FEP Medical Policy Manual

FEP 6.01.01 Bone Mineral Density Studies

Effective Policy Date: April 1, 2021

Original Policy Date: December 2011

Related Policies:

2.04.15 - Bone Turnover Markers for Diagnosis and Management of Osteoporosis and Diseases Associated With High Bone Turnover
6.01.44 - Vertebral Fracture Assessment with Densitometry

Bone Mineral Density Studies

Description

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Bone mineral density (BMD) studies can be used to identify individuals with osteoporosis and monitor response to osteoporosis treatment, with the goal of reducing the risk of fracture. Bone density is most commonly evaluated with dual x-ray absorptiometry (DXA); other technologies are available.

OBJECTIVE

The objective of this evidence review is to examine whether bone mineral density studies improve health outcomes in individuals at risk of osteoporotic fracture.

POLICY STATEMENT

Initial or repeat bone mineral density (BMD) measurement is not indicated unless the results will influence treatment decisions.

An initial measurement of central (hip/spine) BMD using dual x-ray absorptiometry (DXA) may be considered **medically necessary** to assess future 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, independent of other risk factors;
- Men age 70 and older, independent of other risk factors;
- Younger postmenopausal women with an elevated risk factor assessment; (See policy guidelines)
- Men age 50 to 70 with an elevated risk factor assessment; (See policy guidelines)
- Adults with a pathologic condition associated with low bone mass or increased bone loss;
- Adults taking a medication associated with increased bone loss.

Repeat measurement of central (hip/spine) BMD using dual x-ray absorptiometry for individuals who previously tested normal may be considered **medically necessary** at an interval not more frequent than every 3 to 5 years; the interval depends on an updated patient fracture risk assessment.

Repeat measurement of central (hip/spine) BMD using dual x-ray absorptiometry may be considered **medically necessary** at an interval of not more frequent that every 1-2 years in individuals:

- With a baseline evaluation of osteopenia (BMD T- score -1.0 to -2.5)
- Adults with a pathologic condition associated with low bone mass or increased bone loss;
- Adults taking a medication associated with increased bone loss.

Repeat measurement of central (hip/spine) BMD using dual x-ray absorptiometry may be considered **medically necessary** at an interval not more frequent than every 1-3 years in individuals who are receiving pharmacologic treatment for osteoporosis when the information will affect treatment decisions (continuation, change in drug therapy, cessation or resumption of drug therapy).

Peripheral (lower arm, wrist, finger or heel) BMD testing may be considered **medically necessary** when conventional central (hip/spine) DXA screening is not feasible or in the management of hyperparathyroidism, where peripheral DXA at the forearm (ie, radius) is essential for evaluation.

Dual x-ray absorptiometry of peripheral sites is considered **investigational** except as noted above.

BMD measurement using ultrasound densitometry is considered **not medically necessary**.

BMD measurement using quantitative computed tomography is considered **investigational**.

POLICY GUIDELINES

Bone Mineral Density Technologies

Dual x-ray absorptiometry (DXA) of axial central sites (ie, hip and spine) is the most commonly used technique. Central DXA (hip/spine) is required for both the initial diagnosis and repeat bone mineral density (BMD) assessments.

Peripheral (lower arm, wrist, finger or heel) measurement can identify patients with low bone mass but does not predict response to pharmacologic therapy and is not a substitute for central DXA measurements. Peripheral BMD may be appropriate:

- If the hip/spine or hip/hip cannot be done or the patient is over the table limit for weight;
- Hyperparathyroidism, where the forearm is essential for diagnosis.

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

When indicated; repeat dual x-ray absorptiometry (DXA) of axial central sites should ideally be conducted in the same facility with the same machine. Differences between BMD results may simply reflect the inherent variability of the test measurement; thus, testing facilities must calculate the least significant change (LSC) for relevant measurement sites to determine the magnitude of difference that represents a real change. This is determined using a facility's regular technologist(s), patients, and device.

Ultrasound densitometry is an office-based technology. Compared with osteoporotic bone, normal bone demonstrates higher attenuation of the ultrasound wave and is associated with a greater velocity of the wave passing through bone. Ultrasound densitometry has no radiation exposure, and machines may be purchased for use in an office setting. It is unknown whether this technology can be used to predict response to pharmacologic therapy (ie, reduce fractures).

Quantitative computed tomography depends on the differential absorption of ionizing radiation by calcified tissue and is used for central measurements only. Compared with DXA, quantitative computed tomography is less readily available and associated with relatively high radiation exposure and relatively high cost. Analysis of previously obtained clinical computed tomography scans of the pelvis might provide an alternative method of assessing biomechanical bone strength.

Single- and dual-photon absorptiometry and radiographic absorptiometry are now rarely used and may be considered obsolete.

Evidence review 6.01.44 addresses screening for vertebral fractures using dual-energy x-ray absorptiometry which is considered investigational.

The decision to perform a bone density assessment should be based on an individual's fracture risk profile and skeletal health assessment. In addition to age, sex, and BMD, risk factors included in the World Health Organization Fracture Risk Assessment Tool are:

- Low body mass index;
- Parental history of hip fracture;
- Previous fragility fracture in adult life (ie, occurring spontaneously or a fracture arising from trauma, which, in a healthy individual, would not have resulted in a fracture);
- Current smoking or 3 or more units of alcohol daily, where a unit is equivalent to a standard glass of beer (285 mL), a single measure of spirits (30 mL), a medium-sized glass of wine (120 mL), or 1 measure of an aperitif (60 mL);
- A disorder strongly associated with osteoporosis, which includes rheumatoid arthritis, type I (insulin-dependent) diabetes, osteogenesis imperfecta in adults, untreated long-standing hyperthyroidism, hypogonadism or premature menopause (<45 years), chronic malnutrition or malabsorption, and chronic liver disease;
- Current exposure to oral glucocorticoids or exposure to oral glucocorticoids for more than 3 months at a dose of prednisolone 5 mg daily or more (or equivalent doses of other glucocorticoids).

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

Devices that measure bone density have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Some examples are described in Table 1:

Table 1. FDA Cleared Devices to Measure Bone Density

Device Name	Company	510(k) number
Aria	GE Medical Systems	K180782
Ge Lunar Dxa Bone Densitometers With Enc	GE Medical Systems	K161682
Tbs Insight	Medimaps Group Sa	K152299
Single Energy (Se) Femur Exams	Hologic, Inc.	K130277
Tbs Insight	Medimaps Group Sa	K121716
Virtuost	O.N. Diagnostics	K113725
Accudxa2	Lone Oak Medical Technologies, Llc	K113616
Ultrascan 650	Cyberlogic, Inc.	K161919
Bindex Bi-2	Bone Index Finland, Ltd.	K161971
Bindex Bi-100	Bone Index Finland, Ltd.	K152020
Achilles	GE Medical Systems	K123238
Beammed Sunlight Miniomni Bone Sonometer	Beam-Med Ltd	K110646
Achilles	GE Medical Systems	K103633

FDA product codes: KGI, MUA.

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

RATIONALE

Summary of Evidence

For individuals who are eligible for screening of bone mineral density (BMD) based on risk factor assessment who receive dual x-ray absorptiometry (DXA) analysis of central sites (hip or spine), the evidence includes systematic reviews of randomized controlled trials (RCTs) controlled trials and cohort studies. Relevant outcomes are morbid events, functional outcomes, quality of life (QOL), hospitalizations, and medication use. Central DXA is the most widely accepted method for measuring BMD and is the reference standard against which other screening tests are evaluated. BMD measurements with central DXA identify individuals at increased risk of fracture, and osteoporosis medications reduce fracture risk in the population identified as osteoporotic by central DXA. Therefore, test results with initial central DXA can be used to guide therapy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals without osteoporosis on initial screen who receive repeat DXA analysis of central sites (hip or spine), the evidence includes systematic reviews of large cohort and observational studies. Relevant outcomes are morbid events, functional outcomes,

QOL, hospitalizations, and medication use. Little research has been done on the frequency of BMD monitoring for osteoporosis. The available research has evaluated repeat measurement with central DXA. Evidence on whether repeat measurements add to risk prediction compared with a single measurement is mixed. Although the optimal interval may differ depending on risk factors, current evidence does not support repeat monitoring in patients with BMD on DXA in the normal range. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Although the evidence is limited, multiple clinical practice guidelines recommend repeat DXA in 3-5 years in patients at low-risk using risk factor assessment. Similarly, multiple guidelines recommend a repeat screening interval of 1-2 years for high-risk individuals and in individuals with a baseline evaluation near a fracture intervention threshold (osteopenia).

For individuals who are receiving pharmacologic treatment for osteoporosis who receive repeat DXA analysis of central sites (hip or spine), the evidence includes systematic reviews of RCTs and observational studies. Relevant outcomes are morbid events, functional outcomes, QOL, hospitalizations, and medication use. There is no high-quality evidence to guide how often to monitor BMD during osteoporosis treatment. Within-person variation in measurement may exceed treatment effects, and fracture risk has been shown to be reduced in some treatment studies in the absence of changes in BMD. Together, these results suggest that frequent (ie, every 2 years) repeat monitoring has low value. It is unclear whether DXA at the end of the initial 5 years of therapy is sufficiently accurate to guide subsequent therapy. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Although the evidence is limited, multiple clinical practice guidelines recommend repeat DXA at intervals of 1-3 years to monitor treatment response in patients who are receiving pharmacological treatment for osteoporosis or after a change in or cessation of treatment.

For individuals who are eligible for screening of BMD based on risk factor assessment who receive ultrasound densitometry, or quantitative computed tomography, or DXA analysis of peripheral sites, the evidence includes observational studies and systematic reviews. Relevant outcomes are morbid events, functional outcomes, QOL, hospitalizations, and medication use. In comparison with central DXA, other measures of bone health showed area under the curves around 0.80 for the identification of osteoporosis. These technologies are not commonly used for BMD measurements in practice, and no studies have shown that they can select patients who benefit from treatment for osteoporosis. There is little to no evidence on the usefulness of repeat measurement of BMD using these techniques. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Obstetricians and Gynecologists

In 2012 (reaffirmed 2016), the American College of Obstetricians and Gynecologists (ACOG) updated its guidelines on managing osteoporosis in women.[20,] The guidelines recommended that bone mineral density (BMD) screening should begin for all women at age 65 years. In addition, the ACOG recommended screening for women younger than 65 years in whom the Fracture Risk Assessment Tool indicates a 10-year risk of osteoporotic fracture of at least 9.3%. Alternatively, ACOG recommended BMD screening women younger than 65 or with any of the following risk factors (they are similar, but not identical to risk factors in the Fracture Risk Assessment Tool):

- Personal medical history of a fragility fracture
- Parental medical history of hip fracture
- Weight less than 127 lb
- Medical causes of bone loss (i.e., medications or disease)
- Current smoker

- Alcoholism
- Rheumatoid arthritis
- For women who begin medication treatment for osteoporosis, a repeat BMD is recommended 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 to 24 months to document a clinically meaningful change in BMD and thus a 2-year interval after treatment initiation is preferred to 1 year.
- The guidelines do not specifically discuss repeat BMD screening for women who have a normal finding on the initial test.
- Routine BMD screening is not recommended for newly menopausal women as a "baseline" screen.

American Society for Bone and Mineral Research

The 2016 guidelines from an American Society for Bone and Mineral Research task force included the following statement on managing osteoporosis in patients on long-term bisphosphonate treatment:[21,]

"Reassessment includes clinical evaluation, risk assessment including risk factors, and may include bone density measurement by DXA. The monitoring interval with DXA should be based upon changes that are detectable and clinically significant. Reassessment may be necessary at less than 2 years in patients with a new fracture, or in light of anticipated accelerated bone loss (e.g. institution of aromatase inhibitor or glucocorticoid therapy)."

National Osteoporosis Foundation

In 2014, the National Osteoporosis Foundation (NOF) updated its practice guidelines.[22,] The NOF guidelines recommended that all postmenopausal women and men ages 50 and older be evaluated clinically for osteoporosis risk to determine the need for BMD testing.

Indications for BMD testing included:

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

The NOF stated that measurements for monitoring patients should be performed in accordance with medical necessity, expected response, and in consideration of local regulatory requirements. The NOF recommended that repeat BMD assessments generally agree with Medicare guidelines of every 2 years, but recognized that testing more frequently may be warranted in certain clinical situations.

The NOF also indicated that:

"Central DXA [dual x-ray absorptiometry] assessment of the hip or lumbar spine is the <91>gold standard" for serial assessment of BMD. Biological changes in bone density are small compared to the inherent error in the test itself, and interpretation of serial bone density studies depends on appreciation of the smallest change in BMD that is beyond the range of error of the test. This least significant change (LSC) varies with the specific instrument used, patient population being assessed, measurement site, technologist's skill with patient positioning and test analysis, and the confidence intervals used. Changes in the BMD of less than 3-6 % at the hip and 2-4 % at the spine from test to test may be due to the precision error of the testing itself."

American College of Physicians

The 2017 guidelines from the American College of Physicians on the treatment of osteoporosis recommended against bone density monitoring during the 5-year pharmacologic treatment period of osteoporosis in women (weak recommendation, low-quality evidence).[14,] The American College of Physicians noted that data from several studies showed a reduction in fractures with pharmacologic treatment, even when BMD did not increase. In addition, current evidence "does not support frequent monitoring of women with normal bone density for osteoporosis, because data showed that most women with normal CSA scores did not progress to osteoporosis within 5 years."

American College of Radiology

The 2017 update of appropriateness criteria from the American College of Radiology,[23,], state that BMD measurement is indicated whenever a clinical decision is likely to be directly influenced by the result of the test. Indications for DXA of the lumbar spine and hip included but were not limited to the following patient populations:

- All women age 65 years and older and men age 70 years and older (asymptomatic screening)
- Women younger than age 65 years who have additional risk for osteoporosis, based on medical history and other findings. Additional risk factors for osteoporosis include:
    - Estrogen deficiency
    - A history of maternal hip fracture that occurred after the age of 50 years
    - Low body mass (less than 127 lb or 57.6 kg)
    - History of amenorrhea (more than 1 year before age 42 years)
- Women younger than age 65 years or men younger than age 70 years who have additional risk factors, including:
    - Current use of cigarettes
    - Loss of height, thoracic kyphosis
- Individuals of any age with bone mass osteopenia, or fragility fractures on imaging studies such as radiographs, CT [computed tomography], or MRI [magnetic resonance imaging]
- Individuals age 50 years and older who develop a wrist, hip, spine, or proximal humerus fracture with minimal or no trauma, excluding pathologic fractures
- Individuals of any age who develop one or more insufficiency fractures
- Individuals being considered for pharmacologic therapy for osteoporosis.
- Individuals being monitored to:
    - Assess the effectiveness of osteoporosis drug therapy.
    - Follow-up medical conditions associated with abnormal BMD.

International Society for Clinical Densitometry

The 2019 update of the International Society for Clinical Densitometry guidelines recommended bone density testing in the following patients[24]:

- "Women age 65 and older
- For post-menopausal women younger than age 65 a bone density test is indicated if they have a risk factor for low bone mass fracture such as;
    - Low body weight
    - Prior fracture
    - High-risk medication use
    - Disease or condition associated with bone loss.
- Women during the menopausal transition with clinical risk factors for fracture, such as low bone weight, prior fracture or high-risk medication use.
- Men aged 70 and older.
- Men under < 70 years ... if they have risk factors for low bone mass such as;
    - Low body weight
    - Prior fracture
    - High-risk medication use
    - Disease or condition associated with bone loss.
- Adults with a fragility fracture.
- Adults with a disease or condition associated with low bone mass or bone loss....
- Anyone being considered for pharmacologic therapy.
- Anyone being treated, to monitor treatment effect.
- Anyone not receiving therapy in whom evidence of bone loss would lead to treatment."

The 2019 position statement makes the following recommendations on serial BMD measurements:

- Serial BMD testing in combination with clinical assessment of fracture risk, bone turnover markers, and other factors including height loss and trabecular bone score, can be used to determine whether treatment should be initiated in untreated patients, according to locally applicable guidelines.
- Serial BMD testing can monitor response to therapy by finding an increase or stability of bone density.
- Serial BMD testing should be used to monitor individuals following cessation of osteoporosis pharmacologic therapy.
- Serial BMD testing can detect loss of bone density, indicating the need for assessment of treatment adherence, evaluation of secondary causes of osteoporosis, and re-evaluation of treatment options.
- Follow-up BMD testing should be done when the results are likely to influence patient management.

- Intervals between BMD testing should be determined according to each patient's clinical status: typically one year after initiation or change of therapy is appropriate, with longer intervals once therapeutic effect is established.
- In conditions associated with rapid bone loss, such as glucocorticoid therapy, testing more frequently is appropriate.

Medicare National Coverage

The Centers for Medicare and Medicaid pays for a screening bone mass measurement (BMM) once every 2 years (at least 23 months have passed since the month the last covered BMM was performed).[25,] 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 BMM can be found in chapter 15, section 80.5 of Pub. 100-02, Medicare Benefit Policy Manual. Medicare covers BMM under the following conditions:

- "Is ordered by the physician or qualified nonphysician practitioner who is treating the beneficiary following an evaluation of the need for a BMM and determination of the appropriate BMM to be used....
- Is performed under the appropriate level of physician supervision as defined in 42 CFR 410.32(b).
- Is reasonable and necessary for diagnosing and treating the condition of a beneficiary who meets the conditions described in 80.5.6.
- In the case of an individual being monitored to assess the response to or efficacy of an FDA approved osteoporosis drug therapy, is performed with a dual-energy x-ray absorptiometry system (axial skeleton).
- In the case of any individual who meets the conditions of 80.5.6 and who has a confirmatory BMM, is performed by a dual-energy x-ray absorptiometry system (axial skeleton) if the initial BMM was not performed by a dual-energy x-ray absorptiometry system (axial skeleton). A confirmatory baseline BMM is not covered if the initial BMM was performed by a dual-energy x-ray absorptiometry system (axial skeleton)."

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
June 2012	Replace policy	Policy updated with literature search and references. No changes to policy statement.
June 2014	Replace policy	Policy updated with literature review. References 9, 15 & 20 added; other references renumbered or removed. No changes to policy statement

Date	Action	Description
June 2015	Replace policy	Policy updated with literature review. References 18, and 25-26 added and reference 8, 23, 24 updated; policy statements unchanged.
March 2019	Archive policy	A policy statement was added before the investigational statement that “Peripheral BMD testing could be considered medically necessary when conventional central (hip/spine) DXA screening is not feasible or in the management of hyperparathyroidism, where peripheral DXA measurement at the distal forearm (i.e., radius) is essential for evaluation.” The policy statements were edited to clarify BMD measurement using quantitative computed tomography, or dual x-ray absorptiometry of peripheral sites is considered investigational and BMD measurement using ultrasound densitometry is considered not medically necessary. Policy updated with literature review through October 1, 2018; Rationale revised; references 6, 12-13, 15, 18, and 21 added; some references removed. Policy archived..
June 2020	Reactivate policy	Policy reactivated with literature review through November 6, 2019; references added. Rationale section revised to include clinical practice guidelines when evidence was extremely limited. Policy statements revised to add specific information on risk factors and to indicate that more frequent monitoring (1-2 years in asymptomatic individuals and 1-3 years to monitor treatment) may be medically necessary depending on risk factors. For clarification, the last investigational statement was separated into two statements.
March 2021	Replace policy	Policy updated with literature review through December 3, 2020; reference to American Association of Clinical Endocrinologists/American College of Endocrinology Guidelines updated. Minor edits to revise the last policy statement; other statements unchanged.