Policy Number	RAD601.056
Policy Effective Date	01/01/2024
Policy End Date	12/31/2024

Percutaneous Vertebroplasty and Sacroplasty

Table of Contents

Related Policies (if applicable)
RAD601.041: Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation

Disclaimer

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

This medical policy has become inactive as of the end date above. See RAD601.041 Minimally Invasive Approaches to Vertebral Fractures and Osteolytic Lesions of the Spine for dates of service 01/01/2025 and after.

CAREFULLY CHECK STATE REGULATIONS AND/OR THE MEMBER CONTRACT

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

- The treatment of symptomatic osteoporotic vertebral fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy, rest) for at least 6 weeks; OR
- The treatment of symptomatic osteoporotic vertebral fractures that are less than 6 weeks in duration that have led to hospitalization or persist at a level that prevents ambulation; OR
- The treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

Percutaneous vertebroplasty **is considered experimental, investigational and/or unproven** for all other indications, including but not limited to use in acute vertebral fractures due to osteoporosis or trauma.

Percutaneous sacroplasty **is considered experimental, investigational and/or unproven** for all indications, including but not limited to use in sacral insufficiency fractures due to osteoporosis and sacral lesions due to multiple myeloma or metastatic malignancies.

Policy Guidelines

None.

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 those with osteolytic lesions of the spine (e.g., multiple myeloma, metastatic malignancies); as a treatment for sacral insufficiency fractures (SIFs); and as a technique to limit blood loss related to surgery.

Treatment of Vertebral Compression Fracture
Chronic symptoms do not tend to respond to the management strategies for acute pain such as bedrest, immobilization or bracing devices, 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 or physical therapy. Improvements in pain and ability to function are the principal outcomes of interest for treatment of osteoporotic fractures.

Treatment of Sacral Insufficiency Fractures (SIFs)
Similar interventions are used for sacral and vertebral fractures and include bed rest, bracing, and analgesics. Initial clinical improvements may occur quickly; however, resolution of all symptoms may not occur for 9 to 12 months. (1, 2)

Vertebral and Sacral Body Metastasis
Metastatic malignant disease of the spine generally involves the vertebrae/sacrum, with pain being the most frequent complaint.

Treatment of Vertebral and Sacral Body Metastasis
While radiotherapy 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 (e.g., PMMA, bis-glycidal dimethacrylate [Cortoss]) into a fractured vertebra. (3) 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 PMMA through a needle inserted into the fracture zone. Although first described in 2000 as a treatment for symptomatic sacral metastatic lesions, (4, 5) it is most often described as a minimally invasive alternative to conservative management (6-8) 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 another injectate.

Regulatory Status

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

PMMA bone cement was available as a drug product before enactment of the FDA's device regulation and was at first considered what the 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 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® were cleared for marketing by the FDA through the 510(k) process for the fixation of pathologic fractures of the vertebral body using vertebroplasty procedures.

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

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

In 2010, the Parallax® Contour® Vertebral Augmentation Device (ArthroCare) was cleared for marketing by the FDA through the 510(k) process. There have been several other augmentation and bone expander devices (e.g., Balex® Bone Expander System, Arcadia® Balloon Catheter, Kyphon Element® Inflatable Bone Tamp) that were also cleared for marketing by the FDA through the 510(k) process. The devices create a void in cancellous bone that can then be filled with bone cement. FDA product code: HXG.

Rationale

This medical policy was created in February 2015 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through March 6, 2023.

Medical policies assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and 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 technology, two domains are examined: the relevance, and 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

Clinical Context and Therapy Purpose

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 reach clinical diagnosis, and most symptomatic fractures will heal within a few weeks or 1 month with medical management. Nonetheless, some individuals with acute fractures will have severe pain and decreased function that interferes with the ability to ambulate and is not responsive to usual medical management. Also, a minority of patients will exhibit chronic pain following osteoporotic compression fracture that presents challenges for medical management.

The purpose of vertebroplasty is to provide a treatment option that is an alternative to or an improvement on existing therapies in individuals with symptomatic osteoporotic or osteolytic vertebral fractures between 6 weeks and 1 year old.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest are individuals with symptomatic osteoporotic or osteolytic vertebral fractures between 6 weeks and 1 year old. With acute fractures, these individuals experience severe pain, decreased ambulatory function, and a lessened response to conservative medical management. Risk factors for osteoporotic or osteolytic vertebral fractures can include osteopenia, osteoporosis, advanced age, inactivity, corticosteroid use, female sex, and depression.

Interventions

The therapy being considered is vertebroplasty, a procedure for stabilizing compression fractures in the spine, during which bone cement is injected into the fractured vertebra through a small hole in the skin in order to relieve back pain.

Comparators

Comparators of interest include conservative management. Conservative management includes measures to reduce pain and improve mobility. Physical therapy, analgesics, narcotics, and hormone treatments can be prescribed to achieve this. Bed rest and braces may also be utilized as conservative management; however, these modalities are associated with prolonged immobilization which can further exacerbate bone loss and fail to relieve systems.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, QOL, hospitalizations, medication use, and treatment-related morbidity. Negative outcomes can include complications with sedation, further injury during transfer to the radiology table, and the possibility of abuse after the prescription of narcotics. The outcomes of interest for vertebroplasty as a treatment for symptomatic vertebral fractures have varying follow-up times to fully examine the impact on the patient, ranging from shorter term outcomes like medication use to outcomes that require extended follow-up, such as functional outcomes. Given that the existing literature evaluating vertebroplasty as a treatment for symptomatic vertebral fractures between 6 weeks and 1 year old has varying lengths of follow-up, ranging from 6 months to 2 years, follow-up timing of 1 year is appropriate to demonstrate efficacy.

Disability, a major factor on QOL, is measured using various tools throughout the literature. Three such tools include the Roland-Morris Disability Questionnaire (RMDQ), (9) the visual analogue scale (VAS), (10) and QUALEFFO (a QOL questionnaire in patients with vertebral fractures). The RMDQ is a self-administered disability measure in which greater levels of disability are reflected by higher numbers on a 24-point scale and on VAS. The RMDQ has been shown to yield reliable measurements, which are valid for inferring the level of disability, and to be sensitive to change over time for groups of patients with low back pain. VAS is commonly used as the outcome measure for such studies. It is usually presented as a 100-mm horizontal line on which the patient's pain intensity is represented by a point between the extremes of "no pain at all" and "worst pain imaginable." With QUALEFFO (a QOL questionnaire in patients with vertebral fractures), QOL is measured by the scale 0 to 100, higher scores indicating worse QOL.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

Buchbinder et al. (2018) published a Cochrane review of the literature up to November 2014. (11) Studies compared vertebroplasty versus placebo (2 studies with 209 randomized participants), usual care (6 studies with 566 randomized participants), and kyphoplasty (4 studies with 545 randomized participants). The majority of participants were female, between 63.3 and 80 years of age, with symptom duration ranging from 1 week to more than 6 months. At 1 month, disease specific QOL measured by the QUALEFFO (a QOL questionnaire in patients with vertebral fractures; scale 0 to 100, higher scores indicating worse QOL) was 0.40 points worse in the vertebroplasty group. Based upon moderate quality evidence from 3 trials (1 placebo, 2 usual care, 281 participants) with up to 12 months follow-up, it is unclear if vertebroplasty increases the risk of new symptomatic vertebral fractures. Similarly, based upon moderate quality evidence from 2 placebo-controlled trials, it is unclear to what extent risk of other adverse events exists. There were 3/106 adverse events observed in the vertebroplasty group compared with 3/103 in the placebo group; risk ratio, 1.01 (95% confidence interval [CI]:

0.21 to 4.85). Serious adverse events that have been reported with vertebroplasty 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 to determine whether vertebroplasty is more effective than sham in specific subsets of patients. (12) This subset analysis focused on duration of pain (≤6 weeks versus >6 weeks) and severity of pain (score <8 or ≥8 on an 11-point numeric rating scale). The analysis included 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 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 in 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. (2017), in a meta-analysis of RCTs, evaluated the efficacy and safety in percutaneous vertebroplasty and conservative treatment for patients with osteoporotic vertebral compression fractures. (13) Thirteen studies were selected (N =1231 patients; 623 to vertebroplasty, 608 to conservative treatment). Outcomes included pain relief (from 1 week to 6 months), QOL assessments, and the rate of adjacent-level vertebral fracture. Vertebroplasty was superior for pain relief at 1 week and at 1 month. It was inferior to conservative treatment for pain relief at 6 months. Vertebroplasty showed improvement over conservative treatment for QOL, as measured using QUALEFFO. No statistically significant differences were found between treatments for the rate of adjacent-level vertebral fractures. Limitations included the inclusion of several studies with inadequate blinding and heterogenous reporting of patient characteristics outcomes.

Hinde et al. (2020), in a meta-analysis of retrospective and prospective cohort studies, assessed the mortality outcomes of vertebral augmentation versus nonsurgical management in patients with osteoporotic vertebral compression fractures. (14) The meta-analysis included 7 studies (N=2,089,944; 382,070 treated with vertebral augmentation and 1,707,874 treated with nonsurgical management). Vertebral augmentation improved mortality compared with nonsurgical management at both 2- and 5-year follow-up. Limitations included heterogeneity in the number of enrolled patients in included studies as well as differences in health status.

Zhang et al. (2020), in a meta-analysis of RCTs, assessed the efficacy of percutaneous vertebroplasty versus conservative treatment for patients with osteoporotic vertebral compression fractures. (15) Ten studies were included, and outcomes consisted of pain relief at 1 week, 1 month, and 6 months; QOL assessments; and the rate of new vertebral fractures. Compared with conservative treatment, percutaneous vertebroplasty was superior for pain relief at 1 week and 1 month, but not at 3 months. Results varied for QOL assessments with similar outcomes between percutaneous vertebroplasty and conservative treatments on the

RMDQ. Limitations included an imbalance in baseline demographics and the clinical characteristics of patients in included studies.

Chang et al. (2021), in a meta-analysis of RCTs and cohort studies, evaluated the effectiveness and safety of various interventions, including vertebroplasty versus kyphoplasty or conservative treatment, for treating osteoporotic vertebral compression fractures. (16) Thirty-nine studies included vertebroplasty as a comparative arm. Outcomes included scores based on the VAS and Oswestry Disability Index (ODI). Vertebroplasty decreased scores on the VAS and ODI compared with conservative treatment, but had similar outcomes compared with kyphoplasty. The rate of new fractures was similar for vertebroplasty versus conservative treatment and vertebroplasty versus kyphoplasty. Limitations consisted of the differences in indications, data types, follow-up times, and variables in included studies.

Table 1. Characteristics of Systematic Reviews and Meta-Analyses on Percutaneous Vertebroplasty For Vertebral Compression Fractures Between 6 Weeks and 1 Year Old

Study	Dates	Trials	Participants	Intervention	N (Range)	Design
Buchbinder et al. (2018) (11)	2007-2016	21	Patients with osteoporotic vertebral fractures (mean age ranged from 63.3 to 80 years); symptom duration ranged from 1 week to ≥ 6 months	Vertebroplasty	2862 (46-404)	RCT
Staples et al. (2011) (12)	NR	2	Participants with 1-2 painful osteoporotic vertebral fractures >12 months duration and unhealed, as confirmed by MRI, were randomly assigned to vertebroplasty or to a sham procedure	Vertebroplasty vs. placebo (5 studies); kyphoplasty (7 studies); facet joint steroid injection (1)	209 (78-131)	RCT
Xie et al. (2017) (13)	NR-2017	13	Patients with OVCFs	PVP vs. conservative treatment	2561 (NR)	RCT
Hinde et al. (2020) (14)	NR-2018	7	Patients with OVCFs	Vertebral augmentation (vertebroplasty or balloon kyphoplasty) vs. nonsurgical management	2,089,944 (NR)	Retro-spective and cohort studies

Zhang et al. (2020) (15)	NR-2018	10	Patients with OVCFs	PVP vs. conservative treatment	NR	RCT
Chang et al. (2021) (16)	NR-2020	56	Patients with OVCFs	Vertebroplasty vs. conservative treatment (15 studies); kyphoplasty (24 studies)	6974 (14-191)	RCT, cohort studies

NR: not reported; OVCF: osteoporotic vertebral compression fracture; PVP: percutaneous vertebroplasty; RCT: randomized controlled trial; vs: versus.

Table 2. Results of Systematic Reviews and Meta-Analyses on Percutaneous Vertebroplasty For Vertebral Compression Fractures Between 6 Weeks and 1 Year Old

Study	Quality of Life	New Fractures
	QUALEFFO	
Buchbinder et al. (2018) (11)		
Placebo group at 1-month, score (N)	4.58 (71)	NR
Vertebroplasty group at 1-month, score (N)	5.38 (71)	NR
Absolute change between groups	0.4% worse (5% worse-5% better [n=71])	NR
Relative change between groups	0.7% worse (9% worse-8% [n=71])	NR
N. Intervention group (%)	NR	28 (19.58)
N. Placebo group (%)	NR	19 (50.00)
RR (CI)	NR	1.47 (0.39-5.50)
	Duration of Pain	
Staples et al. (2011) (12)		
Mean change score (SD) of pain, at 2 weeks, PVP vs. placebo	2.2 (2.8) vs. 2.5 (3.0)	NR
Adjusted between group difference (CI) at 2 weeks	~0.2 (~0.9-0.6)	
Mean change score (SD) of pain, at 1 month, PVP vs. placebo	2.08 (3.0) vs. 2.2 (3.2)	NR
Adjusted between group difference (CI) at 2 weeks	0.6 (~0.2-1.4)	
	Pain Relief	
Xie et al. (2017) (13)	N=1231	NR
At 1-week (vertebroplasty superior), MD (CI)	1.36 (0.55-2.17)	NR
At 1-month (vertebroplasty superior), MD (CI)	1.56 (0.43-2.70)	NR

At 6-months (vertebroplasty inferior), MD (CI)	-1.59 (-2.9- -0.27) p<0.05	NR
Total (vertebroplasty superior), MD (CI)	-5.03 (7.94 - -2.12)	NR
	Mortality	
Hinde et al. (2020) (14)		
Mortality, 2-year follow up, HR (CI), vertebral augmentation vs nonsurgical management	0.70 (0.69, 0.71)	NR
Mortality, 5-year follow up, HR (CI), vertebral augmentation vs nonsurgical management	0.79 (0.62, 0.9999)	NR
	Pain relief and QOL	
Zhang et al. (2020) (15)		
Pain relief at 1 week (PVP superior), MD (CI)	1.67 (0.84 to 2.51) p<0.0001	
Pain relief at 1 month (PVP superior), MD (CI)	1.98 (0.61 to 3.36) p=0.005	
Pain relief at 3 months, MD (CI)	−0.44 (−2.03 to 1.15)	OR, 1.09 (0.72 to 1.64)
EuroQol questionnaire (PVP superior), MD (CI)	0.11 (0.01 to 0.20) p=0.03	
Quality of Life Questionnaire of the European Foundation for Osteoporosis, MD (CI)	−7.29 (−12.60 to −1.99)	
Roland-Morris Disability Questionnaire, MD (CI)	0.66 (−2.00 to 3.33)	
	Pain and disability relief	
Chang at al. (2021) (16)		
Treatment effect for visual analog scale, mean (CI), vertebroplasty vs conservative treatment	-0.66 (-1.10 to -0.21)	OR, 1.09 (0.79 to 1.50)
Treatment effect for visual analog scale, mean (CI), vertebroplasty vs kyphoplasty	0.28 (-0.06, 0.61)	OR, 0.99 (0.74 to 1.33)
Treatment effect for ODI, mean (CI), vertebroplasty vs conservative treatment	-5.27 (-9.19, -1.35)	
Treatment effect for ODI, mean (CI), vertebroplasty vs kyphoplasty	1.23 (-1.59, 4.04)	

CI: 95% confidence interval; HR: hazard ratio; MD: mean difference; N: number; NR: not reported; ODI: Oswestry Disability Index; OR: odds ratio; PVP: percutaneous vertebroplasty; QOL: quality of life; QUALEFFO: Questionnaire: a quality of life questionnaire in patients with vertebral fractures; RR: relative risk; SD: standard deviation.

Randomized Controlled Trials

Vertebroplasty Versus Medical Management With Sham Controls

Three sham-controlled trials 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. (2009) 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 (i.e., 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. Kroon et al. (2014) reported results of the same trial at 12 and 24 months, maintaining blinding throughout the follow-up period. (19) The primary outcome was overall pain measured on a VAS from 0 to 10, with 1.5 points representing the minimal clinically important difference. 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 QOL observed in both groups, the authors concluded routine use of vertebroplasty provided no benefit.

Kallmes et al. (2009) conducted a multicenter, randomized, double-blind, sham-controlled, investigational vertebroplasty safety and efficacy trial 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 various time points to 1 year post procedure. Ninety-seven percent completed a 1-month follow-up; 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. (20)

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, 51% from the control group and 13% in the vertebroplasty group crossed over ($p<0.001$). Comstock et al. (2013) reported on patient outcomes at 1 year, at which point 16% of patients who underwent vertebroplasty and 60% of control subjects had crossed over to the alternative procedure ($p<0.001$). (21) The as-treated analysis found no significant difference in RMDQ or pain scores between the 2 groups. Intention-to-treat 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). One limitation of this study is that at 14 days, 63% of patients in the control group correctly guessed they had the control intervention, and 51% of patients in the vertebroplasty group correctly guessed they had the vertebroplasty.

Firanescu et al. (2018) published the results of a randomized, double-blind, sham-controlled clinical trial performed in 4 community hospitals in the Netherlands from 2011 to 2015. (22) The main outcome measured was mean reduction in VAS scores at 1 day, 1 week, and 1, 3, 6, and 12 months. The mean reduction in VAS score was statistically significant in the vertebroplasty and sham procedure groups at all follow-up points after the procedure compared with baseline. These changes in VAS scores did not, however, differ statistically significantly between the groups during 12 months' follow-up.

Table 3. Summary of Characteristics of Key RCT Comparing Vertebroplasty Versus Medical Management with Sham Controls

Study	Countries	Sites	Dates	Participants (N)	Interventions	
					Active (n)	**Comparator (n)**
Buchbinder et al. (2009) (17)	U.S.	4	2003-2008	Patients with 1-2 painful OVCF, duration <1 year	Vertebroplasty (38)	Sham procedure[1] (40)
Kallmes et al. (2009) (18)	U.S., UK., Aus	10	2004-2008	Participants with 1-3 painful OVCF, pain ≤ 12 mo, current pain VAS≥ 3	Vertebroplasty (68)	Sham procedure[1] (63)
Firanescu et al. (2018) (22)	Netherlands	4	2011-2015	Participants with acute OVCF	Vertebroplasty (91)	Sham procedure[1] (89)

Mo: month(s); OVCF: osteoporotic vertebral compression fracture; RCT: randomized controlled trial; U.K.: United Kingdom; U.S.: United States; VAS: visual analogue scale.
[1] injection of local anesthetic into the facet capsule and/or periosteum.

Table 4. Summary of Results of Key RCT Comparing Vertebroplasty Versus Medical Management with Sham Controls

Study	VAS	RMDQ
Buchbinder et al. (2009) (17)	N=73, at 3-months	
Intervention (mean±SD)	Reduction: 2.6±2.9	
Control (mean±SD)	Reduction: 1.9±3.3	
Adjusted between-group difference (CI)	0.6 (-0.7-1.8)	
Kallmes et al. (2009) (18)		
Day 14 Mean difference between groups (CI)	0.1 (-0.8-1.1)	-0.6 (-2.4-1.2)
P-value	0.77	0.35
Month 1 Mean difference between groups (CI)	0.7 (-0.3-1.70)	0.7 (-1.3-2.8)

P-value	0.19	0.49
Firanescu et al. (2018) (22)	N=180	
Day 1 Mean difference between groups (CI)	-0.43 (-1.17 - 0.31)	
Week 1 Mean difference between groups (CI)	-0.11 (-0.85 - 0.63)	
Month 1 Mean difference between groups (CI)	0.41 (-0.33 - 1.15)	
Month 3 Mean difference between groups (CI)	0.21 (-0.54 - 0.96)	
Month 6 Mean difference between groups (CI)	0.39 (-0.33 - 1.15)	
Month 12 Mean difference between groups (CI)	0.45 (-0.37-1.24)	

CI: 95% confidence interval; NR: not reported; RCT: randomized controlled trial; RMDQ: Roland-Morris Disability Questionnaire; SD: standard deviation; VAS: visual analogue score.

Table 5. Relevance Study Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-up[e]
Buchbinder et al. (2009) (17)					
Kallmes et al. (2009) (18)				3. No reporting of harms. 5. Investigator modified pain window from 6 to 9 weeks.	
Firanescu et al. (2018) (22)	2. Lack of screening for co-occurring pain conditions. 2. MRI was not conducted.			5. Investigator modified pain window from 6 to 9 weeks.	

MRI: magnetic resonance imaging.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.

[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5. Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not established and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 6. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-up[d]	Power[e]	Statistical[f]
Buchbinder et al. (2009) (17)			2. 30% of eligible participants declined to participate, selection bias cannot be ruled out.			
Kallmes et al. (2009) (18)		1. At 14 days, > 50% of participants in either arm correctly identified their intervention assignment.		4. Due to high crossover the group differences in outcomes were complicated.		
Firanescu et al. (2018) (22)	4. Screening logs not retained.					

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

[d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Vertebroplasty Versus Medical Management Without Sham Controls

Chen et al. (2014) reported on a nonblinded RCT comparing vertebroplasty with conservative management. (23) The trial included 89 patients with chronic compression fractures confirmed by magnetic resonance imaging (MRI) 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 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. (24) Patients had painful osteoporotic vertebral compression fractures that were refractory to analgesic therapy for at least 4 weeks and less than 1 year. Control of pain and improvement in QOL 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. Adverse events include new symptomatic adjacent fractures in 1 patient in the treatment group and 6 in the control group. Additionally, 1 patient experienced epidural cement leakage, which caused severe lower extremity pain and weakness, and had to be treated with bilateral laminectomy and evacuation of the bone cement.

Table 7. Summary of Key RCT Characteristics -Vertebroplasty Versus Medical Management Without Sham Controls

Study	Countries	Sites	Dates	Participants (N)	Interventions	
					Active	Comparator
Chen et al. (2014) (23)	China	1	2007-2012	Patients with chronic compression fractures confirmed by MRI and persistent severe pain for <u><</u>3 months (89)	Vertebroplasty	Conservative Management

Farrokhi et al. (2011) (24)	Iran	1	2004-2005	Patients with painful osteoporotic vertebral compression fractures refractory to analgesic therapy for ≥4, but <1 year (82)	Vertebroplasty	Optimal Medical Management

MRI: magnetic resonance imaging; RCT: randomized controlled trial.

Table 8. Summary of Key RCT Results

Study	Pain Score	ODI Score	RMDQ
	Overall pain (scale 0-10)		
Chen et al. (2014) (N=89) (23)			
Intervention Group, Pooled at 1-year	2.5	15.0	8.1
Control Group, Pooled at 1-year	4.1	32.1	10.7
P-value	P<0.001	P<0.001	P<0.001
Farrokhi et al. (2011) (24)	**VAS Score**		
Week 1 Mean difference between groups (CI); p-value	-3.1 (-3.72- -2.28); <0.001	-14.0 (-15.00- -12.82); <0.028	
Month 2 Mean difference between groups (CI); p-value	-2.9 (-4.9- -0.82); <0.011	-15.0 (-16.76- -13.24); <0.019	
Month 6 Mean difference between groups (CI); p-value	-1.9 (-3.25- -0.55); <0.021	-11.0 (-12.17- -7.83); <0.011	
Month 12 Mean difference between groups (CI); p-value	-1.9 (-2.9-0.9); <0.11	-12.0 (-13.5- -11.5); <0.021	

CI: confidence interval; N: number; ODI: Oswestry Disability Index, RCT: randomized controlled trial; RMDQ: Roland-Morris Disability Questionnaire; VAS: visual analogue scale.

Table 9. Relevance Study Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-up[e]
Chen et al. (2014) (23)			3. Investigator modified duration of the conservative therapy from 6 to 4 weeks		
Farrokhi et al. (2011) (24)				4. Language translation of Oswestry scale not validated	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 10. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-up[d]	Power[e]	Statistical[f]
Chen et al. (2014) (23)		1.,2. This study was not blinded.				
Farrokhi et al. (2011) (24)						

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Nonrandomized Comparative Studies

Edidin et al. (2011, 2015) reported mortality risk rates in Medicare patients who had vertebral compression fractures and had been treated with vertebroplasty, kyphoplasty or nonoperatively. (25, 26) 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. The matched cohort included 100,649 non-operated patients, 36,657 kyphoplasty patients, and 24,313 vertebroplasty patients. Survival was calculated from the index diagnosis date until death or the end of follow-up (up to 4 years). Analysis of the whole data set before matching indicated that patients in the non-operated 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 non-operated 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. (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. (27) The data set consisted of 10,785 Taiwanese patients who were selected through the National Health Insurance Research Database, of whom 1,773 patients received vertebroplasty, and 5,324 did not; a minority of these patients had osteoarthritis. 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.

<u>Section Summary: Percutaneous Vertebroplasty for Vertebral Compression Fractures Between 6 Weeks and 1 Year Old</u>

Despite evidence from numerous RCTs, including several with sham controls, the efficacy of vertebroplasty for painful osteoporotic compression fractures of less than 1 year remains uncertain. Six meta-analysis studies have been published, but all of them have numerous limitations due to heterogeneity of included studies. Another major limitation to several meta-analyses is that they do not specify the timeframe for osteoporotic vertebral compression fractures. 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 PMMA injected, and the inclusion of patients with chronic pain.

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

<u>Clinical Context and Therapy Purpose</u>

The purpose of vertebroplasty is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative management, in individuals with symptomatic osteoporotic vertebral fractures less than 6 weeks old.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest are individuals with symptomatic osteoporotic vertebral fractures less than 6 weeks old. With acute fractures, these individuals experience severe pain, decreased ambulatory function, and a lessened response to conservative medical management.

Interventions
The therapy being considered is vertebroplasty.

Comparators
Comparators of interest include conservative management. A detailed review of the comparators is listed in the above indication.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, QOL, hospitalizations, medication use, and treatment-related morbidity. Symptoms can include backpain and demonstrated fracture on radiography. The most current research available tracks follow-up to 12 months or more. A number of studies have longer term follow-up at more than 5 years, which is ideal for understanding all of the outcomes, particularly the occurrence of new vertebral compression fractures after vertebroplasty.

<u>Study Selection Criteria</u>
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

<u>Randomized Controlled Trials</u>
Vertebroplasty Versus Medical Management with Sham Controls
Clark et al. (2016) reported on results from the Safety and Efficacy of Vertebroplasty of Acute Painful Osteoporotic Fractures (VAPOUR) trial (see Table 11). (28) 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 a numeric rating scale. This trial followed a similar protocol as that used in the Kallmes et al. (2009) trial (discussed above). The primary outcome (the percentage of patients with a numeric rating scale score <4 out of 10 at 14 days

post procedure) 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.

Other outcome measures were significantly improved in the vertebroplasty group at 1 or both of the time points (see Table 12). The benefit of vertebroplasty was found predominantly in the thoracolumbar subgroup, with 48% (95% CI, 27% to 68%) more patients meeting the primary endpoint (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 Versus Medical Management Without Sham Controls

Klazen et al. (2010) reported on the vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures, an open-label randomized trial of 202 patients at 6 hospitals in the Netherlands and Belgium. (29) 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. The primary outcome was pain relief of 3 points measured on a 10-point VAS at 1 month and 1 year.

A total of 101 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 or at 1 year. 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) versus conservative treatment in an RCT with 290 patients (363 affected vertebrae). (30) Patients treated conservatively 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 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. (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. (31) 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 per 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. (32) Vertebroplasty was performed at a mean of 8.4 days after pain onset. Patients in the conservative therapy group were placed on bed rest 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 post treatment, while only 12 (23.5%) patients in the control group could stand up and walk after 2 weeks of bed rest. The average duration of bed rest 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.

Table 11. Summary of Key RCT Characteristics Involving Vertebroplasty Versus Medical Management without Sham Controls

Study; Trial	Countries	Sites	Dates	Participants (N)	Interventions	
					Active (N)	**Comparator (N)**
Klazen et al. (2010) (29)	EU	6	2005-2008	Patients >50 years with radiographically confirmed VCF, backpain r <6 weeks, VAS >5	Vertebroplasty (101)	Medical Management without Sham Controls (101)
Yi et al. (2014) (30)	China	1	2005-2009	Patients with OVCF	PVP or PKP (169)	Conservative treatment (121)

Leali et al. (2010) (31)	International	4	NR	Post-menopausal women with 1 thoracic or lumbar symptomatic OVCF caused by primary or secondary osteoporosis	PVP including analgesic and osteoporosis medication (200)	Conservative care including analgesic and osteoporosis medication (200)
Yang et al. (2015) (32)	China	1	2009-2011	Patients ≥ 70 years with acute OVCF, severe pain from minor or mild trauma	PVP (56 at one year)	Conservative treatment (51 at one year)

N: number; NR: not reported; OVCF: osteoporotic vertebral compression fractures; PKP; percutaneous kyphoplasty; PVP: percutaneous vertebroplasty; RCT: randomized controlled trial; VCF: vertebral compression fracture; VAS: visual analog scale.

Table 12. Summary of Key RCT Results Involving Vertebroplasty Versus Medical Management without Sham Controls

Study	VAS	Quality of Life	Refracture Rate
Klazen et al. (2010) (29)			
Mean difference between groups in reduction of mean VAS score from baseline		RMDQ[1]	Median follow-up of 12.0 months (range: 1-24)
Month 1 (CI)	2.0 (1.13-2.80)	PVP: 12.5	PVP: 18 (16.48%)
p-value	<0.0001	Control: 13.5	Control: 30 (24.71%)
Month 12 (CI)	2.0 (1.13-2.80)	PVP: 9	
p-value	<0.0001	Control: 12	
Yi et al. (2014) (30)			
Month 12 (%)			PVP/PKP: 18 (8.28%)
			Control: 24 (19.83%)
			Time interval of recompression
Intervention			9.7 ± 17.8 months
Control			22.4 ± 7.99 months
p-value			0.017

Leali et al. (2016) **(31)**		ODI, %	
Intervention 24 hours after surgery, mean	2.3	31.7	
p-value	≤0.023	≤0.012	
Yang et al. (2015)[2] (32)			
Analysis of variance models, Month 1 (SD)	PVP: 2.4±1 Control: 4.8±1	PVP: 48±10 Control: 71±7	
Analysis of variance models, Month 12 (SD) p-value	PVP: 1.8±0.3 Control: 3±0.5	PVP: 30±5	PVP: 5 (8.9%) Control: 4 (7.8) <0.0001

CI: 95% confidence interval; ODI: Oswestry Disability Index; PKP: percutaneous kyphoplasty; PVP: percutaneous vertebroplasty; RCT: randomized controlled trials; RMDQ: Roland-Morris Disability Questionnaire; VAS: visual analogue scale; SD: standard deviation.
[1]The RMDQ results from the Klazen paper are based on estimates due to the graphical presentation of the results, rather than the reporting of the numerical values.
[2] The results from the Yang paper are based on estimates due to the graphical presentation of the results; numerical results not reported.

Table 13. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow-up[e]
Klazen et al. (2010) (29)				3. None reported	
Yi et al. (2014) (30)	4. Selection criteria for PVP or PKP unclear, some patients had > fracture				
Leali et al. (2010) (31)	1.Limited to post-menopausal women				1,2 Follow-up period limited to < 6 months
Yang et al. (2015) (32)	4. Study population limited to > 70 years of age at single spine center				

PVP: percutaneous vertebroplasty; PKP: percutaneous kyphoplasty.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4. Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 14. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-up[d]	Power[e]	Statistical[f]
Klazen et al. (2010) (29)		1,2. No masking				
Yi et al. (2014) (30)						
Leali et al. (2010) (31)		1,2,3, unclear if masking occurred	2. Outcomes beyond 48 hours post-surgery not reported			
Yang et al. (2015) (32)		1,2,3 No masking				3. Results reported only in graphic form

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

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

Clinical Context and Therapy Purpose

Sacral insufficiency fractures (SIFs) are the consequence of stress on weakened bone and often cause low back pain in the elderly population. (1) Osteoporosis is the most common risk factor for SIFs. Lourie (1982) described spontaneous fracture of the sacrum in patients with osteoporosis as presenting as lower back and buttock pain with or without referred pain in the legs. (33) Although common, SIFs can escape detection due to low provider suspicion and poor sensitivity on plain radiographs, slowing the application of appropriate intervention.

The purpose of sacroplasty is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative management, in individuals with SIFs.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest are individuals with SIFs. SIFs are a stress fracture, resulting from a regular stress applied to a bone with reduced elasticity. Often, these fractures are associated with underlying metabolic bone disease condition like osteoporosis. Examples of risk factors include corticosteroid therapy use, female sex, pelvic radiation, rheumatoid arthritis, and hyperparathyroidism.

Interventions

The therapy being considered is sacroplasty, a minimally invasive procedure for treating pathological fractures of the sacral vertebral body or sacral ala. The procedure involves percutaneous insertion of 1 or more bone needles into the sacrum and injection of bone cement under fluoroscopy and/or computed tomography visual guidance.

Comparators

Comparators of interest include conservative management. Conservative management includes physical therapy, analgesics, narcotics, and hormone treatments. Examples of conservative management for SIFs are varied and can include bed rest and pain medication to early physical therapy.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, QOL, hospitalizations, medication use, and treatment-related morbidity. Possible negative outcomes include complications with sedation, cement leakage into the presacral space, spinal canal, sacral foramen, or sacroiliac joint, and possible spinal compression due to extravasation of cement. At least 1 year of follow-up is desirable to adequately evaluate outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies;
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought;
- Studies with duplicative or overlapping populations were excluded.

Observational Studies
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. Frey et al. (2008) conducted the largest prospective observational cohort study, assessing 52 consecutive patients undergoing sacroplasty for SIFs using the short-axis technique. (34) Patients had a mean age of 75.9 years, a mean duration of symptoms of 34.5 days (range, 4-89 days), and a 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 post procedure. At each interval, statistically significant improvements over baseline were observed and maintained through 52 weeks.

Kortman et al. (2013) reported on the largest series, a retrospective multicenter analysis. (35) They evaluated 204 patients with painful SIFs and 39 patients with symptomatic sacral lesions treated with the short-axis or long-axis technique. One hundred sixty-nine patients had bilateral SIFs, 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 SIFs 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 versus nonsurgical management. (36) This prospective, observational cohort study spanned 10 years and comprised 240 patients with SIFs. 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 followups. 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]; post treatment 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 1 significant pain improvement score, which was 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 at the 10-year mark whereas the sacroplasty group did receive follow-up.

There are several retrospective reviews with roughly 50 patients per publication. One reported by Dougherty et al. (2014) described a series of 57 patients treated with sacroplasty for SIFs. (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 on percutaneous sacroplasty for sacral insufficiency were identified. The available evidence includes 2 prospective cohort studies and several 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 limited number of patients and the retrospective nature 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 randomized controlled trials (RCTs) comparing vertebroplasty with conservative management, and several meta-analyses. Relevant outcomes are symptoms, functional outcomes, quality of life (QOL), hospitalizations, medication use, and treatment-related morbidity. Despite the completion of multiple 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 (PMMA) injected, and the inclusion of patients with chronic pain. Other meta-analyses had numerous limitations due to the heterogeneity of included studies or not specifying the timeframe for osteoporotic vertebral compression fractures. Overall, conclusions about the effect of vertebroplasty remain unclear. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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, QOL, 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 bed rest. Given the high morbidity associated with extended bed rest in older adults, this procedure is considered to have a significant health benefit. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with sacral insufficiency fractures (SIFs) who receive sacroplasty, the evidence includes 2 prospective cohort studies and a case series. Relevant outcomes are symptoms, functional outcomes, QOL, 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 that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

American College of Radiology

In 2022, the American College of Radiology (ACR) revised its Appropriateness Criteria for the use of percutaneous vertebral augmentation in the management of vertebral compression fractures. (40) Table 15 shows the appropriateness categories for each variant.

Table 15. ACR Appropriateness Criteria for the Use of Percutaneous Vertebral Augmentation for the Management of Vertebral Compression Fractures

Variants	Appropriateness Category
"Asymptomatic, osteoporotic VCF. Initial treatment"	Usually Not Appropriate
"Symptomatic osteoporotic VCF with bone marrow edema or intravertebral cleft. Initial treatment"	Usually Appropriate
"New symptomatic VCF. History of prior vertebroplasty or surgery. Initial treatment."	Usually Appropriate
"Benign VCF with worsening pain, deformity, or pulmonary dysfunction. Initial treatment"	Usually Appropriate
"Pathological VCF with ongoing or increasing mechanical pain. Initial treatment"	Usually Appropriate

ACR: American College of Radiology; CT: computed tomography; MRI: magnetic resonance imaging; VCF: vertebral compression fracture.

In 2014, the ACR and 7 other medical specialty associations, including the Society for Interventional Radiology, updated a 2012 joint position statement on percutaneous vertebral augmentation. (41) 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 published standards...only when nonoperative medical therapy has not provided adequate pain relief or pain is significantly altering the patient's quality of life."

Society of Interventional Radiology (SIR)

In a 2014 quality improvement guideline for percutaneous vertebroplasty from the SIR, failure of medical therapy was defined as follows (42):

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 (AAOS)

In 2011, the AAOS published practice guidelines on the treatment of osteoporotic spinal compression fractures. (43) The AAOS approved "a Strong recommendation against the use of vertebroplasty for patients who present with an acute osteoporotic spinal compression fracture and are neurologically intact."

National Institute for Health and Care Excellence (NICE)

In 2003, the National Institute for Health and Care Excellence (NICE) concluded in its 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…." (44) The guidance also recommended that the procedure be limited to patients whose pain is refractory to more conservative treatment. A 2013 NICE guidance, which was reaffirmed in 2016, 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 to be at the level of the fracture by physical examination and imaging." (45)

In 2008, NICE issued guidance on the diagnosis and management of adults with metastatic spinal cord compression. (46) This guidance indicated that vertebroplasty or kyphoplasty should be considered for "patients who have vertebral metastases and no evidence of metastatic spinal cord compression or spinal instability if they have: mechanical pain resistant to conventional pain management, or vertebral body collapse."

American Society of Pain and Neuroscience
In 2021, the American Society of Pain and Neuroscience (ASPN) published practice guidelines for the interventional management of cancer-associated pain. (47) The guideline included a best practice statement that stated, "vertebral augmentation should be strongly considered for patients with symptomatic vertebral compression fractures from spinal metastases (evidence level 1-A)." However, ASPN noted that there is little data to suggest the superiority of either vertebroplasty or kyphoplasty when treating malignant vertebral compression fractures.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this policy are listed in Table 16.

Table 16. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Unpublished			
NCT02489825	Pilot Study: Does Preventive Adjacent Level Cement Augmentation Positively Affect Reoperation Rates After Osteoporotic Vertebral Compression Fractures?	100	June 2019
NCT02902250	The Comparative Study About the Effect of Vertebral Body Decompression Procedure and Conservative Treatment for Benign Vertebral Compression Fracture -	80	Feb 2022

	Prospective Randomized Control Study		
NCT03617094	Early Percutaneous Vertebroplasty Versus Standard Conservative Treatment in Thoracolumbar Vertebral Fractures. Monocentric, Prospective, Randomised and Compared Clinical Study	42	Oct 2020

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	22510, 22511, 22512, 0200T, 0201T
HCPCS Codes	C7504, C7505

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/31/2024	Document became inactive.
01/01/2024	Document updated with literature review. Coverage unchanged. Added reference 47; others updated.
7/15/2022	Reviewed. No changes.
9/15/2021	Document updated with literature review. Coverage unchanged. Added/updated the following references: 20-22, 39, 48; others updated.
8/15/2020	Reviewed. No changes.
10/15/2019	Document updated with literature review. Coverage unchanged. Added/updated the following references: 10-11, 18, 20, 26, 31, 39, and 43-44.
12/15/2018	Reviewed. No changes.
3/1/2018	Document updated with literature review. The following was added to Coverage: Percutaneous vertebroplasty may be considered medically necessary for the treatment of symptomatic osteoporotic vertebral fractures that are less than 6 weeks in duration that have led to hospitalization or persist at a level that prevents ambulation.
11/1/2016	Document updated with literature review. Coverage unchanged.
2/15/2015	New medical document. Coverage of vertebroplasty and sacroplasty was reviewed and is unchanged; however, “Percutaneous Vertebroplasty and Sacroplasty” were previously discussed on Medical Policy RAD601.041 Percutaneous Vertebroplasty, Percutaneous Kyphoplasty, and Percutaneous Sacroplasty.