

EFFECTIVE DATE: 02|01|2021
POLICY LAST UPDATED: 12|02|2020

OVERVIEW

Bone density 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 also available.

BlueCHiP for Medicare

This policy addresses bone density studies that are not covered for BlueCHiP for Medicare **OR** are covered and not considered preventive services. For bone density studies covered as preventive services, please refer to the Preventive Services for BlueCHiP for Medicare policy.

Commercial Products

This policy addresses bone density studies that are not medically necessary for Commercial Products **OR** are covered and not considered preventive services. For bone density studies covered as preventive services, please refer to the Preventive Services for Commercial Members policy.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Prior authorization review is not required.

POLICY STATEMENT

BlueCHiP for Medicare

Ultrasound bone density measurement using pulse-echo ultrasound is covered.

Bone density (bone mineral content) study, one or more sites; using single photon absorptiometry (SPA) or dual photon absorptiometry (DPA) is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

Bone densitometry testing, using Dual energy X Ray (DXA) of the axial skeleton (eg, hips, pelvis, spine), including vertebral fracture assessment is covered.

Bone densitometry testing, using Dual energy X Ray (DXA) of the appendicular skeleton (peripheral) (e.g. radius, wrist, heel) is covered.

Computed tomography bone mineral density study is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

Ultrasound bone density measurement, including using pulse-echo ultrasound and interpretation and single energy X-ray absorptiometry is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

Bone density (bone mineral content) study, one or more sites; using single photon absorptiometry (SPA) or dual photon absorptiometry (DPA) is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable Diagnostic Imaging, Lab and Machine Tests and not medically necessary/not covered benefits/coverage.

BACKGROUND

BONE MINERAL DENSITY

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 World Health Organization (WHO) has diagnostic thresholds for osteoporosis based on bone mineral density (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 using different techniques in a variety of central (i.e., hip or spine) or peripheral (i.e., wrist, finger, heel) sites. 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. These potential benefits of screening should outweigh the risks of screening (radiation exposure) or false positives (initiation of unnecessary treatment).

Osteoporosis Treatment

Treatment of osteoporosis includes both lifestyle measures (eg, increased intake of calcium and vitamin D, exercise, smoking cessation) and pharmacologic measures. Current pharmacologic options include bisphosphonates such as alendronate (ie, Fosamax), selective estrogen receptor modulators such as raloxifene (ie, Evista), the recombinant human parathyroid hormone teriparatide (ie, Forteo), and calcitonin. An updated 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.

The decision to perform 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 WHO Fracture Risk Assessment (FRAX) Tool2 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).

A 2011 joint position statement from the International Society for Clinical Densitometry and the International Osteoporosis Foundation included the official position that FRAX with BMD predicts risk of fracture better than clinical risk factors or BMD alone. In addition, the joint position statement indicated 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 patients to further assess or treat. The FRAX website states that this is a matter of clinical judgment and recommendations may vary by country.

Measurement Tools

The following technologies are most commonly used to measure BMD.

1. Dual X-Ray Absorptiometry (DXA)

DXA is probably the most commonly used technique to measure BMD because of its ease of use, low radiation exposure, and its ability to measure BMD at both the hip and spine. DXA can also be used to measure peripheral sites, such as the wrist and finger. DXA generates 2 x-ray beams of different energy levels to scan the region of interest and measure the difference in attenuation as the low- and high-energy beams pass through the bone and soft tissue. The low-energy beam is preferentially attenuated by bone, while the high-energy beam is attenuated by both bone and soft tissue. This difference in attenuation between the 2 beams allows for correction for the irregular masses of soft tissue, which surround the spine and hip, and therefore the measurement of bone density at those sites.

2. Quantitative Computed Tomography (QCT)

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

Dual x-ray absorptiometry (DXA) of axial central sites (ie, hip and spine) is the most commonly used technique, but peripheral (appendicular) DXA and quantitative computed tomography scanning are sometimes used, based on local availability. Peripheral measurement can identify patients with low bone mass but does not predict response to pharmacologic therapy and is not a substitute for central DXA measurements. Therefore, central DXA (hip/spine) is required for both the initial diagnosis and repeat bone mineral density (BMD) assessments.

Peripheral measurement of BMD may be appropriate:

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

3. Ultrasound Densitometry

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

These techniques dominate BMD testing. Single- and dual-photon absorptiometry and radiographic absorptiometry are now rarely used and may be considered obsolete.

An initial measurement of BMD at the hip or spine may be considered medically necessary to assess fracture risk and the need for pharmacologic therapy in both women and men who are considered at risk for osteoporosis. BMD testing may be indicated under the following conditions:

- Women age 65 and older, regardless of other risk factors;
- Men age 70 and older, regardless of other risk factors;
- Younger postmenopausal women about whom there is a concern based on their risk factors;
- Men age 50-70 about whom there is a concern based on their risk factors;
- Adults with a condition or taking a medication associated with low bone mass or bone loss.

Note: Covered DXA services must be provided on a device capable of performing a central DXA and must include permanent image storage, interpretation and report.

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 disease-specific survival, morbid events, functional outcomes, health status measures, quality of life, hospitalizations, medication use, and resource utilization. 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 the effects of the technology on health outcomes.

CODING

Please see the Preventive Services for BlueCHiP for Medicare or Preventive Services for Commercial Products policies for coverage of any CPT codes for bone density studies not listed below.

BlueCHiP for Medicare and Commercial Products

The following CPT codes are not covered for BlueCHiP for Medicare and not medically necessary for Commercial Products:

78350 Bone density (bone mineral content) study, one or more sites; single photon absorptiometry (SPA)

78351 Bone density (bone mineral content) study, one or more sites; dual photon absorptiometry (DPA)

BlueCHiP for Medicare

The following CPT code is covered for BlueCHiP for Medicare:

0508T Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia

Commercial Products

The following CPT codes are covered:

77081 Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)

77085 Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine), including vertebral fracture assessment

The following CPT codes are not medically necessary:

76977 Ultrasound bone density measurement and interpretation

77078 Computed tomography, bone mineral density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine)

G0130 Single energy X-ray absorptiometry (SEXA) bone density study, 1 or more sites; appendicular skeleton (peripheral) (e.g. radius, wrist, heel)

- 0508T** Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia
- 0554T** Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; retrieval and transmission of the scan data, assessment of bone strength and fracture risk and bone mineral density, interpretation and report
- 0555T** Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; retrieval and transmission of the scan data
- 0556T** Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; assessment of bone strength and fracture risk and bone mineral density
- 0557T** Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; interpretation and report
- 0558T** Computed tomography scan taken for the purpose of biomechanical computed tomography analysis

RELATED POLICIES

Preventive Services for Commercial
 Preventive Services for BlueCHiP for Medicare
 Vertebral Fracture Assessment

PUBLISHED

Provider Update, February 2021
 Provider Update, July 2019
 Provider Update, January 2019
 Provider Update, November 2017
 Provider Update, February 2017

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2. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD): Category III CPT® Codes (L33392)
3. Centers for Medicare and Medicaid Services (CMS). Local Coverage Article: Category III CPT® Codes- Related to Category III CPT® Codes (L33392) (A56195)
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