Clinical Policy Title: Bone mineral density (BMD) measurement

Clinical Policy Number: 17.01.01

Effective Date: September 1, 2013
Initial Review Date: April 23, 2013
Most Recent Review Date: March 15, 2017
Next Review Date: March 2018

Related policies:

None.

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers the use of bone mineral density (BMD) measurement using dual-energy X-ray absorptiometry (DXA/DEXA) to be clinically proven and, therefore, medically necessary for members when at least one of the following clinical criteria and one of the following equipment criteria are met:

Clinical criteria — At least one of the following clinical conditions:

- Women age 65 and older.
- Men age 70 and older.
- Men or women with a fracture after age 50.
- Postmenopausal women younger than age 65, and/or men ages 50 – 69, based on a personal or familial risk factor that includes, but is not limited to, at least one of the following:
  - A family history of a first-degree relative with osteoporosis or fracture.
  - An individual low body mass index (BMI) and/or low weight (BMI of less than 21 kg per m²),
and/or body weight of 127 pounds or less).
- A 10-year major osteoporosis-related United States-adjusted FRAX® probability of greater than or equal to 9.3 percent.
- A personal history of at least one of the following:
  - Prior history of low-trauma or vertebral fracture.
  - Poor nutrition with low levels of calcium or vitamin D intake.
  - Excessive alcohol intake (more than 14 units/week for women; more than 21 units/week for men).
  - An increased likelihood of falls (may be associated with neurological disorders, pharmaceutical therapy).
  - Low levels of physical activity.
  - Current exposure to cigarettes (smoking).
  - Intake of medications that cause hypogonadism (e.g., androgen deprivation therapy).
  - Hemochromatosis.
  - Homocystinuria.
  - Hypophosphatemia.
  - Multiple myeloma.
  - Thalassemia.
  - Thyrotoxicosis.
- Women currently going through menopause with an associated increased risk factor for fractures, such as current intake of high-risk medication, low body weight and history of low-trauma fracture.
- Postmenopausal women after ending estrogen therapy.
- Postmenopausal women under age 65 with at least one of the following criteria:
  - Asian (nonblack) or Caucasian race.
  - Late menarche and early menopause.
- Women of any age with exercise-induced amenorrhea or oligomenorrhea.
- Individuals of any age with documented vertebral abnormalities indicating osteopenia, osteoporosis, or vertebral fracture as evidenced by X-ray studies.
- Individuals with a history of bariatric surgery.
- Individuals with primary hyperparathyroidism.
- Individuals of any age under current or anticipated pharmaceutical management associated with the development of low bone mass or bone loss, including but not limited to:
  - Glucocorticoid therapy, equivalent to at least 5 mg per day or greater of prednisone for more than a continuous three-month period.
  - A condition associated with a predisposition to bone loss or low bone mass.
  - Other medications known to adversely affect bone mass, such as aromatase inhibitors and anti-seizure drugs.
- Individuals of any age with a documented disorder actively associated with osteoporosis, including but not limited to the following:
  - Cystic fibrosis.
  - Osteogenesis imperfecta.
  - Rheumatoid arthritis.
  - Type 1 insulin-dependent diabetes.
  - Longstanding and untreated chronic liver disease, chronic malabsorption, or malnutrition.
In certain indications, Keystone First considers BMD testing medically necessary and indicated more than once every 23 months, when at least 11 months have elapsed since the previous BMD measurement and testing is limited to the following:

- An individual currently receiving pharmaceutical management with a glucocorticoid (steroid) equivalent to an average of 5.0 mg of prednisone or greater per day for more than three months.
- Confirming baseline BMDs to permit monitoring of members when the initial BMD was not done on the axial skeleton using a DXA/DEXA system. An individual being monitored to assess the response to, or efficacy of, a U.S. Food and Drug Administration (FDA)-approved osteoporosis drug therapy when performed with a DXA/DEXA system (axial skeleton) until, over time, a response to such therapy has been documented.

and

**Tests performed on equipment meeting one of the following criteria:**

- An Keystone First-approved and FDA-approved densitometer is used when the results of the BMD study will be used in treatment decisions.
- A peripheral BMD may be considered to be proven and medically necessary when an FDA-approved densitometer is used for either of the following:
  - An individual physically unable to undergo axial skeleton (hip/spine) measurements due to physical size and surpassing the table limits for the DXA/DEXA device.
  - Individuals diagnosed with hyperparathyroidism for whom a BMD of the forearm is crucial to diagnosis.

All other uses of BMD testing not described within the context of this policy are considered to be unproven and not medically necessary, as their effectiveness is not supported by peer-reviewed professional literature.

**Limitations:**

Keystone First considers the following to be limitations to this policy:

- DXA/DEXA should not be performed if contractures prevent the safe and appropriate positioning of the individual, especially in pediatric cases (ISCD 2007).
- The minimum time interval for repeating a bone density measurement to monitor treatment with a bone-active agent or disease process is six months for pediatric cases (ISCD 2007).
- Only DXA/DEXA (77080) is used to monitor osteoporosis drug therapy.
- BMD measurement must include physician interpretation.
- BMD measurement is a service limited to once every two years (at least 23 months elapsing since the last body mass measurement [BMM] was performed).
- Repeat BMD testing at intervals of less than one year may have untoward effects on reliability when applied to treatment decisions, as the margin of error for the test is usually
greater than the interval treatment effect on BMD.

- Variability of test-to-test results, even with the use of the same testing device, should be considered when addressing the expected effects of treatment.
- Performing both a peripheral and an axial BMD test on the same day is considered not medically necessary.
- BMD testing should be performed at DXA/DEXA facilities using accepted quality assurance measures. Keystone First considers the following BMD tests not reasonable and medically necessary, as the use of these tests is not supported by peer-reviewed professional literature:
  - Single-photon absorptiometry (CT code 78350).
  - Dual-photon absorptiometry (CPT 78351).

All other uses of BMD measurement are not medically necessary.

**Alternative covered services:**

Physician office visits and evaluations.

**Background**

Bone strength is an important factor in an individual's overall mobility and resistance to fractures and is determined in part by bone density. Bone strength and density are determined by the mineral content of a specified area as applied to size and shape (mass) of a bone. Low-density bones are less healthy, more fragile, and prone to fractures. Osteoporosis is a disease marked by the progressive decrease in bone density, increased fragility, and a susceptibility to bone fractures. Osteoporosis-related changes occur when bone loss exceeds bone formation. Osteoporotic changes in the bones are commonly found in postmenopausal women; however, they are seen in both genders and all people of advancing age. Secondary osteoporosis may be caused by conditions that impair the intake and utilization of nutrients, such as anorexia nervosa, bariatric surgery, or prolonged steroid drug treatment.

The United States Preventative Services Task Force (USPSTF) recommendations for BMD testing include all racial and ethnic groups for women age 65 and older, as the consequences of failing to identify and treat women with low BMD are significant. The same recommendations do not define an upper age limit for screening women because of the increased risk for fractures with the advancement in age and the fact that treatment harms remain small. These same guidelines recommend women under age 65 who have a fracture risk greater than or equal to that of a 65-year-old white woman also be screened for BMD (USPSTF 2011). The American College of Physicians states that high-quality evidence shows that age, low body weight, physical inactivity, and weight loss are strong predictors of an increased risk for osteoporosis in men (ACOP 2008).

The National Osteoporosis Foundation (NOF) 2013 recommendations include both men and women.
The NOF agrees with the USPSTF recommendation that women age 65 and older should be screened, and adds recommendations that men age 70 and older be tested regardless of risk factors. The NOF further provides indications for bone mineral testing for men between the ages of 50 and 69. The 2013 updated NOF Clinician’s Guide stresses the importance of screening vertebral imaging to diagnose asymptomatic vertebral fractures; provide updated information on calcium, vitamin D and osteoporosis medications; and address treatment durations.

Various clinical and special interest organizations have published clinical guidelines for osteoporosis and BMD testing. However, at the writing of this policy, no single unifying consensus statement has been formulated. All professional societies acknowledge the aging of the U.S. population will likely lead to an increase in cases of osteoporosis. BMD testing could detect osteoporosis in a large portion of the population and may prevent many fractures and fracture-related illnesses in this population.

Osteoporosis is diagnosed by using the globally accepted World Health Organization (WHO) definition of BMD measurement and fracture risk assessment. The WHO definition of osteoporosis is based on a bone mineral density 2.5 standard deviations (-2.5 T-score) below the mean found in young, healthy adults. Bone mass measurements are performed to identify bone mass (mineral density), detect bone loss, or determine bone quality. The WHO has developed the fracture risk assessment (FRAX®), a tool used to combine the risks associated with a femoral neck BMD and other clinical risk factors for an evaluation of an individual’s overall fracture risk. This computer-based tool, available on the WHO website, also has several simplified paper versions. Access to the web-based tool enables calculations for the major races found on each continent. FRAX® algorithms are used to assess an individual’s 10-year fracture probability for both femoral and other major osteoporotic fractures (clinical spine, forearm, hip, or shoulder fracture).

Skeletal health in children between the ages of 5 and 19 is assessed by the use of fracture prediction and definition of osteoporosis. Fracture prediction is the identification of significant fractures of the long bones, vertebral compression fractures, or two or more long bone fractures of the upper body. A diagnosis of osteoporosis in children is not made solely on the basis of densitometric criteria. The diagnosis must take into account the clinically significant fracture history and BMD or low bone mineral content (BMC). Low BMD or BMC is defined by the presence of a BMC or BMD Z-score less than or equal to -2.0, adjusted for the child’s gender, age, and body size (ISCD 2007).

BMD tests are noninvasive, used to identify individuals with osteoporosis, and may be used to monitor response to osteoporosis treatments. The goal of detecting a low BMD in an individual is to assist with the decision-making toward treatment to prevent a fragility (osteoporotic) fracture. The risk-predicting ability of BMD studies has been compared to the use of cholesterol testing to predict hypertension and heart disease. BMD studies are radiologic or radioisotopic and are performed with an FDA-approved bone densitometer (other than single-photon or dual-photon absorptiometry) or a bone sonometer system. The gold standard and most widely used method for BMD is DXA/DXA.

DEXA requires a short scan time and is used to provide extremely precise and reproducible BMD
measurement. The preferred DEXA measurement sites are located on the central skeleton; these are the
total hip, femoral neck, total lumbar spine, or some combination of these sites. Central skeletal sites are
preferred for baseline and serial BMD measurements and are also more likely than peripheral skeletal
sites to show a response to treatment. Examples of peripheral skeletal sites are the wrist, finger,
forearm, or heel. Peripheral testing only uses one site, and this may be problematic because of
differences in bone density between different skeletal sites. Low bone densities in other skeletal areas
may be overlooked. It is important to note that the diagnostic criteria established by the WHO and
recommendations by the American Association of Clinical Endocrinologists (AACE) apply only to the
peripheral radius site and central (total hip, femoral neck, lumbar spine) site DEXA measurements
(AACE, 2010).

Other BMD techniques use both the central and skeletal sites. In addition to DEXA, the established
methods for BMD testing are the following:

- Quantitative computed tomography (QCT).
- Radiographic absorptiometry (RA; photodensitometry).
- Single-energy X-ray absorptiometry (SEXA).
- Ultrasound BMD studies (i.e., bone sonometry).

QCT is a three-dimensional BMD test that also uses both central and peripheral skeletal sites. The
measurement is calculated using the differential absorption of ionizing radiation by calcified (bone)
tissue. QCT is the only technique that can distinguish between cortical and cancellous bone and may use
standard CT scanners. However, it is expensive, is not widely available, and uses a relatively high amount
of radiation exposure. RA uses plain radiographs of peripheral sites, most commonly from the hand or
heel. Its use decreased as other precise nonradiographic techniques became available. Single-photon
absorptiometry (SPA) uses a single-energy beam usually passed through the wrist to provide a
quantitative measurement of bone mineral and trabecular bone. Dual-photon absorptiometry measures
BMD by the absorption of a dichromatic beam by bone material, and has limited usefulness in
monitoring BMD changes. In current practice, these methods are rarely used. In particular, dual-photon
absorptiometry may be considered obsolete.

Searches

Keystone First searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other
evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on February 28, 2017. Search terms were “bone measurement,” “osteoarthritis,”
“menopause,” and “DEXA” (MeSH).
We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Studies and national guidelines recommend screening for osteoporosis in women age 65 or older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman with no additional risks. The studies may be performed using either single-photon or dual-photon absorptiometry. The frequency of examinations more often than every 23 months has not been demonstrated to improve outcomes.

**Policy updates:**

A systematic review and meta-analysis (Schweiger 2016) evaluated the evidence of low bone mineral density (BMD) in 1,842 depressed and 17,401 nondepressed individuals. Significant negative composite weighted mean effect sizes were identified for the lumbar spine ($d = -0.15$, 95%CL $-0.22$ to $-0.08$), femur ($d = -0.34$, 95%CL $-0.64$ to $-0.05$), and total hip ($d = -0.14$, 95%CL $-0.23$ to $-0.05$) indicating low BMD in depression. Examining men and women showed low bone density in the lumbar spine and femur in women and low bone density in the hip in men. The differences between men and women with mineral density deficit (MDD) and the comparison group tended to be higher when examined by expert interviewers. Low bone density was found in all age groups. The authors concluded that bone mineral density is reduced in patients with depressive disorders.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schweiger (2016) Bone density and depressive disorder: a meta-analysis</td>
<td>Key points:</td>
</tr>
<tr>
<td></td>
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<td></td>
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<tr>
<td>The authors concluded that bone mineral density is reduced in patients with depressive disorders.</td>
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</tbody>
</table>

**Erlichman and Holohan (1996)**

**Yearly density measurements**

**Key points:**
- Explained it is unlikely yearly densitometry would be clinically indicated given the fact that 1% precision error is rarely attained and that a 3% annual loss in bone mass would be distinctly uncommon.
- Precision errors in the range of 2% to 3% and annual bone mass losses of 1% to 2% are parameters more representative of published data.
- In those instances, the minimum interval between densitometry measures necessary to document bone mass loss would be between 3.7 and six years.

**Qaseem et al. (2008)**

**A clinical practice guideline on osteoporosis in men issued by the American College of Physicians (ACP)**

**Key points:**
- Recommended physicians periodically assess elderly men for risk factors for osteoporosis. Although osteoporosis is often viewed as a disease of women, studies show osteoporotic fractures in men are associated with significant morbidity and mortality, resulting in substantial disease burden, death, and health care costs.
- The prevalence of osteoporosis is estimated to be 7% in white men, 5% in black men, and 3% in Hispanic men. Data on prevalence of osteoporosis in Asian-American men and other ethnic groups is lacking.
- The guideline recommended that clinicians assess risk factors for osteoporosis in older men and obtain a DXA scan for men at increased risk for osteoporosis who are candidates for drug therapy.
- Risk factors for osteoporosis in men include age greater than 70; low body weight (BMI less than 20 to 25 kg/m²); weight loss (greater than 10%); lack of regular physical activity such as walking, climbing stairs, carrying weights, housework, or gardening; use of oral corticosteroids; previous osteoporotic fracture; and androgen deprivation therapy.
- ACP also recommended further research to evaluate osteoporosis screening tests in men and that, presently, non-DXA tests are either "too insensitive or have insufficient data to reach conclusions."

**USPSTF (2011)**

**The U.S. Preventive Services Task Force updated its 2002 recommendation on screening for osteoporosis.**

**Key points:**
- The USPSTF evaluated evidence on the diagnostic accuracy of risk assessment instruments for osteoporosis and fractures, the performance of DEXA and peripheral bone measurement tests in predicting fractures, the harms of screening for osteoporosis, and the benefits and harms of drug therapy for osteoporosis in women and men.
- The USPSTF recommends screening for osteoporosis in women age 65 older and in younger women whose fracture risk is equal to or greater than that of a 65-year-old white woman who has no additional risk factors (Grade B recommendation).
- The USPSTF concluded the current evidence is insufficient to assess the balance of benefits and harms of screening for osteoporosis in men.
References

Professional society guidelines/other:


10

Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**
No NCDs identified as of the writing of this policy.

Local Coverage Determinations (LCDs):

L36460 Bone Mass Measurement. CMS website https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=36460&ver=11&CovCoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=bone+mass&KeyWordLookUp=Title&KeyWordSearchType=And&list_type=ncd&bc=gAAACAAAAAAAA%3d%3d&. Accessed March 24, 2017.

Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>77080</td>
<td>Dual energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (e.g., hips, pelvis, spine)</td>
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<td>77081</td>
<td>Dual energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)</td>
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<td>77085</td>
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<tr>
<td>77086</td>
<td>Vertebral fracture assessment via dual-energy X-ray absorptiometry (DXA)</td>
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<table>
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<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tr>
<td>C90.00-C90.02</td>
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<td>Other long term (current) drug therapy</td>
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<td>Z82.62</td>
<td>Family history of osteoporosis</td>
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<td>Z87.310</td>
<td>Personal history of (healed) osteoporosis fracture</td>
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<td>Z87.311</td>
<td>Personal history of (healed) other pathological fracture</td>
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<td>Z87.81</td>
<td>Personal history of vertebral fracture, healed</td>
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<td>Z90.722</td>
<td>Acquired absence of ovaries, bilateral</td>
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<td>Description</td>
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