

<p>SUBJECT: CLINICAL POLICIES – BONE MASS MEASUREMENT (BMM)</p> <p>POLICY NUMBER: HS-CP-M7</p> <p>EFFECTIVE DATE: SEPTEMBER 27, 2023</p> <p>SERVICE/PRODUCT LINE: MEDICARE – MEDICAL & BEHAVIORAL HEALTH</p>	<p>Product Line (check all that apply):</p> <p><input type="checkbox"/> All</p> <p><input type="checkbox"/> Group HMO</p> <p><input type="checkbox"/> Individual HMO</p> <p><input type="checkbox"/> PPO</p> <p><input type="checkbox"/> POS</p> <p><input checked="" type="checkbox"/> Medicare</p> <p><input type="checkbox"/> N/A</p>
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These guidelines are used in conjunction with the independent judgment of a qualified licensed physician and do not constitute the practice of medicine or medical advice. This Clinical Policy 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. This Clinical Policy is not intended to recommend treatment for members. Members should consult with their treating provider in connection with diagnosis and treatment decisions.

Sharp Health Plan develops Clinical Policies that serve as guidelines for medical necessity decisions utilizing evidence-based guidelines, compiled from local, national, governmental, and professional organizations, literature, and current peer-reviewed publications, as described in further detail below.

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I. Benefit Statement: Any service reviewed and approved by this Sharp Health Plan Clinical Policy must be a covered benefit according to the member’s evidence of coverage (EOC). Since benefit plans vary in coverage and some plans may not provide coverage for certain services discussed in this clinical policy, decisions are subject to all terms and conditions of the applicable benefit plan. Benefit determinations should be based in all cases on the member’s contract benefits in effect at the time of service. All reviewers must first identify member eligibility and all decisions of this clinical policy are subject to current state and/or federal law. Clinical policy does not constitute plan authorization, nor is it an explanation of benefits. In the event of a conflict, a member’s benefit plan, EOC, always supersedes the information in the Clinical Policies.

II. Regulatory: Medicare Benefit Policy Manual Chapter 15 80.5, rev 03-16-2023¹

80.5.4 - Conditions for Coverage (Rev. 70, Issued: 05-11-07, Effective: 01-01-07, Implementation: 07-02-07) Medicare covers BMM under the following conditions: 1. Is ordered by the physician or qualified nonphysician practitioner who is treating the beneficiary following an evaluation of the need for a BMM and determination of the appropriate BMM to be used. A physician or qualified nonphysician practitioner treating the beneficiary for purposes of this provision is one who furnishes a consultation or treats a beneficiary for a specific medical problem, and who uses the results in the management of the patient. For the purposes of the BMM benefit,

qualified nonphysician practitioners include physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives. 2. Is performed under the appropriate level of physician supervision as defined in 42 CFR 410.32(b). 3. Is reasonable and necessary for diagnosing and treating the condition of a beneficiary who meets the conditions described in §80.5.6. 4. In the case of an individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy, is performed with a dual-energy x-ray absorptiometry system (axial skeleton). 5. In the case of any individual who meets the conditions of 80.5.6 and who has a confirmatory BMM, is performed by a dual-energy x-ray absorptiometry system (axial skeleton) if the initial BMM was not performed by a dual-energy x-ray absorptiometry system (axial skeleton). A confirmatory baseline BMM is not covered if the initial BMM was performed by a dual-energy x-ray absorptiometry system (axial skeleton).

III. **Description:**

The following Clinical Policy – Bone Mass Measurement – applies to the Medicare Advantage Plan (Sharp Advantage) administered by Sharp Health Plan (Plan) and / or its delegates. The purpose of this policy is to outline the Plan requirements for coverage of bone mass.

IV. **Definitions:**

- A. **Bone Density:** Bone density refers to the ratio of weight to the volume or area of the bones, which accounts for 70% to 85% of bone strength. Bone density is strongly predictive of fracture risk.^{2,3}
- B. **Bone Mass:** Bone mass refers to the weight of the skeleton.²
- C. **Bone Mass Density T-score:** According to the World Health Organization (WHO):⁴
 - 1. A T-score of -1.0 or above is normal bone density. Examples are 0.9, 0 and -0.9.
 - 2. A T-score between -1.0 and -2.5 means you have low bone density or osteopenia. Examples are T- scores of -1.1, -1.6 and -2.4.
 - 3. A T-score of -2.5 or below is a diagnosis of osteoporosis. Examples are T-scores of -2.6, -3.3 and -3.9
- D. **Bone Mass Measurement (BMM):**

BMM is defined as a radiologic, radioisotopic, or other procedure that meets all of the following conditions:

 - 1. Is performed to identify bone mass, detect bone loss, or determine bone quality.
 - 2. Is performed with either a bone densitometer (other than single-photon or dual-photon absorptiometry) or a bone sonometer system that has been cleared for marketing for BMM by the Food and Drug Administration (FDA) under 21 CFR part 807 or approved for marketing under 21 CFR part 814.
 - 3. Includes a physician's interpretation of the results.
- E. **Osteoporosis:**

North American Menopause Society guideline states the diagnosis of osteoporosis is established by measurement of bone mineral density (BMD) by dual-energy x-ray absorptiometry (DXA) of the spine, hip, and/or forearm (T-score of -2.5 or lower) or by the

presence of a low-trauma or fragility fracture.⁵

V. **Medical Necessity:**

Bone mass measurements are covered by the Plan when Medicare coverage criteria are met, as stated in the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) or Local Coverage Determination (LCD) guidance documents. Sharp Advantage (SA) provides coverage of a bone mass measurement that meets the Medicare criteria once every two years (i.e., at least 23 months after the last covered bone mass measurement was performed). For further details, refer to the Coverage Rationale section of this policy and to the CMS criteria.

A. Initial Bone Mass Measurement

1. Medicare's bone mass measurement benefit includes a physician's interpretation of the procedure's results. Medicare provides coverage of bone mass measurements that meet coverage criteria #2: a-f below: ¹
2. The bone mass measurement is performed on a qualified individual. A "qualified individual" means a Medicare beneficiary who meets the medical indications for at least one (1) of the following categories:
 - a) A woman who has been determined by the physician or qualified non-physician practitioner treating her to be estrogen-deficient and at clinical risk for osteoporosis, based on her medical history and other findings; or

NOTE: Since not every woman prescribed estrogen replacement therapy (ERT) may be receiving an "adequate" dose of the therapy, the fact that a woman is receiving ERT should not preclude her treating physician or other qualified treating non-physician practitioner from ordering BMM for her. If a BMM is ordered for a woman following a careful evaluation of her medical need, however, it is expected that the ordering treating physician (or other qualified treating non-physician practitioner) will document in her medical record why he or she believes that the woman is estrogen-deficient and at clinical risk for osteoporosis.
 - b) An individual with vertebral abnormalities, as demonstrated by an X-ray to be indicative of osteoporosis, osteopenia (low bone mass), or vertebral fracture; or
 - c) An individual receiving (or expecting to receive) glucocorticoid (steroid) therapy equivalent to an average of 5.0 mg of prednisone or greater per day for more than three (3) months; or
 - d) An individual with known primary hyperparathyroidism; or
 - e) An individual being monitored to assess the response to, or efficacy of, an FDA-approved osteoporosis drug therapy.
 - f) A screening for osteoporosis with bone mass measurement will be offered for all women over 65 years of age per United States Preventive Services Task Force (USPSTF) and screening in postmenopausal women younger than 65 years who are at increased risk of osteoporosis, as determined by a formal

clinical risk assessment tool (ORAI, OSIRIS, OST, SCORE, and FRAX.)

3. The physician or qualified non-physician practitioner treating the qualified individual must provide an order for a bone mass measurement test, following an evaluation of the need for a bone mass measurement that included a determination of the medically appropriate measurement for the individual.
4. The service must be a radiologic or radioisotopic procedure (or other procedure) that meets the following requirements:
 - a) Is performed with a bone densitometer (other than single-photon or dual-photon absorptiometry) or a bone sonometer (e.g., ultrasound) device approved or cleared for marketing by the FDA;
 - b) Is performed for the purpose of identifying bone mass, detecting bone loss, or determining bone quality; and
 - c) Includes a physician's interpretation of the procedure's results.
5. A qualified supplier or provider must furnish such services under the appropriate level of supervision by a physician.
6. The service must be reasonable and medically necessary to diagnose, treat, or monitor a qualified individual.
7. The service must be performed at a frequency that conforms to the Repeat Bone Mass Measurement section.

B. Repeat Bone Mass Measurement

1. Repeat bone mass measurement screening is considered medically necessary once every two (2) years (at least 23 months have passed since the month the last covered bone mass measurements was performed).¹
2. More frequent bone mass measurements are considered medically necessary more often than every two (2) years including, but are not limited to, the following medical circumstances:
 - a) Monitoring individuals on long-term use of drug therapies associated with increased risk of fracture, including, but not limited to: anticonvulsant medications known to affect bone metabolism, thyroid with evidence of hyperthyroidism (disease related or iatrogenic) of greater than or equal to 3 months, and glucocorticoid therapy greater than or equal to 5 mg per day of more than three (3) months duration. In these cases, repeat bone mass measurement is considered medically necessary no more frequently than every 12 months or
 - b) Testing for osteoporosis is needed, as indicated by one (1) or more of the following:²
3. Individual receiving FDA-approved pharmacologic treatment for osteoporosis (e.g., bisphosphonate): every two (2) years; or ^{7, 8, 9, 10}
4. Untreated postmenopausal female: every two (2) to five (5) years; or ^{2, 9, 11}

5. Change in FDA-approved pharmacologic treatment for osteoporosis where the testing results effect treatment decisions: No earlier than one (1) year following the treatment change. Once a response to such therapy has been documented, testing will be done every 2 years if needed.
6. Any properly installed and validated DXA instrument is appropriate for initial BMD measurement. However, to the extent possible, it is essential that all subsequent BMD studies on an individual patient should be performed on the same DXA instrument as the baseline study.¹¹

VI. Not Medically Necessary:

- A. The Plan does not cover the following bone mass measurement, because they are not considered reasonable and necessary; are experimental, investigational, or unproven; or existing evidence does not support validity:
 1. Single-photon absorptiometry (effective January 1, 2007)¹
 2. Dual-photon absorptiometry (effective January 1, 2007)¹
 3. Screening for osteoporosis in men¹², or for any population other than those described above.
 4. Vertebral fracture assessment by dual-energy x-ray absorption for any other indication.
 5. Measurements of the heel.
- B. It is not medically necessary to have both a peripheral and axial bone mass measurement (BMM) performed on the same day

VII. Process/Procedures:

- A. The member schedules a visit with their PCP to assess bone mineral density.
- B. PCP assesses member and recommend bone mass measurement evaluation and testing based on the member's condition that meets criteria, or other condition that meets criteria, for bone mass measurement as described above.
- C. PCP shall submit an authorization request to the PMG for a bone mass measurement evaluation and testing. The request shall include:
 1. Evaluation and testing results,
 2. Codes for evaluation and testing, and
 3. Justification for evaluation and testing.
 4. Preferred vendor.
- D. The PMG Utilization Management (UM) staff shall follow current Plan Medical Policy to adjudicate requests based on medical necessity according to current Plan Prior Authorization process. The Plan UM staff takes into consideration the severity of bone loss, the type of bone loss, and prior interventions.
- E. The Plan UM staff shall process the determination according to the current Policy & Procedure (P&P):

1. Sharp UM Medicare P&P Organization Determinations (Referrals and Authorizations)
2. Sharp Heath Plan P&P Member and Practitioner UM Denial Letter Notification
3. Sharp Heath Plan Medical Benefit Policy: Bone Mass Measurement

VIII. Codes:

NOTE: The codes listed in this policy are for reference purposes only. Listing of a code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit documents and medical necessity criteria. This list of codes may not be all-inclusive.

<u>ICD-10 Codes</u>
C73 Malignant neoplasm of thyroid gland
E05.00-E05.91 Thyrotoxicosis (hyperthyroidism)
E07.0 Hypersecretion of calcitonin
E21.0-E21.5 Hyperparathyroidism and other disorders of parathyroid gland
E24.0-E24.9 Cushing's syndrome
E27.0 Other adrenocortical over-activity
E28.310-E28.319 Premature menopause
E28.39 Other primary ovarian failure
E29.1 Testicular hypo function
E34.2 Ectopic hormone secretion, not elsewhere classified
E34.50-E34.52 Androgen insensitivity syndrome
E34.9 Endocrine disorder, unspecified
E43 Unspecified severe protein-calorie malnutrition
E44.0-E44.1 Protein-calorie malnutrition of moderate and mild degree
E55.9 Vitamin D deficiency, unspecified
E83.50-E83.59 Disorders of calcium metabolism
E89.40 post-procedural ovarian failure
K50.00-K50.919 Crohn's disease (regional enteritis)
K51.00-K51.919 Ulcerative colitis
K90.0-K90.9 Intestinal malabsorption
M83.9 Adult osteomalacia, unspecified
M80.00-M80.88 Age-related osteoporosis with current pathological fracture
M81.0-M81.8 Osteoporosis without current pathological fracture

M84.361-M84.369 Stress fracture, tibia, and fibula
M84.371-M84.379 Stress fracture, ankle, foot, and toes
M84.38 Stress fracture, other sites
M84.40-M84.48 Pathological fracture, not elsewhere classified
M88.9 Osteitis deformans of unspecified bone
M89.00-M89.09 Algoneurodystrophy
M89.9 Disorder of bone, unspecified
M94.9 Disorder of cartilage, unspecified
N18.1–N18.9 Chronic kidney disease
N25.0-N25.9 Disorders resulting from impaired renal tubular function
N91.2 Amenorrhea, unspecified
N95.1 Menopausal and female climacteric states
N95.8 Other specified menopausal and perimenopausal disorders
Q61.02 Congenital multiple renal cysts
Q61.19 Other polycystic kidney, infantile type
Q61.2 Polycystic kidney, adult type
Q61.3 Polycystic kidney, unspecified
Q61.4 Renal dysplasia
Q61.5 Medullary cystic kidney
Q61.8 Other cystic kidney diseases
Q78.0 Osteogenesis imperfecta
Q78.9 Osteochondrodysplasia, unspecified
Q96.0-Q96.9 Turner’s syndrome
R29.890 Loss of height
R93.6 Abnormal findings on diagnostic imaging of limbs
R93.7 Abnormal findings on diagnostic imaging of other parts of musculoskeletal system
R93.8 Abnormal findings on diagnostic imaging of other specified body structures
R93.9 Diagnostic imaging inconclusive due to excess body fat of patient
S22.000-S22.089 Fracture of thoracic vertebra
S12.00-S12.691 Fracture of cervical vertebra and other parts of the neck
S32.000-S32.399 Fracture of lumbar spine and pelvis

S52.501-S52.516 Fracture of lower end of radius
S72.001-S72.099 Fracture of head and neck of femur
T50.905 Adverse effect of unspecified drugs, medicaments, and biological substances
Z13.820 Encounter for screening for osteoporosis
Z40.02 Encounter for prophylactic removal of ovary
Z78.0 Asymptomatic menopausal state
Z79.01 Long term (current) use of anticoagulants
Z79.02 Long term (current) use of antithrombotics/antiplatelets
Z79.51 Long term (current) use of inhaled steroids
Z79.52 Long term (current) use of systemic steroids
Z79.89-Z79.899 Other long term (current) drug therapy
Z90.71-Z90.79 Acquired absence of genital organ(s)
<u>CPT Codes</u>
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 (central) 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)
77085 Dual energy x-ray absorptiometry (DXA) bone density study, one or more sites, axial skeleton (e.g., hips, pelvis, spine), including vertebral fracture assessment
77086 Vertebral fracture assessment via dual-energy X-ray absorptiometry (DXA)
76977 Ultrasound bone density measurement and interpretation, peripheral site(s), any method
0508T Pulse-echo ultrasound bone density measurement resulting in indicator of axial bone mineral density, tibia
2015 CPT Codes
77086 Vertebral fracture assessment via dual-energy X-ray absorption (DXA)
Codes not Covered by Medicare (February 2008)
78350 Bone density (bone mineral content) study, one or more sites, single photon absorptiometry
78351 Bone density (bone mineral content) study, dual photon absorptiometry, one or more sites

Appendix Clinical Evidence:

- A. Disease Description

1. Osteoporosis is a disease of the bones and is characterized by low bone mass, deterioration of bone tissue and disruption of bone architecture, compromised bone strength, and an increase in the risk of fracture. People with osteoporosis most often break bones in the hip, spine, and wrist.
2. Osteoporosis can occur in both men and women and at any age, but it is most common in older women.
3. Osteoporosis causes more than 8.9 million fractures annually worldwide, of which more than 4.5 million occur in the Americas and Europe. The National Osteoporosis Foundation reports the incident of osteoporosis in the United States is expected to increase significantly as the population ages.

B. Treatment of Disease

1. The primary clinical goal of osteoporosis management is to reduce fracture risk. This may be accomplished by slowing or stopping bone loss, increasing bone mass, or improving bone architecture, maintaining, or increasing bone strength, and minimizing factors that contribute to falls. Management strategies include general preventive health measures and pharmacologic interventions.
2. Patients with osteoporosis or osteopenia may benefit from treatments that prevent fractures.
3. Treatment for osteoporosis includes a balanced diet rich in calcium and vitamin D, an exercise plan, a healthy lifestyle, and medications, if needed. Known treatments include bisphosphonates, estrogen, calcium, and vitamin D. Quantification of bone mineral in the spine and extremities can be used for screening asymptomatic patients for osteoporosis and other age-related bone degeneration conditions when reference measurements are available.
4. In conjunction with osteoporosis screening, individuals require counseling regarding fracture prevention, including lifestyle modification, fall prevention, and possibly pharmacologic intervention.

C. Bone Mass Measurement

1. The American College of Radiology Society of Skeletal Radiology practice guideline states DXA is a clinically proven method of measuring bone mineral density. It is used primarily in the diagnosis and management of osteoporosis and other disease states characterized by abnormal bone mineral density, as well as to monitor response to therapy for these conditions. The primary goal of DXA is to measure bone mineral density accurately and reproducibly and compare that measurement to a reference population of asymptomatic individuals. The DXA measured bone mineral density also helps in determining future fracture risk and need for pharmacologic therapy and fracture prevention programs, as well as evaluating the effectiveness of therapy.
2. Bone density can be measured at several anatomical locations:
 - a) Central (Hip or Spine) bone mineral density with DXA – evidence demonstrates at least moderate certainty of at least moderate. Central DXA is the preferred method for making therapeutic decisions and should be

used confirm a diagnosis whenever possible.²

- b) Peripheral (Forearm or Cortical) bone mineral density with DXA – For repeat monitoring of bone mineral density testing for osteoporosis, evidence demonstrates a net benefit, but of less than moderate certainty.
3. Peripheral DXA screening tests are less reliable than central DXA (per National Osteoporosis Foundation cannot accurately diagnose osteoporosis and they should not be used to see how well an osteoporosis medicine is working). The results of a peripheral test cannot be compared with the results of a central DXA.
 - a) Heel (Calcaneal) – For prediction of fracture risk, evidence is insufficient, conflicting, or poor; additional research is needed.
 - b) Single and combined measurements may be required to diagnose bone disease, monitor bone changes with disease progression, or monitor bone changes with therapy.⁶

IX. References: change letters to numbers and eliminate superscript

- A. ¹Centers for Medicare and Medicaid Services (CMS). CMS Manual System. Publication 100-02 Medicare Benefit Policy Manual. Chapter 15, Section 80.5. Bone Mass Measurements (BMMs); Revised 3/16/2023.
- B. ²MCG Health. Bone Density Study, Central, Dual Energy X-ray Absorptiometry (DXA). Ambulatory Care 27th Edition. 2022. MCG Health. Bone Density Study, Peripheral, Dual Energy X-ray Absorptiometry (DXA). Ambulatory Care 27th Edition. 2023.
- C. ³Osteogenesis Imperfecta Foundation, Inc. Bone Mineral Density: What it Means and How to Measure it. Accessed 7/24/22.
- D. ⁴Journal of Woman's Health, 2104 Jul 1; Osteoporosis Prevention, Screening, and Treatment, A review. Accessed 8/10/23
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- H. ⁸American Association of Clinical endocrinologists and American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and treatment of Postmenopausal Osteoporosis- 2020 Update, Endocrine Practice Vol 26 (Suppl 1) May 2020. Accessed 8/10/23
- I. ⁹UptoDate, Evaluation and treatment of premenopausal osteoporosis, Literature review current through Jul 2023
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X. Revision History:

Date	Modification (Original, Reviewed or Revised)
3/23/2016	Original
6/15/2017	Reviewed/approved QMC
9/26/2018	Reviewed
9/25/19	New Format, Updated references
9/30/20	Revised, Updated references
9/29/21	Reviewed
9/28/22	Reviewed, Updated references
9/27/23	Updated

Approved by:  _____
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Date: 9/27/23