6.01.44	Vertebral Fracture Assessment with Densitometry or Biomechanical Computed Tomography		
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Section:	6.0 Radiology	**Page:**	Page 1 of 18

Policy Statement

I. Screening for vertebral fractures using dual-energy x-ray absorptiometry or biomechanical computed tomography is considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding
Diagnostic codes in the Codes table related to screening and conditions without fracture would be considered investigational.

The CPT coding for this procedure depends on whether it is performed with dual-energy x-ray absorptiometry.

See the Codes table for details.

Description

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. Another method of determining vertebral fracture risk is biomechanical computed tomography (BCT), which evaluates both bone density and strength.

Related Policies

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

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Additional software is needed to perform VFA with a densitometer or BCT, 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. Vertebral Fracture Assessment Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Densitometry				
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
Biomechanical Computed Tomography				
VirtuOst	O.N. Diagnostics	5/19/23	K220402	To assess bone mineral density and strength

Rationale

Background

Diagnosis

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.

Biomechanical computed tomography (BCT) is another method of performing VFA which also minimizes radiation exposure.[2,] Previously obtained CT scans can be used for BCT analysis in many cases. Exceptions include spinal images performed with contrast and images in which metal is present in the transverse plane of the bone of interest. Analysis is performed in a centralized laboratory, to which clinicians must send CT scans. The BCT calculation involves a non-linear finite element analysis to simulate a fracture event, with outputs including T-score and Z-score of the femoral neck and hip, femoral strength, vertebral strength, vertebral trabecular volume, and vertebral Z-score. Patients are classified as high risk if fragile bone strength (defined as ≤3000 to 6500 Newtons depending on patient sex and location [hip or spine]) or osteoporosis at the hip or spine is found. The classification of increased risk is assigned if low bone strength or low bone mass is identified at the hip or spine.

Literature Review

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Vertebral Fracture Assessment with Densitometry

Clinical Context and Test Purpose

Vertebral fractures are highly prevalent in the elderly population, and epidemiologic studies have found that these fractures are associated with an increased risk of future spine or hip fractures independent of bone mineral density (BMD).

The purpose of performing vertebral fracture assessment (VFA) using densitometry by dual-energy x-ray absorptiometry (DXA) is to diagnose whether the individual has a vertebral fracture.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals at risk of vertebral fractures who are not known to have a fracture at the time of assessment.

Interventions
The relevant intervention of interest is VFA with densitometry using DXA.

Comparators
The following tools and tests are currently being used to make decisions about managing individuals at risk for vertebral fracture: Dual-energy x-ray absorptiometry alone for the assessment of BMD as well as spine radiography. Radiography is used to confirm the occurrence of vertebral fractures but is not recommended as a routine component of osteoporosis assessment because of radiation exposure.

Outcomes
Outcomes of interest for diagnostic accuracy include test accuracy and test validity (e.g., sensitivity, specificity). The primary outcome of interest for clinical utility is morbid events, specifically the incidence of future clinical fractures.

Vertebral fracture assessment with densitometry by DXA would occur at the time of osteoporosis screening. The recommended age at which to start screening with DXA and the frequency of screening is addressed in national guidelines.

Study Selection Criteria
For the evaluation of clinical validity of VFA with densitometry, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores);
- Included a suitable reference standard (e.g., spine radiography);
- Patient/sample clinical characteristics were described;
- Patient/sample selection criteria were described.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence
Systematic Reviews
Malgo et al (2017) compared VFA with DXA to conventional spine radiography and published evidence comparing VFA with DXA to conventional spine radiography from a fracture liaison service (FLS) and meta-analysis of comparative studies.[3,] The FLS retrospective diagnostic study included 542 consecutive subjects (25% male) aged 50 years or older assessed for vertebral fractures and osteoporosis between 2012 and 2014 with both VFA and conventional radiography. The diagnostic accuracy of VFA was calculated using conventional radiography as a reference, and observers were blinded to the VFA findings. Normal BMD was reported in 11% of subjects. The sensitivity of VFA with DXA to detect a vertebral fracture greater or equal to Genant grade 2 was 77% and its specificity was 80%. A meta-analysis of 16 studies including 3238 subjects (19% male) with low to intermediate risk of bias revealed a pooled sensitivity of 84% (95% confidence interval [CI], 72% to 92%) and specificity of 90% (95% CI, 84% to 94%). Reviewers did not report separate analyses for the diagnostic accuracy of VFA with DXA in patients at low- versus high-risk of osteoporosis. While the meta-analysis suggests adequate diagnostic performance of VFA with DXA for the detection of vertebral fractures, the study authors caution that these findings could not be replicated in their FLS center.

A systematic review of studies was published by Lee et al (2016).[4,] The authors included studies with postmenopausal women and/or men 50 years and older that compared the diagnostic accuracy of VFA with DXA with spinal radiography. Seventeen studies met selection criteria; 5 were excluded because of an inadequate description of methods or results. Of the remaining 12 studies, 4 examined postmenopausal women, 5 included osteoporotic patients (men and women), and 2 included both populations. Studies were heterogeneous, and thus reviewers did not pool study findings. Among the 8 studies that reported findings on a per-vertebral level, the sensitivity of VFA with DXA ranged from 70% to 93% and the specificity ranged from 95% to 100%. Nine studies reported findings on a per-patient level. Sensitivity ranged from 65% to 100% and specificity from 74% to 100%. Reviewers did not report separate analyses for the diagnostic accuracy of VFA with DXA in osteoporotic versus non-osteoporotic patients.

Nonrandomized Trials

One study included in the systematic review and judged to have a low-risk of bias was published by Domiciano et al (2013).[5,] The authors reported on 429 adults at least 65 years old who had VFA with densitometry and spine radiography on the same day. On VFA, vertebral fractures were identified in 77 (29.7%) of 259 women and in 48 (28.2%) of 170 men. Comparable numbers on spine radiographs were 74 (28.6%) of 259 women and 52 (30.6%) of 170 men. Compared with spine radiography, the sensitivity of VFA was 81.7% (95% CI, 73.9% to 88.1%) and the specificity was 92.7% (95% CI, 89.2% to 95.4%).

The diagnostic performance of VFA with DXA has tended to be lower in older studies. For example, Ferrar et al (2008) evaluated the performance of vertebral assessment using a visual algorithm-based approach.[6,] Subjects in the low-risk group were women ages 55 to 79 years who were randomly selected from their general practitioners' offices. Most had a normal BMD or were osteopenic. Subjects in the high-risk group were recruited after a low-trauma fracture to the hip, forearm, or humerus. Most high-risk patients had osteopenia or osteoporosis. In the per-patient analysis and including all poor or unreadable images, the sensitivity of VFA was 60% in the low-risk group and 81% in the high-risk group; specificity was 97% in both groups. Also, Binkley et al (2005) compared VFA (GE Lunar densitometer) with radiography in 27 osteoporotic, 38 osteopenic, and 15 normal women.[7,] Blinded analysis correctly identified 17 of 18 radiographically evident grade 2 to 3 fractures (false-negative rate, 6%). The study did not describe whether the grade 2 or 3 fractures were found in women with osteoporosis, osteopenia, or normal BMD. Also, only 11 (50%) of 22 grade 1 fractures were identified. Thirty vertebrae were classified as fractured when no fractures were present (38% false-positive), 29 of these were grade 1 fractures by VFA with normal radiography.

Also, VFA identified 40 grade 1 fractures, but only 11 (28%) were true-positive results. Also problematic is that results were compared only in vertebrae evaluable by VFA; 1 patient could not be evaluated due to poor image quality, and 66% of T4 to T6 vertebrae in other subjects could not be adequately visualized.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials (RCTs).

No RCTs comparing health outcomes in individuals screened with VFA plus bone densitometry using DXA with those screened with bone densitometry using DXA alone were identified.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

A chain of evidence for the clinical utility of VFA screening is based on evidence that VFA identifies appropriate candidates for treatment who would not otherwise be identified, and there is evidence that treatment in this population is beneficial. The chain involves evaluating: (1) evidence that VFA is accurate, (2) evidence that VFA identifies appropriate candidates for treatment who would not otherwise be identified, and (3) evidence that treatment in this population is actually beneficial.

In its 2022 clinician's guide, the Bone Health and Osteoporosis Foundation, formerly the National Osteoporosis Foundation, recommends to consider initiating pharmacologic treatment in:[8,]

- "Postmenopausal women and men ≥50 years who have the following:
    - Primary fracture prevention:
        - T-score ≤-2.5 at the femoral neck, total hip, lumbar spine, 33% radius by DXA
        - Low bone mass (osteopenia: T-score between -1.0 and -2.5) at the femoral neck or total hip by DXA with a 10-year hip fracture risk ≥3% or a 10-year major osteoporosis-related fracture risk ≥20% based on the US-adapted FRAX® model
    - Secondary fracture prevention:
        - Fracture of the hip or vertebra regardless of BMD
        - Fracture of the proximal humerus, pelvis, or distal forearm in persons with low bone mass (osteopenia: T-score between -1.0 and -2.5). The decision to treat should be individualized in persons with a fracture of the proximal humerus, pelvis, or distal forearm who do not have osteopenia or low BMD."

Because patients with osteoporosis (T score, ≤-2.5) diagnosed by DXA and patients with low bone mass and other risk factors for fracture would be treated regardless of vertebral fractures, any incremental benefit using a VFA-inclusive strategy would accrue in the population without osteoporosis.

Vertebral Fracture Assessment with Densitometry to Identify Candidates Who Would Not Otherwise Be Identified

As stated above, the Bone Health and Osteoporosis Foundation (2022) guidelines have recommended treating patients with osteoporosis, osteopenia, and other risk factors as well as those with hip or vertebral fractures (clinical or asymptomatic).

Vertebral fracture assessment has been used to identify candidates for treatment when patients with vertebral fractures do not fall into 1 of the other established categories. Few studies were identified that specifically dealt with whether VFA could identify candidates for medication treatment who would not otherwise have been identified but several studies are somewhat informative. Representative studies with larger sample sizes are described next.

Gill et al (2023) published a single-center retrospective study of adults who underwent DXA with VFA for any reason over a 1-year period.[9,] The authors identified 479 eligible scans; 54 patients (11%) had a vertebral fracture, of which 47 (10%) were previously undiagnosed. Among patients with new vertebral fractures, approximately 23% had normal BMD, while approximately 40% and 36% met BMD criteria for osteopenia or osteoporosis, respectively. The mean 10-year probability of major osteoporotic or hip fractures when calculated via FRAX without a documented history of fracture (i.e., prior to detection of vertebral fracture) was 7.1% and 2.8%, respectively; when recalculated to incorporate the detected vertebral fracture, these probabilities increased to 12.4% and 4.8%, respectively (p<.01 for each). Indications for DXA with VFA were not reported.

Yang et al (2020) conducted a systematic review and meta-analysis of 28 studies evaluating detection of vertebral fractures via VFA with DXA in asymptomatic postmenopausal women.[10,] Study sample sizes ranged from 63 to 5156 and mean age ranged from 59.5 to 86.2 years. Among women who had prevalent vertebral fractures, 11.1% to 43% had osteopenia and 3.6% to 32% had normal BMD. The weighted pooled prevalence of VFA-detected vertebral fractures was 28% (95% CI, 23% to 32%) with a high degree of heterogeneity (I^2=98.89%; p<.001). A separate subgroup analysis for women with normal bone density was not conducted.

Kanterewicz et al (2014) in Spain collected data on a population-based cohort of 2968 postmenopausal women between the ages of 59 and 70 years.[11,] A total of 127 (4.3%) women had a vertebral fracture according to VFA. Among them, 48.0% had osteoporosis, and 42.5% had osteopenia. Moreover, 42.5% had previous fragility fractures, and 34.6% had a first-degree family history of fractures. Thus, VFA could identify women who would be eligible for fracture prevention therapy according to Bone Health and Osteoporosis Foundation guidelines (i.e., women who did not have osteoporosis, osteopenia plus a 10 year fracture risk, or other risk factors). The authors did not attempt to define this subgroup of women with normal BMD and other risk factors.

Mrgan et al (2013) in Denmark published a retrospective study evaluating VFA with BMD in 3275 patients presenting for osteoporosis screening or evaluation of anti-osteoporotic medication; 85% were women.[12,] Vertebral fractures were found using VFA in 260 (7.9%) patients. Of them, 156 patients (4.8% of the total sample) had osteoporosis (i.e., BMD at least -2.5) and 104 (3.2% of the total sample) did not, according to BMD. The data suggested that up to 40% (104/250) of patients with vertebral fractures identified would be eligible for treatment by Bone Health and Osteoporosis Foundation guidelines and might not have been identified were DXA alone used. Some patients, however, might have had osteopenia and other risk factors that would have led to their eligibility for treatment.

El Maghraoui et al (2012) published a prospective study evaluating VFA with BMD in 791 asymptomatic men aged between 45 and 89 years with no prior osteoporotic fracture or known diagnosis of osteoporosis in Morocco.[13,] In men with normal BMD, a grade 1 to 3 vertebral fracture was identified in 85/262 (32.4%) men. Grade 2 to 3 vertebral fractures were identified in 6.9% of these subjects. Vertebral fractures were also identified in 144/402 (35.8%) men with osteopenia (11.7% grade 2 to 3) and 89/124 (71.8%) men with osteoporosis (37.9% grade 2 to 3). Stepwise regression analysis indicated that prevalence of vertebral fractures was independently related to osteoporotic status (odds ratio [OR], 4.761; 95% CI, 2.956 to 7.668) and smoking status (OR, 1.717; 95% CI, 1.268 to 2.323).

A similar study by El Maghraoui et al (2013) in 908 asymptomatic postmenopausal women aged between 50 and 91 years identified vertebral fractures in 63 (28.3%) women with normal BMD (8.5% grade 2 to 3).[14,] Stepwise regression analysis indicated that the presence of vertebral fractures was independently related to age, low body mass index, multiparity, history of peripheral fracture, and low BMD. It is unclear whether patients were consecutively enrolled in the El Maghraoui studies.

Jager et al (2011) reported on 2424 consecutive patients (65% female) referred for BMD for a variety of reasons at a single-center in the Netherlands.[15,] Participants underwent VFA with BMD during the same session. Vertebral fractures (reduction in the height of at least 20%) were detected in 541 (22%) patients. The prevalence of vertebral fractures was 14% (97/678) in patients with normal BMD and 21% (229/1100) in patients with osteopenia. Thus, 60.5% (326/541) of the patients with vertebral fracture did not have osteoporosis and would have been eligible for treatment based on Bone Health and Osteoporosis Foundation guidelines if they did not fall into another eligibility category (e.g., osteopenia with other risk factors). Most fractures had not been identified in the past. The vertebral fractures were previously unknown in 74% of patients with normal BMD and 71% of patients with osteopenia.

Pharmacologic Treatment for Vertebral Fracture and Low Bone Mass

Bisphosphonates decrease bone resorption and are the major class of drugs now used to treat osteoporosis.

Several subgroup analyses of large RCTs evaluating the efficacy of bisphosphonates in patients with low bone mass and/or baseline vertebral fractures have been published. The trials were not designed a priori to assess efficacy according to baseline vertebral fracture status or BMD categories. The Fracture Intervention Trial (FIT) study group was the first large multicenter study comparing the effects of treatment between osteoporotic women and women with low bone mass without existing vertebral fractures using the revised National Health and Nutrition Examination Survey cutoffs.[16,] This trial randomized 4432 women to alendronate or placebo and analyzed the treatment group in 3 BMD categories (<-2.5 SD, -2.0 to -2.5 SD , and -1.6 to -2.0 SD below the mean). Women with a BMD less than -2.5 SD had a statistically significant reduction in clinical and vertebral fractures over 4 years. The relative risk (RR) for all clinical fractures among patients with a BMD less than -2.5 SD was 0.6 (95% CI, 0.5 to 0.8). There was no significant reduction in all clinical fractures for women with higher BMD values (RR, 1.1; 95% CI, 0.9 to 1.4), suggesting no benefit among patients with low bone mass or normal BMD.

Quandt et al (2005) reanalyzed FIT study data for the outcome of clinical vertebral fractures (symptomatic and diagnosed by a physician) and radiographically detected (assessed at surveillance intervals) vertebral fractures.[17,] A total of 3737 women at least 2 years postmenopausal with low bone mass (T score between -1.6 and -2.5) were included in the analysis. Among the women with low bone mass and existing radiographically detected vertebral fractures (n=940), the rate of subsequent clinical vertebral fractures was 6 (a rate of 43/10,000 person-years of risk) in the alendronate group and 16 (124/10,000 person-years of risk) in the placebo group. Alendronate treatment compared with placebo was accompanied by an RR of 0.3 (95% CI, 0.1 to 0.8) for clinical vertebral fractures and an RR of 0.5 (95% CI, 0.3 to 0.8) for radiographically detected fractures. Similar risk estimates were found for women having low bone mass without vertebral fractures, but absolute risks were lower (12 vs. 81 fractures per 10,000 person-years for those without and with baseline fractures, respectively).

Kanis et al (2005) reanalyzed data on 1802 women who were at least 5 years postmenopausal from the Vertebral Efficacy with Risedronate Therapy (VERT) trials who were identified on the basis of a prior radiographically detected vertebral fracture regardless of BMD and had radiographs available at baseline and 3 years.[18,] Overall, there was a significantly lower rate of a new vertebral fracture in women with prior vertebral fracture randomized to treatment with risedronate (14.5%) than to placebo (22.3%; p<.001). In the group with a T score greater than -2.5, the rate of new femoral neck fractures was 50 (11%) of 519 in the risedronate group and 71 (15.5%) of 537 in the placebo group (p=.049). In the osteoporotic group, for those with a T score of -2.5 or lower, the rate of new femoral neck fracture was 53 (18.7%) of 355 in the risedronate group and 92 (33.4%) of 318 in the placebo group (p<.001). Findings were similar when the T score at the most severe skeletal site (femoral neck or lumbar spine) was used for stratification.

No RCTs were identified that evaluated the efficacy of bisphosphonate treatment in men with vertebral fractures and low bone density. Several trials have evaluated whether bisphosphonate treatment increases BMD in men at risk for bone loss (e.g., on androgen deprivation therapy).[19,20,] However, vertebral fractures were not assessed and, therefore, conclusions cannot be drawn about the potential benefit of VFA added to densitometry in at-risk men.

Section Summary: Vertebral Fracture Assessment with Densitometry

Several studies have compared VFA with radiography, including in a 2016 systematic review. The sensitivity of VFA compared with standard radiography reported in these studies varied. More recent studies have also reported higher diagnostic accuracy than older studies (i.e., sensitivities in the 80% to 99% range and specificities over 90%). Routine use of VFA with DXA will identify substantial numbers of patients with previously unrecognized vertebral fractures. Many of these vertebral

fractures are found in patients without osteoporosis. Data are limited on how many of the vertebral fractures in non-osteoporotic patients were in patients who would not otherwise be eligible for treatment (i.e., those with osteopenia and other risk factors for fracture).

Evidence from the FIT and VERT studies has suggested that treatment of patients with low bone mass (but not osteoporosis) reduces further fractures. However, the FIT and VERT studies were post hoc subgroup analyses, which are considered to be exploratory. Also, vertebral fracture screening was done using radiography rather than VFA software. Advantages of the studies are that the 2 subgroup re-analyses had large sample sizes and used data from well-conducted randomized trials. Currently, this chain of evidence is insufficient to determine whether treatment of patients with low bone density and vertebral fractures improves outcomes.

Vertebral Fracture Assessment with Biomechanical Computed Tomography

Clinical Context and Test Purpose

The purpose of performing VFA using biomechanical computed tomography (BCT) is to diagnose whether the individual has a vertebral fracture.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals at risk of vertebral fractures who are not known to have a fracture at the time of assessment.

Interventions

The relevant intervention of interest is BCT.

Comparators

The following tools and tests are currently being used to make decisions about managing individuals at risk for vertebral fracture: Dual-energy x-ray absorptiometry (DXA) alone for the assessment of BMD as well as spine radiography. Radiography is used to confirm the occurrence of vertebral fractures but is not recommended as a routine component of osteoporosis assessment because of radiation exposure.

Outcomes

Outcomes of interest for diagnostic accuracy include test accuracy and test validity (e.g., sensitivity, specificity). The primary outcome of interest for clinical utility is morbid events, specifically the incidence of future clinical fractures.

Vertebral fracture assessment with BCT may occur at the time of osteoporosis screening. The recommended age at which to start screening and the frequency of screening is addressed in national guidelines. Vertebral facture assessment (VFA) with BCT can also be conducted on CT scans obtained for other clinical reasons that include images of the spine or hip, which has been called opportunistic osteoporosis screening.

Study Selection Criteria

For the evaluation of clinical validity of VFA with BCT, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores);
- Included a suitable reference standard (e.g., spine radiography);
- Patient/sample clinical characteristics were described;
- Patient/sample selection criteria were described.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence

Nonrandomized Trials

Izzy et al (2021) conducted a retrospective study of 91 patients who were evaluated for liver transplant and received a CT scan within 3 months of a DXA scan (hip or spine).[21,] Compared to DXA as the reference standard, BCT had a sensitivity and specificity of detecting osteoporosis of 83.3% and 65.7%, respectively. The positive predictive value of BCT was 46.5% and the negative predictive value was 91.7%.

Adams et al (2018) conducted a retrospective case-cohort study (FOCUS) of 3938 patients who received an abdominal or pelvic CT scan in the course of routine clinical care and also received a DXA scan within 3 years of the CT.[22,] In women, BCT had a sensitivity and specificity for detecting hip osteoporosis of 0.56 (95% CI, 0.51 to 0.60) and 0.77 (95% CI, 0.72 to 0.81), respectively, while DXA had a sensitivity of 0.52 (95% CI, 0.47 to 0.56) and specificity of 0.77 (95% CI, 0.73 to 0.81). In men, BCT had a sensitivity of detecting hip osteoporosis of 0.45 (95% CI, 0.39 to 0.52) and a sensitivity of 0.82 (95% CI, 0.76 to 0.87) compared to 0.43 (95% CI, 0.37 to 0.50) and 0.83 (95% CI, 0.77 to 0.88), respectively, for DXA. The authors concluded that BCT is at least as effective as DXA in identifying patients who are at high risk of hip fracture.

Fidler et al (2016) retrospectively compared the diagnosis of osteoporosis and fracture risk as determined by BCT and DXA in 136 women who received both scans within 6 months of each other.[23,] For hip and spine results combined, BCT had a sensitivity of 82.8% (95% CI, 65.4% to 92.4%) and specificity of 85.7% (95% CI, 76.2% to 91.8%) for identifying osteoporosis. The positive predictive value was 68.6% and the negative predictive value was 93.0%. For the femoral neck assessment alone, BCT had a sensitivity and specificity of 100% (95% CI, 67.6% to 100%) and 98.4% (95% CI, 94.5% to 99.6%), with a positive predictive value of 80% and a negative predictive value of 100%. Weber et al (2014) conducted a retrospective analysis of 136 patients with inflammatory bowel disease who received CT enterography and a DXA scan.[24,] Compared to DXA, BCT had a sensitivity and specificity for identifying osteoporosis of 85.7% (95% CI, 48.7% to 97.4%) and 98.5% (95% CI, 94.5% and 99.6%). The sensitivity and specificity of BCT in detecting osteopenia was 85.1% (95% CI, 72.3% to 92.6%) and 85.4% (95% CI, 76.6% to 91.3%).

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, more effective therapy, or avoid unnecessary therapy or testing.

Direct Evidence

Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials (RCTs).

No RCTs comparing health outcomes in individuals screened with BCT with those screened with other methods were identified.

Chain of Evidence

Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

A chain of evidence for the clinical utility of VFA screening is based on evidence that VFA identifies appropriate candidates for treatment who would not otherwise be identified, and there is evidence

that treatment in this population is beneficial. The chain involves evaluating: (1) evidence that VFA is accurate, (2) evidence that VFA identifies appropriate candidates for treatment who would not otherwise be identified, and (3) evidence that treatment in this population is actually beneficial.

Section Summary: Vertebral Fracture Assessment with Biomechanical Computed Tomography

Comparative evidence for VFA using BCT is limited to retrospective studies using previously obtained CT scans. Results suggest that BCT has comparable efficacy to DXA in detecting osteoporosis of both the spine and hip. Studies are lacking that demonstrate a benefit of DCT in preventing fractures, influencing treatment decisions, or improving treatment outcomes.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2014 Input

In response to requests, input was received from 5 physician specialty societies and 6 academic medical centers when this policy was under review in 2014. One of the 5 specialty societies only submitted a practice statement and did not respond to questions. Input was mixed on whether vertebral fracture assessment (VFA) using dual-energy x-ray absorptiometry (DXA) is considered investigational. Input was also mixed on whether the diagnostic accuracy of VFA using DXA is sufficiently high to justify its use as an alternative to plain radiographs. There was a near-consensus agreement with National Osteoporosis Foundation recommendations regarding imaging to evaluate for vertebral fractures. Responders did not cite published literature to support the National Osteoporosis Foundation recommendations. Also, there was near-consensus that patients with vertebral fracture alone (i.e., no low bone mineral density and no other signs of osteoporosis) should be treated with medications to reduce fracture risk.

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)[25,] on the diagnosis and treatment of postmenopausal osteoporosis included VFA recommendations similar to those of the International Society for Clinical Densitometry (below) but did not discuss BCT. An update to the guidelines in 2020[26,] 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).[27,] The guideline does not address the use of VFA.

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.[28,] 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.

The 2022 ACR appropriateness criteria do not address BCT.

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.[8,] 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."[8,] 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.

Biomechanical computed tomography is mentioned in the guideline as a fracture risk assessment technology that is used in research settings and occasionally in clinical practice, but no recommendations regarding BCT are made.

International Society for Clinical Densitometry

The International Society for Clinical Densitometry (2023) updated its recommendations for selecting patients for VFA. [29,] 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."

The International Society for Clinical Densitometry 2023 recommendations do not address BCT.

Endocrine Society

The Endocrine Society Clinical Practice Guideline (2019) on pharmacological management of osteoporosis in postmenopausal women states 4 management principles[30,]:
"(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.[31,] 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. Per the position statement, BCT has a small advantage over DXA but its role in routine clinical practice is undefined.

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.[32,] 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.[33,]

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.

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in August 2024 did not identify any ongoing or unpublished trials that would likely influence this review.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	77085	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 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)
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
08/31/2015	BCBSA Medical Policy adoption
11/01/2016	Policy revision without position change
11/01/2017	Policy revision without position change
11/01/2018	Policy revision without position change
12/01/2019	Policy revision without position change
12/01/2020	Annual review. No change to policy statement. Literature review updated.
11/01/2021	Annual review. No change to policy statement. Literature review updated.
11/01/2022	Annual review. No change to policy statement. Literature review updated.
11/01/2023	Annual review. No change to policy statement. Literature review updated.
12/01/2024	Annual review. Policy statement, guidelines, and literature review updated. Policy title changed from Vertebral Fracture Assessment with Densitometry to Vertebral Fracture Assessment with Densitometry or Biomechanical Computed Tomography.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** Blue font: Verbiage Changes/Additions
Vertebral Fracture Assessment with Densitometry 6.01.44 **Policy Statement:** I. Screening for vertebral fractures using dual-energy x-ray absorptiometry is considered **investigational**.	**Vertebral Fracture Assessment with Densitometry or Biomechanical Computed Tomography 6.01.44** **Policy Statement:** I. Screening for vertebral fractures using dual-energy x-ray absorptiometry or biomechanical computed tomography is considered **investigational**.