Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Specific questions asked at consultation:

1. Are there any cost saving interventions or examples of innovative approaches that should be considered for inclusion in this guideline?
2. Do you agree with the decision to exclude non-pharmacological interventions (beyond Vitamin D and Calcium) from this guideline? Please explain the reasons for your response

Stakeholder	Page no.	Line no.	Comments	Developer's response
British Geriatrics Society	General		**Information and support needs for adults with suspected or known risk of 14 fragility fracture and their families and carer**s - While we support 1.1 and 1.2, it must be recognised that many patients with fragility fractures have cognitive impairment, and specific information and support needs are necessary for the carers of these patients. **Identifying adults who should be assessed for fragility fracture risk** - An important group of people who at high risk for fragility fracture are those living in residential / nursing home care. Special recommendations should be considered for these patients. - In addition, there is a significant group of patients who present to medical hospitals wards and fall outside the remit of the FLS. These include older people admitted predominately with vertebral and pubic rami fractures, who are high risk of further fragility fractures. Special recommendations should be considered for these patients.	Thank you for your comment. A question has been added to the guideline to cover the information and support needs of adults with cognitive impairment, a learning disability or autism and who are at risk of fragility fracture or who have osteoporosis. The guideline reviews and recommendations will aim to cover all populations regardless of setting. Recommendations related to specific settings such as those living in residential or nursing homes are unlikely to be included in the guideline. The limitations of the specific risk assessment tools will be considered by the committee when they set the review protocols, evaluate the evidence and make the recommendations. Vertebral fracture assessment by DXA has been added to the review questions related to identifying vertebral fractures. Recommendations related to the T score will

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			Methods of risk assessment A. We welcome the assessment of FRAX and QFracture, in particular QFracture which includes falls and dementia as a recognised risk factor. The omission of this in FRAX needs to be highlighted. B. The limitations of spine DXA particularly in older people with spinal degenerative disease must be recognised, and guidance / recommendations should be given in this setting. **Identifying vertebral fragility fractures** A. Vertebral fracture assessment by DXA should be included in the list of imaging modalities, and recommendations at what T score threshold this should be performed would be helpful. **Treatments to reduce fracture risk** A. Treatment compliance (the way the medication is taken) and treatment persistence (continuing with the medication long-term) are both important for older people, particularly those with swallowing problems, polypharmacy and those with cognitive issues. Specific recommendations need to recognise these important issues. **Treatment monitoring and review (timing and methods)**	be considered by the committee but their ability or confidence to make these recommendations may be limited by the available evidence. Treatment adherence has been included as an outcome for the treatment reviews. It will also be considered as part of the risk reassessment as this is believed to help improve adherence. The committee will consider making specific recommendations if the evidence allows. General recommendations related to supporting adherence are not included in this guideline as they are covered by the NICE guideline on Medicines adherence (https://www.nice.org.uk/guidance/cg76). The limitations of DXA in people with degenerative spinal disease will be considered by the committee when setting the review protocols, evaluating the evidence and making recommendations for both key areas: the methods of risk assessment, and the treatment monitoring and review.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			A. Limitations in spine DXA in older people with degenerative spinal disease need to be recognised.	
British Geriatrics Society	001 - 002		1 and 1.2 While we support 1.1 and 1.2, it must be recognised that many patients with fragility fractures have cognitive impairment, and specific information and support needs are necessary for the carers of these patients.	Thank you for your comment. A question relating to the information and support needs of adults with cognitive impairment, a learning disability or autism and who are at risk of fragility fracture or who have osteoporosis has been added to the guideline.
British Orthopaedic Association	007	027	Add new draft review question 2.3 What is the value of identifying individuals to be referred for screening by a fracture liaison service (FLS) by copying to the FLS all imaging reports of new fractures in the over 50's (plain X-ray, CT, MR or bone scan)? GIRFT adult orthopaedic 'deep dive' visits have shown this is already done by some trusts and seems by far the most efficient and effective first step in secondary fracture prevention.	Thank you for your comment. The guideline will focus on risk assessment and reassessment rather areas related to service delivery. Sending copies of imaging reports to the FLS that were requested by the FLS would need to be agreed between radiology and the FLS. It is beyond the scope of this guideline to include it here.
British Society for Rheumatology	General	General	In response to the question above, several of our members have commented that they do not agree with the decision to exclude non-pharmacological approaches since these might be more effective at reducing fractures than calcium and vitamin D. In addition, 'treatment' might be considered to include treatment of modifiable causes eg assessment and management of modifiable bone risk factors – smoking, alcohol, anorexia, steroids, inflammatory disorder. Etc	Thank you for your comment. Exercise as a treatment for osteoporosis has been added to the guideline. The other modifiable causes of treatment you mention are covered in other NICE guidelines and are therefore not part of the scope in this guideline.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
British Society for Rheumatology	General	General	In response to the question above, we consider that vertebroplasty and kyphoplasty should be revisited. The 2013 guidance is outdated and gives recommendations for treatment (for both VF and KP) that are not supported by evidence. In addition, the role of CT in investigating or diagnosing low bone mass has been proposed by a member. In addition, the role of 1:1 or group patient education has been proposed by a member.	Thank you for your comment. The management of fractures is better covered in other guidelines with surgical expertise. Therefore, vertebroplasty and kyphoplasty have been excluded from this guideline. CT scanning is included as part of the draft review question on bone density assessment. The focus for the reviews on patient information needs will be on what information should be provided rather than how it should be provided.
British Society for Rheumatology	001 - 002	General	Aspects of the introduction wording are considered confusing. Osteoporosis is reduced bone density (rather than reduces). Osteopenia is a classification of bone mineral density and describing it as a 'stage before osteoporosis' is unhelpful and leads to it being considered a condition or pre-disease which the community are trying to move away from. Osteopenia may be entirely normal for large numbers of the population. The term "low bone mass" or "low bone density" is preferred (as per ISCD)	Thank you for your comment. The scope introduction has been updated. The definition for osteoporosis has been edited to mention that traditionally, measurements of bone mineral density (BMD) have been used to diagnose osteoporosis. However, this definition does not recognise that BMD is just one of many factors that influence bone strength and fracture risk, and that most fragility fractures occur in people with a BMD higher than the thresholds used that defined osteoporosis. Mention of osteopenia has been removed from the introduction. Another stakeholder described the term osteopenia as somewhat outdated and best avoided.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
British Society for Rheumatology	002	002	The scope of 'osteoporosis' itself is not clear as the documents refers to both BMD derived osteoporosis and people without osteoporosis but high fracture risk. One member commented: The statement 'Osteoporosis increases the risk of fragility fractures, but the risk is increased by other factors such as likelihood of falling, previous fragility fracture, current or frequent recent use of glucocorticoids, family history of hip fracture, smoking and alcohol intake." is confusing. Many of the 'other' factors cause fractures through osteoporosis. Is this an osteoporosis guideline or a fragility fracture guideline? Including a working definition of osteoporosis, if different to the WHO diagnosis would be extremely helpful to clinicians. We note that the UK QOF states that patients aged 75 and over with fragility fracture can be assumed to have osteoporosis in absence of BMD assessment. Is this NICE's position? The grey area where people are treated based on fracture risk rather than osteoporotic BMD creates uncertainty and is confusing for patients. Having clearer national consensus on when a clinical diagnosis of osteoporosis can be used would be extremely helpful. Please see linked article for further narrative on this point. Bringing osteoporosis up to date: time to address the	Thank you for your comment. The scope introduction has been updated. The definition for osteoporosis has been edited to mention that traditionally, measurements of bone mineral density (BMD) have been used to diagnose osteoporosis. However, this definition does not recognise that BMD is just one of many factors that influence bone strength and fracture risk, and that most fragility fractures occur in people with a BMD higher than the thresholds used that defined osteoporosis. The guideline covers both osteoporosis and the prevention of fragility fractures (but not fragility fracture management). Identifying people at risk of fragility fracture means they could be considered for treatment to prevent them having a fracture. The committee will consider the definitions and appropriate thresholds for treatment when they consider the review protocols and recommendations.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			identity crisis | Age and Ageing | Oxford Academic (oup.com)	
British Society for Rheumatology	002	016	With regard the statement 'Re-assessments may help with decisions to stop or continue treatment.' does this mean for clinicians or patients? One member commented they would like to see reference to 'improving adherence'.	Thank you for your comment. The introduction has been updated to mention that reassessment may be used to help improve adherence to treatment and also informs decisions to stop, continue or switch treatment. NICE believes in the concept of shared decision making and would anticipate that any decisions about treatment would involve a discussion between the clinician and the patient before a decision is reached.
British Society for Rheumatology	004	002	We consider it would be appropriate to add to GP lists or replace with any routine NHS / social care data – GP, hospital, community pharmacy lists may also be relevant. For example, we are aware of trials which have used pharmacy lists as a basis to identify patients for a monitoring intervention.	Thank you for your comment. This has been updated to the use of electronic health and social care records (including GP practice lists).
British Society for Rheumatology	004	005	Could this include an evaluation of trabecular bone score as an extension to DXA, and it's value in increasing the precision of fracture risk assessment.	Thank you for your comment. Trabecular bone score has been added as part of the review questions on the methods of risk assessment.
British Society for Rheumatology	004	011 - 020	Could the role of history taking/clinical consultation and checking pharmacy records be added to the monitoring section.	Thank you for your comment. Appropriate history taking and checking prescription records has not been included as this is a generic good practice for all doctors to follow and not specific to osteoporosis.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
British Society for Rheumatology	007	025	Please see comment 9. We consider it would be appropriate to add to GP lists or replace with any routine NHS / social care data – GP, hospital, community pharmacy lists may also be relevant. For example, we are aware of trials which have used pharmacy lists as a basis to identify patients for a monitoring intervention.	Thank you for your comment. This question has been updated to state "How accurate are electronic health and social care records (including GP practice lists) for identifying adults who should be assessed for fragility fracture risk?".
British Society for Rheumatology	007	028	One member commented 'Risk assessment should be focused on risk factors that determine modifiable risk, e.g. falls risk is not modifiable by bisphosphonate therapy'.	Thank you for your comment. Modifiable bone risk factors are taken into account in specific risk assessment tools such as QFracture which will be assessed in the guideline.
British Society for Rheumatology	008	011 - 015	In identifying vertebral fractures, it would be helpful to consider the role of Vertebral fracture assessment using bone densitometry and also several members commented on considering the role of artificial intelligence tools to identify vertebral fracture using existing radiology images, some of which are CE marked.	Thank you for your comment. vertebral fracture assessment (VFA) by DXA, automated imaging algorithms and computer based diagnostics have been added to the review question for identifying vertebral fractures as suggested.
British Society for Rheumatology	008	017 - 023	Several members commented it would be helpful to also consider the role of HRT with other treatments available.	Thank you for your comment. Hormone replacement therapy has been added as a treatment option and will be looked at in the review.
British Society for Rheumatology	008	024	We consider that calcium and vitamin D should be considered separately. Hopefully this is what is intended as indicated by 'calcium or vitamin D'.	Thank you for your comment. The use of calcium and vitamin D as separate treatments. The review will look at whether when one or both are added to other pharmacological treatments does it help prevent fragility fractures. The guideline will not look at calcium and/or

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
				vitamin D as stand alone treatments when they are not getting other pharmacological treatments for osteoporosis. .
British Society for Rheumatology	009	017	Could major and other fragility fractures also be considered as outcomes.	Thank you for your comment. All fragility fractures will be included. Hip and vertebral are just mentioned as examples of fragility fractures.
Falls and Bone Health OfficerAgile (Chartered Society of Physiotherapists working with Older People)	General	General	Interventions/examples Yes, even if its not in the guideline, maybe as best practice examples, case studies etc. One of our members (community Physiotherapist) mentioned he had identified 60 patients over a year period as he had previously worked as Falls and Bone health practitioner and had retained access to radiology. This is my service, pretty old https://www.gov.uk/government/case-studies/better-bones-osteoporosis-service-from-kingston-public- health and it is Public Health. We may be able to collect similar examples to encourage identification and therefore better management if the guideline decides to include them.	Thank you for your comment and the link. The guideline will cover the use of electronic health and social care records for identifying adults who should be assessed for fragility fracture risk. It will not be covering public health intiatives.
Falls and Bone Health OfficerAgile (Chartered Society of Physiotherapists	General	General	Exclude non pharmacological interventions No, other interventions (e.g. minerals and vitamins) should be included in the guideline. Depending on the evidence base, the guideline should be able to suggest the need or document the non availability of the evidence for these	Thank you for your comment. Exercise as a treatment for osteoporosis has been added to the guideline. Managing the causes of osteoporosis are better are covered by other guidelines and are therefore not included in this guideline.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
working with Older People)			interventions to assist both professionals and patients make informed decisions on these interventions.	
Falls and Bone Health OfficerAgile (Chartered Society of Physiotherapists working with Older People)	008	016	Can opportunistic identification (how, when, where, who) of vertebral fractures be included in this section	Thank you for your comment. Questions related to identifying people who should be assessed for fragility fracture risk are covered in section 2 of the key areas. Question 2.1 has been updated to "How accurate are electronic health and social care records (including GP practice lists) for identifying adults who should be assessed for fragility fracture risk?"
Hyperparathyroid UK Action 4 Change	General	General	We feel it is vitally important that this guideline does not exclude correctable causes of osteoporosis i.e. nutritional problems such as eating disorders, vitamin D deficiency, medications (prednisone, anti-seizure drugs, chemotherapy, Cushing's syndrome, hyperthyroidism, hyperparathyroidism). This presentation by Michael Yeh MD and Masha Livhits MD from UCLA in 2016, discuss definitive information at 20:06 minutes about primary hyperparathyroidism and osteoporosis, describing two thirds of people with primary hyperparathyroidism will develop osteoporosis, and treating the hyperparathyroidism will reverse osteoporosis. That's a very significant number of people considering hyperparathyroidism is regarded as the second most common endocrine condition after diabetes.	Thank you for your comment. The focus of this guideline is on risk assessment and treatment of osteoporosis and prevention of fragility fractures. Managing the causes of osteoporosis are better covered by other guidelines. There is already a NICE guideline on Hyperparathyroidism (primary): diagnosis, assessment and initial management (https://www.nice.org.uk/guidance/ng132) which was developed by experts in its management.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			The important message is 'Primary Hyperparathyroidism is an important , REVERSIBLE cause of osteoporosis.' Please see 20:46 minutes: Updates for Hyperparathyroidism and Osteoporosis | Michael Yeh, MD & Masha Livhits, MD | UCLAMDChat - YouTube	
Hyperparathyroid UK Action 4 Change	001	025 - 026	After 'However, bone loss can occur at any age, usually in response to an underlying medical conditions', we believe primary hyperparathyroidism should be mentioned as steroids are mentioned in line 27, because primary hyperparathyroidism will almost certainly lead to osteopenia/osteoporosis, until primary hyperparathyroidism is surgically cured (which will of course reverse bone loss in most cases).	Thank you for your comment. The scope introduction has been updated. This section is only a brief introduction to the topic of the guideline and does not go into all the details. Hyperparathyroidism is included as part of some of the risk assessment tools such as QFracture and therefore will be included as part of the risk assessment reviews.
Hyperparathyroid UK Action 4 Change	002	003 - 005	'but the risk is increased by other factors such as likelihood of falling, previous fragility fracture, current or frequent recent use of glucocorticoids, family history of hip fracture, smoking and alcohol intake.' Primary Hyperparathyroidism should be included in these examples. Your Guideline for Primary Hyperparathyroidism NG132 states. 'For all people with primary hyperparathyroidism, assess cardiovascular risk and fracture risk in line with the NICE guidelines on cardiovascular disease and osteoporosis.'	Thank you for your comment. This is only a brief introduction and does not go into all the details of the causes and consequences of osteoporosis. Hyperparathyroidism is included as part of some of the risk assessment tools such as QFracture and therefore will be included as part of the risk assessment reviews. Primary hyperparathyroidism, while important, is not the focus of this guideline and is covered in the NICE guideline Hyperparathyroidism (primary): diagnosis,

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			This guideline must therefore also include a similar notice here, rather than a first mention on page five, line three; 'related NICE guidance'. We have over three thousand members with primary hyperparathyroidism. Left untreated, they will all likely develop osteopenia/osteoporosis. This high risk association must be highlighted.	assessment and initial management https://www.nice.org.uk/guidance/ng132 and there is a link to this in the scope section on related NICE guidance.
Hyperparathyroid UK Action 4 Change	002	006 - 008	'In England and Wales, the Falls and Fragility Fracture Audit Programme reported there are over 300,000 fragility fractures every year in patients aged 50 years and over.' How many of the people over 50 years with over 300,000 fragility fractures have been assessed for Primary hyperparathyroidism? Parathyroid UK and The Royal Osteoporosis Society state in their leaflets for Primary Hyperparathyroidism that only people under fifty fit the criteria for a parathyroidectomy, which is strictly untrue. We have seen a great number of people from the ages of 50 to 89 who have benefitted from a parathyroidectomy and reversed bone loss.	Thank you for your comment. This is only a brief introduction and does not go into all the details of the causes and consequences of osteoporosis. Hyperparathyroidism is included as part of some of the risk assessment tools such as QFracture and therefore will be included as part of the risk assessment reviews. Primary hyperparathyroidism, while important, is not the focus of this guideline and is covered in the NICE guideline Hyperparathyroidism (primary): diagnosis, assessment and initial management https://www.nice.org.uk/guidance/ng132 and there is a link to this in the scope section on related NICE guidance.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
Hyperparathyroid UK Action 4 Change	002	008 - 010	'In addition to the pain and reduced quality of life for people who have a fragility fracture, the increased morbidity leads to mortality and increased NHS costs.'This sentence reinforces that primary hyperparathyroidism presenting as both normocalcaemic and hypercalcaemic must be ruled out as a cause of osteopenia/osteoporosis, which can then be surgically cured, restoring bone density, ideally before fragility fractures occur rather than after. Normocalcemic primary hyperparathyroid patients present with elevated PTH and often above mid-range calcium. Normocalcaemic Primary Hyperparathyroid patients are more likely to remain undiagnosed compared to hypercalcaemic, leading to osteoporosis.	Thank you for your comment. This is only a brief introduction and does not go into all the details of the causes and consequences of osteoporosis. Hyperparathyroidism is included as part of some of the risk assessment tools such as QFracture and therefore will be included as part of the risk assessment reviews. Primary hyperparathyroidism, while important, is not the focus of this guideline and is covered in the NICE guideline Hyperparathyroidism (primary): diagnosis, assessment and initial management https://www.nice.org.uk/guidance/ng132 and there is a link to this in the scope section on related NICE guidance.
Hyperparathyroid UK Action 4 Change	002	011 - 014	We completely agree, but we strongly advise including the following sentence here would be most beneficial for both patients and the NHS;'Primary hyperparathyroidism (PHPT) both hypercalcemic and normocalcemic, should always be tested for when a patient presents with a fragility fracture, osteopenia or osteoporosis, as it is a leading cause of secondary bone loss by nature of the disease, which can be improved or reversed following a parathyroidectomy. Normocalcemic primary hyperparathyroid patients are at least equally at risk of	Thank you for your comment. This is only a brief introduction and does not go into all the details of the causes and consequences of osteoporosis. Hyperparathyroidism is included as part of some of the risk assessment tools such as QFracture and therefore will be included as part of the risk assessment reviews. Primary hyperparathyroidism, while important, is not the focus of this guideline and is covered in the NICE guideline Hyperparathyroidism (primary): diagnosis,

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			osteoporosis if not more so, because they are left year after year whilst consultants watch and wait for calcium levels to increase. It is often a missed diagnosis which presents with elevated parathyroid hormone which is usually not currently tested routinely when calcium is within the normal range, leading to a missed diagnosis and opportunity to cure bone loss (and many other symptoms).	assessment and initial management https://www.nice.org.uk/guidance/ng132 and there is a link to this in the scope section on related NICE guidance.
Hyperparathyroid UK Action 4 Change	002	021	After 'treatment with bisphosphonates and non-bisphosphonates' We believe it is vitally important to add 'or parathyroidectomy (PTX) for patients found to have primary hyperparathyroidism', because administering bisphosphonates to patients with osteoporosis who have primary hyperparathyroidism can lead to brittle bones and increased fracture risks building new bone onto osteoporotic bone. Please see this link published in November 2021 in the Journal of bone and mineral metabolism. Skeletal effects of combined bisphosphonates treatment and parathyroidectomy in osteoporotic patients with primary hyperparathyroidism | SpringerLink	Thank you for your comment. Primary hyperparathyroidism, while important, is not the focus of this guideline and is covered in the NICE guideline Hyperparathyroidism (primary): diagnosis, assessment and initial management https://www.nice.org.uk/guidance/ng132 and there is a link to this in the scope section on related NICE guidance.
Hyperparathyroid UK Action 4 Change	002	021	Presentation by Michael Yeh MD and Masha Livhits MD both at UCLA, about primary hyperparathyroidism and osteoporosis. Michael Yeh explains at 30 minutes 11 seconds that there is no benefit to fracture risks of bisphosphonates for PHPT patients, and actually a much	Thank you for your comment. Primary hyperparathyroidism, while important, is not the focus of this guideline and is covered in the NICE guideline Hyperparathyroidism (primary): diagnosis, assessment and initial management

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			higher ten year fracture risk of 85.5 per 1000 patients compared to 20.4 per 1000 patients who had a parathyroidectomy. Please watch this presentation from 30:11 to 33:11. The concluding point is 'Bisphosphonate medications do not reduce fracture risk in Primary hyperparathyroidism'. Michael Yeh does state that bisphosphonates do help bone density for non-primary hyperparathyroidism causes of bone loss at 33:20 Updates for Hyperparathyroidism and Osteoporosis | Michael Yeh, MD & Masha Livhits, MD | UCLAMDChat - YouTube	https://www.nice.org.uk/guidance/ng132 and there is a link to this in the scope section on related NICE guidance.
Hyperparathyroid UK Action 4 Change	004	009 - 010	A further bullet point should read, 'parathyroidectomy for patients with primary hyperparathyroidism'	Thank you for your comment. Management of primary hyperparathyroidism has not been included here as there is a NICE guideline covering its management (https://www.nice.org.uk/guidance/ng132).
Hyperparathyroid UK Action 4 Change	008	004 - 006	We recommend bone density scans to include non-dominant forearm to help ascertain if reduced bone density is likely caused by Primary Hyperparathyroidism which will require a parathyroidectomy instead of drug therapy as explained below;Evaluation and Management of Primary Hyperparathyroidism: Summary Statement and Guidelines from the Fifth International Workshop - Bilezikian - 2022 - Journal of Bone and Mineral Research - Wiley Online Library	Thank you for your comment. The committee will consider how bone density assessment is carried out when they consider the review protocols for the guideline.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			'Fracture risk is increased in patients with PHPT at vertebral and nonvertebral sites. Using either X-rays or vertebral fracture assessment (VFA), by DXA, asymptomatic fractures can be detected in patients who do not have a history of fracture.(106) Because DXA became a widely available clinical tool, in the 1980s, it has become an essential method to determine skeletal involvement in PHPT.(62) Consistent with the known effects of PTH, low BMD by DXA is especially prevalent at sites with high proportions of cortical bone, such as the one-third distal radius.(62, 64) The lumbar spine, primarily comprised of trabecular bone, is generally better preserved by DXA in PHPT. BMD values intermediate between that of the one-third distal radius and the lumbar spine, when compared to age-matched norms, have been reported at the femoral neck, which comprises both trabecular and cortical bone.(62) Whether the same DXA pattern exists in NPHPT has not been established. Although the description of a preferential reduction in cortical bone is a classical densitometric feature of PHPT, many other patterns can be seen. In particular, an opposite pattern with preferential reduction in lumbar spine bone density may be observed in some postmenopausal women.(111) Occasionally, a T-score<U+2009>=<U+2009>-2.5 is observed at the one-third radius only. In studies of the natural history of PHPT, BMD may be stable for several years, but may ultimately decline	

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			at the hip and radius when observation exceeds 10<U+2009>years.(112)'	
Leeds Community Healthcare NHS Trust	004	003	The methods of risk assessment considers bone density assessment and risk prediction tools, but does not mention clinical conditions that may increase the risk but are not covered in specific tools such as the FRAX	Thank you for your comment. This review focuses on the accuracy and effectiveness of using existing interventions as methods of risk assessment. The limitations of the specific risk assessment tools will be considered by the committee when they set the review protocols, evaluate the evidence and make the recommendations.
Leeds Community Healthcare NHS Trust	004	015	Treatment monitoring and review does not currently include non-pharmacological management which is an important consideration in relation to lifestyle factors such as diet and exercise, and in circumstances where the patient cannot tolerate pharmacological management	Thank you for your comment. Exercise has been added as a non-pharmacological treatment and the treatment and monitoring reviews will also cover this. Other treatments related to lifestyle advice are included as part of other NICE guidance and therefore not included in this guideline.
Medimaps Group	General	General	We are happy to provide further details on the TBS application and evidence-base, and to answer any questions from the panel.	Thank you for your comment. Trabecular bone score has been added to the guideline as part of the risk assessment questions.
Medimaps Group	General	General	References 1. Pothuaud, L., Carceller, P. and Hans, D., 2008. Correlations between grey-level variations in 2D projection images (TBS) and 3D microarchitecture: applications in the study of human trabecular bone microarchitecture. Bone, 42(4), pp.775-787.	Thank you for providing these references. These will be considered for inclusion as evidence when the reviews involving trabecular bone score are being done.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			2. Hans, D., Goertzen, A.L., Krieg, M.A. and Leslie, W.D., 2011. Bone microarchitecture assessed by TBS predicts osteoporotic fractures independent of bone density: the Manitoba study. Journal of Bone and Mineral Research, 26(11), pp.2762-2769. 3. Winzenrieth, R., Michelet, F. and Hans, D., 2013. Three-dimensional (3D) microarchitecture correlations with 2D projection image gray-level variations assessed by trabecular bone score using high-resolution computed tomographic acquisitions: effects of resolution and noise. Journal of Clinical Densitometry, 16(3), pp.287-296. 4. Muschitz, C., Kocijan, R., Haschka, J., Pahr, D., Kaider, A., Pietschmann, P., Hans, D., Muschitz, G.K., Fahrleitner-Pammer, A. and Resch, H., 2015. TBS reflects trabecular microarchitecture in premenopausal women and men with idiopathic osteoporosis and low-traumatic fractures. Bone, 79, pp.259-266. 5. Ramalho, J., Marques, I.D.B., Hans, D., Dempster, D., Zhou, H., Patel, P., Pereira, R.M.R., Jorgetti, V., Moyses, R.M.A. and Nickolas, T.L., 2018. The trabecular bone score: Relationships with trabecular and cortical microarchitecture measured by HR-pQCT and histomorphometry in patients with chronic kidney disease. Bone, 116, pp.215-220. 6. Leslie, W.D., Shevroja, E., Johansson, H., McCloskey, E.V., Harvey, N.C., Kanis, J.A. and Hans, D., 2018. Risk-	

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			equivalent T-score adjustment for using lumbar spine trabecular bone score (TBS): the Manitoba BMD registry. Osteoporosis International, 29(3), pp.751-758. 7. Binkley, N., Morin, S.N., Martineau, P., Lix, L.M., Hans, D. and Leslie, W.D., 2020. Frequency of normal bone measurement in postmenopausal women with fracture: a registry-based cohort study. Osteoporosis International, 31(12), pp.2337-2344. 8. Schousboe, J.T., Vo, T., Taylor, B.C., Cawthon, P.M., Schwartz, A.V., Bauer, D.C., Orwoll, E.S., Lane, N.E., Barrett-Connor, E., Ensrud, K.E. and Osteoporotic Fractures in Men (MrOS) Study Research Group, 2016. Prediction of incident major osteoporotic and hip fractures by trabecular bone score (TBS) and prevalent radiographic vertebral fracture in older men. Journal of Bone and Mineral Research, 31(3), pp.690-697. 9. McCloskey EV, Odén A, Harvey NC, Leslie WD, Hans D, Johansson H, Barkmann R, Boutroy S, Brown J, Chapurlat R, Elders PJ. A meta-analysis of trabecular bone score in fracture risk prediction and its relationship to FRAX. Journal of bone and mineral research. 2016 May;31(5):940-8. 10. Pothuaud, L., Barthe, N., Krieg, M.A., Mehsen, N., Carceller, P. and Hans, D., 2009. Evaluation of the potential use of TBS to complement BMD in the diagnosis of osteoporosis: a preliminary spine BMD-matched, case–control study. J Clin Densitom, 12, pp.170-176.	

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			11. Krueger, D., Fidler, E., Libber, J., Aubry-Rozier, B., Hans, D. and Binkley, N., 2014. Spine trabecular bone score subsequent to bone mineral density improves fracture discrimination in women. Journal of Clinical Densitometry, 17(1), pp.60-65. 12. Borgen, T.T., Bjørnerem, Å., Solberg, L.B., Andreasen, C., Brunborg, C., Stenbro, M.B., Hübschle, L.M., Froholdt, A., Figved, W., Apalset, E.M. and Gjertsen, J.E., 2019. High prevalence of vertebral fractures and low trabecular bone score in patients with fragility fractures: a cross-sectional sub-study of NoFRACT. Bone, 122, pp.14-21. 13. Redondo, L., Puigoriol, E., Rodríguez, J.R., Peris, P. and Kanterewicz, E., 2018. Usefulness of the trabecular bone score for assessing the risk of osteoporotic fracture. Revista Clínica Española (English Edition), 218(3), pp.121-127. 14. Siris, E.S., Chen, Y.T., Abbott, T.A., Barrett-Connor, E., Miller, P.D., Wehren, L.E. and Berger, M.L., 2004. Bone mineral density thresholds for pharmacological intervention to prevent fractures. Archives of internal medicine, 164(10), pp.1108-1112. 15. Pasco, J.A., Seeman, E., Henry, M.J., Merriman, E.N., Nicholson, G.C. and Kotowicz, M.A., 2006. The population burden of fractures originates in women with osteopenia, not osteoporosis. Osteoporosis International, 17(9), pp.1404-1409.	

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			16. Sanders, K.M., Nicholson, G.C., Watts, J.J., Pasco, J.A., Henry, M.J., Kotowicz, M.A. and Seeman, E., 2006. Half the burden of fragility fractures in the community occur in women without osteoporosis. When is fracture prevention cost-effective?. Bone, 38(5), pp.694-700. 17. Kanis, J.A., Cooper, C., Rizzoli, R. and Reginster, J.Y., 2019. European guidance for the diagnosis and management of osteoporosis in postmenopausal women. Osteoporosis International, 30(1), pp.3-44. 18. Martineau, P., Leslie, W.D., Johansson, H., Harvey, N.C., McCloskey, E.V., Hans, D. and Kanis, J.A., 2018. In which patients does lumbar spine trabecular bone score (TBS) have the largest effect?. Bone, 113, pp.161-168. 19. Ho-Pham, L.T., Tran, B., Do, A.T. and Nguyen, T.V., 2019. Association between pre-diabetes, type 2 diabetes and trabecular bone score: The Vietnam Osteoporosis Study. Diabetes research and clinical practice, 155, p.107790. 20. Agarwal, A. and Leslie, W.D., 2022. Fracture prediction tools in diabetes. Current Opinion in Endocrinology & Diabetes and Obesity, 29(4), pp.326-332. 21. Khan, A.A., Hanley, D.A., Rizzoli, R., Bollerslev, J., Young, J.E.M., Rejnmark, L., Thakker, R., D'amour, P., Paul, T., Van Uum, S. and Shrayyef, M.Z., 2017. Primary hyperparathyroidism: review and recommendations on evaluation, diagnosis, and management. A Canadian and	

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			international consensus. Osteoporosis International, 28(1), pp.1-19. 22. Kanazawa, I., Inaba, M., Inoue, D., Uenishi, K., Saito, M., Shiraki, M., Suzuki, A., Takeuchi, Y., Hagino, H., Fujiwara, S. and Sugimoto, T., 2020. Executive summary of clinical practice guide on fracture risk in lifestyle diseases. Journal of Bone and Mineral Metabolism, 38(6), pp.746-758. 23. Muschitz, C., Zwick, R.H., Haschka, J., Dimai, H.P., Rauner, M., Amrein, K., Wakolbinger, R., Jaksch, P., Eber, E. and Pietschmann, P., 2021. Osteoporose bei pneumologischen Erkrankungen. Wiener klinische Wochenschrift, 133(4), pp.155-173. 24. Riancho, J.A., Peris, P., González-Macías, J. and Pérez-Castrillón, J.L., 2022. Guías de práctica clínica en la osteoporosis postmenopáusica, glucocorticoidea y del varón (actualización 2022). Revista de Osteoporosis y Metabolismo Mineral, 14(1), pp.13-33. 25. Padlina, I., Gonzalez-Rodriguez, E., Hans, D., Metzger, M., Stoll, D., Aubry-Rozier, B. and Lamy, O., 2017. The lumbar spine age-related degenerative disease influences the BMD not the TBS: the Osteolaus cohort. Osteoporosis international, 28(3), pp.909-915. 26. Hayden, A.C., Binkley, N., Krueger, D., Bernatz, J.T., Kadri, A. and Anderson, P.A., 2022. Effect of degeneration on bone mineral density, trabecular bone score and CT	

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			Hounsfield unit measurements in a spine surgery patient population. Osteoporosis International, pp.1-8. 27. Hernlund, E., Svedbom, A., Ivergård, M., Compston, J., Cooper, C., Stenmark, J., McCloskey, E.V., Jönsson, B.K.J.A. and Kanis, J.A., 2013. Osteoporosis in the European Union: medical management, epidemiology and economic burden. Archives of osteoporosis, 8(1), pp.1-115. 28. Harvey, N.C., Poole, K.E., Ralston, S.H., McCloskey, E.V., Sangan, C.B., Wiggins, L., Jones, C., Gittoes, N. and Compston, J., 2022. Towards a cure for osteoporosis: the UK Royal Osteoporosis Society (ROS) Osteoporosis Research Roadmap. Archives of Osteoporosis, 17(1), pp.1-6. 29. Kanis, J.A., Norton, N., Harvey, N.C., Jacobson, T., Johansson, H., Lorentzon, M., McCloskey, E.V., Willers, C. and Borgström, F., 2021. SCOPE 2021: a new scorecard for osteoporosis in Europe. Archives of osteoporosis, 16(1), pp.1-82. 30. Cosman, F., Dempster, D.W., 2021.Anabolic agents for postmenopausal osteoporosis: how do you choose? Current Osteoporosis Reports,19(2),pp189-205. 31. Cipriani, C., Pepe, J., Silva, B.C., Rubin, M.R., Cusano, N.E., McMahon, D.J., Nieddu, L., Angelozzi, M., Biamonte, F., Diacinti, D. and Hans, D., 2018. Comparative Effect of rhPTH (1-84) on Bone Mineral Density and Trabecular Bone Score in Hypoparathyroidism and Postmenopausal	

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			Osteoporosis. Journal of Bone and Mineral Research, 33(12), pp.2132-2139. 32. Messina, C., Piodi, L.P., Grossi, E., Eller-Vainicher, C., Bianchi, M.L., Ortolani, S., Di Stefano, M., Rinaudo, L., Sconfienza, L.M. and Ulivieri, F.M., 2020. Artificial neural network analysis of bone quality DXA parameters response to teriparatide in fractured osteoporotic patients. Plos one, 15(3), p.e0229820. 33. Dhaliwal, R., Hans, D., Hattersley, G., Mitlak, B., Fitzpatrick, L.A., Wang, Y., Schwartz, A.V., Miller, P.D. and Josse, R.G., 2020. Abaloparatide in postmenopausal women with osteoporosis and type 2 diabetes: a post hoc analysis of the ACTIVE study. JBMR plus, 4(4), p.e10346. 34. Sooragonda, B., Cherian, K.E., Jebasingh, F.K., Dasgupta, R., Asha, H.S., Kapoor, N., Thomas, N. and Paul, T.V., 2019. Longitudinal changes in bone mineral density and trabecular bone score following yearly zoledronic acid infusion in postmenopausal osteoporosis—a retrospective-prospective study from southern India. Archives of Osteoporosis, 14(1), pp.1-5. 35. Sølling, A.S., Harsløf, T. and Langdahl, B., 2021. Treatment With Zoledronate Subsequent to Denosumab in Osteoporosis: A 2-Year Randomized Study. Journal of Bone and Mineral Research, 36(7), pp.1245-1254. 36. Hans, D., Shevroja, E., McDermott, M., Huang, S., Kim, M. and McClung, M., 2022. Updated trabecular bone score	

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			accounting for the soft tissue thickness (TBSTT) demonstrated significantly improved bone microstructure with denosumab in the FREEDOM TBS post hoc analysis. Osteoporosis International, 33(12), pp.2517-2525.	
Medimaps Group	004	001	**Risk factors for fragility fracture'We propose consideration of 'Low Trabecular Bone Score' as a risk factor for fragility fracture for the following reasons:1.** Fragility fracture is a consequence of reduced bone strength which is determined by both bone mass (bone mineral density; BMD) and bone quality (bone microarchitecture). Low BMD is a primary risk factor for fragility fracture, but the guidelines do not currently include a quantifiable risk factor related to the 'microarchitectural deterioration of bone tissue'.2. Trabecular bone score (TBS) is a textural index of trabecular microarchitecture, acquired from lumbar spine DXA images. Ex-vivo and in-vivo studies have consistently demonstrated that TBS is a surrogate of bone microarchitecture, reflecting standard properties of skeletal integrity independent of BMD, such as trabecular number, spacing, connectivity, Structural Model Index and bone volume/tissue volume, validated by microCT or trans-illiac bone biopsies (Pothuaud et al., 2008; Hans et al., 2011; Winzenrieth et al., 2013; Muschitz et al., 2015; Ramalho et al., 2018).3. TBS is now included as a risk factor in the fracture risk assessment tool, FRAX® and in over 1,000 published studies and reviews. The evidence	Thank you for your comment. Trabecular bone score (TBS) has been added to the review questions related to methods of risk assessment and reassessment. It has not been added to the questions related to identifying people at risk of fragility fractures. This is because at this stage in the pathway people would not have had a DXA assessment and therefore a TBS would not be available.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			confirms that TBS is lower in patients (both women and men) who have vertebral, hip or major osteoporotic fractures, and that TBS predicts fragility fracture, independent of BMD and most clinical risk factors. Studies have been conducted across multiple countries and ethnicities and include, but are not limited to, the large Manitoba population-cohort study (Hans et al., 2011; Leslie et al., 2018; Binkley et al., 2020), the MrOs Study (Schousboe et al., 2016), a meta-analysis of 14 multinational, prospective cohort studies of 17,809 men and women (McCloskey et al., 2016), and others (Pothuaud et al., 2009; Krueger et al., 2014; Borgen et al., 2018; Redondo et al., 2018).	
Medimaps Group	004	003	**Methods of risk assessment'In light of the strengthened evidence-base and the inclusion of trabecular bone score (TBS) in FRAX®, we propose that TBS is considered in the updated NICE guidelines - '3. Methods of risk assessment'. We share the following comments to support this:**1. Bone density assessment by DXA is effective in identifying some, but not all, individuals at high risk of fragility fracture. An ongoing clinical challenge is that most fragility fractures occur in individuals who have a BMD T-score in the osteopenic or normal range, which can preclude treatment (Siris et al. 2004; Pasco et al., 2006; Sanders et al., 2006; Binkley et al., 2020). The addition of TBS can help address this challenge, by	Thank you for your comment. Trabecular bone score has been added as part of the review questions on the methods of risk assessment. The citations you have provided will be considered for inclusion in the review on exercise.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			providing an index of bone microarchitecture which alongside BMD and other clinical risk factors, can further characterise an individual's risk profile and identify more people who would benefit from anti-osteoporosis treatment. 2. In practice, TBS can be used alongside or in combination with BMD (BMD T-score adjusted for TBS) and other clinical risk factors (Leslie et al., 2018; Kanis et al., 2019).3. Of relevance and subsequent to the previous update of the NICE guidelines, TBS has been incorporated into the UK-specific FRAX® tool, whereby 10 year probability of fracture can be estimated in a model that accounts for bone quality (TBS) as well as bone mass (BMD), and clinical risk factors. FRAX-adjusted for TBS has been validated for Caucasian and Asian postmenopausal women, and men, aged 40 to 90 years. The inclusion of TBS improves the accuracy of FRAX®, particularly for those who are close to the treatment intervention threshold (McCloskey et al., 2016; Martineau et al., 2018), and in patients with diseases that cause secondary osteoporosis, where bone quality is predominantly affected. For example, patients with type 2 diabetes commonly have normal BMD, lower TBS, and higher risk of fracture (Ho-Pham and Nguyen, 2019; Agarwal and Leslie, 2022). TBS is beneficial for identifying patients at high risk for fracture in other conditions that affect the bone and is thus included in respective international guidelines, for example: Hyperparathyroidism	

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			(Khan et al., 2017); Chronic obstructive pulmonary disease) (Kanazawa et. al., 2020, Muschitz et. al., 2021) and Glucocorticoid induced osteoporosis (Riancho et al., 2022).4. Trabecular bone score is now the most widely used tool for the evaluation of bone microarchitecture and is not impacted by degenerative changes at the spine (Padlina et al., 2017; Hayden et al., 2022). Given that TBS is acquired from lumbar spine DXA scans, integration into clinical practice requires no additional time, exposure to ionising radiation or cost, other than the software license. The direct and indirect cost savings would be seen through primary and secondary fracture prevention, given that more people at high risk of fracture can be identified for anti-osteoporosis therapies (addressing the osteoporosis treatment gap; Hernlund et al., 2013; Harvey et al., 2022). This is relevant given that there are approximately 549,000 fragility fractures each year, costing the NHS in excess of £4.7 billion annually (Kanis et al., 2021).	
Medimaps Group	004	008 & 015	**Treatments to reduce fracture risk' & 'Treatment monitoring and review'We propose consideration of the role of trabecular bone score - a measure of bone microarchitecture - to support treatment decision-making and monitoring.**Anti-osteoporosis therapies have differential effects on bone density and bone microarchitecture. TBS derived from existing DXA scans, provides clinically relevant information on bone	Thank you for your comment. Trabecular bone score has been added as part of the review on treatment monitoring and review. The citations you have provided will be considered for inclusion in the review on exercise.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			microarchitecture and can assist in treatment decision-making making (e.g. a given type of treatment for a given risk profile based on both BMD and TBS), monitoring therapeutic response and management of patients receiving osteoporosis treatments (Cosman and Demster, 2021):1. Bone anabolic treatments function by stimulating bone formation and improving trabecular microarchitecture, and evidence demonstrates clinically significant increases in TBS when patients are receiving osteoanabolic treatments such as PTH, Teriparatide and Abaloparatide (Cipriani et al., 2018; Messina et al., 2020; Dhaliwal et al., 2020). 2. Antiresorptive therapies such as bisphosphonates, calcitonin and monoclonal antibodies (e.g. Denosumab), target osteoclasts and reduce the rate of bone resorption. These agents increase cortical bone and prevent trabecular loss. Studies indicate that there is at least a maintenance of TBS when patients are receiving antiresorptive therapy, such as Zoledronic Acid and Alendronate, and a larger increase with Denosumab (Sooragonda et al., 2019; Solling et al., 2021; Hans et al., 2022). Based on existing and accumulating evidence, we propose that TBS is useful as an additional (but not sole) measure alongside BMD, to inform on anti-osteoporotic therapy and response.	

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
National Osteoporosis Guideline Group	General	General	In response to Question 1 above: Decentralised use of iv Zoledronate. Zoledronate is highly clinically and cost effective. Accessibility can be increased through community delivery of Zoledronate. IV Zoledronate is given through the home-iv service in Nottinghamshire. IV Zoledronate is given through community hospitals providing post-acute rehabilitation in Bath and North East Somerset. Consideration of innovative community-delivery of Zoledronate is recommended to improve equity of access.	Thank you for your comment. Methods of service delivery are not part of the scope of this guideline. Therefore the decentralised use of Zoledronate has not been included as part of the scope.
National Osteoporosis Guideline Group	General	General	In response to Question 2 above:No. Non-pharmacological interventions are really important to patients, and a core component of holistic care for bone health. Exercise particularly, that provides a combination of weight-bearing and muscle strengthening exercise, is beneficial for bone. It is important that a body such as NICE addresses a multidimensional condition such as osteoporosis holistically, as a patient and a clinician would, and not from a pharmacological perspective alone. Otherwise, the risk is that non-pharmacological approaches are de-prioritised by patients and clinicians. Primary care has an opportunity through its scale of consultation to reinforce public health population-level messaging about proactive management of fracture risk and it would be appropriate to provide guidance to primary care practitioners about such interventions.Despite this, if NICE chooses to exclude non-	Thank you for your comment. Exercise as a treatment for osteoporosis has been added to the scope and will be included as part of the guideline.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			pharmacological treatments, then it is advisable to specifically state this is outside of the scope of current guideline.	
National Osteoporosis Guideline Group	001 - 002	General	The conceptual definition of osteoporosis was made by the World Health Organization (WHO) in 1994 as a "progressive systemic skeletal disease characterized by low bone mass and microarchitectural deterioration of bone tissue, with a consequent increase in bone fragility and susceptibility to fracture". Since microarchitectural deterioration could not be measured clinically, the operational description was based on a bone mineral density (BMD) T-Score of =-2.5. Over the years this was adopted as a clinical definition; however, the limitations of focusing on a BMD-based definition alone have since become clear. BMD is now viewed as one, albeit important, risk factor to be considered when assessing fracture risk which is now viewed as the principal necessity. The wording of the introduction does not fully align with the conceptual definition of osteoporosis.	Thank you for your comment. The scope introduction has been updated. The definition for osteoporosis has been edited to mention that traditionally, measurements of bone mineral density (BMD) have been used to diagnose osteoporosis. However, this definition does not recognise that BMD is just one of many factors that influence bone strength and fracture risk, and that most fragility fractures occur in people with a BMD higher than the thresholds used that defined osteoporosis. Mention of osteopenia has been removed from the introduction. Another stakeholder described the term osteopenia as somewhat outdated and best avoided.
National Osteoporosis Guideline Group	001 - 002	General	The use of the term osteopenia is somewhat outdated and best avoided else the risk is to perpetuate it's use.	Thank you for your comment. The scope introduction has been updated. The definition for osteoporosis has been edited to mention that traditionally, measurements of bone mineral density (BMD) have been used to diagnose osteoporosis. However, this definition does not recognise that BMD is just one of many factors that influence bone strength and fracture risk, and that most

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
				fragility fractures occur in people with a BMD higher than the thresholds used that defined osteoporosis. Mention of osteopenia has been removed from the introduction as suggested.
National Osteoporosis Guideline Group	004	003	Consideration of the relative merits of FRAX, with its inclusion of the competing risk of mortality, in preference to QFracture, should be considered, as should the feasibility of mandating inclusion of risk calculators in GP clinical systems through the GP system of choice via NHS Digital as this could make population-level risk assessment feasible.	Thank you for you comment. The focus of this section is how to assess and compare which methods of risk assessment (including FRAX and QFracture) are the best to use. It won't include recommendations related to service delivery such as incorporating risk calculators in GP systems.
National Osteoporosis Guideline Group	004	005	Could consider evaluation of trabecular bone score as an extension to DXA	Thank you for your comment. Trabecular bone score has been added as part of the review questions on the methods of risk assessment.
National Osteoporosis Guideline Group	004	006	Identifying prevalent vertebral fracture is also possible through computer aided diagnostics, which are applicable to both women and men. As the majority of vertebral fractures remain clinically undiagnosed the need for opportunistic identification, at the time of radiographic imaging for another indication, is important.	Thank you for your comment. Automated imaging algorithms and computer based diagnostics have been added as part of the review questions on identifying vertebral fragility fractures.
National Osteoporosis Guideline Group	004	008	As well as bisphosphonate and non-bisphosphonate treatments, there is a need to consider the sequence in which these treatments are used for optimal patient benefit.	Thank you for your comment. Sequencing of treatments will be considered by the committee when they set the review protocols and make recommendations.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			For example, the choice of anabolic therapy prior to anti-resorptive therapy rather than the opposite is associated with greater gains in BMD	
National Osteoporosis Guideline Group	007	025	The question about usefulness of GP patient lists to identify adults for fracture risk assessment is considered to be too vague. The data held in primary care records are partial at best, and may well exclude data necessary for accurate FRAX risk calculation (e.g. determination of corticosteroid use, family history of hip fracture). It would be preferable to assess the potential for use of GP patient lists for risk determination. Relatively new technologies in primary care, such as the FRAX data gathering questionnaire in AccuRx, offer an opportunity to improve the population-level approach to care for people at risk of fracture based on registered GP lists.	Thank you for your comment. The question was added to the scope as it was a research recommendation in the previous version of the NICE guideline on Osteoporosis (https://www.nice.org.uk/guidance/cg146). The committee will review the evidence and comment on the value of these. This question has been updated to state "How accurate are electronic health and social care records (including GP practice lists) for identifying adults who should be assessed for fragility fracture risk?".
National Osteoporosis Guideline Group	008	008	There is an over emphasis on Bindex, which is at best of marginal use, but heavily promoted by companies.	Thank you for your comment. Bindex is used as an example. The committee will consider other methods when they discuss the review protocol. Should the evidence show that the Bindex is not that useful then the committee will be able to make recommendations to reflect that.
National Osteoporosis Guideline Group	008	011	As well as identifying vertebral fractures, there is a need for the presence of vertebral fracture clearly to be communicated to primary care or the fracture liaison services. Terms such as "loss of height" or "wedging" may not be interpreted in primary care as representing an	Thank you for your comment. It is hoped that any vertebral fracture will be reported to primary care or the fracture liaison service using terms that they clearly understand. The terms to use to use in radiographic reports of radiographic reporting have not been included

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			osteoporotic collapse of a vertebra with consequential missed opportunity to intervene	as part of the scope of this guideline because they are already covered by the Royal College of Radiologists' document mentioned in your comment.Their standards for interpretation and reporting of imaging investigations states 'The written report should be clear, and written in a way appropriate to the referrer's expected level of familiarity with the imaging abnormalities detected, the implications for the patient and the referrer's access to requesting further investigations. The wording of the report is likely to differ when it is written to a general practitioner (GP) who may be unfamiliar with a relatively rare condition, compared with a specialist in that particular field'. (https://www.rcr.ac.uk/system/files/publication/field_publication_files/bfcr181_standards_for_interpretation_reporting.pdf).
National Osteoporosis Guideline Group	008	011	Vertebral fracture identification should consider use of computer aided diagnostic algorithms applied to radiographic imaging of the spine in adults, where imaging is conducted for any indication	Thank you for your comment. Automated imaging algorithms and computer based diagnostics have been added to the review question for identifying vertebral fractures as suggested.
National Osteoporosis Guideline Group	008	017	Treatments for osteoporosis in the context of specific drug treatments should be considered, where these drug treatments are associated with bone loss: glucocorticoid therapy for any indication, androgen deprivation therapy for the treatment of prostate cancer in men and aromatase inhibition for the treatment of breast cancer in women.	Thank you for your comment. Drug treatments associated with bone loss are included as part of some

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
				of the risk assessment tools such as QFracture and therefore will be considered as part of risk assessment. Some treatments may be more applicable depending on the comorbidities and their associated treatments. The committee will take this into account when making recommendations. The BNF also notes specific contraindications and MHRA warnings in relation to osteocrenosis in the BNF and these will be considered when making recommendations. More detailed recommendations on specific conditions are likely to be quite specialised areas for treatment and require expert input. These will not be considered in this guideline.
National Osteoporosis Guideline Group	008	022	Non-bisphosphonates should include hormone replacement therapy in younger post-menopausal women. This is currently omitted from the list of possible therapies. This seems to be an oversight.	Thank you for your comment. Hormone replacement therapy has been added as a treatment option and will be looked at in the review.
National Osteoporosis Guideline Group	008	023	Please consider teriparatide biosimilars	Thank you for your comment. Biosimilars, including teriparatide biosimilars will be considered as part of the evidence when looking at the treatments for osteoporosis.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
National Osteoporosis Guideline Group	009	007	The term drug holidays should be replaced throughout for the more professional term 'treatment pauses'. Osteoporosis being a chronic disease, that once identified is a life-long diagnosis.	Thank you for your comment. The question has been updated as suggested to state 'treatment pauses' rather than 'drug holidays'.
National Osteoporosis Guideline Group	009	007	Point 7.3 assumes that a treatment pause is needed, in many it will not, this question would be better rephrased as '7.3 What is the most effective timing and duration of pauses in bisphosphonate treatment, and in whom are they needed?'	Thank you for your comment. The term 'drug holidays' has been changed to 'treatment pauses'. Adding who should get treatment pauses will be considered by the committee when they set the protocols for the review.
National Osteoporosis Guideline Group	009	009	The guideline needs to include management of cessation of denosumab given the now well recognised increased risk of vertebral fracture when denosumab is stopped, and the range of studies that have been performed that aim to mitigate such bone loss through the use of a second agent, commonly.	Thank you for your comment. The sequencing of drugs will be included. The committee will consider making recommendations on this depending on the evidence available. This could include starting on denosumab and changing to a second agent.
National Osteoporosis Guideline Group	009	018	BMD at the lumbar spine ought also to be considered, particularly in younger individuals	Thank you for your comment. This has been updated to just state 'bone mineral density'. The text limiting this to BMD at the femoral neck removed.
NHS England	General	General	It is not clear from the draft scope that steroid use is included in the guideline review – clear inclusion of patients who have taken them – clear link to inflammatory bowel, dermatology and respiratory patients (and others) who may be prescribed steroids regularly.	Thank you for your comment. Steroid use is included as part of some of the risk assessment tools such as QFracture and therefore will be included as part of risk assessment.
NHS England	General	General	Similarly – clear inclusion for consideration of patients with eating disorder and or low BMI	Thank you for your comment. BMI is included as part of the risk assessment tools such as QFracture and and

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
				therefore will be included as part of risk assessment. BMI is seen as an indicator for eating disorders. .
NHS England	General	General	3.5 We strongly suggest adding a line here about ensuring that in delivering the information and support needs of adults with suspected or known risk of fragility fracture, consideration is given to reasonable adjustments for those with learning disability or those who are autistic (and indeed have any other disability)	Thank you for your comment. A question relating to the information and support needs of adults with cognitive impairment, a learning disability or autism and who are at risk of fragility fracture or who have osteoporosis has been added to the guideline.
NHS England	General	General	The current guidance (CG146) does not have any mention at all of either autism or learning disability, so we would really want to see this addressed.	Thank you for your comment. Autism and intellectual disability are mentioned in the Equality Impact Assessment (EIA) form. A question has also been added to the guideline: 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?
NHS England	001	016 - 020	Whilst I understand that this is only the intro to the scoping document, I think it's incorrect to frame osteopenia as a diagnosis. In this para I would reference the World Health Organisation's definition of osteoporosis and osteopenia – i.e. The World Health Organisation has defined osteoporosis as a bone mineral density (BMD) more than 2.5 standard deviations below the mean bone density of a young adult reference range. Osteopenia is defined as BMD between 1 and 2.5 SDs below the mean for a young adult reference range. Whilst having a bone mineral	Thank you for your comment. The scope introduction has been updated. The definition for osteoporosis has been edited to mention that traditionally, measurements of bone mineral density (BMD) have been used to diagnose osteoporosis. However, this definition does not recognise that BMD is just one of many factors that influence bone strength and fracture risk, and that most

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			density within an osteoporotic range significantly increases an individual's risk of fracture, notably a sizeable proportion of people who sustain low trauma fractures have BMD within an osteopenic range.	fragility fractures occur in people with a BMD higher than the thresholds used that defined osteoporosis. Mention of osteopenia has been removed from the introduction. Another stakeholder described the term osteopenia as somewhat outdated and best avoided.
NHS England	002	006 - 008	"In England and Wales, the Falls and Fragility Fracture Audit Programme there are over 300,000 fragility fractures every year in patients aged 50 years and over". This sentence implies that this is the total number of fragility fractures that occur in England and Wales annually. There are two main problems with this assumption. 1) Only where fracture liaison services (FLS) exist will they be reporting to the FLS-DB (many areas don't have an FLS). 2) Even in areas where FLS exist those services might not be reporting their data to the FLS-DB. Therefore, in terms of the total number of fragility fractures occurring, 300,000 is likely to be quite a significant underestimation. Notably the International Osteoporosis Foundation (IOF) suggests that approximately 500,000 fragility fractures occur in the UK annually at present (ref IOF Broken Bones Broken Lives report, 2019)	Thank you for your comment. The introduction has been updated to use the 500,000 figure quoted by the International Osteoporosis Foundation (IOF) to give a more accurate estimate of the number of fragility fractures.
NHS England	007	025	Patient lists could be used to identify adults who could be assessed for fragility fracture risk, but there would need to be a service commissioned for it.	Thank you for your comment. This question aims to review if using lists such as GP lists is an effective way of identifying people at risk of fragility fracture. If they are

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
				considered effective then the guideline committee will also think about the resource impact when considering whether to recommend them. This question has been updated to state "How accurate are electronic health and social care records (including GP practice lists) for identifying adults who should be assessed for fragility fracture risk?". It will only be limited to electronic records
Parkinson's UK	General	General	General response to question 2 We disagree with the decision to exclude non-pharmacological interventions (beyond Vitamin D and Calcium) from this guideline. Exercise is directly beneficial in osteoporosis and fracture risk (Kemmler W, von Stengel S, Bebenek M, Engelke K, Hentschke C, Kalender WA. Exercise and fractures in postmenopausal women: 12-year results of the Erlangen Fitness and Osteoporosis Prevention Study (EFOPS). Osteoporos Int. 2012 Apr;23(4):1267-76. doi: 10.1007/s00198-011-1663-5. Epub 2011 May 28. PMID: 21625881.) and other health benefits, particularly for people with Parkinson's. To exclude exercise from osteoporosis management guidance would deprioritise this important non-pharmacological intervention. We recommend exercise is included as a non-pharmacological intervention in this guideline.	Thank you for your comment. Exercise as a treatment for osteoporosis has been added to the guideline.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
Parkinson's UK	004	001	Despite people with Parkinson's being more than twice as likely to have osteoporosis as people without the condition of the same age (Torsney KM, Noyce AJ, Doherty KM, Bestwick JP, Dobson R, Lees AJ. Bone health in Parkinson's disease: a systematic review and meta-analysis. J Neurol Neurosurg Psychiatry. 2014;85(10):11591166) a UK wide audit of Parkinson's services (UK Parkinson's Audit 2019. https://www.parkinsons.org.uk/professionals/past-audits accessed 22/11/2022) found just under half (47.6%) had any form of bone health assessment. The UK Parkinson's Excellence Network carried out a bone health service improvement initiative (UK Parkinson's Excellence Network (2022) Better Bone Health Service Improvement Project https://www.parkinsons.org.uk/sites/default/files/2022-08/CS3897%20Excellence%20Network%20audit%20report%20covers_final%20%281%29.pdf) using an algorithm for identifying fracture risk in people with Parkinson's (Henderson EJ, Lyell V, Bhimjiyani A, Amin J, Kobylecki C, Gregson CL. Management of fracture risk in Parkinson's: A revised algorithm and focused review of treatments. Parkinsonism Relat Disord. 2019 Jul;64:181-187). This involved 1131 people with Parkinson's who were assessed for bone health and fracture risk by 80 healthcare professionals from 44 specialist services. Through the use of the algorithm, this identified three-quarters of cases	Thank you for your comment. The full list of risk factors to include in the review will be considered by the committee when they develop the review protocol and subsequent recommendations. This scope is only intended to outline the areas and draft review questions that will be covered and not provide the full details of the reviews. Parkinson's Disease is included as part of some of the risk assessment tools such as QFracture and therefore will be included as part of the risk assessment reviews.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			needed an updated bone health assessment. Overall the project saw a 10% absolute increase relative increase of around 67% from pre-project levels in the proportion of people with Parkinson's managed with antiresorptive treatment. We recommend that "innovations in identifying people at risk of fragility fracture" be added to the list of sub-points to point 2 'Identifying adults who should be assessed for fragility fracture risk'.	
Parkinson's UK	005	002	The NICE guideline - Parkinson's disease in adults [NG71] refers to the current NICE clinical guideline - Osteoporosis: assessing the risk of fragility fracture (CG146). People with Parkinson's are more than twice as likely to have osteoporosis compared to unaffected individuals of the same age (Torsney KM, Noyce AJ, Doherty KM, Bestwick JP, Dobson R, Lees AJ. Bone health in Parkinson's disease: a systematic review and meta-analysis. J Neurol Neurosurg Psychiatry. 2014;85(10):11591166) and twice as likely to sustain a fracture, likely resulting from the combination of increased fall risk and osteoporosis (Beydoun HA, Beydoun MA, Mishra NK, Rostant OS, Zonderman AB, Eid SM. Comorbid Parkinson's disease, falls and fractures in the 2010 National Emergency Department Sample. Parkinsonism Relat Disord. 2017 Feb;35:30-35). We recommend that the NICE guideline - Parkinson's	Thank you for your comment. The NICE guideline on Parkinson's disease guideline (https://www.nice.org.uk/guidance/ng71) has been added to the list of related NICE guidance.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			disease in adults [NG71] is included in the list of related NICE guidance.	
Royal College of Physicians	General	General	The RCP is grateful for the opportunity to respond to the above consultation. We have liaised with experts from within our Falls and Fragility Fracture Audit Programme (FFFAP) which includes patient and carer representatives and would like to comment as follows.	Thank you for your response. We have responded to each in turn.
Royal College of Physicians	007	3.1	**What is the diagnostic accuracy of risk assessment tools (including FRAX and QFracture) for predicting the risk of fragility fracture in adults, including those who have had a previous fragility fracture?** Our experts note that FRAX needs to be independently verified.	Thank you for your comment. This will be taken into account when evaluating the evidence relating to the accuracy and effectiveness of FRAX for the review on methods of risk assessment.
Royal College of Physicians	009	027	**Quality Standards 2 & 3** In our experience from the Falls and Fragility Fracture Audit Programme (FFFAP), local data collection is poor. Furthermore, it is often difficult for patients to instigate medications review and/or influence the initiation of medication in primary care de novo.	Thank you for your comment. We will pass on your comments to NICE's quality standards team for this guideline.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			Feedback from our clinical and patient experts recommends that: • The Quality Outcomes Framework is used with defined indicators to promote best practice for both Quality Standards.	
Royal Osteoporosis Society	General	General	'Osteoporosis' itself remains undefined within the scoping document. While definitions do exist, it would help this work if it were clear what the working definition being used is.	Thank you for your comment. The scope introduction has been updated. The definition for osteoporosis has been edited to mention that traditionally, measurements of bone mineral density (BMD) have been used to diagnose osteoporosis. However, this definition does not recognise that BMD is just one of many factors that influence bone strength and fracture risk, and that most fragility fractures occur in people with a BMD higher than the thresholds used that defined osteoporosis.
Royal Osteoporosis Society	002	002	"Osteoporosis increases the risk of fragility fractures, but the risk is increased by other factors such as likelihood of falling, previous fragility fracture, current or frequent recent use of glucocorticoids, family history of hip fracture, smoking and alcohol intake." is confusing. Many of the 'other' factors cause fractures through osteoporosis. Is this an osteoporosis guideline or a fragility fracture guideline?	Thank you for your comment. The scope introduction has been updated. The definition for osteoporosis has been edited to mention that traditionally, measurements of bone mineral density (BMD) have been used to diagnose osteoporosis. However, this definition does not recognise that BMD is just one of many factors that influence bone strength and fracture risk, and that most

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
				fragility fractures occur in people with a BMD higher than the thresholds used that defined osteoporosis. The guideline covers both osteoporosis and the prevention of fragility fractures (but not fragility fracture management). Identifying people at risk of fragility fracture means they could be considered for treatment to prevent them having a fracture. The committee will consider the definitions and appropriate thresholds for treatment when they consider the review protocols and recommendations.
Royal Osteoporosis Society	002	016	The main objective of re-assessments is to improve adherence and should be added to stop or continue treatment.	Thank you for your comment. The introduction has been updated to mention that reassessment may be used to help improve adherence to treatment and also informs decisions to stop, continue or switch treatment.
Royal Osteoporosis Society	004	001	Should replace GP lists with routine NHS / social care data – GP, hospital, community pharmacy lists are also relevant.	Thank you for your comment. This has been updated to the use of electronic health and social care records (including GP practice lists).
Royal Osteoporosis Society	004	006	Is VFRAC validated? Need to include CE marked AI tools as well	Thank you for your comment. The evidence review on identifying vertebral fragility fractures will look for all the evidence including studies that validate its use. Automated imaging algorithms and computer based diagnostics have also been added as part of the review questions on identifying vertebral fragility fractures.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
Royal Osteoporosis Society	004	008	What about assessment and management of modifiable bone risk factors – smoking, alcohol, anorexia, steroids, inflammatory disorders?	Thank you for your comment. Modifiable bone risk factors are taken into account in specific risk assessment tools such as QFracture. The management of modifiable causes of ostreoporosis you mention are covered in other NICE guidelines and are therefore not part of the scope in this guideline.
Royal Osteoporosis Society	004	011	The main method for treatment monitoring is appropriate history taking and checking prescription records and should be added	Thank you for your comment. Appropriate history taking and checking prescription records has not been included as this is a generic good practice for all doctors to follow and not specific to osteoporosis.
Royal Osteoporosis Society	004	021	This should include non-ambulatory fragility fractures (NAFF).	Thank you for your comment. All fragility fractures including non-ambulatory will be considered within the guideline as part of risk assessment and reassessment. However, the management of fractures and immediate follow up will not be covered within the guideline.
Royal Osteoporosis Society	007	028	Risk assessment should be focused on risk factors that determine modifiable risk, e.g. falls risk is not modifiable by bisphosphonate therapy.	Thank you for your comment. Modifiable bone risk factors are taken into account in specific risk assessment tools such as QFracture which will be assessed in the guideline.
Royal Osteoporosis Society	009	018	This should also reference spine bone mineral density.	Thank you for your comment. This has been updated to just state 'bone mineral density'. The text limiting this to BMD at the femoral neck removed.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
Royal Osteoporosis Society	009	019	Better to divide into hip, spine, major and other fragility fractures.	Thank you for your comment. This has been updated to just state 'bone mineral density'. The text limiting this to BMD at the femoral neck removed.
UCB Pharma	General	General	Prevention – the content of the document suggests that the focus of the review will be on 'secondary prevention' of fragility fractures. This is not made clear in the document title or in the introductory text. See for example: https://www.nice.org.uk/guidance/ta160/documents/osteoporosis-secondary-prevention-final-appraisal-determination2 Strategies for 'primary' and 'secondary' prevention of fragility fractures are likely to be very different. We therefore suggest that the document is edited to include a clear definition of 'prevention'.	Thank you for your comment. The aim is for the scope to cover both primary and secondary prevention of fragility fractures. The committee will consider the different options for primary and secondary prevention when they set the review protocols. We have made it clearer in the scope introduction that the guideline will cover both primary and secondary prevention..
UCB Pharma	General	General	Risk – the term 'risk' in relation to fragility fracture is used throughout the document and, in some cases, the meaning is slightly different. Many people will be at risk of fragility fracture which is higher than that of the general population due to their age and sex, but other factors may elevate this risk still further. This is recognised in recent publications including: https://www.nogg.org.uk/full-guideline/summary-main-recommendations	Thank you for your comment. The committee will discuss the level of risk for different groups of people when setting the review protocols and making the subsequent recommendations. The aim of the scope is to provide an overview of the topics and draft review questions covered in the guideline and not go into all the detail.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			https://www.nice.org.uk/guidance/ta791 Furthermore, there is a developing consensus that patients at very high risk of fracture (see for example: Consensus Advisory Statement from the National Osteoporosis Guideline Group (NOGG) and Royal Osteoporosis Society (ROS) on the use of romosozumab, following the 2022 NICE Appraisal. May 2022) should be identified and provided with treatment appropriate to this level of risk. The concept of 'imminent risk' is also important in consideration of treatment strategies, see for example: https://www.nice.org.uk/guidance/ta791 https://www.scottishmedicines.org.uk/medicines-advice/romosozumab-evenity-full-smc2280/ We therefore suggest that a clear definition and categorisation of risk to include the importance of imminent risk and the distinction between 'high' and 'very high' risk, is included in the document. The concept of 'risk' is also pertinent in consideration of strategies of 'primary' and 'secondary prevention'.	

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
UCB Pharma	001	015 - 020	Risk – the term 'risk' in relation to fragility fracture is used throughout the document and, in some cases, the meaning is slightly different. Many people will be at risk of fragility fracture which is higher than that of the general population due to their age and sex, but other factors may elevate this risk still further. This is recognised in recent publications including: https://www.nogg.org.uk/full-guideline/summary-main-recommendations https://www.nice.org.uk/guidance/ta791 Furthermore, there is a developing consensus that patients at very high risk of fracture (see for example: Consensus Advisory Statement from the National Osteoporosis Guideline Group (NOGG) and Royal Osteoporosis Society (ROS) on the use of romosozumab, following the 2022 NICE Appraisal. May 2022) should be identified and provided with treatment appropriate to this level of risk. The concept of 'imminent risk' is also important in consideration of treatment strategies, see for example: https://www.nice.org.uk/guidance/ta791	Thank you for your comment. The committee will discuss the level of risk for different groups of people when setting the review protocols and making the subsequent recommendations. The aim of the scope is to provide an overview of the topics and draft review questions covered in the guideline and not go into all the detail.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			https://www.scottishmedicines.org.uk/medicines-advice/romosozumab-evenity-full-smc2280/ We therefore suggest that a clear definition and categorisation of risk to include the importance of imminent risk and the distinction between 'high' and 'very high' risk, is included in the document. The concept of 'risk' is also pertinent in consideration of strategies of 'primary' and 'secondary prevention'.	
UCB Pharma	002	001	Some fragility fractures occur with no impact, particularly vertebral fractures. Suggest edit this text in line with the definition used by the International Osteoporosis Foundation, see below: "These fractures arise following an event which would otherwise not be expected to result in a fracture. Fractures occurring in a setting of low-level or low-energy trauma, defined as falling from standing height or less, are usually considered as osteoporotic." Fragility fractures | International Osteoporosis Foundation	Thank you for your comment. The scope introduction has been updated to state "Fractures associated with osteoporosis, often described as 'fragility' fractures, typically result from a low impact injury such as a fall from standing height or less which would otherwise not be expected to result in a fracture. Fragility fractures can occur spontaneously with no history of injury and most vertebral fractures do not result from a fall but are precipitated by an activity involving lifting, twisting or bending."
UCB Pharma	002	003 - 005	The list of potential risk factors is not exhaustive. Suggest that text is edited to reflect this or to include a comprehensive list. See:https://www.osteoporosis.foundation/patients/about-	Thank you for your comment. This is only a brief introduction and does not go into all the details of the causes and consequences of osteoporosis. Therefore not all risk factors are included.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			osteoporosis/risk-factors https://www.nogg.org.uk/full-guideline	
UCB Pharma	002	007	The figure of 300,000 would benefit from updating. For example: 'In 2019, 526,974 fragility fractures occurred in the UK, men and women aged 50 and older' (Kanis et al, Arch Osteo, 2021 [SCOPE 2021])	Thank you for your comment. The introduction has been updated to use the 500,000 figure quoted by the International Osteoporosis Foundation (IOF) to give a more accurate estimate of the number of fragility fractures.
UCB Pharma	002	011 - 014	Prevention – the content of the document suggests that the focus of the review will be on 'secondary prevention' of fragility fractures. This is not made clear in the document title or in the introductory text. See for example: https://www.nice.org.uk/guidance/ta160/documents/osteoporosis-secondary-prevention-final-appraisal-determination2 Strategies for 'primary' and 'secondary' prevention of fragility fractures are likely to be very different. We therefore suggest that the document is edited to include a clear definition of 'prevention'. Risk – the term 'risk' in relation to fragility fracture is used throughout the document and, in some cases, the meaning is slightly different. Many people will be at risk of fragility fracture which is higher than that of the general population due to their age and sex, but other factors may elevate this	Thank you for your comment. The aim is for the scope to cover both primary and secondary prevention of fragility fractures. The committee will consider the different options for primary and secondary prevention when they set the review protocols. We have made it clearer in the scope introduction that the guideline will cover both primary and secondary prevention.. The committee will discuss the level of risk for different groups of people when setting the review protocols and making the subsequent recommendations. The aim of the scope is to provide an overview of the topics and draft review questions covered in the guideline and not go into all the detail.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			risk still further. This is recognised in recent publications including: https://www.nogg.org.uk/full-guideline/summary-main-recommendations https://www.nice.org.uk/guidance/ta791 Furthermore, there is a developing consensus that patients at very high risk of fracture (see for example: Consensus Advisory Statement from the National Osteoporosis Guideline Group (NOGG) and Royal Osteoporosis Society (ROS) on the use of romosozumab, following the 2022 NICE Appraisal. May 2022) should be identified and provided with treatment appropriate to this level of risk. The concept of 'imminent risk' is also important in consideration of treatment strategies, see for example: https://www.nice.org.uk/guidance/ta791 https://www.scottishmedicines.org.uk/medicines-advice/romosozumab-evenity-full-smc2280/ We therefore suggest that a clear definition and categorisation of risk to include the importance of imminent	

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			risk and the distinction between 'high' and 'very high' risk, is included in the document. The concept of 'risk' is also pertinent in consideration of strategies of 'primary' and 'secondary prevention'.	
UCB Pharma	002	019 - 020	Risk – the term 'risk' in relation to fragility fracture is used throughout the document and, in some cases, the meaning is slightly different. Many people will be at risk of fragility fracture which is higher than that of the general population due to their age and sex, but other factors may elevate this risk still further. This is recognised in recent publications including:https://www.nogg.org.uk/full-guideline/summary-main-recommendations https://www.nice.org.uk/guidance/ta7 91 Furthermore, there is a developing consensus that patients at very high risk of fracture (see for example: Consensus Advisory Statement from the National Osteoporosis Guideline Group (NOGG) and Royal Osteoporosis Society (ROS) on the use of romosozumab, following the 2022 NICE Appraisal. May 2022) should be identified and provided with treatment appropriate to this level of risk. The concept of 'imminent risk' is also important in consideration of treatment strategies, see for example:https://www.nice.org.uk/guidance/ta791https://ww	Thank you for your comment. The committee will discuss the level of risk for different groups of people when setting the review protocols and making the subsequent recommendations. The aim of the scope is to provide an overview of the topics and draft review questions covered in the guideline and not go into all the detail.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			w.scottishmedicines.org.uk/medicines-advice/romosozumab-evenity-full-smc2280/ We therefore suggest that a clear definition and categorisation of risk to include the importance of imminent risk and the distinction between 'high' and 'very high' risk, is included in the document. The concept of 'risk' is also pertinent in consideration of strategies of 'primary' and 'secondary prevention'.	
UCB Pharma	002	021	Suggest language to discriminate two treatment modes should be 'anabolic and antiresorptive therapies' rather than 'bisphosphonate and non-bisphosphonate'. See https://www.nogg.org.uk/full-guideline	Thank you for your comment. The introduction has been updated and specific mention of categories of pharmacological treatments have been removed. Reference to 'anabolic and antiresorptive therapies' has been made in the section on 'Key areas that will be covered'.
UCB Pharma	003	023	Risk – the term 'risk' in relation to fragility fracture is used throughout the document and, in some cases, the meaning is slightly different. Many people will be at risk of fragility fracture which is higher than that of the general population due to their age and sex, but other factors may elevate this risk still further. This is recognised in recent publications including: https://www.nogg.org.uk/full-guideline/summary-main-recommendations	Thank you for your comment. The committee will discuss the level of risk for different groups of people when setting the review protocols and making the subsequent recommendations. The aim of the scope is to provide an overview of the topics and draft review questions covered in the guideline and not go into all the detail.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			https://www.nice.org.uk/guidance/ta791 Furthermore, there is a developing consensus that patients at very high risk of fracture (see for example: Consensus Advisory Statement from the National Osteoporosis Guideline Group (NOGG) and Royal Osteoporosis Society (ROS) on the use of romosozumab, following the 2022 NICE Appraisal. May 2022) should be identified and provided with treatment appropriate to this level of risk. The concept of 'imminent risk' is also important in consideration of treatment strategies, see for example: https://www.nice.org.uk/guidance/ta791 https://www.scottishmedicines.org.uk/medicines-advice/romosozumab-evenity-full-smc2280/ We therefore suggest that a clear definition and categorisation of risk to include the importance of imminent risk and the distinction between 'high' and 'very high' risk, is included in the document. The concept of 'risk' is also pertinent in consideration of strategies of 'primary' and 'secondary prevention'.	

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
UCB Pharma	003	025	Suggest that the document should explicitly include consideration of effective service models such as fracture liaison service.	Thank you for your comment. Methods of service delivery are not part of the scope of this guideline and therefore this has not been included.
UCB Pharma	004	001	The list of potential risk factors is not exhaustive. Suggest that text is edited to reflect this or to include a comprehensive list. See: https://www.osteoporosis.foundation/patients/about-osteoporosis/risk-factors https://www.nogg.org.uk/full-guideline	Thank you for your comment. The full list of risk factors to include in the review will be considered by the committee when they develop the review protocol and subsequent recommendations. This scope is only intended to outline the areas and draft review questions that will be covered and not provide the full details of the reviews.
UCB Pharma	004	003 - 005	Risk – the term 'risk' in relation to fragility fracture is used throughout the document and, in some cases, the meaning is slightly different. Many people will be at risk of fragility fracture which is higher than that of the general population due to their age and sex, but other factors may elevate this risk still further. This is recognised in recent publications including:https://www.nogg.org.uk/full-guideline/summary-main-recommendations https://www.nice.org.uk/guidance/ta791Furthermore, there is a developing consensus that patients at very high risk of fracture (see for example: Consensus Advisory Statement from the National Osteoporosis Guideline Group (NOGG) and Royal Osteoporosis Society (ROS) on the use of romosozumab, following the 2022 NICE Appraisal. May 2022) should be identified and provided with treatment	Thank you for your comment. The committee will discuss the level of risk for different groups of people when setting the review protocols and making the subsequent recommendations. The aim of the scope is to provide an overview of the topics and draft review questions covered in the guideline and not go into all the detail.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			appropriate to this level of risk. The concept of 'imminent risk' is also important in consideration of treatment strategies, see for example:https://www.nice.org.uk/guidance/ta791https://www.scottishmedicines.org.uk/medicines-advice/romosozumab-evenity-full-smc2280/ We therefore suggest that a clear definition and categorisation of risk to include the importance of imminent risk and the distinction between 'high' and 'very high' risk, is included in the document. The concept of 'risk' is also pertinent in consideration of strategies of 'primary' and 'secondary prevention'.	
UCB Pharma	004	004	The importance of BMD assessment in the risk assessment is noted in the scoping document, implying that that DEXA should be undertaken for all patients regardless of age. Suggest explicit statement that criteria for DEXA based on age and also availability of DEXA scanning is included in the review.	Thank you for your comment. DXA is included as part of the review. The criteria for its inclusion and its availability will be considered by the committee in the review protocols and when making recommendations on the methods of risk assessment.
UCB Pharma	004	006	The scoping document does not mention the activity of case finding which is carried out in some hospitals. Suggest explicit inclusion of case finding in addition to 'identifying vertebral fractures'. See for example: ros-clinical-standards-for-fracture-liaison-services-august-2019.pdf (theros.org.uk)	Thank you for your comment. Questions related to identifying people who should be assessed for fragility fracture risk are covered in section 2 of the key areas. This would include any assessment for fracture risk including vertebral fracture risk. Question 2.1 has been updated to "How accurate are electronic health and social care records (including GP practice lists) for

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			ros-vertebral-fracture-guidelines-november-2017.pdf (theros.org.uk)	identifying adults who should be assessed for fragility fracture risk?"
UCB Pharma	004	006	Suggest that the review should include use of emerging technologies such as algorithms applied to imaging modalities as a way of identifying vertebral fractures. See: VFRAC is a tool aimed at primary care to differentiate between back pain and pain caused by undiagnosed vertebral fractures: An observational cohort study to produce and evaluate an improved tool to screen older women with back pain for osteoporotic vertebral fractures (Vfrac): study protocol (springer.com)Radiological guidance for the recognition and reporting of osteoporotic vertebral fragility fractures (VFFs) | The Royal College of Radiologists (rcr.ac.uk) – contains a section on AI and vert fractures (section 7)	Thank you for your comment. Automated imaging algorithms and computer based diagnostics have been added as part of the review questions on identifying vertebral fragility fractures.
UCB Pharma	004	006 - 007	Suggest that methods of radiographic reporting of vertebral fractures is covered in the review and explicitly stated in this scoping document. See: https://www.rcr.ac.uk/publication/radiological-guidance-recognition-and-reporting-osteoporotic-vertebral-fragility	Thank you for your comment. The methods of radiographic reporting have not been included as part of the scope of this guideline because they are already covered by the Royal College of Radiologists' document mentioned in your comment.
UCB Pharma	004	009 - 010	Suggest language to discriminate two treatment modes should be 'anabolic and antiresorptive therapies' rather than 'bisphosphonate and non-bisphosphonate'. See https://www.nogg.org.uk/full-guideline	Thank you for you comment. This has been updated to 'bisphosphonate medicines' and 'non-bisphosphonate medicines (anabolic and antiresorptive therapies)'.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
UCB Pharma	004	014	Risk – the term 'risk' in relation to fragility fracture is used throughout the document and, in some cases, the meaning is slightly different. Many people will be at risk of fragility fracture which is higher than that of the general population due to their age and sex, but other factors may elevate this risk still further. This is recognised in recent publications including:https://www.nogg.org.uk/full-guideline/summary-main-recommendationshttps://www.nice.org.uk/guidance/ta791 Furthermore, there is a developing consensus that patients at very high risk of fracture (see for example: Consensus Advisory Statement from the National Osteoporosis Guideline Group (NOGG) and Royal Osteoporosis Society (ROS) on the use of romosozumab, following the 2022 NICE Appraisal. May 2022) should be identified and provided with treatment appropriate to this level of risk. The concept of 'imminent risk' is also important in consideration of treatment strategies, see for example:https://www.nice.org.uk/guidance/ta791https://www.scottishmedicines.org.uk/medicines-advice/romosozumab-evenity-full-smc2280/ We therefore suggest that a clear definition and categorisation of risk to include the importance of imminent risk and the distinction between 'high' and 'very high' risk, is included in the document. The concept of 'risk' is also pertinent in	Thank you for your comment. The committee will discuss the level of risk for different groups of people when setting the review protocols and making the subsequent recommendations. The aim of the scope is to provide an overview of the topics and draft review questions covered in the guideline and not go into all the detail.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			consideration of strategies of 'primary' and 'secondary prevention'.	
UCB Pharma	007	010	Suggest inclusion of 'FRAX' as well as the update of the FRAX tool expected during the review period. See: Update of the fracture risk prediction tool FRAX: a systematic review of potential cohorts and analysis plan	Thank you for your comment. This is generic text on how the economic aspects will be taken into account in the guideline. Therefore, there is no mention of specific diagnostic tools or treatments. Searches for evidence are normally rerun towards the end of guideline development and we will look out for any updates related to the FRAX tool.
UCB Pharma	007	016	No comment on the text. Suggestion that it would be helpful to work with iFRAP in regard to how to discuss risk with patients. See Improving uptake of Fracture Prevention Treatments (iFRAP): Development and evaluation of a consultation intervention - NIHR Funding and Awards	Thank you for your comment. NICE guidelines use published evidence rather than getting involved in ongoing research. The uptake of treatments or treatment adherence will be considered as an outcome in some of the reviews for the guideline. Interventions to improve adherence are not part of the scope for this guideline.
UCB Pharma	007	014 - 020	Risk – the term 'risk' in relation to fragility fracture is used throughout the document and, in some cases, the meaning is slightly different. Many people will be at risk of fragility fracture which is higher than that of the general population due to their age and sex, but other factors may elevate this risk still further. This is recognised in recent publications including:https://www.nogg.org.uk/full-guideline/summary-main-recommendations https://www.nice.org.uk/guidance/ta791Furthermore, there is a developing consensus that patients at very high risk of	Thank you for your comment. The committee will discuss the level of risk for different groups of people when setting the review protocols and making the subsequent recommendations. The aim of the scope is to provide an overview of the topics and draft review questions covered in the guideline and not go into all the detail.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			fracture (see for example: Consensus Advisory Statement from the National Osteoporosis Guideline Group (NOGG) and Royal Osteoporosis Society (ROS) on the use of romosozumab, following the 2022 NICE Appraisal. May 2022) should be identified and provided with treatment appropriate to this level of risk. The concept of 'imminent risk' is also important in consideration of treatment strategies, see for example:https://www.nice.org.uk/guidance/ta791https://www.scottishmedicines.org.uk/medicines-advice/romosozumab-evenity-full-smc2280/ We therefore suggest that a clear definition and categorisation of risk to include the importance of imminent risk and the distinction between 'high' and 'very high' risk, is included in the document. The concept of 'risk' is also pertinent in consideration of strategies of 'primary' and 'secondary prevention'.	
UCB Pharma	007	028 - 031	Clear stratification of risk would be very helpful here. See comment 2.	Thank you for your comment. The committee will discuss the level of risk for different groups of people when setting the review protocols and making the subsequent recommendations. The aim of the scope is to provide an overview of the topics and draft review questions covered in the guideline and not go into all the detail.
UCB Pharma	008	007 - 010	Suggest that list of 'bone density assessment techniques' should include 'vertebral fracture assessment (VFA)'	Thank you for your comment. Vertebral fracture assessment is included as part of questions in the

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
				following section on identifying vertebral fragility fractures, questions 4.1 and 4.2.
UCB Pharma	008	011 - 015	Suggest that methods of radiographic reporting of vertebral fractures is covered in the review and explicitly stated in this scoping document. See: https://www.rcr.ac.uk/publication/radiological-guidance-recognition-and-reporting-osteoporotic-vertebral-fragility	Thank you for your comment. The methods of radiographic reporting have not been included as part of the scope of this guideline because they are already covered by the Royal College of Radiologists' document mentioned in your comment.
UCB Pharma	008	030 - 032	Clear stratification of risk would be very helpful in determining cost effectiveness. We therefore suggest that a clear definition and categorisation of risk to include the importance of imminent risk and the distinction between 'high' and 'very high' risk, is included in the document.Risk – the term 'risk' in relation to fragility fracture is used throughout the document and, in some cases, the meaning is slightly different. Many people will be at risk of fragility fracture which is higher than that of the general population due to their age and sex, but other factors may elevate this risk still further. This is recognised in recent publications including:https://www.nogg.org.uk/full-guideline/summary-main-recommendationshttps://www.nice.org.uk/guidance/ta791Furthermore, there is a developing consensus that patients at very high risk of fracture (see for example: Consensus	Thank you for your comment. The committee will discuss the level of risk for different groups of people when setting the review protocols and making the subsequent recommendations. The aim of the scope is to provide an overview of the topics and draft review questions covered in the guideline and not go into all the detail.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			Advisory Statement from the National Osteoporosis Guideline Group (NOGG) and Royal Osteoporosis Society (ROS) on the use of romosozumab, following the 2022 NICE Appraisal. May 2022) should be identified and provided with treatment appropriate to this level of risk. The concept of 'imminent risk' is also important in consideration of treatment strategies, see for example:https://www.nice.org.uk/guidance/ta791https://www.scottishmedicines.org.uk/medicines-advice/romosozumab-evenity-full-smc2280/	
UCB Pharma	009	004 - 005	Clear stratification of risk would be very helpful in determining cost effectiveness. We therefore suggest that a clear definition and categorisation of risk to include the importance of imminent risk and the distinction between 'high' and 'very high' risk, is included in the document.Risk – the term 'risk' in relation to fragility fracture is used throughout the document and, in some cases, the meaning is slightly different. Many people will be at risk of fragility fracture which is higher than that of the general population due to their age and sex, but other factors may elevate this risk still further. This is recognised in recent publications including:https://www.nogg.org.uk/full-guideline/summary-main-recommendationshttps://www.nice.org.uk/guidance/ta791Furthermore, there is a developing consensus that patients at	Thank you for your comment. The committee will discuss the level of risk for different groups of people when setting the review protocols and making the subsequent recommendations. The aim of the scope is to provide an overview of the topics and draft review questions covered in the guideline and not go into all the detail.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			very high risk of fracture (see for example: Consensus Advisory Statement from the National Osteoporosis Guideline Group (NOGG) and Royal Osteoporosis Society (ROS) on the use of romosozumab, following the 2022 NICE Appraisal. May 2022) should be identified and provided with treatment appropriate to this level of risk. The concept of 'imminent risk' is also important in consideration of treatment strategies, see for example:https://www.nice.org.uk/guidance/ta791https://www.scottishmedicines.org.uk/medicines-advice/romosozumab-evenity-full-smc2280/	
UCB Pharma	009	017	Major osteoporotic fractures include humerus and other sites. Suggest edit to include all MOFs.	Thank you for your comment. All fragility fractures will be included. Hip and vertebral are just mentioned as examples of fragility fractures.
University of Oxford, Dept. of Psychiatry	General	General	Scope question 1: Are there any cost saving interventions or examples of innovative approaches that should be considered for inclusion in this guideline? Yes, for people with intellectual disabilities (please see comment 3 for details)	Thank you for your comment. Autism and intellectual disability are mentioned in the Equality Impact Assessment (EIA) form. A question has also been added to cover the the information and support needs of adults with cognitive impairment, a learning disability or autism and who are at risk of fragility fracture or who have osteoporosis. The committee will also consider analysing the data separately for this group when they set the review protocols.
University of Oxford, Dept. of Psychiatry	General	General	Scope question 2: Do you agree with the decision to exclude non-pharmacological interventions (beyond Vitamin D and	Thank you for your comment. Exercise as a treatment for osteoporosis has been added to the guideline.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			Calcium) from this guideline? Please explain the reasons for your response I think a key non-pharmacological intervention, namely weight bearing physical exercise (whenever possible and/or other forms of exercise if weight bearing difficult), should be part of the guideline. This is particularly true for groups of people with a sedentary lifestyle or impaired mobility such as those with intellectual and/or physical disabilities. It would add complexity to the document but the nature of the intervention is so important and the scope for improvement so large that it should not be overlooked	
University of Oxford, Dept. of Psychiatry	General	General	The guideline should also cover people with eating disorders, within the limitations of currently available evidence. This is because they have a high incidence of fragility fractures, and they are protected by the Disability Act.	Thank you for your comment. The list of risk factors to include when assessing the risk of fragility fractures will be considered by the committee when they develop the review protocol and subsequent recommendations for the risk assessment reviews. We will ask the committee to consider including eating disorders as a factor.
University of Oxford, Dept. of Psychiatry	General	General	The guideline is expected to be issued in January 2025. However, highly relevant papers from my research team (Frighi et al.) on osteoporosis in people with intellectual disabilities will be published by May-June 2023. These papers (a total of four, to add to the one already published, DOI: https://doi.org/10.1016/j.eclinm.2022.101656) are expected to have a substantial impact on public health policy. Can their evidence be considered, summarised and	Thank you for your comment. Any published evidence identified that fits the review protocols will be included as part of the guideline. If this evidence is available when the final searches then it will be considered for inclusion in the gujideline.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			published ahead of the full guideline? It will be very difficult to delay public health and clinical action for 18 months if the results of our studies confirm, as expected, the need for change in practice.	
University of Oxford, Dept. of Psychiatry	004	003 - 005	My research team and I have developed and validated a risk score for major osteoporotic fracture and for hip fracture in people with intellectual disabilities (ID). We have assessed the cost-effectiveness of its use vs risk assessment as usual (i.e.current NICE guidelines, same age thresholds and from age 40, assuming QFracture as risk calculator) and vs DXA from age 40 in all people with ID (with subsequent actions according to DXA results). We would like to contribute to the development of the guidance in relation to methods of risk assessment as soon as we'll be able to share the data with NICE (expected February-March 2023).	Thank you for your comment. Any published evidence identified that fits the review protocols will be included as part of the guideline. If this evidence is available when the final searches then it will be considered for inclusion in the gujideline.
University of Oxford, Dept. of Psychiatry	004	008 - 010	There is extremely limited information on osteoporosis medication in people with intellectual disabilities. There is some evidence showing efficacy of bisphosphonates both in fracture reduction and in increasing bone mineral density. Treatment recommendations for this population should take this literature into account.	Thank you for your comment. Any published evidence identified that fits the review protocols will be included as part of the guideline. If this evidence is available when the final searches then it will be considered for inclusion in the gujideline.
University of Oxford, Dept. of Psychiatry	004	008 - 010	I would also like to point out the only study on the side effects of antiresorptives (osteonecrosis of the jaw in particular) in people with intellectual disabilities (Frighi et al. Use and risk of side effects of antiresorptive medication in people with	Thank you for your comment. The committee will consider including these as side effects as outcomes when they set the review protocols for antiresorptives. However, as oral hygiene and dental health are not key

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			intellectual disabilities). This study is going to be published by approximately 15/12/2022 on the NIHR Open Research site (https://openresearch.nihr.ac.uk/browse/articles). The study should be taken into consideration when making recommendations about oral hygiene and dental health in those considered for antiresorptive treatment.	areas prioritised for inclusion in the scope of the guideline specific recommendations in this area are unlikely to be made in the guideline.
White Hart Clinic	004	008	There appears a lack of emphasis on physical activity and particularly Resistance Training in terms of prevention and indication of management of osteoporosis:New guidelines on bone health were recently published in bjsm (Brooke Wavell et al 2022) in the british journal of sport medicine this year:First Key recommendations are that people with osteoporosis should undertake resistance and impact exercise to maximise bone strength; Muscle-strengthening physical activity and exercise is recommended on two or three<U+2009>days of the week to maintain bone strength. Resistance exercises involving major muscle groups should be used to load skeletal sites at risk of osteoporotic fracture, such as the spine, proximal femur and forearmFor maximum benefit, muscle strengthening should include progressive muscle resistance trainingLower intensity exercise ensuring good technique is recommended before increasing intensity levels.All muscle groups should be targeted, including back muscles to promote bone strength in the spineBrooke-Wavell, K. et al. (2022) "Strong, steady and straight: UK consensus	Thank you for your comment. Exercise as a treatment for osteoporosis has been added to the guideline. The interventions to consider in the review will be discussed by the committee when they set the protocol. The citations you have provided will be considered for inclusion in the review on exercise.

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			statement on physical activity and exercise for osteoporosis," British Journal of Sports Medicine, 56(15), pp. 837–846. Available at: https://doi.org/10.1136/bjsports-2021-104634. In 2017 Australian RCT study, looking at over 100 post MP women with low to v low bone mass. It is the LIFTMOR study, if you haven't done so yet, have a read, it stands for 'lifting intervention for Training Muscle and osteoporosis RehabFor 8 months the group participated in 2 weekly supervised HI progressive resistant training and impact weight bearing training. One of the first big study on women with low bone mass that introduced training that was not low intensity and playing it on the safe side. The intervention group did dead lifts, overhead press, back squats, jumping chin ups with drop landings. It was high intensity, 5 sets of 5 repetitions, >85% of their RM (repetition maximum)The control group followed a home base program of low intensity training, more focus on mobility and balanceThe results showed the high intensity training was save, only 1 minor adverse event in more than 2600 training sessions and more importantly the benefit: the women in the intervention group showed improvement in function, bone health and to my surprise there was an Improvement in thoracic kyphosis, not just maintained, even with stress fractures the program reversed some of it.It appears that HiRes & Impact Training to be a highly appealing therapeutic option for the management of	

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			osteoporosis in postmenopausal women with low to very low bone mass.Watson, S., Weeks, B., Weis, L., Harding, A., Horan, S. and Beck, B., 2019. High-Intensity Resistance and Impact Training Improves Bone Mineral Density and Physical Function in Postmenopausal Women With Osteopenia and Osteoporosis: The LIFTMOR Randomized Controlled Trial. Journal of Bone and Mineral Research, 34(3), pp.572-572.Other references:Gunter, J., The menopause manifesto. Helpful evidenced based chapter on ostoeporosisHansen, M., & Kjaer, M. (2016). Sex Hormones and Tendon. Advances in ExperimentalMedicine and Biology, 920, 139–149. https://doi.org/10.1007/978-3-319-33943-6_13Hettchen, M., von Stengel, S., Kohl, M., Murphy, M. H., Shojaa, M., Ghasemikaram, M.,Bragonzoni, L., Benvenuti, F., Ripamonti, C., Benedetti, M. G., Julin, M., Risto, T., &Kemmler, W. (2021). Changes in menopausal risk factors in early postmenopausalosteopenic women after 13 months of high-intensity exercise: The randomized controlledACTLIFE-RCT. Clinical Interventions in Aging, 16, 83–96.Kistler-Fischbacher, M., Weeks, B.K. and Beck, B.R. (2021) "The effect of exercise intensity on bone in Postmenopausal women (part 1): A systematic review," Bone, 143, p. 115696. Available at: https://doi.org/10.1016/j.bone.2020.115696. Kistler-Fischbacher, M., Weeks, B.K. and Beck, B.R. (2021) "The effect of exercise intensity on bone in Postmenopausal	

Osteoporosis: risk assessment, treatment, and fragility fracture prevention (update)

Consultation on draft scope
Stakeholder comments table

27/10/2022 – 01/12/2022

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments	Developer's response
			women (part 2): A meta-analysis," Bone, 143, p. 115697. Available at: https://doi.org/10.1016/j.bone.2020.115697. https://moving medicine.ac.ukHormone Replacement therapy & prevention of Osteoporosis, most recent position statment:For women aged younger than 60 years or who are within 10 years of menopause onset and have no contra-indications, the benefit-risk ratio is favourable for treatment and prevention of bone loss.NAMS POSITION STATEMENT The 2022 hormone therapy position statement of The North American Menopause Society https://www.menopause.org/docs/default-source/professional/nams-2022-hormone-therapy-position-statement. Resources pdf	