

Medical Policy



Title: Bone Mineral Density Studies

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Populations	Interventions	Comparators	Outcomes
Individuals: • Who are eligible for screening of bone mineral density based on risk factor assessment	Interventions of interest are: • Initial dual x-ray absorptiometry analysis of central sites (hip or spine)	Comparators of interest are: • Clinical risk assessment without bone mineral density testing	Relevant outcomes include: • Morbid events • Functional outcomes • Quality of life • Hospitalizations • Medication use
Individuals: • Without osteoporosis on initial screen	Interventions of interest are: • Repeat dual x-ray absorptiometry analysis of central sites (hip or spine)	Comparators of interest are: • Clinical risk assessment without bone mineral density testing	Relevant outcomes include: • Morbid events • Functional outcomes • Quality of life • Hospitalizations • Medication use
Individuals:	Interventions of interest are:	Comparators of interest are:	Relevant outcomes include:

Populations	Interventions	Comparators	Outcomes
<ul style="list-style-type: none"> Who are receiving pharmacologic treatment for osteoporosis 	<ul style="list-style-type: none"> Repeat dual x-ray absorptiometry analysis of central sites (hip or spine) 	<ul style="list-style-type: none"> Clinical risk assessment without bone mineral density testing 	<ul style="list-style-type: none"> Morbid events Functional outcomes Quality of life Hospitalizations Medication use
<p>Individuals:</p> <ul style="list-style-type: none"> Who are eligible for screening of bone mineral density based on risk factor assessment 	<p>Interventions of interest are:</p> <ul style="list-style-type: none"> Ultrasound densitometry Quantitative computed tomography Dual x-ray absorptiometry analysis of peripheral sites 	<p>Comparators of interest are:</p> <ul style="list-style-type: none"> Dual x-ray absorptiometry analysis of central sites 	<p>Relevant outcomes include:</p> <ul style="list-style-type: none"> Morbid events Functional outcomes Quality of life Hospitalizations Medication use

DESCRIPTION

Bone mineral density (BMD) studies can be used to identify individuals with osteoporosis and monitor response to osteoporosis treatment, with the goal of reducing the risk of fracture. Bone density is most commonly evaluated with dual x-ray absorptiometry (DXA); other technologies are available.

OBJECTIVE

The objective of this evidence review is to examine whether bone mineral density studies improve health outcomes in individuals at risk of osteoporotic fracture.

BACKGROUND

Osteoporosis

Osteoporosis is determined using the World Health Organization (WHO) diagnostic thresholds for osteoporosis based on bone mineral density (BMD) measurement compared with a calculated T-score.

Risk factors for fracture include low bone mass, low bone strength, a personal history of fracture as an adult, or a history of fracture in a first-degree relative. Osteoporosis, defined as low bone mass leading to an increased risk of fragility fractures, is an extremely common disease in the elderly population due to age-related bone loss in both sexes and menopause-related bone loss in women. The WHO has diagnostic thresholds for osteoporosis based on BMD measurements compared with a T-score, which is the standard deviation difference between an individual’s BMD and that of a young adult reference population. Conditions that can cause or contribute to osteoporosis include lifestyle factors such as low intake of calcium, high intake of alcohol or cigarette smoking, and thinness. Other risk factors for osteoporosis include certain endocrine, hematologic, gastrointestinal tract and genetic disorders, hypogonadal states, and medications.

Bone mineral density can be measured either centrally (i.e., hip or spine) or peripherally (i.e., wrist, finger, heel). While BMD measurements are predictive of fragility fractures at all sites, central measurements of the hip and spine are the most predictive. Fractures of the hip and spine (i.e., vertebral fractures) are also considered to be the most clinically relevant. Bone mineral density is typically expressed as a T-score.

The utility of screening BMD measurements can be established by demonstrating that screening identifies a population at increased risk of fracture and that, by treating those at-risk individuals, the rate of fractures is reduced, thereby lowering fracture-related morbidity and mortality. The potential benefits of screening should outweigh the risks (radiation exposure) or false-positives (initiation of unnecessary treatment).

Bone Mineral Density

The decision to perform a bone density assessment should be based on an individual's fracture risk profile and skeletal health assessment. In addition to age, sex, and BMD, risk factors included in the WHO Fracture Risk Assessment Tool¹, are:

- Low body mass index;
- Parental history of hip fracture;
- Previous fragility fracture in adult life (i.e., occurring spontaneously or a fracture arising from trauma, which, in a healthy individual, would not have resulted in a fracture);
- Current smoking or 3 or more units of alcohol daily, where a unit is equivalent to a standard glass of beer (285 mL), a single measure of spirits (30 mL), a medium-sized glass of wine (120 mL), or 1 measure of an aperitif (60 mL);
- A disorder strongly associated with osteoporosis, which includes rheumatoid arthritis, type I (insulin-dependent) diabetes, osteogenesis imperfecta in adults, untreated long-standing hyperthyroidism, hypogonadism or premature menopause (<45 years), chronic malnutrition or malabsorption, and chronic liver disease;
- Current exposure to oral glucocorticoids or exposure to oral glucocorticoids for more than 3 months at a dose of prednisolone 5 mg daily or more (or equivalent doses of other glucocorticoids).

Dual x-ray absorptiometry (DXA) is the most commonly used technique to measure BMD because of its ease of use, low radiation exposure, and its ability to measure BMD at both the hip and spine. Dual x-ray absorptiometry generates 2 x-ray beams of different energy levels to scan the region of interest and measures the difference in attenuation as the low- and high-energy beams pass through the bone and soft tissue. The low-energy beam is preferentially attenuated by bone, while the high-energy beam is attenuated by both bone and soft tissue. This difference in attenuation between the 2 beams allows for correction for the irregular masses of soft tissue, which surrounds the spine and hip, and therefore the measurement of bone density at those sites.

A T-score is the standard deviation difference between an individual's BMD and that of a young adult reference population (Table 1).

Table 1. WHO Classification of Bone Mineral Density T-Scores

Assessment	BMD Definition
Normal	Bone density is within 1 SD (+1 or -1) of the young adult mean.
Osteopenia (low bone mass)	Bone density is between 1 and 2.5 SD below the young adult mean (-1 to -2.5 SD).
Osteoporosis	Bone density is 2.5 SD or more below the young adult mean (-2.5 SD or lower).
Severe (established) osteoporosis	Bone density is more than 2.5 SD below the young adult mean, and there have been 1 or more osteoporotic fractures.

BMD: bone mineral density; SD: standard deviation; WHO: World Health Organization.

Other Measurement Tools

Available diagnostic tools use either X-rays or ultrasound. X-ray based methods measure BMD. However, studies suggest that in addition to measuring structural aspects of the bone by assessing BMD, other mechanical features and elastic properties of the bone are also important to predict the risk of fractures. X-ray based methods cannot assess these properties and therefore use of alternative methodologies such as ultrasound densitometry and quantitative computed tomography (CT) have been explored.

Quantitative Computed Tomography

Quantitative CT depends on the differential absorption of ionizing radiation by calcified tissue and is used for central measurements only. Compared with DXA, quantitative CT is less readily available and associated with relatively high radiation exposure and relatively high cost. Analysis of previously obtained clinical CT scans of the pelvis might provide an alternative method of assessing biomechanical bone strength.

Ultrasound Densitometry

Ultrasound densitometry is a technique for measuring BMD at peripheral sites, typically the heel but also the tibia and phalanges. Compared with osteoporotic bone, normal bone demonstrates higher attenuation of the ultrasound wave and is associated with a greater velocity of the wave passing through bone. Ultrasound densitometry has no radiation exposure, and machines may be purchased for use in an office setting.

Single- and dual-photon absorptiometry and radiographic absorptiometry are now rarely used and may be considered obsolete.

Osteoporosis Treatment

Treatment of osteoporosis includes both lifestyle measures (e.g., increased intake of calcium and vitamin D, exercise, smoking cessation) and pharmacologic measures. Current pharmacologic options include bisphosphonates such as alendronate (i.e., Fosamax®), selective estrogen receptor modulators such as raloxifene (i.e., Evista®), the recombinant human parathyroid hormone teriparatide (i.e., Forteo®), and calcitonin. A 2014 systematic review funded by the Agency for Healthcare Research and Quality found good-quality evidence that bisphosphonates, denosumab, teriparatide, and raloxifene reduce fracture risk in postmenopausal women with BMD in the osteoporotic range and/or preexisting hip or vertebral fracture.²

REGULATORY STATUS

Devices that measure bone density have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Some examples are described in Table 2.

Table 2. FDA Cleared Devices to Measure Bone Density

Device Name	Company	510(k) number
Aria	GE Medical Systems	K180782
Ge Lunar Dxa Bone Densitometers With Enc	GE Medical Systems	K161682
Tbs Insight	Medimaps Group Sa	K152299
Single Energy (Se) Femur Exams	Hologic, Inc.	K130277
Tbs Insight	Medimaps Group Sa	K121716
Virtuost	O.N. Diagnostics	K113725
Accudxa2	Lone Oak Medical Technologies, Llc	K113616
Ultrascan 650	Cyberlogic, Inc.	K161919
Bindex Bi-2	Bone Index Finland, Ltd.	K161971
Bindex Bi-100	Bone Index Finland, Ltd.	K152020
Achilles	GE Medical Systems	K123238
Beammed Sunlight Miniomni Bone Sonometer	Beam-Med Ltd	K110646
Achilles	GE Medical Systems	K103633

FDA product codes: KGI, MUA.

FDA: U.S. Food and Drug Administration

In addition, some ultrasound bone sonometers have been approved by the FDA through the premarket approval process. One example is the Sahara® Clinical Bone Sonometer (Hologic), which received approval in March 1998. Its intended use is for quantitative ultrasound measurement of the calcaneus (heel bone), the results of which can be used in conjunction with other clinical risk factors as an aid in the diagnosis of osteoporosis and medical conditions leading to reduced bone density, and ultimately in the determination of fracture risk.

POLICY

Initial or repeat bone mineral density (BMD) measurement is not indicated unless the results will influence treatment decisions.

- A. An initial measurement of central (hip/spine) BMD using dual x-ray absorptiometry may be considered **medically necessary** to assess fracture risk and the need for pharmacologic therapy in individuals who are considered at risk for osteoporosis. BMD testing may be indicated under the following conditions:
1. Individuals age 70 and older, regardless of other risk factors;
 2. Postmenopausal individuals age 65 and over, regardless of other risk factors or younger postmenopausal individuals with an elevated risk factor assessment (see risk factors);
 3. Individuals age 50-70 with an elevated risk factor assessment (see risk factors);
 4. Adults with a pathologic condition or taking a medication associated with low bone mass or bone loss, to include:
 - a. Anorexia Nervosa
 - b. Chronic Renal Failure
 - c. Hyperparathyroidism
 - d. Prolonged immobilization
 - e. Radiographic evidence of Osteopenia
 - f. Malignancies
 - g. Organ Transplantation
 - h. Cystic Fibrosis
 - i. Aluminum-Containing Antacids
 - j. Anti-Seizure Medications (only some), such as Dilantin or Phenobarbital
 - k. Aromatase Inhibitors such as Arimidex, Aromasin, and Femara
 - l. Cancer Chemotherapeutic Drugs
 - m. Cyclosporine A and FK506 (Tacrolimus)
 - n. Gonadotropin-Releasing Hormone (GnRH), such as Lupron or Zoladex
 - o. Heparin, chronic use
 - p. Loop Diuretics such as Bumetanide and Furosemide
 - q. Methotrexate
 - r. Proton Pump Inhibitors (PPIs), prescription strength (not OTC), taken chronically
 - s. Selective Serotonin Reuptake Inhibitors (SSRIs), such as Lexapro, Prozac, or Zoloft
 - t. Tamoxifen (premenopausal use)
 - u. Thyroid Hormone in excess
 - v. Warfarin

Risk Factors (applies to A3 and A4)

In addition to age, sex, and BMD, risk factors included in the World Health Organization Fracture Risk Assessment (FRAX) Tool¹ are:

1. Low body mass index (BMI of 20 or less);
2. Parental history of hip fracture;
3. Previous fragility fracture in adult life (i.e., occurring spontaneously or a fracture arising from trauma which, in a healthy individual, would not have resulted in a fracture);

4. Current smoking or alcohol 3 or more units per day, where a unit is equivalent to a standard glass of beer (285 mL), a single measure of spirits (30 mL), a medium-sized glass of wine (120 mL), or 1 measure of an aperitif (60 mL);
 5. A disorder strongly associated with osteoporosis. These include rheumatoid arthritis, type I (insulin dependent) diabetes, osteogenesis imperfecta in adults, untreated long-standing hyperthyroidism, hypogonadism or premature menopause (<45 years), chronic malnutrition or malabsorption, and chronic liver disease;
 6. Current exposure to oral glucocorticoids or exposure to oral glucocorticoids for more than 3 months at a dose of prednisolone of 5 mg daily or more (or equivalent doses of other glucocorticoids).
- B. An initial measurement of central (hip/spine) BMD using dual x-ray absorptiometry may be considered **not medically necessary**, if the above criteria is not met.
- C. Repeat measurement of central (hip/spine) BMD using dual x-ray absorptiometry may be considered **medically necessary** at an interval not more frequent than every 1-3 years in individuals who are receiving pharmacologic treatment for osteoporosis when the information will affect treatment decisions (continuation, change in drug therapy, cessation or resumption of drug therapy).
- D. Repeat measurement of central (hip/spine) BMD using dual x-ray absorptiometry for individuals who previously tested normal may be considered **medically necessary** at an interval not more frequent than every 3 to 5 years; the interval depends on an updated individual fracture risk assessment.
- E. Repeat measurement of central (hip/spine) BMD using dual x-ray absorptiometry may be considered **medically necessary** at an interval of not more frequent than every 1-2 years in individuals:
1. With a baseline evaluation of osteopenia (BMD T- score -1.0 to -2.5)
 2. Adults with a pathologic condition associated with low bone mass or increased bone loss;
 3. Adults taking a medication associated with increased bone loss.
- F. Bone mineral density measurement using ultrasound densitometry is considered **not medically necessary**.
- G. Bone mineral density measurement using quantitative computed tomography (QCT) is considered **not medically necessary**.

- H. Peripheral (lower arm, wrist, finger or heel) BMD testing may be considered **medically necessary** when conventional central (hip/spine) DXA screening is not feasible or in the management of hyperparathyroidism, where peripheral DXA at the forearm (i.e., radius) is essential for evaluation.
- I. Dual x-ray absorptiometry of peripheral sites is considered **experimental / investigational** except as noted above.
- J. DXA for pediatrics (until age 18) may be considered **medically necessary** when **ANY ONE** of the following is met:
 - 1. Prolonged use of glucocorticoid or corticosteroid therapy; or
 - 2. Chronic inflammatory disease; or
 - 3. Hypogonadism; or
 - 4. Idiopathic juvenile osteoporosis; or
 - 5. Long term immobilization; or
 - 6. Osteogenesis imperfecta; or
 - 7. Completion of chemotherapy two (2) years prior to ordering DXA.
- K. Bone density studies for pediatrics (until age 18) not meeting the criteria as indicated above is considered **not medically necessary**.

POLICY GUIDELINES

Bone Mineral Density Technologies

- A. Ultrasound densitometry is an office-based technology. Compared with osteoporotic bone, normal bone demonstrates higher attenuation of the ultrasound wave and is associated with a greater velocity of the wave passing through bone. Ultrasound densitometry has no radiation exposure, and machines may be purchased for use in an office setting. It is unknown whether this technology can be used to predict response to pharmacologic therapy (i.e., reduce fractures).
- B. Dual x-ray absorptiometry (DXA) of axial central sites (i.e., hip and spine) is the most commonly used technique. Central DXA (hip/spine) is required for both the initial diagnosis and repeat bone mineral density (BMD) assessments.
- C. Peripheral (lower arm, wrist, finger or heel) measurement can identify individuals with low bone mass but does not predict response to pharmacologic therapy and is not a substitute for central DXA measurements.
- D. In pediatric individuals, measurement of total body calcium is preferred because it helps reduce following patients with growing bones. This applies to pediatric individuals who are not skeletally mature as documented by non-closure of growth plates (e.g., 15 years of age or younger).
- E. When indicated; repeat dual x-ray absorptiometry (DXA) of axial central sites should ideally be conducted in the same facility with the same machine. Differences between BMD results may simply reflect the inherent variability of the test measurement; thus, testing facilities must calculate the least significant change (LSC) for relevant measurement sites to determine the magnitude of difference that represents a real change. This is determined using a facility's regular technologist(s), treated individuals, and device.

- F. Quantitative computed tomography depends on the differential absorption of ionizing radiation by calcified tissue and is used for central measurements only. Compared with DXA, quantitative computed tomography is less readily available and associated with relatively high radiation exposure and relatively high cost. Analysis of previously obtained clinical computed tomography scans of the pelvis might provide an alternative method of assessing biomechanical bone strength.
- G. Single- and dual-photon absorptiometry and radiographic absorptiometry are now rarely used and may be considered obsolete.

Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

RATIONALE

This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through July 16, 2024.

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

INITIAL MEASUREMENT OF BONE MINERAL DENSITY

Clinical Context and Therapy Purpose

The purpose of bone mineral density (BMD) measurement testing with dual x-ray absorptiometry (DXA) in individuals who have risk factors for osteoporosis is to assess bone health and guide treatment.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with risk factors for osteoporosis.

In addition to age-related bone loss, conditions that can cause or contribute to osteoporosis include lifestyle factors such as low dietary intake of calcium, high intake of alcohol or cigarette smoking, and thinness. Other risk factors for osteoporosis include certain endocrine, hematologic, gastrointestinal tract and genetic disorders, hypogonadal states, and use of certain classes of pharmacologic agents such as corticosteroids.

Interventions

The test being considered is initial BMD testing with central DXA.

The decision to perform a bone density assessment should be based on an individual's fracture risk profile assessment

Comparators

The following practices are currently being used to make treatment decisions: clinical risk factor assessment.

Outcomes

The general outcomes of interest are the occurrence of fractures and effects on QOL.

Bone mineral density measurements, using DXA of central sites (hip or spine), are most predictive of fragility fractures at hip and spine. Fractures of the hip and spine (i.e., vertebral fractures) are considered the most clinically relevant.

Study Selection Criteria

In addition to the PICO selection criteria, additional selection criteria for studies to assess a therapy are listed below:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs and systematic reviews of these studies.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse effects, single-arm studies that captured longer periods of follow-up and/or larger populations were evaluated.
- To supplement the review of evidence for indications where evidence was extremely limited, clinical practice guidelines were included. Primary guidelines were selected based on the following criteria:
 - Established, recognized professional organization.

- Published guideline process that included conflict of interest, agreed-upon process including grading of recommendations and disclosure of when consensus or expert opinion was used.
- Existence of an associated evidence appraisal (systematic review, comprehensive references, etc.).
- Guideline is accessible (PubMed indexed or freely available through the organizational website).

Other relevant guidelines are summarized in the Supplemental Information Section.

REVIEW OF EVIDENCE

Systematic Review

A 2018 systematic review for the U.S. Preventive Services Task Force (USPSTF) evaluated the evidence on screening for osteoporosis.³ The review considered centrally measured DXA to be the reference standard against which other screening measures were evaluated. Randomized controlled trials included in the systematic review have shown that osteoporosis medications are effective at reducing fracture risk in postmenopausal women with BMD in the osteoporotic range identified by central DXA. A noted limitation of the review was that treatment studies relied on DXA BMD scores to enroll participants into trials and that risk factors beyond bone density, such as bone quality, contribute to osteoporotic fractures. Therefore, "approaches that rely on BMD measurement wholly or in part may not be the most accurate approaches for identifying patients at highest risk for osteoporotic fractures." An update of evidence is in process, which may lead to a subsequent update of USPSTF recommendations.

Clinical Practice Guidelines

The 2018 systematic review formed the basis for the USPSTF recommendations for screening for osteoporosis in women aged 65 years or older and in postmenopausal women younger than 65 years at increased risk of osteoporosis.³ The supporting document refers to multiple instruments to predict risk for low BMD, including the Fracture Risk Assessment Tool.¹

The USPSTF recommendations stated that the scientific evidence is "insufficient" to assess the balance of benefits and harms of screening for osteoporosis in men.

In 2020, the American Association of Clinical Endocrinologists and the American College of Endocrinology issued updated joint guidelines on the diagnosis and treatment of postmenopausal osteoporosis.⁴ The guidelines listed the potential uses for BMD measurements in postmenopausal women as:

- "Screening for osteoporosis
- Establishing the severity of osteoporosis or bone loss in patients with suspected osteoporosis (for example, patients with fractures or radiographic evidence of osteopenia)
- Determining fracture risk - especially when combined with other risk factors for fractures
- Identifying candidates for pharmacologic intervention
- Assessing changes in bone density over time in treated and untreated patients
- Enhancing acceptance of, and perhaps adherence with, treatment
- Assessing skeletal consequences of diseases, conditions, or medications known to cause bone loss."

The Endocrine Society published clinical practice guidelines on osteoporosis in men.⁵ The guidelines recommend BMD testing in men at increased risk of osteoporosis, including those aged 70 or older, and younger men (ages 50 to 69) with pathologic conditions associated with low bone mass or increased bone loss, or those taking medications associated with bone loss. The guideline recommends the use of the Fracture Risk Assessment Tool or another fracture risk calculator to assess fracture risk and select patients for treatment.

Section Summary: Initial Measurement of Bone Mineral Density

Central DXA is the most widely accepted method for measuring BMD. Bone mineral density measurements with central DXA identify individuals at increased risk of fracture, and osteoporosis medications reduce fracture risk in the population identified as osteoporotic by central DXA. Therefore, test results with initial central DXA have been successfully used to make decisions about initiation of fracture intervention pharmacologic therapy.

REPEAT MEASUREMENT OF BONE MINERAL DENSITY FOR INDIVIDUALS WITHOUT OSTEOPOROSIS ON INITIAL SCREEN

Clinical Context and Therapy Purpose

The purpose of BMD measurement with central DXA in individuals without osteoporosis on the initial screen is to assess changes in bone health and guide treatment.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals without osteoporosis as defined by the initial BMD measurement screen.

Interventions

The test being considered is repeat BMD testing with central DXA. .

Comparators

The following practices are currently being used to make treatment decisions: clinical risk factor assessment without BMD testing.

Outcomes

The general outcomes of interest are the occurrence of fractures and effects of fractures on QOL.

Monitoring of fractures may occur until the end of life; these are typically measured within 10 years after screening.

Study Selection Criteria

In addition to the PICO selection criteria, additional selection criteria for studies to assess a therapy are listed below:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs and systematic reviews of these studies.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.

- To assess longer-term outcomes and adverse effects, single-arm studies that captured longer periods of follow-up and/or larger populations were evaluated.
- To supplement the review of evidence for indications where evidence was extremely limited, clinical practice guidelines were included. Primary guidelines were selected based on the following criteria:
 - Established, recognized professional organization.
 - Published guideline process that included conflict of interest, agreed-upon process including grading of recommendations and disclosure of when consensus or expert opinion was used.
 - Existence of an associated evidence appraisal (systematic review, comprehensive references, etc.).
 - Guideline is accessible (PubMed indexed or freely available through the organizational website).

Other relevant guidelines are summarized in the Supplemental Information Section.

REVIEW OF EVIDENCE

Systematic Reviews

The USPSTF concluded the evidence base is sparse on screening intervals in asymptomatic women.³ The 2018 USPSTF systematic review of the evidence on screening interval identified 2 studies with variable BMD that suggested no advantage to repeated bone measurement testing.^{6,7} However, prognostic modeling from other studies suggested that the optimal screening interval varies by baseline BMD, and that age and use of hormone replacement therapy might also influence optimal screening intervals.^{8,9,10}

A review of evidence by the Agency for Healthcare Research and Quality Southern California Evidence-Based Practice Center for the American College of Physicians identified moderate-quality evidence that women do not require frequent monitoring, with 10% of women with normal or mildly osteopenic DXA scores progressing to osteopenia within 15 years.^{11,12}

Clinical Practice Guidelines

The USPSTF did not make a specific recommendation on repeat screening in asymptomatic individuals.

The American Association of Clinical Endocrinologists and the American College of Endocrinology joint guidelines on the diagnosis and treatment of postmenopausal osteoporosis (2020) state that repeat BMD testing may be done to determine if or when to initiate treatment.⁴ The frequency of testing should be individualized based on results of initial testing and on risk assessment. Bone mineral density testing every 1 to 2 years may be appropriate for those close to an intervention threshold on the initial test or with a high likelihood of future fracture based on risk factors.

The guidelines also note: "Differences between BMD results may simply reflect the inherent variability of the test measurement; thus, testing facilities must calculate the least significant change for relevant measurement sites to determine the magnitude of difference that represents a real change. This is determined using a facility's regular technologist(s), patients, and device."

The Endocrine Society Guidelines for Osteoporosis in Men did not make a specific recommendation on repeat BMD testing in asymptomatic men.⁵ However, the supporting document notes that the least significant change approach can be used to identify significant bone loss in men who are untreated. Because the expected rate of bone loss is slower in untreated men than the expected gains during treatment, less frequent measurements (e.g., 2 to 3 years) in untreated men may be a more appropriate screening interval.

Section Summary: Repeat Measurement of Bone Mineral Density for Individuals Without Osteoporosis on Initial Screen

Little research has been done on the frequency of BMD monitoring for osteoporosis. The available research has evaluated repeat measurement with central DXA. Evidence on whether repeat measurements add to risk prediction compared with a single measurement is mixed. Current evidence does not support frequent monitoring, but the optimal interval may differ depending on risk factors. Although the evidence is limited, clinical practice guidelines from the American Association of Clinical Endocrinologists, the American College of Endocrinology, and the Endocrine Society recommend repeat DXA in 3 to 5 years in patients at low-risk. Bone mineral density testing every 1 to 2 years is often appropriate, depending on patient risk factors including age, baseline BMD T-score, and use of medications that adversely affect bone.

REPEAT MEASUREMENT OF CENTRAL BONE MINERAL DENSITY TO MONITOR RESPONSE TO PHARMACOLOGIC TREATMENT

Clinical Context and Therapy Purpose

The purpose of BMD measurement with central DXA in individuals who are being evaluated for osteoporosis is to guide treatment.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals who are being treated for osteoporosis. Multiple classes of pharmacologic agents are available to treat patients with osteoporosis.

Interventions

The test being considered is repeat BMD testing with central DXA.

Comparators

The following practices are currently being used to make treatment decisions: clinical risk assessment without BMD testing.

Outcomes

The general outcomes of interest are the occurrence of fractures and effects on QOL. Monitoring of fractures may occur until the end of life; these are typically measured within 10 years after screening.

Study Selection Criteria

In addition to the PICO selection criteria, additional selection criteria for studies to assess a therapy are listed below:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs and systematic reviews of these studies.

- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse effects, single-arm studies that captured longer periods of follow-up and/or larger populations were evaluated.
- To supplement the review of evidence for indications where evidence was extremely limited, clinical practice guidelines were included. Primary guidelines were selected based on the following criteria:
 - Established, recognized professional organization.
 - Published guideline process that included conflict of interest, agreed-upon process including grading of recommendations and disclosure of when consensus or expert opinion was used.
 - Existence of an associated evidence appraisal (systematic review, comprehensive references, etc.).
 - Guideline is accessible (PubMed indexed or freely available through the organizational website).

Other relevant guidelines are summarized in the Supplemental Information Section.

REVIEW OF EVIDENCE

Systematic Reviews

Several moderate quality studies included in the Agency for Healthcare Research and Quality report showed that fracture risk may be reduced with pharmacologic treatment even when BMD does not increase.^{11,12} In the Fracture Intervention Trial, 6459 women randomized to bisphosphonates or placebo underwent annual bone density scans. A secondary analysis found an average within-person variation in BMD measurement of 0.013 g/cm², which was substantially higher than the average annual increase in BMD (0.0085 g/cm²) in the alendronate group.¹³

Clinical Practice Guidelines

In 2019, the Endocrine Society published clinical practice guidelines on the pharmacological management of osteoporosis in postmenopausal women.¹⁴ Recommendations in these guidelines were based on systematic reviews and meta-analyses, and application of the GRADE methodological framework, including quality of evidence assessments and strength of recommendation designations. When evidence was extremely limited, recommendations were based on expert review.

For women who are being treated for osteoporosis, the guidelines recommended BMD testing with central DXA every 1 to 3 years to assess response to treatment. In women who are taking bisphosphonates, the guideline authors recommended reassessment of fracture risk after 3 to 5 years (5 years for oral, 3 for intravenous) with clinical risk assessment and BMD testing. Women who remain at high-risk of fractures should continue therapy, whereas those who are at low- to moderate-risk of fractures should be considered for a "bisphosphonate holiday." Once a bisphosphonate holiday is initiated, fracture risk should be reassessed every 2 to 4 years. Clinicians should consider reinitiating osteoporosis therapy earlier than the 5-year suggested maximum if there is a significant decline in BMD, a fracture, or other factors that alter the clinical risk status. For women taking denosumab, the guideline authors recommended reassessment of fracture risk with BMD and clinical risk assessment after 5 to 10 years. Women who remain at high-risk of fractures should either continue denosumab or be treated with other osteoporosis

therapies. These guidelines were updated in 2020, but no changes were made to the DXA recommendations.^{15,}

The American Association of Clinical Endocrinologists and the American College of Endocrinology published joint guidelines on the diagnosis and treatment of postmenopausal osteoporosis.^{4,} For patients on osteoporosis pharmacotherapy, the guidelines recommended obtaining a baseline DXA and repeating DXA every 1 to 2 years until findings are stable. Successful treatment of osteoporosis was defined as stable or increasing BMD with no evidence of new fractures or vertebral fracture progression. The guidelines recommended continued follow-up every 1 to 2 years or at a less-frequent interval, depending on clinical circumstances. They also noted that follow-up of patients should ideally be conducted in the same facility with the same machine. Recommendations on length of treatment were as follows:

- "Limit treatment with abaloparatide and teriparatide to 2 years and follow abaloparatide or teriparatide therapy with a bisphosphonate or denosumab
- Limit treatment with romosozumab to 1 year and follow with a drug intended for long-term use, such as a bisphosphonate or denosumab
- For oral bisphosphonates, consider a bisphosphonate holiday after 5 years of treatment if fracture risk is no longer high (such as when the T score is greater than -2.5, or the patient has remained fracture free), but continue treatment up to an additional 5 years if fracture risk remains high
- For oral bisphosphonates, consider a bisphosphonate holiday after 6 to 10 years of stability in patients with very high fracture risk
- For zoledronate, consider a bisphosphonate holiday after 3 years in high-risk patients or until fracture risk is no longer high, and continue for up to 6 years in very-high risk patients
- The ending of a bisphosphonate holiday should be based on individual patient circumstances such as an increase in fracture risk, a decrease in bone mineral density beyond the least significant change (LSC) of the dual-energy X-ray absorptiometry (DXA) machine, or an increase in bone turnover markers
- A holiday is not recommended for non-bisphosphonate antiresorptive drugs (Grade A; BEL [best evidence level] 1), and treatment with such agents should be continued for as long as clinically appropriate
- If denosumab therapy is discontinued, patients should be transitioned to another antiresorptive."

The Endocrine Society Guidelines on Osteoporosis in Men recommended measuring BMD with central DXA every 1 to 2 years to monitor response to treatment, with less frequent monitoring once BMD appears to reach a plateau.^{5,}

Section Summary: Repeat Measurement of Central Bone Mineral Density to Monitor Response to Pharmacologic Treatment

There is no high-quality evidence to guide how often to monitor BMD during osteoporosis treatment. Within-person variation in measurement may exceed treatment effects, and fracture risk may be reduced in the absence of changes in BMD. Although the evidence is limited, multiple professional organizations have published guidelines recommending repeat DXA to monitor treatment response in patients who are receiving pharmacological treatment for osteoporosis. Guidelines from the American Association of Clinical Endocrinologists, the American College of

Endocrinology, and the Endocrine Society recommend repeating DXA every 1 to 3 years after initiation or change in treatment, with longer intervals once therapeutic effect is established.

ULTRASOUND DENSITOMETRY, QUANTITATIVE COMPUTED TOMOGRAPHY, OR DUAL X-RAY

ABSORPTIOMETRY ANALYSIS OF PERIPHERAL SITES

Clinical Context and Therapy Purpose

The purpose of BMD measurement with methods other than central DXA in individuals who have risk factors for osteoporosis is to guide treatment.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with risk factors for osteoporosis.

Interventions

The test being considered is bone tests other than central DXA.

Comparators

The following practices are currently being used to make treatment decisions: clinical risk factor assessment following DXA analysis of central sites.

Outcomes

The general outcomes of interest are the occurrence of fractures and effects on QOL.

Monitoring of fractures may occur until the end of life; these are typically measured within 10 years after screening.

Study Selection Criteria

In addition to the PICO selection criteria, additional selection criteria for studies to assess a therapy are listed below:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs and systematic reviews of these studies.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess longer-term outcomes and adverse effects, single-arm studies that captured longer periods of follow-up and/or larger populations were evaluated.
- To supplement the review of evidence for indications where evidence was extremely limited, clinical practice guidelines were included. Primary guidelines were selected based on the following criteria:
 - Established, recognized professional organization.
 - Published guideline process that included conflict of interest, agreed-upon process including grading of recommendations and disclosure of when consensus or expert opinion was used.
 - Existence of an associated evidence appraisal (systematic review, comprehensive references, etc.).

- Guideline is accessible (PubMed indexed or freely available through the organizational website).

Other relevant guidelines are summarized in the Supplemental Information Section.

REVIEW OF EVIDENCE

Systematic Reviews

In the review of evidence for the USPSTF, 10 studies were identified that compared calcaneal quantitative ultrasound to central DXA.³ Pooled estimates of area under the curves were 0.77 (95% confidence interval[CI], 0.72 to 0.81; 1969 participants) in women and 0.80 (95% CI , 0.67 to 0.94; 5142 participants) in men. Similar findings were observed for digital x-ray radiogrammetry, peripheral DXA, and radiographic absorptiometry. For predicting osteoporotic fractures, no meaningful differences in accuracy by type of bone test were observed. A study by Adams et al (2018) is consistent with the results of the USPSTF systematic review, showing the prediction of fracture with a "biomechanical" computed tomography (CT) analyzed on previously taken clinical CT scans were at least as good as DXA."¹⁶ No studies were identified that guided treatment based on CT scan results.

Clinical Practice Guidelines

The USPSTF did not recommend specific screening tests but said the most commonly used test is central DXA.

Section Summary: Ultrasound Densitometry, Quantitative Computed Tomography, or Dual X-ray Absorptiometry Analysis of Peripheral Sites

In comparison with central DXA, other measures of bone health showed area under the curves around 0.80 for the identification of osteoporosis. No studies have shown that they can select patients who benefit from treatment for osteoporosis. There is little to no evidence on the usefulness of repeat measurement of BMD using these techniques.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Obstetricians and Gynecologists

In 2021, the American College of Obstetricians and Gynecologists (ACOG) released clinical practice guidelines on the prevention, screening, and diagnosis of osteoporosis which was an update from their 2012 osteoporosis guidelines.¹⁷ The guidelines recommend bone mineral density (BMD) screening in all women 65 years and older to prevent osteoporotic fractures. In addition, ACOG recommends screening for women younger than 65 years who are at increased risk of osteoporosis, with at least 1 risk factor, as listed below, or as determined by a formal

clinical risk assessment tool. For example, a woman younger than 65 years of age may benefit from BMD screening if the Fracture Risk Assessment Tool indicates a 10-year risk of osteoporotic fracture of at least 8.4%. Risk factors that may put women younger than 65 at an increased risk include any of the following risk factors (they are similar, but not identical to risk factors in the Fracture Risk Assessment Tool):

- Increasing age
- Parental history of hip or spine fracture
- Body mass index less than 20 kg/m² or body weight less than 127 lbs
- Smoking history
- Excessive alcohol use (i.e., more than 3 drinks daily)
- Conditions, diseases, and medications associated with secondary osteoporosis, including, but not limited to:
 - Acquired immunodeficiency syndrome and human immunodeficiency virus, anorexia nervosa, diabetes mellitus (type 1 and type 2), diminished ovarian reserve, gastric bypass, hyperparathyroidism, hypocalcemia, premature menopause (induced, surgical, or spontaneous), primary ovarian insufficiency, renal impairment, rheumatoid arthritis, Turner syndrome, vitamin D deficiency
 - Antiepileptic drugs (e.g., phenytoin, carbamazepine, primidone, and phenobarbital), antiretroviral drugs, aromatase inhibitors, chemotherapy, depot medroxyprogesterone acetate, glucocorticoids, gonadotropin-releasing hormone agonists, heparin.

ACOG also recommends repeat osteoporosis screening in postmenopausal women with initial BMD test results near treatment thresholds or with any significant changes in risk factors. For most patients, repeat BMD testing should be performed no sooner than 2 years after initial screening.

American College of Physicians

The 2017 guidelines from the American College of Physicians on the treatment of osteoporosis recommended against bone density monitoring during the 5-year pharmacologic treatment period of osteoporosis in women (weak recommendation, low-quality evidence).¹⁸ The American College of Physicians noted that data from several studies showed a reduction in fractures with pharmacologic treatment, even when BMD did not increase. In addition, current evidence “does not support frequent monitoring of women with normal bone density for osteoporosis, because data showed that most women with normal DXA [dual-energy x-ray absorptiometry] scores did not progress to osteoporosis within 15 years.” These guidelines were updated in 2023, but BMD monitoring was not addressed in the update.¹⁹

American College of Radiology

The 2022 update of appropriateness criteria from the American College of Radiology states that BMD measurement is indicated whenever a clinical decision is likely to be directly influenced by the result of the test.²⁰ Indications for dual x-ray absorptiometry (DXA) of the lumbar spine and hip included but were not limited to the following patient populations:

- All women age 65 years and older and men age 70 years and older (asymptomatic screening).
- Women younger than age 65 years who have additional risk for osteoporosis, based on medical history and other findings. Additional risk factors for osteoporosis include:
 - Estrogen deficiency.

- A history of maternal hip fracture that occurred after the age of 50 years.
- Low body mass (less than 127 lb or 57.6 kg).
- History of amenorrhea (more than 1 year before age 42 years).
- Women younger than age 65 years or men younger than age 70 years who have additional risk factors, including:
 - Current use of cigarettes.
 - Loss of height, thoracic kyphosis.
- Individuals of any age with bone mass osteopenia, or fragility fractures on imaging studies such as radiographs, CT [computed tomography], or MRI [magnetic resonance imaging].
- Individuals age 50 years and older who develop a wrist, hip, spine, or proximal humerus fracture with minimal or no trauma, excluding pathologic fractures.
- Individuals of any age who develop 1 or more insufficiency fractures.
- Individuals being considered for pharmacologic therapy for osteoporosis.
- Individuals being monitored to:
 - Assess the effectiveness of osteoporosis drug therapy.
 - Follow-up medical conditions associated with abnormal BMD.

American Society for Bone and Mineral Research

The 2016 guidelines from an American Society for Bone and Mineral Research task force included the following statement on managing osteoporosis in patients on long-term bisphosphonate treatment:^{21,}

"Reassessment includes clinical evaluation, risk assessment including risk factors, and may include bone density measurement by DXA. The monitoring interval with DXA should be based upon changes that are detectable and clinically significant. Reassessment may be necessary at less than 2 years in patients with a new fracture, or in light of anticipated accelerated bone loss (e.g. institution of aromatase inhibitor or glucocorticoid therapy)."

International Society for Clinical Densitometry

The 2019 update of the International Society for Clinical Densitometry official position statements recommended bone density testing in the following patients :^{22,}

- "Women age 65 and older
- For post-menopausal women younger than age 65, a bone density test is indicated if they have a risk factor for low bone mass such as;
 - Low body weight
 - Prior fracture
 - High-risk medication use
 - Disease or condition associated with bone loss
- Women during the menopausal transition with clinical risk factors for fracture, such as low body weight, prior fracture, or high-risk medication use
- Men aged 70 and older
- For men < 70 years ... if they have a risk factor for low bone mass such as:
 - Low body weight
 - Prior fracture
 - High-risk medication use
 - Disease or condition associated with bone loss
- Adults with a fragility fracture

- Adults with a disease or condition associated with low bone mass or bone loss
- Anyone being considered for pharmacologic therapy
- Anyone being treated, to monitor treatment effect
- Anyone not receiving therapy in whom evidence of bone loss would lead to treatment."

The 2019 position statement makes the following recommendations on serial BMD measurements:

- "Serial BMD testing in combination with clinical assessment of fracture risk, bone turnover markers, and other factors including height loss and trabecular bone score, can be used to determine whether treatment should be initiated in untreated patients, according to locally applicable guidelines.
- Serial BMD testing can monitor response to therapy by finding an increase or stability of bone density.
- Serial BMD testing should be used to monitor individuals following cessation of osteoporosis pharmacologic therapy.
- Serial BMD testing can detect loss of bone density, indicating the need for assessment of treatment adherence, evaluation of secondary causes of osteoporosis, and re-evaluation of treatment options.
- Follow-up BMD testing should be done when the results are likely to influence patient management.
- Intervals between BMD testing should be determined according to each patient's clinical status: typically 1 year after initiation or change of therapy is appropriate, with longer intervals once therapeutic effect is established.
- In conditions associated with rapid bone loss, such as glucocorticoid therapy, testing more frequently is appropriate."

In 2023, the International Society for Clinical Densitometry published an official position for follow-up BMD testing which makes the following recommendations: ²³,

- " Follow-up BMD testing should be undertaken with clearly defined objectives and when the results are likely to influence patient management (Grade: good-A-W).
- Follow-up BMD testing should be performed if a fracture has occurred or new risk factors have developed but should not delay treatment for secondary fracture prevention (Grade: fair-B-W).
- Follow-up BMD testing can aid in monitoring response to therapy (Grade: good-B-W).
- Repeat BMD testing intervals must be individualized considering an individual's age, baseline BMD, the type of pharmacological treatment and the presence of clinical risk factors which are associated with bone loss (Grade: good-B-W).
- Shorter intervals between BMD testing may be indicated in the presence of factors associated with rapid change in bone mineral density (Grade: fair-A-W).
- If changes in BMD are outside the expected range for an individual patient and scan quality has been confirmed, this should prompt re-evaluation of the patient and plan of care (Grade: fair-B-W).
- Repeat BMD testing should be used to monitor individuals prior to a temporary cessation of bisphosphonate therapy and during the period of planned interruption of treatment (Grade: Fair-B-W)."

National Osteoporosis Foundation

In 2022, the Bone Health and Osteoporosis Foundation (BHOFF), formerly known as the National Osteoporosis Foundation, updated its practice guidelines.²⁴ The BHOFF guidelines state that bone density measurements are not indicated unless test results will influence treatment and management decisions.

Indications for BMD testing recommended by the BHOFF include:

- Women age 65 and older and men age 70 and older, regardless of clinical risk factors
- Postmenopausal women aged 50 to 64 , regardless of clinical risk factors
- Men aged 50 to 69 years with risk factors for osteoporosis
- Adults age 50 years and older who have a fracture
- Adults with a condition or taking a medication associated with low bone mass or bone loss

The BHOFF stated that repeat bone densitometry should be done in patients exhibiting signs of vertebral fracture, such as height loss or back pain.

The BHOFF stated that measurements for monitoring patients should be performed in accordance with medical necessity, expected response, and in consideration of local regulatory requirements. The BHOFF recommended that a follow-up BMD assessment be performed after 1 year of initial therapy or a change in therapy, with longer intervals once an effective treatment is established. The BHOFF recommends repeat BMD assessments every 2 years in adults ages 65 years and older, but recognized that testing more frequently may be warranted in certain clinical situations, and should be guided by the clinical status of each patient.

U.S. Preventive Services Task Force Recommendations

The US Preventive Services Task Force recommends screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in women 65 years and older and in postmenopausal women younger than 65 years who are at increased risk of osteoporosis, as determined by a formal clinical risk assessment tool (Grade B). The Task Force concluded that the current evidence is insufficient to assess the balance of benefits and harms of screening for osteoporosis to prevent osteoporotic fractures in men (Grade I).³ These recommendations are currently undergoing an update and may be revised within the near future.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in July 2024 did not identify any ongoing or unpublished trials that would likely influence this review.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. This may not be a comprehensive list of procedure codes applicable to this policy.

Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

The code(s) listed below are medically necessary ONLY if the procedure is performed according to the "Policy" section of this document.

CPT/HCPCS	
76977	Ultrasound bone density measurement and interpretation, peripheral site(s), any method
77078	Computed tomography, bone mineral density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine)
77080	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine)
77081	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)
77085	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine), including vertebral fracture assessment
78350	Bone density (bone mineral content) study, 1 or more sites; single photon absorptiometry
78351	Bone density (bone mineral content) study, 1 or more sites; dual photon absorptiometry, 1 or more sites
0554T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; retrieval and transmission of the scan data, assessment of bone strength and fracture risk and bone mineral density, interpretation and report
0555T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; retrieval and transmission of the scan data
0556T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone mineral density
0557T	Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; interpretation and report
0558T	Computed tomography scan taken for the purpose of biomechanical computed tomography analysis
G0130	Single energy x-ray absorptiometry (SEXA) bone density study, one or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)

REVISIONS	
10-19-2009	<p>The Description section updated.</p> <p>The Policy section was updated. The previous policy language was:</p> <ol style="list-style-type: none"> 1. A baseline, central (not peripheral) bone density measurement is considered medically necessary if ONE of the following criteria (a. through g.) is met: <ol style="list-style-type: none"> a. ALL Postmenopausal (amenorrheic for longer than six (6) months) women under age 65 who have one or more risk factors for osteoporotic fracture (besides menopause) listed below: <ol style="list-style-type: none"> 1) Personal history of recent fracture 2) First degree relative with history of osteoporosis 3) Currently smokes tobacco 4) Excessive alcohol intake (history of or current use) b. All women aged 65 and older, regardless of additional risk factors c. Postmenopausal women (amenorrheic for longer than six (6) months) who are considering therapy for osteoporosis when results will facilitate treatment decisions. d. Repeat or follow-up central bone density measurement will be considered medically necessary if at least 23 months have passed since last bone density measurements. e. Primary hyperparathyroidism (male or female) f. Receiving long-term glucocorticoid therapy equivalent to or greater than 7.5 mg/day of prednisone, for three months or longer (male or female). g. Bone density measurement will be considered for the following conditions (male or female): <ol style="list-style-type: none"> 1) Anorexia nervosa 2) Calcitonin deficiency 3) Chemotherapeutic agents which affect bone density 4) Chronic renal failure 5) Chronic use of anti-convulsants (particularly Dilantin) 6) Chronic use of heparin 7) Cushing's Syndrome 8) Fragility fracture 9) Hypersecretion of calcitonin 10) Hyperthyroidism or Hypothyroidism 11) Hypogonadism 12) Lupron therapy in men 13) Malabsorption Syndromes 14) Malignancies (multiple myeloma) 15) Organ transplantation 16) Prolonged amenorrhea (six (6) months duration or longer) 17) Prolonged immobilization 18) Radiologic evidence of osteopenia 19) Rheumatoid arthritis 20) Untreated premature menopause 2. Bone density measurement is considered NOT medically necessary in the following: <ol style="list-style-type: none"> a. Routine screening for osteoporosis or osteoporosis risk when criteria above are not met. b. Individuals who do not intend to use hormonal or non-hormonal therapy c. When the results obtained will not influence treatment decisions. d. Peripheral bone density studies (77079, 77081, 76977 and G0130) e. Bone density measurements done at peripheral sites with tests such as peripheral dual-energy x-ray absorptiometry (pDEXA) of the forearm, radiographic absorptiometry of the phalanges, or ultrasound of the heel may not change

REVISIONS	
	<p>reliably with treatment. Central measurements of the hip and spine are more predictive of fracture than peripheral sites.</p> <p>3. Osteopenia - Bone density Testing will be allowed if the doctor indicates osteopenia in the records or on the claim.</p> <p>4. Sahara Ultrasound System - Sahara Ultrasound System Bone density Testing system will be allowed once per year, based on the same criteria as the DEXA, utilizing Procedure Code 76977 (ultrasound bone density measurement and interpretation, peripheral site(s), any method). The procedure is applicable for the above Diagnosis Code.</p> <p>Procedure code 77080 is to be processed as preventive care. Categories of qualified individuals include ONE of the following:</p> <ul style="list-style-type: none"> • An estrogen-deficient woman at clinical risk for osteoporosis • An individual with vertebral abnormalities • An individual receiving long-term glucocorticoids (steroid) therapy • An individual with primary hyperparathyroidism, or • An individual being monitored to assess the response to or efficacy of an approved osteoporosis drug therapy. <p><u>UTILIZATION</u></p> <p>1. Coverage for follow-up bone mass measurements will be limited to only one measurement every two (2) years for members who receive coverage of bone mass measurements.</p> <p>2. Follow-up bone mass measurements performed more frequently for pathological diagnosis may be covered when medically necessary.</p> <p>The policy updates primarily pertained to the following:</p> <ul style="list-style-type: none"> ▪ More clearly identified men as eligible for BMD measurement and added criteria. ▪ Liberalized the risk factor criteria for which younger postmenopausal women are eligible for BMD measurement. ▪ Provides peripheral measurement of BMD in two situations, when the hip/spine or hip/hip cannot be done or the patient is over the table limit for weight and for hyperparathyroidism, where the forearm is essential for diagnosis ▪ Increased the repeat measurement time frame from "at least 23 months" to "(not more frequent than every 2-3 years)...when the information will affect treatment decisions such as duration of therapy" and "not more frequent than every 3-5 years, depending on patient risk factors...for individuals who previously tested normal". ▪ Removed indication of "Sahara Ultrasound System Bone Density Testing system will be allowed once per year, based on the same criteria as the DEXA...", on the 2003 decision of the Family Practice, OB/GYN, and Internal Medicine Liaison Committees to eliminate eligibility of peripheral bone density studies. <p>In the Coding section:</p> <ul style="list-style-type: none"> ▪ Added CPT/HCPCS codes: 77079, 77081, 77083, 78350, G0130 ▪ Added Diagnoses codes: 244.8, 244.9, 627.2, 627.3, 627.8, 627.9, V07.4, V49.81, V58.69
05-13-2011	<p>Rationale section updated.</p> <p>Reference section updated.</p>
12-09-2011	<p>In the Coding section:</p> <ul style="list-style-type: none"> ▪ Added Diagnoses code: 250.1, 259.5, 263.9, 303.9, 305.1, 345.00-345.91, 577.0, 577.1, 579.0, 579.8, 756.51 ▪ Removed CPT code: 77082. ▪ Removed Diagnosis code: V82.81. <p>Updated the Reference section.</p>
04-13-2012	<p>Updated the Description section.</p>

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	<p>In the Policy section:</p> <ul style="list-style-type: none"> ▪ In Item A, Risk Factors, #7, inserted the following: <ul style="list-style-type: none"> “o. chronic use of medications that can cause bone loss <ul style="list-style-type: none"> • Aluminum-containing antacids • Anti-seizure medications (only some) such as Dilantin or Phenobarbital • Aromatase inhibitors such as Arimidex, Aromasin, and Femara • Cancer chemotherapeutic drugs • Cyclosporine A and FK506 (Tacrolimus) • Glucocorticoids such as cortisone and prednisone • Gonadotropin releasing hormone (GnRH) such as Lupron, Zoladex • Heparin (chronic use) • Proton pump inhibitors (PPIs) prescription strength (not OTC) taken chronically • Selective Serotonin reuptake inhibitors (SSRIs) such as Lexapro, Prozac, Zoloft • Tamoxifen (premenopausal use) ▪ Thyroid hormone in excess” ▪ In Item A, Risk Factors, #7, moved “chronic use of anti-convulsants (particularly Dilantin)” and “chronic use of heparin” to Item A, Risk Factors, #7, o, “Chronic use of medications that can cause bone loss.” ▪ In Item A, Risk Factors, #8 “Current exposure to oral glucocorticoids, or the patient has been exposed to oral glucocorticoids for more than 3 months at a dose of prednisone of 5 mg daily or more (or equivalent doses of other glucocorticoids).” has been included in #7, o. ▪ In Item A, Risk Factors, #7, added “p. pediatric patients with malabsorption disorders” ▪ Removed Item G, “In pediatric patients, total body calcium is preferred because it helps reduce the issue of following patients with growing bones. This applies to pediatric patients who are not skeletally mature as documented by non-closure of growth plates (e.g., 15 years of age or younger).” ▪ Added “E. Quantitative Computed Tomography (QCT) is considered not medically necessary.” ▪ Added “G. For Medroxyprogesterone acetate, the package insert contains a box warning about osteoporosis. However, Up to Date notes that while use of Medroxyprogesterone acetate is associated with decreased mineral density in current users, the effect is mostly reversed after Medroxyprogesterone acetate is stopped. Studies have not shown an increase risk of bone fractures in women who have used Medroxyprogesterone acetate in the past, therefore BMD is considered not medically necessary.”
	<p>In the Coding section:</p> <ul style="list-style-type: none"> ▪ Removed CPT codes: 77079, 77083 ▪ Removed Dx codes: 244.1, 244.2, 244.3, 244.8, 244.9, 250.1, 256.39, 259.5, 303.9, 577.0, 585.1, 627.2, 627.3, 627.8, 627.9, 733.10-733.16, 733.19, 733.90, V07.4, V42.2, V42.5, V49.81 ▪ Added Dx codes: 259.50-259.52, 577.9, 303.90-303.93, 780.33, 805.2, 805.4, 805.6,
	Reference section updated.
10-04-2013	Updated Description section.
	<p>In Policy section:</p> <ul style="list-style-type: none"> ▪ In Item A, Risk Factors, #7m, removed “(multiple myeloma)”. ▪ In Item A, Risk Factors, #7o, added “methotrexate”
	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Added ICD-10 Diagnosis codes (<i>Effective October 1, 2014</i>)
	Updated Rationale section.

REVISIONS	
	Updated Reference section.
05-13-2015	Updated Description section. In Policy section: <ul style="list-style-type: none"> ▪ Added "Policy Guidelines, <ol style="list-style-type: none"> 1. A 2011 joint position statement from the International Society for Clinical Densitometry and the International Osteoporosis Foundation includes the official position that FRAX with BMD predicts risk of fracture better than clinical risk factors or BMD alone.(2) In addition, the joint position statement states that measurements other than BMD or T score at the femoral neck by DXA are not recommended for use with FRAX. 2. The FRAX tool does not include a recommendation about which patients to further assess or treat. The FRAX website(1) states that this is a matter of clinical judgment and recommendations may vary by country. 3. In pediatric patients, total body calcium is preferred because it helps reduce the issue of following patients with growing bones. This applies to pediatric patients who are not skeletally mature as documented by nonclosure of growth plates (e.g., 15 years of age or younger)."
	Updated Rationale section.
	Updated References section.
07-08-2015	In Coding section: <ul style="list-style-type: none"> ▪ Added ICD-9 code 733.90. ▪ Added ICD-10 codes M85.812, M85.811, M85.821, M85.822, M85.831, M85.832, M85.841, M85.842, M85.851, M85.852, M85.861, M85.862, M85.871, M85.872, M85.88, M85.89, M85.9 In Revision section: <ul style="list-style-type: none"> ▪ Revised 10-04-2013, changed 2nd table row, "In Coding section" to "In Policy section".
12-08-2015	Updated Description section. In Policy section: <ul style="list-style-type: none"> ▪ In Item A, removed previous "Risk Factors" and added current FRAX information. ▪ In Item A 5, previous "Risk Factors" not noted in current FRAX information have been added. ▪ In Item C, removed "previously tested normal" and "does", and added "do" to read, "Repeat measurement of central (hip/spine) BMD for individuals who do not require pharmacologic treatment may be considered medically necessary at an interval not more frequent than every 3-5 years; the interval depends on patient risk factors." ▪ Removed Item G. ▪ In Policy Guidelines, removed previous Items 1 and 2.
	Updated Rationale section.
	Updated References section.
05-25-2016	Under title of policy, removed <i>"See also: Vertebral Fracture Assessment with Densitometry"</i> In Coding section: <ul style="list-style-type: none"> ▪ Added CPT code: 77085
10-01-2016	In Coding section: <ul style="list-style-type: none"> ▪ Added ICD-10 code effective 10-01-2016: K90.49 ▪ Termed ICD-10 code effective 09-30-2016: K90.4
04-12-2017	Updated Description section. In Policy section: <ul style="list-style-type: none"> ▪ In Item A, added "central" and "using dual x-ray absorptiometry" and removed "at the" to read, "An initial measurement of central (hip/spine) BMD using dual x-ray

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	<p>absorptiometry may be considered medically necessary to assess fracture risk and the need for pharmacologic therapy in both women and men who are considered at risk for osteoporosis. BMD testing may be indicated under the following conditions:"</p> <ul style="list-style-type: none"> ▪ In Item B, added "(hip/spine)" and "using dual x-ray absorptiometry" to read, "Regular (not more frequent than every 2-3 years) serial measurements of central (hip/spine) BMD using dual x-ray absorptiometry to monitor treatment response may be considered medically necessary when the information will affect treatment decisions such as duration of therapy." ▪ In Item C, added "using dual x-ray absorptiometry" to read, "Repeat measurement of central (hip/spine) BMD using dual x-ray absorptiometry for individuals who do not require pharmacologic treatment may be considered medically necessary at an interval not more frequent than every 3-5 years; the interval depends on patient risk factors." ▪ Added new Item D, "An initial measurement of central (hip/spine) BMD using dual x-ray absorptiometry may be considered medically necessary in patients who are to undergo hip resurfacing procedures." ▪ In Policy Guidelines, added new Items 1 and 2 (previous Item 1 now Item 3). <p>Updated Rationale section.</p> <p>Updated References section.</p>
03-04-2019	<p>Policy published 02-01-2019 with an effective date of 03-04-2019.</p> <p>Updated Description section.</p> <p>Updated Rationale section.</p> <p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Added CPT code: 0508T. ▪ Removed ICD-9 codes. <p>Updated References section.</p>
07-01-2019	<p>In Coding section:</p> <ul style="list-style-type: none"> ▪ Added new CPT codes: 0554T, 0555T, 0556T, 0557T.
10-01-2020	<p>In Coding Section:</p> <ul style="list-style-type: none"> ▪ Added new ICD-10 codes: G40.833, G40.834, N18.31, N18.32 ▪ Removed ICD-10 code N18.3
04-16-2021	<p>Updated Description section</p> <p>In the Policy section</p> <ul style="list-style-type: none"> • Added Items A.5.h., A.5.p, and A.5.v. • In Items B, C, and D, added the underlined section and removed the strike through section: <ul style="list-style-type: none"> B. Regular (not more frequent than every 2-3 years) serial measurements of central (hip/spine) BMD using dual x-ray absorptiometry to monitor treatment response may be considered medically necessary when the information will affect treatment decisions such as duration of therapy. B. <u>Repeat measurement of central (hip/spine) BMD using dual x-ray absorptiometry may be considered medically necessary at an interval not more frequent than every 1-3 years in individuals who are receiving pharmacologic treatment for osteoporosis when the information will affect treatment decisions (continuation, change in drug therapy, cessation or resumption of drug therapy).</u> C. Repeat measurement of central (hip/spine) BMD using dual x-ray absorptiometry for individuals who do not require pharmacologic treatment may be considered medically necessary at an interval not more frequent than every 3-5 years; the interval depends on patient risk factors.

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	<p>C. <u>Repeat measurement of central (hip/spine) BMD using dual x-ray absorptiometry for individuals who previously tested normal may be considered medically necessary at an interval not more frequent than every 3 to 5 years; the interval depends on an updated patient fracture risk assessment.</u></p> <p>D. <u>An initial measurement of central (hip/spine) BMD using dual x-ray absorptiometry may be considered medically necessary in patients who are to undergo hip resurfacing procedures.</u></p> <p>D. <u>Repeat measurement of central (hip/spine) BMD using dual x-ray absorptiometry may be considered medically necessary at an interval of not more frequent than every 1-2 years in individuals:</u></p> <ol style="list-style-type: none"> 8. <u>With a baseline evaluation of osteopenia (BMD T- score -1.0 to -2.5)</u> 9. <u>Adults with a pathologic condition associated with low bone mass or increased bone loss;</u> 10. <u>Adults taking a medication associated with increased bone loss.</u> <ul style="list-style-type: none"> • In the policy guidelines one and two, added the underlined section and removed the strike through section: <u>Bone Mineral Density Technologies</u> <ol style="list-style-type: none"> 1. <u>Ultrasound densitometry is an office-based technology. Compared with osteoporotic bone, normal bone demonstrates higher attenuation of the ultrasound wave and is associated with a greater velocity of the wave passing through bone. Ultrasound densitometry has no radiation exposure, and machines may be purchased for use in an office setting. As discussed further in the Rationale section,</u> it is unknown whether this technology can be used to predict response to pharmacologic therapy (i.e., reduce fractures). 2. <u>Dual x-ray absorptiometry (DXA) of axial central sites (i.e., hip and spine) is the most commonly used technique, but peripheral (appendicular) DXA and quantitative computed tomography scanning are sometimes used, based on local availability. Peripheral measurement can identify patients with low bone mass but does not predict response to pharmacologic therapy and is not a substitute for central DXA measurements. Therefore,</u> <ul style="list-style-type: none"> • Added policy guidelines 4, 5, and 6.
	Updated Rational section
	In the Coding section: • Added Code 0558T
	Updated the Reference section
10-08-2021	In the Coding section • Added CPT code 0691T (Effective 10-01-2021)
11-5-2021	Updated Description section
	Updated Rationale section
	Updated Reference section
01-01-2022	In Coding Section Added: 0691T
03-01-2023	Updated Description Section
	Updated Policy Section <ul style="list-style-type: none"> ▪ Section A: ▪ A1 Removed: "Women age 65 and older, regardless of other risk factors;" ▪ A2 Changed "men" to "Individuals" ▪ A3 Added "Postmenopausal individuals over the age of 65 and over, regardless of other risk factors or" and "with an elevated risk factor assessment" Changed

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	<p>“women” to individuals” Removed “women about whom there is a concern based on their risk factors”</p> <ul style="list-style-type: none"> ▪ A4 Changed “Men age” to “Individuals age”, Removed “about whom there is a concern based on their risk factors”, Added “with an elevated risk factor assessment” ▪ A5 Added “Pathologic” before condition ▪ Section B Added: “An initial measurement of central (hip/spine) BMD using dual x-ray absorptiometry may be considered not medically necessary, if the above criteria is not met.” ▪ Section E: Re-worded to read “Bone mineral density measurement using ultrasound densitometry is considered not medically necessary.” ▪ Section F: Re-worded to read “Bone mineral density measurement using quantitative computed tomography (QCT) is considered not medically necessary.” ▪ Section G: Removed: <p>G. Peripheral measurement can identify patients with low bone mass, but does not predict response to pharmacologic therapy and is not a substitute for central DXA measurements. Therefore, central DXA (hip/spine) is required for both the initial diagnosis and repeat BMD assessments.</p> <p>Peripheral measurement of BMD is considered not medically necessary except:</p> <ol style="list-style-type: none"> 1. when the hip/spine or hip/hip cannot be done or the patient is over the table limit for weight; 2. for hyperparathyroidism, where the forearm is essential for diagnosis” <p>Added: “Peripheral (lower arm, wrist, finger or heel) BMD testing may be considered medically necessary when conventional central (hip/spine) DXA screening is not feasible or in the management of hyperparathyroidism, where peripheral DXA at the forearm (i.e., radius) is essential for evaluation.”</p> ▪ Section H Added “Dual x-ray absorptiometry of peripheral sites is considered experimental / investigational except as noted above” ▪ Section I Added: <p>“I. DXA for pediatrics (until age 18) may be considered medically necessary when ANY ONE of the following is met:</p> <ol style="list-style-type: none"> 1. Prolonged use of glucocorticoid or corticosteroid therapy; or 2. Chronic inflammatory disease; or 3. Hypogonadism; or 4. Idiopathic juvenile osteoporosis; or 5. Long term immobilization; or 6. Osteogenesis imperfecta; or 7. Completion of chemotherapy two (2) years prior to ordering DXA.” ▪ Section J Added: “Bone density studies for pediatrics (until age 18) not meeting the criteria as indicated above is considered not medically necessary.”
	<p>Updated Policy Guidelines</p> <ul style="list-style-type: none"> ▪ Added policy guideline (C) “Peripheral (lower arm, wrist, finger or heel) measurement can identify individuals with low bone mass but does not predict response to pharmacologic therapy and is not a substitute for central DXA measurements.”
	<p>Updated Rationale Section</p>
	<p>Updated Coding Section</p> <ul style="list-style-type: none"> ▪ Converted the following ICD-10 codes M85.811-M85.9, N18.31-18.9, S22.000A-S22.088S, S32.000A- S32.058S, S32.110A- S32.112S, S32.120A- S32.122S, S32.130A- S32.132S, S32.14XA- S32.14XS, S32.15XA-S32.15XS, S32.16XA-S32.16XS, S32.17XA- S32.17XS, S32.19XA- S32.19XS, S32.2XXA- S32.2XXS,

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	M06.011- M06.09, M06.211- M06.29, M06.311- M06.39, M06.811-M06.89, M05.411- M05.49, M05.511- M05.59, M05.711-M05.79, M05.811-M05.89, G40.001- G40.019, G40.101- G40.219, G40.301- G40.319, G40.401-G40.419, G40.801- G40.804, G40.811-G40.814, G40.821-G40.824, F17.201-F17.291, G40.901-G40.919, G40.A01- G40.A19, G40.B01- G40.B19 to ranges to include all codes within range
	Updated References Section
10-24-2023	Updated Description Section
	Updated Rationale Section
	Updated Coding Section <ul style="list-style-type: none"> ▪ Removed ICD-10 Codes ▪ Removed Deleted Code 0508T (eff. 01-01-2024)
	Updated References Section
11-20-2024	Updated Description Section
	Updated Rationale Section
	Updated Coding Section <ul style="list-style-type: none"> ▪ Removed 0619T
	Updated References Section

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