Kansas City

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Vertebral Fracture Assessment with Densitometry

Policy Number: 6.01.44
Origination: 4/2005
Last Review: 10/2014
Next Review: 4/2015

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for vertebral fracture assessment with densitometry. This is considered investigational.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

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

Considerations

If a vertebral fracture assessment is performed with a DXA of the axial skeleton, the vertebral fracture assessment is considered a redundant procedure and not separately payable.

Description of Procedure or Service

Vertebral fracture assessment (VFA) with densitometry is a technique in which vertebral fractures are assessed at the same time as bone mineral density (BMD), by use of dual x-ray absorptiometry (DEXA). The addition of vertebral fractures to BMD may provide additional useful information on an individual's risk of fracture.

Background

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), radiographic vertebral assessment (RVA), dual energy vertebral assessment (DVA), or lateral vertebral assessment (LVA).

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 (mild) representing a 20–

24% reduction in vertebral height, grade II (moderate) representing a 25-39% 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 x-rays and VFA imaging is dependent on radiologic training. Thus, device location and availability of appropriately trained personnel may influence diagnostic accuracy.

Regulatory Status
To perform vertebral fracture assessment with a densitometer, additional software is needed, and it must have 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA). Products that have received FDA clearance include Lunar Dual Energy Vertebral Assessment (General Electric Medical Systems) and Hologic Instant Vertebral Assessment software.

Rationale

The policy was created in 2004 and was updated regularly with searches of the MEDLINE database. Most recently, the literature was reviewed through April 9, 2014. Following is a summary of the key literature published to date.

This policy addresses whether screening for vertebral fracture assessment (VFA) using densitometry improves the net health outcome. The ideal study to evaluate improvement in the net health outcome would be a randomized controlled trial (RCT) comparing health outcomes in individuals screened with VFA in addition to dual-energy x-ray absorptiometry (DEXA) compared with those screened with DXA alone. Because 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: (1) evidence that VFA is accurate, (2) evidence that VFA identifies appropriate candidates for treatment who would not otherwise be identified, and (3) that treatment in this population is actually beneficial.

The National Osteoporosis Foundation (NOF) 2013 Clinician's Guide to Prevention and Treatment of Osteoporosis recommends considering U.S. Food and Drug Administration (FDA)–approved medical treatment for the following groups of patients(1):

- Vertebral fracture (clinical or asymptomatic) or hip fracture
- Hip DXA (femoral neck or total hip) or lumbar spine T-score ≤-2.5
- Low bone mass (osteopenia) and a U.S.-adapted (*World Health Organization*) WHO 10-year probability of a hip fracture ≥3% or 10-year probability of any major osteoporosis-related fracture ≥20%
- Patient preferences may indicate treatment for people with 10-year fracture probabilities above or below these levels”

(For the WHO algorithm, see http://www.shef.ac.uk/FRAX; see also Appendix A.)

Because patients with osteoporosis (T-score, ≤-2.5) 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 patients who do not have osteoporosis.

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

Several recent studies have compared the diagnostic accuracy of VFA and standard radiography. None of these reported findings separately for osteoporotic and nonosteoporotic patients, so conclusions cannot be drawn about diagnostic accuracy of VFA in patients without osteoporosis. Moreover, studies tended to use radiography as the reference standard and did not evaluate potential false positives or false negatives associated with radiography.

In 2013, Domiciano et al reported on 429 adults at least 65 years-old who had VFA with densitometry and spine radiography on the same day.(2) On VFA, vertebral fractures were identified in 77 of 259 women (29.7%) and 48 of 170 men (28.2%). Comparable numbers on spine radiographs were 74 of 259 (28.6%) in women and 52 of 170 (30.6%) in men. Compared with spine radiography, the sensitivity of VFA was 81.7% (95% confidence interval [CI], 73.9% to 88.1%) and the specificity was 92.7% (95% CI, 9.2% to 95.4%). In 2012, Diacinti et al in Italy published 2 studies comparing the diagnostic accuracy of VFA with standard radiographs.(3,4) Neither study, however, reported rates of osteoporosis or reported diagnostic accuracy data in patients without osteoporosis. Both studies found that VFA had high diagnostic accuracy, using conventional radiography as the reference standard. In 1 study, conducted with 930 postmenopausal women, the overall sensitivity and specificity of VFA on a *per* patient level was 97.23% and 98.86%, respectively. The other study included 350 patients; peri- and postmenopausal women, men referred for diagnosis of osteoporosis, and patients enrolled in a study of HIV-related osteoporosis. When analyzed on a *per* patient level, VFA was found to have 96.83% sensitivity and 98.66% specificity compared with conventional radiography. The high overall diagnostic accuracy of VFA in these studies suggests that it has high diagnostic accuracy for all BMD levels.

In the newer studies, especially those by Diacinti et al, the accuracy of VFAs was higher than its performance in earlier studies. For example, in 2007 Ferrar et al evaluated the performance of vertebral assessment using a visual algorithm-based approach.(5) Subjects in the low-risk group were women age 55 to 79 years and were randomly selected from their general practitioners' offices. Most of them had normal bone mineral density (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. In addition, a 2005 study by Binkley et al compared VFA (GE Lunar densitometer) with radiography in 27 osteoporotic, 38 osteopenic, and 15 normal women.(6) Blinded analysis found correct identification for 17 of 18 radiographically evident grade 2 to 3 fractures (a false negative rate of 6%). 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 to T6 vertebrae in other subjects could not be adequately visualized.

Section summary

Several studies have compared VFA with radiography. The sensitivity of VFA compared with standard radiography reported in these studies was variable. Studies published in 2012 and 2013 reported higher diagnostic accuracy than older studies, ie, sensitivities in the 80% to 99% range and specificities over 90%. However, these recent studies did not to present diagnostic accuracy rates separately for patients without osteoporosis. Because of the lack of stratified analyses, it is not possible to determine the sensitivity and specificity of VFA for vertebral fractures with certainty for the subset of patients without osteoporosis.

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

As previously stated,(1) the 2013 NOF guidelines recommend treating patients with osteoporosis, with osteopenia and other risk factors and those with hip or vertebral fractures (clinical or asymptomatic).

Vertebral fracture assessment could identify additional candidates for treatment if patients with vertebral fractures did not fall into one of the other categories eligible for treatment. No studies were identified that specifically dealt with the question of whether VFA would identify candidates for medication treatment who would not otherwise have been identified, but several studies addressed this issue to some extent. Representative studies with larger sample sizes are described next.

A 2014 study by Kanterewiez et al in Spain collected data on a population-based cohort of 2968 postmenopausal women between the ages of 59 and 70 years.(7) A total of 127 women (4.3%) had a vertebral fracture according to VFA. Among these, 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 potentially identify additional women who would be eligible for fracture prevention therapy according to NOF guidelines (ie, 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 eg, they did not report data on women with normal BMD and other risk factors.

In 2013, Mrgan et al in Denmark published a retrospective study evaluating VFA with BMD in 3275 patients presenting for osteoporosis screening or evaluation of antiosteoporotic medication; 85% were female.(8) Vertebral fractures were found on VFA in 260 patients (7.9%). Of these, 156 patients (4.8% of the total sample) had osteoporosis (ie, BMD at least -2.5) and 104 (3.2% of the total sample) did not have osteoporosis, according to BMD. The data suggest that up to 40% (104/250) patients with vertebral fractures identified would be eligible for treatment according to NOF guidelines, and might not have been identified if DEXA alone were used. Some of the patients, however, may have had osteopenia and other risk factors that would lead to their eligibility for treatment.

In 2011, Jager et al reported on 2424 consecutive patients (65% were female) referred for BMD for a variety of reasons at a single center in the Netherlands.(9) Participants underwent VFA with BMD during the same session. 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 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 could be eligible for treatment based on the 2013 NOF guidelines if they did not fall into another eligibility category, eg, osteopenia with other risk factors. Most of the 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.

Section summary

Routine use of VFA with DEXA will identify substantial numbers of patients with previously unrecognized vertebral fractures. Many of these vertebral fractures are found in patients without osteoporosis. Data are not available on how many of the vertebral fractures in nonosteoporotic patients were in patients who would not otherwise be eligible for treatment, ie, those with osteopenia and other risk factors for fracture.

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 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 (NHANES) cutoffs.(10) This trial randomly assigned 4432 women to alendronate or placebo and analyzed the treatment group in 3 BMD categories (<-2.5 SD, -2.0 to -2.5 SD; -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 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.(11) 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 were 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 a RR of 0.3 (95% CI, 0.1 to 0.8) for clinical vertebral fractures and a RR of 0.5 (95% CI, 0.3 to 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 vs 81 fractures/10,000 person-years for those without and with baseline fractures, respectively).

Kanis et al reanalyzed data on 1802 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.(12) 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 with 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 of -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.

Section summary

Evidence from the FIT and VERT studies suggests that treatment of patients with low bone mass (but not osteoporosis) reduces further fractures. However, a limitation of the FIT and VERT studies 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 subanalyses had large sample sizes and used data from well-conducted randomized trials. This evidence is insufficient to determine whether treatment of patients with low bone density and vertebral fractures improves outcomes.

Does VFA improve outcomes in men who are being evaluated for osteoporosis?

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, eg, on androgen deprivation therapy.(13,14) 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.

Clinical Input Received Through Physician Specialty Societies and Academic Medical Centers

In response to requests, input was received through 6 academic medical centers and 5 physician specialty societies 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. 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. Input was mixed on whether vertebral fracture assessment using DEXA is considered investigational. Input was also mixed on whether the diagnostic accuracy of vertebral fracture assessment using DEXA is sufficiently high to justify its use as an alternative to plain radiographs. There was near-consensus agreement with NOF recommendations regarding imaging to evaluate for vertebral fractures. Responders did not cite published literature to support the NOF

recommendations. In addition, there was near-consensus that patients with vertebral fracture alone (ie, no low BMD and no other signs of osteoporosis) should be treated with medications to reduce fracture risk.

Summary

There is a lack of direct evidence from screening trials comparing densitometry with and without vertebral fracture assessment (VFA) that VFA improves health outcomes. Because direct evidence was not available, a causal chain of indirect evidence was examined. Evidence was examined on the diagnostic accuracy of VFA in nonosteoporotic patients, 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 had variable findings; recent studies suggest higher diagnostic accuracy of VFA overall compared with standard radiographs. Even in recent studies, however, diagnostic accuracy data in patients without osteoporosis were not reported separately.

Studies have found that VFA can identify patients without osteoporosis who may be appropriate candidates for treatment according to recommendations from the National Osteoporosis Foundation (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 on treatment are 2 post-hoc subanalyses from larger trials that included 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 1 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. In addition, clinical input was not uniformly in support of VFA. Thus, screening for vertebral fractures using VFA with dual-energy x-ray absorptiometry is considered investigational.

Practice Guidelines and Position Statements

NOF: Their 2013 Clinician's Guide to Prevention and Treatment of Osteoporosis stated: “A vertebral fracture is consistent with a diagnosis of osteoporosis, even in the absence of a bone density diagnosis, and is an indication for pharmacologic treatment with osteoporosis medication to reduce fracture risk. Most vertebral fractures are asymptomatic when they first occur and often are undiagnosed for many years. Proactive vertebral imaging is the only way to diagnose these fractures. The finding of a previously unrecognized vertebral fracture may change the diagnostic classification, alters future fracture risk and subsequent treatment decisions.”(1)

The guide recommends that vertebral imaging tests be considered in the following patients

- All women age 70 and older and all men age 80 and older.
- Women age 65 to 69 and men age 75 to 79 when BMD T-score is -1.5 or below.
- Postmenopausal women age 50 to 64 and men age 50 to 69 with specific risk factors These include:
    - Low trauma fracture
    - Historical height loss of 1.5 inches or more (4 cm)
    - Prospective height loss of 0.8 inches or more (2 cm)
    - Recent or ongoing long-term glucocorticoid treatment

International Society for Clinical Densitometry (ISCD): In 2013, ISCD issued updated recommendations for selecting patients for VFA.(15) The new recommendations were simpler compared to the 2007 recommendations and were intended to be easier to use in clinical practice. 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:

- At least 70 years old for women and at least 80 years old for men
- Historical height loss of at least 4 cm (at least 1.5 inches)
- Self-reported but undocumented prior vertebral fracture
- Glucocorticoid therapy equivalent to at least 5 mg of prednisone per day for at least 3 months.

A 2012 Task Force of the Endocrine Society recommended pharmacologic therapy for men at high risk for fracture.(16) Risk includes but is not limited to the following criteria:

- Men who have had a hip or vertebral fracture without major trauma.
- Men who have not experienced a spine or hip fracture but whose BMD of the spine, femoral neck, and/or total hip is 2.5 SD or more below the mean of normal young white males.
- In the United States, men who have a T-score between -1.0 and -2.5 in the spine, femoral neck, or total hip plus a 10-year risk of experiencing any fracture of 20% or greater or 10-year risk of hip fracture of 3% or greater using FRAX; further studies will be needed to determine appropriate intervention levels using other fracture risk assessment algorithms.
- Men who are receiving long-term glucocorticoid therapy in pharmacologic doses (eg, prednisone or equivalent >7.5 mg/d), according to the 2010 guidelines of the American Society of Rheumatology.

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.(17) 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: In January 2011, 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 was not specifically mentioned.(18)

Medicare National Coverage

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

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Billing Coding/Physician Documentation Information

77082 Dual energy X-ray absorptiometry (DXA), bone density study, one or more sites; vertebral fracture assessment

Additional Policy Key Words

N/A

Policy Implementation/Update Information

4/1/05	New policy added to the Radiology section. Considered investigational.
10/1/05	No policy statement changes.
4/1/06	Policy statement revised replacing morphometric absorptiometry (MXA) with dual x-ray absorptiometry (DEXA or DXA). This procedure remains investigational.
10/1/06	No policy statement changes.
4/1/07	No policy statement changes. Coding Updates.
10/1/07	No policy statement changes.
4/1/08	No policy statement changes.
10/1/08	No policy statement changes.
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4/1/10	No policy statement changes.
10/1/10	No policy statement changes.
4/1/11	No policy statement changes.
10/1/11	No policy statement changes.
4/1/12	Added Appendix A
10/1/12	No policy statement changes.
4/1/13	No policy statement changes.
10/1/13	No policy statement changes.
4/1/14	No policy statement changes.

10/1/14 No policy statement changes.

Appendix A

The risk factors assessed by the FRAX tool include (4):

- Age
- Gender
- Rheumatoid arthritis
- Secondary osteoporosis
- Prior osteoporotic fracture (including morphometric vertebral fracture)
- Parental history of hip fracture
- Femoral neck BMD
- Current smoking
- Low body mass index (kg/m2)
- Alcohol intake (3 or more drinks/d)
- Oral glucocorticoids ≥5 mg/d of prednisone for ≥3 mo (ever)

Charts of the FRAX® tool are available on-line at http://www.shef.ac.uk/FRAX/charts.jsp#USc'. These charts give fracture probabilities according to the number of clinical risk factors (CRF) that are found in an individual. Charts are available for:

- Women and men aged 50 years or more.
- Country-specific charts (USA, China, France, Italy, Japan, Spain, Sweden, Turkey and the UK)
- Ten-year probability of hip fracture or of a major osteoporotic fracture (clinical spine, hip, forearm and humerus fracture)