

<b>6.01.01 Bone Mineral Density Studies</b>	
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<b>Section:</b> 6.0 Radiology	<b>Page:</b> Page 1 of 25

### Policy Statement

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

- I. An initial measurement of central (hip or spine) BMD using dual x-ray absorptiometry (DXA) may be considered **medically necessary** to assess future fracture risk and the need for pharmacologic therapy in individuals who are considered at risk for osteoporosis. BMD testing may be indicated under **any** of the following conditions:
  - A. Women age 65 and older, independent of other risk factors
  - B. Men age 70 and older, independent of other risk factors
  - C. Younger postmenopausal women with an elevated risk factor assessment (See policy guidelines)
  - D. Men age 50 to 70 with an elevated risk factor assessment (See policy guidelines)
  - E. Adults with a pathologic condition associated with low bone mass or increased bone loss
  - F. Adults taking a medication associated with increased bone loss
- II. Repeat measurement of central (hip or spine) BMD using DXA for individuals who previously tested normal and does not require pharmacologic treatment, 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.
- III. Repeat measurement of central (hip or spine) BMD using DXA may be considered **medically necessary** at an interval of not more frequent than every 1 to 2 years in individuals:
  - A. With a baseline evaluation of osteopenia (BMD T-score -1.0 to -2.5)
  - B. Adults with a pathologic condition associated with low bone mass or increased bone loss
  - C. Adults taking a medication associated with increased bone loss
- IV. Repeat measurement of central (hip or spine) BMD using DXA may be considered **medically necessary** at an interval not more frequent than every 1 to 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).
- V. Peripheral (lower arm, wrist, finger or heel) DXA BMD testing may be considered **medically necessary** for **either** of the following indications:
  - A. When conventional central (hip or spine) DXA screening is not feasible
  - B. In the management of hyperparathyroidism, where peripheral DXA at the forearm (i.e., radius) is essential for evaluation
- VI. BMD measurement using ultrasound densitometry is considered **investigational**.
- VII. Dual x-ray absorptiometry of peripheral sites is considered **investigational** except as noted above.
- VIII. BMD measurement using quantitative computed tomography is considered **investigational**.

**NOTE:** Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

## Policy Guidelines

### Bone Mineral Density Technologies

Ultrasound densitometry is an office-based technology. As discussed further in the Rationale section, it is unknown whether this technology can be used to predict response to pharmacologic therapy (i.e., reduce fractures).

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.

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. Peripheral BMD may be appropriate:

- If the hip/spine or hip/hip cannot be done or the individual is over the table limit for weight
- Hyperparathyroidism, where the forearm is essential for diagnosis.

In pediatric individuals, measurement of total body calcium is preferred because it helps reduce following individuals with growing bones. This applies to pediatric individuals who are not skeletally mature, as documented by nonclosure of growth plates (e.g., 15 years of age or younger).

When indicated, repeat 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.

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).

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.

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

Blue Shield of California Medical Policy: Vertebral Fracture Assessment with Densitometry addresses screening for vertebral fractures using DXA, which is considered investigational.

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 World Health Organization (WHO) Fracture Risk Assessment Tool 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)

### Coding

The below Category III CPT code describes Pulse-Echo Ultrasound:

- **0508T**: Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia

The following CPT codes identify BMD testing technologies:

- **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)

Single- and dual-photon absorptiometry are now rarely used and may be considered obsolete. The CPT codes for these techniques are:

- **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

The following Category III CPT codes describe quantitative computed tomography technology:

- **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

## 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.

## Related Policies

- Bone Turnover Markers for the Diagnosis and Management of Osteoporosis and Diseases Associated With High Bone Turnover
- Vertebral Fracture Assessment with Densitometry

## Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

## 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 1.

**Table 1. 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
Beamed 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<sup>®</sup> 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.

## Rationale

### 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 Tool<sup>1</sup> 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 2).

**Table 2. 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 Severe (established)	Bone density is 2.5 SD or more below the young adult mean (-2.5 SD or lower).
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.

Note: Vertebral fracture assessment with DXA is addressed elsewhere (see Blue Shield of California Medical Policy: Vertebral Fracture Assessment with Densitometry).

### 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<sup>®</sup>), selective estrogen receptor modulators such as raloxifene (i.e., Evista<sup>®</sup>), the recombinant human parathyroid hormone teriparatide (i.e., Forteo<sup>®</sup>), 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.<sup>2</sup>

### **Literature Review**

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.<sup>3</sup> 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.<sup>3</sup> The supporting document refers to multiple instruments to predict risk for low BMD, including the Fracture Risk Assessment Tool.<sup>1</sup>



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.<sup>4</sup> 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.<sup>5</sup> 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.<sup>3</sup> 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.<sup>6,7</sup> 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.<sup>8,9,10</sup>

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.<sup>11,12</sup>

#### 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.<sup>4</sup> 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.<sup>5</sup> 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.<sup>11,12</sup> 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/cm<sup>2</sup>, which was substantially higher than the average annual increase in BMD (0.0085 g/cm<sup>2</sup>) in the alendronate group.<sup>13</sup>

### Clinical Practice Guidelines

In 2019, the Endocrine Society published clinical practice guidelines on the pharmacological management of osteoporosis in postmenopausal women.<sup>14</sup> 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.<sup>15</sup>

The American Association of Clinical Endocrinologists and the American College of Endocrinology published joint guidelines on the diagnosis and treatment of postmenopausal osteoporosis.<sup>4</sup> 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.<sup>5</sup>

### **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.<sup>3</sup> 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.<sup>16</sup> 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.<sup>17</sup> 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/m<sup>2</sup> 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).<sup>18</sup> 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.<sup>19</sup>

### **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.<sup>20</sup> 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:<sup>21</sup>

"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:<sup>22</sup>

- "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."

### **National Osteoporosis Foundation**

In 2022, the Bone Health and Osteoporosis Foundation (BHOFF), formerly known as the National Osteoporosis Foundation, updated its practice guidelines.<sup>23</sup> 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 BHOF stated that measurements for monitoring patients should be performed in accordance with medical necessity, expected response, and in consideration of local regulatory requirements. The BHOF 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 BHOF 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).<sup>3</sup> These recommendations are currently undergoing an update and may be revised within the near future.

### Medicare National Coverage

The Centers for Medicare and Medicaid pays for a screening bone mass measurement (BMM) once every 2 years (covered if at least 23 months have passed since the month the last covered BMM was performed).<sup>24</sup> When medically necessary, Medicare may pay for more frequent BMMs. Examples include, but are not limited to, monitoring beneficiaries on long-term glucocorticoid (steroid) therapy of more than 3 months, and confirming baseline BMMs to permit monitoring of beneficiaries in the future.

Conditions for coverage of BMM can be found in chapter 15, section 80.5 of Pub. 100-02, Medicare Benefit Policy Manual. Medicare covers BMM under the following conditions:

- "Is ordered by the physician or qualified nonphysician practitioner who is treating the beneficiary following an evaluation of the need for a BMM and determination of the appropriate BMM to be used....
- Is performed under the appropriate level of physician supervision as defined in 42 CFR 410.32(b).
- Is reasonable and necessary for diagnosing and treating the condition of a beneficiary who meets the conditions described in §80.5.6.
- In the case of an individual being monitored to assess the response to or efficacy of an FDA [Food and Drug Administration] approved osteoporosis drug therapy, is performed with a dual-energy x-ray absorptiometry system (axial skeleton).
- In the case of any individual who meets the conditions of 80.5.6 and who has a confirmatory BMM, is performed by a dual-energy x-ray absorptiometry system (axial skeleton) if the initial BMM was not performed by a dual-energy x-ray absorptiometry system (axial skeleton). A confirmatory baseline BMM is not covered if the initial BMM was performed by a dual-energy x-ray absorptiometry system (axial skeleton)."

### Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in July 2023 did not identify any ongoing or unpublished trials that would likely influence this review.

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## Documentation for Clinical Review

### Please provide the following documentation:

- History and physical from the prescribing MD including:
  - Previous treatment and response, and clinical risk factors for osteoporosis-related fracture
  - Additional reports including: Previous bone mineral density measurement, x-ray reports and laboratory reports
  - Time since last bone mineral density measurement, if applicable

### Post Service (in addition to the above, please include the following):

- DXA report for date of service billed

## Coding

*This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.*

Type	Code	Description
CPT®	0508T	Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia
	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

Type	Code	Description
	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
	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)
	77089	Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture-risk
	77090	Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical preparation and transmission of data for analysis to be performed elsewhere
	77091	Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical calculation only
	77092	Trabecular bone score (TBS), structural condition of the bone microarchitecture; interpretation and report on fracture-risk only by other qualified health care professional
	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
HCPCS	G0130	Single energy x-ray absorptiometry (SEXA) bone density study, one or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)

### Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
07/02/2009	New Policy. Policies combined: Bone Mineral Density Screening for Vertebral Fracture with Dual X-ray Absorptiometry (DEXA)
07/08/2010	Policy Revision Testing interval revised
01/12/2011	Policy Revision - Testing interval revised

Effective Date	Action
04/01/2011	Policy revision with position change
03/13/2012	Coding Update
01/01/2015	Coding Update
08/31/2015	Policy title change from Bone Mineral Density and Vertebral Fracture Assessment. Policy revision with position change.
03/01/2017	Policy revision without position change
05/01/2017	Policy revision with position change
05/01/2018	Coding update
07/01/2018	Policy statement clarification
11/01/2018	Policy revision without position change
03/01/2019	Policy revision without position change. Coding update.
04/01/2020	Annual review. Policy statement, guidelines and literature updated.
03/01/2021	Annual review. Policy statement, guidelines and literature updated.
11/01/2021	No change to policy statement. Literature review updated.
02/01/2022	Coding update.
11/01/2022	Annual review. Policy statement, guidelines and literature updated.
11/01/2023	Annual review. No change to policy statement. Literature review updated.

## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at [www.blueshieldca.com/provider](http://www.blueshieldca.com/provider).

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: [MedPolicy@blueshieldca.com](mailto:MedPolicy@blueshieldca.com)

*Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.*

## Appendix A

## POLICY STATEMENT

(No changes)

## BEFORE

## Bone Mineral Density Studies 6.01.01

**Policy Statement:**

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

- I. An initial measurement of central (hip or spine) BMD using dual x-ray absorptiometry (DXA) may be considered **medically necessary** to assess future fracture risk and the need for pharmacologic therapy in individuals who are considered at risk for osteoporosis. BMD testing may be indicated under **any** of the following conditions:
  - A. Women age 65 and older, independent of other risk factors
  - B. Men age 70 and older, independent of other risk factors
  - C. Younger postmenopausal women with an elevated risk factor assessment (See policy guidelines)
  - D. Men age 50 to 70 with an elevated risk factor assessment (See policy guidelines)
  - E. Adults with a pathologic condition associated with low bone mass or increased bone loss
  - F. Adults taking a medication associated with increased bone loss
- II. Repeat measurement of central (hip or spine) BMD using DXA for individuals who previously tested normal and does not require pharmacologic treatment, 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.
- III. Repeat measurement of central (hip or spine) BMD using DXA may be considered **medically necessary** at an interval of not more frequent than every 1 to 2 years in individuals:
  - A. With a baseline evaluation of osteopenia (BMD T-score -1.0 to -2.5)

## AFTER

## Bone Mineral Density Studies 6.01.01

**Policy Statement:**

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

- I. An initial measurement of central (hip or spine) BMD using dual x-ray absorptiometry (DXA) may be considered **medically necessary** to assess future fracture risk and the need for pharmacologic therapy in individuals who are considered at risk for osteoporosis. BMD testing may be indicated under **any** of the following conditions:
  - A. Women age 65 and older, independent of other risk factors
  - B. Men age 70 and older, independent of other risk factors
  - C. Younger postmenopausal women with an elevated risk factor assessment (See policy guidelines)
  - D. Men age 50 to 70 with an elevated risk factor assessment (See policy guidelines)
  - E. Adults with a pathologic condition associated with low bone mass or increased bone loss
  - F. Adults taking a medication associated with increased bone loss
- II. Repeat measurement of central (hip or spine) BMD using DXA for individuals who previously tested normal and does not require pharmacologic treatment, 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.
- III. Repeat measurement of central (hip or spine) BMD using DXA may be considered **medically necessary** at an interval of not more frequent than every 1 to 2 years in individuals:
  - A. With a baseline evaluation of osteopenia (BMD T-score -1.0 to -2.5)



## POLICY STATEMENT

(No changes)

BEFORE	AFTER
<p>B. Adults with a pathologic condition associated with low bone mass or increased bone loss</p> <p>C. Adults taking a medication associated with increased bone loss.</p> <p>IV. Repeat measurement of central (hip or spine) BMD using DXA may be considered <b>medically necessary</b> at an interval not more frequent than every 1 to 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).</p> <p>V. Peripheral (lower arm, wrist, finger or heel) DXA BMD testing may be considered <b>medically necessary</b> for <b>either</b> of the following indications:</p> <p>A. When conventional central (hip or spine) DXA screening is not feasible</p> <p>B. in the management of hyperparathyroidism, where peripheral DXA at the forearm (i.e., radius) is essential for evaluation</p> <p>VI. BMD measurement using ultrasound densitometry is considered <b>investigational</b>.</p> <p>VII. Dual x-ray absorptiometry of peripheral sites is considered <b>investigational</b> except as noted above.</p> <p>VIII. BMD measurement using quantitative computed tomography is considered <b>investigational</b>.</p>	<p>B. Adults with a pathologic condition associated with low bone mass or increased bone loss</p> <p>C. Adults taking a medication associated with increased bone loss</p> <p>IV. Repeat measurement of central (hip or spine) BMD using DXA may be considered <b>medically necessary</b> at an interval not more frequent than every 1 to 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).</p> <p>V. Peripheral (lower arm, wrist, finger or heel) DXA BMD testing may be considered <b>medically necessary</b> for <b>either</b> of the following indications:</p> <p>A. When conventional central (hip or spine) DXA screening is not feasible</p> <p>B. In the management of hyperparathyroidism, where peripheral DXA at the forearm (i.e., radius) is essential for evaluation</p> <p>VI. BMD measurement using ultrasound densitometry is considered <b>investigational</b>.</p> <p>VII. Dual x-ray absorptiometry of peripheral sites is considered <b>investigational</b> except as noted above.</p> <p>VIII. BMD measurement using quantitative computed tomography is considered <b>investigational</b>.</p>