Medical Coverage Policy

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Bone Mineral Density Measurement

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Related Coverage Resources

eviCore 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 judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted

for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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, vertebral fracture screening, bone strength and fracture-risk assessment.

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)

for ANY of the following indications:

- women ≥ 65 years of age and men ≥ 70 years of age
- younger postmenopausal women, women in the menopausal transition, and men aged 50 to 69 years with clinical risk factors for fracture (see Appendix)
- adults who have a fracture at age 50 years and older
- adults with a condition (e.g., rheumatoid arthritis, organ transplant) or taking a medication (e.g., glucocorticoids, aromatase inhibitors, androgen deprivation therapy) associated with low bone mass or bone loss

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:

- women ≥ 65 years of age and men ≥ 70 years of age
- younger postmenopausal women, women in the menopausal transition, and men aged 50 to 69 years with clinical risk factors for fracture (see Appendix)
- adults who have a fracture at age 50 years and older
- adults with a condition (e.g., rheumatoid arthritis, organ transplant) or taking a medication (e.g., glucocorticoids, aromatase inhibitors, androgen deprivation therapy) associated with low bone mass or bone loss

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 not medically necessary.

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)

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 not medically necessary.

VERTEBRAL FRACTURE ASSESSMENT/SCREENING

Vertebral fracture assessment from dual-energy x-ray absorptiometry (DXA) (CPT® 77085-77086) is considered medically necessary for ANY of the following individuals***:**

- women aged ≥ 65 years and all men aged ≥ 80 years if T-score at the lumbar spine, total hip, or femoral neck is ≤ − 1.0

- men aged 70 to 79 years if T-score at the lumbar spine, total hip, or femoral neck is ≤ −1.5
- postmenopausal women and men age ≥ 50 years with the following specific risk factors:

    - fracture during adulthood (age ≥ 50 years)
    - historical height loss of 1.5 in. or more*
    - prospective height loss of 0.8 in. or more**
    - recent or ongoing long-term glucocorticoid treatment
    - medical conditions associated with bone loss such as hyperparathyroidism

*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

Vertebral fracture assessment from imaging scans other than DXA (e.g., CPT® 0691T, 0743T) for any indication is not covered or reimbursable.

BONE STRENGTH AND FRACTURE RISK ASSESSMENT

Bone strength and fracture risk assessment from imaging scans other than DXA (e.g., CPT® 0554T-0557T, 0558T, 0743T, 0749T-0750T) for any indication is considered experimental, investigational or unproven.

PULSE-ECHO ULTRASOUND (CPT® 0508T, 76999)

Pulse-echo ultrasound for bone mineral density measurement testing is considered experimental, investigational or unproven

TRABECULAR BONE SCORE (TBS) (CPT® 77089 – 77092)

Trabecular bone score for any indication is considered experimental, investigational or unproven.

RADIOFREQUENCY ECHOGRAPHIC MULTI-SPECTROMETRY (REMS) (CPT® 0815T)

Ultrasound-based radiofrequency echographic multi-spectrometry (REMS) for bone density study and fracture-risk assessment is considered experimental, investigational or unproven.

Health Equity Considerations

There is significant disparity in osteoporosis screening among racial and ethnic minorities. Calikyan et al. (2023) conducted a systematic review assessing the racial and ethnic disparities that exist for osteoporosis screening by DXA. A total of 16 studies were included in the final review. The authors noted the overall quality of the studies included was high. Of the 16 articles reviewed, the authors stated that 14 identified significant disparities between racial minority and majority groups and determined that the eligible patients in racial minority groups were less likely to be referred to DXA screening.

General Background

Bone Mineral Density Measurement

A bone mineral density (BMD) test measures calcium and other minerals in bone. Bones containing more minerals are denser, so they tend to be stronger and less likely to break. Bones can become less dense from aging or from certain medical conditions. When too much bone is lost, osteoporosis can develop. Osteoporosis causes bones to become weak and brittle, which increases the risk of fractures.

Bone mineral density testing can:

- Identify and diagnose osteoporosis.
- Measure the risk of fractures (broken bones).
- Monitor the effectiveness of osteoporosis treatment.

Tests

The most common bone mineral density test is a central dual energy x-ray absorptiometry (DXA or DEXA). DXA uses radiation to measure how much calcium and other minerals are in a specific area of your bone. Because the weak bones that tend to break most often are the hip and spine, DXA usually measures bone mineral density in these bones. Other tests can also measure bone mineral density or bone loss:

- Quantitative ultrasound (QUS) of the heel: Shows pictures of your bone and can predict your risk of broken bones and osteoporosis. But it is not used to monitor response to osteoporosis treatment, and it does not measure bone mineral density or give as much information as DXA. If the QUS shows that you have a higher risk of osteoporosis or broken bones, your doctor may recommend a central DXA test to confirm the finding.

- Peripheral DXA: Measures bone mineral density, usually in the wrist and heel, using a portable device. This test does not give as much information as central DXA, so it is less accurate. Results showing a higher risk of broken bones or osteoporosis may need to be confirmed with a central DXA test.

T-score

A T-score is the difference between your bone mineral density and 0, which is the bone mineral density of a healthy young adult. The lower your T-score, the higher your risk of bone fracture. If your T-score is:

- 1 or higher, your bone is healthy.
- −1 to −2.5, you have osteopenia, a less severe form of low bone mineral density than osteoporosis.
- −2.5 or lower, you might have osteoporosis.

The risk of broken bones increases by 1.5 to 2 times with each 1-point drop in the T-score.

Z-score

The Z-score is the difference between your bone mineral density and the average bone mineral density for healthy people of your age, ethnicity, and sex. If your Z-score is −2.0 or less, your bone mineral density is low. This score could mean that you have osteoporosis caused by medications or other diseases and conditions.

FRAX

Bone mineral density measurement tests are not the only tools that doctors use to predict your risk of fractures. Doctors may use the Fracture Risk Assessment Tool (FRAX) to estimate risk for fracture. This score uses your age, sex, medical history, country, and other factors. This information, along with your bone mineral density test results, can help health care providers understand your risk for fracture and can guide treatment. For people with osteoporosis or osteopenia, the FRAX score can predict the chances of a major fracture in the next 10 years. The

FRAX score can also screen women in postmenopause younger than age 65 for osteoporosis risk (National Institutes of Health).

Bone Health & Osteoporosis Foundation (BHOF) / (previously known as National Osteoporosis Foundation (NOF): The BHOF Clinician's Guide to Prevention and Treatment of Osteoporosis (LeBoff, et al., 2022) states Consider BMD testing in the following individuals:

- Women ≥ 65 years of age and men ≥ 70 years of age, regardless of clinical risk factors
- Younger postmenopausal women, women in the menopausal transition, and men aged 50 to 69 years with clinical risk factors for fracture
- Adults who have a fracture at age 50 years and older
- Adults with a condition (e.g., rheumatoid arthritis, organ transplant) or taking a medication (e.g., glucocorticoids, aromatase inhibitors, androgen deprivation therapy) associated with low bone mass or bone loss

DXA measurement of hip and lumbar spine is the preferred method for establishing and/or confirming a diagnosis of osteoporosis, predicting future fracture risk, and monitoring patients. Areal BMD by DXA is expressed in absolute terms of grams of mineral per square centimeter scanned (g/cm2) and as a relationship to two BMD norms: an age-, sex-, and ethnicity-matched reference population (Z-score), or a young-adult reference population (T-score).

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 Obstetricians and Gynecologists (ACOG): The ACOG Clinical Practice Guideline No. 2 (April 2022) "suggests dual energy X-ray absorptiometry (DXA) testing every 1–3 years during osteoporosis pharmacotherapy, depending on clinical circumstances, until findings are stable (conditional recommendation, moderate–quality evidence)."

United States Preventive Services Task Force (USPSTF): The USPSTF (2018, Updated 2021) 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).

Men

For men, osteoporosis is associated with increased morbidity and mortality, specifically following a fracture.

It is currently estimated that approximately 5% of men in the United States have osteoporosis by T-score definition. Although this is less common than in women, increasing attention is being paid to osteoporosis in men given the significant morbidity and mortality associated with this condition. As many as 1 in 4 men older than 50 years will develop at least 1 osteoporosis-related fracture in their lifetime. 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.

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/m^2, Hyperthyroidism, Hyperparathyroidism, Chronic Obstructive Pulmonary Disease, Chronic Liver Disease, Stroke, Parkinson's Disease, Gastrectomy

The BHOF Clinician's Guide to Prevention and Treatment of Osteoporosis (LeBoff, et al., 2022) states Consider BMD testing in:

- men ≥ 70 years of age, regardless of clinical risk factors
- men aged 50 to 69 years with clinical risk factors for fracture
- adults who have a fracture at age 50 years and older
- adults with a condition (e.g., rheumatoid arthritis, organ transplant) or taking a medication (e.g., glucocorticoids, aromatase inhibitors, androgen deprivation therapy) associated with low bone mass or bone loss

The USPSTF (2018) Osteoporosis to Prevent Fractures Screening recommendations state that 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 BHOF Clinician's Guide to Prevention and Treatment of Osteoporosis (LeBoff, et al., 2022) addresses Serial BMD Measurement under the section on Monitoring Treatment Response, and notes the following:

- Central DXA assessment of the total hip, femoral neck, or lumbar spine is the "gold standard" for serial assessment of BMD.
- The BHOF recommends repeating BMD assessments every 2 years in adults ages 65 and older, with the understanding that testing less or more frequently may be warranted in individual patients.
- DXA is currently the preferred approach for monitoring treatment response.

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/Screening from DXA

Many DXA devices have received 510(k) marketing clearance from the FDA, including but not limited to Hologic's Instant Vertebral Assessment (IVA), GE's Dual Energy Vertebral Assessment (DVA) (previously known as Lateral Vertebral Assessment (LVA) and SpineAnalyzer™ (Optasia Medical). Additional software and therefore 510(k) clearance is required to perform VFA on the DXA devices.

Vertebral fracture assessment (VFA) is a low-dose lateral image of the thoracic and lumbar spine that may be added to a standard DXA to determine whether vertebral fractures are present. VFA should be considered in patients with height loss or back pain who have not been assessed by conventional radiographs, CT, or MRI. VFA is intended solely to identify whether spine compression is present and does not replace conventional diagnostic imaging for other purposes.

Vertebral fracture is the most common osteoporotic fracture and indicates a high risk for future fractures, even when the T-score does not meet the threshold for osteoporosis. Prevalent fractures, therefore, may change an individual's diagnostic classification, estimated risk of future fractures, and clinical management. Most vertebral fractures, however, remain undetected unless specifically sought by imaging techniques (spine X-ray or vertebral fracture assessment [VFA]) (Camacho, et. al., 2020).

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

Bone Health & Osteoporosis Foundation (BHOF) / (previously known as National Osteoporosis Foundation (NOF): The BHOF Clinician's Guide to Prevention and Treatment of Osteoporosis (LeBoff, et al., 2022) states that vertebral fracture imaging (X-ray or DXA vertebral fracture assessment) should be performed in high-risk individuals to detect subclinical vertebral fractures. Because subclinical vertebral fractures are so prevalent in older individuals, vertebral fracture assessment is recommended for these high-risk individuals***

- All women aged ≥ 65 years and all men aged ≥ 80 years if T-score at the lumbar spine, total hip, or femoral neck is ≤ − 1.0
- Men aged 70 to 79 years if T-score at the lumbar spine, total hip, or femoral neck is ≤ − 1.5
- Postmenopausal women and men age ≥ 50 years with specific risk factors:
  - Fracture during adulthood (age ≥ 50 years)
  - Historical height loss of 1.5 in. or more*
  - Prospective height loss of 0.8 in. or more**
  - Recent or ongoing long-term glucocorticoid treatment
  - Medical conditions associated with bone loss such as hyperparathyroidism

*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

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

Vertebral Fracture Assessment/Screening and Bone Strength and Fracture Risk Assessment from Imaging Modalities Other than DXA

U.S. Food and Drug Administration (FDA): On June 7, 2002, 510(k) approval was granted for Sectra Osteoporosis Package (K021527) to Sectra Imtec AB (Sweden). Sectra Osteoporosis Package analyzes radiography images obtained directly in digital format. Predicate Device was X-Posure System Version 2 RAD (Pronosco A/S) (K002500, 10/23/2000). Sectra purchased Pronosco in 2002. Indications for Use: The device is intended for use to estimate bone mineral density ("BMD") in the forearm and to assess increased risk of osteoporotic fracture according to World Health Organization ("WHO") criteria. The device is indicated specifically for use to: (1) assist the physician in diagnosing subjects who already have been identified to be at risk for suffering from osteoporosis, together with other known risk factors (e.g., prior history of fractures, advanced age, low body weight, lack of physical exercise, lack of exposure to sunlight, insufficient dietary intake of vitamin D and/or calcium, and smoking); and (2) compare the BMD estimate with a reference population comprised of young normals and age-matched normals to compute T-scores and 2-scores, respectively.

On August 3, 2018, VirtuOst Vertebral Fracture Assessment (O.N. Diagnostics, LLC.) received 510(k) approval (K171435). Indications for use include: "VirtuOst VFA uses sagittal sections from a spine-containing CT scan, with or without contrast enhancement, to visualize and measure vertebral deformities, classify the type and grade of any existing vertebral fracture, and from this identify patients at high risk of a future osteoporosis-related fracture. This information can be interpreted by a physician to diagnose existing vertebral fractures and to manage patients for osteoporosis." Using non-linear finite element analysis (FEA), VirtuOst provides a whole-bone strength (in units of newtons) of the hip and/or spine. The patient's CT scan is sent to the company electronically, the analysis performed by the company and the results sent back to the ordering physician.

On May 12, 2020, 510(k) approval was granted for HealthVCF (K192901) to Zebra Medical Vision Ltd. (Israel). The Indications for Use states: HealthVCF is a passive notification for prioritization-only, parallel-workflow software tool used by clinicians to prioritize specific patients within the standard-of-care bone health setting for suspected vertebral compression fractures. HealthVCF uses an artificial intelligence algorithm to analyze chest and abdominal CT scans and flags those that are suggestive of the presence of at least one vertebral compression at the exam level. These flags are viewed by the clinician in Bone Health and Fracture Liaison Service programs in the medical setting via a worklist application on their Picture Archiving and Communication System (PACS). HealthVCF does not send a proactive alert directly to the user. HealthVCF does not provide diagnostic information beyond triage and prioritization, it does not remove cases from the radiology worklist, and should not be used in place of full patient evaluation, or relied upon to make or confirm diagnosis. Of note, on August 10, 2021 Nanox (Israel) signed an agreement to purchase Zebra. Nanox uses the product name 'Bone Health Solution', instead of HealthVCF.

On April 22, 2022, 510(k) approval was granted for HealthOST (NanoxAI Ltd., Israel), a computed tomography x-ray system. HealthOST is an image processing software that provides qualitative and quantitative analysis of the spine from CT images to support clinicians in the evaluation and assessment of musculoskeletal disease of the spine. HealthOST is indicated for use in patients aged 50 and over undergoing CT scan for any clinical indication, that includes at least four vertebrae in the T1-L4 portion of the spine (for vertebral height loss) and T11-L4 (for bone attenuation) portions of the spine.

According to their website, CurveBeam AI received FDA Breakthrough Device Designation for their OssView™ Bone Fragility Software in September 2022. OssView calculates a Structural Fragility Score (SFS), which determines bone microstructural deterioration, an indicator for bone fragility and fracture risk. SFS is calculated from a high resolution peripheral quantitative computed tomography (HR-pQCT) scan. This is not yet FDA-approved.

According to their website, Naitive® Technologies received FDA Breakthrough Device Designation (October 2023) for OsteoSight™, a technology for estimating bone mineral density (BMD) from routine X-rays. This is not yet FDA-approved.

Literature Review: The use of images other than DXA are proposed to identify individuals at high risk of fracture or identify those with subclinical vertebral fractures. There is an increasing interest in performing concurrent bone health screening on patients who undergo diagnostic CT scans of the abdomen and pelvis. Additionally, digital X-ray radiogrammetry (DXR) is proposed to estimate hand BMD from hand x-ray images.
There is a lack of well-designed clinical trials addressing the impact of algorithmic-based assessments of non-DXA scans on patient-specific long-term health outcomes (Kolanu, et al., 2020 [Zebra Medical Vision®]; Dagan, et al., 2020 [HealthVCF]; Allaire, et al., 2019 [VirtuOst]; Adams, et al., 2018 [VirtuOst]; Kälvesten, et al., 2016 and Wilczek, et al., 2013 [OneScreen, Sectra]; Bach-Mortensen, et al., 2006 [X-posure System™ Sectra Pronosco A/S].

Professional Societies/Organizations: The BHOF Clinician's Guide to Prevention and Treatment of Osteoporosis (LeBoff, et al., 2022) states vertebral fracture imaging (X-ray or DXA vertebral fracture assessment) should be performed in high risk individuals to detect subclinical vertebral fractures. Traditionally, conventional lateral thoracic/lumbar spine X-ray has been considered the gold standard for identification of vertebral fractures and minor vertebral deformities. However, DXA-assisted vertebral fracture assessment (DXA-VFA) is emerging as an alternative to radiography for its convenience, low cost, and minimal radiation exposure. Recently performed MRI or CT imaging studies done for other purposes can and should also be evaluated for presence of vertebral fractures or evidence of vertebral deformity. The BHOF Clinician's Guide

to Prevention and Treatment of Osteoporosis (LeBoff, et al., 2022) does not address the use of digital X-ray radiogrammetry (DXR) to estimate hand BMD.

The AACE 2020 Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis (Camacho, et al., 2020) does not address use of diagnostic CT scans or hand x-rays.

Pulse-echo Ultrasound (CPT® 0508T/76999)

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 utilizing Bindex® on long-term health outcomes (Lewiecki, 2020; Karjalainen, et al., 2018; Schousboe, et al., 2017).

The Endocrine Society does not address measurement of cortical bone thickness in these guidelines:

- Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline (Eastell, et al., 2019)
- Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update (Shoback, et al., 2020)

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).

Trabecular Bone Score (TBS) (CPT® 77089 – 77092)

In 2012, TBS (TBS iNsight®; Med-Imaps, Pessac, France) was approved by the US Food and Drug Administration for use as a complement to DXA analysis for the assessment of fracture risk. The Indications for use read as follows:

> The Med-Imaps TBS iNsight is a software provided for use as a complement to a DEXA analysis. It computes the antero-posterior spine DEXA examination file and calculates a score (Trabecular Bone Score - TBS) that is compared to those of the age-matched controls. The TBS is derived from the texture of the DEXA image and has been shown to be related to bone microarchitecture and fracture risk. This data provides information

independent of BMD value;' it is used as a complement to the data obtained from the DEXA analysis and the clinical examination (questioning by the clinician about patient history, bioassay of bone resorption markers...). The TBS score can assist the health care professional in assessment of fracture risk and in monitoring the effect of treatments on patients across time. Overall fracture risk will depend on many additional factors that should be considered before making diagnostic or therapeutic recommendations. The software does not diagnose disease, or recommend treatment regimens. Only the health care professional can make these judgments (K121716; October 5, 2012).

An update, K152299 (April 29, 2016) states the following Indications for Use:

TBS iNsight is a software provided for use as a complement to both DXA analysis and clinical examination. It computes the antero-posterior spine DXA examination file and calculates a score (Trabecular Bone Score - TBS) that is compared to those of the age matched controls. The TBS is derived from the texture of the DXA image and has been shown to be related to bone microarchitecture.

TBS iNsight provides as an option an assessment of 10-year fracture risk. It provides an estimate of 10-year probability of hip fracture and 10-year probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture). This estimate is based on the WHO's FRAX® Fracture Risk Assessment Tool, after adjustment for the TBS. The tool has been validated for Caucasian and Asian men and post-menopausal women between 40 and 90 years old.

TBS provides information independent of BMD value; it is used as a complement to the data obtained from the DXA analysis and the clinical examination (questioning by the clinician about patient history, bioassay of bone resorption markers).

The results can be used by a physician in conjunction with other clinical risk factors as an aid in the diagnosis of osteoporosis and other medical conditions leading to altered trabecular bone microarchitecture, and ultimately in the assessment of fracture risk.

The TBS score can assist the health care professional in monitoring the effect of treatments on patients across time. Overall fracture risk will depend on many additional factors that should be considered before making diagnostic or therapeutic recommendations. The software does not diagnose disease or recommend treatment regimens. Only the health care professional can make these judgments (K152299; April 29, 2016).

There is a lack of well-designed clinical trials including diverse populations in the peer-reviewed scientific literature addressing the impact of TBS iNsight® (Med-Imaps) on patient-specific health outcomes. Future prospective trials evaluating the use trabecular bone score in place of or in addition to established fracture prediction tools should report if long-term patient health outcomes are improved (McCloskey, et al., 2015; Leslie, et al., 2014; Hans, et al., 2011).

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:

- R22: Pharmacologic therapy is strongly recommended for patients with a T-score between −1.0 and −2.5 if the FRAX® (fracture risk assessment tool) (or if available, trabecular bone score [TBS]-adjusted FRAX®) 10-year probability for major osteoporotic fracture is ≥20% or the 10-year probability of hip fracture is ≥3% in the U.S. or above the country-specific threshold in other countries or regions (Grade A)

Role of Trabecular Bone Score in Adjusting FRAX® Risk

High TBS values (note that TBS is unitless) correlate with homogeneous (i.e., normal) bone texture, while low values are indicative of more variable (i.e., weaker) bone texture. Numerous studies have shown that TBS predicts fracture risk independent of BMD and that it enhances

fracture risk prediction capabilities of FRAX®. Low TBS values increase FRAX® estimated risk, while high TBS values reduce it. TBS adjustment of FRAX® has been validated in 14 prospective international cohorts.

The Endocrine Society does not address TBS in these guidelines:

- Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Clinical Practice Guideline (Eastell, et al., 2019)
- Pharmacological Management of Osteoporosis in Postmenopausal Women: An Endocrine Society Guideline Update (Shoback, et al., 2020)

Ultrasound-based Radiofrequency Echographic Multi-spectrometry (REMS) (CPT® 0815T)

REMS is a non-ionizing technology that evaluates bone status by analyzing raw, unfiltered native ultrasound signals, so-called radio frequency (RF) ultrasound signals, obtained during an ultrasound scan of the lumbar vertebrae and proximal femur. The analysis of native unfiltered ultrasound signals allows for information about the characteristics of bone tissue to be acquired. Bone density is obtained by comparing the spectra of analyzed signal with reference spectral models that have been previously obtained. REMS scans are performed at both the proximal femur and lumbar spine (Al Refaie, et al., 2023).

U.S. Food and Drug Administration (FDA): Echolight S.p.a (Lecce, Italy) received 510(k) approval for their EchoS Family device on February 25, 2021 (K202514). Indications for use include but are not limited to: EchoS Family is a non-invasive ultrasound (US) bone sonometer. EchoS Family works together with EchoStudio software. EchoStudio analyzes the ultrasound signals in order to compute the diagnostic parameters (BMDus, T-score, and Z-score). The BMDus Index is a clinical measure based on ultrasound variables of the lumbar spine or femoral neck. Device Description:

- The EchoS Family is an ultrasound device intended primarily for the diagnosis of osteoporosis. EchoS, through the ultrasound scan of the lumbar or femoral site of interest, picks up the ultrasound signal (RF) and performs an estimate of the bone mineral density (BMD).
- The device therefore allows not only the visualization of ultrasound images, but also the real-time sampling of the RF signal and its appropriate treatment to make it usable for diagnostic algorithms. The EchoS Family consists in two different configurations: EchoS (portable version) and the EchoStation (cart version). Each version consists of two main parts: the equipment device (EchoS and EchoStation) with its own probe and the software EchoStudio.
- EchoStudio is a biomedical software that, used in combination with EchoS Family, allows the evaluation of bone mineral density (BMD) by means of the proprietary method REMS (Radiofrequency Echographic Multi Spectrometry) densitometry.
- By using EchoStudio, it is possible to assess the key diagnostic parameters directly on the anatomical sites with increased fracture risk, such as lumbar spine and proximal femur. EchoStudio analyzes the ultrasound signals and echographic images in order to compute the diagnostic parameters (BMD, T-score, and Z-score) and to estimate the fracture risk by means of the Echolight diagnostic algorithms and non-ionizing technique.

EchoSK and EchoSGyn Modules are additional software/hardware modules for EchoS Family devices that received approval March 16, 2022. Indications for use include but are not limited to:

- EchoSK optional module for EchoS Family devices is intended to provide images of, or signals from, inside the body acquired by an appropriately trained professional in a clinical setting for musculoskeletal applications.
- EchoSGyn optional module for EchoS Family devices is intended to provide images of, or signals from, inside the body acquired by an appropriately-trained professional in a clinical

setting for Fetal and OB/GYN (useful for visualization of the ovaries, follicles, uterus and other pelvic structures) applications.

Literature Review: There is a lack of well-designed clinical trials including diverse populations in the peer-reviewed scientific literature addressing the impact of the use of REMS on long-term patient health outcomes (Lalli, et al., 2022; Cortet, et al., 2021; Adami, et al., 2021).

International

The International Society for Clinical Densitometry (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.

Under 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.

Under Vertebral Fracture Assessment Nomenclature

- Vertebral Fracture Assessment (VFA) is the correct term to denote densitometric spine imaging performed for the purpose of detecting vertebral fractures.

Under Indications for VFA

- Lateral Spine imaging with Standard Radiography or Densitometric VFA is indicated when T-score is < -1.0 and of one or more of the following is present:
  - Women age ≥ 70 years or men ≥ age 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

Under QCT and pQCT
Finite Element Analysis (FEA):

- Vertebral strength as estimated by QCTbased FEA predicts vertebral fracture in postmenopausal women.
- Vertebral strength as estimated by QCTbased FEA is comparable to spine DXA for prediction of vertebral fractures in older men.
- Femoral strength as estimated by QCT-based FEA is comparable to hip DXA for prediction of hip fractures in postmenopausal women and older men.
- FEA cannot be used to diagnose osteoporosis using the current WHO T-score definition.
- Vertebral or femoral strength as estimated by QCT-based FEA can be used to initiate pharmacologic treatment using validated thresholds and in conjunction with clinical risk factors.
- Vertebral or femoral strength as estimated by QCT-based FEA can be used to monitor age- and treatment-related changes.

Under Trabecular Bone Score (TBS)

- TBS is associated with vertebral, hip and major osteoporotic fracture risk in postmenopausal women.
- TBS is associated with hip fracture risk in men over the age of 50 years.
- TBS is associated with major osteoporotic fracture risk in men over the age of 50 years.
- TBS should not be used alone to determine treatment recommendations in clinical practice.
- TBS can be used in association with FRAX and BMD to adjust FRAX-probability of fracture in postmenopausal women and older men.
- In patients receiving anti-fracture therapy:
  - The role of TBS in monitoring antiresorptive therapy is unclear.
  - TBS is potentially useful for monitoring anabolic therapy.
- TBS is associated with major osteoporotic fracture risk in postmenopausal women with type II diabetes.

Under Peri-prosthetic and Orthopedic Uses of DXA
Elective orthopedic and spine surgery patients with the following conditions are at greater risk for impaired bone health and should have DXA testing:

- Diabetes mellitus (long term duration of diabetes (>10yrs) and poor control): Trabecular bone score (TBS) measurement should be obtained in patients with diabetes, if available.

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	Bone (Mineral) Density Studies (150.3)	01/01/2007
LCD		No Determination found	

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

Appendix

Conditions, diseases, and medications that cause or contribute to osteoporosis and/or fractures (LeBoff et al., 2022):

Lifestyle factors Alcohol abuse Excessive thinness Excess vitamin A Frequent falling High salt intake Immobilization Inadequate physical activity Low calcium intake Smoking (active or passive) Vitamin D insufficiency/deficiency **Genetic diseases** Cystic fibrosis Ehlers-Danlos Gaucher's disease Hemochromatosis Hypophosphatasia Hypophosphatemia Marfan syndrome Menkes steely hair syndrome Osteogenesis imperfecta Parental history of hip fracture Porphyria Homocystinuria **Hypogonadal states** Anorexia nervosa Androgen insensitivity Female athlete triad Hyperprolactinemia Hypogonadism Panhypopituitarism Premature menopause (<40 years) Turner's & Klinefelter's Syndromes **Endocrine disorders** Obesity Cushing's syndrome Diabetes mellitus (Types 1 & 2) Hyperparathyroidism Thyrotoxicosis	**Gastrointestinal disorders** Celiac disease Bariatric surgery Gastric bypass Gastrointestinal surgery Inflammatory bowel disease including Crohn's disease and ulcerative colitis Malabsorption syndromes Pancreatic disease Primary biliary cirrhosis **Hematologic disorders** Hemophilia Leukemia and lymphomas Monoclonal gammopathies Multiple myeloma Sickle cell disease Systemic mastocytosis Thalassemia **Rheumatologic and autoimmune diseases** Ankylosing spondylitis Other rheumatic and autoimmune diseases Rheumatoid arthritis Systemic lupus Neurological and musculoskeletal risk factors Epilepsy Muscular dystrophy Multiple sclerosis Parkinson's disease Spinal cord injury Stroke **Miscellaneous conditions and diseases** HIV/AIDS Amyloidosis Chronic metabolic acidosis Chronic obstructive lung disease Congestive heart failure Depression Renal disease (CKD III– CKD V/ESRD) Hypercalciuria Idiopathic scoliosis Post-transplant bone disease Sarcoidosis Weight loss Hyponatremia	**Medications** Aluminum-containing antacids Androgen deprivation therapy Anticoagulants (unfractionated heparin) Anticonvulsants (e.g. phenobarbital, phenytoin, valproate) Aromatase inhibitors Barbiturates Cancer chemotherapeutic drugs Cyclosporine A and tacrolimus Glucocorticoids (≥ 5.0 mg/day prednisone or equivalent for ≥ 3 months) GnRH (Gonadotropin releasing hormone) agonists and antagonists Depot medroxyprogesterone acetate (Depo-Provera) Methotrexate Parenteral nutrition Proton pump Inhibitors Selective serotonin reuptake inhibitors Tamoxifen (premenopausal use for breast cancer treatment) Thiazolidinediones (such as pioglitazone and rosiglitazone) Thyroid replacement hormone (in excess)

Coding Information

Notes:

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
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 (eg, hips, pelvis, spine)
77080	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine)
77081	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; appendicular skeleton (peripheral) (eg, 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
77086	Vertebral fracture assessment via dual-energy x–ray absorptiometry (DXA)

Considered Not Medically Necessary:

CPT®* Codes	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
0743T	Bone strength and fracture risk using finite element analysis of functional data and bone-mineral density, with concurrent vertebral fracture assessment, utilizing data from a computed tomography scan, retrieval and transmission of the scan data, measurement of bone strength and bone mineral density and classification of any vertebral fractures, with overall fracture risk assessment, interpretation and report

Considered Experimental/Investigational/Unproven:

CPT®* Codes	Description
76999†	Unlisted ultrasound procedure (eg, diagnostic, interventional)
77089	Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture-risk
77090	Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical preparation and transmission of data for analysis to be performed elsewhere

CPT®* Codes	Description
77091	Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical calculation only
77092	Trabecular bone score (TBS), structural condition of the bone microarchitecture; interpretation and report on fracture-risk only by other qualified health care professional
0508T	Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia (Deleted effective 12/31/2023)
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
0749T	Bone strength and fracture-risk assessment using digital X-ray radiogrammetry bone mineral density (DXR-BMD) analysis of bone mineral density (BMD) utilizing data from a digital X ray, retrieval and transmission of digital X ray data, assessment of bone strength and fracture-risk and BMD, interpretation and report
0750T	Bone strength and fracture-risk assessment using digital X-ray radiogrammetry bone mineral density (DXR-BMD) analysis of bone mineral density (BMD) utilizing data from a digital X ray, retrieval and transmission of digital X ray data, assessment of bone strength and fracture-risk and BMD, interpretation and report; with single-view digital X-ray examination of the hand taken for the purpose of DXR-BMD
0815T	Ultrasound-based radiofrequency echographic multi-spectrometry (REMS), bone-density study and fracture-risk assessment, 1 or more sites, hips, pelvis, or spine

†Note: Considered Experimental/Investigational/Unproven when used to report pulse-echo ultrasound for bone density measurement testing.

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Revision Details

Type of Revision	Summary of Changes	Date

Annual Review	• Added policy statement for ultrasound-based radiofrequency echographic multi-spectrometry (REMS) (CPT® 0815T) • Revised policy statement for bone mineral density measurement testing.	4/15/2024