



**Kaiser Foundation Health Plan  
of Washington**

**Clinical Review Criteria**

**Vertebroplasty**

[See Separate Criteria for Kyphoplasty](#)

- [Percutaneous Vertebroplasty with Polymethylmethacrylate](#)
- [Radiofrequency Ablation with Vertebral Augmentation for Painful Spinal Metastases](#)

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**Criteria**

**For Medicare Members**

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	<a href="#">Percutaneous Vertebral Augmentation (L34106)</a> .
Local Coverage Article	None

**For Non-Medicare Members**

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

**Background**

Vertebral compression fractures (VCFs) occur when the bones of the spine become compressed and break. It is estimated that about five million new vertebral fractures occur worldwide each year. Most common in elderly populations and females, osteoporosis is responsible for more than 1.5 million fractures annually, the majority of which are vertebral. Other potential causes of VCFs include trauma, steroid use, malignancy in the vertebrae, and haemangioma. In any case, VCFs can be asymptomatic and resolve without treatment, however, they are frequently associated with pain, disability, and reduced quality of life (QoL). To add to this, VCFs are a risk factor for subsequent fractures which can lead to additional complications such as kyphosis, impairment of mobility or balance, and increased mortality to name a few (Chitale and Prasad 2013).

The majority of patients with VCFs are successfully treated with conservative management aimed to alleviate symptoms via external bracing, decreased activity and analgesics. Some patients, however, will experience persistent pain and symptoms refractory to medical therapy and may require additional intervention.

Percutaneous vertebroplasty is an interventional radiology technique developed to provide mechanical support and symptomatic relief in patients with VCFs. The minimally invasive procedure was first performed in France by Deramond and colleagues in 1984 and later, in 1993, was introduced to clinical practice in the US. The procedure was initially performed to strengthen vertebrae weakened by angiomas. Since then, however, indications for vertebroplasty have expanded to include metastatic vertebral cancer, multiple myeloma, as well as, osteoporotic VCFs that have not responded to conservative therapy. Performed under local anesthesia, the procedure involves injection of polymethylmethacrylate (PMMA) into a collapsed vertebral body under fluoroscopic guidance (Deramond, Depriester et al. 1998).

Vertebroplasty has been associated with serious complications such as infection, or more frequently cement

leakage that can lead to pulmonary embolism, adjacent vertebral collapse, nerve root irritation, or spinal cord compression. Cement leakage was reported to occur in 20-65% of all cases. Other less serious complications may include allergic reactions, hypertension, and temporary pain (Majd, Farley et al. 2005).

As a surgical procedure, vertebroplasty is not subject to US Food and Drug Administration (FDA) regulation. The FDA does, however, regulate the injectable bone cement which is integral to the procedure. While various bone cements have been approved, the FDA issued several notifications to orthopedic specialists and other healthcare professionals about the complications related to the use of these products. The Medical Technology and Assessment Committee (MTAC) has previously reviewed vertebroplasty in 2000 and 2005. In each case, the procedure failed MTAC criteria due to insufficient evidence to determine the efficacy of vertebroplasty in augmenting the collapsed vertebrae, and reducing pain in patients with osteoporotic compression fractures.

Vertebroplasty is currently being re-reviewed to update the evidence.

## Evidence and Source Documents

[Percutaneous Vertebroplasty of Low Back Pain](#)

[Percutaneous Vertebroplasty in Treatment of Osteoporotic Vertebral Fracture Radiofrequency](#)

[Ablation with Vertebral Augmentation for Painful Metastases](#)

## Medical Technology Assessment Committee (MTAC)

### ***Percutaneous Vertebroplasty of Low Back Pain***

#### **02/09/2000: MTAC REVIEW**

**Evidence Conclusion:** Efficacy of vertebroplasty in patients with osteoporotic compression fractures cannot be determined from these studies because of the likelihood of selection bias, observation bias, confounding and chance as explanations for some of, or all of, the studies' findings.

**Articles:** Articles were selected on the basis of study type. Because the literature revealed no randomized control trials or meta-analyses, the 14 cohort studies or case series were reviewed by abstract. The largest case series were selected for critical appraisal and evidence tables were created (Weill A, Chrias J, Simon J, et al. Spinal Metastases: Indications for Results of Percutaneous Injection of Acrylic Surgical Cement. Radiology. 1996; 199:241-247. Cortet B, Cotton A, Boutry N, et al. Percutaneous Vertebroplasty in the Treatment of Osteoporotic Vertebral Compression Fractures: An Open Prospective Study. J Rheumatol. 1999;26:2222-8.) Weill A, Chrias J, Simon J, et al. Spinal Metastases: Indications for and Results of Percutaneous Injection of Acrylic Surgical Cement. Radiology 1996; 199:241-247. See [Evidence Table](#). Cortet B, Cotton A, Boutry N, et al. Percutaneous vertebroplasty in the treatment of osteoporotic vertebral compression fractures: An open prospective study. J Rheumatol. 1999;26:2222-8. See [Evidence Table](#). Deramond H, Depriester C, Galibert P, et al. Percutaneous Vertebroplasty with Polymethylmethacrylate: Techniques, Indications, and Results. Radiologic Clinics of North America, Vol 36(3); May 1998:533-546. See [Evidence Table](#).

The use of percutaneous vertebroplasty of low back pain has been approved by the FDA and therefore meets *Kaiser Permanente Medical Technology Assessment Criteria*.

### ***Percutaneous Vertebroplasty in Treatment of Osteoporotic Vertebral Fracture***

#### **06/06/2005: MTAC REVIEW**

**Evidence Conclusion:** The studies reviewed do not provide sufficient evidence to determine the efficacy of the procedure, its long-term benefits, or late complications. No direct randomized studies comparing the intervention with standard, non-operative care are available.

Diamond et al's study had the advantage of comparing the intervention with conservative therapy. However, it was not randomized, and conservative therapy was offered to those who denied percutaneous vertebroplasty, which might be a potential source of selection bias. The study was also subject to observation bias as it was not blinded and all outcomes were subjective. Moreover, the follow-up duration might be insufficient to determine the long-term effects of the vertebroplasty. The Grohs' study compared kyphoplasty head to head with vertebroplasty. However, it was small, nonrandomized and unblinded. Postoperative comparison was made vs. baseline condition for each intervention with no direct comparison between the two techniques. The results of the study show that both procedures offered significant pain relief, which was maintained at a lower level with the kyphoplasty. The functional disability on the other hand was significantly improved only with kyphoplasty and not vertebroplasty. The results of the study also indicate that the rate of fracture of an adjacent vertebra seems to be higher with the kyphoplasty vs. vertebroplasty (21% vs. 4%). Gangi's study was a case series with potential selection and observation bias, with no control or comparison group, and the authors did not provide sufficient data on patient selection for the intervention, their characteristics, and follow-up, or long-term outcomes.

**Articles:** The search yielded 179 articles, most of which were review articles, discussion pieces and technical reports. A nonrandomized trial comparing percutaneous vertebroplasty with conservative therapy, and another

comparing it to kyphoplasty were identified, as well as several case series. *The two studies with comparison groups, as well as the largest case series (N=868), were selected for critical appraisal:* Diamond T, Champion B, and Clark W. Management of acute osteoporotic vertebral fractures: A nonrandomized trial comparing percutaneous vertebroplasty with conservative therapy. *Am J Med.* 2003;114:257-265. See [Evidence Table](#).

Grohs JG, Matzner M, Trieb K, et al. Minimal invasive stabilization of osteoporotic vertebral fractures. A prospective nonrandomized comparison of vertebroplasty and balloon kyphoplasty. *J Spinal Disord Tech* 2005;18:238-242. See [Evidence Table](#). Gangi A, Guth S, Imbert JP, et al. Percutaneous vertebroplasty: Indications, technique, and results. *Radiographics.* 2003;23:e10-e10. See [Evidence Table](#).

The use of Percutaneous Vertebroplasty in Treatment of Osteoporotic Vertebral Fractures does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

#### 09/04/2009: MTAC REVIEW

##### **Percutaneous Vertebroplasty in Treatment of Osteoporotic Vertebral Fracture**

**Evidence Conclusion:** There is fair evidence from two randomized controlled trials that vertebroplasty does not have a significant benefit over sham treatment in reducing pain and pain-related disability in patients with osteoporotic vertebral fractures. [Kallmes, et al 2009 trial:](#) Kallmes and colleagues randomly assigned 131 patients with 1-3 painful osteoporotic compression vertebral fractures (between T4 and L5), that was <1 year old and not responding to standard medical therapy, to undergo vertebroplasty or a sham treatment that simulated the procedure but without PMMA infusion. The primary outcomes were scores on the modified Roland-Morris Disability Questionnaire (RDQ) and patient's rating of average pain intensity during the preceding 24 hours at 1 month. Patients were allowed to cross over to the other study group after one month. The results of the trial show no significant differences in the primary outcome between the two groups (difference in RDQ score 0.7; 95%CI, -1.3 to 2.8, p=0.49, and difference in pain rating 0.7; 95% CI, -0.3 to 1.7, p=0.19). One serious adverse event occurred in each of the 2 study groups (injury to the thecal sac in the vertebroplasty procedure, and tachycardia and rigors in the control group) At 3 months there was a higher rate of cross over in the control group (43%) than the vertebroplasty group (12%), p<0.001. The study had generally valid methodology, but not without limitations. It was randomized, controlled, blinded, multicenter, with well defined inclusion/ exclusion criteria, sufficient statistical power to detect differences between the study groups, and analysis was based on ITT. The limitations of the trial included allowing cross-over between the two treatment groups after 1 month which did not allow evaluating the long-term efficacy of the procedure. Moreover, no adjustments were made for other medical treatments received, or other causes of pain all of which are potential confounders. [Buchbinder, et al 2009:](#) Buchbinder and colleagues randomized 78 patients with one or two painful. MRI confirmed unhealed osteoporotic vertebral fractures. <12 months duration to undergo vertebroplasty or a sham procedure. Patients were followed up for 6 months, and the primary outcome was overall pain at 3 months. Secondary outcomes included functional status and QoL at 1week, 1, 3, and 6 months after the procedures. The trial had generally valid methodology but was relatively small. It was randomized, controlled, blinded, multicenter, with sufficient statistical power to detect significant differences between the study groups, and analysis was based on ITT. The results show no significant difference between the vertebroplasty and sham treatment in any of the outcomes. The mean reduction in pain was 2.6 +2.9 and 1.9+3.3 respectively with an adjusted difference between the two groups of 0.6; 95% CI, -0.7 to 1.8. Both groups showed a significant reduction of pain at three months vs. baseline. 7 new of clinical vertebral fractures occurred during the 6-month follow-up (three in the vertebroplasty group and 4 in the control group. **Conclusion:** The published literature provides fair evidence that vertebroplasty has no significant benefit over a sham procedure in the treatment of patients with osteoporotic vertebral fractures.

Articles: Two trials on vertebroplasty for osteoporotic spinal fractures were recently published: Buchbinder R, Osborne RH, Ebeling PR, et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. *N Engl J Med* 2009;36:557-568. Kallmes DF, Comstock BA, Heagerty PJ, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. *N Engl J Med* 2009;36:569-579.

The use of Percutaneous Vertebroplasty in Treatment of Osteoporotic Vertebral Fractures does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

#### 02/09/2015: MTAC REVIEW

##### **Percutaneous Vertebroplasty in Treatment of Osteoporotic Vertebral Fracture**

**Evidence Conclusion:** *Effectiveness:* In the first RCT, detailed in evidence table one, Buchbinder and colleagues included 78 subjects with back pain, ≤12 months in duration, who had up to two VCF evidenced by the presence of vertebral collapse, edema and/or a fracture line on MRI. Patients were randomized into either the vertebroplasty treatment group or a group that received sham procedure. Outcomes were measured at baseline and several points in time up to six months following the procedure. The primary endpoint was overall pain at three months, however, the study also included QoL measures and a survey specific to osteoporotic vertebral fractures.

Ultimately the study found no beneficial effect of vertebroplasty over the sham procedure at any time. In fact, the only significant between-group difference was seen on the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO) total score at one week, favoring the sham group [-4.0 (95%CI -7.8 to -0.2)] (Buchbinder, Osborne et al. 2009). [Evidence Table](#). The second study, by Kallmes and colleagues, also randomized osteoporotic patients with up to three painful VCFs (n=131) to vertebroplasty or sham procedures. After one month, if patients did not achieve adequate pain relief, the investigators allowed cross-over to the alternate therapy. The primary outcomes, pain and disability, were assessed at one month, however, investigators also describe outcomes up to three months to assess the effects of cross-over. At one month, both the vertebroplasty and sham groups demonstrated substantial improvements, however, no significant differences were seen between groups in either of the primary outcomes. The mean Roland-Morris Disability Questionnaire (RDQ) in the vertebroplasty group was 12.0±6.3 and 13.0±6.4 in the sham group (adjusted treatment effect, 0.7; 95% CI, -1.3 to 2.8; P=0.49). Similarly, the mean pain-intensity rating was 3.9±2.9 in the vertebroplasty group and 4.6±3.0 in the sham group (adjusted treatment effect, 0.7; 95% CI, -0.3 to 1.7; P=0.19). The investigators note, however, that the control group saw a higher rate of cross-over than the vertebroplasty group (51% vs. 13%, P<0.001). Despite this significance, the investigators concluded that improvements in pain and pain-related disability associated with osteoporotic VCF in patients treated with vertebroplasty were similar to the improvements seen in the sham group (Kallmes, Comstock et al. 2009). [Evidence Table](#). **Safety:** Adverse events were documented in both studies and included hospitalizations from the procedure, as well as, subsequent fractures. Cement leakage was not reported by Kallmes and colleagues, however, Buchbinder et al. reported 37% cement leakage rate with no symptomatic events. Neither of the studies provided extended follow-up of safety and adverse events with the longest follow-up limited to six months following procedure. Previous reviews of vertebroplasty failed MTAC criteria with the available evidence offering little value due to methodological limitations such as a lack of randomization, inappropriate comparators and the likelihood of selection bias, observation bias, confounding and chance as explanations for study findings. Currently, however, the literature is more robust with two RCTs that compare vertebroplasty to sham procedures. The design of both studies was strengthened by the use of a sham procedure replicating verbal and visual cues allowing for the blinding of patients. With that said, an additional control group receiving no treatment would have benefited the outcome comparisons. Other limitations include sample size. Despite relatively lax inclusion criteria, both of the studies experienced difficulties recruiting patients resulting in a modification of sample size in the study by Kallmes et al. and the inability to assess two year follow-up in the Buchbinder study. Ultimately, the studies provide adequate evidence to suggest that vertebroplasty is no better than sham treatment for treating patients with VCF due to osteoporosis.

**Conclusions:** There is evidence to suggest that vertebroplasty is no more effective than sham therapy for the treatment of vertebral compression fractures in osteoporotic patients. There is insufficient evidence to assess the safety of vertebroplasty for the treatment of vertebral compression fractures in osteoporotic patients.

**Articles:** The search yielded a large quantity of publications relating to vertebroplasty. The majority of the literature was comprised of non-randomized, observational studies, many of which sought to compare vertebroplasty with kyphoplasty. A supplemental search of the clinical trials database revealed several studies relating to vertebroplasty that are currently recruiting or on-going. Since the last MTAC review, two randomized trials comparing percutaneous vertebroplasty with a sham procedure therapy were published and selected for critical appraisal. The following articles were selected for critical appraisal: Buchbinder R, Osborne RH, Ebeling PR, et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. *NEJM*. 2009; 361(6):557-568. [Evidence Table 1](#). Kallmes DF, Cornstock BA, Heagerty PJ, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. *NEJM*. 2009;261(6):569-571. [Evidence Table 2](#).

The use of Percutaneous Vertebroplasty in Treatment of Osteoporotic Vertebral Fractures does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

## **Radiofrequency Ablation with Vertebral Augmentation for Painful Metastases**

### **BACKGROUND**

The number of patients living with cancer in the United States (US) is estimated to be 4.86 million. Virtually all cancers have the potential to spread, or metastasize, with bone being one of the more common sites of metastasis. Generally speaking, skeletal metastases are associated with debilitating symptoms such as intolerable pain and hypercalcemia compromising the quality of life. Occurrence in the vertebral column, as does with a third of all cancer patients, contributes the additional complexity of complications such as vertebral compression factors (VCF) and spinal cord or nerve root compression that can cause potentially irreversible loss of neurologic function (Coleman 2000).

Depending on the primary tumor, prognosis is variable with five year survival ranging from 2% in patients with lung cancer to 44% in those with thyroid cancer. Treatment presents a challenge in that there is no currently available cure, nor has there been any established treatment proven to increase life expectancy. Instead, the goals of treatment aim to control pain, limit complications and preserve function. Depending on individual patient factors,

management options range from medications and systemic therapy all the way to surgical resection (Dunning, Butler et al. 2012).

Due to the advanced nature of metastatic cancer and its accompanying comorbidities, populations with skeletal metastases are usually at a higher surgical risk, making minimally invasive techniques an attractive option. Vertebral augmentation (VA) techniques, aimed at stabilizing vertebral compression fractures (VCF), have been documented to provide immediate and sustained relief (Weill, Chiras et al. 1996). In the same way, radiofrequency ablation (RFA), a technique that utilizes thermal energy to destroy cancer cells, has also been demonstrated to reduce pain (Goldberg and Dupuy 2001; Kassamali, Ganeshan et al. 2011). Most recently, RFA and VA, in combination, have been considered a promising treatment option for treating metastatic lesions of the spine (Grönemeyer, Schirp et al. 2002; Schaefer, Lohrmann et al. 2002; Schaefer, Lohrmann et al. 2003).

The STAR™ Tumor Ablation System was developed by DFINE, Inc. (San Jose, CA) specifically for metastatic spinal lesions. The system itself consists of the SpineSTAR™ Ablation Instrument and the corresponding MetaSTAR™ RF Generator which work in unison to deliver energy and provide access and navigation to the tumor within the vertebrae. Subsequent to tumor ablation, stabilization is carried out with the StabiliT® Vertebral Augmentation System, also developed by DFINE, Inc. Put simply, the StabiliT® System allows for the delivery of highly viscous bone cement to the tumor bed. In combination, the procedures require a small incision under local anesthesia with conscious sedation and offer the advantages of unipedicular access, and real-time monitoring of ablation zone allowing for the targeting of tumor cells and controlled cement delivery.

#### 04/20/2015: MTAC REVIEW

##### **Radiofrequency Ablation with Vertebral Augmentation for Painful Metastases**

**Evidence Conclusion:** *Effectiveness:* In a small RCT, Orgera and colleagues, sought to compare the combined techniques of RFA and VA with VA alone. Following baseline assessment, the investigators randomized 36 patients into the two treatment groups and followed them up for six weeks. Outcomes of interest included surgery success, pain relief and the amount of analgesia administered. The investigators reported a 100% technical success rate in both groups with no significant differences noted between treatment groups with regard to pain as measured on a Visual Analogue Scale (VAS) or Roland Morris Questionnaire (RMQ). In addition, medication use decreased significantly in both groups but the investigators found no significant difference between groups.

Ultimately, the results led the investigators to conclude that the addition of RFA did not offer any additional benefit (Orgera, Krokidis et al. 2014). [Evidence Table 1] A retrospective review of 128 metastatic lesions in 92 patients who underwent 96 procedures was carried out by Anchala and colleagues. The studies intent was to assess the safety and efficacy of RFA of malignant spinal lesions using the SpineSTAR ablation instrument. The investigators determined that RFA was 'technically successful' in all metastatic lesions. Post-operative pain rated on a Visual Analogue Scale (VAS) demonstrated significant changes at all time points when compared to baseline. The investigators also reported that within the largest institution, 54% of patients reported a decrease in pain medication. Ultimately, the investigators concluded that the STAR system was safely and effectively used in the treatment of spine metastatic osseous lesions (Anchala, Irving et al. 2014). [Evidence Table 2]

*Safety* Although the follow-up period was limited, Orgera and colleagues reported several complications such as cement leakage (11%), death (5%) and opioid toxicity (8%). Anchala and colleagues, on the other hand, did not explicitly report safety details, but did note asymptomatic cement extravasation in two patients. Although Orgera's study was randomized and blinded, the population size was small and the follow-up period short. Limitations of Anchala's study include the lack of an adequate comparator and retrospective design. The investigators also highlight limitations such as a heterogeneous population and variable availability of data collected from each treatment center. Finally, it should be noted that at least two of the investigators from the retrospective review disclosed financial relationships with the device manufacturer. Collectively, the body of evidence is limited in nature and should be interpreted with caution.

**Conclusions:** There is insufficient evidence to support the effectiveness of the combination of RFA and VA, compared with VA alone, for the management of pain in metastatic spinal tumors. There is insufficient evidence to support the safety of RFA and VA, compared with VA alone, for the management of pain in metastatic spinal tumors.

**Articles:** A search of the literature returned a variety of publications relating to both RFA and VA, in general. The majority of publications returned were case studies/series. One study was identified comparing the combination of RFA and VA with balloon kyphoplasty, however, this study was performed in cadaveric models (Dalton, Kohm et al. 2012). A recent study identified in the search, by Song and colleagues, investigated the use of RFA and vertebral augmentation in 12 patients, however, this study was not selected for critical appraisal due to the small sample size and lack of a comparator (Song, Gu et al. 2014). The best evidence identified was a small randomized controlled trial (RCT) comparing RFA+VA with VA alone in patients with multiple myeloma (Orgera, Krokidis et al. 2014). In addition, a retrospective analysis, by Anchala and colleagues, evaluating the combination of RFA with VA for treating metastatic spinal lesions was also included (Anchala, Irving et al. 2014). An additional search of the clinical trials database identified a few prospective observational studies sponsored by DFINE, Inc. currently in the

recruitment phase. The following articles were selected for critical appraisal: Orgera G, Krokidis M,Matteoli M, et al. Percutaneous vertebroplasty for pain management in patients with multiple myeloma: is radiofrequency necessary? 2014;37:203-210. See [Evidence Table](#). Anchala PR, Irving WD, Hillen TJ, et al. Treatment of metastatic lesions with a navigational bipolar radiofrequency ablation device: a multicenter retrospective study. Pain Physician. 2014;17:317-327. See [Evidence Table](#).

The use of Radiofrequency Ablation with Vertebral Augmentation for Painful Spinal Metastases does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Date Created	Date Reviewed	Date Last Revised
11/26/1999	06/04/2013 <sup>MDCRPC</sup> , 12/03/2013 <sup>MPC</sup> , 05/06/2014 <sup>MPC</sup> , 03/03/2015 <sup>MPC</sup> , 01/05/2016 <sup>MPC</sup> , 11/01/2016 <sup>MPC</sup> , 08/07/2018 <sup>MPC</sup>	06/02/2015

<sup>MDCRPC</sup> Medical Director Clinical Review and Policy Committee  
<sup>MPC</sup> Medical Policy Committee

Revision History	Description
06/02/2015	MPC adopted MTAC recommendation of insufficient evidence for the use of Radiofrequency Ablation with Vertebral Augmentation for Painful Spinal Metastases.
06/11/2015	Codes Added
09/08/2015	Revised LCD L34168 and L34106
11/30/2015	Revised CPT codes

## Codes

Kyphoplasty CPT codes: 22513, 22514, 22515  
 Vertebroplasty CPT codes: 22510, 22511, 22512  
 Radio Frequency Ablation with Vertebroplasty: 20983  
 This code was deleted 1/1/2015 - 72291