FEP Medical Policy Manual

FEP 6.01.44 Vertebral Fracture Assessment with Densitometry

Annual Effective Policy Date: January 1, 2024

Original Policy Date: January 2021

Related Policies:

6.01.01 - Bone Mineral Density Studies
6.01.40 - Whole Body Dual X-Ray Absorptiometry to Determine Body Composition

Vertebral Fracture Assessment with Densitometry

Description

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Vertebral fracture assessment (VFA) with densitometry is a technique to assess vertebral fractures at the same time as bone mineral density (BMD), using additional software with dual-energy x-ray absorptiometry (DXA). The addition of VFA to BMD may augment diagnostic information on fracture risk.

Only 20% to 30% of vertebral fractures are recognized clinically; the rest are discovered incidentally on lateral spine radiographs or other imaging studies.[1,] 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 (BMD) study using dual-energy x-ray absorptiometry (DXA). However, several densitometers with specialized software can perform vertebral fracture assessment (VFA) in conjunction with DXA. 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 semiquantitative 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 depends on radiologic training. Thus, device location and availability of appropriately trained personnel may influence diagnostic accuracy.

OBJECTIVE

The objective of this evidence review is to determine whether vertebral fracture assessment with dual-energy x-ray absorptiometry improves the net health outcome in individuals who are at risk of having vertebral fractures but are not known to have them.

POLICY STATEMENT

Screening for vertebral fractures using dual-energy x-ray absorptiometry is considered **investigational**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Although the primary benefit of vertebral fracture assessment is in patients with osteopenia, because densitometry and vertebral fracture assessment are done simultaneously, it is not possible to use findings from bone mineral density testing to determine eligibility for vertebral fracture assessment during a particular testing session.

FDA REGULATORY STATUS

Additional software is needed to perform VFA with a densitometer, and it must be cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Products cleared for marketing are shown in Table 1 below. FDA product code KGI.

Table 1. Densitometry Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
GEHC DXA Bone Densitometers with enCORE version 18	GE Medical Systems Ultrasound & Primary Care Diagnostics LLC	9/19/2019	K191112	For use in vertebral fracture assessment
Aria	GE Medical Systems Ultrasound & Primary Care Diagnostics LLC	4/20/2018	K180782	For use in vertebral fracture assessment

GE Lunar DXA Bone Densitometers with enCORE version 17	GE MEDICAL SYSTEMS ULTRASOUND & PRIMARY CARE DIAGNOSTICS LLC	12/2/2016	K161682	For use in vertebral fracture assessment
TBS iNsight	MEDIMAPS GROUP SA	4/29/2016	K152299	For use in vertebral fracture assessment
QCT PRO ASYNCHRONOUS CALIBRATION MODULE CLINIQCT™	MINDWAYS SOFTWARE INC.	8/29/2014	K140342	For use in vertebral fracture assessment
ENCORE VERSION 16 SOFTWARE FOR GE LUNAR DXA BONE DENSITOMETERS	GE MEDICAL SYSTEMS ULTRASOUND & PRIMARY CARE DIAGN	5/15/2014	K133664	For use in vertebral fracture assessment

RATIONALE

Summary of Evidence

For individuals who are at risk of having vertebral fractures but are not known to have them who receive vertebral fracture assessment (VFA) with densitometry by dual-energy x-ray absorptiometry (DXA) , 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 of 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 (ie, 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 Bone Health and Osteoporosis Foundation. However, there is limited evidence on the effectiveness of treatment in this population. No treatment data have been published on patients whose vertebral fractures were identified using VFA software with densitometry. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Association of Clinical Endocrinologists and the American College of Endocrinology

The joint guidelines from the American Association of Clinical Endocrinologists and American College of Endocrinology (2016)[20,] on the diagnosis and treatment of postmenopausal osteoporosis included VFA recommendations similar to those of the International Society for Clinical Densitometry (below). An update to the guidelines in 2020[21,] includes stratification of women with osteoporosis into high-risk and very-high-risk features to drive choice and duration of initial therapy. The guidelines also introduce romosozumab into the treatment algorithm and elucidate treatment transitions from agents such as denosumab.

American College of Physicians

The American College of Physicians' guidelines (2017) on the treatment of low bone density or osteoporosis include the following recommendations (Table 2).[22,]

Table 2. Guidelines on the Treatment of Low Bone Density or Osteoporosis

Recommendation	GOE	QOE
"ACP recommends that clinicians offer pharmacologic treatment with bisphosphonates to reduce the risk for vertebral fracture in men who have clinically recognized osteoporosis."	Weak	Low
"ACP recommends that clinicians should make the decision whether to treat osteopenic women 65 years of age or older who are at a high risk for fracture based on a discussion of patient preferences, fracture risk profile, and benefits, harms, and costs of medications."	Weak	Low

ACP: American College of Physicians; GOE: grade of evidence; QOE: quality of evidence.

American College of Radiology

The American College of Radiology (ACR) published updated appropriateness criteria for osteoporosis and bone mineral density (BMD) in 2022.[23,] DXA VFA is not mentioned among imaging studies in patients undergoing osteoporosis screening or initial imaging of clinically suspected low BMD. For follow-up imaging of patients demonstrated to have risk for fracture or surveillance of established low BMD, DXA VFA is usually not appropriate by ACR criteria. Conversely, for follow-up imaging of patients with T-scores less than -1.0 by DXA, DXA VFA is usually appropriate by ACR criteria in patients who meet 1 or more of the following criteria:

- Females ≥70 years of age or males ≥80 years of age;
- Historical height loss >4 cm (>1.5 inches);
- Self-reported but undocumented prior vertebral fracture;
- Glucocorticoid therapy equivalent to ≥5 mg prednisone equivalent per day for ≥3 months.

Bone Health and Osteoporosis Foundation

The Bone Health and Osteoporosis Foundation, formerly the National Osteoporosis Foundation, published an updated clinician's guide to the prevention and treatment of osteoporosis in 2022.[7,] Per the guide, "a vertebral fracture in an adult ≥ 50 years is diagnostic of osteoporosis, even in the absence of a bone density diagnosis. Unfortunately, most vertebral fractures are subclinical 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 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."

Traditionally, conventional lateral thoracic/lumbar spine X-ray has been considered the gold standard for identification of vertebral fractures; however, the guide notes that "DXA-assisted VFA is emerging as an alternative to radiograph for its convenience, low cost, and minimal radiation exposure."[7,] The guide recommends that in order to "to detect subclinical vertebral fractures," clinicians should perform vertebral fracture imaging (X-ray or DXA VFA) in the following:

- Women aged ≥ 65 years if T-score is ≤ -1.0 at the femoral neck;
- Women ≥ 70 years and men ≥ 80 years if T-score is ≤ -1.0 at the lumbar spine, total hip, or femoral neck;
- Men aged 70 to 79 years if T-score is ≤ -1.5 at the lumbar spine, total hip, or femoral neck;
- Postmenopausal women and men ≥50 years with the following specific risk factors:

- Fracture(s) during adulthood (any cause).
- Historical height loss of ≥ 1.5 inches (defined as the difference between the current height and peak height).
- Prospective height loss of ≥ 0.8 inches (defined as the difference between the current height and last documented height measurement).
- Recent or ongoing long-term glucocorticoid treatment.
- Diagnosis of hyperparathyroidism.

International Society for Clinical Densitometry

The International Society for Clinical Densitometry (2019) updated its recommendations for selecting patients for VFA;[24,] these recommendations remain the same as in a 2015 update.[25,] Lateral spine imaging with either standard radiography or densitometric VFA is indicated for patients with a T score of less than -1.0 when at least 1 of the following factors are present:

- "Women age ≥70 years or men ≥80 years
- Historical height loss greater than 4 cm (1.5 inches)
- Self-reported but undocumented prior vertebral fracture
- Glucocorticoid therapy equivalent to ≥5 mg of prednisone or equivalent per day for ≥3 months."

An update to the International Society for Clinical Densitometry official positions is in progress.

Endocrine Society

The Endocrine Society Clinical Practice Guideline (2019) on pharmacological management of osteoporosis in postmenopausal women states 4 management principles[26,]:

"(i) The risk of future fractures in postmenopausal women should be determined using country-specific assessment tools to guide decision-making.

(ii) Patient preferences should be incorporated into treatment planning.

(iii) Nutritional and lifestyle interventions and fall prevention should accompany all pharmacologic regimens to reduce fracture risk.

(iv) Multiple pharmacologic therapies are capable of reducing fracture rates in postmenopausal women at risk with acceptable risk-benefit and safety profiles."

North American Menopause Society

The North American Menopause Society updated its position statement on the management of osteoporosis in postmenopausal women in 2021.[27,] The Society states that in order to identify asymptomatic compression vertebral fractures, "evaluation by a lateral thoracolumbar radiograph or VFA by DXA" may be utilized.

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (2018) updated its recommendations on screening for osteoporosis to prevent fractures.[28,] The recommendations included: "Most treatment guidelines recommend using BMD, as measured by central DXA, to define osteoporosis and the treatment threshold to prevent osteoporotic fractures." Peripheral DXA and quantitative ultrasound are also described as common bone measurement screening tests for osteoporosis. Vertebral fracture assessment was not specifically mentioned. An update of this topic is currently in progress with plans to address vertebral fracture assessment per the draft research plan.[29,]

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

1. Alsoof D, Anderson G, McDonald CL, et al. Diagnosis and Management of Vertebral Compression Fracture. Am J Med. Jul 2022; 135(7): 815-821. PMID 35307360
2. 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
3. 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
4. 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
5. 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
6. 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
7. LeBoff MS, Greenspan SL, Insogna KL, et al. The clinician's guide to prevention and treatment of osteoporosis. Osteoporos Int. Oct 2022; 33(10): 2049-2102. PMID 35478046
8. Gill SM, Hassan A. Routine Use of Lateral Vertebral Assessment With DXA Scan for Detection of Silent But Debilitating Vertebral Fractures. Clin Nucl Med. Feb 01 2023; 48(2): 107-111. PMID 36607360
9. 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
10. Kanterewicz E, Puigoriol E, Garca-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
11. 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. 2013; 16(4): 549-53. PMID 23769657
12. 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
13. 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
14. 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
15. 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
16. 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 neck: the Fracture Intervention Trial. Mayo Clin Proc. Mar 2005; 80(3): 343-9. PMID 15757015
17. 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
18. 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
19. 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
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. 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
23. American College of Radiology. ACR Appropriateness Criteria, Osteoporosis and Bone Mineral Density. 2022; https://acsearch.acr.org/docs/69358/Narrative/. Accessed July 25, 2023

24. International Society for Clinical Densitometry. 2019 ISCD Official Positions Adult. 2019; https://iscd.org/wp-content/uploads/2021/09/2019-Official-Positions-Adult-1.pdf. Accessed August 4, 2023.
25. 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. 2015; 18(3): 274-86. PMID 26277847
26. 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.
27. 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
28. 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
29. U.S. Preventive Services Task Force (USPSTF). Draft Research Plan. Osteoporosis to Prevent Fractures: Screening. August 12, 2021; https://www.uspreventiveservicestaskforce.org/uspstf/document/draft-research-plan/osteoporosis-screening-prevent-fractures. Accessed August 4, 2023

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2020	New policy	Policy updated with literature review through June 19, 2020; VFA is investigational.
December 2021	Replace policy	Policy updated with literature review through July 29, 2021; no references added. Policy statement unchanged.
December 2022	Replace policy	Policy updated with literature review through July 20, 2022; references added. Policy statement unchanged.
December 2023	Replace policy	Policy updated with literature review through July 25, 2023; references added. Policy statement unchanged.