fracture risk.

Rationale

Risk assessment of adults who may be at increased risk of a fragility fracture enables healthcare professionals to estimate their fracture risk. This can be used to consider options for prevention and treatment, which will reduce the risk of future fractures.

Quality measures

Structure

Evidence of local arrangements to ensure that adults who have had a fragility fracture, use systemic glucocorticoids or have a history of falls, have an assessment of their fracture risk.

Data source: Local data collection, for example, service specifications. The Fracture Liaison Service Database (FLS-DB) collects data on whether there is a dedicated fracture liaison service.

Process

a) Proportion of adults who have had a fragility fracture who have an assessment of their fracture risk.

Numerator – the number in the denominator who have an assessment of their fracture risk.

Denominator – the number of adults who have had a fragility fracture.

Data source: Local data collection, for example, local audit of patient records. The Quality and Outcomes Framework captures data on patients aged 50 to 74 with a record of a fragility fracture and a diagnosis of osteoporosis confirmed on dual-energy X-ray absorptiometry (DXA) scan, and aged 75 or over with a record of a fragility fracture and a diagnosis of osteoporosis. The FLS-DB collects data on people aged 50 years and over who have had a fragility fracture, including whether the risk of fracture was assessed using FRAX or Q-Fracture.

b) Proportion of adults who use systemic glucocorticoids who have an assessment of their fracture risk.

Numerator – the number in the denominator who have an assessment of their fracture risk.

Denominator – the number of adults who use systemic glucocorticoids.

Data source: Local data collection, for example, local audit of patient records.

c) Proportion of adults aged 50 and over who have a history of falls who have an assessment of their fracture risk.

Numerator – the number in the denominator who have an assessment of their fracture risk.

Denominator – the number of adults aged 50 and over who have a history of falls.

Data source: Local data collection, for example, local audit of patient records.

Outcome

Incidence of fragility fractures.

Data source:Local data collection, for example, local audit of patient records. The FLS-DB collects data on people aged 50 years and over who have had a fragility fracture.

What the quality statement means for different audiences

Service providers (general practices, secondary care services and fracture liaison services) ensure that systems are in place for adults who have had a fragility fracture, use systemic glucocorticoids or have a history of falls, to have an assessment of their fracture risk.

Healthcare professionals (GPs, specialists, specialist nurses and fracture liaison practitioners) assess fracture risk, or confirm that assessment has taken place, in adults who have had a fragility fracture, use systemic glucocorticoids or have a history of falls, to estimate their risk of fracture and determine their treatment options.

Commissioners (clinical commissioning groups and NHS England) ensure that they commission services in which adults who have had a fragility fracture, use systemic glucocorticoids or have a

history of falls, have their fracture risk assessed.

Adults who have had a fragility fracture or falls in the past, or who are taking steroid treatment have their risk of fracture assessed. Fragility fractures happen in people with fragile bones that break easily, usually older people with osteoporosis. There are treatments available to help prevent fractures in people who are at increased risk. An assessment can help to decide if treatment will reduce the chance of having a fracture.

Source guidance

Osteoporosis: assessing the risk of fragility fracture (2012) NICE guideline CG146, recommendations 1.1 and 1.2

Definitions of terms used in this quality statement

Fragility fracture

Fragility fractures are fractures that result from mechanical forces that would not ordinarily result in fracture, known as low-level (or 'low energy') trauma. The World Health Organization has quantified this as forces equivalent to a fall from a standing height or less. Fragility fractures occur most commonly in the spine (vertebrae), hip (proximal femur) and wrist (distal radius). They may also occur in the arm (humerus), pelvis, ribs and other bones.

[NICE's guideline on osteoporosis: assessing the risk of fragility fracture, introduction]

Use of systemic glucocorticoids

Adults currently using systemic glucocorticoids, or who have been using systemic glucocorticoids for more than 3 months, at a dose of prednisolone of 5 mg daily or more (or equivalent doses of other glucocorticoids).

[Expert opinion and The University of Sheffield's FRAX fracture risk assessment tool]

History of falls

One or more falls in the last 12 months. A fall is defined as an unintentional or unexpected loss of balance resulting in coming to rest on the floor, the ground, or an object below knee level. Adults aged 50 and over should have a fracture risk assessment if they have a history of falls.

[NICE's clinical knowledge summary on falls – risk assessment and NICE's guideline on osteoporosis: assessing the risk of fragility fracture, recommendations 1.1 and 1.2]

Assessment of fracture risk

An assessment of fracture risk should include estimating absolute fracture risk (for example, the predicted risk of major osteoporotic or hip fracture over 10 years, expressed as a percentage). Either FRAX (without a bone mineral density [BMD] value if a DXA scan has not previously been undertaken) or QFracture should be used within their allowed age ranges. Above the upper age limits defined by the tools, consider people to be at high risk. Measure BMD to assess fracture risk in people aged under 40 years.

[Adapted from NICE's guideline on osteoporosis: assessing the risk of fragility fracture, recommendations 1.3, 1.4 and 1.9]

Quality statement 2: Starting drug treatment

Quality statement

Adults at high risk of fragility fracture are offered drug treatment to reduce fracture risk.

Rationale

Fragility fractures can cause substantial pain and severe disability, often leading to a reduced quality of life and sometimes to decreased life expectancy. Taking drug treatment to improve bone density reduces the chance of future fractures and related problems.

Quality measures

Structure

Evidence of local arrangements to ensure that adults at high risk of fragility fracture are offered drug treatment to reduce fracture risk.

Data source: Local data collection, for example, local protocols. The Fracture Liaison Service Database (FLS-DB) collects data on which interventions can be recommended or started by the fracture liaison service.

Process

Proportion of adults at high risk of fragility fracture receiving drug treatment to reduce fracture risk.

Numerator – the number in the denominator who receive drug treatment to reduce fracture risk.

Denominator – the number of adults at high risk of fragility fracture.

Data source: Local data collection, for example, local audit of patient records. The Quality and Outcomes Framework captures data on patients aged 50 to 74 with a record of a fragility fracture and a diagnosis of osteoporosis confirmed on dual-energy X-ray absorptiometry (DXA) scan, and aged 75 or over with a record of a fragility fracture and a diagnosis of osteoporosis, who are currently treated with an appropriate bone-sparing agent. The FLS-DB collects data on people aged 50 years and over who have had a fragility fracture, and records if drug treatment to reduce fracture risk is recommended and, if so, which treatment.

Outcomes

a) Incidence of fragility fractures.

Data source:Local data collection, for example, local audit of patient records. The FLS-DB collects data on people aged 50 years and over who have had a fragility fracture.

b) Hospital admission rates for fragility fractures.

Data source:Local data collection, for example, Hospital episode statistics from NHS Digital.

What the quality statement means for different audiences

Service providers (general practices and secondary care services) ensure that systems are in place for adults at high risk of fragility fracture to be offered drug treatment to reduce fracture risk.

Healthcare professionals (GPs, specialists and specialist nurses) are aware of when to prescribe drug treatments to reduce fracture risk, and offer them to adults at high risk of fragility fracture.

Commissioners (clinical commissioning groups and NHS England) ensure that they commission services in which adults at high risk of fragility fracture are offered drug treatment to reduce fracture risk.

Adults with a high chance of fragility fracture are offered medicine to help strengthen their bones and prevent fractures.

Source guidance

- Clinical guideline for the prevention and treatment of osteoporosis (2017) National Osteoporosis Guideline Group, section 6 and section 11, recommendation 7
- Osteoporosis – prevention of fragility fractures (2016) NICE clinical knowledge summary

Definitions of terms used in this quality statement

At high risk of fragility fracture

Women with a prior fragility fracture (particularly hip or vertebral fracture) and men and women with a 10-year probability of a major osteoporotic fracture derived from FRAX, above the upper

assessment threshold, should be considered for treatment (see table 1). Men and women with a 10-year probability between the upper and lower assessment threshold should be referred for bone mineral density measurement and their fracture probability reassessed. If their 10-year fracture probability is above the intervention threshold after reassessment (see table 1), treatment should be offered.

Table 1. Lower and upper assessment thresholds and intervention thresholds for major osteoporotic fracture probability based on fracture probabilities derived from FRAX (BMI set to 25 kg/m^2)

	10-year probability of a major osteoporotic fracture (%)		
Age (years)	Lower assessment threshold	Upper assessment threshold	Intervention threshold
40	2.6	7.1	5.9
45	2.7	7.2	6.0
50	3.4	8.6	7.2
55	4.5	11	9.4
60	5.9	14	12
65	8.4	19	16
≥70	11	24	20
Reproduced with permission from McCloskey et al. (2015) FRAX-based assessment and intervention thresholds – an exploration of thresholds in women aged 50 years and older in the UK. Osteoporosis International 26 (8), 2091–9			

[Adapted from National Osteoporosis Guideline Group's Clinical guideline for the prevention and treatment of osteoporosis, section 11, recommendation 7]

Drug treatment to reduce fracture risk

Drugs that can be prescribed to prevent fragility fractures include bisphosphonates (alendronate, ibandronate, risedronate and zoledronic acid) and non-bisphosphonates (raloxifene, denosumab, teriparatide, calcitriol and hormone replacement therapy).

[Adapted from National Osteoporosis Guideline Group's Clinical guideline for the prevention and

treatment of osteoporosis, section 6]

Full details of the licensed indications for these drugs can be found in the summary of product characteristics. At the time of publication (April 2017), not all bisphosphonate and non-bisphosphonate drugs have UK marketing authorisation for preventing osteoporosis. The prescriber should follow relevant professional guidance, taking full responsibility for the decision to prescribe an unlicensed medicine. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

Equality and diversity considerations

Guidance on treatment to prevent fragility fractures has been focused on treating post-menopausal women, because of their increased risk. Clinicians should ensure that other populations who might benefit from recommended treatments are also considered.

Quality statement 3: Adverse effects and adherence to treatment

Quality statement

Adults prescribed drug treatment to reduce fracture risk are asked about adverse effects and adherence to treatment at each medication review.

Rationale

People prescribed drugs to prevent fragility fractures sometimes stop taking them because of adverse effects. Adherence to treatment, including taking their medicine by the recommended method, is needed to ensure that fracture risk is reduced effectively. Checking how well a person is managing their treatment at each medication review means that any problems can be discussed and their treatment adjusted if needed, which will improve adherence and quality of life.

Quality measures

Structure

Evidence of local arrangements to ensure that adults prescribed drug treatment to reduce fracture risk are asked about adverse effects and adherence to treatment at each medication review.

Data source: Local data collection, for example, service specifications.

Process

Proportion of medication reviews for adults prescribed drug treatment to reduce fracture risk that include a record of adverse effects and adherence to treatment.

Numerator – the number in the denominator that include a record of adverse effects and adherence to treatment.

Denominator – the number of medication reviews for adults prescribed drug treatment to reduce fracture risk.

Data source: Local data collection, for example, local audit of patient records.

Outcomes

a) Adults adhering to drug treatment to reduce fracture risk.

Data source:Local data collection, for example, local audit of patient records. The Fracture Liaison Service Database (FLS-DB) records adherence to drug treatment at 12 to 16 weeks and at 12 months.

b) Incidence of fragility fracture.

Data source:Local data collection, for example, local audit of patient records. The FLS-DB collects data on people aged 50 years and over who have had a fragility fracture.

What the quality statement means for different audiences

Service providers (general practices, secondary care services and pharmacies) ensure that systems are in place for adults prescribed drug treatment to reduce fracture risk to be asked if they have had any adverse effects and about adherence to treatment at each medication review.

Healthcare professionals (GPs, specialists, specialist nurses and pharmacists) carry out medication reviews with adults prescribed drug treatments to reduce fracture risk. At the reviews, they ask if the person has had any adverse effects and if they are taking their medicine by the recommended method and as prescribed. If any problems are raised, these should be discussed and treatment adjusted if needed, which may involve input from a specialist.

Commissioners (clinical commissioning groups and NHS England) ensure that they commission services in which adults prescribed drug treatment to reduce fracture risk are asked if they have had any adverse effects and about adherence to treatment at each medication review.

Adults taking medicine to help prevent fractures have regular medicine reviews with their doctor to check if they are having any side effects, such as heartburn or reflux, and that they are taking the medicine correctly. The review gives the chance for any problems to be discussed and treatment can be adjusted if needed to help with side effects.

Source guidance

- Osteoporosis – prevention of fragility fractures (2016) NICE clinical knowledge summary
- Medicines optimisation (2015) NICE guideline NG5, recommendations 1.4.1 and 1.4.3

- Medicines adherence (2009) NICE guideline CG76, recommendations 1.1.21 and 1.3.3

Definitions of terms used in this quality statement

Drug treatment to reduce fracture risk

Drugs that can be prescribed to prevent fragility fractures include bisphosphonates (alendronate, ibandronate, risedronate and zoledronic acid) and non-bisphosphonates (raloxifene, denosumab, teriparatide, calcitriol and hormone replacement therapy).

[Adapted from National Osteoporosis Guideline Group's Clinical guideline for the prevention and treatment of osteoporosis, section 6]

Full details of the licensed indications for these drugs can be found in the summary of product characteristics. At the time of publication (April 2017), not all bisphosphonate and non-bisphosphonate drugs have UK marketing authorisation for preventing osteoporosis. The prescriber should follow relevant professional guidance, taking full responsibility for the decision to prescribe an unlicensed medicine. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

Medication review

The review should include:

- asking about adverse effects, including upper gastrointestinal adverse effects (such as dyspepsia or reflux), symptoms of atypical fracture (including new onset hip, groin, or thigh pain), and dental problems
- asking about adherence to treatment, including following the recommended method of taking the treatment
- discussing alternative treatment options if adverse effects are unacceptable or the person has difficulty adhering to treatment.

[Expert opinion and NICE's clinical knowledge summary on osteoporosis – prevention of fragility fractures]

Quality statement 4: Long-term follow-up

Quality statement

Adults having long-term bisphosphonate therapy have a review of the need for continuing treatment.

Rationale

The optimal duration of bisphosphonate therapy is unclear and there are possible adverse effects of long-term treatment. A medication review for people having long-term bisphosphonate therapy gives the opportunity to consider whether continuing treatment is the best option, or if treatment should be changed or stopped. The response to treatment may also be evaluated to help determine whether to continue treatment.

Quality measures

Structure

a) Evidence of local arrangements to ensure that adults taking zoledronic acid for 3 years have a review of the need for continuing treatment.

Data source: Local data collection, for example, local protocols.

b) Evidence of local arrangements to ensure that adults taking alendronate, ibandronate or risedronate for 5 years have a review of the need for continuing treatment.

Data source: Local data collection, for example, local protocols.

Process

a) Proportion of adults taking zoledronic acid for 3 years who have a review of the need for continuing treatment.

Numerator – the number in the denominator who have a review of the need for continuing treatment.

Denominator – the number of adults taking zoledronic acid for 3 years.

Data source: Local data collection, for example, local audit of patient records.

b) Proportion of adults taking alendronate, ibandronate or risedronate for 5 years who have a review of the need for continuing treatment.

Numerator – the number in the denominator who have a review of the need for continuing treatment.

Denominator – the number of adults taking alendronate, ibandronate or risedronate for 5 years.

Data source: Local data collection, for example, local audit of patient records.

Outcomes

a) Patient satisfaction with long-term bisphosphonate therapy.

Data source:Local data collection, for example, patient surveys.

b) Health-related quality of life for adults having long-term bisphosphonate therapy.

Data source:Local data collection, for example, patient surveys.

What the quality statement means for different audiences

Service providers (general practices, secondary care services and pharmacies) ensure that systems are in place for adults having long-term bisphosphonate therapy to have a review of the need for continuing treatment.

Healthcare professionals (GPs, specialists, specialist nurses and pharmacists) offer adults having long-term bisphosphonate therapy a medication review to discuss the risks and benefits of continuing treatment and assess their response to treatment, if needed.

Commissioners (clinical commissioning groups and NHS England) ensure that they commission services in which adults having long-term bisphosphonate therapy have a review of the need for continuing treatment.

Adults taking a type of medicine called a bisphosphonate over a long timeto help prevent fractures have a review to discuss the risks and benefits of continuing with the treatment. They might also

have a scan to check whether their bone strength has improved to help decide whether to continue treatment.

Source guidance

- Clinical guideline for the prevention and treatment of osteoporosis (2017) National Osteoporosis Guideline Group, section 7, recommendations 1 and 6
- Multimorbidity: clinical assessment and management (2016) NICE guideline NG56, recommendation 1.6.16

Definitions of terms used in this quality statement

Long-term bisphosphonate therapy

Adults who have been taking zoledronic acid for 3 years or alendronate, ibandronate or risedronate for 5 years should have a review of the need for continuing treatment.

[National Osteoporosis Guideline Group's Clinical guideline for the prevention and treatment of osteoporosis, section 7, recommendation 6]

Review of the need for continuing treatment

Continuation of treatment is recommended for people with any of the following risk factors:

- age over 75 years
- previous hip or vertebral fracture
- one or more low trauma fractures during treatment (after poor adherence to treatment, for example less than 80% of treatment has been taken, and causes of secondary osteoporosis have been excluded)
- current treatment with oral glucocorticoids of 7.5 mg or more prednisolone/day or equivalent.

For people without risk factors, arrange a dual-energy X-ray absorptiometry (DXA) scan and consider:

- Continuing treatment if the T-score is less than -2.5, and reassessing fracture risk and bone mineral density (BMD) every 3 to 5 years.

- Stopping treatment if the T-score is greater than -2.5, and reassessing their fracture risk and BMD after 2 years.

[Adapted from NICE's clinical knowledge summary on osteoporosis – prevention of fragility fractures and National Osteoporosis Guideline Group's Clinical guideline for the prevention and treatment of osteoporosis, section 7, recommendation 4]

Update information

Minor changes since publication

July 2018: The Fracture Liaison Service Database has been added to the data sources for measures in statements 1, 2 and 3.

October 2017: Information about drug licensing for bisphosphonate and non-bisphosphonate drugs has been included in the definitions sections for statements 2 and 3.

June 2017: The definition of drug treatment to reduce fracture risk in quality statements 2 and 3 has been updated to remove reference to strontium ranelate. This change has been made in order to match the National Osteoporosis Guideline Group's Clinical guideline for the prevention and treatment of osteoporosis.

About this quality standard

NICE quality standards describe high-priority areas for quality improvement in a defined care or service area. Each standard consists of a prioritised set of specific, concise and measurable statements. NICE quality standards draw on existing NICE or NICE-accredited guidance that provides an underpinning, comprehensive set of recommendations, and are designed to support the measurement of improvement.

Information about how NICE quality standards are developed is available from the NICE website.

See quality standard advisory committees on the website for details of standing committee 4 members who advised on this quality standard. Information about the topic experts invited to join the standing members is available on the quality standard's webpage.

This quality standard has been incorporated into the NICE pathways on osteoporosis, medicines optimisation and multimorbidity.

NICE has produced a quality standard service improvement template to help providers make an initial assessment of their service compared with a selection of quality statements. This tool is updated monthly to include new quality standards.

NICE produces guidance, standards and information on commissioning and providing high-quality healthcare, social care, and public health services. We have agreements to provide certain NICE services to Wales, Scotland and Northern Ireland. Decisions on how NICE guidance and other products apply in those countries are made by ministers in the Welsh government, Scottish government, and Northern Ireland Executive. NICE guidance or other products may include references to organisations or people responsible for commissioning or providing care that may be relevant only to England.

Improving outcomes

This quality standard is expected to contribute to improvements in the following outcomes:

- health-related quality of life for people with osteoporosis
- fragility fracture incidence
- mortality rates associated with fragility fractures

- admissions associated with fragility fractures.

It is also expected to support delivery of the Department of Health's outcome frameworks:

- Adult social care outcomes framework 2015–16
- NHS outcomes framework 2016–17
- Public health outcomes framework for England, 2016–19.

Resource impact

NICE quality standards should be achievable by local services. The potential resource impact is considered by the quality standards advisory committee, drawing on resource impact work for the source guidance. Organisations are encouraged to use the resource impact products for the source guidance to help estimate local costs:

- costing report and template for the NICE guideline on osteoporosis: assessing the risk of fragility fracture
- resource impact statement for the NICE guideline on multimorbidity: clinical assessment and management.

Diversity, equality and language

During the development of this quality standard, equality issues were considered and equality assessments are available. Any specific issues identified during development of the quality statements are highlighted in each statement.

Commissioners and providers should aim to achieve the quality standard 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 quality standard should be interpreted in a way that would be inconsistent with compliance with those duties.

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Endorsing organisation

This quality standard has been endorsed by NHS England, as required by the Health and Social Care Act (2012)

Supporting organisations

Many organisations share NICE's commitment to quality improvement using evidence-based guidance. The following supporting organisations have recognised the benefit of the quality standard in improving care for patients, carers, service users and members of the public. They have agreed to work with NICE to ensure that those commissioning or providing services are made aware of and encouraged to use the quality standard.

- Bone Research Society
- National Osteoporosis Society
- Royal College of Nursing
- Society and College of Radiographers
- British Geriatrics Society