POLICY STATEMENT:

I. Based upon our criteria and review of the peer-reviewed literature, and in accordance with New York State Insurance Law, the Health Plan covers bone density measurements and tests according to criteria under the Federal Medicare program and the National Institutes of Health (NIH). Bone mineral density (BMD) testing using DEXA (dual energy x-ray absorptiometry), QCT (quantitative computed tomography), SEXA (single energy x-ray absorptiometry), bone density of the heel using ultrasound, or quantitative ultrasound (QUANTUS) is considered medically appropriate in any of the following situations and for whom the results will influence treatment decisions:

A. All women aged 65 and older regardless of additional risk factors;
B. 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;
C. All men age 70 or older regardless of additional risk factors;
D. Men and women previously diagnosed as having osteoporosis;
E. All postmenopausal women under age 65, who have one or more additional risk factors for osteoporotic fracture (please refer to description section for risk factors for osteoporosis in women);
F. Men age 50-70 with clinical risk factors for osteoporotic fracture (please refer to description section for risk factors for osteoporosis in men);
G. Men and women on a prescribed drug regimen (e.g., anticonvulsants, aromatase inhibitors, cytotoxic drugs, Depo-Provera contraceptive injection, or hormone replacement therapy) posing a significant risk of osteoporosis;
H. Men and women receiving (or expecting to receive) long-term glucocorticoid therapy (e.g., glucocorticoids in a daily dose greater than or equal to 5 mg prednisone or equivalent for greater than or equal to 3 months);
I. Men and women being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy;
J. Men and postmenopausal women age 50 and older with a hip or vertebral fracture;
K. Men and postmenopausal women age 50 and older with other prior fractures and low bone mass (T-score between -1.0 and -2.5 at the femoral neck, total hip, or spine);
L. Individuals with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia (low-bone mass) or vertebral fracture;
M. Men and women with primary hyperparathyroidism;
N. Men and women with suspected cases of secondary osteoporosis due to a broad range of disease states (e.g., hyperthyroidism, rheumatoid arthritis, and Type 1 diabetes mellitus);
O. Estrogen-deficient women at clinical risk for osteoporosis (please refer to description section for risk factors for osteoporosis in women);

P. Postmenopausal women who have discontinued hormone replacement therapy within the past five years;

Q. Androgen deprivation therapy, either surgical or medical, in men diagnosed with prostate cancer.

II. Based upon our criteria and review of the peer-reviewed literature, single photon absorptiometry (SPA) and dual photon absorptiometry (DPA) are not medically necessary because they are considered obsolete.

III. Per the National Osteoporosis Foundation (NOF), BMD measurement is not routinely indicated in healthy young men less than 50 years or pre-menopausal women.

IV. The decision to test for BMD should be based on an individual’s risk profile. Testing is not indicated unless the results would influence a treatment decision.

V. Follow up testing:

The growing prevalence of osteoporosis, the management of the associated morbidity of osteoporotic fractures, and the monitoring of fracture prevention strategies present unique challenges. Unfortunately, there is little scientific data and thus, a lack of consensus regarding the value, role, and interval of follow-up bone mineral density testing in peer-reviewed literature. Changes in bone mineral density may not be detected in less than two years of treatment because of the measurement technique, but a follow-up scan may be appropriate sooner in selected patients. Follow up scans can help to detect treatment failure and secondary disease.

Follow-up BMD testing is indicated:

A. Every two years (if at least 23 months have passed since the month the last BMD testing was performed) except for patients starting on Bisphosphonate therapy when testing every three years after initiation of therapy is recommended; or

B. More frequently than every two years if medically necessary, in situations such as but not limited to:
   1. Monitoring individuals on long-term glucocorticoid (steroid) therapy of more than three months; and
   2. Allowing for a confirmatory baseline BMD testing (either central or peripheral) to permit monitoring of individuals in the future if the initial test was performed with a technique that is different from the proposed monitoring method (e.g., if the initial test was performed using bone sonometry and monitoring is anticipated using bone densitometry, a baseline measurement using bone densitometry is allowed); and

C. Women receiving estrogen replacement therapy (ERT) should not be precluded from receiving follow-up or repeat BMD testing.

VI. Based upon our criteria and review of the peer-reviewed literature, screening for vertebral fracture with dual x-ray absorptiometry (DEXA) or single absorptiometry (SEXA) is considered investigational.

POLICY GUIDELINES:

I. Refer to the member’s subscriber contract for determination of New York State Law applicability and the specific benefit effective date of the Law on the contract.

II. According to the Affordable Care Act, non-grandfathered plans or policies are required to cover, in-network, without cost-sharing, the preventive services recommended by the United States Preventive Services Task Force (USPSTF), including osteoporosis screening according to Policy Statement I.A. and I.B. above.

III. Whenever possible, use of central (axial skeleton) DEXA is preferred; since clinical evidence supports that this method has one of the lowest standard error rates in measurement and predictive accuracy. However peripheral DEXA may be used as a substitute when technical problems preclude adequate imaging with a central DEXA machine or a central DEXA machine is unavailable.

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IV. A DEXA study is representative of one or more sites, therefore, a study of multiple sites should be reported and will be processed as a single unit of service.

V. This policy addresses coverage for adults only. Requests for adolescents and children will be reviewed based on diseases and risk factors that are present. Per the National Osteoporosis Foundation, BMD measurement is not recommended in children or adolescents.

DESCRIPTION:

The New York State Insurance Law mandates coverage must be provided for bone density tests as well as prescription drugs and devices that are approved by the FDA for the detection and treatment of osteoporosis. The law provides that individuals qualifying for coverage shall at a minimum include individuals having:

I. A previous diagnosis or having a family history of osteoporosis; or
II. Symptoms or conditions indicative of the presence or significant risk of osteoporosis; or
III. A prescribed drug regimen posing a significant risk of osteoporosis; or
IV. Lifestyle factors posing a significant risk of osteoporosis; or
V. Age, gender, and/or physiological characteristics which pose a significant risk of osteoporosis.

Individuals are eligible for bone density measurements and tests according to criteria under the Federal Medicare program and the National Institutes of Health (NIH) for the detection of osteoporosis.

Defining osteoporosis by BMD:

The World Health Organization has established the following definitions based on BMD of the spine, hip or forearm by DEXA. T scores are reported as standard deviations (SD):

I. Normal: T-score at -1.0 and above (within 1 SD of a young healthy adult).
II. Osteopenia (low bone mass): T-score between -1 to -2.5 (1 to 2.5 SD below that of a young healthy adult).
III. Osteoporosis: T-score at or below -2.5 (2.5 SD or more below that of a young healthy adult).
IV. Severe osteoporosis: T-score of -2.5 or less with fragility fractures.

Although these definitions are necessary to establish the prevalence of osteoporosis, they should not be used as the sole determinant of treatment decisions.

Risk for factors for Osteoporosis in Women:

There are certain symptoms, conditions, physiologic characteristics or lifestyle factors indicative of the significant risk of osteoporosis. Per the National Institutes of Health, risk factors for postmenopausal women under age 65 include, but are not limited to:

I. Personal history of a non-traumatic fracture as an adult;
II. Family history of osteoporosis (e.g., history of early, non-traumatic fracture in first-degree relative);
III. Ethnicity - Caucasian and Asian women are at highest risk. African American and Latino women have a lower but significant risk;
IV. Poor health/frailty;
V. Cigarette smoking;
VI. Body size – small, thin-boned women are at greater risk;
VII. Extended estrogen deficiency;
VIII. Age - Risk increases with age since bones become less dense and weaker with age;
IX. Eating disorders such as anorexia nervosa;
X. Excessive use of alcohol;
XI. Low calcium and vitamin D intake (lifelong);
XII. Sedentary lifestyle or extended bed rest; or
XIII. Osteopenia.
The American College of Obstetricians and Gynecologists defines postmenopausal as: The time in a woman’s life when she stops having menstrual periods - specifically, when she has gone 12 consecutive months with no menstrual period. Menopause marks the end of the reproductive years that began in puberty.

Risk for factors for Osteoporosis in Men:

There are certain symptoms, conditions, physiologic characteristics or lifestyle factors indicative of the significant risk of osteoporosis. Per the National Institutes of Health, risk factors for osteoporosis in men include:
I. Chronic disease that affect the kidneys, lungs, stomach and intestines or alter hormone levels;
II. Regular use of certain medications, such as glucocorticoids;
III. Low levels of testosterone;
IV. Unhealthy lifestyle habits (e.g. smoking, excessive alcohol use, low calcium intake and inadequate physical exercise);
V. Age – the older the individual, the greater the risk;
VI. Race – Caucasian men appear to be at particularly high risk, but all men can develop osteoporosis.

RATIONALE:

Several DEXA central bone densitometers have been approved by the U.S. Food and Drug Administration (FDA), such as the Norland XR 46 DXA (Central) Bone Densitometer. Several bone ultrasonometers have been cleared for marketing by the FDA, such as Myriad’s Soundscan® (approved May 1998) and Hologic’s Sahara Clinical Bone Sonometer® (approved March 1998). To perform vertebral fracture assessment on DEXA devices, additional software is needed and it must have 510(4k) marketing clearance from the FDA as well.

Bone Mineral Density studies:

While there are a number of tests available to assess bone mineral density, clinical evidence supports that DEXA of the hip or lumbar sacral spine and quantitative CT have the lowest standard error in measurement and predictive accuracy. In addition, studies that show reduced fracture with treatment have used results from hip/spine DEXA machines.

The value of universal BMD screening, especially in perimenopausal women, has not been established.

The U.S. Preventive Services Task Force (USPSTF)(2011) recommends that women aged 65 and older be screened routinely for osteoporosis and 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. The USPSTF makes no recommendation for or against routine osteoporosis screening in postmenopausal women who are younger than 60 or in women aged 60-64 who are not at increased risk for osteoporotic fractures. In addition, the USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for osteoporosis in men. These recommendations are currently being updated (2017).

National Osteoporosis Foundation (NOF). 2010 “Clinicians Guide to Prevention and Treatment of Osteoporosis” includes recommendation for BMD testing for women age 65 years and older and for men age 70 years and older. The guidelines also recommend BMD testing in postmenopausal women and in men age 50-70 years when there is concern based on an individual’s risk factor profile. Those at highest risk include postmenopausal women and older men with a diagnosis of osteoporosis, based on a BMD test T-score of -2.5 or lower, or those with a clinical diagnosis based on having sustained a hip or spine fracture.

American College of Physicians. 2008 clinical practice guideline, “Screening for Osteoporosis in Men,” recommends:(1) using an individualized assessment, clinicians should periodically evaluate older men for risk factors for osteoporosis (grade: strong recommendation, moderate quality evidence); (2) DXA scan should be performed in men who are at increased risk for osteoporosis and are candidates for drug therapy (grade: strong recommendation, moderate quality evidence); (3) additional research to evaluate osteoporosis screening tests in men.
The US National Osteoporosis Foundation and the American Association of Clinical Endocrinologists recommend routine monitoring of bone mineral density within two years of starting treatment with bisphosphonates. However, a 2009 study by Bell et al., which used data from the Fracture Intervention Trial (FIT) found small between-person differences in the effects of alendronate on bone mineral density when compared to the background variation in bone mineral density measurement within patients. Even though the changes in the bone mineral density tests were small, the majority of the patients seemed to benefit from treatment with bisphosphonates. The authors concluded that even though the effects of alendronate varied between individuals, the size of this variation was not clinically relevant and monitoring individual response is not needed. The authors support a recommendation against routine monitoring in the first three years after potent bisphosphonate therapy is started.

The Endocrine Society Clinical Practice Guideline: Osteoporosis in Men (2012) recommends testing higher risk men [aged greater than or equal to 70 years and men aged 50–69 years who have risk factors (e.g., low body weight, prior fracture as an adult, smoking, etc.)] using central dual-energy x-ray absorptiometry. The group suggests measuring forearm DXA (1/3 or 33% radius) when spine or hip BMD cannot be interpreted and for men with hyperparathyroidism or receiving androgen deprivation therapy (ADT) for prostate cancer.

Ventral Fracture Assessment using DEXA:

Vertebral fractures are highly prevalent in the elderly populations, and epidemiologic studies have found that these fractures are associated with an increased risk of future spine or hip fractures independent of BMD. Only 20-30% of vertebral fractures are recognized clinically; the rest are discovered incidentally on lateral spine radiographs. Lateral spine x-rays have not been recommended as a component of risk assessment for osteoporosis, because of the cost, radiation exposure, and the fact that the x-ray would require a separate procedure in addition to the BMD study. However, lateral spine images can be obtained using DEXA (vertebral fracture assessment) at the same time a subject is undergoing assessment of BMD. Although VFA may provide a rapid and convenient assessment, the images obtained are not of sufficient quality to establish the presence or absence of vertebral fractures. Literature suggests that densitometry may not accurately diagnose vertebral fractures in the population of interest (women with osteopenia or normal BMD). There is a lack of evidence that the test is accurate in detecting fractures among subjects without osteoporosis. Available evidence is insufficient to assess what health outcomes would result from vertebral assessment using DEXA as a screening test for osteoporosis. Evidence supporting the use of vertebral assessment using DEXA is not strong enough to make conclusions about its effect on health outcomes.

**CODES:**

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<th>Number</th>
<th>Description</th>
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<tr>
<td>76977</td>
<td>Ultrasound bone density measurement and interpretation, peripheral sites(s), any method</td>
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<td>77078</td>
<td>Computed tomography bone mineral density study, one or more sites; axial skeleton, (e.g., hips, pelvis, spine)</td>
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<td>77080</td>
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<td>Appendicular skeleton (peripheral) (e.g., radius, wrist, heel)</td>
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<td>77085</td>
<td>Dual-energy x-ray absorptiometry (DXA), bone density study, 1 or more sites;</td>
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Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/appropriate = (NMN).

**CPT:**

76977 Ultrasound bone density measurement and interpretation, peripheral sites(s), any method

77078 Computed tomography bone mineral density study, one or more sites; axial skeleton, (e.g., hips, pelvis, spine)

77080 Dual energy x-ray absorptiometry (DEXA), bone density study, one or more sites; axial skeleton (e.g., hips, pelvis, spine)

77081 Appendicular skeleton (peripheral) (e.g., radius, wrist, heel)

77085 Dual-energy x-ray absorptiometry (DXA), bone density study, 1 or more sites;

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axial skeleton (e.g., hips, pelvis, spine), including vertebral fracture assessment

77086 (E/I)  Vertebral fracture assessment via dual-energy x-ray absorptiometry (DXA)

78350 (NMN)  Bone density (bone mineral content) study, one or more sites; single photon absorptiometry

78351 (NMN)  Bone density (bone mineral content) study, one or more sites; dual photon absorptiometry

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

ICD9:  252.00-252.08  Hyperparathyroidism
  255.0  Cushing’s Syndrome
  256.2  Postablative ovarian failure
  256.31  Premature menopause
  256.39  Other ovarian failure
  257.2  Other testicular hypofunction
  259.3  Ectopic hormone secretion, not elsewhere classified
  626.0  Absence of menstruation
  627.0-627.9  Menopausal and post-menopausal disorders (code range)
  733.00-733.09  Other disorders of bone and cartilage, osteoporosis (code range)
  733.12  Pathologic fracture of distal radius and ulna
  733.13  Pathologic fracture of vertebrae
  733.14  Pathologic fracture of neck of femur
  733.19  Pathologic fracture of unspecified site
  733.90  Disorder of bone and cartilage, unspecified
  733.99  Other disorders of bone and cartilage
  758.6  Gonadal dysgenesis
  781.91  Loss of height
  V13.51  Personal history of pathologic fracture
  V13.52  Personal history of stress fracture
  V45.77  Acquired absence of organ, genital organs
  V49.81  Asymptomatic postmenopausal status (age related) (natural)
  V58.65  Long-term (current) use of steroids
  V67.51  Follow-up examination following completed treatment with high-risk medications, not elsewhere classified
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M85.9 Disorder of bone density and structure, unspecified
M89.9 Disorder of bone, unspecified
M94.9 Disorder of cartilage, unspecified
Q96.0-Q96.9 Turner's syndrome (code range)
R29.890 Loss of height
Z08 Encounter for follow-up examination after completed treatment for malignant neoplasm
Z09 Encounter for follow-up examination after completed treatment for conditions other than malignant neoplasm
Z13.820 Encounter for screening for osteoporosis
Z78.0 Asymptomatic menopausal state
Z79.51-Z79.52 Long term (current) use of steroids (code range)
Z87.310 Personal history of (healed) osteoporosis fracture
Z87.311 Personal history of (healed) other pathological fracture
Z87.312 Personal history of (healed) stress fracture
Z90.721-Z90.722 Acquired absence of ovaries (code range)
Z90.79 Acquired absence of other genital organ(s)

REFERENCES:


KEY WORDS:


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**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

There is currently a National Coverage Determination (NCD)) for Bone (Mineral) Density Studies. Please refer to the following NCD website for Medicare Members: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=256&ncdver=2&bc=AgAAgAAAAAA&.