Introduction

A bone density test is done to estimate the strength of bones. It looks at concentration of certain minerals like calcium. Bone density tests, which are also called bone mineral density tests or BMD tests, help doctors know if a person is at risk of broken bones due to osteoporosis. Osteoporosis means “porous bone.” It’s caused by the body’s loss of too much bone, its inability to make enough bone, or both. Risk factors include age, low body mass index, and other conditions associated with osteoporosis such as rheumatoid arthritis and diabetes. A bone density test also is used to measure how well osteoporosis treatment is working. A bone mineral density test generally uses a special type of x-ray or ultrasound. This policy describes when a bone density test may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Initial or repeat bone mineral density (BMD) measurement is not indicated unless the results will influence treatment decisions.

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Medical Necessity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Initial measurement</strong></td>
<td>An initial measurement of BMD at the hip or spine using dual x-ray 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:</td>
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<tr>
<td></td>
<td>• Women age 65 and older, regardless of other risk factors (Covered under the ACA as a preventive benefit)</td>
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<td>• Men age 70 and older, regardless of other risk factors</td>
</tr>
<tr>
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<td>• Women age &lt;65 years whose 10-year risk of a major osteoporotic fracture is 9.3% or greater based upon the Fracture Risk Assessment (FRAX) Tool</td>
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<td>• Men age 50 to 70 about whom there is a concern based on their risk factors</td>
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<td></td>
<td>• Adults with a condition or taking a medication associated with low bone mass or bone loss</td>
</tr>
<tr>
<td><strong>Repeat Measurement – no osteoporosis/osteopenia</strong></td>
<td>Repeat measurement of central (hip/spine) BMD using dual x-ray absorptiometry for individuals who previously tested normal (no osteoporosis/osteopenia and not taking a medicine for treatment) may be considered medically necessary at an interval not more frequent than every 5 years.</td>
</tr>
<tr>
<td><strong>Repeat Measurement – osteopenia</strong></td>
<td>Repeat measurement of central (hip/spine) BMD using dual x-ray absorptiometry for individuals who previously tested as having osteopenia and not requiring pharmacologic treatment may be considered medically necessary at an interval not more frequent than every 2-3 years.</td>
</tr>
<tr>
<td><strong>Repeat Measurement – monitoring pharmacologic treatment</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>
**Documentation Requirements**

The patient’s medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- For initial measurement to assess fracture risk and the need for pharmacologic therapy in both women and men who are considered at risk for osteoporosis, clinical documentation of **ANY** of the following:
  - Women age 65 and older, regardless of other risk factors (covered under the Affordable Care Act as a preventive benefit)
  - Men age 70 and older, regardless of other risk factors
  - Women age <65 years whose 10-year risk of a major osteoporotic fracture is 9.3% or greater based upon the Fracture Risk Assessment (FRAX) Tool
  - Men age 50 to 70 about whom there is a concern based on their risk factors
  - Adults with a condition or taking a medication associated with low bone mass or bone loss

- For repeat measurement to monitor pharmacologic treatment:
  - Documentation on how the result will affect treatment decisions such as duration of therapy

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**Coding**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CPT</strong></td>
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<tr>
<td>0508T</td>
<td>Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia</td>
</tr>
<tr>
<td>76977</td>
<td>Ultrasound bone density measurement and interpretation, peripheral site(s), any method</td>
</tr>
<tr>
<td>77080</td>
<td>Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine)</td>
</tr>
<tr>
<td>77081</td>
<td>Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)</td>
</tr>
<tr>
<td>78350</td>
<td>Bone density (bone mineral content) study, 1 or more sites; single photon absorptiometry</td>
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<tr>
<td>78351</td>
<td>Bone density (bone mineral content) study, 1 or more sites; dual photon absorptiometry, 1 or more sites</td>
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<td>Code</td>
<td>Description</td>
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<tr>
<td>HCPCS</td>
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Single energy x-ray absorptiometry (SEXA) bone density study, one or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information

### Definition of Terms (World Health Organization)

**Normal bone density:** T-score between 0.00 and -1.00

**Osteopenia:** T-score between -1.01 and -2.49

**Osteoporosis:** T-score -2.50 and below

The decision to perform bone density assessment should be based on an individual’s fracture risk profile and skeletal health assessment.\(^1\) In addition to age, gender, and BMD, risk factors included in the World Health Organization (WHO) **Fracture Risk Assessment (FRAX) Tool** are:

- Low body mass index
- Parental history of hip fracture
- Previous fragility fracture in adult life (ie, 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 /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)
- 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
• Current exposure to oral glucocorticoids or the patient has been exposed 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)

A 2011 joint position statement from the International Society for Clinical Densitometry (ISCD) and the International Osteoporosis Foundation (IOF) 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.

The FRAX tool does not include a recommendation about which patients to further assess or treat. The FRAX website¹ states that this is a matter of clinical judgment and recommendations may vary by country.

**Bone Mineral Density Technologies**

Ultrasound densitometry is an office-based technology. It is unknown whether this technology can be used to predict response to pharmacologic therapy (ie, reduce fractures). 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. Together, these results indicate that frequent (ie, every two years) repeat monitoring has low value.

Dual x-ray absorptiometry (DXA) of axial central sites (ie, hip and spine) is the most commonly used technique, but peripheral (appendicular) DXA and quantitative computed tomography (QCT) 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, central DXA (hip/spine) is required for both the initial diagnosis and repeat BMD assessments.

Peripheral measurement of BMD may be appropriate:

• If the hip/spine or hip/hip cannot be done or the patient is over the table limit for weight

• Hyperparathyroidism, where the forearm is essential for diagnosis

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

Under the Patient Protection and Affordable Care Act, preventive services with a U.S. Preventive Services Task Force recommendation grade of A or B will be covered with no cost-sharing requirements. Plans that have been grandfathered are exceptions to this rule and are not subject to this coverage mandate. Therefore, review of subscriber contracts or certificates of coverage is needed regarding coverage for screening and coverage for diagnostic tests for asymptomatic individuals and those who are symptomatic and carry a diagnosed illness.

Preventive Care Services

Affordable Care Act covered preventive services: Osteoporosis screening in women has a US Preventive Services Task Force rating of B in the following populations:

- Women age 65 and older, with no known risk factors for osteoporosis
- Women age<65 whose 10 year fracture risk is equal to or greater than that of the average 65 year old white woman without additional risk factors. The standard 10-year fracture risk described by USPSTF is a FRAX score of 9.3% or greater.

Consideration of Age

The ages in this policy for which the initial measurement of bone mineral density is considered medically necessary to assess risk and need for therapy are based on covered preventive services outlined in the Patient Protection and Affordable Care Act, National Osteoporosis Foundation, American College of Physicians, and the American College of Radiology.

Evidence Review

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), although other technologies are available.

Background

**Bone Mineral Density**

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 World Health Organization 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.

BMD can be measured either centrally (ie, hip or spine) or peripherally (ie, wrist, finger, heel) sites. 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 (ie, vertebral fractures) are also considered to be the most clinically relevant. BMD 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. These potential benefits of screening should outweigh the risks of screening (radiation exposure) or false positives (initiation of unnecessary treatment).

**Osteoporosis Treatment**

Treatment of osteoporosis includes both lifestyle measures (eg, increased intake of calcium and vitamin D, exercise, smoking cessation) and pharmacologic measures. Current pharmacologic options include bisphosphonates such as alendronate (ie, Fosamax), selective estrogen receptor modulators such as raloxifene (ie, Evista), the recombinant human parathyroid hormone
teriparatide (ie, Forteo), and calcitonin. An updated 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.1

**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 have been explored. The most commonly used technologies are described next.

**Dual X-Ray Absorptiometry**

DXA is probably 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. DXA can also be used to measure peripheral sites, such as the wrist and finger. DXA generates two x-ray beams of different energy levels to scan the region of interest and measure 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 two beams allows for correction for the irregular masses of soft tissue, which surround the spine and hip, and therefore the measurement of bone density at those sites.

**Quantitative Computed Tomography**

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.
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.

Summary of Evidence

For individuals who are eligible for screening of BMD based on risk factor assessment who receive DXA analysis of central sites (hip or spine), the evidence includes systematic reviews of randomized controlled trials and cohort studies. The relevant outcomes are morbid events, functional outcomes, quality of life, hospitalizations, and medication use. Central DXA is the most widely accepted method for measuring BMD and is the reference standard against which other screening tests are evaluated. BMD 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 can be used to guide therapy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals without osteoporosis on initial screen who receive repeat DXA analysis of central sites (hip or spine), the evidence includes systematic reviews of large cohort and observational studies. The relevant outcomes are morbid events, functional outcomes, quality of life, hospitalizations, and medication use. 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. Although the optimal interval may differ depending on risk factors, current evidence does not support repeat monitoring in patients with BMD on DXA in the normal range. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are receiving pharmacologic treatment for osteoporosis who receive repeat DXA analysis of central sites (hip or spine), the evidence includes systematic reviews of
randomized controlled trials and observational studies. The relevant outcomes are morbid events, functional outcomes, quality of life, hospitalizations, and medication use. 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 has been shown to be reduced in some treatment studies in the absence of changes in BMD. Together, these results suggest that frequent (ie, every two years) repeat monitoring has low value. It is unclear whether DXA at the end of the initial five years of therapy is sufficiently accurate to guide subsequent therapy. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are eligible for screening of BMD based on risk factor assessment who receive ultrasound densitometry, or quantitative computed tomography, or DXA analysis of peripheral sites, the evidence includes observational studies and systematic reviews. The relevant outcomes are morbid events, functional outcomes, quality of life, hospitalizations, and medication use. In comparison with central DXA, other measures of bone health showed area under the curves around 0.80 for the identification of osteoporosis. These technologies are not commonly used for BMD measurements in practice, and 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in November 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

Clinical Input Received From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 4 physician specialty societies (7 reviewers) and 2 academic medical centers while this policy was under review in 2008. In addition, seven
unsolicited letters were received through two additional physician specialty societies. Reviewers agreed with the policy statement that an initial bone mineral density (BMD) test may be medically necessary. They also recommended an interval of three to five years between measurements in subjects who previously tested normal, depending on risk factors. Reviewers considered serial measurement of BMD important to guide treatment decisions (eg, continuing or changing medication).

Based on the consensus of clinical opinion regarding the value of the information provided by monitoring treatment response, serial BMD measurements (at least a two-year interval) may be considered appropriate when this information will impact patient care. It should be noted that within the margin of error of BMD measurements with dual x-ray absorptiometry, questions remain about the interval over which a clinically significant change can be observed. The minimal clinically significant change also raises concerns about the potential for over-interpretation of small fluctuations with repeat testing.

Practice Guidelines and Position Statements

**American College of Obstetricians and Gynecologists**

The American College of Obstetricians and Gynecologists (ACOG) (2012, reaffirmed 2016) updated its guidelines on managing osteoporosis in women. The guidelines recommended that BMD screening should begin for all women at age 65 years. In addition, the ACOG recommended screening for women younger than 65 years in whom the Fracture Risk Assessment Tool indicates a 10-year risk of osteoporotic fracture of at least 9.3%. Alternatively, ACOG also recommended BMD screening women younger than 65 with any of the following risk factors (they are similar, but not identical to risk factors in the Fracture Risk Assessment Tool):

- Personal medical history of a fragility fracture
- Parental medical history of hip fracture
- Weight less than 127 lb
- Medical causes of bone loss (ie, medications or disease)
- Current smoker
- Alcoholism
• Rheumatoid arthritis

For women who begin medication treatment for osteoporosis, a repeat BMD is recommended one to two years later to assess effectiveness. If BMD is improved or stable, additional BMD testing (in the absence of new risk factors) is not recommended. The guideline notes that it generally takes 18 to 24 months to document a clinically meaningful change in BMD and thus a 2-year interval after treatment initiation is preferred to 1 year.

The guidelines do not specifically discuss repeat BMD screening for women who have a normal finding on the initial test.

Routine BMD screening is not recommended for newly menopausal women as a “baseline” screen.

National Osteoporosis Foundation

The National Osteoporosis Foundation (NOF) (2014) updated its practice guidelines. The NOF guidelines recommend that all postmenopausal women and men age 50 and older should be evaluated clinically for osteoporosis risk to determine the need for BMD testing.

Indications for BMD testing included:

• “Women age 65 and older and men age 70 and older,” regardless of other risk factors;
• “Postmenopausal women and men above age 50-69, based on risk factors profile”
• “Postmenopausal women and men age 50 and older who have had an adult age fracture…”
• “Adults with a condition...or taking a medication... associated with low bone mass or bone loss”

The NOF stated that measurements for monitoring patients should be performed in accordance with medical necessity, expected response and in consideration of local regulatory requirements. The NOF recommended that repeat BMD assessments generally agree with Medicare guidelines of every two years, but recognized that testing more frequently may be warranted in certain clinical situations.

The NOF also indicated that, “Central DXA (dual x-ray absorptiometry) assessment of the hip or lumbar spine is the ‘gold standard’ for serial assessment of BMD. Biological changes in bone density are small compared to the inherent error in the test itself, and interpretation of serial bone density studies depends on appreciation of the smallest change in BMD that is beyond the
range of error of the test. This least significant change (LSC) varies with the specific instrument used, patient population being assessed, measurement site, technologist’s skill with patient positioning and test analysis, and the confidence intervals used. Changes in the BMD of less than 3-6% at the hip and 2-4% at the spine from test to test may be due to the precision error of the testing itself.

**American College of Physicians**

The guidelines from the American College of Physicians (2017) 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). 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 CSA scores did not progress to osteoporosis with 15 years.”

**American College of Radiology**

Appropriateness criteria from the American College of Radiology, updated in 2017, state that BMD measurement is indicated whenever a clinical decision is likely to be directly influenced by the result of the test. Indications for DXA of the lumbar spine and hip included but were not limited to the following patient populations:

1. All women age 65 years and older and men age 70 years and older (asymptomatic screening)

2. 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:
   a. Estrogen deficiency
   b. A history of maternal hip fracture that occurred after the age of 50 years
   c. Low body mass (less than 127 lbs or 57.6 kg)
   d. History of amenorrhea (more than 1 year before age 42 years)
3. Women younger than age 65 years or men younger than age 70 years who have additional risk factors, including:
   a. Current use of cigarettes
   b. Loss of height, thoracic kyphosis

4. Individuals of any age with bone mass osteopenia, or fragility fractures on imaging studies such as radiographs, computed tomography (CT), or magnetic resonance imaging (MRI)

5. Individuals age 50 years and older who develop a wrist, hip, spine, or proximal humerus fracture with minimal or no trauma, excluding pathologic fractures

6. Individuals of any age who develop one or more insufficiency fractures

7. Individuals being considered for pharmacologic therapy for osteoporosis.

8. Individuals beginning monitored to:
   a. Assess the effectiveness of osteoporosis drug therapy.
   b. Follow-up medical conditions associated with abnormal BMD.

**International Society for Clinical Densitometry**

The 2013 update of the International Society for Clinical Densitometry guidelines recommended bone density testing in the following patients:\textsuperscript{19}

- “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 fracture such as:
  o Low body weight
  o Prior fracture
  o High risk medication use
  o Disease or condition associated with bone loss

- Women during the menopausal transition with clinical risk factors for fracture, such as low bone weight, prior fracture or high-risk medication use
Men aged 70 and older

Men under age 70 years...if they have risk factors 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.”

**American Association of Clinical Endocrinologists et al**

The American Association of Clinical Endocrinologists and American College of Endocrinology (2016) issued updated joint guidelines on the diagnosis and treatment of postmenopausal osteoporosis. The guidelines listed the potential uses for BMD measurements in postmenopausal women as:

- “Screening for osteoporosis
- Establishing the severity of osteoporosis or bone loss...
- Determining fracture risk...
- Identifying candidates for pharmacologic intervention
- Assessing changes in bone density over time...
- Enhancing acceptance of, and perhaps adherence with, treatment
- Assessing skeletal consequences of diseases, conditions, or medications known to cause bone loss”
U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (USPSTF) (2018) updated recommendations on screening for osteoporosis with bone density measurements. The USPSTF recommended screening for osteoporosis in women aged 65 years or older and in postmenopausal women younger than 65 years at increased risk of osteoporosis. The supporting document notes there are multiple instruments to predict risk for low BMD, including the Fracture Risk Assessment Tool. The updated USPSTF recommendations stated that the scientific evidence is “insufficient” to assess the balance of benefits and harms of screening for osteoporosis screening in men. The Task Force did not recommend specific screening tests but said that the most commonly used tests are DXA of the hip and lumbar spine and quantitative ultrasound of the calcaneus.

The USPSTF concluded the evidence base is sparse on screening interval. While two studies showed no advantage to repeated testing, other evidence suggested that the optimal screening interval may vary by baseline BMD, age, and use of hormone replacement therapy.

Medicare National Coverage

The Centers for Medicare and Medicaid pays for a screening bone mass measurement (BMM) once every 2 years (at least 23 months have passed since the month the last covered BMM was performed). 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 three 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-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)."

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

<table>
<thead>
<tr>
<th>Device Name</th>
<th>Company</th>
<th>510(k) number</th>
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<tbody>
<tr>
<td>Aria</td>
<td>GE Medical Systems</td>
<td>K180782</td>
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<tr>
<td>Ge Lunar Dxa Bone Densitometers With Enc</td>
<td>GE Medical Systems</td>
<td>K161682</td>
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<tr>
<td>Tbs Insight</td>
<td>Medimaps Group Sa</td>
<td>K152299</td>
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<tr>
<td>Single Energy (Se) Femur Exams</td>
<td>Hologic, Inc.</td>
<td>K130277</td>
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<td>Tbs Insight</td>
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<td>Virtuost</td>
<td>O.N. Diagnostics</td>
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<td>Accuadx2</td>
<td>Lone Oak Medical Technologies, Llc</td>
<td>K113616</td>
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<td>Ultrascan 650</td>
<td>Cyberlogic, Inc.</td>
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<td>Bindex Bi-2</td>
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<td>GE Medical Systems</td>
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<td>Beammed Sunlight Miniomni Bone Sonometer</td>
<td>Beam-Med Ltd</td>
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<td>Achilles</td>
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FDA product codes: KGI, MUA.
In addition, some ultrasound bone sonometers have been approved by 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.

References


5. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Ultrasonography of peripheral sites for diagnosing and selecting patients for pharmacologic treatment for osteoporosis. TEC Assessments. 2002;Volume 17:Tab 5.


### History

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td>09/08/14</td>
<td>New policy, add to Radiology section. Policy created based on a literature review through February 11, 2014. An initial measurement of BMD at the hip or spine may be considered medically necessary to assess fracture risk and the need for pharmacologic therapy when criteria are met. Repeat measurement of BMD may be considered medically necessary when criteria are met. Policy approved with a hold for provider notification and will be effective February 15, 2015.</td>
</tr>
<tr>
<td>04/14/15</td>
<td>Annual Review. Policy updated with literature review through February 6, 2015; references 18, and 25-28 added and references 8, 23, 24 updated. Policy statement regarding initial measurement of women age &lt;65 clarified. Repeat measurement now described in 3 categories – no osteoporosis/osteopenia, osteopenia and monitoring pharmacologic treatment. Interval of repeat testing when no osteoporosis/osteopenia is present has been changed to 5 years.</td>
</tr>
<tr>
<td>02/09/16</td>
<td>Annual Review. Policy updated with literature review through January 2016. Summary statement revised. No change to the policy statement.</td>
</tr>
<tr>
<td>Date</td>
<td>Comments</td>
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<tr>
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</tr>
<tr>
<td>12/01/16</td>
<td>Minor update approved November 8, 2016. Language added to the Rationale section to indicate that the age range specifications within this policy for which the initial measurement of bone mineral density is considered medically necessary to assess risk and need for therapy are based on covered preventive services outlined in the Patient Protection and Affordable Care Act, National Osteoporosis Foundation, American College of Physicians, and the American College of Radiology. No change in policy statements.</td>
</tr>
<tr>
<td>01/01/18</td>
<td>Annual Review, approved December 12, 2017. Policy moved into new format. Policy statements clarified, but the intent remains unchanged. References and Practice Guidelines were updated.</td>
</tr>
<tr>
<td>07/01/18</td>
<td>Coding update, added new CPT code 0508T, effective 7/1/18.</td>
</tr>
<tr>
<td>02/01/19</td>
<td>Annual Review, approved January 22, 2019. Policy updated with literature review through October 2018; references 6, 12-13, 15, 18, and 21 added; some references removed. Policy statements unchanged except for minor editing for clarity.</td>
</tr>
</tbody>
</table>

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2019 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
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Premera Blue Cross complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability or sex.

Premera:
- Provides free aids and services to people with disabilities to communicate effectively with us, such as:
  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592. TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room S09F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):
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يحتوي هذا الإشعار معلومات هامة. قد يكون هذا الإشعار معلومات مهمة بخصوص طبيبك أو عائلتك. لا توجد تأكيدات أخرى على تلك المعلومات. لا يوجد تأكيدات أخرى على تلك المعلومات. قد تكون تأكيدات أخرى على تلك المعلومات.

Chinese (Chinese):
本通知有重要的讯息。本通知可能有关於您透过 Premera Blue Cross 提交的申请或保单的重要讯息。本通知可能有关於重要日期。您可能需要在截止日期之前采取行动，以保留您的健康保险或费用补贴。您有权利免费以您的母语得到本讯息和帮助。请拨电話 800-722-1471 (TTY: 800-842-5357).

Italiano (Italiani):
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Korean:

Premera Blue Cross (TTY: 800-842-5357)

Japanese:

Premera Blue Cross (TTY: 800-842-5357)

Russian:

Premera Blue Cross (TTY: 800-842-5357)

Spanish:

Premera Blue Cross (TTY: 800-842-5357)

Vietnamese:

Premera Blue Cross (TTY: 800-842-5357)