Clinical UM Guideline

Subject:	Bone Mineral Density Testing Measurement		
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Description

This document addresses bone mineral density (BMD) measurements and vertebral fracture assessment (VFA).

BMD measurement is a non-invasive technique that is used to measure bone mineral content and bone mineral density. Its primary role is to detect osteoporosis, predict the risk of fractures and to assess the response to, or efficacy of, medication for the treatment of osteoporosis. DEXA is the most commonly used technique to measure BMD. VFA (formerly referred to as vertebral morphometry, instant vertebral assessment and vertebral absorptiometry) uses central DEXA to obtain images of the thoracic and lumbar spine to identify vertebral fractures. Screening for vertebral fractures can be done at the same time a subject is undergoing assessment of BMD.

BMD can be measured in a variety of locations (central or peripheral) using several different techniques. The following techniques can be used to obtain BMD measurements:

- Central (hip or spine) BMD; or
- Peripheral (appendicular skeleton) BMD:
  - heel densitometry;
  - peripheral dual energy x-ray absorptiometry (pDEXA);
  - radiographic absorptiometry of the fingers;
  - single energy X-ray absorptiometry (SEXA);
  - single photon absorptiometry (SPA);
  - dual X-ray and laser (DXL).

Clinical Indications

Medically Necessary:

I. CENTRAL BONE MINERAL DENSITY MEASUREMENTS USING DUAL X-RAY ABSORPTIOMETRY

A. Initial Central Bone Mineral Density Measurements

1. In general, a baseline central bone mineral density (BMD) measurement may be considered **medically necessary** whenever there is a reasonable expectation that the findings will be abnormal and a treatment decision may be influenced by the outcome of the test.
2. Specifically, an initial (baseline) central (hip or spine) bone density measurement is considered **medically necessary** when performed in **any** of the following settings:

a. Screening for osteoporosis in postmenopausal individuals 65 years of age or older; **or**
b. Screening for osteoporosis in men 70 years of age or older; **or**
c. Individuals (male or female) with clinical evidence of vertebral osteoporosis as indicated by any of the following:
   - Decrease in height of greater than 1.5 inches; **or**
   - Presence of kyphosis; **or**
   - X-ray identification of vertebral compression fractures, osteoporosis, or osteopenia (low bone mass).
d. Individuals who are known or suspected to have a condition that may underlie the osteoporosis, including but not limited to the following:
   - Anorexia nervosa; **or**
   - Chemotherapeutic agents which affect bone density; **or**
   - Chronic liver disease; **or**
   - Chronic renal failure; **or**
   - Chronic use of anti-convulsants (particularly Dilantin); **or**
   - Chronic use of heparin; **or**
   - Cushing's Syndrome (hypercortisolism); **or**
   - Fragility or pathologic fracture; **or**
   - Hypercalciuria; **or**
   - Hyperthyroidism; **or**
   - Hypothyroidism; **or**
   - Hypogonadism; **or**
   - Inflammatory bowel disease; **or**
   - Lupron therapy in men; **or**
   - Malabsorption syndromes; **or**
   - Malignancies (multiple myeloma); **or**
   - Organ transplantation; **or**
   - Osteogenesis imperfecta; **or**
   - Prolonged amenorrhea (6 months duration or longer); **or**
   - Prolonged immobilization; **or**
   - Radiologic evidence of osteopenia; **or**
   - Receiving aromatase inhibitor therapy; **or**
   - Receiving long-term glucocorticoid therapy (greater than three months or the equivalent dose of 7.5 mg prednisone [or 30 mg cortisone] or more per day), provided intervention is an option; **or**
   - Rheumatoid arthritis; **or**
   - Untreated premature menopause; **or**
   - Vertebral abnormalities.

B. Repeat Central Bone Mineral Density Measurements

1. Individuals Not On Therapy Related To Osteoporosis:

a. For those without significant osteopenia or not at high risk for accelerated bone loss, repeat testing is considered **medically necessary** every 3 to 5 years.
b. For individuals with significant osteopenia or at high risk for accelerated bone loss including individuals with any one of the conditions listed in bullet "C" above, repeat measurement is considered **medically necessary** every 2 to 3 years.
c. Individuals who have an initial BMD measurement well above the minimal desirable level may not need a repeat measurement.

2. Individuals On Therapy Related To Osteoporosis:

a. Repeat measurements of BMD as a technique to monitor response to therapy for osteoporosis are considered **medically necessary** when performed at intervals of 2 years or greater.

C. CENTRAL BONE DENSITY MEASUREMENTS for ASYMPTOMATIC HYPERPARATHYROIDISM

1. Bone density measurement using the spine (trabecular bone), or hip (mixed cortical and trabecular bone) is considered **medically necessary** when performed for individuals (male or female) with asymptomatic primary hyperparathyroidism (PHPT) where consideration for surgery is in large part determined by bone density level.

II. VERTEBRAL FRACTURES USING DUAL X-RAY ABSORPTIOMETRY

A. Screening for vertebral fractures using dual x-ray absorptiometry as an adjunct to bone mineral density measurement is considered **medically necessary** for the following:
1. Women greater than or equal to 70 years of age and men greater than or equal to 80 years of age if the BMD T score is less than or equal to -1.0 at the spine, hip or femoral neck; **or**
2. Women 65 to 69 years of age and men age 70 to 79 years of age if the BMD T score is less than or equal to -1.5 at the spine, hip or femoral neck; **or**
3. Postmenopausal women and men greater than or equal to 50 years of age with **any** of the following risk factors:
a. Low trauma fracture at age 50 years or older; **or**
b. Historical height loss* of greater than or equal to 1.5 inches; **or**
c. Prospective height loss§ of 0.8 inch or more; **or**
d. Recent or ongoing treatment with glucocorticoids.

* Current height compared to maximum height during young adulthood
§ Cumulative height loss measured during interval medical evaluation

III. PERIPHERAL BONE DENSITY MEASUREMENTS USING DUAL X-RAY ABSORPTIOMETRY

A. Peripheral dual energy x-ray absorptiometry (pDEXA) bone density measurement using the forearm (cortical bone), is considered **medically necessary** when either of the following criteria is met:
1. performed for individuals (male or female) with asymptomatic primary hyperparathyroidism (PHPT) where consideration for surgery is in large part determined by bone density level; **or**

2. when central (spine or hip) DEXA measurements cannot be reliably performed and interpreted (for example: as a result of spinal instrumentation, bilateral hip replacement, or obesity).

Not Medically Necessary:

I. CENTRAL BONE DENSITY MEASUREMENTS USING DUAL X-RAY ABSORPTIOMETRY

A. Central bone density measurement is considered **not medically necessary** when the medically necessary criteria above is not met, including but not limited to any of the following circumstances:
1. Routine screening for osteoporosis or osteoporosis risk for individuals who do not meet the criteria above.
2. Individuals starting hormone therapy for treatment of menopausal symptoms or who are being monitored for effects of hormone therapy prescribed for menopausal symptoms and who do not meet the criteria above.
3. Monitoring therapy response in individuals on therapy related to osteoporosis at intervals of less than 2 years.

II. VERTEBRAL FRACTURES USING DUAL X-RAY ABSORPTIOMETRY

A. Screening for vertebral fractures using dual x-ray absorptiometry as an adjunct to bone mineral density measurement is considered **not medically necessary** in individuals not meeting the medically necessary criteria above**.**

III. PERIPHERAL BONE DENSITY MEASUREMENTS

A. Peripheral dual energy x-ray absorptiometry (pDEXA) bone density measurements are considered **not medically necessary** for all indications not listed above.

B. Peripheral bone density measurements using a method other than dual energy x-ray absorptiometry (pDEXA), are considered **not medically necessary** for all indications, including but not limited to, the following methods:
1. Radiographic absorptiometry of the fingers
2. Single energy X-ray absorptiometry (SEXA)
3. Single photon absorptiometry (SPA)
4. Dual X-ray and laser (DXL)
5. Ultrasound of the heel
6. Pulse-echo ultrasound of the tibia.

C. Peripheral bone density measurements are considered **not medically necessary** for asymptomatic primary hyperparathyroidism if performed on any part of the body other than the cortical bone (for example, radiographic absorptiometry of the fingers, ultrasound of the heel).

IV. BONE STRENGTH AND FRACTURE RISK ASSESSMENT USING IMAGING MODALITIES OTHER THAN DUAL X-RAY ABSORPTIOMETRY

A. Bone strength and fracture risk assessment using imaging scans other than dual x-ray absorptiometry (for example, a computed tomography scan or digital X-ray data) is considered **not medically necessary** for all indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Central Bone Mineral Density Measurement
When services may be Medically Necessary when criteria are met:

CPT

77080	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine)
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)
78351	Bone density (bone mineral content) study, 1 or more sites; dual photon absorptiometry, 1 or more sites [DPA]

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

Peripheral Bone Mineral Density Measurement
When services may be Medically Necessary when criteria are met:

CPT

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

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:
For the procedure code listed above when criteria are not met.

Other studies

When services are Not Medically Necessary:

For the following procedure codes, or when the code describes a procedure designated in the Clinical Indications section as not medically necessary.

CPT

76977	Ultrasound bone density measurement and interpretation, peripheral site(s), any method
76999	Unlisted ultrasound procedure (eg, diagnostic, interventional) [when specified as pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density Bindex®]
78350	Bone density (bone mineral content) study, 1 or more sites; single photon absorptiometry [SPA]
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
0743T	Bone strength and fracture risk using finite element analysis of functional data and bone mineral density (BMD), with concurrent vertebral fracture assessment, utilizing data from a computed tomography scan, retrieval and transmission of the scan data, measurement of bone strength and BMD and classification of any vertebral fractures, with overall fracture-risk assessment, interpretation and report
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

HCPCS

G0130	Single energy x-ray absorptiometry (SEXA) bone density study, one or more sites; appendicular skeleton (peripheral) (eg, radius, wrist, heel)

ICD-10 Diagnosis

All diagnoses

Discussion/General Information

Osteoporosis
Osteoporosis is characterized by slow, prolonged bone loss. The National Osteoporosis Foundation (NOF) in 2014 noted that in the United States, 9.9 million individuals are estimated to have osteoporosis. In addition, 43.1 million Americans have low bone density of the hip. Approximately one out of every two Caucasian women will experience an osteoporosis-related fracture at some point in her lifetime, as will approximately one in five men. While osteoporosis occurs less frequently in African Americans, those with osteoporosis have the same elevated fracture risk as Caucasians. The incidence of osteoporosis in the U.S. is expected to increase significantly in the future as the population ages (NOF, 2014).

The goal of osteoporosis treatment is to prevent or decrease the rate of bone loss. Such treatment may include, but is not necessarily limited to calcium and vitamin supplementations, exercise and medications such as calcitonin, parathyroid hormone, estrogens, bisphosphonates (alendronate, ibandronate and risedronate), and raloxifene. Treatment planning represents a joint decision by the individual and their treating physician following discussion of the potential risks and benefits of therapy.

Bone Mineral Density Testing- Description of Technology
BMD tests are non-invasive technique used to measure bone mineral content in order to predict fracture risks and the need for medical therapy. BMD can be measured at several anatomical locations. Central measurements are more commonly performed because bone loss most frequently occurs in the spine and hip regions. However, there are some conditions (such as hyperparathyroidism) in which bone loss occurs more rapidly at the peripheral sites (wrist, forearm, finger or heel) and peripheral measurements may therefore be more appropriate. Peripheral BMD are generally determined by obtaining measurements at the wrist, forearm, finger or heel, while central BMD measurements are obtained by obtaining measurements from the hip or spine. BMD is typically expressed as the T-score (for example, the number of standard deviations [SD] below the mean for non-osteopenic, healthy, young women). The World Health Organization defines osteopenia as a T-score of between –1.0 and -2.5 SD, and osteoporosis as a score of –2.5 SD or more.

Dual-energy X-ray absorptiometry (DXA) is the gold standard for bone quality measurement in children as well as adults, due to precision, reproducibility, and availability of standardized data. Nevertheless, DEXA is not without limitations. Disrupting factors such as movement during measurement, contractures, metallic implants, and sometimes even scoliosis can cause results to be uninterpretable. Additionally, the Z-scores are based on calendar age and do not take into consideration bone age, which may result in inaccurate findings. Finally, DXA supplies measurement of areal BMD (g/cm2), rather than volumetric density (g/cm3), which may result in underestimation of BMD in children with narrow small bones and overestimation of BMD in tall children (Leijten, 2019).

Initial and Repeat Central Bone Mineral Density Measurements
There is adequate evidence to support the use of central bone density studies to assess the risk of osteoporosis in settings where the results may influence medical therapy. Studies have demonstrated the efficacy of bone mineral studies for several populations at higher risk for this process, including postmenopausal women, especially those over the age of 65, individuals currently receiving medications for osteoporosis prophylaxis, those receiving glucocorticoid therapy and individuals with endocrinopathies or other conditions which predispose to osteoporosis. Examples of these include: hyperthyroidism and hypothyroidism, hyperparathyroidism, corticosteroid use, and rheumatoid arthritis. Currently both the American Association of Clinical Endocrinologist (AACE) Medical Guidelines for Clinical Practice for the Prevention and Treatment of Postmenopausal Osteoporosis (Camacho, 2020) and the U.S. Preventive Services Task Force (USPSTF) statement on Osteoporosis to Prevent Fractures: Screening (2018) recommend a screening BMD scan for all women over the age of 65 (USPSTF B recommendation). The American College of Obstetricians and Gynecologists (ACOG) recommends screening for osteoporosis in postmenopausal patients 65 years and older with BMD testing to prevent osteoporotic fractures (strong recommendation, high-quality evidence). Regarding individuals at increased risk for osteoporosis, as determined by a formal clinical risk assessment tool, ACOG recommends that screening be conducted using BMD testing to prevent osteoporotic fractures in postmenopausal patients younger than 65 years (strong recommendation, high-quality evidence) (ACOG, 2021).

The timing of additional studies after the initial screening is a topic of discussion. According to ACOG, after treatment has been initiated, one DEXA scan 1 – 2 years later can be used to assess the effect of treatment. If the BMD is improved or stable (no significant change), and there are no new risk factors, the DEXA does not usually need to be repeated (ACOG, 2021). This is based upon the results of several trials that evaluated the change in BMD in individuals undergoing therapy for various conditions. These studies found that change in bone density could not be meaningfully assessed until late in the second year of therapy because some individuals actually continue to lose bone density during the first year but have subsequent significant increases during the second year of therapy. Alternatively, the AACE recommends BMD monitoring for individuals undergoing therapy for osteoporosis prevention every 1 to 2 years until bone mass is stable, then, continue with follow-up DEXA every 1 - 2 years or at a less-frequent interval, depending on clinical circumstances (ACR, 2021; Camacho, 2020; Eastell, 2019).

Vertebral Fractures
Vertebral fractures (VFs) are a strong indicator of future fractures of all types (Klotzbuecher, 2000). The presence of a vertebral fracture is associated with a 2-3 fold increase in the risk of other fractures, regardless of bone mineral density status. Although elderly individuals frequently experience a vertebral fracture, many of these individuals are initially asymptomatic and clinically unrecognized. Although most of vertebral fractures are initially clinically silent, these fractures are often associated with symptoms of pain, deformity, disability, and mortality. Repeated or multiple thoracic fractures may result in restrictive lung disease, and lumbar fractures may alter abdominal anatomy, resulting in constipation, abdominal pain, distention, reduced appetite, and premature satiety (Cosman 2014). It has been estimated that approximately two-thirds of VFs are not clinically detected and one-third are discovered incidentally on lateral spine radiographs. However, lateral spine radiographs are not routinely conducted on elderly individuals due to several factors including but not limited to inconvenience and the associated radiation exposure.

Even in the absence of a bone density diagnosis, a vertebral fracture is consistent with a diagnosis of osteoporosis, and is an indication for pharmacologic therapy to reduce subsequent fracture risk. VFA has been explored as an imaging tool to proactively identify vertebral fractures. The detection of fractures in some individuals with low bone mineralization is a predictor of future fractures and allows for their risk restratification and the potential initiation of pharmacotherapy.

Vertebral Fracture Assessment - Description of Technology
Image quality of VFA now approaches that of a standard radiograph. Its radiation dose is less than 1% of a comparable radiograph, and is considered quite low at (30-50 uSv). VFA can be performed using most modern DEXA machines and may be performed at the time of BMD assessment (Cosman, 2014).

Vertebral Fracture Assessment - Initial and Repeat Measurements
Studies have investigated the use of DEXA as a screening tool for vertebral fractures as an adjunct to BMD measurements in asymptomatic individuals. These studies have reported that asymptomatic vertebral fractures may be present in up to 20% of postmenopausal women who have normal BMD measurements. Studies comparing DEXA vertebral fracture assessment to lateral spine X-rays (considered the "gold standard" for diagnosis of vertebral fractures) have shown high levels of agreement between the two techniques.

The utility of VFA is in the identification of individuals who would otherwise not qualify for treatment under the guidelines based solely on BMD measurements (Expert Panel on Musculoskeletal Imaging, 2017). Several studies have demonstrated VFA resulted in the identification of unknown vertebral fractures and led to individuals being reclassified due to the identification of a vertebral fracture. Jager and colleagues (2011) conducted a prospective diagnostic evaluation study which involved a total of 2500 consecutive subjects referred for BMD. Study participants underwent VFA after BMD testing. Questionnaires were used to evaluate the clinician's perceived added value of VFA. Results were evaluable for 2424 participants (1573 women) and were considered unreliable in 76 (3%) of the subjects. The researchers found that VFA detected an unknown vertebral fracture in 69% of the participants. Amongst the female subjects, the prevalence was 20% versus 27% found in men ($p<0.0001$). The prevalence of vertebral fractures in subjects with normal BMD was 14% (97/678), increased to 21% (229/1100) in individuals with osteopenia and to 26% in those with osteoporosis (215/646) by WHO criteria. In 468 of 942 questionnaires (50% response rate), 27% of the referring physicians reported the results of VFA to impact patient management.

According to the American College of Radiology (ACR, 2017), studies have confirmed that 10%–17% of individuals with osteopenia as measured by DEXA had grade 2 or 3 vertebral fractures detected by VFA. Because as much as 50% of fragility fractures appear in postmenopausal women with T-scores greater than −2.5, "identification of this population's increased risk is essential for potential medical treatment that has been shown to be beneficial in multiple studies". According to the ACR, VFA is appropriate in individuals with T-scores less than −1.0 and any one of the following:

- 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 (Expert Panel on Musculoskeletal Imaging, 2017).

Because vertebral fractures occur so frequently in older individuals and often produce no acute symptoms, the NOF (Cosman, 2014) recommends that vertebral imaging be considered for the following individuals:

- In all women age 70 and older and all men age 80 and older if BMD T-score is ≤ -1.0 at the spine, total hip, or femoral neck
- In women age 65 to 69 and men age 70 to 79 if BMD T-score is ≤ -1.5 at the spine, total hip, or femoral neck
- In postmenopausal women and men age 50 and older with specific risk factors:
  - Low-trauma fracture during adulthood (age 50 and older)
  - Historical height loss (difference between the current height and peak height at age 20) of 1.5 in. or more (4 cm)
  - Prospective height loss (difference between the current height and a previously documented height measurement) of 0.8 in. or more (2 cm)
  - Recent or ongoing long-term glucocorticoid treatment
- If bone density testing is not available, vertebral imaging may be considered based on age alone.

The NOF also stipulates that vertebral imaging should be repeated if there is documentation of prospective height loss, new back pain or postural changes. A follow-up vertebral imaging test is also recommended in individuals who are being considered for a medication holiday, since the cessation of medication would not be recommended in individuals who have experienced recent vertebral fractures (Cosman, 2014).

The Endocrine Society guidelines on Osteoporosis in Men recommend VFA using DEXA equipment for men with osteopenia or osteoporosis who might have previously undiagnosed vertebral fractures. If VFA is technically limited or not available, lateral spine radiographs should be considered (Watts, 2012).

Peripheral Bone Mineral Density Measurements of the Cortical Bone (Forearm)
The American Association of Clinical Endocrinologists (AACE) and the American Association of Endocrine Surgeons' (AAES, 2005) position statement on the diagnosis and management of primary hyperparathyroidism indicates that losses of bone mineral density (BMD) from primary hyperparathyroidism (PHPT) are more pronounced in the forearm (cortical bone) than in the spine (trabecular bone) and hip (mixed cortical and trabecular bone) but may occur at all skeletal sites. Although forearm losses of BMD may be more commonly associated with PHPT, the benefit from surgical treatment is more notable for the hip and spine because of the morbidity and mortality associated with fracture. The position statement asserts that individuals with PHPT should undergo DXA scanning of these three sites for reliable documentation of their BMD status as a criterion for recommending parathyroidectomy.

Chappard and colleagues (2006) studied females with primary hyperparathyroidism and healthy women to assess the bone mineral density (BMD) status in primary hyperparathyroidism (PHPT). Their results suggested that low BMD at lumbar spine and femur is encountered preferentially in premenopausal women. The BMD decrease predominates at limbs in PHPT with presumably a gradient from proximal to distal part of the limbs. Indeed, the distal part of the limbs are the most affected areas in PHPT whatever the amount of cortical or trabecular bone.

The American College of Radiology and Society of Skeletal Radiology practice guideline for the performance of dual-energy x-ray (DXA) recognizes that there may be instances (extensive abdominal aortic calcification, degenerative disease of the lumbar spine or hip, scoliosis, fractures, orthopedic implants), where central DXA measurements are not feasible and alternate sites (the opposite hip, nondominant forearm, or whole body) can be used for evaluating the individual. The guideline also states that "DXA of the nondominant forearm may be useful in individuals who exceed the weight limit of the DXA table and in individuals with hyperparathyroidism" (ACR-SSR, 2013).

Other Peripheral Bone Mineral Density Measurements (Exclusion of Cortical Bone)
Other methods used to evaluate peripheral bone density are not in accordance with generally accepted standards of medical practice, including radiographic absorptiometry of the fingers, single energy X-ray absorptiometry (SEXA), single photon absorptiometry (SPA), dual X-ray and laser (DXL), ultrasound of the heel, pulse-echo ultrasound of the tibia.

Ultrasound Heel Densitometry versus DXA
Because of the slow changes in bone mineral density and the precision of measuring technologies, specifically DXA, monitoring response to therapy prior to 2 years is unlikely to detect changes. In addition, changes in bone mineral density at central sites (for example, hip and spine) are often not reflected by changes in bone mineral density at peripheral sites.

Nayak and colleagues (2006) conducted a meta-analysis to determine the sensitivity and specificity of calcaneal quantitative ultrasound for identifying individuals who meet the World Health Organization's diagnostic criteria for osteoporosis. DXA was used as the reference standard. Of the 1908 articles identified, 25 met the inclusion criteria and calculated the sensitivity and specificity of quantitative ultrasound over a range of thresholds. The authors found that the results of calcaneal quantitative ultrasound at commonly used cutoff thresholds do not definitively exclude or confirm DXA-determined osteoporosis and that additional research is needed before use of this test can be recommended in evidence-based screening programs for osteoporosis.

The 2011 U.S. Preventive Services Task Force (USPSTF) recommendations on screening for osteoporosis state that quantitative ultrasonography seems to be equivalent to DXA for predicting fractures. However, the current diagnostic criteria for osteoporosis utilize DXA measurements as cutoffs, and the measurements obtained from quantitative ultrasonography are not interchangeable with those obtained from DXA. The USPSTF guidelines also point out that trials evaluating drug therapies for osteoporosis use DXA measurements as inclusion criteria. Therefore, in order for quantitative ultrasonography to be relevant and clinically useful, a method for converting or adapting the results of quantitative ultrasonography to the DXA scale needs to be developed.

Ultrasound heel densitometry may be shown to have clinical potential as a screening tool for osteoporosis, however, at the present time, data are mixed and do not indicate strong and consistent support for the routine use of ultrasound densitometry as a screening or diagnostic tool or as a means to monitor response to therapy. The full potential of this technology cannot be realized without additional studies on the precision, accuracy, reproducibility, and validity of ultrasound densitometry in the clinical setting.

Pulse-echo Ultrasound of the Tibia

Pulse-echo ultrasound of the tibia is being evaluated as a tool to assist with the identification and diagnosis of individuals considered to be at increased risk for osteoporosis and for the determination of fracture risk. At least one such device has been granted FDA premarket approval. In January 2017, the Center for Devices and Radiological Health of the Food and Drug Administration (FDA) granted pre-market approval (K161971) for marketing Bindex® BI-2 pulse-echo ultrasound device (Bone Index, Kuopio, Finland). According to the FDA approval letter:

> 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 BI-2 device: is comprised of a handheld ultrasound transducer and software. Bindex BI-2 is connected to the USB port of a computer and operated with computer software. Bindex BI-2 measures the thickness of the cortical bone and calculates the Density Index (DI), a parameter which estimates bone mineral density at the hip as measured with DXA. To obtain tibial measurements, gel is applied to the skin and the ultrasound transducer is manually placed on the measurement location. The standardized measurement location is at the proximal tibia (1/3 length of tibia). The operator then manually orients the transducer perpendicularly to the surface of the cortical bone to obtain the measurement. This process is repeated five times at each measurement location. The transducer is then disinfected by removing the gel with an isopropyl alcohol moistened cloth.

The intended place in therapy for this device would be to utilize it in addition to current algorithmic fracture risk assessment tools (for example, FRAX). When the algorithmic fracture risk assessment tool suggests an intermediate or high risk of osteoporotic fracture, the pulse-echo device could be employed to determine whether referral for DXA scan is appropriate (in the case of confirmed intermediate risk) or not (if low risk).

Several articles have been published which explore the use of the pulse-echo ultrasound device as a tool to screen for osteoporosis (Karjalainen, 2016; Karjalainen, 2018; Schousboe, 2017). While there are no safety concerns regarding the use of pulse-echo ultrasound of the tibia, the peer-reviewed evidence exploring this technology is limited to uncontrolled, non-randomized trials evaluating Caucasian females. It has not yet been determined if the results demonstrated in the studies referenced above will be replicated in other ethnic groups. There is currently no prospective evidence showing the Bindex pulse-echo ultrasound can predict fracture risk; this evidence is essential for an osteoporosis assessment tool given that treatments are aimed at reducing fracture risk. No prospective studies demonstrating the effect of pulse-echo ultrasound of the tibia on the need for DXA scans were identified at the time of this review. Additionally, there are limited data on the correlation between tibial bone thickness and femoral bone mineral density. Also no professional medical society guidelines which recommended or supported the use of pulse-echo ultrasound of the tibia as a means to screen for or diagnose osteoporosis were identified.

Digital X-ray Radiogrammetry

Digital X-ray radiogrammetry (DXR) employs digital x-ray images of the hand and web-based software to calculate the bone age and quality (expressed as bone health index [BHI]) based on the cortical thickness, width, and length of the metacarpals. This technology is being explored as an alternative to DEXA to estimate BMD, predict fracture risk and to diagnose disease-related osteoporosis (Bach-Mortensen, 2006; Bottcher, 2006; Kälvesten, 2016; Leijten, 2019; Wilczek, 2013).

Several studies (evaluating pediatric, adolescent, and adult populations) have demonstrated that bone quality measured by DXR may correlate well with DXA measurement (Dhainaut, 2010; Rosholm 2001; Schundeln, 2016; Thodberg, 2010; van Rijn 2006). However, other studies have shown that the sensitivity and specificity of DXR compared to DXA of the lumbar spine and/or total body bone mineral density may vary from 40–90 to 79–93%, respectively (Neelis, 2017; Nusman, 2015). Standardized DXR reference ranges and additional well-designed prospective studies that demonstrate that DXR is as accurate as BMD are needed. DXR is not considered in accordance with generally accepted standards of practice for BMD measurements. At the time of this review, no professional or medical society guidelines were identified that address the use of DXR to estimate hand BMD.

Finite Element Analysis
Finite element analysis (FEA), an engineering method to predict bone strength and fracture risk, employs computer models of images and data from high-resolution peripheral computer tomography of the spine or hip to simulate the mechanical behavior of bones (Dall'Ara, 2012; Zysset, 2013). Finite element analysis is being investigated as an alternative means to determine bone strength and fracture risk.

Redepenning and colleagues (2019) noted that applying finite element modeling to clinical applications has been growing in popularity, but there is a lack of consensus on guidelines adopted for reporting FE models. In 2012 a Finite Element Model Grading Procedure (FEMGP) was proposed for the express purpose of "disseminating biomechanical models, publishing, and evaluating others' simulation research; for journal editors and reviewers judging manuscript quality; for agencies and grant reviewers" (Erdemir, 2012). The researchers reported the results of a systematic review of rotator cuff focused finite element models and characterized the reporting quality of those articles. The researchers found that 5/22 articles had scores of 75% or higher and fell within the "exceptional" reporting quality range. The majority of the articles (16/22) were assigned a "good" reporting quality rating with scores between 50% and 75%. However, 9/16 articles which had been assigned a "good" reporting quality rating had scores below 60%. The authors concluded that this study demonstrated that improved guidelines and standards for good reporting practices must be made in the field of finite element modeling. Additionally, the researchers supported the use of the Finite Element Model Grading Procedure as an objective method for evaluating the quality of finite element model reporting in the literature.

Westbury and colleagues (2019) conducted a study to determine the extent to which bone microarchitectural and FEA parameters improve fracture discrimination compared to using areal BMD (aBMD) alone. The researchers hypothesized that combining bone microarchitectural parameters, geometry, BMD and FEA estimates of bone strength from high-resolution peripheral computed tomography as a composite of bone strength might improve discrimination of fragility fractures. The secondary aim was to repeat the cluster analyses in order to determine whether FEA parameters altered the identified phenotypes previously associated with fracture. The analysis consisted of a total of 359 participants (aged 72 to 81 years) from the Hertfordshire Cohort Study (HCS). Fracture history was established by self-report and vertebral fracture assessment. Participants underwent high-resolution peripheral computed tomography scans of the distal radius and DXA scans of the lateral spine and proximal femur. Poisson regression with robust variance estimation was utilized to derive relative risks (RRs) for the relationship between individual bone micro-architectural and FEA parameters and previous fracture. Cluster analysis of these parameters was carried out in order to identify phenotypes associated with fracture prevalence. Receiver operating characteristic analysis suggested that bone micro-architectural parameters enhanced fracture discrimination compared to aBMD alone, whereas the additional inclusion of FEA parameters resulted in minimal improvements.

Cluster analysis (k-means) detected 4 clusters. The first had lower Young modulus, cortical thickness, cortical volumetric density and Von Mises stresses compared to the wider sample; fracture rates were only significantly greater among females (RR compared to lowest risk cluster: 2.55; 95% confidence interval [CI], 1.28 to 5.07; p=0.008). The second cluster in females had greater trabecular separation, lower trabecular volumetric density and lower trabecular load with an increase in fracture rate compared to lowest risk cluster (1.93 [0.98 to 3.78], p=0.057). Cluster analysis revealed a cortical and a trabecular deficiency phenotype, which both showed lower aBMD in men and women. Women with the cortical deficiency phenotype had significantly increased risk of previous fractures. The authors concluded that in this cohort, the addition of bone micro-architectural parameters to aBMD could better predict previous fracture, but further addition of FEA conferred little benefit.

Finite element analysis to predict bone strength and fracture risk is an emerging technology. While some studies suggest that fine element analysis may have a future role in the identification of hip and vertebral fractures additional studies on the precision, accuracy, reproducibility, and validity of finite element analysis in the clinical setting are needed.

Use of data from existing computed tomography scan or digital X-rays to estimate bone strength and fracture risk assessment is not considered in accordance with generally accepted standards of practice.

Definitions

Fracture Risk Assessment Tool (FRAX): A score that utilizes an individual's age, sex, medical history, country, and bone mineral density test results to determine the risk of fracture.

Z-score: A measurement that compares an individual's bone density to the average values for a person of the same age and gender. A low Z-score (below -2.0) may indicate the individual has less bone mass (and/or may be losing bone more rapidly) than expected for someone the individual's age.

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History

Status	Date	Action
	12/28/2023	Updated Coding section with 01/01/2024 CPT changes; added 0815T, also added 76999 NOC replacing 0508T deleted as of 01/01/2024.
Revised	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Added phrase "using Dual-X-Ray Absorptiometry" to bullets I and III of MN criteria and to bullets I and IV of NMN criteria. Added NMN position statement for bone strength and fracture risk assessment using imaging scans other than DXA. Updated Description, Rationale, Definitions, References, Websites for Additional Information, Index and History sections. Updated Coding section, added CPT codes 0554T-0558T, 0743T, 0749T, and 0750T.
Reviewed	08/11/2022	MPTAC review. Updated Discussion/General Information, References and History sections.
Reviewed	08/12/2021	MPTAC review. Updated References and history sections.
Reviewed	08/13/2020	MPTAC review. Updated Rationale and References sections. Reformatted Coding section.
Revised	08/22/2019	MPTAC review. Document expanded to address central and peripheral BMD testing as well as screening for vertebral fractures using DEXA. Content of RAD.00004 Peripheral Bone Mineral Density Measurement moved to this document. Title changed to "Bone Mineral Density Testing Measurement". Updated Description, Clinical Indications, Discussion/General Information, References, Index and History sections. Updated Coding section; added CPT codes 76977, 77081, 78350, 0508T and HCPCS code G0130.
Reviewed	01/24/2019	MPTAC review. Updated Rationale, References and History sections of the document.
Revised	01/25/2018	MPTAC review. Revised Clinical Indications section to indicate (1) An initial BMD screening is considered medically necessary in men greater than 70 years of age (2) Vertebral fracture assessment (VFA) is considered medically necessary when criteria are met; (3) Removed calcitonin from the list of conditions that may underlie osteoporosis; (4). Revised the not medically necessary statement for VFA to indicate that VFA is considered not medically necessary when the individual does not meet the medically necessary criteria. Updated the Discussion/General Information, References and History sections.
Revised	11/02/2017	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated Medically Necessary Clinical

		Indications section by changing bullet A from "An initial examination in menopausal or post-menopausal individuals to screen for osteoporosis. No additional criteria are required" to "Screening for osteoporosis in postmenopausal individuals 65 years of age or older". Minor format change in the Repeat Central Bone Mineral Density Measurements section of the Clinical Indications. Updated Description/General Information, References and History sections.
Revised	11/03/2016	MPTAC review. In the Initial Central Bone Mineral Density Measurements section, revised bullet A by replacing the word "women" with the word "individuals". Updated the References and History sections and formatting in the "Clinical Indications" section.
Revised	11/05/2015	MPTAC review. Updated review date, Description and Discussion/General Information, References and History sections of document. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Updated review date, Description, Discussion/General Information, References and History sections of document. Updated Coding section with 01/01/2015 CPT changes; removed 77082 deleted 12/31/2014.
Reviewed	11/14/2013	MPTAC review. Updated review date, Rationale, References and History sections of document.
Reviewed	11/08/2012	MPTAC review. Updated review date, Rationale, Discussion/General Information and History sections of document.
Reviewed	11/17/2011	MPTAC review. Updated review date, References and History sections of document.
Reviewed	11/18/2010	MPTAC review. Updated review date, References and History sections of document.
	10/14/2010	Category number changed from CG-RAD-18 to CG-MED-39. Removed CPT code 77078 from the Coding section of document. Updated Website information.
Reviewed	11/19/2009	MPTAC review. Removed "Place of Service/Duration" section. Updated the review date, Discussion/ General Information, references and history sections.
	06/04/2009	Removed the passage addressing the "Interventional Society of Clinical Densitometry" from the discussion/general information section of the document.
Revised	11/20/2008	MPTAC review. Document revised to address screening of vertebral fractures using DEXA which is considered not medically necessary. Osteogenesis imperfecta and inflammatory bowel disease added to conditions which may contribute to the development of osteoporosis. Title changed to Central (Hip or Spine) Bone Density Measurement and Screening for Vertebral Fractures Using Dual Energy X-Ray Absorptiometry. Updated Discussion/General Information, References, Coding and History sections.
Reviewed	11/29/2007	MPTAC review. Updated review date, discussion/general information, references and history sections. No change in patient selection criteria.
Revised	08/23/2007	MPTAC review. Modified language in the "Repeat BMD Measurements" section to clarify that all individuals listed in bullet #3 are considered at high

		risk for osteoporosis. Under the NMN section, deleted the words "or cardiac prophylaxis from bullet #2. Updated the discussion/general information, place of service, references and history sections.
New	12/07/2006	MPTAC initial guideline development. Guideline addresses central bone density measurements. Peripheral bone density measurement and screening of vertebral fractures using DEXA are now addressed in RAD.00004 – Peripheral Bone Mineral Density Measurement and Screening for Vertebral Fractures Using DEXA.