DESCRIPTION
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). Only 20–30% of vertebral fractures are recognized clinically; the rest are discovered incidentally on lateral spine radiographs. Lateral spine x-rays have not been recommended as a component of risk assessment for osteoporosis because of the cost, radiation exposure, and the fact that the x-ray would require a separate procedure in addition to the BMD study using dual x-ray absorptiometry (DEXA). However, several densitometers with specialized software are able to perform vertebral fractures assessment (VFA) in conjunction with DEXA. 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 onto the left decubitus position.
VFA differs from radiologic detection of fractures, as VFA uses a lower radiation exposure and can detect only fractures, while traditional x-ray 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 (IVA), or radiographic vertebral assessment (RVA) (Hologic), or dual energy vertebral assessment (DVA™), previously known as lateral vertebral assessment (LVA™) (GE Lunar Medical Systems).

For both lateral spine x-rays and images with densitometry, vertebral fractures are assessed visually. While a number of grading systems have been proposed, the semiquantitative system of Genant is commonly used. This system grades the deformities from I to III, with grade I representing a 20–24% reduction in vertebral height and ranging up to grade III, which is a 40% 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 x-rays and VFA imaging is dependent on radiologic training. Thus, device location and availability of appropriately trained personnel may influence diagnostic accuracy.

**POLICY**

Screening for vertebral fractures using dual x-ray absorptiometry (DEXA or DXA) is considered *experimental / investigational*.

**Policy Guidelines**

1. The CPT code was moved effective January 1, 2007. The code was 76077 (with the same wording from January 1, 005 to December 31, 2006).
2. Although the primary benefit of vertebral fracture assessment is in individuals with osteopenia, because densitometry and vertebral fracture assessment are done simultaneously, it is not possible to use the findings from BMD testing to determine eligibility for VFA during a particular testing session.

**RATIONALE**

This policy addresses whether screening for vertebral fracture assessment (VFA) using densitometry improves the net health outcome. The ideal study would be a randomized controlled trial (RCT) comparing health outcomes in individuals screened with VFA in addition to DEXA compared to those screened with DEXA alone. Since no RCTs of this type have been published, an alternative strategy is to examine a chain of indirect evidence. This chain of evidence involves searching for (in addition to evidence that VFA is accurate) a) evidence that VFA identifies appropriate candidates for treatment who would not otherwise be identified and, b) that treatment in this population is actually beneficial.
The National Osteoporosis Foundation (NOF) 2010 Clinician's Guide to Prevention and Treatment of Osteoporosis recommends treatment for the following groups of patients (1):

- Hip or vertebral (clinical or morphometric) fractures
- BMD T-scores equal to or less than -2.5 at the femoral neck or spine by DEXA
- Postmenopausal women and men age 50 years and older with low bone mass (T-score between -1.0 and -2.5, osteopenia) at the femoral neck or spine and a 10-year hip fracture probability at least 3% or a 10-year major osteoporosis-related fracture probability at least 20% based on the US-adapted World Health Organization (WHO) absolute fracture risk model (available online at www.shef.ac.uk/FRAX; Also see Appendix A).

Since patients with osteoporosis (T-score -2.5 or less) diagnosed by DEXA 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. Thus, the literature review will focus on individuals who do not have osteoporosis.

In patients without osteoporosis, what is the diagnostic accuracy of VFA with DEXA in identifying vertebral fractures, compared to standard x-rays?

A study by Binkley and colleagues evaluated whether VFA with densitometry can accurately detect fractures in women with low bone mass. (2) In this study, VFA (GE Lunar densitometer) was compared with the gold standard (radiography) in 27 osteoporotic, 38 osteopenic, and 15 normal women. Blinded analysis found correct identification for 17 of 18 radiographically evident grade 2 to 3 fractures (a false-negative rate of 6%). However, the study did not describe whether the grade 2 and 3 fractures were found in women with osteoporosis, osteopenia, or normal BMD. Also, only 11 of 22 (50%) 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. In addition, VFA identified a total of 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-T6 vertebrae in other subjects could not be adequately visualized.

Another study, published in 2006, reported that VFA (Delphi W device) provided evaluable images for 81% of vertebrae from T4 through L4 and accurate diagnosis in 74% of patients (136 postmenopausal women) but misclassified 11.2% in comparison with x-ray. (3) A limitation of this study is that x-rays were not performed when the vertebrae were considered to be legible and normal on VFA. As shown in the study above, many grade 1 fractures may be missed with densitometry. This literature suggests that densitometry may not accurately diagnose vertebral fractures in the population of interest (women with osteopenia or normal BMD).

Ferrar et al. evaluated the performance of vertebral assessment using a visual algorithm-based approach. (4) Subjects in the low-risk group were women age 55-79 years and were randomly selected from their general practitioners’ offices. Most of them had 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 of the high-risk patients had osteopenia or osteoporosis. In 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. On a per-
vertebrae analysis, 52 of 68 false-negative fractures in the low-risk and 60 of 98 false-negatives
in the high-risk group were reported as mild fractures. The location of false-negatives also
differed by risk group. In the high-risk group, 46% (n=36) of false-negatives were at vertebrae
T6-T9, and 25% (n=5) of all false-positives were at L1. In the low-risk group, 23% (n=10) of
false-negatives were at vertebrae T4, and 48% (n=12) of the false-positives were at vertebrae
T12-L1.

Does vertebral assessment identify candidates for treatment who would not otherwise be
identified?

As stated above (1), the NOF recommends treating patients with hip or vertebral fractures, with
osteoporosis and with osteopenia plus other characteristics that would sufficiently increase their
risk of future fracture. Several studies have reported the prevalence of asymptomatic vertebral
fractures in individuals with normal BMD or low BMD (but not osteoporosis). Recent studies
include Jager and colleagues’ evaluation of 2424 consecutive individuals (65% were female)
referred for BMD for a variety of reasons at a single center in the Netherlands. (5) Participants
underwent VTA with BMD during the same session using a Hologic Discovery A densitometer.
Vertebral fractures (reduction in height of at least 20%) were detected in a total of 541 (22%) of
patients. The prevalence of vertebral fractures was 14% (97/678) in individual with normal BMD
and 21% (229/1100) in patients with osteopenia. The vertebral fractures were previously
unknown in 74% of patients with normal BMD and 71% of patients with osteopenia.

Questionnaires were sent to 942 physicians, with a response rate of 50%. Of these 468
responses, 323 (69%) of physicians reported that VFA findings had no impact on patient
management, 100 (21%) reported some impact, 29 (6%) reported a large impact and there were
16 (3%) unknown responses. A total of 58 responses indicated that VFA findings impacted
medication decisions.

Another recent study from the Netherlands included 566 women aged 50 years and older with
clinical risk factors for fracture who were not being treated for osteoporosis and had not
previously been diagnosed with a vertebral fracture. (6) Women underwent DEXA and VTA
screening with a Hologic W DEXA system. A total of 174 (31%) had one or more moderate or
severe vertebral fracture (height reduction of 25% or more). Mild vertebral fractures were not
reported. Of the 174 women with vertebral fractures, 44 (25%) were found to have
osteoporosis and therefore would have been eligible for treatment based on their BMD alone.
However, the remaining 130 (75%) women with vertebral fractures had normal BMD (n=32) or
osteopenia (n=43). It is not known how many of the women with osteopenia would have
otherwise been considered potential candidates for treatment due to the combination of low
bone mass and other risk factors. Among women with vertebral fractures, 17 (10%) used
glucocorticoids, 91 (52%) had a previous fracture before age 50 and 39 (22%) had a first-
degree relative with a hip fracture. The authors did not report women’s overall risk of fracture
using the FRAX model.

A 2010 article had the primary aim of evaluating the impact of VFA on the Canadian risk
classification system. (7) The study reported on data collected on VFA with densitometry in the
Netherlands, and the article was written by researchers from the Netherlands and Canada. The
study included 958 individuals at least 18 years-old who had been referred for BMD
measurements. Their mean age was 53 years; 609 (64%) were women, and 93 (10%) were
already known to have a vertebral fracture. In 937 of the 958 patients (98%), VFA was considered technically adequate. Using VFA, a vertebral fracture was identified in 244 of 937 (26%) of those with an adequate scan. This included 18% of the 257 patients found on DEXA to have normal BMD, 23% in the 404 patients with osteopenia, and 29% of the 275 patients with osteoporosis. Using the Canadian risk classification tool categorizing fracture risk according to age, gender, and BMD T-score, the proportion of patients who would have been categorized as low, moderate, and high risk was 650 (68%), 184 (19%), and 124 (13%), respectively. After taking VFA into account, 133 patients with a low risk who were found to have 1 or more vertebral fractures would have been moved to the moderate-risk class. Moreover, 59 of the moderate-risk patients were found to have 1 or more vertebral fractures, which moved them to the high-risk category. In total, 192 patients (20% of the cohort) moved up 1 risk class. The study did not compare the VFA findings to a reference standard and did not evaluate the effect of treatment on preventing fracture in patients placed into risk categories that used data from VFA with densitometry.

A 2011 study by Sullivan and colleagues evaluated the prevalence of vertebral fracture in men at increased risk of bone loss who were undergoing DEXA screening. (8) The study included 116 men with non-metastatic prostate cancer who had been taking androgen deprivation therapy for at least 6 months. A total of 37 (37%) men were found to have normal BMD on DEXA; 9 (24%) of these had at least 1 vertebral fracture. In addition, 67 (59%) of men were found to have low BMD/osteopenia; 23 (34%) had at least 1 vertebral fracture. A total of 32 of the 104 (31%) men with normal or low BMD had a least one vertebral fracture. Patients also underwent radiographic confirmation of fractures. Compared to radiography, the sensitivity of VFA was 100% and the specificity was 95%. Thus, according to the NOF recommendations, 32 men (28% of the sample) with normal or low bone density would be recommended for osteoporosis treatment based on their radiologically identified vertebral fracture. (Androgen deprivation therapy is not currently included in the WHO absolute fracture risk model so those men with osteopenia and ADT would not have been recommended to receive treatment).

Does pharmacologic treatment in patients with vertebral fracture and low bone mass improve health outcomes?

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 groups was the first large multicenter study comparing the effects of treatment between osteoporotic and women with low bone mass without existing vertebral fractures using the revised National Health and Nutrition Examination Survey (NHANES) cutoffs. (9) This trial randomly assigned 4,432 women to alendronate or placebo and analyzed the treatment group in 3 BMD categories (less than -2.5 standard deviation (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% confidence interval [CI]: 0.5-0.8). There was no significant reduction in all clinical fractures
for women with higher BMD values (RR 1.1, 95% CI: 0.9–1.4), suggesting no benefit among patients with low bone mass or normal BMD.

Quandt and colleagues reanalyzed the FIT study analyzing data for the outcome of both clinical vertebral fractures (symptomatic and diagnosed by physician) and radiographically detected (assessed at surveillance intervals) vertebral fractures. (10) A total of 3,737 women at least 2 years’ post-menopausal 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 were 6 (a rate of 43 per 10,000 person-years of risk) in the alendronate group and 16 (124 per 10,000 person-years of risk) in the placebo group. Alendronate treatment compared to placebo was accompanied by a RR of 0.3 (95% CI: 0.1–0.8) for clinical vertebral fractures and a RR of 0.5 (95% CI: 0.3–0.8) for radiographically detected fractures. Similar RR estimates were found for women having low bone mass without vertebral fractures, but absolute risks were lower (12 versus 81 fractures/10,000 person-years for those without and with baseline fractures, respectively).

Kanis and colleagues reanalyzed data on 1,802 women 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. (11) Overall, there was a significantly lower rate of a new vertebral fracture in women with prior vertebral fracture randomly assigned to treatment with risedronate compared to placebo (14.5% vs. 22.3%, respectively; p<0.001). In the group with a T-score greater than -2.5, the rate of new femoral neck fractures was 50 of 519 (11%) in the risedronate group and 71 of 537 (15.5%) in the placebo group (p=0.049). In the osteoporotic group, those with a T-score -2.5 or lower, the rate of new femoral neck fracture was 53 of 355 (18.7%) in the risedronate group and 92 of 318 (33.4%) in the placebo group (p<0.001). Findings were similar when the T-score at the most severe skeletal site (femoral neck or lumbar spine) was used for stratification.

A limitation of the FIT and VERT studies described above is that they are post-hoc subgroup analyses, which are generally considered to be exploratory. In addition, vertebral fracture screening was done using radiography rather than VFA software. Advantages of the studies are that the 2 sub-analyses had large sample sizes and used data from well-conducted randomized trials.

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. (e.g., 12, 13) However, vertebral fractures were not assessed and therefore conclusions cannot be drawn about the potential added benefit of VFA in addition to densitometry in at-risk men.

**Summary**

There is a lack of direct evidence from screening trials comparing densitometry with and without VFA that VFA improves health outcomes. Since direct evidence was not available, a causal chain of indirect evidence was examined. Some evidence exists regarding the diagnostic performance of vertebral assessment. Using the vertebra as the unit of analysis, sensitivity ranged from 54% to 72% and specificities ranged from 94% to 99%. Regarding clinical utility, studies have found
that vertebral fracture assessment can identify individuals without osteoporosis who may be appropriate candidates for treatment according to the NOF. However, there is limited evidence on the effectiveness of treatment in this population. No trials have been published that were designed to evaluate whether treating patients with vertebral fracture and without osteoporosis reduces risk of future fracture. The available data are 2 post-hoc sub-analyses from larger treatment trials including patients with low bone density and baseline vertebral fractures with medication versus placebo; both found a benefit of treatment. Baseline vertebral fracture was defined differently in the 2 analyses: clinical or radiographically detected vertebral fracture in one study and radiographically detected vertebral fracture-only in the other. No treatment data have been published in patients whose vertebral fracture had been identified using VFA software with densitometry. Moreover, data on clinical utility are only available on postmenopausal women. Thus, screening for vertebral fractures using DEXA is considered investigational.

**Practice Guidelines and Position Statements**

**National Osteoporosis Foundation**: Their 2010 Clinician's Guide to Prevention and Treatment of Osteoporosis includes the following statement on vertebral fracture assessment, “Independent of BMD, age and other clinical risk factors, radiographically confirmed vertebral fractures are a strong predictor of new vertebral fractures, and they also predict other fractures. VFA imaging of the thoracic and lumbar spine using central DXA scanners should be considered at the time of BMD assessment when the presence of a vertebral fracture not previously identified may influence clinical management of the patient.” (1)

**International Society for Clinical Densitometry (ISCD)**: They issued an updated position statement in 2007 recommending vertebral fracture assessment for selected patients with the following criteria (14):

Post-menopausal women with low bone mass (osteopenia) by bone mineral density (BMD) criteria PLUS one of the following:
- Age greater than or equal to 70 yr
- Historical height loss greater than 4 cm (1.6 in)
- Prospective height loss greater than 2 cm (0.8 in)
- Self-reported prior vertebral fracture (not previously documented)
- Two or more of the following:
  - Age 60 to 69 yr
  - Self-reported prior non-vertebral fracture
  - Historical height loss of 2 to 4 cm
  - Chronic systemic diseases associated with increased risk of vertebral fractures (for example, moderate to severe chronic obstructive pulmonary disease (COPD), seropositive rheumatoid arthritis, Crohn's disease)

Men with low bone mass (osteopenia) by BMD criteria, PLUS one of the following:
- Age 80 yr or older
- Historical height loss greater than 6 cm (2.4 in)
- Prospective height loss greater than 3 cm (1.2 in)
- Self-reported vertebral fracture (not previously documented)
- Two or more of the following:
  - Age 70 to 79 yr
  - Self-reported prior non-vertebral fracture
- Historical height loss of 3 to 6 cm
- On pharmacologic androgen deprivation therapy or following orchiectomy
- Chronic systemic diseases associated with increased risk of vertebral fractures (for example, moderate to severe COPD, seropositive rheumatoid arthritis, Crohn’s disease)

**North American Menopause Society**: Their 2010 position statement on management of osteoporosis does not include a recommendation for or against vertebral fracture assessment as part of the screening process. (15) The statement states that vertebral fracture must be confirmed by lateral spine radiographs or VFA visualization of fracture at the time of BMD testing.

**U.S. Preventive Services Task Force (USPSTF)**: In January 2011, the USPSTF updated their recommendations for osteoporosis screening. The recommendations state that “current diagnostic and treatment criteria rely on dual-energy x-ray absorptiometry of the hip and lumbar spine”. Vertebral fracture assessment is not specifically mentioned. (16)

**CODING**

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<td>77082</td>
<td>Dual energy x-ray absorptiometry (DXA), bone density study, 1 or more sites; vertebral fracture assessment</td>
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**DIAGNOSIS**

- V82.81 Special screening; osteoporosis

**ICD-10 Diagnosis (Effective October 1, 2014)**

- Z13.820 Encounter for screening for osteoporosis

**REVISIONS**

- 11-29-2013 Policy added to the bcbsks.com web site.

**REFERENCES**


