MEDICAL POLICY

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POLICY TITLE	VERTEBRAL FRACTURE ASSESSMENT WITH DENSITOMETRY
POLICY NUMBER	MP-5.046

Original Issue Date (Created):	**April 26, 2011**
Most Recent Review Date (Revised):	**September 24, 2013**
Effective Date:	**November 1, 2013**

I. POLICY

Screening for vertebral fractures using dual x-ray absorptiometry (DEXA or DXA) is considered **investigational.** There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:
MP-5.037 Whole Body Dual X-Ray Absorptiometry (DEXA) to Determine Body Composition
MP-5.001 Bone Mineral Density

II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids
[N] PPO
[N] HMO
[Y] SeniorBlue HMO**
[Y] SeniorBlue PPO**
[N] Indemnity
[N] SpecialCare
[N] POS
[Y] FEP PPO*

*The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

** Refer to Centers for Medicare and Medicaid (CMS) National Coverage Determination (NCD) 150.3. Bone (Mineral) Density Studies and Medicare Benefit Policy Manual, Chapter 15, section 80.5 of Pub. 100-02, Bone Mass Measurements (BMMs). Also see chapter 13, section 140 of Pub. 100-04, Medicare Claims Processing Manual, Bone Mass Measurements (BMMs).

III. DESCRIPTION/BACKGROUND

[Note: Final page is signature page and is kept on file, but not issued with Policy.]

POLICY TITLE	VERTEBRAL FRACTURE ASSESSMENT WITH DENSITOMETRY
POLICY NUMBER	MP-5.046

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.

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. 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 bone mineral density 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.

Vertebral fracture assessment (VFA) differs from radiological 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 radiological 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 FDA a. Products that have received FDA clearance include Lunar Dual Energy Vertebral Assessment (General Electric Medical Systems) and Hologic Instant Vertebral Assessment software.

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IV. RATIONALE

The policy is updated regularly with searches of the MEDLINE database. The most recent literature search using MEDLINE was for the period November 2011 through November 2012. 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 would be a randomized controlled trial (RCT) comparing health outcomes in individuals screened with VFA in addition to dual x-ray absorptiometry (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: 1) evidence that VFA is accurate, b) evidence that VFA identifies appropriate candidates for treatment who would not otherwise be identified, and c) 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 [body mass index] 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 U.S.-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?

In 2012, Diacinti and colleagues in Italy published 2 studies comparing the diagnostic accuracy of VFA to standard x-rays. (2, 3) 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 one study, conducted with 930 post-menopausal 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 post-menopausal women, men referred for diagnosis of osteoporosis, and patients enrolled in a study of human immunodeficiency virus (HIV)-related osteoporosis. When analyzed on a *per* patient level, VFA was found to have 96.83% sensitivity and 98.66% specificity compared to conventional radiography. The high overall diagnostic accuracy of VFA in these studies suggests that it has high diagnostic accuracy for all bone mineral density (BMD) levels. However, results were not reported separately for non-osteoporotic individuals, so conclusions cannot be drawn about diagnostic accuracy of VFA in this population.

The accuracy of VFA in the Diacinti studies was higher than its performance in earlier studies. For example, in 2007 Ferrar and colleagues 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.

In addition, a 2005 study by Binkley and colleagues compared VFA (GE Lunar densitometer) to radiography in 27 osteoporotic, 38 osteopenic, and 15 normal women. (5) 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-T6 vertebrae in other subjects could not be adequately visualized.

Conclusions: Several studies have compared VFA to radiography. The sensitivity of VFA reported in these studies was variable. Some have reported relatively low sensitivities in the 50-60% range while other studies, including a 2012 study, have reported sensitivities of over 90%. The specificity in these studies has been higher, with some studies reporting specificities of >95%. However, at least one study reported a specificity of 62%. Moreover, studies tended

not to present diagnostic accuracy rates separately for individuals without osteoporosis. Due to the variability in these results and the lack of stratified analyses, it is not possible to determine the sensitivity and specificity of VFA for vertebral fractures with certainty, either for patients as a whole or for the subset of patients without osteoporosis.

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

As stated above, (1) 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. The studies by Diacinti, described above, did not provide data on other potential risk factors in patients identified by VFA as having a vertebral fracture. Recent studies include Jager and colleagues' evaluation of 2,424 consecutive individuals (65% were female) referred for BMD for a variety of reasons at a single center in the Netherlands. (6) Participants underwent VFA 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 individuals with normal BMD and 21% (229/1,100) 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.

A 2011 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. (7) Women underwent DEXA and VFA 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 years, 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. (8) 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 body mass

index (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. (9) The study included 116 men with non-metastatic prostate cancer who had been taking androgen deprivation therapy (ADT) 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 1 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).

Conclusions: Routine use of VFA with DEXA will identify substantial numbers of individuals with previously unrecognized vertebral fractures. Many of these vertebral fractures are found in individuals without osteoporosis. Since screening for vertebral fractures is not currently part of the recommended workup for osteoporosis, it is not clear how to combine a positive result on VFA with other risk factors to make management decisions.

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 randomized controlled trials (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 4,432 women to alendronate or placebo and analyzed the treatment group in 3 BMD categories (less than a -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. (11) 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. (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 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.

Conclusions: 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 sub-analyses 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 e.g., 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.

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. Since direct evidence was not available, a causal chain of indirect evidence was examined. Evidence was examined on the diagnostic accuracy of VFA in non-osteoporotic patients, the ability of VFA to identify patients for treatment who would not otherwise be identified, and the effectiveness of treatment in this population. Recent studies suggest high diagnostic accuracy of VFA overall compared to standard x-rays; however, accuracy data in individuals without osteoporosis was not reported in these studies. Older studies found lower accuracy of VFA and some of these reported accuracy separately in lower-risk (i.e., non-osteoporotic) individuals. Because of the variability in these results, the true sensitivity and specificity of VFA cannot be determined, including for individuals without osteoporosis.

Studies have found that vertebral fracture assessment can identify individuals without osteoporosis who may be appropriate candidates for treatment according to recommendations from the National Osteoporosis Foundation. However, there is limited evidence on the effectiveness of treatment in this population. No 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 sub-analyses 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 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 (NOF): 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): Their 2007 position statement recommended vertebral fracture assessment for selected patients with the following criteria (15):

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)

A 2012 Task Force of the Endocrine Society recommended pharmacological 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 standard deviations (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-yr risk of experiencing any fracture ≥20% or 10-yr risk of hip fracture ≥3% 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 pharmacological doses (e.g., 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 (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 was not specifically mentioned. (18)

V. DEFINITIONS

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

DUAL X-RAY ABSORPTIOMETRY (DXA) is probably the most commonly used technique to measure BMD, because of its ease of use, low radiation exposure, and its ability to measure BMD at both the hip and spine. DXA generates two x-ray beams of different energy levels to scan the region of interest and measure the difference in attenuation as the low- and high-energy beams pass through the bone and soft tissue

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VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VII. DISCLAIMER

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

VIII. REFERENCES

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21. ***C**enters for Medicare and Medicaid Services (CMS) Medicare Benefit Policy Manual Publication 100-02. Chapter 15 Section 80,5 Effective 5/11/07 Bone Mass Measurements (BMMs) [Website]: http://www.cms.gov/transmittals/downloads/R70BP.pdf. Accessed August 5, 2013.*

22. *Centers for Medicare and Medicaid Services (CMS) Medicare Claims Processing Manual Publication 100-04 Chapter 13 Section 140 Effective 5/11/07 Bone Mass Measurements (BMMs) [Website]: http://www.cms.gov/transmittals/downloads/R1236CP.pdf. Accessed August 5, 2013.*

IX. CODING INFORMATION

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

Screening for vertebral fractures using dual x-ray absorptiometry (DEXA or DXA) is considered **investigational; therefore not covered:**

CPT Codes®								
77082								

X. Policy History

MP 5.046	**CAC 4/26/11** New Policy Adopt BCBSA. No previous policy statement related to this diagnostic testing.
	CAC 6/26/12 Consensus. No change to policy statement. References updated.
	7-29-13 Admin coding review complete--rsb
	CAC 9-24-13. Consensus. No change to policy statements. References updated. Rationale section added.

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APPENDIX

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/tool.jsp.

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)

POLICY TITLE	VERTEBRAL FRACTURE ASSESSMENT WITH DENSITOMETRY
POLICY NUMBER	MP-5.046

[Note: Final page is signature page and is kept on file, but not issued with Policy.]