BlueCross BlueShield of Alabama

Name of Policy:

Bone Mineral Density Testing

Policy #: 191
Category: Radiology

Latest Review Date: April 2013
Policy Grade: A

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

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. Current practice guidelines published by the National Osteoporosis Foundation (NOF) recommend that measurement of bone mineral density (BMD) be performed in all women over age 65 and in postmenopausal women with additional risk factors. Additional risk factors include a personal history of fracture as an adult, history of fracture in first-degree relative, current cigarette smoking, and low body weight (<127 lbs.). Patients receiving glucocorticoid therapy are also at risk for bone loss, no matter what the age. Therefore, BMD measurements are often performed before initiating therapy.

BMD is one of the key determinants for the need for pharmacologic therapy. 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 NOF guidelines recommend that pharmacologic therapy be initiated in women with BMD T scores below –2 in the absence of other risk factors, and in women with BMD T scores below –1.5 if other risk factors are present. Current pharmacologic options include hormone replacement therapy, bisphosphonates such as alendronate (i.e., Fosamax), selective estrogen receptor modulators (SERMs) such as raloxifene (i.e., Evista), and calcitonin. While BMD measurements are typically used to determine the need for pharmacologic therapy, serial monitoring of BMD to determine treatment response is also commonly performed.

Bone mineral density can be measured with a variety of techniques in a variety of sites. Sites are broadly subdivided into central sites (i.e., hip or spine) and peripheral (i.e., wrist, finger, heel). While BMD measurements are predictive of fragility fractures at all sites, central measurements of the hip and spine are the most predictive. In addition, fractures of the hip and spine (i.e., vertebral fractures) are the most clinically relevant. 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 uses two x-ray beams of different energy levels to scan the region of interest and measure the attenuation as the beam passes through the bone. Low-energy beams experience greater attenuation than high-energy beams, and bone attenuates x-rays more than soft tissue. Based on this discrepancy, corrections for soft tissue can be made, which are particularly important due to the individual variability in soft tissue content around the hip and spine.

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 relative new 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 techniques dominate BMD testing. Single and dual photon absorptiometry and radiographic absorptiometry are now rarely used. In particular, dual photon absorptiometry may be considered obsolete.

Lunar iDXA is a new DEXA machine that measures the bone density and also the body composition in one scan. This should be coded as a DEXA scan and subject to the same coverage criteria and limitations.

Policy:

❖ Children and Adolescents

Bone mineral density testing meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for any of the following risk factors **(effective 04/12/2011)**:

- A child or adolescent patient who has been treated for cancer with agents that predispose to reduced bone mineral density, including glucocorticoids, cranial radiation, methotrexate, or hematopoietic cell transplant (HCT). These patients may have one test that is usually done within two years post-treatment.

❖ Females

Bone mineral density testing meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for **any** of the following risk factors when the results of the testing will affect a treatment or regimen program:

- Women age 65 and older, regardless of other risk factors
- A woman with breast cancer who becomes menopausal due to treatment of breast cancer.
- A woman with breast cancer who is being treated with aromatase inhibitors
- A patient with a recent fracture when the fracture is suspected to be associated with osteoporosis;
- A patient with long-term corticosteroid therapy which is defined as greater than three months on the equivalent of 30 mg of cortisone or greater per day
- A patient on long-term (greater than one month) heparin therapy
- A patient on long-term (greater than three months) phenytoin therapy. This is drug therapy of the treatment of seizures
- A patient with known hyperparathyroidism when the test result is used to determine if the patient needs a parathyroidectomy;
- A patient with excessive doses of thyroid replacement (for this indication the test is covered only if the patient has a subnormal TSH level while on thyroid replacement);
- A woman with primary ovarian failure or post-ablative ovarian failure before the age of 40, who is suspected of having osteoporosis;
- A patient with known osteoporosis or osteopenia
- A woman with documented estrogen deficiency and at clinical risk for osteoporosis;

- All postmenopausal women under age 65 who have one or more additional risk factors for osteoporosis, including personal history of fracture as an adult, current fracture or history of fracture in first-degree relative, current cigarette smoking, low body weight (<127 lb.);
- As part of the initial workup prior to the initiation of glucocorticoid therapy. The most commonly used glucocorticoids include prednisone, prednisolone, betamethasone, and dexamethasone (Decadron).

Repeat bone mineral density testing meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage when **performed every 24 or more months**.

Repeat bone mineral density testing performed more often than every 24 months in females who **do not develop new risk factors does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage. This also applies to patients currently being treated with medications to increase bone density.

Repeat bone mineral density testing performed more often than every 24 months in females who **develop new risk factors meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage.

❖ Males

Bone mineral density testing for osteoporosis in males meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for men with **one of the following risk factors**:

- Age, >70;
- Low body weight (see Key Points);
- Weight loss (see Key Points);
- Physical inactivity (see Key Points);
- Previous osteoporotic fracture;
- Prolonged systemic corticosteroid therapy;
- Androgen deprivation therapy.

Repeat bone mineral density testing meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage when **performed every 24 or more months**.

Repeat bone mineral density testing performed more often than every 24 months in males who **do not develop new risk factors does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage. This also applies to patients currently being treated with medications to increase bone density.

Repeat bone mineral density testing performed more often that every 24 months in males who **develop new risk factor meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage

Effective for dates of service on or after February 1, 2012 and prior to February 12, 2013:

❖ **All Patients**

The following indications also apply:

- One study per day is covered when multiple bone mineral studies of different sites are performed per same method.
- Initial testing may be performed using the Appendicular DEXA or other covered bone mineral density study.
- Appendicular DEXA coverage is limited to once every 24 months. If the test is negative, then repeat testing would be covered after 24 months, if one of the above risk factors is present.
- If the Appendicular DEXA is positive or equivocal, then a confirmatory test is covered. (The Appendicular DEXA is not considered confirmatory testing.)
- If the same provider performs the Appendicular DEXA and confirmatory test, reimbursement will be allowed only for the greater service (confirmatory test).
- If the confirmatory test is negative, repeat testing is covered after 24 months, if one of the above risk factors is present.
- If the confirmatory test is positive and pharmacological therapy is documented, repeat testing will be covered after 12 months while on prescription drug therapy.
- If the confirmatory test is positive, but pharmacological therapy is not initiated, repeat testing will be covered after 24 months.
- If a different risk factor presents during the time period waiting for retesting, repeat testing will be covered based on the new risk factor, without waiting for the time period (24 months) to be served.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

Osteoporosis, the most common type of metabolic bone disease, is characterized by a parallel reduction in bone mineral and bone matrix so that bone is decreased in amount but is of normal composition. Osteoporosis affects 20 million Americans and leads to approximately 1.3 million fractures in the United States each year. During the course of their lifetime, women lose about 50% of their trabecular bone and 30% of their cortical bone, and 30% of all postmenopausal white women eventually sustain osteoporotic fractures. By extreme old age, one third of all women and one sixth of all men will have a hip fracture. The annual cost of health care and lost productivity due to osteoporosis is nearly $14 billion in the United States.

Osteoporosis is asymptomatic unless it results in a fracture--usually a vertebral compression fracture or a fracture of the wrist, hip, ribs, pelvis, or humerus. Vertebral compression fractures often occur with minimal stress, such as with sneezing, bending, or lifting a light object. The

middle and lower thoracic and upper lumbar regions are most frequently involved. Back pain usually begins acutely and produces pain that often radiates laterally to the flanks and anteriorly. The pain subsides gradually over a period of weeks to months and recurs with the occurrence of new fractures. Patients with fractures that result in spinal deformity may have a chronic backache that is made worse by standing. Such patients lose height and may develop the characteristic dorsal kyphosis and cervical lordosis known as the "dowager's hump."

The American College of Obstetricians and Gynecologist (ACOG) recently issued guidelines for the clinical management of osteoporosis in women, including recommendations for screening, prevention and treatment of this condition. According to ACOG, the preferred method for diagnosing osteoporosis is bone mineral density testing. Dual-energy x-ray absorptiometry (DEXA) is the technical standard for measuring bone mineral density because it measures at important sites of osteoporotic fractures, has high precision and accuracy, is relatively inexpensive, and has modest radiation exposure. Also, the new ACOG guidelines recommend that screening should not be performed more often than every two years in women who do not develop new risk factors.

Another issue related to BMD testing is the need for serial monitoring to assess treatment response. The NOF guidelines did not explicitly address serial monitoring, although the cost-effectiveness analysis in the background report assumed that the patient would undergo a single assessment of BMD. (The NOF screening guidelines were based in part on this cost-effectiveness analysis.) However, serial monitoring using DXA was the subject of a second 1999 TEC Assessment that offered the following conclusions:

- There is no direct evidence regarding the utility of BMD monitoring in patients undergoing treatment for osteoporosis.
- Lacking this direct evidence, the chain of logic supporting BMD monitoring is very weak and does not indicate a benefit. Given the precision of BMD measurement using DXA, the expected changes in BMD, and variability of those changes as a result of treatment, it is only possible under situations in which there is a great loss of bone where it is possible to identify a patient who is not responding to treatment. Even then, patients may actually be responding by losing less BMD than they would have without treatment.
- There is no direct evidence that alternative treatments or adjustments in management will be effective in those judged to be non-responders to their initial treatment.
- Based on the above considerations, serial monitoring with DXA did not meet the TEC criteria.

The above TEC Assessment only addressed the use of DXA as a technique for serial monitoring. However, for unknown reasons, treatment-related changes in BMD are not observed at peripheral sites and thus ultrasound densitometry of the heel cannot be used for serial monitoring. This suggests that if serial monitoring is considered, a central DXA BMD measurement should be the initial BMD test performed in patients at high risk for osteoporosis. A central DXA measurement will simultaneously establish the diagnosis of osteoporosis and provide a baseline. However, a study by Cummings et al. demonstrated the problems of interpreting interim BMD values by showing that persons who lost BMD initially while

undergoing treatment were highly likely to gain BMD after a subsequent measurement. The imprecision of BMD measurement led to poor prediction of treatment response.

It should be noted that currently Medicare tacitly endorses serial monitoring. The interim rule regarding Medicare coverage of BMD testing recommends coverage of one BMD measurement every two years. In addition, Medicare policy does not distinguish among the different technologies available for bone mineral density testing.

Women who have had breast cancer treatment may be at increased risk for osteoporosis for several reasons. Certain chemotherapy drugs can cause ovaries to stop making estrogen, bringing on early menopause. Also, if the ovaries are removed or irradiated, early menopause may result. These reduced levels of estrogen can cause bone loss. Aromatase inhibitors are a new type of hormonal therapy used to treat postmenopausal women with breast cancer. Some studies suggest that these drugs may lead to a loss of bone density, but the long-term results are not yet known.

Osteoporosis in men is underdiagnosed and undertreated worldwide and in the United States. A 60-year-old white man has a 25% lifetime risk for an osteoporotic fracture, and the consequences of the fracture can be severe. The one-year mortality rate in men after hip fracture is twice that of females.

The American College of Physicians recommends that clinicians:

- Periodically perform individualized assessment of risk factors for osteoporosis in older men;
- Obtain dual energy x-ray absorptiometry for men who are at increased risk of osteoporosis and are candidates for drug therapy.

A meta-analysis showed that the most important risk factors for **osteoporosis in men** are age (>70 years), **low body weight (body mass index <20 to 25 kg/m^2 or lower), weight loss (>10% [compared with the usual young or adult weight or weight loss in recent years]), physical inactivity (participates in no physical activity on a regular basis [walking, climbing stairs, carrying weights, housework, or gardening]),** use of oral corticosteroids, androgen deprivation therapy, and previous fragility fracture.

The National Osteoporosis Foundation (NOF) updated its practice guidelines in 2010. M 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 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 three months) associated with low bone mass or bone loss;
- Anyone being considered for pharmacologic therapy for osteoporosis;
- Anyone being treated for osteoporosis, to monitor treatment effect;
- Anyone not receiving therapy in whom evidence of bone loss would lead to treatment;
- Postmenopausal women discontinuing estrogen should be considered for bone density testing.

The NOF guidelines state that serial monitoring of BMD is appropriate for monitoring bone loss in patients on pharmacotherapy. They generally recommend testing every two 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
• 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 ten-year probability of a hip fracture of at least 3% or a ten-year probability of a major osteoporosis-related fracture of at least 20% (based on the U.S. adapted WHO algorithm).

July 2010 Update

The literature search was performed and two new studies on the timing of repeat BMD measurements. Frost and colleagues developed a prognostic model to determine the optimal screening interval for an individual without osteoporosis (defined as T-score more than -2.5). 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 two 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 two variables. In the table of estimated time to reach 20% risk of sustaining a fracture or osteoporosis, most of the time estimates were three 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 three- to five-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.

Bell et al conducted a secondary analysis of data from the Fracture Intervention Trial (FIT), which randomized 6,459 post-menopausal women with low BMD to receive treatment with bisphosphonates or placebo; women underwent annual bone density scans. 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 bone mineral density scans for monitoring response to treatment. After three years, the mean cumulative increase in hip bone mineral density 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 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. The policy statement that serial measurement of BMD is considered medically necessary at an interval not more frequent than two to three years remains unchanged.

Recently, there has been interest in gastric bypass surgery as a potential risk factor for osteoporosis. Several case series have found a significant decrease in BMD at one or more sites following gastric bypass surgery. For example, Carrasco and colleagues reported on a series of 42 women, mean age 38 years, who underwent gastric bypass surgery. A year after surgery there was a significant reduction of 3% in total BMD, reduction of 10.5% in hip BMD and reduction of 7.4% in spine BMD. Another case series by Fleischer and colleagues included 23 individuals, aged 20–64 years, who had gastric bypass surgery. After one year of follow-up, there was a significant decrease in hip BMD, a mean loss of 9.2% at the femoral neck and 8.0% of the total hip. There was not a significant difference in lumbar spine BMD. Decline in BMD was strongly associated with the extent of weight loss and the authors speculated that this change might, in part, be due to unloading of the skeleton. Moreover, the authors comment that the study had a small sample size and larger longer-term studies are needed to answer the question of how bone density loss accompanying weight loss affects bone quality and fracture risk. The one comparative study that was identified had a different finding as regards hip BMD. This was a retrospective cohort study by Valderas et al. It included 26 post-menopausal women (mean age 58 years) who underwent Roux-en-Y gastric bypass and 26 women non-operated women matched for age and body mass index. After a mean of 3.1 years after surgery, the mean decrease in femoral neck BMD s 0.892 g/cm2 in the gastric bypass group and 0.934 cm2 in the comparison group; this difference was not statistically significant. Differences in lumbar spine BMD also did not differ significantly. Two clinical guidelines, the National Osteoporosis Foundation (NOF) and the American Association of Clinical Endocrinologists (AACE) list gastric surgery as one of many factors linked to an increased risk of osteoporosis or fracture.

April 2011 Update

The Children's Oncology Group (COG) published a review in 2008 that summarized the existing literature that has defined characteristics of cancer survivors at risk for bone mineral deficits and contributed to the surveillance and counseling recommendations outlined in the COG long-term follow-up guidelines. Children and adolescents may experience bone problems and endocrine problems during and after therapy for oncologic problems. Reduced bone mineral density (BMD) is particularly common among survivors of hematologic malignancies and brain tumors. Some of the risk seems to be related to the underlying cancer: bone mineral is already decreased, compared to normal for age, at the time of diagnosis of ALL. Chemotherapy and/or radiation therapy further increases these risks. Reduced BMD is often clinically invisible and unrecognized until a fracture occurs. Symptoms of fractures associated with osteoporosis may include bone pain, abnormal gait, vertebral collapse, back pain, or low-impact fractures. Most

survivors of childhood cancer will regain bone mass with increasing time after therapy. However, BMD may be permanently reduced if the cancer or its treatment reduces peak bone mass, so children treated during puberty are particularly at risk. In addition, there may be progressive effects on BMD if the individual has a treatment related endocrinopathy (e.g., growth hormone deficiency or hypogonadism), or nephropathy causing chronic renal phosphate loss (e.g., Fanconi syndrome associated with ifosfamide). Glucocorticoids are an important component of chemotherapy for many childhood cancers. They contribute to bone loss through a variety of mechanisms, including direct inhibitory effects on osteoblasts and by inhibiting production of growth hormone, insulin-like growth factor (IGF-1), androgens, and estrogens. Current guidelines from the Children's Oncology Group recommend that all patients treated with agents that predispose to reduced BMD, including glucocorticoids, cranial radiation, methotrexate, or HCT, have a quantitative measure of BMD at the time of entry into long-term follow up, which typically occurs two years after completion of cancer chemotherapy. BMD should be measured with either dual energy x-ray absorptiometry (DXA) or quantitative computed tomography (QCT). The methodology employed may influence the results, and the optimal approach has not been established. The DXA results must be interpreted using age-and gender-specific standards (Z-scores) and not adult standards (T-scores). Results from the baseline evaluation and other clinical factors should determine the need for follow-up. In general, patients with normal BMD study results (e.g., Z-score -1) do not require follow-up examinations. Patients wit significant BMD deficits (e.g., Z-scores < -2), recurrent fractures, or medical risk factors for decreasing BMD such as GHD or hypogonadism, require endocrine evaluation and treatment, counseling to optimize lifestyle factors affecting bone health, and long-term follow up of BMD.

February 2012

In January 2011, the U.S. Preventative Services Task Force (USPSTF) issued updated recommendations on screening for osteoporosis with bone density measurements. 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 FRAX tool. 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 recommendations state the following on 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."

A 2012 multicenter prospective study by Gourlay et al provided data on the optimal bone density screening interval in a large cohort of women with normal BMD or osteopenia at an initial screen. The investigators included a total of 4,957 women age 67 years or older that had BMD data at two or more examinations or at one examination before a competing risk event (hip or

clinical vertebral fracture). More than 99% of the sample reported they were white. The study only included women who were candidates for osteoporosis screening. Other women, 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. The primary 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 also 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. The data from this study have not yet been incorporated into national recommendations on osteoporosis screening.

March 2013 Update

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

Policy updates have identified additional data supporting the conclusion that BMD predicts fracture risk.

A systematic review of the evidence to update U.S. Preventive Services Task Force (USPSTF) recommendations on screening for osteoporosis was published in 2010. 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.

Updated National Osteoporosis Foundation (NOF) guidelines, issued in 2010, 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. (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).

Conclusions

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

A 2007 study by Hillier and colleagues did not find that follow-up BMD measurements eight 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.

Conclusions

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, including studies by Gourlay and Hillier, suggest 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

There is little evidence on the clinical benefit of serial measurement of BMD for patients receiving pharmacologic osteoporosis treatment. A recent 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.

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 two-year interval in BMD measurement to monitor response to treatment. In addition, the available evidence suggests that at least a three- to five-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. 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. 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. 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 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 18-24 months to document a clinically meaningful change in BMD and thus a two-year interval after treatment initiation is preferred to one 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.

Key Words:

Bone mineral density testing, BMD, bone mineral density studies, bone mineral studies, Dual X-ray Absorptiometry, DXA, Dual-energy x-ray absorptiometry, DEXA, Quantitative Computed Tomography QCT, Ultrasound Densitometry, dual photon absorptiometry, radiographic absorptiometry, single photon absorptiometry, Lunar iDXA

Approved by Governing Bodies:

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 BMD, comparison of measurements to reference databases, estimation of fracture risk, body composition analysis, and measurement of periprosthetic BMD.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan.
Pre-certification/Pre-determination requirements: Not applicable.

Current Coding:

CPT codes:

76977	Ultrasound bone density measurement and interpretation, peripheral site(s), any method
77078	Computed tomography, bone mineral density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine)
77080	Dual-energy x-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine)
77081	Dual-energy x-ray absorptiometry (DXA), bone density study, 1 or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)

HCPCS code:

G0130	Single energy x-ray absorptiometry (SEXA) bone density study, one or more sites; appendicular skeleton peripheral)(e.g., radius, wrist, heel)

Previous Coding:

76070	Computerized tomography, bone mineral density study, one or more sites; axial skeleton (e.g., hips, pelvis, spine) **(deleted 01/01/2007)**
76071	Computed tomography, bone mineral density study, one or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel) **(deleted 01/01/2007)**
76075	Dual energy x-ray absorptiometry (DXA), bone density study, one or more sites; axial skeleton (e.g., hips, pelvis, spine) **(deleted 01/01/2007)**
76076	Dual energy x-ray absorptiometry (DXA), bone density study, one or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel) **(deleted 01/01/2007)**
76078	Radiographic absorptiometry, (e.g., photodensitometry, radiogrammetry), one or more sites **(deleted 01/01/2007)**
77079	Computed tomography, bone mineral density study, 1 or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel) **(deleted 01/01/2012)**

77083 Radiographic absorptiometry (e.g., photodensitometry, radiogrammetry), 1 or more sites **(deleted 01/1/2012)**

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Policy History:

Medical Policy Group, March 1998
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Medical Policy Group, August 2004 **(2)**
Medical Policy Administration Committee, September 2004
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Medical Policy Group, April 2011: Updated Policy (Children & Adolescents), Key Points and References
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Medical Policy Group, January 2012 **(3)**: 2012 Code Updates deleted 77079 & 77083
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