



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 ©2009 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
- postmenopausal women discontinuing estrogen
- 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, low body weight, physical inactivity, smoking)
 - genetic factors (e.g., parental history of hip fracture)
 - endocrine conditions (e.g., 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 history of a fracture occurring after age 50
- peri- or postmenopausal women less than 65 years of age with a history of a fragility fracture
- men with a 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

The diagnosis of normal bone mass, low bone mass, osteoporosis and severe or established osteoporosis is established by measurement of bone mineral density (BMD). The BMD diagnosis of osteoporosis and severe or established osteoporosis is based on the World Health Organization (WHO) diagnostic classification. Specifically, according to the WHO diagnostic classification, osteoporosis is defined by BMD at the hip or spine that is less than or equal to 2.5 standard deviations below the young normal mean reference population. BMD has been shown to correlate with bone strength and is an excellent predictor of future fracture risk. Instead of a specific threshold, fracture risk increases exponentially as BMD decreases.

U.S. Food and Drug Administration (FDA)

Bone densitometers are medical devices regulated by the FDA.

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 (2007) 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
- counseling females age 11 and older to maintain adequate calcium intake prevent osteoporosis

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). In October 2003, ACOG released a "Statement of The American College of Obstetricians and Gynecologists on Hormone Therapy for the Prevention and Treatment of Postmenopausal Osteoporosis." It noted that periodic reassessment of the need for hormone therapy is recommended at least at every annual visit, or more frequently if indicated.

International Society for Clinical Densitometry (ISCD): The 2007 ISCD official position is for worldwide application except where otherwise noted, and lists the following indications for BMD testing:

- women aged 65 and older
- postmenopausal women under age 65 with risk factors
- 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
- men under age 70 with clinical risk factors for fracture
- 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 whom evidence of bone loss would lead to treatment

Women discontinuing estrogen should be considered for bone density testing according to the indications listed above. The ISCD notes that DXA assessment may be indicated in children and adolescents with disease that may affect the skeleton.

The ISCD (Lewiecki, et al., 2004) notes that the NOF identified many of the risk factors for osteoporosis and related fractures in white postmenopausal women. Major risk factors are personal history of fracture as an adult, history of fragility fracture in a first-degree relative, low body weight (≤ 57.7 kg [127 lbs]), current smoking, and use of oral glucocorticoid therapy for more than three months. Additional risk factors are impaired vision, estrogen deficiency at an early age (< 45 years), poor health/frailty, recent falls, low calcium intake (lifelong), low physical activity, and alcohol in amounts greater than two drinks per day. Medical conditions associated with increased risk of osteoporosis include chronic obstructive pulmonary disease, gastrectomy, hyperparathyroidism, hypogonadism, multiple myeloma, and celiac disease. Medications, in addition to oral

glucocorticoids, that are associated with reduced bone mass in adults include anticonvulsants, gonadotropin-releasing hormone (GnRH) agonists, excessive T4 doses, and lithium.

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.

The ISCD 2007 official position notes some of the following points regarding serial BMD:

- Follow-up BMD testing should be done when the expected change in BMD equals or exceeds the least significant change
- Intervals between BMD testing should be determined according to each patient's clinical status. Typically, one year after initiation or change of therapy is appropriate, with longer intervals once therapeutic effect is established.
- In conditions associated with rapid bone loss, such as glucocorticoid therapy, testing more frequently is appropriate.

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 areal 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).

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).

The ISCD 2007 official position states that Vertebral Fracture Assessment (VFA) is the correct term to denote densitometric spine imaging performed for the purpose of detecting vertebral fractures. The ISCD states the following indications for VFA:

1. Consider VFA when the results may influence clinical management.
2. Postmenopausal women with low bone mass (osteopenia) by BMD criteria, PLUS any one of the following:
 - Age greater than or equal to 70 years
 - Historical height loss greater than 4 cm (1.6 in.)
 - Prospective height loss greater than 2 cm (0.8 in.)
 - Self-reported vertebral fracture (not previously documented)
 - Two or more of the following;
 - Age 60 to 69 years
 - Self-reported prior non-vertebral fracture
 - Historical height loss of 2 to 4 cm
 - Chronic systemic diseases associated with increased risk of vertebral fractures (for example, moderate to severe COPD or COAD, seropositive rheumatoid arthritis, Crohn’s disease)
3. Men with low bone mass (osteopenia) by BMD criteria, PLUS any one of the following:
 - Age 80 years or older
 - Historical height loss greater than 6 cm (2.4 in)
 - Prospective height loss greater than 3 cm (1.2 in)
 - Self-reported vertebral fracture (not previously documented)
 - Two or more of the following;
 - Age 70 to 79 years
 - Self-reported prior non-vertebral fracture
 - Historical height loss of 3 to 6 cm
 - On pharmacologic androgen deprivation therapy or following orchiectomy
 - Chronic systemic diseases associated with increased risk of vertebral fractures (for example, moderate to severe COPD or COAD, seropositive rheumatoid arthritis, Crohn’s disease)
4. Women or men on chronic glucocorticoid therapy (equivalent to 5 mg or more of prednisone daily for three (3) months or longer).
5. Postmenopausal women or men with osteoporosis by BMD criteria, if documentation of one or more vertebral fractures will alter clinical management.

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 bone mineral density measurement in individuals with conditions, diseases and/or on certain medications that cause or contribute to osteoporosis and fractures. 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 use 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)

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[®]) © 2008 American Medical Association: Chicago, IL.

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Policy History

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

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