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MEDICAL POLICY – 6.01.521

Bone Mineral Density Studies

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Introduction

A bone density test is done to estimate the strength of bones. It looks at the concentration of certain minerals like calcium. Bone density tests, which are also called bone mineral density tests or BMD tests, help doctors know if a person is at risk of broken bones due to osteoporosis. Osteoporosis means "porous bone." It's caused by the body's loss of too much bone, its inability to make enough bone, or both. Risk factors include age, low body mass index, and other conditions associated with osteoporosis such as rheumatoid arthritis and diabetes. A bone density test also is used to measure how well osteoporosis treatment is working. A bone mineral density test generally uses a special type of X-ray or ultrasound. This policy describes when a bone density test may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

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

Measurement	Medical Necessity
Initial measurement	**An initial measurement of central BMD at the hip or spine using dual X-ray absorptiometry (DXA) may be considered medically necessary to assess future fracture risk and the need for pharmacologic therapy in individuals who are considered at risk for osteoporosis. BMD testing may be indicated under the following conditions:** • Women aged 65 and older, regardless of other risk factors (see **Related Policies**) • Men aged 70 and older, regardless of other risk factors • Women younger than age 65 years whose 10-year risk of a major osteoporotic fracture is 9.3% or greater based upon the **Fracture Risk Assessment (FRAX) Tool** • Men aged 50 to 70 with an elevated risk factor assessment (see **Related Information**) • Adults with a pathologic condition associated with low bone mass, or increased bone loss, or taking a medication associated with increased bone loss
Repeat Measurement – no osteoporosis/osteopenia	**Repeat measurement of central (hip/spine) BMD using dual X-ray absorptiometry for individuals who previously tested normal (no osteoporosis/osteopenia and not taking a medicine for treatment) may be considered medically necessary at an interval not more frequent than every 5 years.**
Repeat Measurement – osteopenia	**Repeat measurement of central (hip/spine) BMD using dual X-ray absorptiometry for individuals who previously tested as having osteopenia and not requiring pharmacologic treatment may be considered medically necessary at an interval not more frequent than every 2-3 years.**
Repeat Measurement – monitoring pharmacologic treatment	**Regular (not more frequent than every 2-3 years) serial measurements of central (hip/spine) BMD using dual X-ray absorptiometry to monitor response to pharmacologic treatment may be considered medically necessary when the information will affect treatment decisions (such as duration of therapy).**

Documentation Requirements

The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following:

- For initial measurement to assess fracture risk and the need for pharmacologic therapy in individuals who are considered at risk for osteoporosis, clinical documentation of **ANY** of the following:
  - Women aged 65 and older, regardless of other risk factors (covered under the Affordable Care Act as a preventive benefit)
  - Men aged 70 and older, regardless of other risk factors
  - Women younger than age 65 years whose 10-year risk of a major osteoporotic fracture is 9.3% or greater based upon the FRAX Tool
  - Men aged 50 to 70 with an elevated risk factor assessment
  - Adults with a pathologic condition associated with low bone mass, or increased bone loss, or taking a medication associated with increased bone loss
- For repeat measurement to monitor pharmacologic treatment:
  - Documentation on how the result will affect treatment decisions (such as duration of therapy)

Coding

Code	Description
CPT	
76977	Ultrasound bone density measurement and interpretation, peripheral site(s), any method
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	
G0130	Single energy X-ray absorptiometry (SEXA) bone density study, one or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)

Related Information

Definition of Terms (World Health Organization)

Normal bone density: T-score between 0.00 and -1.00

Osteopenia: T-score between -1.01 and -2.49

Osteoporosis: T-score -2.50 and below

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, sex, and bone mineral density (BMD), risk factors included in the World Health Organization (WHO) **Fracture Risk Assessment (FRAX) Tool** 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 3 or more units of alcohol/day, where a unit is equivalent to a standard glass of beer (285 mL [milliliter]), 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 of 5 milligram daily or more (or equivalent doses of other glucocorticoids).

A 2010 joint position statement from the International Society for Clinical Densitometry and the International Osteoporosis Foundation includes the official position that FRAX with BMD predicts risk of fracture better than clinical risk factors or BMD alone.[25] 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 tool does not include a recommendation about which individuals 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. It is unknown whether this technology can be used to predict response to pharmacologic therapy (i.e., reduce fractures). There is no high-quality evidence to guide how often to monitor BMD during osteoporosis treatment. Within-person variation in measurement may exceed treatment effects, and fracture risk may be reduced in the absence of changes in BMD. Together, these results indicate that frequent (i.e., every two years) repeat monitoring has low value.

DXA of axial central sites (i.e., 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 assessments.

Peripheral (appendicular [lower arm, wrist, finger, or heel]) measurement can identify individuals with low bone mass but does not predict response to pharmacologic therapy and is not a substitute for central DXA measurements.

Peripheral measurement of BMD may be appropriate:

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

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

When indicated; repeat X-ray 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 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), treated individuals, 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 (i.e., 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.

Benefit Application

Under the Patient Protection and Affordable Care Act, preventive services with a United States (US) Preventive Services Task Force (USPSTF) recommendation grade of A or B will be covered with no cost-sharing requirements. Plans that have been grandfathered are exceptions to this rule and are not subject to this coverage mandate. Therefore, review of subscriber contracts or certificates of coverage is needed regarding coverage for screening and coverage for diagnostic tests for asymptomatic individuals and those who are symptomatic and carry a diagnosed illness.

Preventive Care Services

Affordable Care Act covered preventive services: Osteoporosis screening in women has a UUSPSTF rating of B in the following populations:[3]

- Women aged 65 and older, with no known risk factors for osteoporosis
- Women younger than age 65 years whose 10-year fracture risk is equal to or greater than that of the average 65-year-old white woman without additional risk factors. The standard 10-year fracture risk described by USPSTF is a FRAX score of 9.3% or greater

- The updated (2018) USPSTF recommendations stated that the scientific evidence is "insufficient" to assess the balance of benefits and harms of screening for osteoporosis screening in men

Consideration of Age

The ages in this policy for which the initial measurement of bone mineral density is considered medically necessary to assess risk and need for therapy are based on covered preventive services outlined in the Patient Protection and Affordable Care Act, National Osteoporosis Foundation, American College of Physicians, and the American College of Radiology.

Evidence Review

Description

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), although other technologies are available.

Background

Osteoporosis

Osteoporosis is determined using the World Health Organization (WHO) diagnostic thresholds for osteoporosis based on bone mineral density measurement compared with a calculated T-score.

Risk factors for fracture include low bone mass, low bone strength, a personal history of fracture as an adult, or a history of fracture in a first-degree relative. Osteoporosis, defined as low bone mass leading to an increased risk of fragility fractures, is an extremely common disease in the elderly population due to age-related bone loss in both sexes and menopause-related bone loss in women. The WHO has diagnostic thresholds for osteoporosis based on BMD measurements compared with a T-score, which is the standard deviation difference between an individual's

BMD and that of a young adult reference population. Conditions that can cause or contribute to osteoporosis include lifestyle factors such as low intake of calcium, high intake of alcohol or cigarette smoking, and thinness. Other risk factors for osteoporosis include certain endocrine, hematologic, gastrointestinal tract and genetic disorders, hypogonadal states, and medications.

BMD can be measured either centrally (i.e., hip or spine) or peripherally (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. Fractures of the hip and spine (i.e., vertebral fractures) are also considered to be the most clinically relevant. BMD is typically expressed as a T-score.

The utility of screening BMD measurements can be established by demonstrating that screening identifies a population at increased risk of fracture and that, by treating those at-risk individuals, the rate of fractures is reduced thereby lowering fracture-related morbidity and mortality. The potential benefits of screening should outweigh the risks of screening (radiation exposure) or false positives (initiation of unnecessary treatment).

Bone Mineral Density

DXA is 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 generates 2 X-ray beams of different energy levels to scan the region of interest and measures the difference in attenuation as the low- and high-energy beams pass through the bone and soft tissue. The low-energy beam is preferentially attenuated by bone, while the high-energy beam is attenuated by both bone and soft tissue. This difference in attenuation between the 2 beams allows for correction for the irregular masses of soft tissue, which surrounds the spine and hip, and therefore the measurement of bone density at those sites.

A T-score is the standard deviation difference between an individual's BMD and that of a young adult reference population (Table 1).

Table 1. WHO Classification of Bone Mineral Density T-Scores

Assessment	BMD Definition
Normal	Bone density is within 1 SD (+1 or −1) of the young adult mean.

Assessment	BMD Definition
Osteopenia (low bone mass)	Bone density is between 1 and 2.5 SD below the young adult mean (−1 to −2.5 SD).
Osteoporosis	Bone density is 2.5 SD or more below the young adult mean (−2.5 SD or lower).
Severe (established) osteoporosis	Bone density is more than 2.5 SD below the young adult mean, and there have been one or more osteoporotic fractures.

BMD: bone mineral density; SD: standard deviation; WHO: World Health Organization.

Other Measurement Tools

Available diagnostic tools use either X-rays or ultrasound. X-ray based methods measure BMD. However, studies suggest that in addition to measuring structural aspects of the bone by assessing BMD, other mechanical features and elastic properties of the bone are also important to predict the risk of fractures. X-ray based methods cannot assess these properties and therefore the use of alternative methodologies such as ultrasound densitometry and quantitative computed tomography (CT) have been explored.

Quantitative Computed Tomography

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

Ultrasound Densitometry

Ultrasound densitometry is a technique for measuring BMD at peripheral sites, typically the heel but also the tibia and phalanges. Compared with osteoporotic bone, normal bone demonstrates higher attenuation of the ultrasound wave and is associated with a greater velocity of the wave passing through bone. Ultrasound densitometry has no radiation exposure, and machines may be purchased for use in an office setting.

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

Osteoporosis Treatment

Treatment of osteoporosis includes both lifestyle measures (e.g., increased intake of calcium and vitamin D, exercise, smoking cessation) and pharmacologic measures. Current pharmacologic options include bisphosphonates such as alendronate (i.e., Fosamax), selective estrogen receptor modulators such as raloxifene (i.e., Evista), the recombinant human parathyroid hormone teriparatide (i.e., Forteo), and calcitonin. A 2014 systematic review funded by the Agency for Healthcare Research and Quality found good-quality evidence that bisphosphonates, denosumab, teriparatide, and raloxifene reduce fracture risk in postmenopausal women with BMD in the osteoporotic range and/or preexisting hip or vertebral fracture.[2]

Summary of Evidence

For individuals who are eligible for screening of BMD based on risk factor assessment who receive DXA analysis of central sites (hip or spine), the evidence includes systematic reviews of randomized controlled trials (RCTs) and cohort studies. The relevant outcomes are morbid events, functional outcomes, quality of life, hospitalizations, and medication use. Central DXA is the most widely accepted method for measuring BMD and is the reference standard against which other screening tests are evaluated. BMD measurements with central DXA identify individuals at increased risk of fracture, and osteoporosis medications reduce fracture risk in the population identified as osteoporotic by central DXA. Therefore, test results with initial central DXA can be used to guide therapy. The evidence is sufficient to determine that the technology results in 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. The relevant outcomes are morbid events, functional outcomes, quality of life, hospitalizations, and medication use. Little research has been done on the frequency of BMD monitoring for osteoporosis. The available research has evaluated repeat measurement with central DXA. Evidence on whether repeat measurements add to risk prediction compared with a single measurement is mixed. Although the optimal interval may differ depending on risk factors, current evidence does not support repeat monitoring in individuals 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 individuals 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. The relevant outcomes are morbid events, functional outcomes, quality of life, hospitalizations, and medication use. There is no high-quality evidence to guide how often to monitor BMD during osteoporosis treatment. Within-person variation in measurement may exceed treatment effects, and fracture risk has been shown to be reduced in some treatment studies in the absence of changes in BMD. Together, these results suggest that frequent (i.e., every two years) repeat monitoring has low value. It is unclear whether DXA at the end of the initial five years of therapy is sufficiently accurate to guide subsequent therapy. The evidence is insufficient to determine 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 individuals 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, quantitative computed tomography, or DXA analysis of peripheral sites, the evidence includes observational studies and systematic reviews. The relevant outcomes are morbid events, functional outcomes, quality of life, hospitalizations, and medication use. In comparison with central DXA, other measures of bone health showed area under the curves around 0.80 for the identification of osteoporosis. These technologies are not commonly used for BMD measurements in practice, and no studies have shown that they can select individuals 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.

Ongoing and Unpublished Clinical Trials

A search of **ClinicalTrials.gov** in July 2024 did not identify any ongoing or unpublished trials that would likely influence this review.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a United States (US) professional society, an international society with US representation, or National Institute for Health and Care Excellence. Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American College of Obstetricians and Gynecologists

In 2021, the American College of Obstetricians and Gynecologists (ACOG) released clinical practice guidelines on the prevention, screening, and diagnosis of osteoporosis which was an update from their 2012 osteoporosis guidelines.[17] The guidelines recommended BMD screening in all women 65 years and older to prevent osteoporotic fractures. In addition, ACOG recommended screening for women younger than 65 years who are at increased risk of osteoporosis, with at least 1 risk factor, as listed below, or as determined by a formal clinical risk assessment tool. For example, a woman younger than 65 years of age may benefit from BMD screening if the Fracture Risk Assessment Tool indicates a 10-year risk of osteoporotic fracture of at least 8.4%. Risk factors that may put women younger than 65 at an increased risk include any of the following risk factors (they are similar, but not identical to risk factors in the Fracture Risk Assessment Tool):

- Increasing age
- Parental history of hip or spine fracture
- Body mass index less than 20 kg/m^2 or body weight less than 127 lbs.
- Smoking history
- Excessive alcohol use (i.e., more than 3 drinks daily)
- Conditions, diseases, and medications associated with secondary osteoporosis, including, but not limited to:
    - Acquired immunodeficiency syndrome and human immunodeficiency virus, anorexia nervosa, diabetes mellitus (type 1 and type 2), diminished ovarian reserve, gastric bypass,

hyperparathyroidism, hypocalcemia, premature menopause (induced, surgical, or spontaneous), primary ovarian insufficiency, renal impairment, rheumatoid arthritis, Turner syndrome, vitamin D deficiency

- Antiepileptic drugs (e.g., phenytoin, carbamazepine, primidone, and phenobarbital), antiretroviral drugs, aromatase inhibitors, chemotherapy, depot medroxyprogesterone acetate, glucocorticoids, gonadotropin-releasing hormone agonists, heparin.

ACOG also recommends repeat osteoporosis screening in postmenopausal women with initial BMD test results near treatment thresholds or with any significant changes in risk factors. For most patients, repeat BMD testing should be performed no sooner than 2 years after initial screening.

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).[18] 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 DXA [dual-energy X-ray absorptiometry] scores did not progress to osteoporosis within 15 years." These guidelines were updated in 2023, but BMD monitoring was not addressed in the update.[19]

American College of Radiology

The 2022 update of appropriateness criteria from the American College of Radiology states that BMD measurement is indicated whenever a clinical decision is likely to be directly influenced by the result of the test.[20] Indications for DXA of the lumbar spine and hip included but were not limited to the following patient populations:

1. All women aged 65 years and older and men aged 70 years and older (asymptomatic screening)
2. Women younger than age 65 years who have additional risk for osteoporosis, based on medical history and other findings. Additional risk factors for osteoporosis include:

a. Estrogen deficiency

b. A history of maternal hip fracture that occurred after the age of 50 years

c. Low body mass (less than 127 lbs. or 57.6 kg)

d. History of amenorrhea (more than 1 year before age 42 years)

3. Women younger than age 65 years or men younger than age 70 years who have additional risk factors, including:

    a. Current use of cigarettes

    b. Loss of height, thoracic kyphosis

4. Individuals of any age with bone mass osteopenia, or fragility fractures on imaging studies such as radiographs, computed tomography (CT), or magnetic resonance imaging (MRI)

5. Individuals aged 50 years and older who develop a wrist, hip, spine, or proximal humerus fracture with minimal or no trauma, excluding pathologic fractures

6. Individuals of any age who develop one or more insufficiency fractures

7. Individuals being considered for pharmacologic therapy for osteoporosis.

8. Individuals being monitored to:

    a. Assess the effectiveness of osteoporosis drug therapy.

    b. Follow-up medical conditions associated with abnormal BMD.

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 individuals 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)."

International Society for Clinical Densitometry

The 2019 update of the International Society for Clinical Densitometry official position statements recommended bone density testing in the following individuals:[22]

- "Women aged 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 body weight, prior fracture or high-risk medication use
- Men aged 70 and older
- Men < 70 years…if they have a risk factor 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."

In 2023, the International Society for Clinical Densitometry published an official position for follow-up BMD testing which makes the following recommendations: [23]

- " Follow-up BMD testing should be undertaken with clearly defined objectives and when the results are likely to influence patient management (Grade: good-A-W).
- Follow-up BMD testing should be performed if a fracture has occurred, or new risk factors have developed but should not delay treatment for secondary fracture prevention (Grade: fair-B-W).
- Follow-up BMD testing can aid in monitoring response to therapy (Grade: good-B-W).

- Repeat BMD testing intervals must be individualized considering an individual's age, baseline BMD, the type of pharmacological treatment and the presence of clinical risk factors which are associated with bone loss (Grade: good-B-W).
- Shorter intervals between BMD testing may be indicated in the presence of factors associated with rapid change in bone mineral density (Grade: fair-A-W).
- If changes in BMD are outside the expected range for an individual patient and scan quality has been confirmed, this should prompt re-evaluation of the patient and plan of care (Grade: fair-B-W).
- Repeat BMD testing should be used to monitor individuals prior to a temporary cessation of bisphosphonate therapy and during the period of planned interruption of treatment (Grade: Fair-B-W)."

National Osteoporosis Foundation

In 2022, the Bone Health and Osteoporosis Foundation (BHOF), formerly known as the National Osteoporosis Foundation, updated its practice guidelines.[24] The BHOF guidelines state that bone density measurements are not indicated unless test results will influence treatment and management decisions.

Indications for BMD testing recommended by the BHOF include:

- Women aged 65 and older and men aged 70 and older, regardless of clinical risk factors
- Postmenopausal women aged 50-64, regardless of clinical risk factors
- Men aged 50 to 69 years with risk factors for osteoporosis
- Adults aged 50 years and older who have a fracture
- Adults with a condition or taking a medication associated with low bone mass or bone loss

The BHOF stated that repeat bone densitometry should be done in individuals exhibiting signs of vertebral fracture, such as height loss or back pain.

The BHOF stated that measurements for monitoring individuals should be performed in accordance with medical necessity, expected response, and in consideration of local regulatory requirements. The BHOF recommended that a follow-up BMD assessment be performed after one year of initial therapy or a change in therapy, with longer intervals once an effective

treatment is established. The BHOF recommends repeat BMD assessments every two years in adults ages 65 years and older but recognized that testing more frequently may be warranted in certain clinical situations and should be guided by the clinical status of each individual.

US Preventive Services Task Force Recommendations

The US Preventive Services Task Force recommends screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in women 65 years and older and in postmenopausal women younger than 65 years who are at increased risk of osteoporosis, as determined by a formal clinical risk assessment tool (Grade B). The Task Force concluded that the current evidence is insufficient to assess the balance of benefits and harms of screening for osteoporosis to prevent osteoporotic fractures in men (Grade I).[3] These recommendations are currently undergoing an update and may be revised within the near future.

Medicare National Coverage

The Centers for Medicare and Medicaid pays for a screening bone mass measurement (BMM) once every two years (covered if 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 three months and confirming baseline BMMs to permit monitoring of beneficiaries in the future.

Conditions for coverage of BMM can be found in chapter 15, section 80.5 of Pub. 100-02, Medicare Benefit Policy Manual. Medicare covers BMM under the following conditions:

- "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 [Food and Drug Administration]-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)."

Regulatory Status

Devices that measure bone density have been cleared for marketing by the US Food and Drug Administration (FDA) through the 510(k) process. Some examples are described in **Table 2**:

Table 2. 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. FDA: US Food and Drug Administration

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.

References

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History

Date	Comments
09/08/14	New policy, add to Radiology section. Policy created based on a literature review through February 11, 2014. 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 when criteria are met. Repeat measurement of BMD may be considered

Date	Comments
	medically necessary when criteria are met. Policy approved with a hold for provider notification and will be effective February 15, 2015.
04/14/15	Annual Review. Policy updated with literature review through February 6, 2015; references 18, and 25-28 added and references 8, 23, 24 updated. Policy statement regarding initial measurement of women age <65 clarified. Repeat measurement now described in 3 categories – no osteoporosis/osteopenia, osteopenia and monitoring pharmacologic treatment. Interval of repeat testing when no osteoporosis/osteopenia is present has been changed to 5 years.
02/09/16	Annual Review. Policy updated with literature review through January 2016. Summary statement revised. No change to the policy statement.
12/01/16	Minor update approved November 8, 2016. Language added to the Rationale section to indicate that the age range specifications within this policy for which the initial measurement of bone mineral density is considered medically necessary to assess risk and need for therapy are based on covered preventive services outlined in the Patient Protection and Affordable Care Act, National Osteoporosis Foundation, American College of Physicians, and the American College of Radiology. No change in policy statements.
01/01/18	Annual Review, approved December 12, 2017. Policy moved into new format. Policy statements clarified, but the intent remains unchanged. References and Practice Guidelines were updated.
07/01/18	Coding update, added new CPT code 0508T, effective 7/1/18.
12/01/18	Annual Review, approved November 6, 2018. Reference 30 added. Policy statement unchanged.
02/01/19	Annual Review, approved January 22, 2019. Policy updated with literature review through October 2018; references 6, 12-13, 15, 18, and 21 added; some references removed. Policy statements unchanged except for minor editing for clarity.
04/01/20	Annual Review, approved March 3, 2020. Policy updated with literature review through November 2019; references added. Minor edits; otherwise policy unchanged.
04/01/21	Annual Review, approved March 2, 2021. Policy updated with literature review through December 3, 2020. Policy statements unchanged. Removed CPT codes 0508T, 78350, & 78351.
12/01/21	Interim Review, approved November 2, 2021. Policy updated with literature review through August 2, 2021; no references added. Policy statements unchanged except for minor edits made for greater clarity.
12/01/22	Annual Review, approved November 7, 2022. Policy updated with literature review through August 5, 2022; references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.

Date	Comments
12/01/23	Annual Review, approved November 6, 2023. Policy updated with literature review through July 20, 2023; references added. Policy statements unchanged.
12/01/24	Annual Review, approved November 11, 2024. Policy updated with literature review through July 16, 2024; reference added. Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.