



Medical Coverage Policy

Effective Date..... 4/15/2021
Next Review Date..... 4/15/2022
Coverage Policy Number 0300

Bone Mineral Density Measurement

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Related Coverage Resources

[eviCore Adult Musculoskeletal Imaging Guideline \(Osteoporosis\)](#)
[Preventive Care Services](#)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgement and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses bone mineral density measurement using various testing methods and vertebral fracture assessment by using dual-energy x-ray absorptiometry (DXA).

Coverage Policy

In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

SCREENING

Coverage for preventive care including bone mineral density measurement for screening for osteoporosis varies across plans. Refer to the customer's benefit plan document for coverage details.

Any of the following bone mineral density measurement testing methods is considered medically necessary as screening for osteoporosis:

- peripheral ultrasound (CPT® 76977)
- central dual x-ray absorptiometry (DXA) (CPT® 77080)
- peripheral DXA (CPT® 77081)
- peripheral single energy x-ray absorptiometry (HCPCS code G0130)

for ANY of the following indications:

- woman age ≥65 years
- postmenopausal women younger than 65 years who are at increased risk of osteoporosis, as determined by a formal clinical risk assessment tool (e.g., FRAX*)
- man age >50 years with at least one factor related to an increased risk of osteoporosis (i.e., age > 70, low body weight, weight loss >10%, physical inactivity, corticosteroid use, androgen deprivation therapy, hypogonadism and previous fragility fracture)

Computed tomography (CT) (CPT® 77078) for bone mineral density measurement testing is considered medically necessary as screening for osteoporosis when DXA scanner is unavailable or known to be inaccurate for ANY of the following indications:

- woman age ≥65 years
- postmenopausal women younger than 65 years who are at increased risk of osteoporosis, as determined by a formal clinical risk assessment tool (e.g., FRAX*)
- man age >50 years with at least one factor related to an increased risk of osteoporosis (i.e., age > 70, low body weight, weight loss >10%, physical inactivity, corticosteroid use, androgen deprivation therapy, hypogonadism and previous fragility fracture)

* Fracture Risk Assessment (FRAX®) tool, developed by the World Health Organization (Sheffield, United Kingdom)

Repeat bone density measurement is considered medically necessary every two years.

Bone mineral density measurement for screening for osteoporosis for any other population is considered experimental, investigational or unproven.

NON-SCREENING/MONITORING

Any of the following bone mineral density measurement testing methods is considered medically necessary:

- peripheral ultrasound (CPT® 76977)
- central dual x-ray absorptiometry (DXA) (CPT® 77080)
- peripheral DXA (CPT® 77081)
- peripheral single energy x-ray absorptiometry (HCPCS code G0130)

for ANY of the following indications:

- prior to and during pharmacologic treatment for osteoporosis*
- child or adolescent with a disease process known to adversely affect the skeleton
- known osteoporotic fracture
- individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture

*central DXA assessment of the hip or lumbar spine is preferred

Computed tomography (CT) (CPT® 77078) for bone mineral density measurement testing is considered medically necessary when DXA scanner is unavailable or known to be inaccurate for ANY of the following indications:

- multiple healed compression fractures
- significant scoliosis
- advanced arthritis of the spine due to increased cortical sclerosis often with large marginal osteophytes.
- follow-up in cases where QCT was the original study
- obese individual over the weight limit of the DXA exam table or BMI >35kg/m²
- extremes in body height (i.e., very large and very small individuals)
- extensive degenerative disease of the spine
- a clinical scenario that requires sensitivity to small changes in trabecular bone density (parathyroid hormone and glucocorticoid treatment monitoring)

Repeat bone density measurement is considered medically necessary no earlier than one year following a change in treatment regimen, and only when the results will directly impact a treatment decision.

Non-screening/monitoring bone mineral density measurement for any other indication is considered experimental, investigational or unproven.

PULSE-ECHO ULTRASOUND

Pulse-echo ultrasound for bone mineral density measurement testing is considered experimental, investigational or unproven (CPT® 0508T).

VERTEBRAL FRACTURE ASSESSMENT

Vertebral fracture assessment by dual-energy x-ray absorptiometry (DXA) for any indication is considered experimental, investigational or unproven.

General Background

Osteoporosis is the most common bone disease in humans; characterized by low bone mass, deterioration of bone tissue and disruption of bone architecture, compromised bone strength and an increase in the risk of fracture. Osteoporosis is a silent disease until it is complicated by fractures—fractures that can occur following minimal trauma. Osteoporosis can be prevented, diagnosed and treated before any fracture occurs. Importantly, even after the first fracture has occurred, there are effective treatments to decrease the risk of further fractures. It is estimated that 24.5% of women and 5.1% of men 65 years of age and over have osteoporosis of the femur neck or lumbar spine.

Bone Mineral Density (BMD)

Testing of bone mineral density (BMD) is useful for screening and monitoring therapy in people at high risk for osteoporosis (e.g., postmenopausal women, patients with hyperparathyroidism or other bone disorders, or those being treated with medications associated with bone loss [e.g., glucocorticoids]), if evidence of bone loss would result in modification of therapy. Testing of BMD is the gold standard in diagnosing osteoporosis; however, not everyone has access to BMD testing. Therefore, the decision to measure BMD should be based on an individual's clinical fracture risk profile and skeletal health assessment.

Dual-energy X-ray Absorptiometry (DXA) of the lumbar spine and proximal femur (hip) provides accurate and reproducible BMD measurements at important sites of osteoporosis-associated fracture. Optimally, both hips should be initially measured to prevent misclassification and to have a baseline for both hips in case a fracture or replacement occurs in one hip. These axial sites are preferred over peripheral sites for both baseline and serial measurements. The most reliable comparative results are obtained when the same instrument and, ideally, the same technologist are used for serial measurements at a high-quality DXA facility.

Diagnostic criteria, therapeutic studies, and cost-effectiveness data have been based primarily on DXA measurements of the total hip, femoral neck, and/or lumbar spine (L1 to L4) and are the preferred measurement sites. The 1/3 radius can also be used as a diagnostic site, particularly when other preferred sites are not

available. Use of other subregions within the proximal femur (i.e., Ward's triangle or trochanter) or of an individual vertebra has not been validated and is not recommended.

For BMD measurement, several other techniques are available, including quantitative computed tomography for measurement of both central and peripheral sites, quantitative ultrasonometry, radiographic absorptiometry, and single-energy X-ray absorptiometry. Peripheral bone density measurements can identify patients at increased risk for fracture; however, the diagnostic DXA criteria established by the World Health Organization (WHO) and recommended by the American Association of Clinical Endocrinologists (AACE) apply only to the axial measurements (i.e., lumbar spine, femoral neck, and total hip) and distal 1/3 of the radius. Thus, other technologies should not be used to diagnose osteoporosis but may be used to assess fracture risk (American Association of Clinical Endocrinologists/Camacho, et al., 2020).

FRAX®

BMD testing is a powerful tool, but clinical risk factors also significantly influence fracture risk in individual patients. The FRAX® (Fracture Risk Assessment) tool is widely available and incorporates multiple clinical risk factors that predict fracture risk, largely independent of BMD. The FRAX® tool has been developed by World Health Organization Collaborating Centre for Metabolic Bone Diseases (Sheffield, United Kingdom) to evaluate fracture risk of patients. It is based on individual patient models that integrate the risks associated with clinical risk factors as well as BMD at the femoral neck. The FRAX models have been developed from studying population-based cohorts from Europe, North America, Asia and Australia. In their most sophisticated form, FRAX is available on newer DXA machines or with software upgrades that provide the FRAX scores on the bone density report. The FRAX tool is computer-driven and is available online. Also, several simplified paper versions, based on the number of risk factors are also available, and can be downloaded for office use. The FRAX algorithms give the 10-year probability of fracture. The output is a 10-year probability of hip fracture and the 10-year probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture).

Professional Societies/Organizations

National Osteoporosis Foundation (NOF): The NOF Clinician's Guide to Prevention and Treatment of Osteoporosis (Cosman, et. al., 2014/2015) states BMD testing should be performed:

BMD testing should be performed:

- in women age 65 and older and men age 70 and older,
- in postmenopausal women and men above age 50-69, based on risk factor profile.
- in post-menopausal women and men over age 50 who have had an adult age fracture, to diagnose and determine degree of osteoporosis.
- at DXA facilities using accepted quality assurance measures.

DXA measurement of the hip and spine is the gold standard used to establish or confirm a diagnosis of osteoporosis, predict future fracture risk, and monitor patients. Measurement by validated pDXA devices can be used to assess vertebral and overall fracture risk in postmenopausal women. pDXA is not appropriate for monitoring BMD after treatment. Validated heel quantitative ultrasound densitometry (QUS) devices predict fractures in postmenopausal women (vertebral, hip, and overall fracture risk) and in men 65 and older (hip and non-vertebral fractures). QUS is not appropriate for monitoring response to therapy. In postmenopausal women, QCT measurement of spine trabecular BMD can predict vertebral fractures, whereas pQCT of the forearm at the ultradistal radius predicts hip but not vertebral fractures. pDXA, pQCT, and QUS Peripheral skeletal sites do not respond with the same magnitude as the spine and hip to medications and thus are not appropriate for monitoring response to therapy at this time.

Peripheral dual-energy x-ray absorptiometry (pDXA) and quantitative ultrasound densitometry (QUS) are often used for community-based screening programs because of the portability of the equipment. Results are not equivalent to DXA and abnormal results should be confirmed by physical examination, risk assessment, and central DXA.

United States Preventive Services Task Force (USPSTF): The USPSTF (2018) Osteoporosis to Prevent Fractures: Screening recommendations:

- The USPSTF recommends screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in women 65 years and older (Grade B - The USPSTF recommends the service).
- The USPSTF recommends screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures 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 USPSTF recommends the service).
- The USPSTF concludes 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 – Insufficient).

Several tools are available to assess osteoporosis risk: the Simple Calculated Osteoporosis Risk Estimation (SCORE; Merck), Osteoporosis Risk Assessment Instrument (ORAI), Osteoporosis Index of Risk (OSIRIS), and the Osteoporosis Self-Assessment Tool (OST). These tools seem to perform similarly and are moderately accurate at predicting osteoporosis. The FRAX tool (University of Sheffield), which assesses a person's 10-year risk of fracture, is also a commonly used tool.

American Association of Clinical Endocrinologists (AACE): The AACE and American College of Endocrinology (ACE) Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis (Camacho, et. al., 2020) list these indications for bone mineral density testing:

- All women 65 years of age or older
- All postmenopausal women
 - With a history of fracture(s) without major trauma
 - With osteopenia identified radiographically
 - Starting or taking long-term systemic glucocorticoid therapy (≥3 months)
- Other perimenopausal or postmenopausal women with risk factors for osteoporosis if willing to consider pharmacologic interventions
 - Low body weight (<127 lb or body mass index <20 kg/m²)
 - Long-term systemic glucocorticoid therapy (≥3 months)
 - Family history of osteoporotic fracture
 - Early menopause
 - Current smoking
 - Excessive consumption of alcohol
- Secondary osteoporosis

American College of Radiology (ACR): The ACR Appropriateness Criteria® for Osteoporosis and Bone Mineral Density (2016) address various testing modalities in the scenario of asymptomatic BMD screening or screening individuals with established or clinically suspected low BMD (e.g., older women):

- DXA: DXA bone densitometry measurement of BMD has been shown to accurately predict fracture risk. DXA is the mainstay of bone densitometry and a clinically proven method of measuring BMD in the lumbar spine, proximal femur, forearm, and whole body. DXA is utilized as an initial screening and follow-up method to evaluate therapy for osteopenia and osteoporosis. DXA accuracy and reproducibility has led to the establishment of standards for the diagnosis of osteoporosis set forth by the WHO. BMD, as measured by DXA, aids in determining fracture risk when compared to a gender-matched asymptomatic reference population. Two sites are routinely evaluated with DXA: the lumbar spine and hip. The third site, the forearm, is primarily utilized for patients with hyperparathyroidism.
- Peripheral Ultrasound: Peripheral ultrasound (QUS) represents a low-cost alternative easily accessible to primary care providers. The heel represents the only validated site for the clinical use of QUS. QUS does not measure BMD and therefore the WHO classification system cannot be utilized and a diagnosis of osteoporosis cannot be made. Additionally, discordance between QUS and central DXA is not infrequent. However, QUS in conjunction with clinical risk factors can predict an increased risk for fractures as well as identifying populations that demonstrate no increased risk.

- Quantitative Computed Tomography (QCT): QCT provides a volumetric BMD, in contrast to the areal BMD of the DXA, which is based on a 2-D projectional area measurement. QCT can be performed on the vast majority of commercially available CT scanners, provided they include densitometry analysis software. The WHO's spine T-scores that define osteoporosis were derived from DXA measurements and do not apply to QCT. Projectional QCT of the hip, by contrast, provides a calculated post-processed areal BMD that is comparable to DXA, thus enabling the use of the WHO classification system. Indications for QCT include the same indications as DXA; however, DXA is recommended as the first-line screening and follow-up test for bone density. If DXA is not available, QCT may be used as a secondary technique. Specific cases in which QCT is considered superior to DXA include:
 - extremes in body height (ie, very large and very small patients)
 - patients with extensive degenerative disease of the spine
 - severely obese patients (BMI >35 kg/m²)
 - a clinical scenario that requires increased sensitivity to small changes in trabecular bone density (parathyroid hormone and glucocorticoid treatment monitoring)
- In males and females >50 years of age with advanced degenerative changes of the spine with or without scoliosis, QCT is ideally suited for the evaluation of the vertebral body in the setting of advanced degeneration as it selectively samples only the cancellous portion of the vertebral body, excluding the end plates, cortices, and posterior elements. Sensitivity to change is greater in QCT than in DXA in degenerative spines.
- Peripheral QCT: pQCT utilizes scans of the forearm. pQCT radiation is low relative to central QCT and its accuracy is superior to DXA. However, correlation with central DXA is poor and the high variability of positioning limits the use of pQCT as a screening tool. The WHO classification cannot be utilized. pQCT of the forearm has been shown to predict hip, but not spine, fractures in postmenopausal women. There is a lack of evidence to support utilization for men.
- Other: Although radiographs may detect fragility fractures, their use as a primary screening tool is limited due to their low sensitivity to bone loss. DXA is utilized at the forearm and is less expensive than central DXA. BMD evaluation is comparable at the forearm with DXA. However, the tests are substantially less predictive of hip and spine fractures relative to central DXA.

The ACR Practice Guideline for the Performance of Dual-energy x-ray Absorptiometry (DXA) (2018) states that dual-energy X-ray absorptiometry (DXA) is a clinically proven, accurate, and reproducible method of measuring bone mineral density (BMD) in the lumbar spine, proximal femur, forearm, and whole body. It is used primarily in the diagnosis and management of osteoporosis and other disease states characterized by abnormal BMD, as well as to monitor response to therapy for these conditions. DXA may also be used to measure whole-body composition, including non-bone lean mass (LM) and fat mass (FM). DXA-measured LM and FM may be helpful in assessing a number of conditions, including sarcopenia and cachexia.

Contraindications: There are no absolute contraindications to performing DXA. However, a DXA examination may be of limited value or require modification of the technique or rescheduling of the examination in some situations, including:

- Recently administered oral contrast or radionuclides
- Pregnancy
- Severe degenerative changes or fracture deformity in the measurement area
- Implants, hardware, devices, or other foreign material in the measurement area
- The patient's inability to attain correct position and/or remain motionless for the measurement
- Extremes of high or low body mass index that may adversely affect the ability to obtain accurate measurements. QCT may be a desirable alternative in these individuals.

The ACR Practice Guideline for the Performance of Quantitative Computed Tomography (QCT) Bone Densitometry (2018) states that musculoskeletal quantitative computed tomography (QCT) can be used to accurately and reproducibly measure bone mass or muscle mass. QCT is a clinically proven method of

measuring bone mineral density (BMD) in the spine and proximal femur. QCT is used primarily in the diagnosis and management of osteoporosis and other disease states that may be characterized by abnormal BMD, as well as to monitor response to therapy for these conditions.

For BMD measurement, QCT has some advantages over dual-energy X-ray absorptiometry (DXA). DXA measurements may be significantly biased by severe degenerative changes of the hip or spine, vascular calcifications, oral contrast agents, and foods or dietary supplements containing significant quantities of calcium or other heavier minerals or elements. QCT is also accurate in patients with extremely high or low body mass index.

Contraindications: There are no absolute contraindications to performing QCT. However, a QCT examination may be of limited value or require modification of the technique or rescheduling of the examination in some situations, including:

- Administration of intravascular iodinated contrast. If a QCT of the spine and contrast enhanced examination of the abdomen are performed simultaneously, the bone or muscle may be altered by the contrast enhancement.
- Pregnancy
- Severe degenerative changes or fracture deformity in the measurement area
- Implants, hardware, devices, or other foreign material in the measurement area
- Inability to position the patient completely within the scanning field of view

American College of Obstetricians and Gynecologists (ACOG): ACOG Practice Bulletin Osteoporosis (2012, reaffirmed 2019) states:

All major guidelines state that DXA screening should begin at age 65 years for women. Most guidelines also agree that DXA screening can be used selectively for women younger than 65 years if they are postmenopausal and have other risk factors for fracture. Alternatively, FRAX can be used in women younger than 65 years to determine which women should have a DXA scan. Those women with a FRAX 10-year risk of major osteoporotic fracture of 9.3% could justifiably be referred for DXA because that is the risk of fracture found in a 65-year-old Caucasian woman with no risk factors. Routine screening of newly menopausal women is not recommended nor is a “baseline” screen recommended. After treatment initiation, one DXA scan 1 year or 2 years later can be used to assess the effect of treatment. If the BMD is improved or stable (no significant change), the DXA does not usually need to be repeated in the absence of new risk factors. Testing generally should not be undertaken before 2 years after initiation of treatment because it often takes 18–24 months to document a clinically meaningful change.

When to Screen for Bone Density Before Age 65 Years

Bone density should be screened in postmenopausal women younger than 65 years if any of the following risk factors are noted:

- medical history of a fragility fracture
- body weight less than 127 lb
- medical causes of bone loss (medications or diseases)
- parental medical history of hip fracture
- current smoker
- alcoholism
- rheumatoid arthritis

Recommendations regarding screening:

- bone density screening for women should begin at age 65 years. Dual-energy X-ray absorptiometry screening can be used selectively for women younger than 65 years if they are postmenopausal and have other significant risk factors for osteoporosis or fracture
- in the absence of new risk factors, DXA screening should not be performed more frequently than every 2 years

- in the absence of new risk factors, DXA monitoring of therapy should not be repeated once BMD has been determined to be stable or improved

The American Board of Internal Medicine's (ABIM) Foundation Choosing Wisely® Initiative: The American College of Rheumatology (2013) recommends not routinely repeating DXA scans more often than once every two years. The American Academy of Family Physicians (2012) recommends that DXA scan not be used for screening for osteoporosis in women younger than 65 or men younger than 70 with no risk factors. The American Academy of Family Physicians states 'Don't use dual-energy x-ray absorptiometry (DEXA) screening for osteoporosis in women younger than 65 or men younger than 70 with no risk factors' (Released April 4, 2012).

Men

For men, osteoporosis is associated with increased morbidity and mortality, specifically following a fracture. This relationship is complex depending on multiple factors including comorbidities, the fragility of the individual, and even the implementation of measures to prevent fractures, i.e., fall prevention. The clinical measurement of bone mineral density using DXA remains the gold standard for diagnosis of osteoporosis in males; and fracture risk assessment is now recognized as a preferred approach to guide treatment decisions. Utilizing surrogate end-points such as increasing bone mineral density and decreasing concentrations of bone resorption markers, clinical trials have demonstrated efficacy in pharmacological treatment of osteoporosis in the adult male. Unfortunately, few studies have evaluated the anti-fracture benefits in this population (Korpi-Steiner, et al., 2014).

In a review article, Adler et al. (2018) recommends targeted DXA testing for osteoporosis in men:

- Age ≥80
- Oral Glucocorticoid Use
- Androgen Deprivation Therapy for Prostate Cancer
- High Pre-screening FRAX Risk Score using BMI instead of BMD
- Age ≥65 plus at least one of the following: Traditional Anti-Epileptic Drugs, Rheumatoid Arthritis, Alcohol Abuse, Current Smoking, BMI <25 kg/m², Hyperthyroidism, Hyperparathyroidism, Chronic Obstructive Pulmonary Disease, Chronic Liver Disease, Stroke, Parkinson's Disease, Gastrectomy

The NOF Clinician's Guide to Prevention and Treatment of Osteoporosis (Cosman, et. al., 2014/2015) states BMD testing should be performed in men:

- age 70 and older, regardless of clinical risk factors
- age 50-69, with clinical risk factors for fracture
- over age 50 who have had an adult age fracture
- with a condition (e.g., rheumatoid arthritis) or taking a medication (e.g., glucocorticoids in a daily dose ≥ 5 mg prednisone or equivalent for ≥ three months) associated with low bone mass or bone loss

The USPSTF (2018) Osteoporosis to Prevent Fractures Screening recommendations state 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 – Insufficient).

The Endocrine Society Clinical Practice Guideline on Osteoporosis in Men recommends BMD testing should be performed in men who are higher risk men (aged ≥70 and men aged 50–69 who have risk factors (e.g. low body weight, prior fracture as an adult, smoking, etc.) The Endocrine Society recommends using DXA of the spine and hi or forearm DXA (when spine or hip BMD cannot be interpreted) and for men with hyperparathyroidism or receiving androgen deprivation therapy (ADT) for prostate cancer (Watts, et al., 2012).

Serial BMD

The NOF Clinician's Guide to Prevention and Treatment of Osteoporosis (Cosman, et. al., 2014/2015) states:

- Perform BMD testing 1 to 2 years after initiating therapy to reduce fracture risk and every two years thereafter.
- More frequent testing may be warranted in certain clinical situations.
- The interval between repeat BMD screenings may be longer for patients without major risk factors and who have an initial T-score in the normal or upper low bone mass range.

The USPSTF (2018 Statement) Screening Intervals section states “Some observational and modeling studies have suggested screening intervals based on age, baseline BMD, and calculated projected time to transition to osteoporosis. However, limited evidence from 2 good-quality studies found no benefit in predicting fractures from repeating bone measurement testing 4 to 8 years after initial screening”.

Regarding monitoring treatment, the American Association of Clinical Endocrinologists (AACE) state to repeat DXA every 1 to 2 years until findings are stable. The 1/3 radius may be considered as an alternate site when the lumbar spine/hip are not evaluable or as an additional site in patients with primary hyperparathyroidism. Continue with follow-up DXA every 1 to 2 years or at a less frequent interval, depending on clinical circumstances. Follow-up of patients should ideally be conducted in the same facility with the same DXA system (Camacho, et al., 2020).

Vertebral Fracture Assessment (VFA)

The gold standard for diagnosing vertebral fractures is lateral spine x-rays. Image quality of VFA by DXA has been reported in studies as equal to and inferior to radiography, with sensitivity and specificity ranging from 0.65–0.84 and 0.97–0.98, respectively. Image quality was inferior with VFA, resulting in 14 missed VFs in the consensus VFA results. The main limitation related to VFA is the inferior resolution of image quality compared with other techniques, particularly in the upper thoracic spine. Proponents of VFA propose vertebral fracture is an independent risk factor for incident fragility fracture. However, if a vertebral fracture is identified in an asymptomatic individual, studies generally do not report the impact of that finding on long-term health outcomes including changes in treatment based on vertebral fracture identification (Shetty, et al., 2020; Borges, et al., 2017; Deleskog, et al., 2016; Lee, et al., 2016; Bazzocchi et al. 2012; Fuerst, et al., 2009).

Lee et al. (2016) conducted a systematic review of diagnostic accuracy of vertebral fracture assessment (VFA) and concluded VFA had moderate sensitivity and high specificity for detecting VF when compared with spinal radiography. The author noted that the findings are insufficient to assess whether spinal radiography should be replaced by VFA.

Cai et al. (2020) retrospective evaluated 502 postmenopausal women aged ≥ 50 years with no pain or chronic pain in the lumbar spine. This was the first BMD measurement, and participants had no treatment with any anti-osteoporotic therapy. The population included 71 patients with recognized fragility fractures before BMD assessment (4 patients had a single level of vertebral fracture, 22 patients had multiple levels of vertebral fractures, and 45 patients had non-vertebral fractures [hip, proximal humerus, distal radius]). There were 162 patients (32.3%) with 345 fractured vertebrae identified by VFA. Among 162 fractured patients identified by VFA, 26 (22+4) patients had the recognized vertebral fractures before BMD assessment and 136 (84%) were newly identified. The authors noted that the diagnosis rate of osteoporosis and severe osteoporosis was increased from 257 patients (51.2%) by BMD alone to 301 patients (60%) by both BMD and VFA. The authors stated that among 313 patients with osteoporosis or severe osteoporosis, 221 patients received bisphosphonate medications. Also, the author said that VFA changed the osteoporosis management in 27 patients out of 211 patients receiving bisphosphonate medications who did not meet the BMD standard of osteoporosis and the indication for bisphosphonate medications by DXA alone.

American Association of Clinical Endocrinologists (AACE): The AACE and American College of Endocrinology (ACE) Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis (Camacho, et. al., 2020) states Lateral spine imaging with standard radiography or VFA with DXA is indicated when:

- T-score is less than -1.0 AND One or more of the following is present:
- Women aged ≥ 70 years or men aged ≥ 80 years
- Historical height loss >4 cm (>1.5 inches)

- Self-reported but undocumented prior vertebral fracture
- Glucocorticoid therapy equivalent to ≥ 5 mg of prednisone or equivalent per day for ≥ 3 months

USPSTF: The most recent recommendation from the U. S. Preventive Services Task Force on screening for osteoporosis does not address this technology.

National Osteoporosis Foundation (NOF): The NOF Clinician's Guide to Prevention and Treatment of Osteoporosis (Cosman, et. al., 2014/2015) states Because vertebral fractures are so prevalent in older individuals and most produce no acute symptoms, consider vertebral imaging tests for the following individuals***:

- all women age 70 and older and all men age 80 and older if BMD T-score at the spine, total hip or femoral neck is ≤ -1.0
- women age 65 to 69 and men age 70 to 79 if BMD T-score at the spine, total hip or femoral neck is ≤ -1.5
- postmenopausal women and men age 50 and older with specific risk factors:
 - low trauma fracture during adulthood (age 50)
 - historical height loss of 1.5 inches or more (4 cm)*
 - prospective height loss of 0.8 inches or more (2 cm)**
 - recent or ongoing long term glucocorticoid treatment

* Current height compared to peak height during young adulthood

** Cumulative height loss measured during interval medical assessment

*** If bone density testing is not available, vertebral imaging may be considered based on age alone (NOF 2014).

Pulse-echo Ultrasound (CPT® 0508T)

The Bindex BI-100 device (Bindex® Osteoporosis Measurement, Bone Index Ltd., Finland) received FDA 510(k) approval on May 13, 2016 (K152020). The Bindex® BI-2 device (Bone Index Ltd., Finland) received FDA 510(k) approval on January 9, 2017 (K161971). According to the FDA, Bindex® measures apparent cortical bone thickness at the proximal tibia and can be used in conjunction with other clinical risk factors or patient characteristics as an aid to the physician in the diagnosis of osteoporosis and other medical conditions leading to reduced bone strength and in the determination of fracture risk.

The Bindex system includes ultrasound pulser, transducer and software. Bindex is connected to the USB port of a computer and controlled with computer software. Bindex is used for measurement of cortical bone thickness and it provides Density Index (DI), a parameter which estimates bone mineral density at the hip as measured with DXA. Published articles suggest pulse-echo ultrasound Density Index (DI) algorithm be used in conjunction with established fracture risk assessment tools (for example, FRAX) to aid in determining whether referral for DXA scan is appropriate.

The peer-reviewed scientific literature lacks well-designed studies evaluating the impact of Bindex® on long-term health outcomes (Lewiecki, 2020; Karjalainen, et al., 2018; Schousboe, et al., 2017).

The American Association of Clinical Endocrinologists (AACE) states For BMD measurement, several other techniques are available, including quantitative computed tomography for measurement of both central and peripheral sites, quantitative ultrasonometry, radiographic absorptiometry, and single-energy X-ray absorptiometry. The AACE also notes that peripheral bone density measurements can identify patients at increased risk for fracture; however, the diagnostic DXA criteria established by the WHO and recommended by AACE apply only to the axial measurements (i.e., lumbar spine, femoral neck, and total hip) and distal 1/3 of the radius. Thus, other technologies should not be used to diagnose osteoporosis but may be used to assess fracture risk (Camacho, et al., 2020).

The American College of Radiology (ACR) Appropriateness Criteria® for Osteoporosis and Bone Mineral Density (2016) address various testing modalities in the scenario of asymptomatic BMD screening or screening individuals with established or clinically suspected low BMD (e.g., older women). The ACR noted that although peripheral ultrasound (QUS) represents a low-cost alternative easily accessible to primary care providers, the heel represents the only validated site for the clinical use of QUS.

Use Outside of the US

International Society for Clinical Densitometry (ISCD): The ISCD Official Adult Position (2019) indications for BMD Testing:

- 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 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.
- For men < 70 years of age a bone density test is indicated 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.
- Adults taking medications 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 who evidence of bone loss would lead to treatment.

Note: Women discontinuing estrogen should be considered for bone density testing according to the indications listed above.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Bone (Mineral) Density Studies (150.3)	01/01/2007
LCD	First Coast Service Options, Inc.	Bone Mineral Density Studies (L36356)	02/05/2019

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

- Note:** 1) This list of codes may not be all-inclusive.
 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
76977	Ultrasound bone density measurement and interpretation, peripheral site(s), any method
77078	Computed tomography, bone mineral density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine)
77080	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine)

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

HCPCS Codes	Description
G0130	Single energy X-ray absorptiometry (sexa) bone density study, one or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)

Considered Experimental/Investigational/Unproven:

CPT®* Codes	Description
77085	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine), including vertebral fracture assessment
77086	Vertebral fracture assessment via dual-energy x-ray absorptiometry (DXA)
0508T	Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia

***Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.**

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