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Medical Policy Bone Mineral Density Studies

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Policy Number: 450

BCBSA Reference Number: 6.01.01 (For Plan internal use only)

Related Policies

- Vertebral Fracture Assessment with Densitometry, #449
- Bone Turnover Markers for Diagnosis and Management of Osteoporosis and Diseases Associated with High Bone Turnover, #<u>549</u>

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

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 <u>MEDICALLY NECESSARY</u> to assess 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 age 65 and older, regardless of other risk factors;
- Men age 70 and older, regardless of other risk factors;
- Younger postmenopausal women with an elevated risk factor assessment;*
- Men age 50 to 70 with an elevated risk factor assessment;*
- Adults with a condition associated with low bone mass or increased bone loss
- Adults taking a medication associated with increased bone loss.

*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 (insulindependent) 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 three months at a dose of prednisolone 5 mg daily or more (or equivalent doses of other glucocorticoids).

Repeat measurement of central (hip/spine) BMD using dual x-ray absorptiometry for individuals who previously tested normal may be considered <u>MEDICALLY NECESSARY</u> 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 <u>MEDICALLY NECESSARY</u> 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 measure of central (hip/spine) BMD using dual x-ray absorptiometry may be considered <u>MEDICALLY NECESSARY</u> 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 <u>MEDICALLY NECESSARY</u> 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.

BMD measurement using ultrasound densitometry is considered INVESTIGATIONAL.

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

BMD measurement using quantitative computed tomography is considered INVESTIGATIONAL.

Prior Authorization Information

Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed <u>inpatient</u>.

Outpatient

 For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above <u>medical necessity criteria MUST</u> be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

CPT Codes

CPT Codes	Code Description
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)

The following CPT codes are considered investigational for <u>Commercial Members: Managed Care</u> (HMO and POS), PPO, and Indemnity:

CPT Codes

CPT Codes	Code Description
0691T	Automated analysis of an existing computed tomography study for vertebral fracture(s), including assessment of bone density when performed, data preparation, interpretation, and report
0815T	Ultrasound-based radiofrequency echographic multi-spectrometry (REMS), bonedensity study and fracture-risk assessment, 1 or more sites, hips, pelvis or spine
76977	Ultrasound bone density measurement and interpretation, peripheral site(s), any method

Description

Osteoporosis

Osteoporosis is determined using the World Health Organization (WHO) diagnostic thresholds for osteoporosis based on bone mineral density (BMD) 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.

Bone mineral density can be measured either centrally (ie, hip or spine) or peripherally (ie, 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 (ie, vertebral fractures) are also considered to be the most clinically relevant. Bone mineral density 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 (radiation exposure) or false-positives (initiation of unnecessary treatment).

Bone Mineral Density

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 WHO Fracture Risk Assessment Tool^{1,} 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 (insulindependent) 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).

Dual x-ray absorptiometry (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. Dual x-ray absorptiometry 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).

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

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

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 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.

Note: Vertebral fracture assessment with DXA is addressed elsewhere (see MP #449).

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. 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

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.

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) 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. Bone mineral density 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 to 5 years in patients at low-risk using risk factor assessment. Similarly, multiple guidelines recommend a repeat screening interval of 1 to 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 to 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, 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.

Policy Hist	
Date	Action
11/2024	Annual policy review. References updated. Policy statements unchanged.
1/2024	Clarified coding information.
11/2023	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
11/2022	Annual policy review. References added. Minor editorial refinements to policy statements; intent unchanged.
1/2022	Clarified coding information.
10/2021	Annual policy review. Policy statements unchanged.
3/2021	Annual policy review. Minor edits to revise the last policy statement; other statements unchanged.
1/2021	Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference.
6/2020	Annual policy review. 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. Effective 6/1/2020.
2/2019	Annual policy review. Description, summary and references updated. Policy statements unchanged.
7/2018	Clarified coding information.
8/2017	Annual policy review. New medically necessary and investigational indications described. Policy statements edited to clarify that central dual x-ray absorptiometry (DXA) is medically necessary and other methods of measurement are investigational. Clarified coding information. Effective 8/1/2017.
1/2016	Added coding language.
5/2015	Annual policy review. New references added.
5/2014	Annual policy review. New references added.
5/2013	Annual policy review. New references added.
11/2011-	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No
4/2012	changes to policy statements.
10/2011	Updated to reflect coverage in accordance with National Health Care Reform.

Policy History

9/2011	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
1/2011	Annual policy review. No changes to policy statements.
10/2010	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
11/2009	Annual policy review. Changes to policy statements.
10/2009	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
10/2008	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
10/2007	Reviewed - Medical Policy Group - Urology and Obstetrics/Gynecology. No changes to policy statements.
8/2007	Annual policy review. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information: <u>Medical Policy Terms of Use</u> <u>Managed Care Guidelines</u> <u>Indemnity/PPO Guidelines</u> <u>Clinical Exception Process</u> <u>Medical Technology Assessment Guidelines</u>

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