

POLICY TITLE	VERTEBRAL FRACTURE ASSESSMENT AND TRABECULAR BONE SCORE
POLICY NUMBER	MP 5.046

CLINICAL BENEFIT	☑ MINIMIZE SAFETY RISK OR CONCERN.
	☑ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS.
	☐ ASSURE APPROPRIATE LEVEL OF CARE.
	☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS.
	☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET.
	☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	2/1/2024

POLICY	PRODUCT VARIATIONS	DESCRIPTION/BACKGROUND
RATIONALE	<u>DEFINITIONS</u>	BENEFIT VARIATIONS
DISCLAIMER	<b>CODING INFORMATION</b>	<u>REFERENCES</u>
POLICY HISTORY	APPENDIX	

## I. POLICY

Screening for vertebral fractures using dual x-ray absorptiometry (DEXA or DXA) may be considered **medically necessary** for any of the following:

- Individuals assigned female at birth aged 65 years or older if T-score is less than or equal to -1.0 at the femoral neck;
- Individuals assigned female at birth aged 70 years or older and individuals assigned male at birth aged 80 years or older if T-score is less than or equal to -1.0 at the lumbar spine, total hip, or femoral neck;
- Individuals assigned male at birth aged 70-79 years if T-score is less than or equal to -1.5 at the lumber spine, total hip, or femoral neck;
- Postmenopausal individuals and individuals assigned male at birth aged 50 years or older with any of the following specific risk factors:
  - Fracture(s) during adulthood for any cause (fracture has to occur after becoming postmenopausal or reaching the age of 50);
  - Historical height loss of greater than or equal to 1.5 inches (defined as the difference between the current height and peak height);
  - Prospective height loss of greater than or equal to 0.8 inches (defined as the difference between the current height and last documented height measurement);
  - Recent or ongoing long-term glucocorticoid treatment;
  - o Medical conditions associated with bone loss such as hyperparathyroidism



POLICY TITLE	VERTEBRAL FRACTURE ASSESSMENT AND TRABECULAR BONE SCORE
POLICY NUMBER	MP 5.046

Vertebral fracture assessment using DEXA or DXA is considered **investigational** in all other situations. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Trabecular bone score to predict fracture risk is considered **investigational**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

#### Cross-reference:

**MP 5.037** Whole Body Dual X-Ray Absorptiometry to Determine Body Composition

### **II. PRODUCT VARIATIONS**

**TOP** 

This policy is only applicable to certain programs and products administered by Capital Blue Cross please see additional information below, and subject to benefit variations as discussed in Section VI below.

**FEP PPO:** Refer to the FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:

https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-quidelines/medical-policies.

## III. DESCRIPTION/BACKGROUND

**TOP** 

#### **VERTEBRAL FRACTURE ASSESSMENT**

## **Diagnosis**

Per the Bone Health and Osteoporosis Foundation (BHOF) – formerly the National Osteoporosis Foundation, vertebral fracture in an adult aged 50 years or older is diagnostic of osteoporosis, even in the absence of a bone density diagnosis. The presence of a single vertebral fracture signified a 5-fold increased risk for additional vertebral fractures and a 2- to 3-fold increased risk for hip or other fractures. Unfortunately, most vertebral fractures are subclinical and/or completely asymptomatic. As a result, they may go undiagnosed for many years. At the same time, a high proportion of women with asymptomatic vertebral fractures have bone mineral density (BMD) levels that would not warrant treatment based on BMD alone. The finding of a previously unrecognized vertebral fracture may change a patient's diagnostic classification, alter fracture risk calculations, and determine treatment decisions. Proactive investigation is required to detect these fractures so that further bone damage can be prevented.

Only 20% to 30% of vertebral fractures are recognized clinically; the rest are discovered incidentally on lateral spine radiographs. Lateral spine radiographs have not been recommended as a component of risk assessment for osteoporosis because of the cost, radiation exposure, and the fact that the radiograph would require a separate procedure in addition to the bone mineral density study using dual-energy x-ray absorptiometry. However,



POLICY TITLE	VERTEBRAL FRACTURE ASSESSMENT AND TRABECULAR BONE SCORE
POLICY NUMBER	MP 5.046

several densitometers with specialized software can perform vertebral fracture assessment (VFA) in conjunction with dual-energy x-ray absorptiometry. The lateral spine scan is performed by using a rotating arm. Depending on the densitometer used, the patient can either stay in the supine position after the bone density study or is required to move to the left decubitus position.

Vertebral fracture assessment differs from radiologic detection of fractures because VFA uses a lower radiation exposure and can detect only fractures, while traditional radiograph images can detect other bone and soft tissue abnormalities in addition to spinal fractures. Manufacturers have also referred to this procedure as instant vertebral assessment, radiographic vertebral assessment, dual-energy vertebral assessment, or lateral vertebral assessment.

For both lateral spine radiographs and images with densitometry, vertebral fractures are assessed visually. A number of grading systems have been proposed, and the Genant semi quantitative method is commonly used. This system grades deformities from I to III, with grade I (mild) representing a 20% to 24% reduction in vertebral height, grade II (moderate) representing a 25% to 39% reduction in height, and grade III (severe) representing a 40% or greater reduction in height. The location of the deformity within the vertebrae may also be noted. For example, if only the mid height of the vertebrae is affected, the deformity is defined as an endplate deformity; if both the anterior and mid heights are deformed, it is a wedge deformity; and if the entire vertebrae is deformed, it is classed as a crush deformity. A vertebral deformity of at least 20% loss in height is typically considered a fracture. Accurate interpretation of both lateral spine radiographs and VFA imaging dependent on radiologic training. Thus, device location and availability of appropriately trained personnel may influence diagnostic accuracy.

#### TRABECULAR BONE SCORE

Trabecular bone score (TBS) is an assessment of how evenly or unevenly mineral is structurally distributed in trabecular bone. A TBS is generated from lumbar spine BMD images using software installed on a DXA machine. No additional scan time or radiation exposure is required. The TBS gray-scale texture model captures local differences in mineral concentrations, providing an index of bone microarchitecture that predicts fracture risk independent of BMD and the WHO's fracture assessment tool (FRAX®). However, adding TBS to FRAX®, which is possible on late-model densitometry devices, increases the ability of FRAX® to predict fractures (TBS-adjusted FRAX®).

TBS is most applicable to patients who have low bone mass, rather than those with osteoporosis according to BMD criteria, for whom treatment is already indicated. TBS is FDA approved and provides additional utility in fracture risk assessment among people with secondary causes of bone loss and fractures, such as type 2 diabetes.

#### **Regulatory Status**

Additional software is needed to perform VFA and TBS with a densitometer, and it must be cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process. Products cleared for marketing include, but are not limited to, GEHC DXA Bone Densitometers with enCORE version 18, Aria, GE Lunar DXA Bone Densitometers with enCORE version 17,



POLICY TITLE	VERTEBRAL FRACTURE ASSESSMENT AND TRABECULAR BONE SCORE
POLICY NUMBER	MP 5.046

TBS iNsight, QCT Pro Asynchronous Calibration Module Clinqct, and Encore Version 16 Software for GE Lunar DXA bone densitometers. Food and Drug Administration product code KGI.

IV. RATIONALE <u>TOP</u>

## **Summary of Evidence**

For individuals who are at risk of having vertebral fractures but are not known to have them who receive VFA with densitometry by dual-energy x-ray absorptiometry, the evidence includes diagnostic accuracy studies and subgroup re-analyses of treatment studies. Relevant outcomes are test accuracy, test validity, and morbid events. There is a lack of direct evidence from screening trials that use densitometry with VFA improves health outcomes. Because direct evidence was not available, a chain of evidence was sought. Evidence was examined on the diagnostic accuracy of VFA in non-osteoporotic patients (i.e., those not already eligible for treatment), the ability of VFA to identify patients for treatment who would not otherwise be identified, and the effectiveness of treatment in this population. Diagnostic accuracy studies have reported variable findings; recent studies have suggested higher diagnostic accuracy of VFA overall compared with standard radiographs than older studies. Studies have found that VFA can identify patients without osteoporosis who may be appropriate candidates for treatment according to recommendations from the National Osteoporosis Foundation. However, there is limited evidence on the effectiveness of treatment in this population. No treatment data have been published in patients whose vertebral fracture had been identified using VFA software with densitometry. The evidence is insufficient to determine the effects of the technology on health outcomes.

The American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis 2020 update, states that lateral spine imaging with standard radiography or VFA with DXA is indicated when T-score is less than -1.0 and one or more specific risk factors are present. This society's recommendations are directly in line with the 2023 position statement by The International Society for Clinical Densitometry.

The Bone Health and Osteoporosis Foundation (BHOF) – formerly the National Osteoporosis Foundation, in their 2022 Clinician's Guide to Prevention and Treatment of Osteoporosis, they state that because subclinical vertebral fractures are so prevalent in older individuals, vertebral fracture assessment is recommended for specific high-risk individuals.

Due to input from these two prominent societies, the evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Trabecular bone score is an emerging tool in the evaluation of osteoporosis. In the 2023 International Society for Clinical Densitometry position statement added that "In routine clinical practice, monitoring and reporting TBS change is not recommended." Additional studies are needed to assess its utility in clinical practice. The evidence is insufficient to determine the effects of the technology on health outcomes.



POLICY TITLE	VERTEBRAL FRACTURE ASSESSMENT AND TRABECULAR BONE SCORE
POLICY NUMBER	MP 5.046

V. DEFINITIONS TOP

**BONE DENSITY OR BONE MINERAL DENSITY (BMD)** is the average mineral concentration of a specimen of bone; skeletal mass. Bone mineral density is reduced in osteopenia and osteoporosis.

**DUAL X-RAY ABSORPTIOMETRY (DXA)** is probably 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 two x-ray beams of different energy levels to scan the region of interest and measure the difference in attenuation as the low- and high-energy beams pass through the bone and soft tissue.

#### **VI. BENEFIT VARIATIONS**

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER TOP

Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

## VIII. CODING INFORMATION

TOP

**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore not covered for trabecular bone score:



POLICY TITLE	VERTEBRAL FRACTURE ASSESSMENT AND TRABECULAR BONE SCORE
POLICY NUMBER	MP 5.046

Procedu	re Codes					
77089	77090	77091	77092			

# Covered when medically necessary:

Procedu	re Codes				
77085	77086				

ICD-10-CM Diagnosis Code*	Description
E21.0	Primary hyperparathyroidism
E21.1	Secondary hyperparathyroidism, not elsewhere classified
E21.2	Other hyperparathyroidism
E21.3	Hyperparathyroidism, unspecified
M80.00XA - M80.8B9S	Osteoporosis with current pathological fracture
M81.0-M81.8	Osteoporosis without current pathological fracture
M85.851	Other specified disorders of bone density and structure, right thigh
M85.852	Other specified disorders of bone density and structure, left thigh
M85.859	Other specified disorders of bone density and structure, unspecified thigh
M85.88	Other specified disorders of bone density and structure, other site
R29.890	Loss of height
Z13.820	Encounter for screening for osteoporosis
Z13.828	Encounter for screening for other musculoskeletal disorder
Z78.0	Asymptomatic menopausal state
Z79.52	Long term (current) use of systemic steroids

<sup>\*</sup>Note: If postmenopausal or assigned male at birth and 50 years older or older, then any fracture diagnosis in adulthood would also apply.



POLICY TITLE	VERTEBRAL FRACTURE ASSESSMENT AND TRABECULAR BONE SCORE
POLICY NUMBER	MP 5.046

IX. REFERENCES TOP

- Malgo F, Hamdy NAT, Ticheler CHJM, et al. Value and potential limitations of vertebral fracture assessment (VFA) compared to conventional spine radiography: experience from a fracture liaison service (FLS) and a meta-analysis. Osteoporos Int. Oct 2017; 28(10): 2955-2965. PMID 28842721
- 2. Lee JH, Lee YK, Oh SH, et al. A systematic review of diagnostic accuracy of vertebral fracture assessment (VFA) in postmenopausal women and elderly men. Osteoporos Int. May 2016; 27(5): 1691-9. PMID 26782682
- 3. Domiciano DS, Figueiredo CP, Lopes JB, et al. Vertebral fracture assessment by dual X-ray absorptiometry: a valid tool to detect vertebral fractures in community-dwelling older adults in a population-based survey. Arthritis Care Res (Hoboken). May 2013; 65(5): 809-15. PMID 23212896
- 4. Ferrar L, Jiang G, Clowes JA, et al. Comparison of densitometric and radiographic vertebral fracture assessment using the algorithm-based qualitative (ABQ) method in postmenopausal women at low and high risk of fracture. J Bone Miner Res. Jan 2008; 23(1): 103-11. PMID 17892377
- 5. Binkley N, Krueger D, Gangnon R, et al. Lateral vertebral assessment: a valuable technique to detect clinically significant vertebral fractures. Osteoporos Int. Dec 2005; 16(12): 1513-8. PMID 15834512
- 6. LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis. Osteoporos Int. Apr 28 2022. PMID 35478046
- 7. Yang J, Mao Y, Nieves JW. Identification of prevalent vertebral fractures using Vertebral Fracture Assessment (VFA) in asymptomatic postmenopausal women: A systematic review and meta-analysis. Bone. Jul 2020; 136: 115358. PMID 32268210
- 8. Kanterewicz E, Puigoriol E, Garcia-Barrionuevo J, et al. Prevalence of vertebral fractures and minor vertebral deformities evaluated by DXA-assisted vertebral fracture assessment (VFA) in a population-based study of postmenopausal women: the FRODOS study. Osteoporos Int. May 2014; 25(5): 1455-64. PMID 24599272
- 9. Mrgan M, Mohammed A, Gram J. Combined vertebral assessment and bone densitometry increases the prevalence and severity of osteoporosis in patients referred to DXA scanning. J Clin Densitom. Oct-Dec 2013; 16(4): 549-53. PMID 23769657
- 10. El Maghraoui A, Mounach A, Rezqi A, et al. Vertebral fracture assessment in asymptomatic men and its impact on management. Bone. Apr 2012; 50(4): 853-7. PMID 22240446
- 11. El Maghraoui A, Rezqi A, Mounach A, et al. Systematic vertebral fracture assessment in asymptomatic postmenopausal women. Bone. Jan 2013; 52(1): 176-80. PMID 23017663
- 12. Jager PL, Jonkman S, Koolhaas W, et al. Combined vertebral fracture assessment and bone mineral density measurement: a new standard in the diagnosis of osteoporosis in academic populations. Osteoporos Int. Apr 2011; 22(4): 1059-68. PMID 20571773
- 13. Cummings SR, Black DM, Thompson DE, et al. Effect of alendronate on risk of fracture in women with low bone density but without vertebral fractures: results from the Fracture Intervention Trial. JAMA. Dec 1998; 280(24): 2077-82. PMID 9875874
- 14. Quandt SA, Thompson DE, Schneider DL, et al. Effect of alendronate on vertebral fracture risk in women with bone mineral density T scores of-1.6 to -2.5 at the femoral



POLICY TITLE	VERTEBRAL FRACTURE ASSESSMENT AND TRABECULAR BONE SCORE
POLICY NUMBER	MP 5.046

- neck: the Fracture Intervention Trial. Mayo Clin Proc. Mar 2005; 80(3): 343-9. PMID 15757015
- Kanis JA, Barton IP, Johnell O. Risedronate decreases fracture risk in patients selected solely on the basis of prior vertebral fracture. Osteoporos Int. May 2005; 16(5): 475-82. PMID 15875093
- 16. Bhoopalam N, Campbell SC, Moritz T, et al. Intravenous zoledronic acid to prevent osteoporosis in a veteran population with multiple risk factors for bone loss on androgen deprivation therapy. J Urol. Nov 2009; 182(5): 2257-64. PMID 19758618
- 17. Greenspan SL, Nelson JB, Trump DL, et al. Effect of once-weekly oral alendronate on bone loss in men receiving androgen deprivation therapy for prostate cancer: a randomized trial. Ann Intern Med. Mar 20 2007; 146(6): 416-24. PMID 17371886
- 18. International Society for Clinical Densitometry. 2019 ISCD Official Positions Adult. 2019
- 19. Shepherd JA, Schousboe JT, Broy SB, et al. Executive Summary of the 2015 ISCD Position Development Conference on Advanced Measures From DXA and QCT: Fracture Prediction Beyond BMD. J Clin Densitom. Jul-Sep 2015; 18(3): 274-86. PMID 26277847
- 20. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis - 2016. Endocr Pract. Sep 02 2016; 22(Suppl 4): 1-42. PMID 27662240
- 21. Camacho PM, Petak SM, Binkley N, et al. American Association of Clinical Endocrinologists/American College of Endocrinology Clinical Practice Guidelines for the Diagnosis and Treatment of Postmenopausal Osteoporosis 2020 Update. Endocr Pract. May 2020; 26(Suppl 1): 1-46. PMID 32427503
- 22. Eastell R, Rosen CJ, Black DM, et al. Pharmacological management of osteoporosis in postmenopausal women: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. May 2019;104(5):1595-1622.
- 23. Qaseem A, Forciea MA, McLean RM, et al. Treatment of Low Bone Density or Osteoporosis to Prevent Fractures in Men and Women: A Clinical Practice Guideline Update From the American College of Physicians. Ann Intern Med. Jun 06 2017; 166(11): 818-839. PMID 28492856
- 24. McClung MR, Pinkerton JV, Blake J, et al. Management of osteoporosis in postmenopausal women: the 2021 position statement of The North American Menopause Society. Menopause. Sep 01 2021; 28(9): 973-997. PMID 34448749
- 25. Curry SJ, Krist AH, Owens DK, et al. Screening for Osteoporosis to Prevent Fractures: US Preventive Services Task Force Recommendation Statement. JAMA. Jun 26 2018; 319(24): 2521-2531. PMID 29946735
- 26. U.S. Preventive Services Task Force (USPSTF). Draft Research Plan. Osteoporosis to Prevent Fractures: Screening. August 12, 2021
- 27. Shuhart CR, Yeap SS, Anderson PA, et al. Executive Summary of the 2019 ISCD Position Development Conference on Monitoring Treatment, DXA Cross-calibration and Least Significant Change, Spinal Cord Injury, Peri-prosthetic and Orthopedic Bone Health, Transgender Medicine, and Pediatrics. J Clin Densitom. 2019;22(4):453-471. doi:10.1016/j.jocd.2019.07.001



POLICY TITLE	VERTEBRAL FRACTURE ASSESSMENT AND TRABECULAR BONE SCORE
POLICY NUMBER	MP 5.046

- 28. International Society for Clinical Densitometry. 2019 ISCD Official Positions Adult. 2023
- 29. LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis. Osteoporos Int. Apr 28 2022. PMID 35478046
- 30. Blue Cross Blue Shield Association Medical Policy Reference Manual. 6.01.44, Vertebral Fracture Assessment with Densitometry. October 2023

# X. POLICY HISTORY TOP

MP 5.046	7/17/19 Consensus code review. No changes recommended.
	10/2/19 Consensus review. No change to the policy statement. Background and
	references updated.
	8/31/20 Consensus review. No change to the policy statement. Background
	reviewed and references updated.
	10/27/2021 Consensus review. Policy statement unchanged. FEP language
	updated. Background, Rationale and References updated.
	<b>12/22/2022 Major review.</b> VFA is now MN with criteria. Added INV statement re:
	TBS and associated procedure codes placed into coding table. Updated
	background, rationale, coding table and references.
	9/5/2023 Administrative review. Added new osteoporosis ICD-10 codes
	(M80.0BXX and M80.8BXX series). Effective date 10/1/2023.
	10/17/2023 Consensus. No change to policy statement. Updated rationale and
	references.

Top

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