Bone Mineral Density Studies

Policy Number: 6.01.01  Last Review: 5/2014

Policy
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.

When Policy Topic is not covered
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, 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.

**Description of Procedure or Service**
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 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 due to age-related bone loss in both sexes and menopause-related bone loss in women. 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 and genetic disorders, hypogonadal states, and medications. Low bone mineral density (BMD) is a primary indication for pharmacologic therapy. Current pharmacologic options include bisphosphonates such as alendronate (i.e., Fosamax), selective estrogen receptor modulators (SERMs) such as raloxifene (i.e., Evista), the recombinant human parathyroid hormone teriparatide (Forteo), and calcitonin.

Bone mineral density can be measured with a variety of techniques in a variety of central (i.e., hip or spine) or peripheral (i.e., wrist, finger, and heel) sites. While BMD measurements are predictive of
Frailty fractures at all sites, central measurements of the hip and spine are the most predictive. Fractures of the hip and spine (i.e., vertebral fractures) are also considered to be the most clinically relevant. BMD is typically expressed in terms of the number of standard deviations (SD) the BMD falls below the mean for young healthy adults. This number is termed the T score.

The following technologies are most commonly used.

1. Dual X-Ray Absorptiometry (DXA)
   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 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 differential 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.

2. Quantitative Computed Tomography (QCT)
   QCT depends on the differential absorption of ionizing radiation by calcified tissue and is used for central measurements only. Compared to DXA, QCT is less readily available and associated with relatively high radiation exposure and relatively high cost.

3. Ultrasound Densitometry
   Ultrasound densitometry is a technique for measuring BMD at peripheral sites, typically the heel, but also the tibia and phalanges. Compared to 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.

The above 3 techniques dominate BMD testing. Single and dual photon absorptiometry and radiographic absorptiometry are now rarely used and may be considered obsolete.

Regulatory Status

Various devices are commercially available.

In October 2003, the Hologic QDR-3000 Explorer X-Ray Done Densitometer (Hologic, Bedford, MA) was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for use in measurement of bone mineral content (BMC), estimation of bone mineral density (BMD), comparison of measurements to reference databases, estimation of fracture risk, body composition analysis and measurement of periprosthetic BMD.

Rationale

This policy was originally created in 1995 and was updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period January 22, 2013 through February 11, 2014. Following is a summary of the key literature to date:

Initial measurement of bone mineral density (BMD) (type of technology, sites to measure, patient populations)

Early versions of this policy were based in part on 1998 guidelines from the National Osteoporosis Foundation (NOF) and TEC Assessments from 1999 and 2002. (3-5) Since no data were available from randomized screening trials, the TEC Assessments focused on the evaluating the utility of BMD measurement in selecting patients for pharmacologic treatment to reduce risk of fracture. The TEC Assessments concluded that while both dual x-ray absorptiometry (DXA) and ultrasound densitometry were equivalent in predicting fracture risk, the 2 techniques appeared to identify different populations of at-risk patients. In addition, calcaneal ultrasound densitometry did not meet the TEC criteria as a technique to predict response to pharmacologic therapy.
Policy updates have identified additional data supporting the conclusion that BMD predicts fracture risk. For example, a 2005 meta-analysis of data from 9,891 men and 29,082 women (from 12 cohort studies in Europe and Canada) found that BMD measurement at the femoral neck was a strong predictor of hip fractures for both genders. (6) At age 65 years, the risk ratio increased by 2.94 in men and by 2.88 in women for each standard deviation (SD) decrease in BMD.

A systematic review of the evidence to update U.S. Preventive Services Task Force (USPSTF) recommendations on screening for osteoporosis was published in 2010. (7) The authors state that most DXA testing includes central DXA i.e., measurements at the hip and lumbar spine, and that most randomized controlled trials (RCTs) of osteoporosis medications have had study inclusion criteria based on the findings of central DXA. The authors found that calcaneal quantitative ultrasound (QUS) measurement can also predict fracture but has a low correlation with DXA. Consequently, the clinical relevance of calcaneal QUS findings is unclear because medication studies have not selected patients based on QUS findings. In addition, the investigators reviewed large population-based cohorts on DXA screening and concluded that the predictive performance of DXA is similar for women and men.

National Osteoporosis Foundation (NOF) guidelines, last updated in 2013, recommend initial measurement of BMD using DXA of the hip and spine in women age 65 and older and men 70 and older, regardless of risk factors, and in younger individuals with selected risk factors. (8) (For details on risk factors in the NOF guidelines and information on statements from other national organizations, see section on Practice Guidelines and Position Statements below).

In 2014, Gadam and colleagues performed a cross-sectional analysis of data to evaluate the incremental predictive ability of BMD when added to the FRAX model. The study included 151 individuals (145 women and 6 men) over 50 years of age without a prior osteoporosis diagnosis and who were not being treated with FDA-approved medications for treating osteoporosis. (9) Of the 151 individuals, predictions of 10-year fracture risk were identical for 127 patients (84%) when BMD was added to the FRAX model compared to the FRAX model without BMD. Of the individuals who had different risk estimates, the difference in risk prediction resulted in an additional 2 patients meeting the NOF threshold for treatment when BMD was added to the FRAX model. Age was the only risk factor that differed significantly between participants with identical versus different recommendations (p<0.001). Individuals who were younger (mean age: 64 years) were more likely to receive identical predictions than older individuals (mean age: 76 years). The study had a relatively small sample size and lacked longitudinal data on fracture. It provides some initial evidence that BMD may not add substantially to the predictive ability of the FRAX models, but these findings need to be corroborated in prospective studies with larger sample sizes.

Section summary: Studies have found a statistically significant association between baseline DXA in appropriately selected patients and subsequent risk of fracture. An initial DXA is recommended in national guidelines for older women and men, as well as younger individuals with risk factors; exact recommendations vary. The clinical significance of other techniques for assessing bone mineral density is uncertain.

Repeat measurement of central BMD for individuals without osteoporosis on the initial screen

Recommendations from the U.S. Preventative Services Task Force (USPSTF) issued in January 2011 state that there is a lack of evidence on the optimal interval for repeat screening and a lack of evidence on whether repeat screening is necessary in women found to have normal BMD during initial screening. (10)

In 2007, Frost and colleagues published a prognostic model to determine the optimal screening interval for an individual without osteoporosis (defined as T score >-2.5). (11) They used prospective population-based data collected from 1,008 women and 750 men who were non-osteoporotic at baseline; participants received BMD screening every 2 years and received a median follow-up of 7.1
years. The prognostic model included the variables of age and initial BMD score; results were presented in complex tables stratified by these 2 variables. In the table of estimated time to reach 20% risk of sustaining a fracture or osteoporosis, most of the time estimates were 3 years or longer. The shortest time to reach a 20% risk was estimated at 2.4 years; this was for women 80 years and older with a baseline T score of -2.2. For a typical screening candidate, a 65-year-old woman with a baseline T score of –1.0, the estimated time to reach a 10% risk of fracture was 3.8 years and to reach a 20% risk of fracture was 6.5 years. Overall, the study suggests that the 3- to 5-year time interval included in the policy for repeat measurement of BMD in people who tested normal is reasonable but that an individualized model could result in longer or shorter recommended re-testing intervals.

Findings of other studies suggest that a longer time interval may be reasonable. Most notably, a 2012 multicenter prospective study by Gourlay and colleagues provided data on the optimal bone density screening interval in a large cohort of women with normal BMD or osteopenia at an initial screen. (12) The investigators included 4,957 women age 67 years or older who had BMD data at 2 or more examinations or at one examination before a competing risk event (hip or clinical vertebral fracture). More than 99% of the women reported they were white. The study only included women who were candidates for osteoporosis screening. Other individuals, such as those with osteoporosis at baseline or with a history of a hip or clinical vertebral fracture were excluded, as they would already be candidates for pharmacological treatment. (13) The primary study outcome was the estimated time interval for 10% of participants to make the transition from normal BMD or osteopenia at baseline to osteoporosis before a hip or clinical vertebral fracture occurred and before starting osteoporosis treatment. For women with normal BMD at baseline, the estimated BMD testing interval was 16.8 years (95% confidence interval [CI]: 11.5 to 24.6). The study found that the estimated BMD testing interval was 17.3 years (95% CI: 13.9 to 21.5) for women with mild osteopenia at baseline, 4.7 years (95% CI: 4.2 to 5.2) with moderate osteopenia, and 1.1 years (95% CI: 1.0 to 1.3) for women with advanced osteopenia.

Other studies suggesting that a longer time interval may be used or that repeat BMD measurements may not be critical include a 2007 study by Hillier and colleagues. (14) The study did not find that follow-up BMD measurements 8 years after a baseline screen provided substantial value in terms of predicting risk of fracture The study included 4,124 women age 65 years and older and assessed total hip BMD at initial and follow-up screening examinations. In analyses adjusted for age and weight change, the initial and repeat BMD measurements had similar associations with fracture risk; this included risk of vertebral fractures, non-vertebral fractures and hip fractures. Stratifying the analysis by initial BMD T scores (i.e., normal, osteopenic or osteoporotic) did not alter findings. Moreover, a 2013 study by Berry and colleagues did not find that changes in BMD 4 years after initial measurement added substantially to the prediction of fracture risk in untreated individuals. (15) The authors conducted a population-based cohort study including 210 women and 492 men (mean age: 75 years) who had 2 BMD measurement a mean of 3.7 years apart and did not have a hip fracture prior to the second test. Median follow-up was 9.6 years after the second BMD test. During this time, 76 individuals experienced a hip fracture and 113 had a major osteoporotic fracture (fracture of the hip, spine, forearm or shoulder). In receiver operating curve (ROC) analyses, adding repeat BMD to a model containing baseline BMD did not meaningfully improve the model’s ability to predict hip fracture (area under the curve [AUC]: 0.72 (95% CI: 0.66 to 0.79). When percent change in BMD was used, the AUC was 0.71 (95% CI: 0.65 to 0.78) in a model including only baseline BMD and 0.68 (95% CI: 0.62 to 0.75) in a model including percent change in BMD.

In other research, longitudinal changes in BMD, as a function of age and antiresorptive agents, were reported in 2008 by the Canadian Multicentre Osteoporosis Study Research Group. (16) Of a random selection of 9,423 men and women from 9 major Canadian cities, 4,433 women and 1,935 men (70%) were included for analysis. The subjects were 25 years of age or older with BMD measurements repeated 3 or 5 years apart; they tended to have better health than the 30% who did not have longitudinal data and who were excluded from analysis. Results showed that annual rates of bone loss, measured at the hip or femoral neck, increased between 25 to 85 years of age in women who were not on antiresorptive therapy, with accelerated periods of bone loss around menopausal transition (40–54...
years of age) and after 70 years of age. Antiresorptive therapy, which primarily consisted of hormone replacement when the study began in 1995, was associated with attenuated bone loss across all age ranges. In women 50–79 years of age, the average loss in BMD over a 5-year period was 3.2% in nonusers of antiresorptive therapy and 0.2% in women who used antiresorptive therapy. The pattern in men was generally similar to that of women with 2 exceptions, BMD loss began earlier in men, and the rate of change remained relatively constant between 40 and 70 years of age. Notably, BMD at the lumbar spine did not parallel measurements at the hip and femoral neck, suggesting that vertebral bone density assessment may be obscured by degenerative changes in the spine or other artifact. The report concluded that “although current guidelines recommend that measurements of bone density be repeated once every 2–3 years, our data suggest that, at this rate of testing, the average person would exhibit change well below the margin of error, especially since only 25% of women experienced a loss of bone density that exceeded 5% over 5 years.”

Section summary: There is sparse evidence on the optimal screening interval with DXA and the optimal patient population that might benefit from repeat screening. The available evidence suggested that, for most patients, longer intervals than those currently recommended in national guidelines might be sufficient.

Serial measurement of central BMD to monitor treatment response

In 2009, Bell and colleagues conducted a secondary analysis of data from the Fracture Intervention Trial (FIT), which randomly assigned 6,459 post-menopausal women with low BMD to receive treatment with bisphosphonates or placebo; women underwent annual bone density scans. (17) In their analysis, the investigators estimated between-person (treatment-related) variation and within-person (measurement-related) variation in hip and spine BMD over time to assess the value of repeat BMD scans for monitoring response to treatment. After 3 years, the mean cumulative increase in hip BMD was 0.30 g/cm2 in the alendronate group compared to a mean decrease of 0.012 g/cm2 in the placebo group. Moreover, 97.5% of patients treated with alendronate had increases in hip bone mineral density of at least 0.019 g/cm2, suggesting that there was a clinically significant response. However, the study also found large within-person variability in year-to-year bone density measurements. The average within-person variation in BMD measurement was 0.013 g/cm2, which was substantially higher than the average annual increase in BMD in the alendronate group, 0.085 g/cm2. This finding suggests that the precision of BMD measurement is not reliable from year to year, and thus annual re-testing is not useful. Additional studies are needed to determine the optimal time interval for re-screening after starting bisphosphonate treatment.

Section summary: There is little evidence on the clinical benefit of serial measurement of BMD for patients receiving pharmacologic osteoporosis treatment. A 2009 analysis of RCT data found substantial year-to-year variation in BMD measurement suggesting that a longer testing interval might be preferable to annual screening.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

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, 7 unsolicited letters were received through 2 additional physician specialty societies. 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. The reviewers agreed with the policy statement that an initial BMD test may be medically necessary. They also recommended an interval of 3–5 years between measurements in individuals who previously tested normal, depending on risk factors. Reviewers considered serial measurement of BMD important to guide treatment decisions (e.g., 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 2-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 DXA, 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.

**Summary**

There is evidence that bone mineral density (BMD) measurements predict fracture risk and may be useful for individuals at increased risk of fracture who are considering pharmacologic therapy. The greatest amount of support is for central BMD measurements using dual x-ray absorptiometry (DXA). There is less evidence on serial or repeat measurement of BMD. The available evidence and the consensus of clinical opinion support at least a 2-year interval in BMD measurement to monitor response to treatment. In addition, the available evidence suggests that at least a 3- to 5-year timeframe is reasonable for repeat measurement of BMD in individuals who initially tested normal.

**Practice Guidelines and Position Statements**

In January 2011, the U.S. Preventative Services Task Force (USPSTF) issued updated recommendations on screening for osteoporosis with bone density measurements. (10) The USPSTF recommends routine osteoporosis screening in women age 65 years or older and in younger women whose risk of fracture is at least equal to that of a 65-year-old average-risk white woman. This represents a change from the previous (2002) version in which there was no specific recommendation regarding screening in women younger than 65 years-old. The supporting document notes that there are multiple instruments to predict risk for low BMD and that the USPSTF used the WHO Fracture Risk Assessment Tool i.e., FRAX. (1) The updated USPSTF recommendations state that the scientific evidence is insufficient to recommend for or against routine 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 recommendations state the following on BMD screening intervals: “…A lack of evidence exists about the optimal intervals for repeat screening and whether repeated screening is necessary in a woman with normal BMD. Because of limitations in the precision of testing, a minimum of two years may be needed to reliably measure a change in BMD; however, longer intervals may be necessary to improve fracture risk prediction.”

In 2012, the American College of Obstetricians and Gynecologists (ACOG) issued updated guidelines on managing osteoporosis in women. (18) The guidelines recommend that BMD screening should begin for all women at age 65 years. In addition, they recommend screening for women younger than 65 years in whom the Fracture Risk Assessment (FRAX) Tool indicates a 10-year risk of osteoporotic fracture of at least 9.3%. Alternatively, they recommend BMD screening women in younger than 65 or with any of the following risk factors (these are similar, but not identical to risk factors in FRAX):

- 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 1 to 2 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 18-24
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.

The National Osteoporosis Foundation (NOF) updated its practice guidelines in 2013. (8) NOF guidelines recommend that all postmenopausal women and older men should be evaluated clinically for osteoporosis risk to determine the need for BMD testing. In general, the more risk factors that are present, the greater the risk of fracture. BMD assessment is indicated in:
- Women age 65 and older and men age 70 and older, regardless of other risk factors;
- Younger postmenopausal women, peri-menopausal women and men aged 50–70 about whom you have concern based on their clinical risk factor profile;
- Women in the menopausal transition if there is a specific risk factor associated with increased fracture risk such as low body weight, prior low-trauma fracture, or high-risk medication;
- Adults who have a fracture after age 50;
- Adults with a condition (e.g., rheumatoid arthritis) or taking a medication (e.g., glucocorticoids, 5 mg/day for 3 months) associated with low bone mass or bone loss;

The NOF guidelines state that serial monitoring of BMD is appropriate for monitoring bone loss in patients on pharmacotherapy. They generally recommend testing every 2 years in this group but recognize that more frequent testing may be warranted in certain clinical situations. The NOF guidelines recommend that treatment be considered in postmenopausal women and men over age 50 who present with any of the following:
- Hip or vertebral fracture (clinical or asymptomatic)
- T-score -2.5 or lower at the femoral neck or spine (after secondary causes have been excluded)
- T-score between -1.0 and -2.5 at the femoral neck or spine and a 10-year probability of a hip fracture of at least 3% or a 10-year probability of a major osteoporosis-related fracture of at least 20% (based on the U.S. adapted WHO algorithm).

2008 guidelines from the American College of Physicians (ACP) recommend that clinicians periodically perform individualized assessment of risk factors for osteoporosis in men older than 50 years (Grade: strong recommendation; moderate-quality evidence). (19) Factors that increase the risk for osteoporosis in men include age (>70 years), low body mass index (BMI), weight loss, physical inactivity, corticosteroid use, androgen deprivation therapy, and previous fragility fracture. The ACP recommends that clinicians obtain DXA for men who are at increased risk for osteoporosis and are candidates for drug therapy (Grade: strong recommendation; moderate-quality evidence). The guidelines indicate that bone density measurement with DXA is the accepted reference standard for diagnosing osteoporosis in men; because treatment trials have not measured the effectiveness of therapy for osteoporosis diagnosed by ultrasound densitometry rather than DXA, the role of ultrasound in diagnosis remains uncertain. This evidence review found no studies that evaluated the optimal intervals for repeated screening by using BMD measurement with DXA in men.

Practice guidelines from the American College of Radiology (ACR), last amended in 2010, state that BMD measurement is usually appropriate in the following patient populations: (20)
- Postmenopausal females, greater than 50 years of age, females in menopausal transition (late 40s) and males greater than 50 years of age with risk factors.
- Premenopausal females with risk factors and males 20 to 50 years of age with risk factors.
- Males and females greater than 50 years of age with advanced degenerative changes of the spine with or without scoliosis.
- Individuals with suspected fracture, incident or prevalent, of a vertebral body based on clinical history, height loss, or patient treated with corticosteroids
- Follow-up in patients demonstrated to have risk for fracture or low density.
- Follow-up to low BMD in premenopausal females with risk factors and males 20 to 50 years of age with risk factors.
The 2007 International Society for Clinical Densitometry guidelines recommend bone density testing in the following patients (21):

- Women age 65 and older;
- Postmenopausal women under age 65 with risk factors for fracture;
- Women during the menopausal transition with clinical risk factors for fracture, such as low bone weight, prior fracture or high-risk medication use;
- Men age 70 and older;
- Men under age 70 with clinical risk factors for fracture;
- Adults with a fragility fracture;
- Adults with a disease or condition associated with low bone mass or bone loss;
- Adults taking medications associated with low bone mass or bone loss;
- Anyone being considered for pharmacologic therapy;
- Anyone not receiving therapy in whom evidence of bone loss would lead to treatment.

**Medicare National Coverage**

Medicare 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). (22) When medically necessary, Medicare may pay for more frequent BMMs. Examples include, but are not limited to, monitoring beneficiaries on long-term glucocorticoid (steroid) therapy of more than 3 months, and confirming baseline BMMs to permit monitoring of beneficiaries in the future.

Conditions for coverage of bone mass measurements (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).

**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.

Billing Coding/Physician Documentation Information

76977 Ultrasound bone density measurement and interpretation, peripheral site(s)
77078 Quantitative Computerized Tomography bone mineral density study, one or more sites, axial skeleton (eg hips, pelvis spine)
77080 Dual energy x-ray absorptiometry (DEXA), bone density study, one or more sites, axial skeleton (eg hips, pelvis, spine)
77081 Dual energy x-ray absorptiometry (DEXA), bone density study, one or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)
78350 Bone density (bone mineral content) study, 1 or more sites; single photon absorptiometry
78351 Bone density (bone mineral content) study, 1 or more sites; dual photon absorptiometry, 1 or more sites
G0130 Single energy x-ray absorptiometry bone density study, one or more sites; appendicular skeleton (peripheral - e.g., radius, wrist, heel)

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

Additional Policy Key Words
**Policy Implementation/Update Information**

<table>
<thead>
<tr>
<th>Date</th>
<th>Change Description</th>
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<tbody>
<tr>
<td>10/1/88</td>
<td>New policy added to Radiology section. Considered medically necessary for high risk individuals and those receiving therapy for osteoporosis to monitor bone mass.</td>
</tr>
<tr>
<td>3/1/00</td>
<td>No policy statement change.</td>
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<tr>
<td>3/1/01</td>
<td>Additional high risk criteria added, definition updated to include description of various techniques that may be used.</td>
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<tr>
<td>3/1/02</td>
<td>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.</td>
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<tr>
<td>3/1/03</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>3/1/04</td>
<td>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.</td>
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<tr>
<td>5/1/05</td>
<td>Policy statement revised to indicate <strong>axial</strong> 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.</td>
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<tr>
<td>4/1/06</td>
<td>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.</td>
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<tr>
<td>3/1/07</td>
<td>No policy statement changes. CPT codes updated, rationale updated.</td>
</tr>
<tr>
<td>3/1/08</td>
<td>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.</td>
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<tr>
<td>12/11/08</td>
<td>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.</td>
</tr>
<tr>
<td>3/1/09</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>3/1/10</td>
<td>No policy statement changes. Policy clarified in Considerations section regarding reimbursement for peripheral scans.</td>
</tr>
<tr>
<td>3/1/11</td>
<td>No policy statement changes.</td>
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<tr>
<td>3/1/12</td>
<td>No policy statement changes.</td>
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<tr>
<td>3/1/13</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>3/1/14</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>5/1/14</td>
<td>No policy statement changes.</td>
</tr>
</tbody>
</table>

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