MEDICAL POLICY

SUBJECT: BONE DENSITOMETRY/ BONE DENSITY STUDIES	**EFFECTIVE DATE: 10/18/01** **REVISED DATE: 06/20/02, 10/16/02, 10/15/03, 11/18/04, 09/15/05, 02/06/06, 07/20/06, 05/17/07, 06/19/08, 09/17/09, 09/16/10, 09/15/11, 09/20/12, 09/19/13, 09/18/14, 09/17/15, 09/15/16, 09/21/17, 09/20/18**
POLICY NUMBER: 6.01.05 **CATEGORY: Technology Assessment**	**PAGE: 1 OF: 11**

- ***If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.***
- ***If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.***
- ***If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.***

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 (QUS) 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. All men age 70 or older regardless of additional risk factors;

C. Men and women previously diagnosed as having osteoporosis;

D. 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) or who are at increased risk of osteoporosis, as determined by a formal clinical risk assessment tool (e.g., FRAX);

E. Men age 50-70 with clinical risk factors for osteoporotic fracture (please refer to description section for risk factors for osteoporosis in men);

F. 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;

G. 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);

H. Men and women being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy;

I. Men and postmenopausal women age 50 and older with a hip or vertebral fracture;

J. 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);

K. Individuals with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia (low-bone mass) or vertebral fracture;

L. Men and women with primary hyperparathyroidism;

M. 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);

N. Estrogen-deficient women at clinical risk for osteoporosis *(*please refer to description section for risk factors for osteoporosis in women);

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

P. 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**.

VII. Based upon our criteria and assessment of the peer-reviewed literature, pulse-echo ultrasound bone density measurement of the tibia, has not been medically proven to be effective and is considered **investigational** for osteoporosis screening.

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.

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 *screenin*g, especially in perimenopausal women, has not been established.

The U.S. Preventive Services Task Force (USPSTF) updated their recommendations in 2018. Currently the USPSTF recommends screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in women 65 years and older. They also recommend screening for osteoporosis with bone measurement testing to prevent osteoporotic fractures in postmenopausal women younger than 65 years who are at increased risk of osteoporosis, as determined by a formal clinical risk assessment tool. 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.

National Osteoporosis Foundation (NOF). 2014 "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, regardless of clinical risk factors. The guidelines also recommend BMD testing in a) postmenopausal women in the menopausal transition and men age 50 to 69 with clinical risk factors for fracture, b) adults who have a fracture after age 50, and c) 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. BMD measurement is not recommended in children or adolescents and is not routinely indicated in healthy young men or premenopausal women unless there is a significant fracture history or there are specific risk factors for bone loss. Follow up testing is recommended one to two years after initiating medical therapy for osteoporosis and every two years thereafter.

American College of Physicians (ACP) 2017 clinical practice guideline recommend against bone density monitoring during the 5-year pharmacologic treatment period for osteoporosis in women. (Grade: weak recommendation; low quality evidence). Data from several studies showed women treated with bisphosphonates and other pharmacologic treatment benefited from reduced fractures with treatment even if BMD did not increase. There is no evidence from RCTs regarding how often to monitor BMD during osteoporosis treatment. There is moderate-quality evidence which

suggests that most women do not need regular monitoring.

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.

Vertebral 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.

Pulse-Echo Ultrasound:

Bone Index Finland, Ltd. received Section 510(k) approval from the FDA in May 2016 for Bindex, BI-100 and Bindex BI-2 in January 2017. Bindex is a handheld pulse-echo ultrasound device used to measure apparent cortical bone thickness at the proximal tibia to aid the physician in the diagnosis of osteoporosis. Use of pulse-echo ultrasonometry is being promoted as a cost-effective screening option to determine appropriateness for DXA measurement. There is limited research and no randomized controlled trials demonstrating the effectiveness of pulse-echo ultrasound as compared to DXA.

CODES: Number Description

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;

		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
	0508T **(E/I)**	Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia - (effective 07/1/18)

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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)
ICD10:	E21.0-E21.3	Hyperparathyroidism and other disorders of parathyroid gland (code range)
	E24.0-E24.9	Cushing's syndrome (code range)
	E28.310-E28.319	Premature menopause (code range)
	E28.39	Other primary ovarian failure
	E29.1	Testicular hypofunction
	E34.2	Ectopic hormone secretion, not elsewhere classified
	E89.40	Asymptomatic postprocedural ovarian failure
	E89.41	Symptomatic postprocedural ovarian failure
	N91.0-N91.2	Absent, scanty and rare menstruation (code range)
	N92.4	Excessive bleeding in the premenopausal period
	N95.0-N95.9	Menopausal and other perimenopausal disorders (code range)
	M48.50xA-M48.58xA	Collapsed vertebra, not elsewhere classified (code range)
	M80.011A	Age-related osteoporosis with current pathological fracture, right shoulder, initial encounter for fracture
	M80.012A	Age-related osteoporosis with current pathological fracture, left shoulder, initial encounter for fracture
	M80.019A	Age-related osteoporosis with current pathological fracture, unspecified shoulder, initial encounter for fracture
	M80.031A	Age-related osteoporosis with current pathological fracture, right forearm, initial encounter for fracture
	M80.032A	Age-related osteoporosis with current pathological fracture, left forearm, initial encounter for fracture
	M80.039A	Age-related osteoporosis with current pathological fracture, unspecified forearm, initial encounter for fracture
	M80.041A	Age-related osteoporosis with current pathological fracture, right hand, initial

	encounter for fracture
M80.042A	Age-related osteoporosis with current pathological fracture, left hand, initial encounter for fracture
M80.049A	Age-related osteoporosis with current pathological fracture, unspecified hand, initial encounter for fracture
M80.051A	Age-related osteoporosis with current pathological fracture, right femur, initial encounter for fracture
M80.052A	Age-related osteoporosis with current pathological fracture, left femur, initial encounter for fracture
M80.059A	Age-related osteoporosis with current pathological fracture, unspecified femur, initial encounter for fracture
M80.061A	Age-related osteoporosis with current pathological fracture, right lower leg, initial encounter for fracture
M80.062A	Age-related osteoporosis with current pathological fracture, left lower leg, initial encounter for fracture
M80.069A	Age-related osteoporosis with current pathological fracture, unspecified lower leg, initial encounter for fracture
M80.071A	Age-related osteoporosis with current pathological fracture, right ankle and foot, initial encounter for fracture
M80.072A	Age-related osteoporosis with current pathological fracture, left ankle and foot, initial encounter for fracture
M80.079A	Age-related osteoporosis with current pathological fracture, unspecified ankle and foot, initial encounter for fracture
M80.08xA	Age-related osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M80.811A	Other osteoporosis with current pathological fracture, right shoulder, initial encounter for fracture
M80.812A	Other osteoporosis with current pathological fracture, left shoulder, initial encounter for fracture
M80.819A	Other osteoporosis with current pathological fracture, unspecified shoulder, initial encounter for fracture
M80.831A	Other osteoporosis with current pathological fracture, right forearm, initial encounter for fracture
M80.832A	Other osteoporosis with current pathological fracture, left forearm, initial encounter for fracture
M80.839A	Other osteoporosis with current pathological fracture, unspecified forearm, initial encounter for fracture
M80.841A	Other osteoporosis with current pathological fracture, right hand, initial encounter for fracture

M80.842A	Other osteoporosis with current pathological fracture, left hand, initial encounter for fracture
M80.849A	Other osteoporosis with current pathological fracture, unspecified hand, initial encounter for fracture
M80.851A	Other osteoporosis with current pathological fracture, right femur
M80.852A	Other osteoporosis with current pathological fracture, left femur
M80.859A	Other osteoporosis with current pathological fracture, unspecified femur
M80.861A	Other osteoporosis with current pathological fracture, right lower leg, initial encounter for fracture
M80.862A	Other osteoporosis with current pathological fracture, left lower leg, initial encounter for fracture
M80.869A	Other osteoporosis with current pathological fracture, unspecified lower leg, initial encounter for fracture
M80.871A	Other osteoporosis with current pathological fracture, right ankle and foot, initial encounter for fracture
M80.872A	Other osteoporosis with current pathological fracture, left ankle and foot, initial encounter for fracture
M80.879A	Other osteoporosis with current pathological fracture, unspecified ankle and foot, initial encounter for fracture
M80.88xA	Other osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M81.0-M81.8	Osteoporosis without current pathological fracture (code range)
M84.48xA	Pathological fracture, other site, initial encounter for fracture
M84.58xA	Pathological fracture in neoplastic disease, other site, initial encounter for fracture
M84.68xA	Pathological fracture in other disease, other site, initial encounter for fracture
M85.80	Other specified disorders of bone density and structure, unspecified site
M85.811-M85.819	Other specified disorders of bone density and structure, shoulder (code range)
M85.821-M85.829	Other specified disorders of bone density and structure, upper arm (code range)
M85.831-M85.839	Other specified disorders of bone density and structure, forearm (code range)
M85.841-M85.849	Other specified disorders of bone density and structure, hand (code range)
M85.851-M85.859	Other specified disorders of bone density and structure, thigh (code range)
M85.861-M85.869	Other specified disorders of bone density and structure, lower leg (code range)
M85.871-M85.879	Other specified disorders of bone density and structure, ankle and foot (code range)
M85.88	Other specified disorders of bone density and structure, other site
M85.89	Other specified disorders of bone density and structure, multiple sites
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)

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KEY WORDS:

BMD, bone mineral density, DEXA, Fracture Risk Assessment Tool, FRAX, vertebral fracture assessment, morphometric x-ray absorptiometry.

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=AgAAgAAAAAAA&.