

WellCare Health Plans, Inc.

The WellCare Group of Companies

Clinical Coverage Guideline



WellCare Prescription Insurance, Inc.

*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*

WellCare Health Insurance of Illinois, Inc.



WellCare Health Insurance of New York, Inc.

Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

WellCare of Texas, Inc.

WellCare Health Plans of New Jersey, Inc.

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WellCare of New York, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

Harmony Health Plan of Illinois, Inc.

WellCare of Ohio, Inc.

Bone Mass Measurement (BMM)

Guideline Number: HS-042

Original Effective Date: 8/25/2008

Revision Date: 8/31/2009

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

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DISCLAIMER

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APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

CLINICAL COVERAGE GUIDELINE

Bone mass measurement (BMM) is considered medically necessary if ANY of the following criteria are met:

- A woman determined to be estrogen-deficient and at clinical risk for osteoporosis based on medical history, age and other findings; **OR**,
- An individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture; **OR**,
- An individual receiving (or expecting to receive) glucocorticoid therapy equivalent to an average of 5.0 mg of prednisone, or greater, per day, for more than 3 months; **OR**,
- An individual with primary hyperparathyroidism; **OR**,
- An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy

Frequency Standards

BMM screening **is considered medically necessary** once every 2 years (given at least 23 months have passed since the month the last covered BMM was performed).

More frequent BMM **is considered medically necessary** for, but not limited to, the following indications:

- Monitoring members on long-term glucocorticoid therapy of more than three months
- Confirming baseline BMMs to permit monitoring of members in the future

The use of single and dual photon absorptiometry **is considered investigational, and is NOT a covered method** of bone mass measurement.

BACKGROUND

General Information

According to the Centers for Medicare and Medicaid Services (CMS), bone mass measurement (BMM) is defined as a radiologic, radioisotopic, or other procedure that meets all of the following conditions: A) is performed to identify bone mass, detect bone loss, or determine bone quality; B) is performed with either a bone densitometer (other than single-photon or dual-photon absorptiometry) or a bone sonometer system that has been cleared for marketing for BMM by the FDA; and C) includes a physician's interpretation of the results.

One-half of all postmenopausal women will have an osteoporosis-related fracture during their lives, including 25 percent who will develop a vertebral deformity and 15 percent who will suffer a hip fracture. Risk for fracture increases steadily as bone density declines, with no threshold. The commonly used definition of osteoporosis, derived from the World Health Organization (WHO) recommendations for epidemiologic studies, defines a bone mass density (BMD) more than 2.5 standard deviations (SD) below the mean for a young healthy adult woman as osteoporosis, and a BMD between 1 and 2.5 SD below the mean as osteopenia. Based on the WHO criteria and DXA measurements at the femoral neck, population-based studies estimate that 41 percent of white women older than 50 have osteopenia. When bone density is measured at the hip, spine, and wrist, 15 percent of white women aged 50-59 and 70 percent of white women older than 80 have osteoporosis by WHO criteria at least one site.

The prevalence of osteoporosis in Mexican-American women is similar to the prevalence in white women. While rates of osteoporosis in African-American women are approximately one-half those of the other groups, they are still substantial (8 percent among women older than 50). Including all races, an estimated 14 million women older than 50 have osteopenia, and over 5 million have osteoporosis. The actuarial risk of a 65-year-old white woman sustaining a fracture by age 90 is 16 percent for the hip, 9 percent for distal forearm, and 5 percent for proximal humerus. Sixteen percent of postmenopausal women have osteoporosis of the lumbar spine (USPSTF, 2002).

Risk of Osteoporosis

Risk for osteoporosis increases steadily and substantially with age. Relative to women aged 50-54, the odds of having osteoporosis were 5.9-fold higher in women aged 65-69 and 14.3-fold higher in women aged 75-79, in a study of over 200,000 postmenopausal women. 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 (USPSTF, 2002).

Measurement Techniques

Bone mineral density (BMD) can be measured with a variety of techniques in a variety of sites. Sites are broadly subdivided into central sites (e.g. hip or spine) and peripheral sites (e.g. wrist, finger, heel). While BMD measurements are predictive of fragility fractures at all sites, central measurements of the hip and spine are the most predictive. Additionally, fractures of the hip and spine (e.g. vertebral fractures) are the most clinically relevant. The most commonly used techniques are Dual-energy X-ray Absorptiometry (DXA), Quantitative computed tomography (QCT), and Ultrasound Densitometry. Dual-energy X-ray Absorptiometry (DXA) is considered the gold standard because it is the most extensively validated test against fracture outcomes. ***In general, a central DXA measurement should be strongly considered for initial screening purposes due to its reproducibility and ability to simultaneously establish the diagnosis of osteoporosis and provide a baseline if one is needed. Also peripheral DXA absorptiometry, due to the possibility of inconclusive readings, is NOT recommended. CMS states that single-photon and dual-photon absorptiometry are not covered under Medicare because they are not considered reasonable and necessary.***

Radiation Safety

The American College of Radiology (2006) made the following statement concerning radiation safety.

“Radiologists, medical physicists, radiologic technologists, and all supervising physicians have a responsibility to minimize radiation dose to individual patients, to staff, and to society as a whole, while maintaining the necessary diagnostic image quality. This is the concept “As Low As Reasonably Achievable (ALARA)”. Facilities, in consultation with the medical physicist, should have in place and should adhere to policies and procedures, in accordance with ALARA, to vary examination protocols to take into account patient body habitus, such as height and/or weight, body mass index or lateral width. The dose reduction devices that are available on imaging equipment should be active or manual techniques should be used to moderate the exposure while maintaining the necessary diagnostic image quality. Patient radiation doses should be periodically measured by a medical physicist in accordance with the appropriate ACR Technical Standard.”

Physician Qualifications

The examination must be performed under the supervision of and interpreted by a licensed physician with the following qualifications (American College of Radiology, 2006):

- a. Knowledge and understanding of bone structure, metabolism, and osteoporosis;
- b. Documented training and understanding of the physics of X-ray absorption and radiation protection, including the potential hazards of radiation exposure to both members and personnel and the monitoring requirements;
- c. Knowledge and understanding of the process of absorptiometry data and image acquisition, including proper patient positioning and placement of regions of interest, and artifacts and anatomic abnormalities that may falsely increase or decrease BMM values;
- d. Knowledge and understanding of reporting parameters, including, but not limited to: bone density measurements, percent of mean, T-score, Z-score, fracture risk, and World Health Organization (WHO) classification system;
- e. Knowledge and understanding of the criteria for accurate and precise comparison of serial measurements, including limitations of comparing measurements made by different techniques and different devices;
- f. Knowledge and understanding of the utility of the entire spectrum of bone density techniques, such as pDXA, DXA, SXA, QCT, radiographic absorptiometry (RA), and quantitative ultrasound (QUS) to fulfill a consultative role in recommending further bone density studies, future serial measurements, or diagnostic procedures to confirm suspected abnormalities seen on absorptiometry images.

Equipment Specifications

According to CMS guidelines BMM must be performed with either a bone densitometer (other than single-photon or dual-photon absorptiometry) or a bone sonometer system that has been cleared for marketing for BMM by the FDA under 21 CFR part 807, or approved for marketing under 21 CFR part 814.

Multiple equipment designs are available that can accurately and precisely measure bone density using X-ray absorptiometry. The equipment should provide the following (American College of Radiology, 2006):

- a. Normal young adult and age-matched control population standards matched for sex and applicable to the equipment being used must be available. Some devices also provide standards matched for ethnicity, weight, and body mass index;
- b. A phantom or other standard must be provided to evaluate the accuracy and precision of BMM measurement;
- c. Labeled images of the anatomic site measured and measurement results should be recorded permanently for patient records;
- d. Precision error of measurements of the phantom or standard should not exceed the specifications or recommendations of the manufacturers and should be less than 1%. In vitro (phantom) precision should not be equated with in-vivo (member) precision, as the role of the technologist in positioning and scan analysis is critical.

CODING

Covered CPT®* Codes

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

Covered ICD-9-CM Procedure Codes

88.98 Bone Mineral Density Studies

Covered HCPCS Codes

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

Covered ICD-9-CM Diagnosis Codes

252.01	Primary Hyperparathyroidism
733.00 - 733.09	Osteoporosis
733.10 - 733.19	Pathologic fracture
733.90	Osteopenia
805.00 - 806.9	Fracture of vertebral column
V07.4	Hormone replacement therapy (postmenopausal)
V49.81	Asymptomatic postmenopausal status (age-related) (natural)
V58.65	Long-term (current) use of steroids [glucocorticoid therapy]

*Current Procedural Terminology (CPT®) ©2009 American Medical Association: Chicago, IL.

REFERENCES

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3. National Osteoporosis Foundation. Bone Mass Measurement. 2008.
4. The International Society for Clinical Densitometry (ISCD). 2007 Official Positions of the International Society for Clinical Densitometry.
5. U.S. Preventive Services Task Force (USPSTF). Screening for Osteoporosis in Postmenopausal Women: Recommendations and Rationale. September 2002. Agency for Healthcare Research and Quality. Rockville, MD.