HEALTH PLANS
UNIVERSITY OF UTAH

**Medical Policy**

# Bone Mineral Density Studies

**Policy** MP-041

**Origination Date:** 08/28/2024

**Reviewed/Revised Date:** 04/16/2025

**Next Review Date:** 04/16/2026

**Current Effective Date:** 06/16/2025

**Disclaimer:**

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, CHIP and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

## Description:

Osteoporosis is a systemic, progressive skeletal disease characterized by low bone mass and microarchitectural tissue deterioration, leading to bone fragility and increased risk of fracture. The term low bone mass is used interchangeably with low bone mineral density (BMD). Osteoporosis is common and can have serious consequences. For example, the worldwide risk of hip fracture is 1 in 3 for women 50 years of age or older and osteoporotic hip fracture increases the risk of mortality in the year following fracture. Any osteoporotic fracture predicts future fracture. Early detection of osteopenia or osteoporosis is important so that drugs and other therapies can be used to reduce the incidence of fragility fractures.

Dual-energy 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. Earlier technologies, such as single and dual photon absorptiometry are rarely used and dual photon absorptiometry is considered obsolete. DXA is the gold standard for bone quality measurement in children as well as adults, due to precision, reproducibility, and availability of standardized data. Nevertheless, DXA is not without limitations. Disrupting factors such as movement during measurement, contractures, metallic implants, and sometimes even scoliosis can cause results to be uninterpretable.

In children and adolescents, DXA is the preferred method for assessing bone mineral content (BMC) and areal bone mineral density (BMD). The posterior-anterior (PA) spine and total body less head (TBLH) are the preferred sites for these measurements in pediatric subjects.

Depending on clinical needs, other sites such as the proximal femur, 1/3 radius, and distal femur may also be useful.

In pediatric DXA reports, the term "osteopenia" should not be used. "Osteoporosis" should only be mentioned if there is a clinically significant fracture history. When BMC or areal BMD Z-scores are ≤ -2.0 SD, the preferred term is "low bone mineral mass or bone mineral density." (2019 ISCD Peds)

Trabecular bone score (TBS) is calculated with proprietary software called TBS iNsight ™ (Medimaps Group) and represents a measure of bone microarchitecture quality. The TBS value is derived from imaging data produced by a standard lumbar spine DXA scan. TBS is not intended to replace BMD measurements or scores derived from fracture risk tools but rather to add complementary information and thereby improve risk assessment, treatment selection, and treatment monitoring. TBS is correlated with 3-dimensional bone microarchitecture parameters independent of its correlation with BMD. Lower TBS values are associated with previous fragility (osteoporosis-related) fracture regardless of whether BMD values meet the diagnostic criteria for osteoporosis or osteopenia.

Ultrasound-based Radiofrequency Echographic Multi-spectrometry (REMS) is a non-ionizing technology that evaluates bone status by analyzing raw, unfiltered native ultrasound signals, so-called radio frequency (RF) ultrasound signals, obtained during an ultrasound scan of the lumbar vertebrae and proximal femur. The analysis of native unfiltered ultrasound signals allows for information about the characteristics of bone tissue to be acquired. Bone density is obtained by comparing the spectra of analyzed signal with reference spectral models that have been previously obtained. REMS scans are performed at both the proximal femur and lumbar spine.

## Policy Statement and Criteria

### 1. Commercial Plans/CHIP

**U of U Health Plans considers central dual-energy x-ray absorptiometry (DXA scan) (77080) medically necessary when used as a screening tool for osteoporosis with any of the following indications:**

A. Women aged ≥ 65 years

B. Postmenopausal women ≤ 65 years of age who have one of the following risk factors:

   i. Menopause, natural or surgical, before age 40

   ii. History of non-traumatic fracture after age 45 in a first-degree relative

   iii. Current smoker (one pack or more per day)

   iv. On no hormone replacement therapy OR on hormone replacement therapy greater than 10-15 years

C. Women ≥ 65 years of age whose fracture risk is at least equal to that of an average risk 65 year old woman according to the FRAX (Fracture Risk Assessment) tool

D. Men aged ≥ 50 years with at least one factor related to an increased risk of osteoporosis (i.e., aged ≥ 70 years, low body weight, weight loss > 10%, physical inactivity, corticosteroid use, androgen deprivation therapy, gonadal insufficiency (primary and secondary) (includes androgen suppression) and previous fragility fracture)

**U of U Health Plans does NOT cover bone mineral density measurement when screening for osteoporosis for any other population as it is considered experimental/investigational or unproven.**

**U of U Health Plans considers posterior-anterior (PA) spine and total body less head (TBLH) dual-energy x-ray absorptiometry (DXA scan) (76499) in pediatric members medically necessary when used as a diagnostic tool for low bone mineral mass or density (including osteoporosis) with any of the following indications:**

A. To confirm diagnosis of osteoporosis as indicated by: one or more vertebral compression (crush) fractures in the absence of local disease or high- energy trauma and/or a clinically significant fracture history as indicated by:

   i. Two or more long bone fractures by age 10 years; or

   ii. Three or more long bone fractures at any age up to age 19 years.

B. In patients with primary or secondary bone disease, when interventions may help reduce the risk of clinically significant fractures

C. The minimum interval is between 6-12 months for repeat scans.

**U of U Health Plans considers central DXA scan (77080) medically necessary when used as a diagnostic or monitoring tool when the member has any of the following indications:**

A. Prior to and during pharmacologic treatment for osteoporosis

B. Prolonged use of medications associated with low bone mass or bone loss (e.g., anticonvulsants, heparin, lithium, gonadotropin-releasing hormone agonists)

C. Child or adolescent with a disease process known to adversely affect the skeleton

D. Primary hyperparathyroidism

E. Celiac sprue

F. Known osteoporotic fracture

G. History of pathologic fracture

H. History of low-impact fracture

I. Vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture

J. Adults (age 18 years and older) with spinal cord injury resulting in permanent motor or sensory dysfunction

K. Receiving (or expected to receive) systemic glucocorticoid therapy equivalent to prednisone at least 5 mg per day for greater than 3 months

L. Women with Turner syndrome

**Computed tomography (CT) (CPT® 77078) for bone mineral density measurement testing is considered medically necessary as a screening tool for osteoporosis when DXA scanner is unavailable or known to be inaccurate for ANY of the following indications:**

A. Women ≥ 65 years of age and men ≥ 70 years of age

B. Younger postmenopausal women, women in the menopausal transition, and men aged 50 to 69 years with clinical risk factors for fracture

C. Adults who have a fracture at age 50 years and older

D. Adults with a condition (e.g., rheumatoid arthritis, organ transplant) or taking a medication (e.g., glucocorticoids, aromatase inhibitors, androgen deprivation therapy) associated with low bone mass or bone loss

**U of U Health Plans does NOT cover non-screening or monitoring of bone mineral density measurement for any other indication (e.g., evaluation of osteoporosis/osteoporotic fractures in persons with schizophrenia who are on anti-psychotic medications, and monitoring individuals who are on anti-depressive agents) as it is considered experimental/investigational or unproven.**

**U of U Health Plans does NOT cover trabecular bone score (TBS) (77089-77092) for any indication as there is insufficient evidence in the published medical literature to demonstrate the safety, efficacy and long term outcomes. Therefore, TBS is considered experimental/investigational or unproven.**

**U of U Health Plans does NOT cover pulse-echo ultrasound (76999) for bone mineral density measurement testing as it is considered experimental, investigational or unproven.**

**U of U Health Plans does NOT cover ultrasound-based Radiofrequency Echographic Multi-Spectrometry (REMS) (0815T) for bone density study and/or fracture-risk assessment as it is considered experimental, investigational or unproven.**

2. **Medicaid Plans**
   **Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: https://medicaid.utah.gov/utah-medicaid-official-publications/ or the Utah Medicaid code Look-Up tool**

   **CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.**

## Clinical Rationale

A 2016 systematic review (Lee et al) was conducted to compare the diagnostic accuracy of vertebral fracture assessment with densitometry (VFA) and dual X-ray absorptiometry (DXA) for identification of vertebral fractures (VFs), from their inception to May 2013. VFA appeared to have moderate sensitivity and high specificity for detecting VFs when compared with spinal radiography. VFs are recognized as the hallmark of osteoporosis, and a previous VFs increases the risk of a future fracture. Comparison was done by analyzing the sensitivity and specificity using a 2 x 2 contingency table. Subgroup analyses were also performed on studies with a low risk of bias and applicability. Twelve studies were analyzed for the diagnostic accuracy of VFA. The sensitivity and specificity were 0.70-0.93 and 0.95-1.00, respectively, analyzed on a per-vertebra basis, and 0.65-1.00 and 0.74-1.00 on a per-patient basis. The sensitivity and specificity of five studies in subgroups with a low risk of bias in the intervention test were 0.70-0.84 and 0.96-0.99, respectively. In studies with a low risk of bias in the patient selection, those based on a per-vertebra basis in three studies were 0.70-0.93 and 0.96-1.00, respectively. The authors concluded that VFA had moderate sensitivity and high specificity for detecting VFs when compared with DXA. However, the present findings are insufficient to assess whether DXA should be replaced by VFA. Therefore, further more robust studies are needed to confirm these findings.

In UpToDates's overview of dual-energy x-ray absorptiometry (DXA) the authors found the following for diagnosis of osteoporosis – The World Health Organization (WHO) has established a classification of BMD according to T-score that is the worldwide standard for diagnosis of osteoporosis. The WHO criteria should be used for diagnostic classification in postmenopausal females, perimenopausal females, and for males age 50 years and older. They should not be used for premenopausal females, males under age 50 years, or children. In these populations, Z-scores rather than T-scores should be used. As for the skeletal site selection – The Bone Health and Osteoporosis Foundation (BHOF) and the International Society for Clinical Densitometry (ISCD) recommend that the diagnosis of osteoporosis be made using the lowest T-score measured by DXA of the lumbar spine (L1-L4), total proximal femur, femoral neck, or one-third radius. The WHO and the ISCD recommend the use of the National Health and Nutrition Examination Survey (NHANES) III young adult reference database for calculation of T-score at the hip, using a White female database for females and for males. Application of this recommendation may vary according to local requirements. Also, the same DXA instrument should be used for serial BMD testing whenever possible. As it is not possible to quantify BMD changes on measurements made on different instruments unless a cross-calibration study has been done. And

finally, identification of previously undetected vertebral fractures (VFs) may change the diagnostic classification, fracture risk assessment, and clinical management. Vertebral fracture assessment (VFA) by DXA is a method of visualizing the spine to detect VFs. VFA compares favorably with spine radiographs in detecting moderate and severe VFs, but it does not perform as well for diagnosing mild VFs.

In 2023, Hayes evaluated "the effectiveness and safety of the trabecular bone score (TBS) as an adjunct to bone mineral density (BMD) measurement and/or other validated tools incorporating patient information for prediction of fracture risk and guidance of preventive treatment in postmenopausal women. The evidence base comprised 8 cohort studies; 5 were prospective and 3 were retrospective. Studies were designed to assess improvement in the accuracy of fracture prediction when TBS was combined with BMD, with BMD and other risk factors, or with fracture risk assessment tool (FRAX) scores. The reference standard for fracture prediction was the occurrence of new fractures during the study follow-up period." The review concluded, a low-quality body of inconstant evidence did not demonstrate that the use of TBS improves the accuracy of fracture prediction as an adjunct to BMD or FRAX score. Small and inconsistent increases in accuracy were seen with adjunct TBS, which raises concerns about whether use of TBS will provide meaningful improvements in management of postmenopausal women at risk for fragility fractures; however, no studies of the clinical utility of TBS were identified. Thus, further more robust studies are needed to evaluate clinical utility and to determine whether combining TBS with BMD or FRAX score provides clinically meaningful improvements in fracture prevention in postmenopausal women, and to evaluate the adjunct use of the TBS on health outcomes.

Also in 2023, Hayes conducted an Evidence Analysis Research Brief to summarize the volume of publications and to determine whether there is adequate published peer-reviewed literature to evaluate the evidence related to quantitative computed tomography (QCT) compared with dual-energy x-ray absorptiometry (DXA) for screening of osteopenia or osteoporosis in postmenopausal female persons. Six cross-sectional studies evaluating QCT for the screening of osteopenia or osteoporosis were identified. No systematic reviews with or without meta-analysis were identified. No clinical utility studies evaluating QCT for screening of osteopenia or osteoporosis were identified. Six position statements or guidelines were identified. Based on a review of full-text clinical practice guidelines and position statements, guidance appears to confer weak support for QCT for screening of osteopenia or osteoporosis in postmenopausal female persons. The review of abstracts suggests that there is adequate published peer-reviewed literature to evaluate the evidence related to QCT for screening of osteopenia or osteoporosis in postmenopausal female persons.

The Endocrine Society guidelines on Osteoporosis in Men recommend vertebral fracture assessment (VFA) using DXA equipment for men with osteopenia or osteoporosis who might have previously undiagnosed vertebral fractures. If VFA is technically limited or not available, lateral spine radiographs should be considered (Watts, 2012).

There is adequate evidence to support the use of central bone density studies to assess the risk of osteoporosis in settings where the results may influence medical therapy. Studies have demonstrated the efficacy of bone mineral studies for several populations at higher risk for this process, including postmenopausal women, especially those over the age of 65, individuals currently receiving medications for osteoporosis prophylaxis, those receiving glucocorticoid therapy and individuals with endocrinopathies or other conditions which predispose to osteoporosis. Examples of these include: hyperthyroidism and hypothyroidism, hyperparathyroidism, corticosteroid use, and rheumatoid arthritis. Currently both the American Association of Clinical Endocrinologist (AACE) Medical Guidelines for Clinical Practice for the Prevention and Treatment of Postmenopausal Osteoporosis (Camacho, 2020) and the U.S. Preventive Services Task Force (USPSTF) statement on Osteoporosis to Prevent Fractures:

Screening (2018) recommend a screening BMD scan for all women over the age of 65 (USPSTF B recommendation). The American College of Obstetricians and Gynecologists (ACOG) recommends screening for osteoporosis in postmenopausal patients 65 years and older with BMD testing by way of DXA scan to prevent osteoporotic fractures (strong recommendation, high-quality evidence). Regarding individuals at increased risk for osteoporosis, as determined by a formal clinical risk assessment tool, ACOG recommends that screening be conducted using BMD testing by way of DXA scan to prevent osteoporotic fractures in postmenopausal patients younger than 65 years (strong recommendation, high-quality evidence) (ACOG, 2021).

As far as additional testing after the initial screening, ACOG recommends that after treatment has been initiated, one DXA scan 1 – 2 years later can be used to assess the effect of treatment. If the BMD is improved or stable (no significant change), and there are no new risk factors, the DXA does not usually need to be repeated (ACOG, 2021). This is based upon the results of several trials that evaluated the change in BMD in individuals undergoing therapy for various conditions. These studies found that change in bone density could not be meaningfully assessed until late in the second year of therapy because some individuals actually continue to lose bone density during the first year but have subsequent significant increases during the second year of therapy. Alternatively, the AACE recommends BMD monitoring for individuals undergoing therapy for osteoporosis prevention every 1 to 2 years until bone mass is stable, then, continue with follow-up DXA every 1 - 2 years or at a less-frequent interval, depending on clinical circumstances (ACR, 2021; Camacho, 2020; Eastell, 2019).

The use of images other than DXA are proposed to identify individuals at high risk of fracture, or identify those with subclinical vertebral fractures. There is an increasing interest in performing concurrent bone health screening on patients who undergo diagnostic CT scans of the abdomen and pelvis. Additionally, digital X-ray radiogrammetry (DXR) is proposed to estimate hand BMD from hand x-ray images. Studies by Kolanu, et al., 2020 [Zebra Medical Vision®]; Dagan, et al., 2020 [HealthVCF]; Allaire, et al., 2019 [VirtuOst]; Adams, et al., 2018 [VirtuOst]; Kälvesten, et al., 2016 and Wilczek, et al., 2013 [OneScreen, Sectra]; Bach-Mortensen, et al., 2006 [X-posure System™ Sectra Pronosco A/S] have all been published. There is a lack of well-designed clinical trials addressing the impact of algorithmic-based assessments of non-DXA scans on patient-specific long-term health outcomes and thus conclusions cannot be reached as it relates to comparative accuracy, and safety of these methodologies in performance of osteoporosis screening.

Pulse-echo ultrasound (CPT® 76999) measures apparent cortical bone thickness at the proximal tibia and can be used in conjunction with other clinical risk factors or patient characteristics as an aid to the physician in the diagnosis of osteoporosis and other medical conditions leading to reduced bone strength and in the determination of fracture risk.

Lewiecki in 2020, Karjalainen et al in 2018 and Schousboe et al in 2017 all published studies assessing the utility of this method for assessing for osteoporosis. Though suggestive of potential utility, the peer-reviewed scientific literature lacks well-designed studies evaluating the impact of utilizing pulse-echo ultrasound on long-term health outcomes.

Multiple studies have been performed to assess the sensitivity and specificity of REMS in assessing for osteoporosis. These include studies by Al Refaie et al., 2023, Lalli, et al., 2022, Cortet, et al., 2021 and Adami, et al., 2021. Each study has significant limitations. There is a lack of well-designed clinical trials including diverse populations in the peer-reviewed scientific literature addressing the impact of the use of REMS on long-term patient health outcomes.

There is a lack of well-designed clinical trials including diverse populations in the peer-reviewed scientific literature addressing the impact of TBS iNsight® (Med-Imaps) on patient-specific health outcomes.

Future prospective trials evaluating the use trabecular bone score in place of or in addition to established fracture prediction tools should report if long-term patient health outcomes are improved (McCloskey, et al., 2015; Leslie, et al., 2014; Hans, et al., 2011).

The assessment of pediatric bone mineral content (BMC) and density (BMD) is an evolving field. Primary osteoporosis in pediatrics is often genetic, including conditions like osteogenesis imperfecta, other syndromes, metabolic disorders, and idiopathic juvenile osteoporosis. Secondary osteoporosis may result from nutritional deficits, decreased mobility and muscle mass, increased inflammatory cytokines, hormonal deficiencies, or osteotoxic drugs used for chronic diseases. Impaired bone mass accrual during childhood and adolescence leads to lower peak bone mass, decreased bone strength, and increased risk of osteoporosis in adulthood.

In 2021, the ISCD Pediatric Official Positions (Khalatbari et. al.) emphasized identifying children and adolescents at higher risk for clinically significant fractures who might benefit from interventions. They defined diagnostic criteria for osteoporosis and low bone mass or BMD, stating that DXA is appropriate for clinical densitometry in infants and young children. Osteoporosis diagnosis in pediatrics requires either one or more vertebral compression fractures without local disease or high-energy trauma, or a clinically significant fracture history and a BMD Z-score of ≤ -2.0. A clinically significant fracture history includes two or more long-bone fractures by age 10 or three or more long-bone fractures up to age 19. DXA studies in children and adolescents differ from those in adults due to factors such as changes in skeletal growth, lack of validated adjustment techniques for short stature or growth delay and limited normative databases. The preferred sites for measurement are the total body less head and lumbar spine. Additional sites include the hip (right or left), 1/3 radius (nondominant hand), and lateral distal femur.

## Applicable Coding

### CPT Codes

*Possibly covered (if criteria are met)*

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|---|---|
| **77078** | Computed tomography, bone mineral density study, 1 or more sites, axial skeleton (eg, hips, pelvis, spine) |
| **77080** | Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (eg, hips, pelvis, spine) |
| **77081** | ; appendicular skeleton (peripheral) (eg, radius, wrist, heel) |
| **77085** | ; axial skeleton (eg, hips, pelvis, spine), including vertebral fracture assessment |
| **77086** | Vertebral fracture assessment via dual-energy X-ray absorptiometry (DXA) |
| **76499** | Unlisted diagnostic radiographic procedure **(Total Body Less Head for pediatrics)** |

*Not covered*

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| **76977** | Ultrasound bone density measurement and interpretation, peripheral site(s), any method |

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| **77089** | Trabecular bone score (TBS), structural condition of the bone microarchitecture; using dual X-ray absorptiometry (DXA) or other imaging data on gray-scale variogram, calculation, with interpretation and report on fracture-risk |
| **77090** | Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical preparation and transmission of data for analysis to be performed elsewhere |
| **77091** | Trabecular bone score (TBS), structural condition of the bone microarchitecture; technical calculation only |
| **77092** | Trabecular bone score (TBS), structural condition of the bone microarchitecture; interpretation and report on fracture-risk only by other qualified health care professional |
| **76999** | Unlisted ultrasound procedure (e.g., diagnostic, interventional)[when used to report pulse-echo ultrasound for bone density measurement testing |
| **0554T** | Bone strength and fracture risk using finite element analysis of functional data, and bone-mineral density, utilizing data from a computed tomography scan; retrieval and transmission of the scan data, assessment of bone strength and fracture risk and bone mineral density, interpretation and report |
| **0555T** | ; retrieval and transmission of the scan data |
| **0556T** | ; assessment of bone strength and fracture risk and bone mineral density |
| **0557T** | ; interpretation and report |
| **0558T** | Computed tomography scan taken for the purpose of biomechanical computed tomography analysis |
| **0691T** | Automated analysis of an existing computed tomography study for vertebral fracture(s), including assessment of bone density when performed, data preparation, interpretation, and report |
| **0743T** | Bone strength and fracture risk using finite element analysis of functional data and bone mineral density (BMD), with concurrent vertebral fracture assessment, utilizing data from a computed tomography scan, retrieval and transmission of the scan data, measurement of bone strength and BMD and classification of any vertebral fractures, with overall fracture-risk assessment, interpretation and report |
| **0749T** | Bone strength and fracture-risk assessment using digital X-ray radiogrammetry-bone mineral density (DXR-BMD) analysis of bone mineral density (BMD) utilizing data from a digital X ray, retrieval and transmission of digital X-ray data, assessment of bone strength and fracture risk and BMD, interpretation and report; |
| **0750T** | ; with single-view digital X-ray examination of the hand taken for the purpose of DXR-BMD |

**0815T** Ultrasound-based radiofrequency echographic multi-spectrometry (REMS), bone-density study and fracture-risk assessment, 1 or more sites, hips, pelvis, or spine

## HCPCS Codes

*Not covered*

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

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