Medical Policy

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Title: Percutaneous Vertebroplasty and Sacroplasty

Professional
Original Effective Date: October 18, 2004
Revision Date(s): April 21, 2005; September 7, 2005; December 14, 2005; February 21, 2006; May 9, 2006; July 27, 2006; September 14, 2006; October 31, 2006; January 1, 2007 July 23, 2009; January 1, 2012; October 4, 2013; December 31, 2013; January 1, 2015; October 21, 2015; January 1, 2016; January 19, 2018; May 23, 2018; August 1, 2018
Current Effective Date: January 19, 2018

Institutional
Original Effective Date: July 1, 2005
Revision Date(s): September 7, 2005; December 14, 2005; February 21, 2006; May 9, 2006; July 27, 2006; September 14, 2006; October 31, 2006; January 1, 2007; July 23, 2009; January 1, 2012; October 4, 2013; December 31, 2013; January 1, 2015; October 21, 2015; January 1, 2016; January 19, 2018; May 23, 2018; August 1, 2018
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Populations	Interventions	Comparators	Outcomes
Individuals: • With symptomatic osteoporotic vertebral fractures between 6 weeks and 1 year old	Interventions of interest are: • Vertebroplasty	Comparators of interest are: • Conservative management	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Hospitalizations • Medication use • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: • With symptomatic osteoporotic vertebral fractures less than 6 weeks old	Interventions of interest are: • Vertebroplasty	Comparators of interest are: • Conservative management	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Hospitalizations • Medication use • Treatment-related morbidity
Individuals: • With sacral insufficiency fractures	Interventions of interest are: • Sacroplasty	Comparators of interest are: • Conservative management	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Hospitalizations • Medication use • Treatment-related morbidity

DESCRIPTION

Percutaneous vertebroplasty is an interventional technique involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) into a weakened vertebral body. The technique has been investigated to provide mechanical support and symptomatic relief in patients with osteoporotic vertebral compression fractures or in those with osteolytic lesions of the spine (eg, multiple myeloma or metastatic malignancies). Percutaneous vertebroplasty has also been investigated as a technique to limit blood loss related to surgery. Injection of PMMA is also being investigated as a treatment of sacral insufficiency fractures.

OBJECTIVE

The objective of this policy is to evaluate whether vertebroplasty or sacroplasty improves the net health outcome in individuals with osteoporotic vertebral compression fractures or sacral insufficiency fractures.

BACKGROUND

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. In addition, a minority of patients will exhibit chronic pain following osteoporotic compression fracture that presents challenges for 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.[1,2] 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.[1,3]

Vertebral and 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.

Surgical Treatment Options

Percutaneous Vertebroplasty: Vertebroplasty is a surgical procedure that involves the injection of synthetic cement (eg, polymethylmethacrylate [PMMA], bis-glycidal dimethacrylate [Cortoss][4]) 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: Sacroplasty evolved from the treatment of insufficiency fractures in the thoracic and lumbar vertebrae with vertebroplasty. The procedure, essentially identical to vertebroplasty, entails guided injection of polymethylmethacrylate (PMMA) through a needle inserted into the fracture zone. While first described in 2000 as a

treatment for symptomatic sacral metastatic lesions,[5,6] it is most often described as a minimally invasive alternative to conservative management[7-9] for SIFs.

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 other injectate[4].

REGULATORY STATUS

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

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 or kyphoplasty 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 and Osteopal® V), as the 510(k) marketing clearance was for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Sacroplasty was not included. FDA product code: NDN.

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-glycidal 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. FDA product code: HXG.

POLICY

A. Percutaneous vertebroplasty may be considered **medically necessary** for:

1. The treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies; **OR**

2. The treatment of symptomatic osteoporotic vertebral fractures that have failed to respond to conservative treatment (eg, rest, analgesics, physical therapy) for at least 6 weeks; **OR**

3. The treatment of symptomatic osteoporotic vertebral fractures that are less than 6 weeks in duration that have led to hospitalization or persists at a level that prevents ambulation.

B. Percutaneous vertebroplasty is considered **experimental / investigational** for all other indications, including use in acute vertebral fractures due to trauma.

C. Percutaneous sacroplasty is considered **experimental / investigational** for all indications, including use in sacral insufficiency fractures due to osteoporosis and spinal lesions due to metastatic malignancies or multiple myeloma.

RATIONALE

The most recent literature review was performed through February 22, 2018. Following is a summary of key studies to date.

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 of Between 6 Weeks and 1 Year Old

This evidence review was informed by a TEC Assessment (2000), which was updated periodically through 2010.[10-15] Subsequent evidence includes a number of RCTs, two of which included a sham control, and numerous RCTs that compared vertebroplasty with conservative management.

Systematic Reviews

A Cochrane review by Buchbinder et al (2015) evaluated the evidence on vertebroplasty for the treatment of vertebral compression fractures.[16] Eleven RCTs and a quasi-RCT were included. Two trials identified compared vertebroplasty with a sham procedure (n=209 patients; Buchbinder et al [2009][17] and Kallmes et al [2009],[18] detailed below), six compared vertebroplasty with usual care (n=566), and four 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 did not result in clinically significant improvements in pain, disability, quality of life, or treatment success. Results did not differ for patients who had pain durations of 6 weeks or less compared with pain lasting more than 6 weeks. Sensitivity analysis indicated that studies comparing vertebroplasty with 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 (2011) 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.[19] 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. Responder analyses were also conducted based on a 3-unit improvement in pain scores, a 3-unit improvement in 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% confidence interval [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 (2017), in a meta-analysis of RCTs, evaluated efficacy and safety in percutaneous vertebroplasty and conservative treatment for patients with osteoporotic vertebral compression fractures.[20] 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 published in 2009 were included in the systematic reviews described above. The 2 RCTs compared vertebroplasty with medical management using a sham control (that included local anesthetic), which mimicked the vertebroplasty procedure up to the point of cement injection.[17,18] Buchbinder et al reported on results for 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.[17] Patients were assigned to vertebroplasty or sham procedure (ie, injection of local anesthetic into the facet capsule and/or periosteum). 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.[21]

The primary outcome was overall pain (over the course of the previous week) measured on a visual analog scale (VAS) from 0 to 10, with 1.5 points representing the minimal clinically important difference. A sample size of 24 per group was calculated to provide sufficient power to show a 2.5-point postprocedure difference assuming a 3-point standard deviation. All analyses were performed using intention-to-treat (ITT) principles. For the primary outcome, reviewers reported no significant differences 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 (2009) 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 vertebroplasty or sham procedure (injection of local anesthetic into the facet capsule and/or periosteum).[18] 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, and at various time points to 1 year postprocedure. Ninety-seven percent completed a 1-month follow-up, and 95% completed 3 months. The primary outcomes were RMDQ scores and average back pain intensity during the preceding 24 hours at 1 month, with a reduction of 30% in RMDQ and VAS pain scores considered a clinically meaningful difference.[22] The trial initially had 80% power to detect differences in both primary and secondary outcomes with 250 patients, with a 2.5-unit advantage for vertebroplasty over placebo on the RMDQ and 1.0-point difference on the VAS. After recruitment difficulty and interim analysis on the first 90 participants, the target sample size was decreased to 130 participants with 80% power for primary aims maintained. All primary analyses were performed using ITT principles and results presented as mean scores for the RMDQ and pain intensity.

For the primary end points 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, 51% from the control group and 13% in the vertebroplasty group crossed over ($p<0.001$). The crossovers did not affect trial outcomes because they occurred after the primary outcome assessment. By 1 year, 16% of patients who underwent vertebroplasty and 60% of control subjects had crossed over to the alternative procedure ($p<0.001$).[23] The 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 and no significant difference in RMDQ score. 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 (2014) reported on a nonblinded RCT comparing vertebroplasty with conservative management.[24] The trial included 89 patients with chronic compression fractures confirmed by magnetic resonance imaging and persistent severe pain for 3 months or longer. The evaluation was performed at 1 week and 1, 3, 6, and 12 months. Over the course of 1 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 and 34.9% of controls. The final Oswestry Disability Index (ODI) 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 ($p<0.001$).

Farrokhi et al (2011) reported on a blinded RCT that compared vertebroplasty with optimal medical management in 82 patients.[25] 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 group were not aware of the treatment 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 statistically 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

Edidin et al (2011, 2015) reported on mortality risk rates in Medicare patients who had vertebral compression fractures and were treated with vertebroplasty, kyphoplasty, or nonoperatively.[26,27] 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 dataset 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 before 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 with 42.3% in the kyphoplasty group ($p<0.001$) and 46.2% in the vertebroplasty group ($p<0.001$).

Lin et al (2017) 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.[28] 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 nonvertebroplasty 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 of Between 6 Weeks and 1 Year Old

Despite evidence from numerous RCTs, including two 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 is controversial, 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 might not have been optimal, because 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

Clark et al (2016) reported on results from the VAPOUR trial (see Table 1).[29] 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. This trial followed a similar protocol as that used in the Kallmes trial (discussed above). 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

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

Adapted from Clark et al (2016).[29]
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 one 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 nonthoracolumbar 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; one underwent decompressive surgery and the other, not a surgical candidate, became paraplegic.

Vertebroplasty vs Medical Management Without Sham Controls

Klazen et al (2010) reported on VERTOS II, an open-label randomized trial of 202 patients at 6 hospitals in the Netherlands and Belgium.[30] 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 (ie, 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 in the treatment group and 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) or 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 (2014) assessed the occurrence of new vertebral compression fractures after treatment with cement augmenting procedures (vertebroplasty or kyphoplasty) vs conservative treatment in an RCT with 290 patients (363 affected vertebrae).[31] 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 2 months for 59.2% of conservatively treated patients. All patients were evaluated with radiographs and magnetic resonance imaging 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 (2016) published a brief report on a multicenter RCT enrolling 400 patients with osteoporotic thoracic or lumbar vertebral compression fractures who were treated with vertebroplasty or conservative therapy.[32] 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 scores 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 managed 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 (2016) compared vertebroplasty with 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.[33] 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 days (range, 2-15 days) in the vertebroplasty group compared with 32.5 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 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 fewer 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 with conservatively managed patients.

Percutaneous Sacroplasty

Sacroplasty is an evolving technique achieved using numerous methods (short-axis, long-axis, balloon-assisted short-axis, iliosacral screws). No randomized trials of sacroplasty were identified. The largest prospective report is an observational cohort study by Frey et al (2008) who assessed 52 consecutive patients undergoing sacroplasty for sacral insufficiency fractures using the short-axis technique.[34] Patients had a mean age of 75.9 years, mean duration of symptoms of 34.5 days (range, 4-89 days), and mean VAS score of 8.1 at baseline. Improvements in VAS scores were measured at 30 minutes and 2, 4, 12, 24, and 52 weeks postprocedure. At each interval, statistically significant improvements over baseline were observed and maintained through 52 weeks.

The largest series identified is a retrospective multicenter analysis by Kortman et al (2013) who evaluated 204 patients with painful sacral insufficiency fractures and 39 patients with symptomatic sacral lesions treated with the short-axis or long-axis technique.[35] One hundred sixty-nine patients had bilateral sacral insufficiency fractures, and 65 patients had additional fractures of the axial skeleton. VAS scores 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 1 case of radicular pain due to extravasation of cement requiring surgical decompression.

Frey et al (2017) reported on patients treated with percutaneous sacroplasty, particularly the long-term efficacy of sacroplasty vs nonsurgical management.[36] 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 reported by Dougherty et al (2014) described a series of 57 patients treated with sacroplasty for sacral insufficiency fractures.[37] The short- or the long-axis approach was dictated by the length and type of the fracture and patient anatomy. Follow-up data at 2.5 weeks were available for 45 (79%) patients, 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 outcomes data, 37 (82%) had experienced a numeric or descriptive decrease from initial pain of at least 30%.

Adverse Events

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.[38] Performing sacroplasty only on zone 1 fractures can minimize these risks.[39]

Section Summary: Percutaneous Sacroplasty

No RCTs evaluating percutaneous sacroplasty for sacral insufficiency were identified. The available evidence includes two prospective cohort studies and a retrospective series. 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 sample 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.

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 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 of the sham procedure to have 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

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 fewer 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 2 prospective cohort studies 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 of 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.

CLINICAL INPUT RECEIVED FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS

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

2014 Input

In response to requests, input was received from 2 physician specialty societies and 3 academic medical centers while this policy was under review in 2014. Focused input was sought on the treatment of acute vertebral fractures when there is severe pain that has led to hospitalization or persists at a level that prevents ambulation, and on the treatment of traumatic fractures that have remained symptomatic after 6 weeks of conservative treatment. Clinical input on these issues was mixed.

2008 Input

In response to requests, input was received from 5 physician specialty societies and 2 academic medical centers while this policy was under review in 2008. Unsolicited input was received from a sixth physician specialty society. All reviewers disagreed with the proposed policy and provided references in support of the use of vertebroplasty.

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.[40] 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 was defined as follows[41]:

1. "For 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. For 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. For 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

In 2010, the American Academy of Orthopaedic Surgeons (AAOS) approved practice guidelines on the treatment of osteoporotic spinal compression fractures.[42] 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. As a note, these recommendations were based on a literature review through September 2009; therefore, the 2010 Klazen trial was not included in the systematic review.

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…."[43] 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."[44]

In 2008, NICE issued guidance on the diagnosis and management of adults with metastatic spinal cord compression.[45] 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.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Ongoing trials that might influence this policy are listed in Table 2.

Table 2. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT02370628	Vertebroplasty in the treatment of acute fracture trial (The VITTA Trial)	495	Apr 2018
NCT02902250	The Comparative Study About the Effect of Vertebral Body Decompression Procedure and Conservative Treatment for Benign Vertebral Compression Fracture - Prospective Randomized Control Study	80	Apr 2018
NCT02489825	Pilot Study: Does Preventive Adjacent Level Cement Augmentation Positively Affect Reoperation Rates After Osteoporotic Vertebral Compression Fractures?	100	Dec 2018

NCT: national clinical trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

22510	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic
22511	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral
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)
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed

ICD-10 Diagnoses

C41.2	Malignant neoplasm of vertebral column
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
D18.09	Hemangioma of other sites
D47.Z9	Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
M48.50XA	Collapsed vertebra, not elsewhere classified, site unspecified, initial encounter for fracture

M48.51XA	Collapsed vertebra, not elsewhere classified, occipito-atlanto-axial region, initial encounter for fracture
M48.52XA	Collapsed vertebra, not elsewhere classified, cervical region, initial encounter for fracture
M48.53XA	Collapsed vertebra, not elsewhere classified, cervicothoracic region, initial encounter for fracture
M48.54XA	Collapsed vertebra, not elsewhere classified, thoracic region, initial encounter for fracture
M48.55XA	Collapsed vertebra, not elsewhere classified, thoracolumbar region, initial encounter for fracture
M48.56XA	Collapsed vertebra, not elsewhere classified, lumbar region, initial encounter for fracture
M48.57XA	Collapsed vertebra, not elsewhere classified, lumbosacral region, initial encounter for fracture
M48.58XA	Collapsed vertebra, not elsewhere classified, sacral and sacrococcygeal region, initial encounter for fracture
M80.08XA	Age-related osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M80.88XA	Other osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M81.0	Age-related osteoporosis without current pathological fracture
M81.8	Other osteoporosis without current pathological fracture
M84.48XA	Pathological fracture, other site, initial encounter for fracture
M84.58XA	Pathological fracture in neoplastic disease, vertebrae, initial encounter for fracture
M84.68XA	Pathological fracture in other disease, other site, initial encounter for fracture

REVISIONS

04-21-2005	Added "or kyphoplasty" to policy #C.
12-14-2005	In "Policy" section, #C., added 'and cervical percutaneous vertebroplasty and kyphoplasty' based on Radiology Liaison Committee recommendations from 02-12-2002.
	In "Coding" CPT/HCPCS section, added CPT codes 22523, 22524, and 22525, and added "or vertebral augmentation including cavity creation" to CPT code 76012 to reflect changes in CPT book.
	In "Coding" CPT/HCPCS section, deleted HCPCS codes S2360 and S2361 because 'cervical' is considered E/I by the Radiology Liaison Committee 02-12-2002.
12-21-2006	In "Coding", Covered Diagnosis section, added Percutaneous vertebroplasty or Kyphoplasty – CPT Codes – 22520, 22521, 22522, 22523, 22524, 22525, 76012, 76013, S2362, S2363 to the current listing of diagnosis codes.
07-27-2006 effective 10-01-2006	Deleted S2362 and S2363, the codes were deleted from HCPCS 4-1-06.
10-31-2006 effective 01-01-2007	In "Coding", CPT/HCPCS deleted CPT codes 76012 and 76013 and added CPT codes 72291 and 72292 due to the 2007 CPT changes.
07-23-2009	Removed percutaneous vertebroplasty and kyphoplasty policy language from the policy entitled: Minimally Invasive Procedures for Spine Pain creating a free-standing policy entitled: Percutaneous Vertebroplasty, Kyphoplasty and Sacroplasty.
	Description section:

	Updated description to reflect discussion of percutaneous vertebroplasty, kyphoplasty and sacroplasty
	Policy section: Revised policy language from: C. Percutaneous vertebroplasty or kyphoplasty is considered medically necessary after failure of standard medical therapy in patients when any of the following criteria is met. Medical conditions not listed and cervical percutaneous vertebroplasty and kyphoplasty will be denied experimental/investigational. 1. Osteolytic vertebral metastasis or myeloma with severe back pain related to destruction of the vertebral body not involving the major part of the cortical bone, and chemotherapy and radiation therapy have failed to relieve symptoms; or 2. Vertebral hemangiomas with aggressive clinical signs (severe pain or nerve compression) and/or aggressive radiological signs, and radiation therapy has failed to relieve symptoms; or 3. Osteoporotic vertebral collapse with persistent debilitating pain that has not responded to accepted standard medical therapy as documented in the medical records. Standard medical therapy may include initial bed rest with progressive activity, analgesics, physical therapy, bracing and exercises to correct postural deformity and increase muscle tone, salmon calcitonin, bisphosphonates and calcium supplementation; or 4. Painful vertebral eosinophilic granuloma with spinal instability. To: Percutaneous vertebroplasty and kyphoplasty may be considered medically necessary for the treatment of: severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies vertebral hemangiomas with pain, nerve compression or aggressive radiologic signs, and radiation therapy has failed to relieve symptoms painful vertebral eosinophilic granuloma vertebral compression fracture with persistent debilitating pain Sacroplasty may be considered medically necessary for the treatment of sacral insufficiency fractures that have failed to respond to conservative treatment. Percutaneous vertebroplasty, kyphoplasty and sacroplasty are considered experimental / investigational for all other indications.
	Rationale section: Added Rationale section.
	Coding section: Added CPT/HCPCS Codes: 0200T, 0201T, S2360, S2361. Deleted ICD-9 Code: 213.2. Added ICD-9 Codes: 203.01, 238.6.
01-01-2012	In the Coding section: Revised CPT nomenclature for the following codes: 22520, 22521, 22522
10-04-2013	Added Medical Policy and Coding Disclaimers.
	Description section updated.
	In the Policy section: • Revised medical policy language from the following: Percutaneous vertebroplasty and kyphoplasty may be considered medically necessary for the treatment of: A. severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies B. vertebral hemangiomas with pain, nerve compression or aggressive radiologic signs, and radiation therapy has failed to relieve symptoms

	C. painful vertebral eosinophilic granuloma D. osteoporotic vertebral compression fracture with persistent debilitating pain Sacroplasty may be considered medically necessary for the treatment of sacral insufficiency fractures that have failed to respond to conservative treatment. Percutaneous vertebroplasty, kyphoplasty and sacroplasty are considered experimental / investigational for all other indications.
	Rationale section updated.
	In Coding section: ▪ Added ICD-10 Diagnosis *(Effective October 1, 2014)*
	Reference section updated.
12-31-2013	In Policy section: ▪ In Item I, E, added "/bone scan" to read "The treatment of MRI / bone scan documented acute osteoporotic vertebral…"
01-01-2015	In Coding section: ▪ Added CPT Codes: 22510, 22511, 22512, 22513, 22514, 22515 (Effective January 1, 2015) ▪ Deleted CPT Codes: 22520, 22521, 22522, 22523, 22524, 22525, 72291, 72292 (Effective January 1, 2015) ▪ Revised CPT Codes: 0200T, 0201T (Effective January 1, 2015)
10-21-2015	Policy title changed from "Percutaneous Vertebroplasty, Kyphoplasty and Sacroplasty". A new medical policy was created with information on kyphoplasty titled "Percutaneous Balloon Kyphoplasty and Mechanical Vertebral Augmentation".
	Updated Description section.
	In Policy section: ▪ In Item A, removed "or kyphoplasty" to read "Percutaneous vertebroplasty may be considered medically necessary for:" ▪ In Item B, removed "or kyphoplasty" to read, "Percutaneous vertebroplasty is considered experimental / investigational for all other indications, including use in acute vertebral fractures due to trauma."
	Updated Rationale section.
	In Coding section: ▪ Removed CPT codes 22513, 22514, and 22515.
	Updated References section.
10-21-2015	Published 10-20-2015, effective 10-21-2015.
	In Policy section: ▪ In Item B, removed "or kyphoplasty" as indicated above to read, "Percutaneous vertebroplasty is considered experimental / investigational for all other indications, including in acute vertebral fractures due to trauma." (Not included as intended with previous 10-21-2015 publication.)
01-01-2016	In Coding section: ▪ Removed HCPCS codes S2360 and S2361.
01-19-2018	Updated Description section.
	In Policy section: ▪ Removed previous Items A 2 and 3, "2. Vertebral hemangiomas with pain, nerve compression or aggressive radiologic signs, and radiation therapy has failed to relieve symptoms; OR 3. Painful vertebral eosinophilic granuloma; OR" ▪ In previous Item A 4 (now Item A 2), removed "MRI documented acute," "compression," "with persistent debilitating pain," "with graduated activity, back bracing," "and calcitonin," "or these treatments are contraindicated," and added "symptomatic" to read, "The treatment of symptomatic osteoporotic vertebral fractures that have failed to respond to conservative treatment (eg, rest, analgesics, physical therapy) for at least 6 weeks;"

	▪ In previous Item A 5 (now Item A 3), removed "MRI/bone scan documented," "acute," "compression," "with persistent debilitating pain requiring," "admission and parenteral narcotics for treatment" and added "symptomatic," "that are less than 6 weeks in duration that have led to," "or persists at a level that prevents ambulation" to read, "The treatment of symptomatic osteoporotic vertebral fractures that are less than 6 weeks in duration that have led to hospitalization or persists at a level that prevents ambulation."
	Updated Rationale section.
	In Coding section: ▪ Removed ICD-9 codes.
	Updated References section.
05-23-2018	Updated Description section.
	Updated Rationale section.
	Updated References section.
08-01-2018	Updated Rationale section.

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