



# CIGNA MEDICAL COVERAGE POLICY

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

**Subject Bone Mineral Density Measurement**

**Effective Date ..... 3/15/2011**  
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## Hyperlink to Related Coverage Policies

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer'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 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 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 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 ©2011 CIGNA

## Coverage Policy

Coverage of bone mineral density measurement for screening for osteoporosis is generally subject to the terms, conditions and limitations of a preventive services benefit as described in the applicable benefit plan's schedule of copayments. Please refer to the applicable benefit plan document and schedules to determine benefit availability and the terms, conditions and limitations of coverage.

If coverage for bone mineral density measurement for screening for osteoporosis is available, the following conditions apply.

### Screening

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

- woman age ≥65 years without previous known fractures or secondary causes of osteoporosis
- woman age <65 years whose 10-year fracture risk is equal to or greater than that of a 65-year-old white woman without additional risk factors (a 9.3% 10-year risk for any osteoporotic fracture) as determined by FRAX\* score
- man age >50 years with at least one factor related to an increased risk of osteoporosis (i.e., age > 70, low body weight, weight loss >10%, physical inactivity, corticosteroid use, androgen deprivation therapy, hypogonadism and previous fragility fracture)

CIGNA covers repeat bone density measurement every two years.

\* Fracture Risk Assessment (FRAX<sup>®</sup>) tool, developed by the World Health Organization (Sheffield, United Kingdom)

### **Monitoring**

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

- prior to and during pharmacologic treatment for osteoporosis
- child or adolescent 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.**

### **Other**

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

- known osteoporotic fracture
- individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture

**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.**

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## **General Background**

More than 10 million Americans have osteoporosis, and more than 34 million others have low bone mass and are therefore at increased risk for developing osteoporosis and for fracturing. About 80% are women, most of them postmenopausal. Despite effective screening and therapy, less than a third of the cases of osteoporosis have been diagnosed, and only a seventh of the American women with osteoporosis receive treatment. A clinical diagnosis of osteoporosis and decision to initiate pharmacologic therapy can be made without bone mineral density (BMD) testing in postmenopausal women who have fragility fractures of the hip or spine. Nevertheless, BMD measurement is useful in these patients to quantify fracture risk and to establish a baseline for monitoring the response to treatment. BMD testing is useful for screening people at high risk for osteoporosis (e.g., postmenopausal women), for disease management in patients with hyperparathyroidism and other disorders or those taking medications (e.g., glucocorticoids) associated with bone loss, if evidence of bone loss would result in modification of therapy, and for monitoring of pharmacologic therapy with bone-active agents. In order to identify those patients who are most likely to sustain a fracture, BMD results must be used in combination with other clinical risk factors for osteoporosis-related fractures for accurate assessment of fracture risk and appropriate treatment decisions (American Association of Clinical Endocrinologists [AACE], 2010).

### **Bone Mineral Density**

Bone mineral density (BMD) is expressed in absolute terms of grams of mineral per square centimeter scanned ( $\text{g}/\text{cm}^2$ ) 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 1994 World Health Organization (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 International Society for Clinical Densitometry (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<sup>®</sup> Tool**

The FRAX<sup>®</sup> tool (Fracture Risk Assessment) has been developed by World Health Organization Collaborating Centre for Metabolic Bone Diseases (Sheffield, United Kingdom) to evaluate fracture risk of patients. It is based on individual patient models that integrate the risks associated with clinical risk factors as well as BMD at the femoral neck. The FRAX models have been developed from studying population-based cohorts from Europe, North America, Asia and Australia. In their most sophisticated form, the FRAX tool is computer-driven and is available online. Several simplified paper versions, based on the number of risk factors are also available, and can be downloaded for office use. The FRAX algorithms give the 10-year probability of fracture. The output is a 10-year probability of hip fracture and the 10-year probability of a major osteoporotic fracture (clinical spine, forearm, hip or shoulder fracture) (WHO, 2011).

The American Association of Clinical Endocrinologists (AACE) states that FRAX is the best effort to date to incorporate risk factors into determination of fracture risk and is more effective in conjunction with BMD than without. Important risk factors—risks that are amenable to intervention—can be determined easily. FRAX can be used for men as well as women and is validated globally, with output and utility of results adaptable to individual populations or regional/national standards, but there are also major limitations (AACE, 2010). The National Osteoporosis Foundation (NOF, 2010) notes that the WHO algorithm used in their guide was calibrated to US fracture and mortality rates; the fracture risk figures within NOF guidelines are specific for the US population. 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. There are four US FRAX algorithms, for Blacks, Hispanics, Asians and Caucasians. Application of US-FRAX in the US:

- FRAX is intended for postmenopausal women and men age 50 and older; it is not intended for use in younger adults or children.
- FRAX applies only to previously untreated patients.
- in the absence of femoral neck BMD, total hip BMD may be substituted; however, use of BMD from non-hip sites in the algorithm is not recommended because such use has not been validated (NOF, 2010).

### **Screening**

**National Osteoporosis Foundation (NOF):** The NOF (2010) 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' noted the population screen included as low as age 50. The ACP recommends assessing men before age 65 for risk factors; recommending DXA scans only for those with an increased risk of osteoporosis based on the presence of one or more risk factors and are candidates for drug therapy (i.e., age  $> 70$ , low body weight, weight loss  $>10\%$ , physical inactivity, corticosteroid use, androgen deprivation therapy, and previous fragility fracture (Qaseem, et al., 2008).

**United States Preventive Services Task Force (USPSTF):** The USPSTF recommendations on screening for osteoporosis in postmenopausal women (2011) states the following populations should be screened:

- women age  $\geq 65$  years without previous known fractures or secondary causes of osteoporosis
- women age  $<65$  years whose 10-year fracture risk is equal to or greater than that of a 65-year-old white woman without additional risk factors

The USPSTF states:

- current diagnostic and treatment criteria rely on dual-energy x-ray absorptiometry (DXA) of the hip and lumbar spine.
- evidence is lacking about optimal intervals for repeated screening.
- evidence is insufficient to assess the balance of benefits and harms of screening for osteoporosis in men.

The USPSTF used the FRAX tool to estimate 10-year risks for fractures. Based on the U.S. FRAX tool, a 65-year-old white woman with no other risk factors has a 9.3% 10-year risk for any osteoporotic fracture. White women between the ages of 50 and 64 years with equivalent or greater 10-year fracture risks based on specific risk factors include but are not limited to the following persons: 1) a 50-year-old current smoker with a BMI less than 21 kg/m<sup>2</sup>, daily alcohol use, and parental fracture history; 2) a 55-year-old woman with a parental fracture history; 3) a 60-year-old woman with a BMI less than 21 kg/m<sup>2</sup> and daily alcohol use; and 4) a 60-year-old current smoker with daily alcohol use. The FRAX tool also predicts 10-year fracture risks for black, Asian, and Hispanic women in the United States. In general, estimated fracture risks in nonwhite women are lower than those for white women of the same age. Although the USPSTF recommends using a 9.3% 10-year fracture risk threshold to screen women aged 50 to 64 years, clinicians also should consider each patient's values and preferences and use clinical judgment when discussing screening with women in this age group. Menopausal status is one factor that may affect a decision about screening in this age group.

The USPSTF found convincing evidence that bone measurement tests predict short-term risk for osteoporotic fractures in women and men, and that drug therapies reduce subsequent fracture rates in postmenopausal women. The USPSTF found no studies that assessed the effect on patient outcomes of using risk prediction instruments alone or in combination with bone measurement tests.

**American Association of Clinical Endocrinologists (AACE):** The AACE medical guideline for clinical practice for the diagnosis and treatment of postmenopausal osteoporosis (2010) are limited to postmenopausal women.

Indications for BMD testing:

- all women 65 years of age or older
- all postmenopausal women
  - with a history of fracture(s) without major trauma after age 40 to 45 years
  - with osteopenia identified radiographically
  - starting or taking long-term systemic glucocorticoid therapy ( $\geq 3$  mo)

- 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/m<sup>2</sup>)
  - ever use of long-term systemic glucocorticoid therapy (≥3 mo)
  - family history of osteoporotic fracture
  - early menopause
  - current smoking
  - excessive consumption of alcohol
- secondary osteoporosis

Important risk factors for osteoporosis-related fractures are:

- prior low-trauma fracture as an adult
- advanced age
- low bone mineral density
- low body weight or low body mass index (not significant if adjusted for bone mineral density)
- family history of osteoporosis
- use of corticosteroids
- cigarette smoking
- excessive alcohol consumption
- secondary osteoporosis (for example, rheumatoid arthritis)

**American College of Obstetricians and Gynecologists (ACOG):** ACOG Practice Bulletin Osteoporosis (2004, reaffirmed 2008) states:

- bone mineral density testing should be recommended to all postmenopausal women aged 65 years or older.
- bone mineral density testing may be recommended for postmenopausal women younger than 65 years who have 1 or more risk factors\* for osteoporosis.
- bone mineral density testing should be performed on all postmenopausal women with fractures to confirm the diagnosis of osteoporosis and determine disease severity.
- in the absence of new risk factors, screening should not be performed more frequently than every 2 years.

Risk factors\* for osteoporotic fracture in postmenopausal women

- history of prior fracture
- family history of osteoporosis
- caucasian race
- dementia
- poor nutrition
- smoking
- low weight and body mass index
- estrogen deficiency\*
- early menopause (age younger than 45 years) or bilateral oophorectomy
- prolonged premenopausal amenorrhea (>1 year)
- long-term low calcium intake
- alcoholism
- impaired eyesight despite adequate correction
- history of falls
- inadequate physical activity

**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 (2010).

**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  $\geq 65$  years and in younger postmenopausal women who have  $\geq 1$  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  $\geq 50$  years, especially if they have  $\geq 1$  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 states “evidence is lacking about optimal intervals for repeated screening” (2011).

AACE does not address screening frequency but states a repeated DXA at 1 to 2 years after initiation of osteoporosis therapy until bone density is stable. This testing pattern can be continued at every 2-year interval and reduced with evidence of persistent BMD stability (2010).

### **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. Peripheral 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 (2010).

The AACE states that DXA of the lumbar spine and proximal femur (hip) provides accurate and reproducible BMD measurements at important sites of osteoporosis-associated fracture. 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. Of note, the diagnostic criteria established by WHO and recommended by AACE apply only to central DXA measurements (specifically, lumbar spine, femoral neck, and total hip) and to DXA of the 1/3 (33%) radius site. Thus, other technologies cannot be used to diagnose osteoporosis but may be used to assess fracture risk (2010).

### 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 ACR states “criteria for use of VFA include: documented height loss of greater than 2 cm or reported height loss of 4 cm since age 21; history of a fracture after age 50; treatment with long-term steroids; undocumented history of back pain suspicious for vertebral fracture” (2010).

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 <sup>®</sup> * 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)

<b>HCPCS Codes</b>	<b>Description</b>
G0130	Single energy x-ray absorptiometry (SXA) bone density study, one or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)

<b>ICD-9-CM Diagnosis Codes</b>	<b>Description</b>
733.00-733	Osteoporosis
733.10-733.19	Pathologic fracture
733.90-733.99	Other and unspecified disorder of bone and cartilage
V07.4	Hormone replacement therapy (postmenopausal)
V07.59	Use of other agents affecting estrogen receptors and estrogen levels
V13.51-V13.59	Personal history of other musculoskeletal
V49.81	Asymptomatic postmenopausal status (age-related) (natural)
V58.65	Long term (current) use of steroids
V82.81	Screening for other specified condition; Osteoporosis
V87.43	Personal history of estrogen therapy
V87.45	Personal history of systemic steroid therapy

**Experimental/Investigational/Unproven/Not Covered:**

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

<b>ICD-9-CM Diagnosis Codes</b>	<b>Description</b>
	All codes

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

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## Policy History

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

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