

Corporate Medical Policy

Bone Mineral Density Studies

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Origination:	12/1999
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Description of Procedure or Service

Osteoporosis is determined using the World Health Organization diagnostic thresholds for osteoporosis based on bone mineral density measurement (BMD) compared with a calculated T-score.

Risk factors for fracture include low bone mass, low bone strength, a personal history of fracture as an adult, or a history of fracture in a first-degree relative. Osteoporosis, defined as low bone mass leading to an increased risk of fragility fractures, is an extremely common disease in the elderly population due to age-related bone loss in both sexes and menopause-related bone loss in women. The World Health Organization (WHO) has diagnostic thresholds for osteoporosis based on bone mineral density (BMD) measurements compared with a T score, which is the standard deviation difference between an individual's BMD and that of a young-adult reference population. Conditions that can cause or contribute to osteoporosis include lifestyle factors such as low intake of calcium, high intake of alcohol or cigarette smoking, and thinness. Other risk factors for osteoporosis include certain endocrine, hematologic, gastrointestinal tract and genetic disorders, hypogonadal states, and medications.

BMD can be measured either centrally (ie, hip or spine) or peripherally (ie, wrist, finger, heel) sites. While BMD measurements are predictive of fragility fractures at all sites, central measurements of the hip and spine are the most predictive. Fractures of the hip and spine (ie, vertebral fractures) are also considered to be the most clinically relevant. BMD is typically expressed as a T-score.

The utility of screening BMD measurements can be established by demonstrating that screening identifies a population at increased risk of fracture and that, by treating those at-risk individuals, the rate of fractures is reduced thereby lowering fracture-related morbidity and mortality. These potential benefits of screening should outweigh the risks of screening (radiation exposure) or false-positives (initiation of unnecessary treatment).

Bone mineral density studies can be used to identify individuals with osteoporosis and monitor response to osteoporosis treatment, with the goal of reducing the risk of fracture. Bone density is most commonly evaluated with dual x-ray absorptiometry (DXA); other technologies are available.

Dual X-ray Absorptiometry (DXA)

Dual x-ray absorptiometry (DXA) is the most commonly used technique to measure BMD because of its ease of use, low radiation exposure, and its ability to measure BMD at both the hip and spine. DXA generates 2 x-ray beams of different energy levels to scan the region of interest and measures the difference in attenuation as the low- and high-energy beams pass through the bone and soft tissue. The low-energy beam is preferentially attenuated by bone, while the high-energy beam is attenuated by both bone and soft tissue. This difference in attenuation between the 2 beams allows for correction for the irregular masses of soft tissue, which surrounds the spine and hip, and therefore the measurement of bone density at those sites.

A T-score is the standard deviation difference between an individual's BMD and that of a young adult reference population.

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Whole body dual X-ray absorptiometry (DXA) uses x-rays of two different energy levels to measure lean tissue mass and total and regional body fat as well as bone density.

Quantitative Computed Tomography (QCT)

Quantitative CT depends on the differential absorption of ionizing radiation by calcified tissue and is used for central measurements only. Compared with DXA, quantitative CT is less readily available and associated with relatively high radiation exposure and relatively high cost. Analysis of previously obtained clinical CT scans of the pelvis might provide an alternative method of assessing biomechanical bone strength.

Ultrasound Densitometry

Ultrasound densitometry is a technique for measuring BMD at peripheral sites, typically the heel but also the tibia and phalanges. Compared to osteoporotic bone, normal bone demonstrates higher attenuation of the ultrasound wave, and is associated with a greater velocity of the wave passing through bone. Ultrasound densitometry has no radiation exposure, and machines may be purchased for use in an office setting.

Single- and dual-photon absorptiometry and radiographic absorptiometry are now rarely used and may be considered obsolete.

NOTE: This policy does not address the use of DXA as a technique to screen for vertebral fractures. That application of DXA is addressed in a separate policy, Screening for Vertebral Fracture with Dual X-Ray Absorptiometry.

Regulatory Status

Devices that measure bone density have been cleared for marketing by the FDA through the 510(k) process. Some examples are described in Table 1:

Table 1. FDA Cleared Devices to Measure Bone Density

Device Name	Company
Aria	GE Medical Systems
Ge Lunar Dxa Bone Densitometers With Enc	GE Medical Systems
Tbs Insight	Medimaps Group Sa
Single Energy (Se) Femur Exams	Hologic, Inc.
Tbs Insight	Medimaps Group Sa
Virtuost	O.N. Diagnostics
Accudxa2	Lone Oak Medical Technologies, Llc
Ultrascan 650	Cyberlogic, Inc.
Bindex Bi-2	Bone Index Finland, Ltd.
Bindex Bi-100	Bone Index Finland, Ltd.
Achilles	GE Medical Systems
Beammed Sunlight Miniomni Bone Sonometer	Beam-Med Ltd
Achilles	GE Medical Systems

In addition, some ultrasound bone sonometers have been approved by the FDA through the premarket approval process. One example is the Sahara® Clinical Bone Sonometer (Hologic), which received

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approval in March 1998. Its intended use is for quantitative ultrasound measurement of the calcaneus (heel bone), the results of which can be used in conjunction with other clinical risk factors as an aid in the diagnosis of osteoporosis and medical conditions leading to reduced bone density, and ultimately in the determination of fracture risk.

Related Policy:

Bone Turnover Markers Testing AHS – G2051

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Bone Mineral Density (BMD) Studies when they are determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Bone Mineral Density Studies are covered

Initial or repeat bone mineral density (BMD) measurement is not indicated unless the results will influence treatment decisions.

An initial measurement of central (hip/spine) BMD using dual x-ray absorptiometry may be considered **medically necessary** to assess fracture risk and the need for pharmacologic therapy in individuals who are considered at risk for osteoporosis. BMD testing may be indicated under the following conditions:

- Women age 65 and older, regardless of other risk factors;
- Men age 70 and older, regardless of other risk factors;
- Younger postmenopausal women about whom there is a concern based on their risk factors;
- Men age 50-70 about whom there is a concern based on their risk factors;
- Adults with a condition or taking a medication associated with low bone mass or bone loss.

Repeat measurement of central (hip/spine) BMD using dual x-ray absorptiometry for individuals who previously tested normal (does not require pharmacologic treatment) may be considered medically necessary at an interval not more frequent than every 3–5 years; the interval depends on patient risk factors.

Regular (not more frequent than every 2–3 years) serial measurements of central (hip/spine) BMD using dual x-ray absorptiometry to monitor treatment response may be considered medically necessary when the information will affect treatment decisions such as duration of therapy.

Peripheral measurement of BMD may be considered medically necessary:

- If the hip/spine or hip/hip cannot be done or the patient is over the table limit for weight;
- For hyperparathyroidism, where the forearm is essential for diagnosis

When Bone Mineral Density Studies are not covered

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Bone mineral density studies are considered not medically necessary if the criteria listed above are not met.

Screening individuals who are at low risk for osteoporosis is considered not medically necessary.

Bone mineral density measurement using ultrasound densitometry or quantitative computed tomography is considered investigational.

Peripheral or appendicular bone density studies are considered not medically necessary except as noted above.

Dual x-ray absorptiometry (DXA) body composition studies are considered investigational.

Policy Guidelines

For individuals who are eligible for screening of BMD based on risk factor assessment who receive DXA analysis of central sites (hip or spine), the evidence includes systematic reviews of RCTs controlled trials and cohort studies. Relevant outcomes are morbid events, functional outcomes, quality of life (QOL), hospitalizations, and medication use. Central DXA is the most widely accepted method for measuring BMD and is the reference standard against which other screening tests are evaluated. BMD measurements with central DXA identify individuals at increased risk of fracture, and osteoporosis medications reduce fracture risk in the population identified as osteoporotic by central DXA. Therefore, test results with initial central DXA can be used to guide therapy. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals without osteoporosis on initial screen who receive repeat DXA analysis of central sites (hip or spine), the evidence includes systematic reviews of large cohort and observational studies. Relevant outcomes are morbid events, functional outcomes, QOL, hospitalizations, and medication use. Little research has been done on the frequency of BMD monitoring for osteoporosis. The available research has evaluated repeat measurement with central DXA. Evidence on whether repeat measurements add to risk prediction compared with a single measurement is mixed. Although the optimal interval may differ depending on risk factors, current evidence does not support repeat monitoring in patients with BMD on DXA in the normal range. The evidence is insufficient to determine the effects of the technology on health outcomes. Although the evidence is limited, multiple clinical practice guidelines recommend repeat DXA in 3-5 years in patients at low-risk using risk factor assessment. Similarly, multiple guidelines recommend a repeat screening interval of 1-2 years for high-risk individuals and in individuals with a baseline evaluation near a fracture intervention threshold (osteopenia).

For individuals who are receiving pharmacologic treatment for osteoporosis who receive repeat DXA analysis of central sites (hip or spine), the evidence includes systematic reviews of RCTs and observational studies. Relevant outcomes are morbid events, functional outcomes, QOL, hospitalizations, and medication use. There is no high-quality evidence to guide how often to monitor BMD during osteoporosis treatment. Within-person variation in measurement may exceed treatment effects, and fracture risk has been shown to be reduced in some treatment studies in the absence of changes in BMD. Together, these results suggest that frequent (ie, every 2 years) repeat monitoring has low value. It is unclear whether DXA at the end of the initial 5 years of therapy is sufficiently accurate to guide subsequent therapy. The evidence is insufficient to determine the effects of the technology on health outcomes. Although the evidence is limited, multiple clinical practice guidelines recommend repeat DXA at intervals of 1-3 years to monitor treatment response in patients who are receiving pharmacological treatment for osteoporosis or after a change in or cessation of treatment.

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For individuals who are eligible for screening of BMD based on risk factor assessment who receive ultrasound densitometry, or quantitative computed tomography, or DXA analysis of peripheral sites, the evidence includes observational studies and systematic reviews. Relevant outcomes are morbid events, functional outcomes, QOL, hospitalizations, and medication use. In comparison with central DXA, other measures of bone health showed area under the curves around 0.80 for the identification of osteoporosis. These technologies are not commonly used for BMD measurements in practice, and no studies have shown that they can select patients who benefit from treatment for osteoporosis. There is little to no evidence on the usefulness of repeat measurement of BMD using these techniques. The evidence is insufficient to determine the effects of the technology on health outcomes.

Bone mass measurement must be done with a device that has been approved by the FDA.

Practice Guidelines and Position Statements

The decision to perform bone density assessment should be based on an individual's fracture risk profile and skeletal health assessment. In addition to age, gender, and bone mineral density (BMD), risk factors included in the World Health Organization (WHO) Fracture Risk Assessment Tool (FRAX) are:

- Low body mass index;
- Parental history of hip fracture;
- Previous fragility fracture in adult life (i.e., occurring spontaneously, or a fracture arising from trauma which, in a healthy individual, would not have resulted in a fracture);
- Current smoking or alcohol 3 or more units/day, where a unit is equivalent to a standard glass of beer (285ml), a single measure of spirits (30ml), a medium-sized glass of wine (120ml), or 1 measure of an aperitif (60ml);
- A disorder strongly associated with osteoporosis. These include rheumatoid arthritis, type I (insulin dependent) diabetes, osteogenesis imperfecta in adults, untreated long-standing hyperthyroidism, hypogonadism or premature menopause (<45 years), chronic malnutrition or malabsorption, and chronic liver disease;
- Current exposure to oral glucocorticoids or the patient has been exposed to oral glucocorticoids for more than 3 months at a dose of prednisolone of 5 mg daily or more (or equivalent doses of other glucocorticoids).

In 2012 (reaffirmed 2016), the ACOG updated its guidelines on managing osteoporosis in women. The guidelines recommended that bone mineral density (BMD) screening should begin for all women at age 65 years. In addition, the ACOG recommended screening for women younger than 65 years in whom the Fracture Risk Assessment Tool indicates a 10-year risk of osteoporotic fracture of at least 9.3%. Alternatively, ACOG recommended BMD screening women younger than 65 or with any of the following risk factors (they are similar, but not identical to risk factors in the Fracture Risk Assessment Tool):

- Personal medical history of a fragility fracture
- Parental medical history of hip fracture
- Weight less than 127 lb.
- Medical causes of bone loss (i.e., medications or disease)
- Current smoker
- Alcoholism
- Rheumatoid arthritis
- For women who begin medication treatment for osteoporosis, a repeat BMD is recommended 1 to 2 years later to assess effectiveness. If BMD is improved or stable, additional BMD testing (in the absence of new risk factors) is not recommended. The guideline notes that it generally takes 18 to 24 months to document a clinically meaningful change in BMD and thus a 2-year interval after treatment initiation is preferred to 1 year.
- The guidelines do not specifically discuss repeat BMD screening for women who have a normal finding on the initial test.
- Routine BMD screening is not recommended for newly menopausal women as a "baseline" screen.

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The 2019 update of the International Society for Clinical Densitometry guidelines recommended bone density testing in the following patients:

- Women age 65 and older
- For post-menopausal women younger than age 65 a bone density test is indicated if they have a risk factor for low bone mass fracture such as;
 - o Low body weight
 - o Prior fracture
 - o High-risk medication use
 - o Disease or condition associated with bone loss.
- Women during the menopausal transition with clinical risk factors for fracture, such as low bone weight, prior fracture or high-risk medication use.
- Men aged 70 and older.
- Men under < 70 years ... if they have risk factors for low bone mass such as;
 - o Low body weight
 - o Prior fracture
 - o High-risk medication use
 - o Disease or condition associated with bone loss.
- Adults with a fragility fracture.
- Adults with a disease or condition associated with low bone mass or bone loss....
- Anyone being considered for pharmacologic therapy.
- Anyone being treated, to monitor treatment effect.
- Anyone not receiving therapy in whom evidence of bone loss would lead to treatment.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 76499, 77078, 77080, 77081, 77085, 76977, 78350, 78351, G0130, 0508T, 0554T, 0555T, 0556T, 0557T

Documentation requirements:

The procedure must be ordered by a physician or qualified practitioner after a complete assessment of the patient's condition determines that a bone mass measurement is medically necessary. If diagnosis, frequency, or documentation does not support medical necessity, coverage will be denied.

The need for bone mass measurement more frequently than every 2 years must have documentation defining the medical necessity. Documentation must include the complete medical record including previous bone densitometry study results and any other pertinent test findings, medication lists, and office notes. Letters summarizing the medical record may be useful, but are not considered adequate documentation.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

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BCBSA Medical Policy Reference Manual

Physician Advisory Group - 1/25/96

American Association of Clinical Endocrinologists Clinical Guidelines, 1996.

“Screening for Postmenopausal osteoporosis”, Guide to clinical Preventive Services, 2nd Ed. Report of the U.S. Preventive Services Task force, 1996.

Consultant Review 11/18/97

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Medical Policy Advisory Group - 3/99

Specialty Matched Consultant Advisory Panel - 11/1999

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Naganathan V, March L, Hunter D, et al. Quantitative heel ultrasound as a predictor for osteoporosis. *Med J Aust.* 1999 Sep 20;171(6):297-300.

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TEC Assessment - 2002; Tab 5

Specialty Matched Consultant Advisory Panel - 8/2003

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Specialty Matched Consultant Advisory Panel - 8/25/05

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BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.01, 4/17/07

Specialty Matched Consultant Advisory Panel - 8/29/07

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U.S. Preventive Services Task Force. Screening for Osteoporosis in Postmenopausal Women: Recommendations and Rationale. September 2002. Agency for Healthcare Research and Quality, Rockville, MD. <http://www.ahrq.gov/clinic/3rduspstf/osteoporosis/osteorr.htm>

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- Specialty Matched Consultant Advisory Panel 9/2020
- BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.01, 1/16/2020
- Specialty Matched Consultant Advisory Panel 9/2021
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Policy Implementation/Update Information

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|-------|---|
| 10/98 | Policy revised. See policy (L)78350.ARC for policy prior to date. |
| 1/99 | Added new codes; deleted QUS; changed screening codes to not medically necessary; and DPA and US codes as investigational. |
| 3/99 | Medical Policy Advisory Group - 3/99 |
| 6/99 | Reformatted, Description of procedure or service changed, Medical Term Definitions added. |
| 12/99 | Reaffirmed, Medical Policy Advisory Group |
| 10/00 | System coding changes. |
| 9/01 | Specialty Matched Consultant Advisory Panel review. Policy reformatted for ease of understanding. Ultrasound is listed as investigational. Policy key word added. |

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- 11/01 Title changed to Bone Mineral Density Studies.
- 9/02 System coding changes.
- 12/03 Specialty Matched Consultant Advisory Panel review 8/2003. Under "When Covered" section, A. added "or 5" to "any of the following" (1,2,3,4); Changed B. to C., B. now reads "Peripheral bone density is covered for a patient with a recent long bone fracture." Added CPT code 76071 to Billing/Coding section and removed HCPCS Level II codes G0131 and G0132 as they are no longer valid codes as of 12/31/02. Added "D" to "vitamin" in second paragraph, second sentence of "Description" section. Typos corrected.
- 8/12/04 Reference sources added.
- 7/7/05 Under When Covered section, A.3 - second sentence "These include:...." added..."but are not limited to:". Also added A.3.e - Long-term, Depo-Provera Contraceptive Injections (e.g., longer than 2 years)". Key word and Reference sources added.
- 9/1/05 Added reference to separate policy for screening for vertebral fracture with DXA under "Description" section. Under "When Covered", C. re: Follow up BMD added #3- "Monitoring patients on long-term glucocorticoid therapy of more than three months." Added reference source. Specialty Matched Consultant Advisory Panel review - 8/25/05. Following review, under "When Covered", B. Peripheral bone density-added "using DXA or QCT".
- 1/17/07 CPT codes 77078, 77079, 77080, 77081 and 77083 effective January 1, 2007 added to Billing/Coding section. Removed deleted CPT codes 76070, 76071, 76075, 76076 and 76078. (pmo)
- 10/8/07 Under "**When Covered**" section, changed "*those*" to "*women or men*"; also added "The patient is postmenopausal, aged 65 years or older regardless of additional risk factors." Reference sources added. (pmo)
- 4/27/10 Description section revised. Information in the When BMD Studies Are Covered was changed to read: An initial measurement of BMD at the hip or spine may be considered medically necessary to assess fracture risk and the need for pharmacologic therapy in both women and men who are considered at risk for osteoporosis. Repeat measurement of central BMD for individuals who previously tested normal may be considered medically necessary at an interval not more frequent than every 3-5 years; the interval depends on patient risk factors. Regular (not more frequent than every 2-3 years) serial measurements of central BMD to monitor treatment response may be considered medically necessary when the information will affect treatment decisions such as duration of therapy. The following statement added to the When Not Covered section: Dual x-ray absorptiometry (DEXA) body composition studies are considered investigational. Information in the Policy Guidelines section updated. Information regarding whole body dual x-ray absorptiometry added to policy. CPT 76499 added to Billing/Coding section. Notice given 4/27/10 for effective date of 8/3/10. (adn)
- 1/18/2011 Specialty Matched Consultant Advisory Panel review 12/16/2010. Policy Statement unchanged. Policy accepted as written. (adn)
- 10/11/11 Added the following statement to the When Covered section: "Peripheral measurement of BMD may be considered medically necessary if the hip/spine or hip/hip cannot be done or the patient is over the table limit for weight; for hyperparathyroidism, where the forearm is essential for diagnosis." The When BMD Studies Are Not Covered section was revised to read: "Bone mineral density studies are considered not medically necessary if the criteria listed above are not met. Screening individuals who are at low risk for osteoporosis is considered not medically necessary. Ultrasound technology to measure and interpret bone density at peripheral sites by any method is considered investigational. Peripheral or appendicular bone density studies are considered not medically necessary except as noted above. Dual x-ray absorptiometry (DEXA) body composition studies are considered

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- investigational.” Rationale in the Policy Guidelines section updated. Added information from U.S. Preventive Services Task Force guidelines. The statement: The procedure must be ordered by a physician or qualified practitioner after a complete assessment of the patient’s condition determines that a bone mass measurement is medically necessary. If diagnosis, frequency, or documentation does not support medical necessity, coverage will be denied” was added to the Billing/Coding section. Specialty Matched Consultant Advisory Panel review 9/28/11. (adn)
- 1/1/12 CPT codes 77079 and 77083 deleted from Billing/Coding section. (adn)
- 10/1/12 Specialty Matched Consultant Advisory Panel review 9/21/12. Policy Statement unchanged. (sk)
- 5/28/13 Reference added. No change to Policy Statement. (sk)
- 5/27/14 Specialty Matched Consultant Advisory Panel review 9/18/13. References added. Policy Statement unchanged. (sk)
- 10/14/14 Specialty Matched Consultant Advisory Panel 9/30/14. No change to Policy statement. (sk)
- 12/30/14 Code 77085 added to Billing/Coding section for effective date 1/1/2015. (sk)
- 2/24/15 Reference added. (sk)
- 4/28/15 Reference added. (sk)
- 10/30/15 Specialty Matched Consultant Advisory Panel 9/30/15. Removed related guideline “Bone Turnover Markers for the Diagnosis and Management of Osteoporosis” as that guideline has been archived. (sk)
- 11/24/15 References added. Policy guidelines updated. (sk)
- 4/1/16 Reference added. Policy Guidelines updated. (sk)
- 11/22/16 Specialty Matched Consultant Advisory Panel review 9/28/2016. No change to policy statement. (an)
- 4/28/17 Minor wording changes to “When Covered” section. No change to policy statement or criteria. Reference added. (an)
- 10/13/17 Specialty Matched Consultant Advisory Panel review 9/27/2017. No change to policy statement. (an)
- 06/29/18 Added code 0508T to Billing/Coding section. (an)
- 10/26/18 Minor update to Description section. 3rd item in the Not Covered section was clarified to read: Bone mineral density measurement using ultrasound densitometry, quantitative computed tomography, or dual x-ray absorptiometry of peripheral sites is considered investigational. Policy Guidelines updated. References added. Specialty Matched Consultant Advisory Panel review 10/3/2018. (an)
- 4/1/19 Policy archived. See new policy titled “Bone Turnover Markers for Diagnosis and Management of Osteoporosis and Diseases Associated with High Bone Turnover AHS – G2051.” (an)
- 6/11/19 Policy archived in error. Codes added to Billing/Coding section to be effective July 1, 2019: 0554T, 0555T, 0556T, 0557T. (an)
- 10/1/19 Specialty Matched Consultant Advisory Panel review 9/18/2019. References, descriptions, and policy guidelines sections updated. No change to policy statement. (eel)
- 2/25/20 Removed “dual x-ray absorptiometry of peripheral sites” from When not covered section. (eel)

Bone Mineral Density Studies

- 10/13/20 Specialty Matched Consultant Advisory Panel review 9/29/2020. Description, Policy guidelines and References updated. “Axial (central)” removed from policy statement. (eel)
- 10/1/21 Description and references updated. Specialty Matched Consultant Advisory Panel review 9/2021. Medical Director review 9/2021. No change to Policy statement. (jd/tt)

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