

Clinical Policy: Bone Mass Measurement

Reference Number: WNC.CP.292

Last Review Date:

Coding Implications
Revision Log

See <u>Important Reminder</u> at the end of this policy for important regulatory and legal information.

Note: When state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Description¹ - Bone Mass Measurement (BMM) is a radiologic procedure performed for quantifying bone mass, measuring changes in bone mass over time, or assessing bone quality. BMM can be used to establish the diagnosis of osteoporosis, to assess an individual's risk of fracture, or to determine the efficacy of osteoporosis drug therapy.

Policy/Criteria¹

- I. WellCare of North Carolina[®] shall cover BMM when it is medically necessary: **AND**:
 - **A.** Ordered and provided by or under the general supervision of a licensed physician or other licensed non-physician practitioner within the scope of his or her practice. General supervision is defined in 42 CFR 410.32(b) (3) (i);
 - **B.** Provided in an office or similar facility other than a hospital outpatient department or clinic; **AND**;
 - C. Performed with a DXA system that is approved and regulated by the FDA
- II. WellCare of North Carolina[®] shall cover BMM when the health record documents that the Member meets the medical indications for **at least one** of the categories listed below:
 - **A.** A female Member determined to be estrogen deficient and at clinical risk for osteoporosis or low bone mineral content based on medical history and other findings;
 - **B.** A Member with vertebral abnormalities, as demonstrated by an Xray, that are indicative of osteoporosis, osteopenia, low bone mineral content, or vertebral fracture;
 - **C.** A Member at risk of osteoporosis or low bone mineral content due to long-term medication including:
 - 1. Long-term (anticipated or actual) glucocorticoid therapy equivalent to 5.0 mg of prednisone, or greater, per day, for three months or greater
 - 2. Long-term or excess thyroid replacement therapy with evidence for hyperthyroidism
 - 3. Long-term anti-convulsant therapy for three months or greater
 - 4. Long-term heparin therapy for one month or greater **OR**
 - 5. Long-term Depo-Provera therapy (for two years or greater).
 - **D.** A Member with primary hyperparathyroidism;
 - **E.** A Member being monitored to assess the response to or efficacy of FDA-approved drug therapy for low bone mineral content;
 - **F.** A Member with a history of low non-traumatic (fragility) fractures or pathologic fracture; **OR**

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- **G.** A Member with other conditions or currently receiving medical therapies known to cause low bone mass including celiac disease, cerebral palsy, anorexia nervosa and hypogonadism.
- H. Peripheral measurement of BMD will be considered medically necessary:
 - 1. If the hip-spine or hip-hip cannot be done or the patient is over the table limit for weight: **OR**
 - 2. For hyperparathyroidism, where the forearm is essential for diagnosis.
- III. Dual energy X-Ray Absorptiometry (DXA), bone density study for one or more sites is the only BMM test covered by WellCare of North Carolina® for the monitoring of drug therapy for osteoporosis or low bone mineral content drug therapy. Refer to **Table 1**, **Covered** CPT Codes for the applicable CPT codes.
- IV. WellCare of North Carolina® shall cover BMM based on age factor alone for:
 - A. A female Medicaid Member 65 year or older; OR
 - **B.** A male Medicaid Member 70 year or older.
- V. WellCare of North Carolina® shall not cover BMM for the CPT codes listed in Table 2, Non-Covered CPT Codes.
 - **A.** Bone mineral density measurement using ultrasound densitometry, quantitative computed tomography, or dual x-ray absorptiometry of peripheral sites. Screening individuals who are at low risk for osteoporosis is considered not medically necessary.
 - **B.** Pulse-Echo Ultrasound Density Measurement.
 - C. Dual x-ray absorptiometry (DXA) body composition studies..
- VI. WellCare of North Carolina® shall not cover BMM for female members under the age of 65 or male members under the age of 70 who do not meet medical necessity Criteria IV, listed above.

Background¹

I. Osteoporosis is a debilitating disease in which bones become fragile and more likely to break. Any bone can be affected, but osteoporosis of the hip, spine, and wrist are of special concern, as fractures at these sites can be associated with significant morbidity and mortality. Osteoporosis is a common disorder of reduced bone strength that predisposes one to an increased risk for fractures in older individuals.

The standard criterion for the diagnosis of osteoporosis in postmenopausal women and older men is a T-score of less than -2.5 at the lumbar spine, femur neck, or total hip by bone mineral density testing. The results of a bone density test are expressed either as a "T" or a "Z" score. T-scores represent numbers that compare the condition of your bones

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with those of an average young person with healthy bones where Z-scores represent numbers that compare the condition of your bones with those of an average person your age.

While BMM can be performed using a variety of systems approved by the Food and Drug Administration (FDA), only Dual Energy X-ray absorptiometry (DXA), bone density study, one or more sites; axial skeleton (hips, pelvis, spine), can be used to diagnose osteoporosis based on WHO T-score criteria.

- **A.** The categories for diagnosis are:
 - 1. Normal (T-score -1.0 and above);
 - 2. Low bone mass, referred to as osteopenia (T-score between -1.0 and -2.5);
 - 3. Osteoporosis (T-score -2.5 and below); and
 - 4. Severe osteoporosis (T -score -2.5 and below with history of a fracture).

If either the spine or hip is not evaluable, then the 33% radius (sometimes called one-third radius) may be used for diagnostic purposes if it is the lowest of the skeletal sites measured. of the non-dominant forearm for diagnosis using DXA.

- **B.** The following methods are established procedures of bone mass measurements of the axial (central) or peripheral skeleton:
 - 1. Dual Energy X-Ray Absorptiometry (DXA);
 - 2. Quantitative Computed Tomography (QCT); and
 - 3. Ultrasound bone density measurement.

II. Pediatric

A diagnosis of osteoporosis in children from infancy to adolescence should not be made on the basis of densitometric criteria alone. T-scores, ethnic or race adjusted Z-scores must be used. Low bone mineral content (BMC) or bone mineral density (BMD) is defined as a BMC or areal BMD Z-score that is less than or equal to -2.0, adjusted for age, gender and body size, as appropriate.

The finding of one or more vertebral compression (crush) fractures is indicative of osteoporosis, in the absence of local disease or high-energy trauma. In such children and adolescents, measuring BMD adds to the overall assessment of bone health. In the absence of vertebral compression (crush) fractures, the diagnosis of osteoporosis is indicated by the presence of both a clinically significant fracture history and a BMD Z-score less than or equal to -2.0.

- **A.** A clinically significant fracture history is one or more of the following:
 - 1. two or more long bone fractures by age of 10 years; or
 - 2. three or more long bone fractures at any age up to age 19 years.

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A BMC BMD Z-score greater than -2.0 does not preclude the possibility of skeletal fragility and increased fracture risk.

T scores must not appear in pediatric DXA reports. The term osteoporosis must not appear in pediatric DXA reports without knowledge of clinically significant fracture history. Low bone mineral mass or bone mineral density is the preferred term for pediatric DXA reports when BMC or areal BMD Z-scores are less than or equal to - 2.0 standard deviation (SD).

- **B.** In members with primary bone disease, or at risk for a secondary bone disease, a DXA may be performed when:
 - 1. the patient may benefit from interventions to decrease their elevated risk of a clinically significant fracture, and
 - 2. the DXA results influence management.

DXA must not be performed, if safe and appropriate positioning of the child cannot be assured.

III. Baseline DXA Report

- **A.** Baseline DXA reports must contain the following information:
 - 1. DXA manufacturer, model, and software version;
 - 2. Referring licensed physician or other licensed non-physician practitioner;
 - 3. Member age, gender, race or ethnicity, weight, and height;
 - 4. Relevant medical history including previous fractures;
 - 5. Indication for study;
 - 6. Tanner Stage of bone age results, if available;
 - 7. Technical quality;
 - 8. BMC and areal BMD;
 - 9. BMC or areal BMD Z-score;
 - 10. Source of reference data for Z-score calculations;
 - 11. Adjustments made for growth and interpretation; and
 - 12. Recommendations for the necessity and timing of the next DXA study are optional.

IV. DXA Interpretation and Reporting in Children and Adolescents

- **A.** DXA is the preferred method for assessing BMC and areal BMD.
- **B.** DXA Interpretation and Reporting in Children and Adolescents includes:
 - 1. The posterior-anterior (PA) spine and total body less head (TBLH), are the preferred skeletal sites for performing BMC and areal BMD measurements in most pediatric subjects. Other sites may be useful depending on the clinical need;
 - 2. If a follow-up DXA scan is indicated, the minimum interval between scans is 6-12 months;
 - 3. Soft tissue measures in conjunction with whole body scans may be helpful in evaluating members with chronic conditions associated with malnutrition (such as

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- anorexia nervosa, inflammatory bowel disease, cystic fibrosis), or with both muscle and skeletal deficits (such as idiopathic juvenile osteoporosis);
- 4. The hip (including total hip and proximal femur) is not a preferred site for measurement in growing children due to significant variability in skeletal development and lack of reproducible regions (of interest);
- 5. In children with short stature or growth delay, spine and TBLH BMC and areal BMD results should be adjusted. For the spine, adjust using either BMAD or the height Z-score. For TBLH, adjust using the height Z-score.
- 6. An appropriate reference data set must include a sample of healthy representatives of the general population sufficiently large to capture variability in bone measures that takes into consideration gender, age, and race or ethnicity; AND
- 7. When upgrading densitometer instrumentation or software, it is essential to use reference data valid for the hardware and software technological updates.

V. Definitions

- **A.** T-score Is a standardized score comparing bone marrow density to average values to young, healthy women.
- **B.** Z-score Is a measure of how many standard deviations below or above the population mean a raw score it.
- **C.** Areal BMD Is a bone mineral content, measured by DXA, divided by the bone area in square centimeters.

Coding Implications

This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2024, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

Table 1 – COVERED CPT CODES

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CPT®*	Description			
Codes				
77078	Computed tomography, bone mineral density study, 1 or more sites, axial skeleton			
	(e.g., hips, pelvis, spine)			
77080	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial			
	skeleton (e.g., hips, pelvis, spine)			
77081	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites;			
	appendicular skeleton (peripheral) (e.g., radius, wrist, heel)			
76977	Ultrasound bone density measurement and interpretation, peripheral site(s), any			
	method			

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TABLE 2 – NON COVERED CPT CODES

CPT®*	Description
Codes	
77086	Vertebral fracture assessment via dual-energy X-ray absorptiometry (DXA)
78350	Bone density (bone mineral content) study, 1 or more sites; single photon
	absorptiometry
78351	Bone density (bone mineral content) study, 1 or more sites; dual photon
	absorptiometry, 1 or more sites

Reviews, Revisions, and Approvals	Reviewed Date	Approval Date		
Original approval date				

References

 State of North Carolina Medicaid. Medicaid and Health Choice Clinical Coverage Policy No:1K-2 Bone Mass Measurement. <u>Program Specific Clinical Coverage Policies | NC Medicaid (ncdhhs.gov)</u>. Published February 15, 2024. Accessed February 15, 2024.

North Carolina Guidance

Eligibility Requirements

- 1. An eligible beneficiary shall be enrolled in the NC Medicaid Program (Medicaid is NC Medicaid program, unless context clearly indicates otherwise);
- 2. Provider(s) shall verify each Medicaid beneficiary's eligibility each time a service is rendered.
- 3. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.

EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

• 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act] Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age if the service is medically necessary health care to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

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Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

- **I.** that is unsafe, ineffective, or experimental or investigational.
- II. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

EPSDT and Prior Approval Requirements

- If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does NOT eliminate the requirement for prior approval.
- IMPORTANT ADDITIONAL INFORMATION about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below:

NCTracks Provider Claims and Billing Assistance Guide: https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html EPSDT provider page: https://medicaid.ncdhhs.gov/

Provider(s) Eligible to Bill for the Procedure, Product, or Service
To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

- i. meet Medicaid qualifications for participation;
- ii. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; and
- iii. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

Compliance

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Provider(s) shall comply with the following in effect at the time the service is rendered:

- **A.** All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
- **B.** All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

Claims-Related Information

Provider(s) shall comply with the NC Tracks Provider Claims and Billing Assistance Guide, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid:

- Claim Type as applicable to the service provided:
 Professional (CMS-1500/837P transaction)
 Institutional (UB-04/837I transaction)
 Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
- International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS) Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.
- Code(s) Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy. If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service

- Modifiers Providers shall follow applicable modifier guidelines.
- Billing Units Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
- Co-payments -For Medicaid refer to Medicaid State Plan:

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https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan

• Reimbursement - Provider(s) shall bill their usual and customary charges. For a schedule of rates, refer to: https://medicaid.ncdhhs.gov/.

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.



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