KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Vertebroplasty + Kyphoplasty

- Percutaneous Vertebroplasty with Polymethylmethacrylate
- Radiofrequency Ablation with Vertebral Augmentation for Painful Spinal Metastases

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L34106)
Local Coverage Article	Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (A56573)
KPWA Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, Percutaneous Sacroplasty, for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

Kaiser Permanente has elected to use coverage guidance from the Noridian Local Coverage Determination (LCD) L34106 *Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)* for medical necessity determinations for non-Medicare members.

*Note: Provisions in the LCD and related coding article only address Vertebral Augmentation for Osteoporotic Vertebral Compression Fracture (VCF). Coverage will remain available for medically necessary procedures for other conditions not included in the LCD, such as other pathologic vertebral compression fractures.

Percutaneous vertebral augmentation is not covered if the procedure includes the following:

A. Radiofrequency-assisted vertebral augmentation with ultrahigh viscosity cement, including but not limited to Radiofrequency-Targeted Vertebral Augmentation™ (RF-TVA™) with the StabiliT® System
B. Mechanical vertebral augmentation using any device other than a balloon device, including but not limited to use of the following:
    1. Use of the Kiva®

Percutaneous Sacroplasty – 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.

If requesting this service, please send the following documentation to support medical necessity:

- Last 6 months of clinical notes from requesting provider &/or specialist

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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, Kaiser Permanente 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.

Over the last twenty years, two minimally invasive techniques to augment the vertebral bodies and reduce pain have been developed as a treatment option for refractory VCFs. The first technique, percutaneous vertebroplasty, was first introduced in France by Deramond and colleagues in 1984 and later, in 1993, was introduced into clinical practice in the United States (US). The procedure, initially performed to strengthen vertebrae weakened by angiomas, involved injection of polymethylmethacrylate (PMMA) into a collapsed vertebral body under fluoroscopic guidance (Deramond, Depriester et al. 1998). 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. The second procedure, kyphoplasty, was devised in 1998 after mounting concerns over flaws in the vertebroplasty technique. With the same aims and desired outcomes as vertebroplasty, kyphoplasty employs the use of inflatable balloon tamps to restore vertebral height and reduce kyphotic deformity before stabilization with PMMA. It is believed that the cavity formation and the use of more viscous cement introduced with less pressure, compared to vertebroplasty leads to lower risk of cement extravasation (Atalay, Caner et al. 2005; Wardlaw, Cummings et al. 2009).

Medical Technology Assessment Committee (MTAC)

06/07/2001: MTAC REVIEW
Kyphoplasty
Evidence Conclusion: The published evidence consists of one poorly described case series that is insufficient to draw conclusions about the safety and efficacy of kyphoplasty.
Articles: The literature search yielded one published article. The article reported on a study using cadavers and does not have data appropriate for MTAC review. One other published article was received from Kyphon. This was largely a review article; it included one paragraph about the use of the kyphoplasty procedures. No details on study methodology were given so that this study also could not be evaluated. There is also one article documented to be in-press in Spine. An evidence table was created for this case series. Lieberman IH, Dudeney S, Reinhardt M-K, Bell G. Initial outcome and efficacy of “kyphoplasty” in the treatment of painful osteoporotic vertebral compression fractures. Spine 2001; in-press. See Evidence Table.

Kyphoplasty for the treatment of vertebral body compression fractures refractory to maximal medical management does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

07/14/2004: MTAC REVIEW
Kyphoplasty
Evidence Conclusion: The evidence is insufficient to draw conclusions about the safety and efficacy of kyphoplasty. It consists of two small (fewer than 30 patients) case series, one published in 2001 and one with the abstract published electronically in April 2004 ahead of the print version.
Articles: The search yielded 41 articles, most of which were discussion pieces and technical reports. The single new empirical study was an “electronic publication ahead of print” and was not yet available. An inspection of the

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abstract showed that this was a case series with 27 patients.

Kyphoplasty for the treatment of vertebral body compression fractures refractory to maximal medical management does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

06/06/2005: MTAC REVIEW
Kyphoplasty
Evidence Conclusion: There are no randomized controlled studies that compared the short and long-term outcomes of kyphoplasty with those of the more conservative standard therapies. The Grohs' study compared kyphoplasty head to head with vertebroplasty however, it was small, nonrandomized and unblinded. Postoperative comparison was made versus 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 observed improvement was statistically significant for the first year only. 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%). The other article reviewed was a case series with some advantages: it was relatively large, had inclusion/exclusion criteria, and had objective outcomes. However, like all case series it lacks a control or comparison group and has potential selection and observation bias. Overall its results showed that the pain was completely relieved in 78% of the patients, and, that the vertebral height significantly improved after kyphoplasty. There were no long-term follow-up data to determine the long-lasting effects or late complications of the intervention. In conclusion, the published literature does not provide sufficient evidence to determine the effects of the procedure on the spine, or its long-lasting effect on pain relief. A European multicenter prospective randomized controlled trial comparing kyphoplasty with the standard pharmacological therapy is underway (Ohlin 2004).
Articles: The search yielded 70 articles, most of which were review articles, discussion pieces and technical reports. There was no randomized controlled trial that compared the short and long-term outcomes with conservative therapies. The search revealed a recent nonrandomized study that compared kyphoplasty head-to head with percutaneous vertebroplasty, as well as several small prospective case series, and retrospective reviews of cases that underwent the procedure. *The following controlled study, as well as the largest case series (N=222), were selected for critical appraisal:* 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. Majd ME, Farley S, and Holt RT. Preliminary outcomes and efficacy of the first 360 consecutive kyphoplasties for the treatment of painful osteoporotic vertebral compression fractures. *Spine J.* 2005; 5:244-255. See Evidence Table.

Kyphoplasty for the treatment of vertebral body compression fractures refractory to maximal medical management does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

08/04/2008: MTAC REVIEW
Kyphoplasty
Evidence Conclusion: The body of evidence on the safety and efficacy of balloon kyphoplasty (BKP) in the treatment of vertebral compression fractures consisted of multiple case series and few non-randomized studies that compared BKP to either vertebroplasty or the standard conservative therapy. Several authors pooled the results of these comparative and non-comparative series in a number of meta-analyses. However, the quality of meta-analyses and the strength of their conclusions depend on the quality of the included studies. The studies included in the published meta-analyses for BKP were too small, and had their methodological flaws and potential selection and observation bias. The comparative studies were non-randomized and the authors did not discuss how and why patients were selected for each of the procedures. There was evidence of publication bias as well as significant heterogeneity between the studies included in the meta-analyses. The studies differed their inclusion/exclusion criteria, outcome measures, scales used, and scoring systems, as well as duration and completeness of follow-up. Moreover, the results were unblinded and many of the outcomes were subjective.
The comparative studies published after the meta-analyses were also too small, non- randomized, unblinded, with relatively short follow-up duration, as well as other validity threats and do not allow making conclusions as regard the efficacy and safety of the procedure. In conclusion, the published literature does not provide sufficient evidence to determine the benefit of the procedure in relieving pain, improving function, and reducing rate of vertebral fractures. There is also insufficient evidence to determine its long-lasting effect on pain relief or its adverse effects on the spine. Large well conducted randomized controlled trials, with long term follow-up duration are needed to objectively compare balloon kyphoplasty to conventional treatment and other percutaneous techniques, and to determine its long-term safety and efficacy in improving function and reducing pain, disability, and complications

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associated with vertebral compression fractures.
Articles: The search yielded over 90 articles on balloon kyphoplasty. Many were reviews and technical reports. No randomized controlled trials that compared the procedure with vertebroplasty or conservative therapy were identified. There were four meta-analyses of non-randomized controlled studies and case series. All four included almost the same studies, and two were performed by the same group of authors. The search also revealed two non-randomized comparative studies published after the meta-analyses. One (N=21) compared kyphoplasty to vertebroplasty for the treatment of painful osteoporotic or traumatic VCFs, and the other (N=60) compared kyphoplasty with standard medical treatment of osteoporotic or traumatic VCF. The studies on the use of kyphoplasty for severe back pain due to metastatic disease were small case series with no control or comparison groups. The most recent meta-analysis and the two comparative studies were critically appraised. Taylor RS, Fritzell P, Taylor RJ. Balloon kyphoplasty in the management of vertebral compression fractures: an updated systematic review and meta-analysis. *Eur Spine J* 2007; 16:1085-1100. See Evidence Table. De Negri P, Tirri T, paternoster G, et al. Treatment of painful osteoporotic or traumatic vertebral compression fractures by percutaneous vertebral augmentation procedures. *Clin J Pain.* 2007; 5:425-430. See Evidence Table. Grafe IA, Fonseca KD, Hillmeier J, et al. Reduction of pain and fracture incidence after kyphoplasty: 1-year outcomes of a prospective controlled trial of patients with osteoporosis. *Osteoporos Int* 2005; 16:2005-2012. See Evidence Table.

Kyphoplasty for the treatment of vertebral body compression fractures refractory to maximal medical management does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

12/07/2009: MTAC REVIEW
Kyphoplasty
Evidence Conclusion: A recently published RCT (Wardlaw et al 2009) compared kyphoplasty plus standard medical therapy to medical therapy alone in 300 patients from 21 sites in eight countries. The trial was randomized and controlled, however kyphoplasty was not compared to a sham procedure or an alternative invasive or noninvasive surgical procedure. The medical therapy was not standardized and varied according to the standard practices of the participating centers, and neither the patients nor the investigators were blinded to the treatment received. Medtronic Spine LLC, the manufacturer of the kyphoplasty balloon technology was involved in the study design, data monitoring, analysis, and reporting of the results. The results of the trial shows that patients in the kyphoplasty group experienced greater reduction in pain and improved function at one month compared to the control group. The significant improvement observed at one month in the short form -36 physical component summary (SF-36 PCS) scale, the primary outcome the trial, declined along the following months and was statistically insignificant by the 12th months, when the controls showed improvement. The results also show a higher rate of vertebral fractures and/or worsening of fractures among the patients in the kyphoplasty group vs. the controls. The difference was not statistically significant, but the study was not powered to detect significant differences in fracture rates. The authors did not report on any cement leakage associated with kyphoplasty.
In conclusion, the published literature does not provide sufficient evidence to determine that kyphoplasty is a safe and an appropriate procedure for relieving pain, improving function, reducing rate of vertebral fractures and disability in patients with vertebral compression fractures.
Articles: The search identified one recent randomized controlled trial (Wardlaw et al 2009) that compared balloon kyphoplasty with non-surgical care for vertebral compression fracture No randomized controlled trials that compared the procedure with a sham treatment were identified. A relatively small RCT with only 6 months of follow-up compared the kyphoplasty to vertebroplasty in patients with osteoporotic vertebral fractures. Wardlaw et al's RCT was selected for critically appraised. Wardlaw D, Cummings SR, Van Meirhaeghe J. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomized controlled trial. Lancet. 2009; 373:1016-24. See Evidence Table.

Kyphoplasty for the treatment of vertebral body compression fractures refractory to maximal medical management does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

02/09/2015: MTAC REVIEW
Kyphoplasty
Evidence Conclusion: *Effectiveness* In 2009, Wardlaw and colleagues reported results from an RCT comparing kyphoplasty to non-surgical management (NSM) in 300 patients from 21 sites in eight countries. The results of the trial indicate that patients in the kyphoplasty group experienced greater reduction in pain and improved function at one month compared to the control group. The significant improvement observed at one month in the short form- 36 (SF-36) physical component summary (PCS) scale, the primary outcome the trial, declined along the following months and was statistically insignificant by 12 months. The kyphoplasty group also experienced statistically

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significant reductions in back pain and improvement in both back function and quality of life scales early on, however, this effect diminished over time (Wardlaw, Van Meirhaeghe et al. 2012). In 2010, Boonen and colleagues expand on the results of the FREE-trial including an additional 12 months of follow-up. With the exception of pain and QoL, most criteria were no longer statistically significant at 24 months indicating that any benefit for both groups occurs within the first year. The investigators do note that averaged scores, across the 24 month period, did show significance when compared with NSM in physical symptoms, as assessed by the SF-36 PCS (3.24 points, 95% CI 1.47-5.01, p=0.0004), and on the QoL scale as assessed by the Euro quality-of-life questionnaire (EQ-5D) (0.12 points, 95% CI, 0.06 to 0.18, p=0.0002). The investigators concluded that, compared with NSM, kyphoplasty rapidly reduces pain and improves function, disability, and QoL over the course of two years (Boonen, Van Meirhaeghe et al. 2011). [Evidence Table 1] *Safety* At 24 months, the investigators report that the overall frequency of patient with adverse events (AE) and serious adverse events (SAE) was similar between treatment groups. With that said, the investigators did report two serious adverse events, hematoma and urinary tract infection (UTI), that were considered to be related to the procedure. In addition, the investigators identified cement leakage in one patient who had undergone kyphoplasty. Finally, the kyphoplasty group had a higher rate of subsequent vertebral fractures when compared with the NSM group (47.5% vs. 44.1%; 3.4% difference, 95% CI -16.5 to 9.9, p=0.68), however, this difference was not statistically significant, and the study was not powered to detect significant differences in fracture rates. The FREE-trial has the advantage of being multi-centered, randomized and controlled. In addition, the analysis was based on intention-to-treat (ITT) and the study was adequately powered. Limitations of the study, however, include an inadequate comparator. Ideally, kyphoplasty should have been compared with a sham procedure or an alternative surgical procedure. Instead, the investigators compare the procedure to conservative management which, with 21 sites spanning eight different countries, was variable and not standardized. To add to this limitation, the differences in the treatment of the control and the intervention groups did not allow for blinding of both patients and the investigators opening the study up to selection and information bias. A further limitation of the study includes the investigators failure to stratify the data in analysis according to indication (osteoporosis vs. myeloma vs. metastasis) limiting the applicability of the results. Finally, it should be noted that the manufacturer of the kyphoplasty balloon technology, Medtronic Spine LLC, was involved in the study design, data monitoring, analysis, and reporting of results. For these reasons, the results of the study should be interpreted with caution and does not provide sufficient evidence to determine safety and effectiveness of kyphoplasty for treating VCF. *Conclusions:* There is insufficient evidence to support the effectiveness of kyphoplasty over non-surgical management for the treatment of VCF caused by osteoporosis, myeloma or malignancy. There is insufficient evidence to support the safety of kyphoplasty for the treatment of VCF caused by osteoporosis, myeloma or malignancy.

Articles: The literature search sought to update the evidence from the end date of the last MTAC review. The search revealed a large quantity of publications including a variety of systematic reviews and retrospective observational studies. No RCTs were identified that compared kyphoplasty to sham treatment. The largest RCT to date, the fracture reduction evaluation (FREE), included 300 patients with 12 months follow-up and was critically appraised by MTAC in 2009 (Wardlaw, Van Meirhaeghe et al. 2012). Since then, Boonen and colleagues have published a follow-up analysis reporting the 24-month outcomes of the FREE trial. The following articles were selected for critical appraisal: Wardlaw D, Cummings SR, Van Meirhaeghe J, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomized controlled trial. Lancet. 2009; 373(9668):1016-1024. Evidence Table 1. Boonen S, Van Meirhaeghe J, Bastian L, et al. Balloon Kyphoplasty for the treatment of acute vertebral compression fractures: 2-year results from a randomized trial. JBMR. 2011; 26(7):1627-1637. Evidence Table 1.

Kyphoplasty for the treatment of vertebral body compression fractures refractory to maximal medical management does meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

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;

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199;241-247. See Evidence Table. Cortet B, Cotten 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 als 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 moths 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, bur 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

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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

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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

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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.*

Applicable Codes

Kyphoplasty - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
22513	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic
20983	Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; cryoablation

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22514	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar
22515	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)

Vertebroplasty - Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT® Codes	Description
22510	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic
22511	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral
22512	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body (List separately in addition to code for primary procedure)

Sacroplasty - Considered Not Medically Necessary:

CPT® Codes	Description
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**.

Date Created	Date Reviewed	Date Last Revised
06/07/2001	04/02/2013[MDCRPC], 02/04/2014[MPC], 05/06/2014[MPC], 03/03/2015[MPC], 01/05/2016[MPC], 11/01/2016[MPC], 09/05/2017[MPC], 08/07/2018[MPC], 08/06/2019[MPC], 08/04/2020[MPC], 08/03/2021[MPC], 08/02/2022[MPC], 08/01/2023[MPC]	12/28/2023

[MDCRPC] Medical Director Clinical Review and Policy Committee
[MPC] Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD for Percutaneous Vertebral Augmentation (L34106).
08/04/2020	Added Medicare LCA A56573
05/03/2022	MPC approved to adopt Medicare criteria for Non-Commercial members for Vertebroplasty; merged Kyphoplasty and Vertebroplasty into one policy
12/28/2023	Adopted commercial criteria for MA members for Percutaneous Sacroplasty.

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