BlueCross BlueShield of Alabama

Name of Policy:

Percutaneous Vertebroplasty~~, Kyphoplasty, Mechanical Vertebral Augmentation~~ and Sacroplasty

Policy #: 004
Category: Radiology/Surgical

Latest Review Date: April 2018
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *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 that patient's illness, injury or disease.*

Description of Procedure or Service:

Percutaneous vertebroplasty is an interventional technique involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) through a needle inserted into a weakened vertebral body. The technique has been investigated as an option to provide mechanical support and symptomatic relief in patients with osteoporotic vertebral compression fracture or in those with osteolytic lesions of the spine, i.e., multiple myeloma or metastatic malignancies. Percutaneous vertebroplasty has also been investigated as an adjunct to surgery for aggressive vertebral body hemangiomas, and as a technique to limit blood loss related to surgery.

Osteoporotic Fracture

Vertebral Compression Fracture

Osteoporotic compression fractures are common. It is estimated that up to one-half of women and approximately one-quarter of men will have a vertebral fracture at some point in their lives. However, only about one-third of vertebral fractures actually reach clinical diagnosis, and most symptomatic fractures will heal within a few weeks or 1 month. Nonetheless, some individuals with acute fractures will have severe pain and decreased function that interferes with ability to ambulate and is not responsive to usual medical management.

Treatment

Chronic symptoms do not tend to respond to the management strategies for acute pain such as bedrest, immobilization or bracing device, and analgesic medication, sometimes including narcotic analgesics. The source of chronic pain after vertebral compression fracture may not be from the vertebra itself but may be predominantly related to strain on muscles and ligaments secondary to kyphosis. This type of pain frequently does not improve with analgesics and may be better addressed through exercise. Improvements in pain and ability to function are the principal outcomes of interest for treatment of osteoporotic fractures.

Sacral Insufficiency Fractures

Sacral insufficiency fractures (SIFs) are the consequence of stress on weakened bone and often cause low back pain in the elderly population. Osteoporosis is the most common risk factor for SIF. Spontaneous fracture of the sacrum in patients with osteoporosis was described by Lourie in 1982 and presents as lower back and buttock pain with or without referred pain in the legs. Although common, SIFs can escape detection due to low provider suspicion and poor sensitivity on plain radiographs, slowing the application of appropriate intervention.

Treatment

Similar interventions are used for sacral and vertebral fractures and include bedrest, bracing, and analgesics. Initial clinical improvements may occur quickly; however, resolution of all symptoms may not occur for 9 to 12 months.

Vertebral/Sacral Body Metastasis

Metastatic malignant disease of the spine generally involves the vertebrae/sacrum, with pain being the most frequent complaint.

Treatment

While radiation and chemotherapy are frequently effective in reducing tumor burden and associated symptoms, pain relief may be delayed days to weeks, depending on tumor response. Further, these approaches rely on bone remodeling to regain strength in the vertebrae/sacrum, which may necessitate supportive bracing to minimize the risk of vertebral/sacral collapse during healing. Improvements in pain and function are the primary outcomes of interest for treatment of bone malignancy with percutaneous vertebroplasty or sacroplasty.

Percutaneous Vertebroplasty

Vertebroplasty is a surgical procedure that involves the injection of synthetic cement (e.g., polymethylmethacrylate [PMMA], bis-glycidal dimethacrylate [Cortoss]) into a fractured vertebra. It has been suggested that vertebroplasty may provide an analgesic effect through mechanical stabilization of a fractured or otherwise weakened vertebral body. However, other mechanisms of effect have been postulated, including thermal damage to intraosseous nerve fibers.

Percutaneous Sacroplasty

Percutaneous sacroplasty evolved from the treatment of insufficiency fractures in the thoracic and lumbar vertebrae with vertebroplasty. The procedure, essentially identical, entails guided injection of PMMA through a needle inserted into the fracture zone. While first described in 2000 as a treatment for symptomatic sacral metastatic lesions, it is most often described as a minimally invasive procedure employed as an alternative to conservative management for sacral insufficiency fractures (SIFs). SIFs are the consequence of stress on weakened bone and are often the cause of low back pain among the elderly population. Osteoporosis is the most common risk factor for SIF.

Pain and function are subjective outcomes and, thus, may be susceptible to placebo effects. Furthermore, the natural history of pain and disability associated with these conditions may vary. Therefore, controlled comparison studies would be valuable to demonstrate the clinical effectiveness of vertebroplasty and sacroplasty over and above any associated nonspecific or placebo effects and to demonstrate the effect of treatment compared with alternatives such as continued medical management.

In all clinical situations, adverse effects related to complications from vertebroplasty and sacroplasty are the primary harms to be considered. Principal safety concerns relate to the incidence and consequences of leakage of the injected PMMA or another injectate.

Vertebral Hemangiomas

Vertebral hemangiomas are relatively common lesions noted in up to 12% of the population based on autopsy series; however, only rarely do these lesions display aggressive features and produce neurologic compromise and/or pain. Treatment of aggressive vertebral hemangiomas has evolved from radiotherapy to surgical approaches using anterior spinal surgery for resection and decompression. There is the potential for large blood loss during surgical resection, and vascular embolization techniques have been used as adjuncts to treatment to reduce blood loss. Percutaneous vertebroplasty has been proposed as a way to treat and stabilize some hemangioma

to limit the extent of surgical resection and as an adjunct to reduce associated blood loss from the surgery.

Kyphoplasty and mechanical vertebral augmentation are addressed separately in medical policy, **#648-** ***Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty and Mechanical Vertebral Augmentation*****.**

Policy:

Percutaneous vertebroplasty meets Blue Cross and Blue Shield of Alabama's medical criteria for coverage for the treatment of **symptomatic osteoporotic vertebral fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy, and rest) for at least six (6) weeks.**

Percutaneous vertebroplasty meets Blue Cross and Blue Shield of Alabama's medical criteria for the **treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.**

Percutaneous vertebroplasty meets Blue Cross and Blue Shield of Alabama's medical criteria for the treatment of **vertebral hemangiomas with severe pain or nerve compression.**

Percutaneous vertebroplasty does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational for all other indications.**

Percutaneous sacroplasty does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage is considered **investigational** for all indications**, including use in sacral insufficiency fractures due to osteoporosis and spinal lesions due to metastatic malignancies or multiple myeloma.**

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature update for this policy was performed through February 22, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function- including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Percutaneous Vertebroplasty for Vertebral Compression Fractures between 6 Weeks and 1 Year Old

This evidence review was originally informed by a 2000 TEC Assessment, which was updated periodically through 2010. Subsequent evidence includes a number of RCTs, 2 of which included a sham control, and numerous RCTs that compared vertebroplasty with conservative management.

Systematic Reviews

A 2015 Cochrane review by Buchbinder et al evaluated the evidence on vertebroplasty for the treatment of vertebral compression fractures. Eleven RCTs and 1 quasi-RCT were included in the systematic review. Two trials identified compared vertebroplasty with a sham procedure (n=209 patients; Buchbinder et al and Kallmes et al detailed below), 6 compared vertebroplasty with usual care (n=566), and 4 compared vertebroplasty with kyphoplasty (n=545). The sham-controlled trials were considered to be at low risk of bias. All other trials were judged at high risk of bias due to lack of blinding. Evidence was rated as moderate quality based on the low number of subjects in the sham-controlled trials. Meta-analysis of the 2 sham-controlled trials indicated that vertebroplasty does not result in clinically significant improvements in pain, disability, quality of life, or treatment success. Results did not differ for patients with pain durations of 6 weeks or less compared to pain lasting more than 6 weeks. Sensitivity analysis indicated that studies comparing vertebroplasty to conservative management were likely to have overestimated the treatment effect. The rate of serious adverse events did not differ significantly between the vertebroplasty and control groups, but serious adverse events related specifically to the

vertebroplasty procedure included osteomyelitis, cord compression, thecal sac injury, and respiratory failure.

Staples et al conducted a patient-level meta-analysis of the 2 sham-controlled trials (described below) to determine whether vertebroplasty is more effective than sham in specific subsets of patients. This subset analysis focused on duration of pain (≤6 weeks vs >6 weeks) and severity of pain (score <8 or ≥8 on an 11-point numeric rating scale [NRS]). Included in the analysis were 209 participants (78 from the Australian trial, 131 from the U.S. trial); 27% had pain of recent onset and 47% had severe pain at baseline. The primary outcome measures (pain scores and function on the Roland-Morris Disability Questionnaire [RMDQ] at 1 month) did not differ significantly between groups. Responders' analyses were also conducted based on a 3-unit improvement in pain scores, a 3-unit improvement on RMDQ scores, and a 30% improvement in each of the pain and disability outcomes. The only difference observed between groups was a trend for a higher proportion of the vertebroplasty group to achieve at least 30% improvement in pain scores (relative risk, 1.32; 95% CI, 0.98 to 1.76; p=0.07), a result that may have been confounded by the greater use of opioid medications in that group.

Xie et al, in a meta-analysis of RCTs, evaluated efficacy and safety in percutaneous vertebroplasty and conservative treatment for patients with osteoporotic vertebral compression fractures. Thirteen studies were selected (total N=1231 patients; 623 to vertebroplasty, 608 to conservative treatment); among them were the two sham-controlled trials described below. Outcomes included pain relief (from 1 week to 6 months), quality of life assessments, and the rate of adjacent-level vertebral fracture. Vertebroplasty was superior for pain relief at 1 week (mean difference [MD], 1.36; 95% CI, 0.55 to 2.17) and 1 month (MD=1.56; 95% CI, 0.43 to 2.70); it was inferior to conservative treatment for pain relief at 6 months (MD = -1.59; 95% CI, -2.9 to -0.27; p<0.05). Vertebroplasty showed improvement over conservative treatment for quality of life, as measured using the Quality of Life Questionnaire of the European Foundation for Osteoporosis (MD = -5.03; 95% CI, 7.94 to -2.12). No statistically significant differences were found between treatments for the rate of adjacent-level vertebral fractures (relative risk: 0.59; 95% CI, 0.43 to 0.81). Limitations included the inclusion of several studies with inadequate blinding and heterogenous reporting of patient characteristics outcomes.

Randomized Controlled Trials

Vertebroplasty vs Medical Management with Sham Controls

Two sham-controlled trials were published in 2009 and were included in the systematic reviews described above. The 2 RCTs compared vertebroplasty to medical management using a sham control (that included local anesthetic), which mimicked the vertebroplasty procedure up to the point of cement injection. Buchbinder et al reported results of a 4-center, randomized, double-blind, sham-controlled trial with 78 patients with 1 or 2 painful osteoporotic vertebral fractures with a duration of less than 1 year. Patients were assigned to vertebroplasty or to sham procedure (i.e., injection of local anesthetic into the facet capsule and/or periosteum).17 Ninety-one percent of participants completed 6 months of follow-up. The participants, investigators (other than the radiologists performing the procedure), and outcome assessors were blinded to the treatment assignment. Blinding was maintained through 24-month follow-up of this trial.

The primary outcome was overall pain (over the course of the previous week) measured on a 0 to 10 VAS, with 1.5 representing the minimal clinically important difference. A sample size of 24 per group was calculated to provide 80% power with 2-sided α 0.05 to show a 2.5-point post-procedure difference assuming a three point standard deviation (SD). All analyses were performed according to intention-to-treat principles. Results are presented as difference from baseline. For the primary outcome of overall pain, the authors reported no significant difference in VAS pain score at 3, 12, or 24 months. With reductions in pain and improvements in quality of life observed in both groups, the authors concluded vertebroplasty provided no benefit.

Kallmes et al conducted a multicenter, randomized, double-blind, sham-controlled trial (INVEST) in which 131 participants with 1 to 3 painful osteoporotic vertebral fractures were assigned to undergo vertebroplasty or sham procedure (injection of local anesthetic into the facet capsule and/or periosteum). Participants had back pain for no more than 12 months and had a current pain rating of at least 3 on VAS at baseline. Participants were evaluated at baseline, then again at various time points to 1 year post-procedure. Ninety-seven percent completed a one month follow-up, and 95% completed three months. The primary outcomes were scores on the Roland-Morris Disability Questionnaire (RMDQ) and average back pain intensity during the preceding 24 hours at 1 month, with a reduction of 30% on the RMDQ and VAS pain considered a clinically meaningful difference. The study initially had 80% power to detect differences in both primary and secondary outcomes with 250 patients, with a 2-sided alpha of 0.05 on the basis of a 2.5-unit advantage for vertebroplasty over placebo on the RMDQ and 1.0 point difference on VAS. After recruitment difficulty and interim analysis on the first 90 participants, target sample size was decreased to 130 participants with 80% power for primary aims maintained. All primary analyses were performed according to intention-to-treat principles and results presented as mean score for the RMDQ and pain intensity.

For the primary endpoints at 1 month, there were no significant between group differences. There was a trend toward a higher clinically meaningful improvement in pain at 1 month (30% reduction from baseline) in the vertebroplasty group (64% vs. 48%, respectively; p=0.06). At 3 months, 43% from the control group vs. 12% in the vertebroplasty group crossed over ($p<0.001$). The crossovers did not affect study outcomes, as they occurred after the primary outcome assessment. However, significantly more participants in the control group chose to cross over than in the vertebroplasty group. By 1 year, 16% of patients who underwent vertebroplasty and 60% of control subjects had crossed over to the alternative procedure ($p<0.001$). As-treated analysis found no significant difference in RMDQ or pain scores between the 2 groups. ITT analysis found a modest 1-point difference in pain rating, but no significant difference in RMDQ. There was a significant difference in the percentage of patients showing a 30% or greater improvement in pain (70% of patients randomized to vertebroplasty vs 45% of patients randomized to the control group).

Vertebroplasty vs Medical Management without Sham Controls

Chen et al reported a nonblinded RCT of vertebroplasty compared with conservative management in 2014. The study included 89 patients with chronic compression fractures confirmed by magnetic resonance imaging (MRI) and persistent severe pain for three months or longer. Evaluation was performed at one week and at 1, 3, 6, and 12 months. Over the course of the year, pain scores decreased from 6.5 to 2.5 in the vertebroplasty group and from 6.4 to 4.1 in

the control group (p<0.001). Complete pain relief was reported by 84.8% of patients in the vertebroplasty group compared with 34.9% of controls. The final Oswestry Disability Index score was 15.0 in the vertebroplasty group and 32.1 in the conservative management group (p<0.001), and the final RMDQ score was 8.1 for vertebroplasty and 10.7 for controls (p<0.001).

In 2011, Farrokhi et al reported blinded RCT that compared vertebroplasty with optimal medical management in 82 patients. Patients had painful osteoporotic vertebral compression fractures that were refractory to analgesic therapy for at least 4 weeks and less than 1 year. The patients and the physicians involved in the treatment were not aware of the treatment that the other group was receiving. Control of pain and improvement in quality of life were measured by independent raters before treatment and at 1 week and 2, 6, 12, 24, and 36 months after treatment began. Radiologic evaluation to measure vertebral body height and correction of deformity was performed before and after treatment and after 36 months of follow-up. At 1 week, the mean VAS score decreased from 8.4 to 3.3 in the vertebroplasty group and from 7.2 to 6.4 in the conservative management group, with between-group differences that remained significant through 6 months of follow-up. Group differences on the ODI lower back pain score were significantly lower in the vertebroplasty group throughout the 36 months of the study. New symptomatic adjacent fractures developed in 1 (2.6%) patient in the vertebroplasty group and 6 (15.4%) patients in the conservative management group. In 1 patient, epidural cement leakage caused severe lower-extremity pain and weakness that was treated with bilateral laminectomy and evacuation of bone cement.

Nonrandomized Comparative Studies

In 2011 and 2015, Edidin et al reported mortality risk rates in Medicare patients who had vertebral compression fractures and had been treated with vertebroplasty, kyphoplasty or nonoperatively. These studies were industry-funded. In the 2015 report, they identified 1,038,956 patients who had vertebral compression fractures between 2005 and 2009. The data set included 141,343 kyphoplasty patients and 75,364 vertebroplasty patients. Survival was calculated from the index diagnosis date until death or the end of follow-up (up to 4 years). Propensity matching was used to control for multiple covariates, which included age, sex, race, census region, socioeconomic status, comorbidities in 12 months prior to diagnosis, type of fracture, and year of fracture. The matched cohort included 100,649 nonoperated patients, 36,657 kyphoplasty patients, and 24,313 vertebroplasty patients. Analysis of the whole data set before matching indicated that patients in the nonoperated cohort had a 55% (95% CI, 53% to 56%, p<0.001) higher risk of mortality than the kyphoplasty cohort and a 25% (95% CI, 23% to 26%, p<0.001) higher mortality risk than the vertebroplasty cohort. After propensity matching, the risk of mortality at 4 years was 47.2% in the nonoperated group compared to 42.3% in the kyphoplasty group (p<0.001) and 46.2% in the vertebroplasty group (p<0.001).

Lin et al reported on mortality risk in elderly patients (>70 years old) who had vertebral compression fractures and were treated with early vertebroplasty (within 3 months) or conservative therapy. The data set consisted of 10,785 Taiwanese patients who were selected through the National Health Insurance Research Database, of whom 1773 patients received vertebroplasty, and 5324 did not; a minority of these patients had osteoarthritis. Using conditional Cox proportional hazard modeling to determine the risk of death and respiratory-related issues, the authors found that a “significant difference in survival curves of mortality and

respiratory failure" existed between both groups of patients (p<0.05). The incidence of death at 1 year in the vertebroplasty group was 0.46 per 100 person-months (95% CI, 0.38 to 0.56). The incidence of death at 1 year in the non-vertebroplasty group was 0.63 per 100 person-months (95% CI, 0.57 to 0.70). With regard to respiratory failure, hazard ratio between groups was 1.46 (95% CI, 1.04 to 2.05; p=0.028). Limitations of this study included the broad selection of the population, which was not restricted only to patients with osteoporotic lesions. Also, authors were limited by the database, which did not report on pain or functional outcomes.

Section Summary: Percutaneous Vertebroplasty for Vertebral Compression Fractures between 6 Weeks and 1 year Old

Despite evidence from numerous RCTs, including 2 with sham controls, the efficacy of vertebroplasty for painful osteoporotic compression fractures of less than 1 year remains uncertain. Two meta-analysis studies are present, both of which include the 2 randomized, sham-controlled trials from 2009, but have mixed results. There remains some uncertainty related to the interpretation of these conclusions. While the use of a sham procedure is a major methodologic strength to control for nonspecific (placebo) effects, the sham used in the trial was not without controversy, given that the effect of injecting local anesthetic in the facet capsule and/or periosteum is unknown. Also, the appropriateness of outcome measures used to detect clinically meaningful differences in pain may not have been optimal, as the studies were underpowered to detect differences in clinical response rates. Questions have also been raised about the low percentage of patients screened who participated in the trial, the volume of polymethylmethacrylate (PMMA) injected, and the inclusion of patients with chronic pain.

Percutaneous Vertebroplasty for Vertebral Compression Fractures of Less than 6 Weeks Old

Randomized Controlled Trials

Vertebroplasty vs Medical Management with Sham Controls

In 2016, Clark et al reported on results from the VAPOUR trial (see Table 1). VAPOUR was a multicenter double-blind trial of vertebroplasty in 120 patients with vertebral fractures of less than 6 weeks in duration and back pain of at least 7 out of 10 on an NRS. Two authors had participated in the 2009 study published by Kallmes et al and the trial followed a similar protocol. Both outcomes assessors and patients were masked to treatment allocation, and independent statisticians unmasked the data and prepared the trial report. The sham-vertebroplasty procedure included subcutaneous lidocaine but no periosteal numbing. Manual skin pressure and tapping on the needle was performed to simulate the needle advance, and the investigators discussed PMMA mixing and injection during the procedure. The primary outcome (the percentage of patients with an NRS score <4 out of 10 at 14 days postprocedure) was met in a greater percentage of patients in the vertebroplasty group (44%) than in the sham control group (21%). This between-group difference was maintained through 6 months.

Table 1. Results From the Sham-Controlled Trial of Vertebroplasty by Clark et al (2016)[27]

Outcomes	Vertebroplasty		Sham		Difference (95% CI)	p
	N	n (%) or Mean (SD)	N	n (%) or Mean (SD)		
Proportion of patients with NRS score <4[a]						
14 days	55	24 (44%)	57	12 (21%)	23 (6 to 39)	0.011

6 months	51	35 (69%)	51	24 (47%)	22 (3 to 40)	0.027
Reduction in NRS pain score						
14 days	55	4.2 (2.7)	57	3.0 (3.0)	1.2 (0.1 to 2.3)	0.026
6 months	51	6.1 (3.3)	51	4.8 (3.1)	1.3 (0 to 2.6)	0.043
Reduction in RMDQ scores						
14 days	53	5.9 (5.8)	56	4.1 (6.3)	1.8 (-0.5 to 4.1)	0.121
6 months	49	11.7 (6.5)	51	7.4 (6.9)	4.2 (1.6 to 6.9)	0.002
VAS pain score (patient-reported)						
14 days	41	39 (28)	47	49 (28)	10 (-2 to 22)	0.096
6 months	42	23 (26)	46	34 (27)	11 (0 to 23)	0.050
VAS pain score (physician-observed)						
14 days	41	25 (23)	48	39 (29)	14 (3 to 26)	0.015
6 months	39	14 (21)	46	19 (20)	5 (-4 to 13)	0.301
QUALEFFO score						
14 days	48	49 (13)	54	55 (14)	6 (1 to 11)	0.029
6 months	46	38 (15)	48	45 (16)	7 (1 to 13)	0.032
EQ-5D score						
14 days	49	0.69 (0.10)	56	0.68 (0.11)	-0.01 (-0.06 to 0.03)	0.471
6 months	47	0.80 (0.11)	50	0.74 (0.12)	-0.06 (-0.10 to -0.01)	0.012
Analgesic use[b]						
14 days	56	49 (88%)	57	52 (91%)	4 (-8 to -15)	0.520
6 months	50	29 (58%)	51	39 (76%)	18 (1 to 36)	0.048

CI: confidence interval; EQ-5D; EuroQoL 5 dimensions questionnaire; NRS: Numeric rating scale pain; RMDQ: Roland-Morris Disability Questionnaire; QUALEFFO: Quality of life questionnaire of the European Foundation for Osteoporosis; VAS: visual analog scale.

[a] Primary end point.

[b] Proportion of patients using analgesic medication within the previous 24 hours.

Other outcome measures were significantly improved in the vertebroplasty group at 1 or both of the time points (see Table 1). The benefit of vertebroplasty was found predominantly in the thoracolumbar subgroup, with 48% (95% CI, 27% to 68%) more patients meeting the primary end point (61% in the vertebroplasty group vs 13% in the control group). The investigators commented that the thoracolumbar junction is subject to increased dynamic load, and fractures at this junction have the highest incidence of mobility. No benefit from vertebroplasty was found in the non-thoracolumbar subgroup. Postprocedural hospital stay was reduced from a mean of 14 days in the control group to 8.5 days after vertebroplasty, even though physicians who determined the discharge date remained blinded to treatment. In the vertebroplasty group, there were 2 serious adverse events due to sedation and transfer to the radiology table. In the control group, 2 patients developed spinal cord compression; 1 underwent decompressive surgery and the other, not a surgical candidate, became paraplegic.

Vertebroplasty vs Medical Management without Sham Controls

Klazen et al reported on VERTOS II, an open-label randomized trial of 202 patients at 6 hospitals in the Netherlands and Belgium. Of 431 patients eligible for randomization, 229 (53%) had spontaneous pain relief during assessment. Participants with at least 1 painful osteoporotic vertebral fracture of 6 weeks or less in duration were assigned to vertebroplasty or conservative management (i.e., bedrest, analgesia, cast, physical support). The primary outcome was pain relief of 3 points measured on a 10-point VAS at 1 month and 1 year. A sample size of 100 per group was calculated to provide sufficient power to show a 25% difference in pain relief. All

analyses were performed using ITT principles. Clinically significant pain relief was defined as a 30% change in VAS score (0-10 scale).

One hundred one subjects were enrolled into the treatment group and 101 into the control arm; 81% completed 12-month follow-up. There were no significant differences in the primary outcome (pain relief of 3 points) measured at 1 month and 1 year. Vertebroplasty resulted in greater pain relief than did medical management through 12 months (<0.001); there were significant between-group differences in mean VAS scores at 1 month (2.6; 1.74 to 3.37; p<0.001) and at 1 year (2.0; 1.13 to 2.80; p<0.001). Survival analysis showed significant pain relief was quicker (29.7 days vs 115.6 days) and was achieved by more patients after vertebroplasty than after conservative management.

Yi et al assessed the occurrence of new vertebral compression fractures after treatment with cement augmenting procedures (vertebroplasty or kyphoplasty) versus conservative treatment in an RCT with 290 patients (363 affected vertebrae). Surgically treated patients were discharged the next day. Patients treated conservatively (pain medication, bedrest, body brace, physical therapy) had a mean length of stay of 13.7 days. Return to usual activity occurred at 1 week for 87.6% of operatively treated patients and at 2 months for 59.2% of conservatively treated patients. All patients were evaluated with radiographs and MRI at 6 months and then at yearly intervals until the last follow-up session. At a mean follow-up of 49.4 months (range, 36-80 months), 10.7% of patients had experienced 42 new symptomatic vertebral compression fractures. There was no significant difference in the incidence of new vertebral fractures between the operative (18 total; 9 adjacent, 9 nonadjacent) and conservative (24 total; 5 adjacent, 16 nonadjacent, 3 same level) groups, but the mean time to a new fracture was significantly shorter in the operative group (9.7 months) than in the nonoperative group (22.4 months).

Leali et al published a short report on a multicenter RCT enrolling 400 patients with osteoporotic thoracic or lumbar vertebral compression fractures who were treated with vertebroplasty or conservative therapy. Fractures were treated within 2 weeks of pain onset. Details of randomization and rates of follow-up were not reported. At 1 day after treatment, the vertebroplasty group had a reduction in pain scores and improvement in physical function, with VAS pain scores decreasing from 4.8 (maximum, 5.0) to 2.3 (p=0.023) and ODI score improving from 53.6% to 31.7% (p=0.012). Sixty-five percent of patients treated with vertebroplasty had stopped all analgesic use within 48 hours. The conservatively group showed no benefit in the first 48 hours, but by 6 weeks VAS and ODI scores were described as similar in both groups (specific data not reported). Evaluation of this trial was limited by incomplete reporting.

Yang et al compared vertebroplasty to conservative therapy in 135 patients over 70 years of age with severe back pain due to an osteoporotic vertebral fracture after minor or mild trauma. Vertebroplasty was performed at a mean of 8.4 days after pain onset. Patients in the conservative therapy group were placed on bedrest and analgesics for at least 2 weeks after diagnosis, followed by bracing and assistive devices. All patients receiving vertebroplasty could stand and walk with a brace at 1 day posttreatment while only 12 (23.5%) patients could stand up and walk after 2 weeks of bedrest. The average duration of bedrest from pain onset was 7.8 (SD=4.7) days (range, 2-15 days) in the vertebroplasty group compared to 32.5 (SD=14.3) days (range, 14-60 days) in the conservative therapy group. At 1-year follow-up, there was a similar percentage of

additional compression fractures, but a significantly higher complication rate in the conservative therapy group (35.3%) than in to the vertebroplasty group (16.1%; p<0.001). Complications included pneumonia, urinary tract infection, deep vein thrombosis, depression, and sleep disorders.

Section Summary: Percutaneous Vertebroplasty for Vertebral Compression Fractures of Less Than 6 Weeks Old
In a sham-controlled randomized trial, where no anesthetic was injected into the periosteum, there was a significant benefit of vertebroplasty in patients who had severe pain of less than 6 weeks in duration following vertebral fracture at the thoracolumbar junction. Other RCTs without sham controls have reported that vertebroplasty is associated with significant improvements in pain, earlier improvements in function, and reductions in the duration of bedrest compared to conservatively managed patients.

Percutaneous Sacroplasty
Sacroplasty is an evolving technique with numerous methods (short axis, long axis, balloon-assisted short axis, and iliosacral screws). No randomized trials of sacroplasty have been reported. The largest prospective report is an observational cohort study of 52 consecutive patients undergoing sacroplasty for sacral insufficiency fractures using the short-axis technique. Patients had a mean age of 75.9 years and a mean duration of symptoms of 34.5 days (range: 4-89 days) and mean VAS score of 8.1 at baseline. Improvement on the VAS scale was measured at 30 minutes and 2, 4, 12, 24, and 52 weeks postprocedure. At each interval, statistically significant improvement over baseline was observed and maintained through 52 weeks.

The largest series is a retrospective multicenter analysis of 204 patients with painful sacral insufficiency fractures and 39 patients with symptomatic sacral lesions treated with either the short-axis or long-axis technique. One hundred and sixty-nine patients had bilateral sacral insufficiency fractures and 65 patients had additional fractures of the axial skeleton. VAS improved from 9.2 before treatment to 1.9 after treatment in patients with sacral insufficiency fractures, and from 9.0 to 2.6 in patients with sacral lesions. There was one case of radicular pain due to extravasation of cement requiring surgical decompression.

Frey et al reported on patients treated with percutaneous sacroplasty, particularly the long-term efficacy of sacroplasty vs nonsurgical management. This prospective, observational cohort study spanned ten years and comprised 240 patients with sacral insufficiency fractures. Thirty-four patients were treated with nonsurgical methods, and 210 patients were treated with sacroplasty. Pain, as measured by VAS, was recorded before treatment and at several follow-ups. Mean pretreatment VAS for the sacroplasty group was 8.29; for the nonsurgical treatment group, it was 7.47. Both forms of treatment resulted in significant VAS improvement from pretreatment to the 2-year follow-up (p<0.001). However, the sacroplasty treatment group experienced significant VAS score improvement consistently at many of the follow-up points (pretreatment to post [p<0.001]; posttreatment through 2 weeks [p>0.001]; 12 weeks through 24 weeks [p=0.014]; 24 weeks through 1 year [p=0.002]). Meanwhile, the group with nonsurgical treatment only experienced one significant pain improvement score—at the 2-week follow-up posttreatment (p=0.002). One major limitation of this study was that the nonsurgical treatment group was not followed up with at the 10-year mark whereas the sacroplasty group did receive follow-up.

There are several retrospective reviews with about 50 patients each. One of these described a series of 57 patients treated with sacroplasty under computed tomography (CT) guidance for sacral insufficiency fractures. The short- or long-axis approach was dictated by the length and type of the fracture and patient anatomy. Follow-up data at 2.5 weeks was available for 45 patients (79%), and the outcome measures were inconsistent. For example, activity pain scores were collected from 13 patients, and rest pain scores were collected from 29 patients. Of the 45 patients with outcome data, 37 (82%) were reported to have experienced either a numerical or descriptive decrease from initial pain of at least 30%.

There are complications related to cement leakage with sacroplasty that are not observed with vertebroplasty. Leakage of PMMA into the presacral space, spinal canal, sacral foramen, or sacroiliac joint may result in pelvic injection of PMMA, sacral nerve root or sacral spinal canal compromise, or sacroiliac joint dysfunction. Performing sacroplasty only on zone 1 fractures can minimize these risks.

Section Summary: Percutaneous Sacroplasty
No RCTs on percutaneous sacroplasty for sacral insufficiency were identified. The available evidence includes two prospective cohort studies with 52 patients and a retrospective series with 243 patients. These studies have reported rapid and sustained decreases in pain following percutaneous sacroplasty. Additional reports are mostly consistent in reporting immediate improvement following the procedure. Due to the small size of the evidence base, harms associated with sacroplasty have not been adequately studied. The small numbers of treated patients leave uncertainty regarding the impact of sacroplasty on health outcomes.

Vertebral Hemangiomas
For symptomatic vertebral body hemangioma with aggressive features, no studies reported pre- and post-procedure pain evaluations. Therefore, the findings of all studies that reported more than a single case (six studies, totaling 64 patients) were evaluated. The studies using percutaneous cementoplasty as an adjunct to surgical treatment suggest that the use of percutaneous cementoplasty to treat the vertebral body component of the vascular lesion may contribute to avoiding the substantial blood loss that has been historically described with primary surgical resection (curettage). However, the additional use of other procedures in these studies may make it difficult to attribute the lower blood loss to this procedure. These studies do not provide controlled comparisons of the morbidity of treating hemangiomas with percutaneous cementoplasty as an adjunct to surgery and the morbidity of surgical treatment without cementoplasty.

Cement leakage, although reduced in kyphoplasty relative to vertebroplasty, remains a concern. There continue to be case reports of right ventricle perforation, cardiac tamponade, and embolism of cement into pulmonary vessels.

Summary of Evidence
For individuals who have symptomatic osteoporotic vertebral fractures of between 6 weeks and 1 year old who receive vertebroplasty, the evidence includes 2 randomized sham-controlled trials, nonblinded randomized controlled trials (RCTs) comparing vertebroplasty with conservative

management, and systematic reviews of these RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, hospitalizations, medication use, and treatment-related morbidity. Despite the completion of numerous RCTs, including 2 with sham controls, the efficacy of vertebroplasty for painful osteoporotic compression fractures remains uncertain. Two meta-analysis studies which included the 2 sham-controlled trials have demonstrated mixed results. The 2 studies had methodologic issues, including the choice of sham procedure and the potential effect of the sham procedure having a therapeutic effect by reducing pain. Questions have also been raised about the low percentage of patients screened who participated in the trial, the volume of polymethylmethacrylate injected, and the inclusion of patients with chronic pain. Overall, conclusions about the effect of vertebroplasty remain unclear. However, clinical input in 2008 provided uniform support for the use of vertebroplasty in painful osteoporotic fractures. After consideration of the available evidence and input, the consistent results of numerous case series, including large prospective reports, were sufficient to determine that vertebroplasty was a reasonable treatment option in patients with vertebral fractures who have failed to respond to conservative treatment (at least 6 weeks with analgesics, physical therapy, and rest). It is also clinically reasonable to consider the evidence supporting the clinical benefit of vertebroplasty in osteoporotic vertebral fracture to support its use in osteolytic lesions of the spine (e.g., multiple myeloma, metastatic malignancies).

For individuals with symptomatic osteoporotic vertebral fractures less than 6 weeks old who receive vertebroplasty, the evidence includes a randomized sham-controlled trial and other nonblinded RCTs comparing vertebroplasty with conservative management. Relevant outcomes are symptoms, functional outcomes, quality of life, hospitalizations, medication use, and treatment-related morbidity. For acute fractures, conservative therapy consisting of rest, analgesics, and physical therapy is an option, and symptoms will resolve in a large percentage of patients with conservative treatment only. However, a sham-controlled randomized trial in patients who had severe pain of less than 6 weeks in duration found a significant benefit of vertebroplasty for the treatment of osteoporotic vertebral fracture at the thoracolumbar junction. Other RCTs without sham controls have reported that vertebroplasty is associated with significant improvements in pain and reductions in the duration of bedrest. Given the high morbidity associated with extended bedrest in older adults, this procedure is considered to have a significant health benefit. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with sacral insufficiency fractures who receive sacroplasty, the evidence includes a prospective cohort study and a case series. Relevant outcomes are symptoms, functional outcomes, quality of life, hospitalizations, medication use, and treatment-related morbidity. No RCTs have been reported. The available evidence includes a prospective cohort study and a retrospective series with 243 patients. These studies have reported rapid and sustained decreases in pain following percutaneous sacroplasty. Additional literature has mostly reported immediate improvements following the procedure. However, due to the small size of the evidence base, the harms associated with sacroplasty have not been adequately studied. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

American College of Radiology et al

The American College of Radiology and 4 other medical specialty associations updated a 2012 joint position statement on percutaneous vertebral augmentation in 2014. The statement indicated that percutaneous vertebral augmentation with the use of vertebroplasty or kyphoplasty is a safe, efficacious, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures, when performed in accordance with public standards. The document also stated that these procedures are offered only when nonoperative medical therapy has not provided adequate pain relief, or pain is significantly altering patients' quality of life.

Society for Interventional Radiology

In a 2014 quality improvement guideline from SIR, failure of medical therapy is defined as follows:

1. A patient rendered nonambulatory as a result of pain from a weakened or fractured vertebral body, pain persisting at a level that prevents ambulation despite 24 hours of analgesic therapy;
2. A patient with sufficient pain from a weakened or fractured vertebral body that physical therapy is intolerable, pain persisting at that level despite 24 hours of analgesic therapy; or
3. Any patient with a weakened or fractured vertebral body, unacceptable side effects such as excessive sedation, confusion, or constipation as a result of the analgesic therapy necessary to reduce pain to a tolerable level.

American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons (AAOS) approved practice guidelines (2010) on the treatment of osteoporotic spinal compression fractures. AAOS approved a strong recommendation against the use of vertebroplasty for patients who "present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact." With this recommendation, AAOS expressed its confidence that future evidence is unlikely to overturn the existing evidence. These recommendations were based on a literature review through September 2009; therefore, the 2010 Klazen trial was not considered.

National Institute for Health and Care Excellence

The U.K.'s National Institute for Health and Care Excellence (NICE) concluded in its 2003 guidance on percutaneous vertebroplasty that the current evidence on the safety and efficacy of vertebroplasty for vertebral compression fractures appeared "adequate to support the use of this procedure" to "provide pain relief for people with severe painful osteoporosis with loss of height and/or compression fractures of the vertebral body…."The guidance also recommended that the procedure be limited to patients whose pain is refractory to more conservative treatment. A 2013 NICE guidance indicated that percutaneous vertebroplasty and percutaneous balloon kyphoplasty "are recommended as options for treating osteoporotic vertebral compression fractures" in persons having "severe, ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management" and whose "pain has been confirmed o be at the level of the fracture by physical examination and imaging."

In 2008, NICE issued guidance on the diagnosis and management of adults with metastatic spinal cord compression. This guidance indicated that vertebroplasty or kyphoplasty should be considered for "patients who have vertebral metastases and no evidence of MSCC [metastatic spinal cord compression] or spinal instability if they have: mechanical pain resistant to conventional pain management, or vertebral body collapse."

U.S Preventive Services Task Force Recommendations
Not applicable.

Key Words:

Percutaneous vertebroplasty, vertebroplasty, polymethylmethacrylate, PMMA, osteoporosis, vertebral body compression fracture, vertebral fracture, vertebral compression fracture, PV, VCF, optiplasty, OptiMesh, Arcuate XP device, Arcuplasty, ARCUATE™ Vertebral Augmentation System, sacroplasty, Cortoss Bone Augmentation Material, Osteopal, SpineFix, Parallax Contour Vertebral Augmentation device

Approved by Governing Bodies:

Vertebroplasty is a surgical procedure and, as such, is not subject to U.S. Food and Drug Administration (FDA) approval.

Polymethylmethacrylate (PMMA) bone cement was available as a drug product before enactment of FDA's device regulation and was at first considered what FDA terms a "transitional device." It was transitioned to a class III device requiring premarketing applications. Several orthopedic companies have received approval of their bone cement products since 1976. In October 1999, PMMA was reclassified from class III to class II, which requires future 510(k) submissions to meet "special controls" instead of "general controls" to assure safety and effectiveness. Thus, use of PMMA in vertebroplasty represented an off-label use of an FDA-regulated product before 2005. In 2005, PMMA bone cements such as Spine-Fix® Biomimetic Bone Cement and Osteopal® V were issued 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty procedures.

The use of PMMA in sacroplasty represents an off-label use of an FDA-regulated product (bone cements such as Spine-Fix® Biomimetic Bone Cement [Teknimed] and Osteopal® V [Heraeus]), as the 510(k) marketing clearance was for the fixation of pathologic fractures of the vertebral body using vertebroplasty procedures. Sacroplasty was not included.

In May 2009, Cortoss® (Stryker) Bone Augmentation Material was cleared for marketing by FDA through the 510(k) process. Cortoss® is a nonresorbable synthetic material that is a composite resin-based, bis-glycidyl dimethacrylate. FDA classifies this product as a PMMA bone cement.

In February 2010, the Parallax® Contour® Vertebral Augmentation Device (ArthroCare) was cleared for marketing by FDA through the 510(k) process. The device creates a void in cancellous bone that can then be filled with bone cement.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT Codes:	**01936**	Anesthesia for percutaneous image guided procedures on the spine and spinal cord; therapeutic
	0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, one or more needles, includes imaging guidance and bone biopsy, when performed
	0201T	; two or more needles includes imaging guidance and bone biopsy, when performed
	22510	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic **(Effective 01/01/15)**
	22511	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral **(Effective 01/01/15)**
	22512	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body (List separately in addition to code for primary procedure) **(Effective 01/01/15)**
	64999	Unlisted procedure, nervous system

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Policy History:

Medical Policy Group, November 1999
Medical Review Committee, January 2000
TEC Review, April 2000
Medical Policy Group, January 2001
Medical Review Committee, March 2001
TEC Review, May 2001
Medical Policy Group, February 2002 **(2)**
Medical Review Committee, March 2002
Available for Comment April 15-May 29, 2002
Medical Policy Group, June 2003 **(2)**

Medical Review Committee, June 2003
Medical Review Committee, July 2003
Medical Policy Administration Committee, July 2003
Available for comment July 28-September 10, 2003
Medical Policy Group, August 2003 **(2)**
Medical Review Committee, September 2003
Medical Policy Administration Committee, October 2003
Available for comment October 7-November 20, 2003
Medical Policy Group, October 2005 **(2)**
Medical Policy Administration Committee, November 2005
Available for comment November 30, 2005-January 13, 2006
Medical Policy Group, July 2006 **(1)**
Medical Policy Administration Committee, July 2006
Available for comment July 18-August 31, 2006
Medical Policy Group, January 2007 **(2)**
Medical Policy Group, June 2007 **(2)**
Medical Policy Group, July 2007 **(2)**
Medical Policy Administration Committee, July 2007
Available for comments July 16-September 3, 2007
Medical Policy Group, March 2008 **(2)**
Medical Policy Administration Committee, April 2008
Available for comment April 4-May 18, 2008
Medical Policy Group, May 2008 **(2)**
Medical Policy Administration Committee, June 2008
Available for comment June 11-July 26, 2008
Medical Policy Group, June 2009 **(2)**
Medical Policy Administration Committee, July 2009
Available for comment July 1-August 14, 2009
Medical Policy Panel, February 2010
Medical Policy Group, March 2010 **(2)**
Medical Policy Administration Committee, April 2010
Available for comment April 12-May 26, 2010
Medical Policy Panel, February 2011
Medical Policy Group, June 2011 **(2):** Key Points and Reference Updated
Medical Policy Group, December 2011 **(3):** Updated verbiage on CPT 22520 & 22521 for 2012 code update.
Medical Policy Panel, April 2013
Medical Policy Group, August 2013 **(2):** Title change to include Mechanical Vertebral Augmentation. Policy statement added that all other percutaneous mechanical vertebral augmentation devices, including but not limited to Kiva are investigational. Description, Key Points, Approved by Governing Bodies, Key Words, and Reference updated to support new policy statement and literature search.
Medical Policy Administration Committee, September 2013
Available for comment September 19 through November 2, 2013
Medical Policy Group, March 2014 **(2):** Corrected policy statement with addition of coverage for vertebral hemangiomas with severe pain or nerve compression.

Medical Policy Group, March 2014 **(5):** Added ICD-9 and ICD-10-CM diagnosis under Coding; no change to policy statement.
Medical Policy Panel, July 2014
Medical Policy Group, July 2014 **(3):** 2014 Updates to Key Points, Governing Bodies & References; no change in policy statements; removed policy statements for 2010 & prior years
Medical Policy Group, November 2014 **(3):** 2015 Annual Coding update; added CPT codes 22510-22515 and moved previous codes 22520-22525 and 72291-72292; changed verbiage on 0200T & 0201T by adding 'includes imaging guidance and bone biopsy, when performed.
Medical Policy Panel, April 2015
Medical Policy Group, May 2015 (**2**): 2015 Updates to Description, Key Points, Current Coding, and References; no change to policy statement.
Medical Policy Group, November 2015: 2016 Annual Coding Update; Moved HCPCS codes S2360 and S2361 from current coding to previous coding.
Medical Policy Panel, November 2016
Medical Policy Group, November 2016 **(7)**: 2016 Updates to Key Points, Coding- Removed previous codes deleted in 2006 and ICD-9 and ICD-10-CM diagnosis under Coding Section. No change to policy statement.
Medical Policy Panel, April 2018
Medical Policy Group, April 2018 **(7)**: 2018 Updates to Title, Description, Key Points, Key Words, Approved by Governing Bodies and References; removed all aspects of kyphoplasty and mechanical augmentation, now in separate policy, #648. Policy Statement clarified- removed "including use in acute vertebral fractures due to osteoporosis or trauma". No change in intent.
Medical Review Committee, May 2018
