KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Kyphoplasty

See separate criteria for vertebroplasty.

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	Percutaneous Vertebral Augmentation (L34106).
Local Coverage Article	None

For Non-Medicare Members

I. Percutaneous balloon kyphoplasty may be considered medically necessary for the treatment of no more than 3 symptomatic vertebral fractures of the **T5-L5** spine when **ALL of the following criteria are met:**
   A. Appropriate imaging (plain film x-ray or MRI) has been performed preoperatively and the findings of such imaging correlate unequivocally with the patient's pain; **and**
   B. There is documentation in the medical record that the member's pain is predominantly, if not solely, related to the demonstrated fracture(s); **and**
   C. The member has failed to respond to conservative treatment (e.g., analgesics, physical therapy, rest) for at least 6 weeks; **and**
   D. Prior to the procedure a documented assessment confirms the absence of the following contraindications:
      1. Chronic (>12 months) fracture at the same vertebral level
      2. Untreated symptomatic foraminal or canal stenosis, facet arthropathy, or other significant coexistent spinal or bony pain generators
      3. Bone fragment retropulsion
      4. Symptoms that cannot be related to a fracture
      5. Unstable fracture or requirement for stabilization procedure in same or adjacent spinal region
      6. Active osteomyelitis whether fungal, bacterial or mycobacterial, or any other active infection, including urinary tract infection (UTI)
      7. Uncorrected coagulation disorders
      8. Known allergy to any of the materials used in these procedures

II. Percutaneous kyphoplasty with a balloon device is not covered for all other indications, including but not limited to the following:
   A. Acute vertebral fractures due to osteoporosis or trauma (before 6 weeks of conservative therapy as noted above)
   B. Vertebrae of the cervical spine and thoracic levels T1-5
   C. Stabilization of insufficiency fractures or lesions of the sacrum (sacroplasty) or coccyx (coccygeoplasty)
   D. Prophylactic treatment for osteoporosis of the spine or for chronic back pain of long-standing duration, even if associated with old compression fracture(s).
   E. Absence of a confirmed acute or subacute fracture
   F. Symptoms that cannot be related to a fracture;

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G. Radicular symptoms that are explained by bone impinging on nerves or another anatomic lesion;
H. Unstable fracture;
I. Asymptomatic vertebral compression fracture;
J. Active osteomyelitis, whether fungal, bacterial or mybacterial;
K. Burst fracture with retropulsed fragments demonstrated by imaging study;
L. Uncorrected coagulation disorders; and
M. Known allergy to any of the materials used in either procedure
N. Compression fractures shown by the medical record to be more than one year old.

III. Percutaneous vertebral augmentation by any technique other than inflatable balloon is not covered which includes but not limited to the following:
A. Vertebroplasty – See separate criteria for vertebroplasty
B. Radiofrequency-assisted vertebral augmentation with ultrahigh viscosity cement, including but not limited to Radiofrequency-Targeted Vertebral Augmentation™ (RF-TVA™) with the StabiliT® System – See separate criteria for Radiofrequency Ablation for Vertebral Augmentation
C. 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® system

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.

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, kypohplasty, 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

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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 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

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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 percutaneoustechniques, and to determine its long-term safety and efficacy in improving function and reducing pain, disability, and complications 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

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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 randomised 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 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 colleaguesexpand 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, kypohplasty 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-

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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.*

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]	03/03/2015

[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).

Codes

Kyphoplasty : 22513, 22514, 22515
Vertebroplasty: 22510, 22511, 22512
Sacroplasty: 0200T, 0201T

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