



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Bone Mineral Density Measurement

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INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), 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 participant'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 participant's benefit plan document **always supercedes** 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 group 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. 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. Proprietary information of CIGNA. Copyright ©2010 CIGNA

Coverage Policy

CIGNA covers bone mineral density measurement as medically necessary for ANY of the following indications:

- women age 65 or older or men age 70 or older regardless of risk factors
- peri- or postmenopausal women less than 65 or men greater than 50 years of age with at least ONE factor related to an increased risk of osteoporosis or fracture:
 - lifestyle factors (e.g., a personal history of falling, , fracture after age 50, low body weight, physical inactivity, smoking)
 - genetic factors (e.g., parental history of hip fracture)
 - endocrine conditions (e.g., estrogen-deficiency, hyperparathyroidism, androgen deprivation therapy [pharmacologic and orchiectomy])
 - gastrointestinal or other conditions that decrease calcium absorption (e.g., gastric bypass, celiac disease, alcoholism)
 - medications associated with bone mineral loss (e.g., glucocorticoids [greater than or equal to 5 mg/d of prednisone or equivalent for greater than or equal to 3 months])
- individuals with a personal history of a fragility fracture
- prior to initiation of pharmacologic treatment for osteoporosis
- to monitor treatment effect in individual being treated for osteoporosis
- individuals with at least one factor related to an increased risk of osteoporosis not receiving treatment for osteoporosis, in whom evidence of low bone mass would lead to treatment

- individuals with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture
- children or adolescents with a disease process known to adversely effect the skeleton

CIGNA covers repeat bone density measurement no earlier than one year following a change in treatment regimen, and only when the results will directly impact a treatment decision, and every two years otherwise.

When bone mineral density testing is medically necessary, CIGNA covers ANY ONE of the following techniques:

- central or peripheral dual-energy x-ray absorptiometry (DXA or DEXA)
- peripheral single-energy x-ray absorptiometry (SXA)
- central or peripheral quantitative computed tomography (QCT)
- peripheral quantitative ultrasound densitometry (QUS)

CIGNA does not cover vertebral fracture assessment by dual-energy x-ray absorptiometry (DXA) because it is considered experimental, investigational or unproven.

General Background

Before the advent of bone mineral density (BMD) measurement, the diagnosis of osteoporosis depended on the presence of a fragility fracture. With the ability to measure bone mass and the recognition of the relation between reductions in bone mass and increases in fracture risk, the diagnosis of osteoporosis, using World Health Organization (WHO) criteria modified by International Society for Clinical Densitometry (ISCD) to apply to males and females of all races over 50 years of age, can and should be made according to the level of bone mass as determined by BMD before fractures occur. Diagnosing osteoporosis before a fracture occurs is justified by the recognized inverse and exponential relationship between low bone mass and future fracture risk and the exceedingly high risk observed for a second fracture once the first fracture has occurred (Wasnich, et al., 1989; Ross, et al., 1991; American College of Radiology, 2007).

BMD is expressed in absolute terms of grams of mineral per square centimeter scanned (g/cm^2) and as a relationship to two norms: compared to the expected BMD for the patient's age and sex (Z-score), or compared to "young normal" adults of the same sex (T-score). The difference between the patient's score and the norm is expressed in standard deviations (SD) above or below the mean. The BMD diagnosis of normal, low bone mass, osteoporosis and severe or established osteoporosis is based on the WHO diagnostic classification:

- Normal: BMD is within 1 SD of a "young normal" adult (T-score at -1.0 and above).
- Low bone mass (osteopenia): BMD is between 1.0 and 2.5 SD below that of a "young normal" adult (T-score between -1.0 and -2.5).
- Osteoporosis: BMD is 2.5 SD or more below that of a "young normal" adult (T-score at or below -2.5). Patients in this group who have already experienced one or more fractures are deemed to have severe or "established" osteoporosis.

(Based on BMD measurement at the spine, hip or forearm by DXA).

In postmenopausal women and men age 50 years and older, the WHO diagnostic T-score criteria (normal, low bone mass and osteoporosis) are applied to BMD measurement by central DXA at the lumbar spine and femoral neck. In premenopausal women, men less than 50 years of age and children, the WHO BMD diagnostic classification should not be applied. In these groups, the diagnosis of osteoporosis should not be made on the basis of densitometric criteria alone. The ISCD recommends that instead of T-scores, ethnic or race adjusted Z-scores should be used, with Z-scores of -2.0 or lower defined as either "low bone mineral density for chronological age" or "below the expected range for age" and those above -2.0 being "within the expected range for age."

FRAX™ is a fracture risk assessment tool that integrates the future osteoporotic fracture risk associated with clinical risk factors with that associated with femoral neck BMD. It is becoming available on newer DXA

scanners. FRAX is most useful in patients with low hip BMD. Utilizing FRAX in patients with low BMD at the spine but a relatively normal BMD at the hip requires special consideration. Specifically, the WHO algorithm has not been validated for the use of spine BMD. As such, clinicians will need to use clinical judgment in this situation, since FRAX may underestimate fracture risk in these individuals based on the exclusive use of femoral neck BMD (National Osteoporosis Foundation, 2008).

Screening

National Osteoporosis Foundation (NOF): The NOF (2008) lists these indications for BMD testing:

- women age 65 and older and men age 70 and older, regardless of clinical risk factors
- younger postmenopausal women and men age 50 to 69 about whom you have concern based on their clinical risk factor profile
- women in the menopausal transition if there is a specific risk factor associated with increased fracture risk such as low body weight, prior low-trauma fracture or high risk medication
- adults who have a fracture after age 50
- adults with a condition (e.g., rheumatoid arthritis) or taking a medication (e.g., glucocorticoids in a daily dose \geq 5 mg prednisone or equivalent for \geq three months) associated with low bone mass or bone loss
- anyone being considered for pharmacologic therapy for osteoporosis
- anyone being treated for osteoporosis, to monitor treatment effect
- anyone not receiving therapy in whom evidence of bone loss would lead to treatment
- postmenopausal women discontinuing estrogen should be considered for bone density testing

American College of Physicians (ACP): The ACP clinical practice guideline 'Screening for Osteoporosis in Men' recommends clinicians periodically perform individualized assessment of risk factors for osteoporosis in older men and obtain DXA for men who are at increased risk for osteoporosis and are candidates for drug therapy (Qaseem, et al., 2008).

American Academy of Family Physicians (AAFP): The AAFP Summary of Recommendations for Clinical Preventive Services (2009) states the AAFP recommends:

- routinely screening women aged 65 and older for osteoporosis
- routinely screening women aged 60 and older at increased risk for osteoporotic fractures

United States Preventive Services Task Force (USPSTF): The USPSTF recommendations (2002) state that women age 65 and older should be screened routinely for osteoporosis. The USPSTF recommends that routine screening begin at age 60 for women at increased risk[†] for osteoporotic fractures. The USPSTF makes no recommendation for or against routine osteoporosis screening in postmenopausal women who are younger than 60 or in women age 60–64 who are not at increased risk for osteoporotic fractures.

[†] Low body weight or body-mass index (BMI) and not using estrogen replacement were also consistently associated with osteoporosis but to a lesser degree than age. Other risk factors for fracture or low bone density found in some, but not all, studies include white or Asian ethnicity, history of fracture, family history of osteoporotic fracture, history of falls, low levels of physical activity, smoking, excessive alcohol or caffeine use, low calcium or vitamin D intake, and the use of various medications.

American Association of Clinical Endocrinologists (AACE): The AACE medical guidelines for clinical practice for the diagnosis and treatment of menopause (2006) state that menopausal women receiving estrogen therapy should be appropriately monitored with use of dual-energy x-ray absorptiometry as well as known clinical factors of fracture risk to determine the adequacy of an administered dose of estrogen.

American College of Obstetricians and Gynecologists (ACOG): ACOG states that, in the absence of new risk factors, screening should not be performed more frequently than every two years (2004). For fracture risk assessment, the most valuable risk factor appears to be BMD, age, prior fracture history, and risk of falling (2008).

American College of Radiology (ACR): BMD measurement is used to identify patients with low bone density and increased fracture risk. DXA is the gold standard and the only BMD technology for which WHO criteria for diagnosis of osteoporosis, originally for postmenopausal Caucasian women over age 65, can be used. ISCD has expanded the diagnostic category to include patients over age 50 of any race or gender. T-scores are used

for men and women after age 50 or menopause to make a diagnosis and assess fracture risk. Z-scores are used for all individuals under age 50 to determine low bone density. Fracture risk is not assessed based on BMD in individuals under age 50 (2007).

Infectious Diseases Society of America: Primary care guidelines for the management of persons infected with human immunodeficiency virus (HIV) (Aberg, et al. 2009) states the following recommendations relating to long-term metabolic complications associated with antiretroviral therapy:

- Baseline bone densitometry measurement should be obtained in postmenopausal women aged ≥ 65 years and in younger postmenopausal women who have ≥ 1 risk factor for premature bone loss, (other than being female and postmenopausal) (Grade B: Moderate evidence to support a recommendation for use).
- Routine screening for osteoporosis in HIV-infected patients without other risk factors for premature bone loss is not recommended at this time, on the basis of available data, but it should be considered in persons aged ≥ 50 years, especially if they have ≥ 1 risk factor for premature bone loss (Grade B)

Serial BMD

Under the subheading of monitoring effectiveness of treatment, the NOF (2008) states “measurements for monitoring patients should be performed in accordance with medical necessity, expected response and in consideration of local regulatory requirements.” NOF recommends “repeat BMD assessments generally agree with Medicare guidelines of every two years,” but recognizes “testing more frequently may be warranted in certain clinical situations.”

The USPSTF notes that no studies have evaluated the optimal intervals for repeated screening (2002). Because of limitations in the precision of testing, the USPSTF states that a minimum of two years may be needed to reliably measure a change in bone mineral density. Longer intervals may be adequate for repeated screening to identify new cases of osteoporosis. The USPSTF notes that yield of repeated screening will be higher in older women, those with lower BMD at baseline, and those with other risk factors for fracture.

Types of BMD Testing

The NOF states that although available technologies measuring central (spine and hip) and peripheral skeletal sites (forearm, heel, fingers) provide site-specific and global (overall risk at any skeletal site) assessment of future fracture risk, dual-energy x-ray absorptiometry (DXA) measurement at the hip is the best predictor of future hip fracture risk. DXA measurement of the hip and spine is the technology now used to establish or confirm a diagnosis of osteoporosis, predict future fracture risk and monitor patients by performing serial assessments.

The NOF notes that other bone mass measurement technologies including peripheral DXA (pDXA), quantitative computed tomography absorptiometry (QCT), and quantitative ultrasound densitometry (QUS), are capable of predicting both site-specific and overall fracture risk; however, T-scores from these technologies cannot be used according to the WHO diagnostic classification because they are not equivalent to T-scores derived from DXA. pDXA measures a real bone density of the forearm, finger or heel. Measurement by validated pDXA devices can be used to assess vertebral and overall fracture risk in postmenopausal women. There is lack of sufficient evidence for fracture prediction in men. pDXA is associated with exposure to trivial amounts of radiation. pDXA is not appropriate for monitoring BMD after treatment. QCT measures volumetric trabecular and cortical bone density at the spine and hip, whereas peripheral QCT (pQCT) measures the same at the forearm or tibia. In postmenopausal women, QCT measurement of spine trabecular BMD can predict vertebral fractures whereas pQCT of the forearm at the ultra distal radius predicts hip, but not vertebral fractures. There is lack of sufficient evidence for fracture prediction in men. QCT and pQCT are associated with greater amounts of radiation exposure than central DXA or pDXA. QUS does not measure BMD directly but rather speed of sound (SOS) and/or broadband ultrasound attenuation (BUA) at the heel, tibia, patella and other peripheral skeletal sites. A composite parameter using SOS and BUA may be used clinically. Validated heel QUS devices predict fractures in postmenopausal women (vertebral, hip and overall fracture risk) and in men 65 and older (hip and non-vertebral fractures). QUS is not associated with any radiation exposure (NOF, 2008).

The American College of Radiology notes that BMD technologies are not interchangeable. A patient cannot be scanned on DXA and then followed by QCT without establishing a baseline on QCT (2007). In situations where DXA is not readily accessible to the target population, such as in small rural practices, QCT is the best

alternative test, because body CT scanners are widely available. Although QCT (unlike DXA) can selectively evaluate high-turnover cancellous bone and is the best predictor of vertebral fracture risk, its relative disadvantages include higher radiation dose, lower precision, accuracy, and speed, and lower patient throughput because it is not performed on dedicated densitometric equipment.

Vertebral Fracture Assessment (VFA)

The gold standard for diagnosing vertebral fractures is lateral spine x-rays. Image quality of vertebral fracture assessment (VFA) by DXA is inferior to radiography, with sensitivity and specificity ranging from 0.65–0.84 and 0.97–0.98, respectively (Fuerst, et al., 2008).

The Blue Cross Blue Shield Technology Evaluation Center (TEC) conducted an assessment to determine whether the available evidence demonstrates that screening for vertebral fractures using DXA improves selection of patients for treatment and consequently reduces risk of future fractures (February, 2006). The authors stated “conclusions about the utility of the test, given its diagnostic characteristics, must be placed in context of the clinical use of the test in making treatment decisions. At present, the diagnostic performance of vertebral fracture assessment using DXA has not been adequately evaluated in the population of interest. However, the clinical context of osteoporosis screening and fracture prevention is evolving. Recent publications of large trials of pharmacologic treatments for osteoporosis suggest that pharmacologic treatment also benefits for subjects with osteopenia. Thus, the threshold for treatment may currently be in flux, and it is unknown whether vertebral fracture assessment using DXA would yield a population of patients that would not otherwise have been treated based on BMD alone.”

The NOF states that VFA imaging of the thoracic and lumbar spine using central DXA scanners should be considered at the time of BMD assessment when the presence of a vertebral fracture not previously identified may influence clinical management of the patient (NOF, 2008).

There is insufficient evidence in the published peer-reviewed scientific literature demonstrating what impact, if any, screening for vertebral fractures using DXA may have on prevention, treatment or outcomes (Schousboe, et al., 2006; Chapurlat, et al., 2006; Howat, et al., 2007).

Summary

Evidence in the published, peer-reviewed scientific literature supports the clinical utility of bone mineral density measurement in individuals with conditions, diseases and/or on certain medications that cause or contribute to osteoporosis and fractures. In addition bone mineral density measurement is supported by specialty societies and in consensus guidelines. Measurement of bone mineral density using dual energy x-ray absorptiometry (DXA), single energy x-ray absorptiometry (SXA), quantitative computer tomography (QCT) or quantitative ultrasound (QUS) is acceptable. There is insufficient evidence in the published peer-reviewed scientific literature to support the clinical utility of DXA for screening for vertebral fractures (i.e., vertebral fracture assessment [VFA]).

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT® Codes	Description
76977	Ultrasound bone density measurement and interpretation, peripheral sites, any method
77078	Computed tomography, bone mineral density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine)
77079	Computed tomography, bone mineral density study, 1 or more sites; appendicular skeleton (peripheral (e.g., radius, wrist, heel)
77080	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine)

77081	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)
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HCPCS Codes	Description
G0130	Single energy x-ray absorptiometry (SXA) bone density study, one or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)

ICD-9-CM Diagnosis Codes	Description
	Multiple/varied

Experimental/Investigational/Unproven/Not Covered:

CPT* Codes	Description
77082	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; vertebral fracture assessment

*Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	3/15/2008	0300	Bone Mineral Density Measurement

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