Bone Mineral Density Studies
Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy # 00010
Original Effective Date: 07/18/1996
Archived Date: 06/20/2012

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: This policy does not address the use of Dual x-ray absorptiometry (DXA) as a technique to screen for vertebral fractures.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider bone mineral density studies to be eligible for coverage.

Based on review of available data, the Company may consider an initial measurement of bone mineral density to assess fracture risk and the need for pharmacologic therapy in those considered at risk for osteoporosis to be eligible for coverage.

Patient Selection Criteria
Coverage eligibility will be considered when any of the following criteria are met:

- Perimenopausal women, when used in the decision to initiate estrogen replacement therapy based on information regarding the probability of future fractures; or
- Women deficient in estrogen following menopause, bilateral oophorectomy, or amenorrhea of six months duration or more; or
- Not on estrogen replacement therapy due to contraindication; or
- Undecided about estrogen replacement therapy and knowledge of her risk of osteoporosis would be the determining factor in her decision; or
- 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 (<127lbs.); or
- All women aged 65 and older regardless of additional risk factors; or
- Women who have been taking hormone replacement therapy for prolonged periods; or
- 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).
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Bone mineral density is considered medically appropriate for monitoring of secondary osteoporosis in individuals who:

- Have asymptomatic primary hyperparathyroidism, where consideration for surgery is in large part determined by bone density level; or
- Are receiving long-term glucocorticoid therapy where bone density substantiates need for glucocorticoid reduction.

Follow-up bone mineral density studies are considered medically appropriate to determine the efficacy of treatment and monitor the progression of osteoporosis if at least 23 months have passed since the last bone density measurement.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers bone mineral density studies to be investigational* when the listed patient selection criteria are not met.

Background/Overview

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 (<127lbs). 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.

Bone mineral density is one of the key determinants for the need for pharmacologic therapy. Bone mineral density 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.
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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, and 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)**
   Dual x-ray absorptiometry 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. Dual x-ray absorptiometry can also be used to measure peripheral sites, such as the wrist and finger. Dual x-ray absorptiometry 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)**
   Quantitative computed tomography 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 relatively 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 three 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.

**FDA or Other Governmental Regulatory Approval**
U.S. Food and Drug Administration (FDA)
Various devices are commercially available.
In October 2003, the Hologic QDR-3000 Explorer X-Ray Bone Densitometer (Hologic, Bedford, MA) was cleared for marketing by the U.S. 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.

**Rationale/Source**
The NOF guidelines exist in two formats, a formal background report and a summary version presented as a “Physician’s Guide.” Although BMD measurements at the clinically relevant central sites (i.e., hip and spine) are most predictive of future fracture risk, the Physician’s Guidelines do not recommend one particular type or site of BMD testing technology, although the background report states that hip measurements are preferred. However, a 1999 TEC Assessment specifically addressed the use of ultrasound densitometry of the heel, not only to assess fracture risk but to predict response to drug therapy. Although these outcomes may seem the same, there is a subtle but important distinction. The TEC Assessment concluded that while both DXA and ultrasound densitometry were equivalent in predicting fracture risk, the correlation coefficient was only modest, suggesting that the two techniques identified different populations of at-risk patients. Recent randomized trials of various drug therapies, such as bisphosphonates, selective estrogen receptor modulators, and calcitonin have all used DXA to measure therapy-induced changes in bone mineral density. Thus, it is not clear whether the results of these trials can be extrapolated to the potentially different population of at-risk patients identified by ultrasound densitometry. Therefore, on this basis, ultrasound densitometry did not meet the TEC criteria as a technique to predict response to pharmacologic therapy. In 2002, a TEC Assessment focused on the use of ultrasound densitometry performed at peripheral sites other than the heel, i.e., at the phalanges or tibia. This Assessment concluded the same limitations regarding the evidence of ultrasonography of the heel applied to other peripheral sites. Specifically, ultrasound of any site is a poor predictor of DXA and thus cannot be used to direct patients’ treatment.

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 nonresponders to their initial treatment.
Based on the above considerations, serial monitoring with DXA did not meet the TEC criteria.

The latter 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 BMD testing.

In 2004, a literature search was performed for the period of 2003 through December 2005, with a particular focus on serial monitoring of BMD, and the role of heel ultrasonometry as a technique of measurement of BMD. No new studies were identified that would prompt reconsideration of the existing coverage statement.

A search of the MEDLINE database for the period of December 2005 through February 2007 identified a number of publications related to the predictive value of BMD measurements. One study prospectively measured total hip BMD in 4,124 women with assessment of vertebral fractures by x-ray in 2,129 of these women; BMD was repeated after eight years and spine fractures were measured after an average of 11.4 years. Analysis showed that the initial and repeat BMD measurements were similarly associated with fracture risk for nonspine (hazard ratio, 1.6), spine (odds ratio, 1.8-1.9), and hip (hazard ratio, 2.0-2.2) fractures. These results support the conclusion reached above that repeating a measurement of BMD up to eight years later provides little additional value to the initial BMD measurement for predicting incident fractures. No studies were identified that evaluated whether repeat BMD measurement might improve clinical decision making.

Several recent articles assessed the predictive value of BMD for future fractures in men. One meta-analysis of data from 9,891 men and 29,082 women (from 12 different European, Scandinavian, and Canadian cohorts) found that BMD was a strong predictor of hip fractures for both genders. At the age of 65 years, risk ratio increased by 2.94 in men and by 2.88 in women for each standard deviation decrease in BMD. The meta-analysis, along with a number of other recent articles, suggests that while not as precise as central measurements, peripheral measurements of BMD are also predictive of future fracture.

A population study from Canada (2,699 women and 1,032 men 65 years of age or older) determined that the number needed to screen to detect one previously undiagnosed case of osteoporosis is six women.
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Aged greater or equal to 65 years, 13 men aged greater or equal to 65 years, and 10 men aged greater or equal to 70 years. Although 26% of the women and 9% of the men from the study population had osteoporosis as defined by BMD, the majority (77% of the women and 93% of the men) were not aware of it. Another retrospective review of 1,171 men from a non-profit health care organization found that BMD measurement had been conducted in only 1% of the men aged 65 or older and that only 16% of those with a hip or vertebral fracture had received medication for osteoporosis following the index fracture.

The International Society for Clinical Densitometry (ISCD) recommends that men 65 years of age and older with a T-score of -2.5 or less (from a male reference database) be diagnosed with osteoporosis. The Institute for Clinical Systems Improvement (ICSI) recommends BMD testing in both men and women who present with significant acquired kyphosis and/or a height loss of 1 inch, or who present with low impact fracture if they are willing to accept treatment. However, the ICSI does not recommend bone density testing in eugonadal men who have not had a fracture with minor trauma, are not on glucocorticoid therapy, and do not have another chronic disease associated with bone loss.

The following are patient selection criteria for osteoporosis testing that have been published by the National Osteoporosis Foundation:

1. All postmenopausal women aged 65 and older regardless of risk factors.
2. Younger postmenopausal women with one or more risk factors (other than being white, post menopausal and female).
3. Postmenopausal women who present with fractures (to confirm diagnosis and determine disease severity).

A note in the NOF guide states that, "It does not address men, premenopausal women, or women of other races, since there are insufficient data available to formulate comparable recommendations for these populations. This does not imply that osteoporosis affects only postmenopausal white women. Until we have enough data to make specific recommendation for other populations, the risk factors currently identified for white women should be used for others on an individual basis to determine the need for bone density testing and treatment."

Due in large part to accessibility of the procedure, BMD is at this time the most established measure of fracture risk. It should be noted that as research on the determinants of bone strength proceeds, the specific BMD threshold(s) used to identify the patients at highest risk for fracture, and the standards for treatment, are likely to change. BMD measurement is thus considered appropriate to aid treatment decisions in both men and women who are considered candidates for treatment by current standards.

References
2. Blue Cross and Blue Shield Association, Technology Assessment Center, Ultrasonography of Peripheral Sites for Selecting Patients for Pharmacologic Treatment for Osteoporosis; Volume 17, No.5. July 2002.

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Accessed 07/02/08.

5. Louisiana Medicare Services.

Coding
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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

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Policy History

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08/20/2001 Managed Care Advisory Council approval
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07/19/2006 Medical Policy Committee approval. Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged
06/13/2007 Medical Director review
06/20/2007 Medical Policy Committee approval. No change to coverage eligibility.
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08/20/2008 Medical Policy Committee approval. No change to coverage eligibility.
08/06/2009 Medical Policy Committee approval
08/26/2009 Medical Policy Implementation Committee approval. No change to coverage eligibility.
07/01/2010 Medical Policy Committee approval
07/21/2010 Medical Policy Implementation Committee approval. No change to coverage eligibility.
07/07/2011 Medical Policy Committee approval
07/20/2011 Medical Policy Implementation Committee approval. No change to coverage eligibility.
06/14/2012 Medical Policy Committee approval
06/20/2012 Medical Policy Implementation Committee approval. Removed the coverage statement that said peripheral bone mineral density studies are considered investigational. Archived.

Next Scheduled Review Date: Archived.

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:
A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
   1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
   2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
   3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:
A. in accordance with nationally accepted standards of medical practice;
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B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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