Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for bone density studies when it is determined to be medically necessary because the criteria shown below are met.

**When Policy Topic is covered**

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 in both women and men who are considered at risk for osteoporosis. BMD testing may be indicated under the following conditions:

- Women age 65 and older, regardless of other risk factors;
- Men age 70 and older, regardless of other risk factors;
- Younger postmenopausal women about whom there is a concern based on their risk factors;
- Men age 50-70 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.

Repeat measurement of central (hip/spine) BMD for individuals who previously tested normal (does not require pharmacologic treatment) may be considered **medically necessary** at an interval not more frequent than every 3–5 years; the interval depends on patient risk factors.

Regular (not more frequent than every 2-3 years) serial measurements of central BMD to monitor treatment response may be considered **medically necessary** when the information will affect treatment decisions such as duration of therapy.

Peripheral BMD testing may be considered **medically necessary** when conventional central (hip/spine) DXA screening is not feasible or in the management of hyperparathyroidism, where peripheral DXA at the forearm (ie, radius) is essential for evaluation.
**When Policy Topic is not covered**
BMD measurement using ultrasound densitometry, quantitative computed tomography, or dual x-ray absorptiometry of peripheral sites is considered investigative except as noted above.

A bone density study is considered *screening* for those individuals not considered at high risk for osteoporosis.

Initial or repeat BMD measurement is not indicated unless the results will influence treatment decisions.

**Considerations**
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 bone mineral density (BMD), risk factors included in the World Health Organization (WHO) Fracture Risk Assessment Model (FRAX) 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 alcohol 3 or more units/day, where a unit is equivalent to a standard glass of beer (285ml), a single measure of spirits (30ml), a medium-sized glass of wine (120ml), or 1 measure of an aperitif (60ml);
- A disorder strongly associated with osteoporosis. These include rheumatoid arthritis, osteopenia, 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 5mg 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 model does not include a recommendation about which patients to further assess or treat. The FRAX website (1) states that this is a matter of clinical judgment and recommendations may vary by country.
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 central sites (i.e., hip and spine) is the most commonly used technique, but peripheral DXA and quantitative CT 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 is not a substitute for central DXA measurements. Therefore, central DXA is required for both the initial diagnosis and repeat BMD assessments.

Peripheral scans performed concurrently with axial scans are considered mutually exclusive and are not eligible for separate reimbursement. The peripheral scan will disallow as a component of the axial scan.

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 the issue of following patients with growing bones. This applies to pediatric patients who are not skeletally mature, as documented by nonclosure of growth plates (eg, ≤15 years).

### Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions of interest are:</th>
<th>Comparators of interest are:</th>
<th>Relevant outcomes include:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals: Who are eligible for screening of bone mineral density based on risk factor assessment</td>
<td>Initial dual x-ray absorptiometry analysis of central sites (hip or spine)</td>
<td>Clinical risk assessment without bone mineral density testing</td>
<td>Morbid events, Functional outcomes, Quality of life, Hospitalizations, Medication use</td>
</tr>
<tr>
<td>Individuals: Without osteoporosis on initial screen</td>
<td>Repeat dual x-ray absorptiometry analysis of central sites (hip or spine)</td>
<td>Clinical risk assessment without bone mineral density testing</td>
<td>Morbid events, Functional outcomes, Quality of life, Hospitalizations, Medication use</td>
</tr>
<tr>
<td>Individuals: Who are receiving pharmacologic treatment for osteoporosis</td>
<td>Repeat dual x-ray absorptiometry analysis of central sites (hip or spine)</td>
<td>Clinical risk assessment without bone mineral density testing</td>
<td>Morbid events, Functional outcomes, Quality of life, Hospitalizations, Medication use</td>
</tr>
<tr>
<td>Individuals: Who are eligible for</td>
<td></td>
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</tbody>
</table>
Bone density 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 also available.

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.

**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 (WHO) has diagnostic thresholds for osteoporosis based on bone mineral density (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 using different techniques in a variety of central (ie, hip or spine) or peripheral (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

The decision to perform 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 (FRAX) Tool² 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 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).

A 2011 joint position statement from the International Society for Clinical Densitometry and the International Osteoporosis Foundation included the official position that FRAX with BMD predicts risk of fracture better than clinical risk factors or BMD alone. In addition, the joint position statement indicated that measurements other than BMD or T score at the femoral neck by DXA are not recommended for use with FRAX.³ The FRAX tool does not include a recommendation about which patients to further assess or treat. The FRAX website states that this is a matter of clinical judgment and recommendations may vary by country.²

**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**
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 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 surround the spine and hip, and therefore the measurement of bone density at those sites.

**Quantitative Computed Tomography**
Quantitative computed tomography (QCT) depends on the differential absorption of ionizing radiation by calcified tissue and is used for central measurements only. Compared with DXA, QCT 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.

These techniques dominate BMD testing. 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.

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

FDA product codes: KGI, MUA.

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

**Rationale**

This evidence review was created in 1995. Early versions of this evidence review were informed in part on 1998 guidelines from the National Osteoporosis Foundation and 2 TEC Assessments (1999, 2002). The evidence review has since been updated regularly with searches of the MEDLINE database. The most recent literature review was performed through October 1, 2018. Following is a summary of key literature to date.

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, 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 a technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one 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 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.

**Initial Measurement of Bone Mineral Density**

**Clinical Context and Therapy Purpose**
The purpose of BMD measurement in patients who have risk factors for osteoporosis is to assess bone health and guide treatment.

The question addressed in this evidence review is: Does BMD testing with dual x-ray absorptiometry (DXA) improve the net health outcome in individuals with risk factors for osteoporosis?

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant population of interest are individuals with risk factors for osteoporosis.

**Interventions**
The test being considered is BMD testing with central DXA.

**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 quality of life.

**Timing**
Pharmacological treatment for osteopenia is recommended for three to five years. Monitoring of fractures may occur until the end of life; these are typically measured within ten years after screening.

**Setting**
The setting is outpatient primary care.

**Review of Evidence**
A 2018 systematic review for the U.S. Preventive Services Task Force (USPSTF) evaluated the evidence on screening for osteoporosis. 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.”

**Section Summary: Initial Measurement of BMD**
Central DXA is the most widely accepted method for measuring BMD. 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 have been successfully used to guide therapy.

**REPEAT MEASUREMENT OF BMD FOR INDIVIDUALS WITHOUT OSTEOPOOROSIS ON INITIAL SCREEN**

**Clinical Context and Therapy Purpose**
The purpose of BMD measurement in patients without osteoporosis on the initial screen is to assess changes in bone health and guide treatment.

The question addressed in this evidence review is: Does repeat BMD testing with central DXA improve the net health outcome in individuals with risk factors for osteoporosis?

The following PICOTS were used to select literature to inform this review.

**Patients**
The relevant population of interest are individuals without osteoporosis on the initial 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 quality of life.

**Timing**
Monitoring of fractures may occur until the end of life; these are typically measured within 10 years after screening. Setting
The setting is outpatient primary care.

Review of Evidence
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.7,8 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.9,10,11 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.12,13

Section Summary: Repeat Measurement of BMD 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. Although the optimal interval may differ depending on risk factors, current evidence does not support frequent monitoring.

Serial Measurement of Central BMD to Monitor Response to Pharmacologic Treatment

Clinical Context and Therapy Purpose
The purpose of BMD measurement in patients who are being evaluated for osteoporosis is to guide treatment.

The question addressed in this evidence review is: Does BMD testing with central DXA improve the net health outcome in individuals who are being treated for osteoporosis?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest are individuals who are being treated for 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: duration of treatment as it relates to clinical risk assessment without BMD testing.
Outcomes
The general outcomes of interest are the occurrence of fractures and effects on quality of life.

Timing
Pharmacological treatment for osteopenia is recommended for three to five years. Monitoring of fractures may occur until the end of life; these are typically measured within ten years after screening.

Setting
The setting is outpatient primary care.

Review of Evidence
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. In the Fracture Intervention Trial, 6459 women randomized to bisphosphonates or to placebo underwent annual bone density scans. A secondary analysis found an average within-person variation in BMD measurement of 0.013 g/cm², which was substantially higher than the average annual increase in BMD (0.0085 g/cm²) in the alendronate group.

Section Summary: Serial Measurement of Central BMD to Monitor Response to Bisphosphonate 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. Together, these results indicate that frequent (ie, every two years) repeat monitoring has low value.

ULTRASOUND DENSITOMETRY, OR QUANTITATIVE COMPUTED TOMOGRAPHY, OR DXA ANALYSIS OF PERIPHERAL SITES

Clinical Context and Therapy Purpose
The purpose of bone density measurement with methods other than central DXA in patients who have risk factors for osteoporosis is guide treatment.

The question addressed in this evidence review is: Does BMD testing with tests other than central DXA improve the net health outcome in individuals with risk factors for osteoporosis?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest are individuals with risk factors for osteoporosis.
Interventions
The test being considered are 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 quality of life.

Timing
Pharmacological treatment for osteopenia is recommended for three to five years. Monitoring of fractures may occur until the end of life; these are typically measured within ten years after screening.

Setting
The setting is outpatient primary care.

Review of Evidence
In the review of evidence for the USPSTF, 10 studies were identified that compared calcaneal quantitative ultrasound to central DXA. Pooled estimates of area under the curves were 0.77 (95% CI, 0.72-0.81; 1969 participants) in women and 0.80 (95% CI, 0.67-0.94; 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 analyzed on previously taken clinical computed tomography scans that were at least as good as DXA. No studies were identified that guided treatment based on computed tomography scan results.

Section Summary: Ultrasound Densitometry, or Quantitative Computed Tomography, or DXA 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.

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.

SUPPLEMENTAL INFORMATION
Clinical Input 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 evidence review was under review in 2008. In addition, seven unsolicited letters were received through two additional physician specialty societies. Reviewers agreed with the evidence review 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 on 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, with 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 overinterpretation of small fluctuations with repeat testing.

Practice Guidelines and Position Statements
American College of Obstetricians and Gynecologists
The ACOG (2012, reaffirmed 2016) updated its guidelines on managing osteoporosis in women.16 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 recommended BMD screening women younger than 65 or 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 (i.e., 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 NOF (2014) updated its practice guidelines. The NOF guidelines recommended that all postmenopausal women and men ages 50 and older be evaluated clinically for osteoporosis risk to determine the need for BMD testing.

Indications for BMD testing included:

- “[W]omen age 65 and older and men age 70 and older” regardless of clinical risk factors
- “[P]ostmenopausal women and men above age 50-69, based on risk factors profile”
- “[P]ostmenopausal 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 lb 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, CT [computed tomography], or MRI [magnetic resonance imaging]
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 being 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:

- 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;
  - Low body weight
  - 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 < 70 years ... if they have a risk factors for low bone mass such as;
  o Low body weight
  o Prior fracture
  o High risk medication use
  o 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 USPSTF (2018) updated its 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 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:

1. 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.
2. Is performed under the appropriate level of physician supervision as defined in 42 CFR 410.32(b).
3. Is reasonable and necessary for diagnosing and treating the condition of a beneficiary who meets the conditions described in §80.5.6.
4. 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).
5. 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 November 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

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. PMID


### Billing Coding/Physician Documentation Information

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<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)</td>
</tr>
<tr>
<td>77078</td>
<td>Quantitative Computerized Tomography bone mineral density study, one or more sites, axial skeleton (eg hips, pelvis spine)</td>
</tr>
<tr>
<td>77080</td>
<td>Dual energy x-ray absorptiometry (DEXA), bone density study, one or more sites; axial skeleton (eg, hips, pelvis, spine)</td>
</tr>
<tr>
<td>77081</td>
<td>Dual energy x-ray absorptiometry (DEXA), bone density study, one or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)</td>
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<td>78350</td>
<td>Bone density (bone mineral content) study, 1 or more sites; single photon absorptiometry</td>
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<tr>
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<td>G0130</td>
<td>Single energy x-ray absorptiometry bone density study, one or more sites; appendicular skeleton (peripheral - e.g., radius, wrist, heel)</td>
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</tbody>
</table>

### ICD10 Codes:

- M81.0 Age-related osteoporosis without current pathological fracture
- M81.6 Localized osteoporosis
- M81.8 Other osteoporosis without current pathological fracture
- M85.80 Other specified disorders of bone density and structure, unspecified site

CPT codes 77079 and 77083 were deleted effective 1/1/2012.

### Additional Policy Key Words

N/A

### Policy Implementation/Update Information

- **10/1/88**: New policy added to Radiology section. Considered medically necessary for high risk individuals and those receiving therapy for osteoporosis to monitor bone mass.
- **3/1/00**: No policy statement change.
- **3/1/01**: Additional high risk criteria added, definition updated to include description of various techniques that may be used.
- **3/1/02**: Policy statement revised to indicate Appendicular studies are not medically necessary, low risk individuals are contract exclusions, and ultrasound of a peripheral site is investigational.
- **3/1/03**: No policy statement changes.
- **3/1/04**: Policy statement revised to include current fracture or history of fracture in first-degree relative as a risk factor in the criteria for Postmenopausal women under age 65 who have one or more risk factors.
- **5/1/05**: Policy statement revised to indicate **axial** bone mineral density by either DXA or QCT may be considered medically necessary for high risk individuals, added depo-provera to the list of high-risk, changed serial
measurements from medically necessary to not medically necessary, changed ultrasound of any site to not medically necessary.

4/1/06 Clarified policy statement regarding patients who are at low risk for developing osteoporosis. Those individuals not meeting the criteria for high risk are considered low risk; bone density screening would therefore be a contract exclusion.

3/1/07 No policy statement changes. CPT codes updated, rationale updated.

3/1/08 Policy statement clarified to specify both women and men. Specific criteria are no longer in the policy statement. The description and rationale reference criteria used.

12/11/08 Interim update: Policy updated with literature review; references added and reordered. Clinical input reviewed. Policy statement added; repeat measurement (3-5 year interval) may be medically necessary if previously normal; serial testing (at least 2 year interval) changed to medically necessary. Policy title changed from Bone Density Studies to Bone Mineral Density Studies.

3/1/09 No policy statement changes.

3/1/10 No policy statement changes. Policy clarified in Considerations section regarding reimbursement for peripheral scans.

3/1/11 No policy statement changes.

3/1/12 No policy statement changes.

3/1/13 No policy statement changes.

3/1/14 No policy statement changes.

5/1/14 No policy statement changes.

5/1/15 No policy statement changes.

5/1/16 No policy statement changes.

3/1/17 No policy statement changes.

5/1/17 The policy statements were edited to clarify that central dual x-ray absorptiometry (DXA) is medically necessary and other methods of measurement are investigational. A policy statement was added before the investigational statement that “Peripheral BMD testing could be considered medically necessary when conventional central (hip/spine) DXA screening is not feasible or in the management of hyperparathyroidism, where peripheral DXA measurement at the distal forearm (ie, radius) is essential for evaluation.”

3/1/18 No policy statement changes.

6/1/18 Updated Considerations to include osteopenia. Added ICD10 M85.80.

3/1/19 No policy statement changes.

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