Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation

**Policy Number:** 6.01.38  
**Last Review:** 10/2017  
**Origination:** 6/2004  
**Next Review:** 9/2018

**Policy**

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for percutaneous kyphoplasty when it is determined to be medically necessary because the criteria shown below are met.

**When Policy Topic is covered**

Percutaneous kyphoplasty and Kiva® may be considered **medically necessary** for the treatment of symptomatic osteoporotic vertebral fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy, and rest) for at least 6 weeks.

Percutaneous kyphoplasty and Kiva® may be considered **medically necessary** for the treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

**When Policy Topic is not covered**

Percutaneous kyphoplasty and Kiva® is considered **investigational** for all other indications, including use in acute vertebral fractures due to osteoporosis or trauma.

Percutaneous radiofrequency kyphoplasty or percutaneous mechanical vertebral augmentation using any other device, is considered **investigational**.

**Description of Procedure or Service**

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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</thead>
<tbody>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>• With osteoporotic</td>
<td>• Balloon kyphoplasty or mechanical vertebral</td>
<td>• Conservative care</td>
<td>• Symptoms</td>
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<tr>
<td>vertebral compression</td>
<td>augmentation (Kiva)</td>
<td></td>
<td>• Functional outcomes</td>
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<tr>
<td>fractures</td>
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<td>• Quality of life</td>
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<td>• Hospitalizations</td>
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<td>• Treatment-related morbidity</td>
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Percutaneous balloon kyphoplasty and mechanical vertebral augmentation with Kiva VCF Treatment System are interventional techniques involving the fluoroscopically guided injection of polymethylmethacrylate into a cavity created in the vertebral body with a balloon or mechanical device. These techniques have been investigated as options to provide mechanical support and symptomatic relief in patients with osteoporotic vertebral compression fracture or in those with osteolytic lesions of the spine (ie, multiple myeloma, metastatic malignancies).

For individuals who have osteoporotic vertebral compression fractures who receive balloon kyphoplasty or mechanical vertebral augmentation (Kiva), the evidence includes randomized controlled trials (RCTs) and meta-analyses of RCTs. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. Two moderately sized unblinded RCTs compared kyphoplasty to conservative care and found short-term benefits in pain and other outcomes. Other RCTs, summarized in a meta-analysis, reported similar outcomes for kyphoplasty and vertebroplasty. Two randomized trials that compared mechanical vertebral augmentation (Kiva) to kyphoplasty reported similar outcomes for the 2 procedures. A major limitation of all these RCTs is the lack of a sham procedure. Due to the possible sham effect observed in the recent trials of vertebroplasty, the validity of the results from non-sham-controlled trials is unclear. Therefore, it is not possible to conclude that these improvements are a true treatment effect. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have osteolytic vertebral body lesions who receive balloon kyphoplasty or mechanical vertebral augmentation (Kiva), the evidence includes small case series. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. In the early literature reviews, 3 case series were evaluated (total N=52 patients). Outcome measures varied across these 3 studies, but all showed improvements either in visual analog scale pain scores, several aspects of physical functioning as measured by the 36-Item Short-Form Health Survey, or improvement in disability scores. There are no RCTs of kyphoplasty for vertebral body lesions. Because the results of the comparative studies of vertebroplasty have suggested possible placebo or natural history effects, case series are insufficient to draw conclusions about the effect of kyphoplasty on health outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

After consideration of uniform clinical input, it was concluded that although the scientific evidence does not permit conclusions about the impact on health outcomes and that comparative studies with long-term outcomes are lacking,
numerous case series, including large prospective reports, have consistently shown that vertebroplasty or kyphoplasty may alleviate pain and improve function in patients with vertebral fractures who fail to respond to conservative treatment (at least 6 weeks) with analgesics, physical therapy, and rest. More recent randomized trials that have compared kyphoplasty with medical management have also reported benefit, so have not affected these conclusions. Given the absence of alternative treatment options and the morbidity associated with extended bedrest, kyphoplasty and mechanical vertebral augmentation may be considered reasonable treatment options in patients with vertebral fractures who fail to improve after 6 weeks of conservative therapy and therefore may be considered medically necessary both for this patient population and populations with severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

**Background**
There is insufficient evidence to permit conclusions on the use of kyphoplasty for an acute (<6 weeks) vertebral fracture. The scientific evidence does not permit conclusions about the impact on net health outcome; sham-controlled comparative studies are needed. There are no additional data to alter these conclusions.

Two randomized comparative trials show similar outcomes for Kiva® as compared with kyphoplasty. The matched pair comparison reported favorable outcomes for Kiva®, although this study is limited by the retrospective nature of the study and the nonconcurrent controls.

Early evidence suggests that vertebral body stenting may have worse outcomes compared with balloon kyphoplasty and is considered investigational.

Balloon kyphoplasty is a variant of vertebroplasty and uses a specialized bone tamp with an inflatable balloon to expand a collapsed vertebral body as close as possible to its natural height before injection of the PMMA. Radiofrequency kyphoplasty is a modification of balloon kyphoplasty. In this procedure, an ultrahigh viscosity cement is injected into the fractured vertebral body, and radiofrequency is used to achieve the desired consistency of the cement. The ultrahigh viscosity cement is designed to restore height and alignment to the fractured vertebra, along with stabilizing the fracture.

It has been proposed that kyphoplasty may provide an analgesic effect through mechanical stabilization of a fractured or otherwise weakened vertebral body. However, other possible mechanisms of effect have been postulated, one of which is thermal damage to intraosseous nerve fibers given that PMMA undergoes a heat-releasing (exothermic) reaction during its hardening process.

Kiva® is another mechanical vertebral augmentation technique that uses an implant for structural support of the vertebral body and to provide a reservoir for bone cement. The Kiva® VCF system consists of a shaped memory coil and a Kiva® implant, which is filled with bone cement. The coil is inserted into the vertebral body over a removable guide wire. The coil reconfigures itself into a
stack of loops within the vertebral body and can be customized by changing the number of loops of the coil. The implant, made from PEEK-OPTIMA®, a biocompatible polymer, is deployed over the coil. The coil is then retracted and PMMA is injected through the lumen of the implant. The PMMA cement flows through small slots in the center of the implant, which fixes the implant to the vertebral body and contains the PMMA in a cylindrical column. The proposed advantage of the Kiva system is a reduction in cement leakage.

Another variant of kyphoplasty is vertebral body stenting, which utilizes an expandable scaffold instead of a balloon to restore vertebral height. The proposed advantages of vertebral body stenting are to reduce the risk of cement leakage by formation of a cavity for cement application and to prevent the loss of correction that is seen following removal of the balloon used for balloon kyphoplasty.

OSTEOPOROTIC VERTEBRAL COMPRESSION FRACTURE
Osteoporotic compression fractures are common problem. It is estimated that up to 50% of women and 25% of men will have a vertebral fracture at some point in their lives. However, only about one-third of vertebral fractures actually reach clinical diagnosis, and most symptomatic fractures will heal within a few weeks or 1 month. A minority of patients will exhibit chronic pain following osteoporotic compression fracture that presents challenges for medical management. Chronic symptoms do not tend to respond to the management strategies for acute pain such as bedrest, immobilization or bracing device, and analgesic medication, sometimes including narcotic analgesics. The source of chronic pain after vertebral compression fracture may not be from the vertebra itself but may be predominantly related to strain on muscles and ligaments secondary to kyphosis. This type of pain frequently is not improved with analgesics and may be better addressed through exercise.

OSTEOLYTIC VERTEBRAL BODY LESIONS
Vertebral body fractures can also be pathologic, due to osteolytic lesions, most commonly from metastatic tumors. Metastatic malignant disease involving the spine generally involves the vertebral bodies, with pain being the most frequent complaint. While radiation and chemotherapy are frequently effective in reducing tumor burden and associated symptoms, pain relief may be delayed days to weeks, depending on tumor response. Further, these approaches rely on bone remodeling to regain vertebral body strength, which may necessitate supportive bracing to minimize the risk of vertebral body collapse during healing.

REGULATORY STATUS
Kyphoplasty is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration (FDA). Balloon kyphoplasty requires the use of an inflatable bone tamp. In July 1998, 1 such tamp, the KyphX® inflatable bone tamp, was cleared for marketing by FDA through the 510(k) process. Other devices with FDA 510(k) marketing clearance include the AVAmax® Vertebral Balloon system (CareFusion), NeuroTherm Parallax® Balloon Inflatable Bone Tamp (NeuroTherm), Stryker iVAS® Balloon catheter, and Synthes Synflate™ Vertebral Balloon System (Synthes). FDA product code NDN.
In 2014, the Kiva® VCF Treatment System (Benvenue Medical) was cleared for marketing by FDA through the 510(k) process. FDA product code NDN.

Polymethylmethacrylate (PMMA) bone cement was available as a drug product before enactment of FDA’s device regulation and was at first considered what FDA terms a “transitional device.” It was transitioned to a class III device and then to a class II device, which required future 510(k) submissions to meet “special controls” instead of “general controls” to assure safety and effectiveness. In July 2004, KyphX® HV-RTM bone cement was cleared for marketing by FDA through the 510(k) process for the treatment of pathologic fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a balloon kyphoplasty procedure. Subsequently, other products such as Spine-Fix® Biomimetic Bone Cement, KYPHON® HV-R® Bone Cement, and Osteopal® V have received issued 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. FDA product code: NDN.

**Rationale**

This evidence review was originally based on a 2000 TEC Assessment,(1) updated with TEC Assessments in 2004,(2) 2005,(3) 2008,(4) 2009,(5) and 2010,(6) and since then with periodic literature searches of the MEDLINE database. The most recent literature update was performed through October 3, 2016.

For treatment of osteoporosis and malignancy with percutaneous kyphoplasty, the primary beneficial outcomes of interest are relief of pain and improvement in ability to function. Kyphoplasty may also restore lost vertebral body height and reduce kyphotic deformity. Potential health outcomes related to kyphotic deformity include pulmonary or gastrointestinal compression and associated symptoms, and vertebral compression fractures (VCFs) may be associated with lower health-related quality of life.

The natural history of pain and disability associated with these conditions vary. In addition, pain and functional ability are subjective outcomes, susceptible to placebo effects. Nonspecific or placebo effects can be quite large for an invasive procedure such as kyphoplasty for which there is no blinding.(7,8) The placebo effect may be on the order of 6 to 7 mm on a 100-mm scale, for invasive procedures,(7-10) and even larger effects (10%) have been observed in the sham-controlled vertebroplasty trials.(11,12) Therefore, sham-controlled comparison studies are important to demonstrate the clinical effectiveness of kyphoplasty over and above any associated nonspecific or placebo effects.

Adverse effects related to kyphoplasty are the primary harms to be considered. Principal safety concerns relate to the incidence and consequences of leakage of the injected polymethylmethacrylate (PMMA).
OSTEOPOROTIC VERTEBRAL COMPRESSION FRACTURES
The evidence on the treatment of VCFs includes 2 multicenter randomized controlled trials (RCTs) that compared kyphoplasty to conservative care, a comparative analysis of mortality risk from the Medicare dataset, a meta-analysis of trials that compared kyphoplasty to vertebroplasty, and 2 RCTs that compared mechanical vertebral augmentation to balloon kyphoplasty.

Balloon Kyphoplasty Compared to Conservative Care
In 2009, Wardlaw et al reported on the FREE trial, a nonblinded industry-sponsored multisite RCT in which 300 adult participants with 1 to 3 painful osteoporotic VCFs of less than 3 months in duration were assigned to kyphoplasty or conservative care.(13) Twenty-four-month results were reported by Boonen et al (2011) and by Van Meirhaeghe et al (2013).(14,15) Scores for the primary outcome, 1-month change in 36-Item Short-Form Health Survey (SF-36) Physical Component Summary (PCS) score, were significantly higher for those in the kyphoplasty group. The difference between groups was 5.2 points (95% confidence interval, 2.9 to 7.4 points; p<0.001). Kyphoplasty was associated with greater improvements in SF-36 PCS scores at 6-month follow-up (3.39 points), but not at 12- or 24-month follow-ups. Greater improvement in back pain was observed over 24 months for kyphoplasty (-1.49 points) and remained statistically significant at 24 months. Participants in the kyphoplasty group also reported greater improvements in quality of life and Roland-Morris Disability Questionnaire (RMDQ) scores at short-term follow-up. At 12 months, fewer kyphoplasty patients (26.4% vs 42.1%) had received physical therapy or walking aids, back braces, wheelchairs, miscellaneous aids, or other therapy. Fewer kyphoplasty patients used opioid medications through 6 months (29.8% vs 42.9%) and fewer pain medications through 12 months (51.7% vs. 68.3%). Other differences between groups were no longer apparent at 12 months, possibly due to natural healing of fractures.

Berenson et al reported the results of an international multicenter RCT in 2011.(16) They enrolled 134 patients with cancer who were at least 21 years of age. Participants had at least 1 and not more than 3 painful VCFs. The primary outcome was change in functional status from baseline at 1 month as measured by the RMDQ. Treatment allocation was not blinded, and the primary outcome at 1 month was analyzed using all participants with data both at baseline and at 1 month. Participants needed to have a pain score of at least 4 on a 0-to-10 scale. Crossover to the balloon kyphoplasty arm was allowed after 1 month. The authors reported scores for the kyphoplasty and nonsurgical groups of 17.6 and 18.2 at baseline, respectively, and 9.10 and 18.0 at 1-month follow-ups (between-group difference in scores, p<0.001).

In 2011, Edidin et al reported mortality risk in Medicare patients who had VCFs and had been treated with vertebroplasty, kyphoplasty, or nonoperatively.(17) This study was industry-funded. Using the U.S. Medicare dataset, they identified 858,978 patients who had VCFs between 2005 and 2008. The data set included 119,253 kyphoplasty patients and 63,693 vertebroplasty patients. Survival was calculated from the index diagnosis date until death or the end of follow-up (up to
4 years). Cox regression analysis was used to evaluate the joint effect of multiple covariates, which included sex, age, race/ethnicity, patient health status, type of diagnosed fracture, site of service, physician specialty, socioeconomic status, year of diagnosis, and census region. After adjusting for covariates, patients in the surgical cohorts (vertebroplasty or kyphoplasty) had a higher adjusted survival rate (60.8%) than patients in the nonsurgical cohort (50.0%) and were 37% less likely to die. The adjusted survival rates for vertebroplasty or kyphoplasty were 57.3% and 62.8%, respectively, a 23% lower relative risk for kyphoplasty. As noted by the authors, a causal relation could not be determined from this study.

**Balloon Kyphoplasty Compared to Vertebroplasty**
In 2015, Chang et al reported a meta-analysis of prospective studies that compared vertebroplasty and kyphoplasty.(18) Included were 6 RCTs and 14 prospective comparative studies (total N=1429 patients). Outcomes were compared for the short (≤1 week after surgery) and long (>6 months) terms. The time to perform vertebroplasty was significantly shorter than kyphoplasty. There was no significant difference between groups in visual analog scale (VAS) pain scores or Oswestry Disability Index (ODI) scores at either short- or long-term follow-up. There was no significant difference between treatments in adjacent-level fractures. Cobb angle at long-term follow-up was improved in the kyphoplasty group compared with vertebroplasty. Kyphoplasty had a significantly lower number of procedures with cement extravasion, although the percentage of cases with cement leakage is high for both procedures. For example, a 2014 RCT by Dohm et al (KAVIAR study) reported overall cement extravasion in 157 (73.4%) of 214 levels treated with kyphoplasty compared with 164 (81.6%) of 201 levels treated with vertebroplasty (p=0.047).(19) Intravascular cement extravasion occurred in 59 (27.6%) of 214 levels treated with kyphoplasty compared with 76 (37.8%) of 201 levels treated with vertebroplasty. The clinical significance of a 10% difference in cement extravasion is uncertain; the occurrence of device-related cement embolism was similar, with 1 (0.5%) case in each group. Kyphosis correction was better in the kyphoplasty group by 1.42° (p=0.036). Pain and function improvements were similar for the 2 procedures.

**Mechanical Vertebral Augmentation Plus Kiva Compared to Balloon Kyphoplasty**
Vertebroplasty with the Kiva VCF System was compared to balloon kyphoplasty in a pivotal noninferiority RCT.(20) This industry-sponsored, multicenter open-label (KAST) trial was conducted in 300 patients with 1 or 2 osteoporotic VCFs. Included were patients with VAS scores for back pain of at least 70 mm (/100 mm) after 2 to 6 weeks of conservative care or a VAS scores of at least 50 mm after 6 weeks of conservative care, and ODI scores of at least 30%. The primary end point at 12 months was a composite of a reduction in fracture pain by at least 15 mm on the VAS, maintenance or improvement in function on the ODI, and absence of device-related serious adverse events. The primary end point was met for 94.5% of patients treated with Kiva and 97.6% of patients treated with kyphoplasty (Bayesian posterior probability of 99.92% for noninferiority, using as-treated analysis). In the 285 treated patients, Kiva resulted in a mean improvement of 70.8 points in VAS scores, compared with a
71.8-point improvement for kyphoplasty. There was a 38.1-point improvement in ODI score for the Kiva group compared with a 42.2-point improvement for the kyphoplasty group. There were no device-related serious adverse events. The total volume of cement was 50% less with Kiva and there was less cement extravasion (16.9%) compared with kyphoplasty (25.8%).

In 2013, Korovessis reported on a randomized trial comparing mechanical vertebral augmentation with the Kiva device to balloon kyphoplasty in 180 patients with osteoporotic vertebral body fractures.(21) The groups showed similar improvements in VAS scores for back pain, SF-36 scores, and ODI scores. For example, there was a more than 5.5-point improvement in VAS scores in 54% of patients in the Kiva group and in 43% of patients in the balloon kyphoplasty group. Radiologic measures of vertebral height were similar in both groups. Kiva reduced the Gardner kyphotic angle, while residual kyphosis of more than 5° was more frequently observed in the balloon kyphoplasty group. Patients and outcome assessors were reported to be unaware of group assignments, although it is not clear if the Kiva device was visible on radiographs. Cement leakage into the canal only occurred in 2 patients treated with balloon kyphoplasty, necessitating decompression, compared with none following the Kiva procedure.

**Adverse Events**

Yi et al assessed the occurrence of new VCFs after treatment with cement augmenting procedures (vertebroplasty or kyphoplasty) versus conservative treatment in an RCT with 290 patients (363 affected vertebrae).(22) Surgically treated patients were discharged the next day. Patients treated conservatively (pain medication, bedrest, a body brace, physical therapy) had a mean length of stay of 13.7 days. Return to usual activity occurred at 1 week for 87.6% of surgically treated patients and at 2 months for 59.2% of conservatively treated patients. All patients were evaluated with radiographs and magnetic resonance imaging at 6 months and then at yearly intervals until the last follow-up session. At a mean follow-up of 49.4 months (range, 36-80 months), 10.7% of patients had experienced 42 new symptomatic VCFs. There was no significant difference in the incidence of new vertebral fractures between the operative (n=18; 9 adjacent, 9 nonadjacent) and conservative (n=24; 5 adjacent, 16 nonadjacent, 3 same level) groups, but the mean time to a new fracture was significantly shorter in the surgical group (9.7 months) compared with the nonoperative group (22.4 months).

**Section Summary: Osteoporotic Vertebral Compression Fractures**

Two moderately sized unblinded RCTs have reported short-term benefits of kyphoplasty for pain and other outcomes in patients with painful osteoporotic fractures compared with conservative care. Other RCTs, summarized in a meta-analysis, found similar outcomes for kyphoplasty and vertebroplasty. For mechanical vertebral augmentation with Kiva, evidence to date includes a large industry-sponsored, multicenter investigational device exemption trial and a large independent randomized trial. The 2 randomized comparative trials showed outcomes similar to kyphoplasty.
The major limitation of these RCTs was the lack of a sham procedure. Due to the possible sham effect observed in the recent trials of vertebroplasty, the validity of results from non-sham-controlled trials are questionable. Therefore, it is not possible to conclude that these improvements are a true treatment effect. Cement leakage, although slightly reduced in kyphoplasty relative to vertebroplasty, remains a concern.

**OSTEOLYTIC VERTEBRAL COMPRESSION LESIONS**

In the early literature reviews, 3 case series were assessed (total N=52 patients). (23-25) Outcome measures varied across these 3 studies, but all showed improvements either in VAS pain scores, several aspects of physical functioning as measured by the SF-36, or improvement in disability scores. There are no RCTs of kyphoplasty for vertebral body metastasis. Because the results of the comparative studies of vertebroplasty suggested possible placebo or natural history effects, case series are insufficient to draw conclusions about the effect of kyphoplasty on health outcomes.

**SUMMARY OF EVIDENCE**

For individuals who have osteoporotic vertebral compression fractures who receive balloon kyphoplasty or mechanical vertebral augmentation (Kiva), the evidence includes randomized controlled trials (RCTs) and meta-analyses of RCTs. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. Two moderately sized unblinded RCTs compared kyphoplasty to conservative care and found short-term benefits in pain and other outcomes. Other RCTs, summarized in a meta-analysis, reported similar outcomes for kyphoplasty and vertebroplasty. Two randomized trials that compared mechanical vertebral augmentation (Kiva) to kyphoplasty reported similar outcomes for the 2 procedures. A major limitation of all these RCTs is the lack of a sham procedure. Due to the possible sham effect observed in the recent trials of vertebroplasty, the validity of the results from non-sham-controlled trials is unclear. Therefore, it is not possible to conclude that these improvements are a true treatment effect. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have osteolytic vertebral body lesions who receive balloon kyphoplasty or mechanical vertebral augmentation (Kiva), the evidence includes small case series. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. In the early literature reviews, 3 case series were evaluated (total N=52 patients). Outcome measures varied across these 3 studies, but all showed improvements either in visual analog scale pain scores, several aspects of physical functioning as measured by the 36-Item Short-Form Health Survey, or improvement in disability scores. There are no RCTs of kyphoplasty for vertebral body lesions. Because the results of the comparative studies of vertebroplasty have suggested possible placebo or natural history effects, case series are insufficient to draw conclusions about the effect of kyphoplasty on health outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.
SUPPLEMENTAL INFORMATION

CLINICAL INPUT FROM PHYSICIAN SPECIALTY SOCIETIES AND ACADEMIC MEDICAL CENTERS
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

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

2008 Input
In response to requests, input was received from 6 physician specialty societies (1 unsolicited) and 2 academic medical centers while this policy was under review in 2008. All reviewers disagreed with the proposed policy, referring to a body of evidence from uncontrolled studies that supported use of kyphoplasty.

PRACTICE GUIDELINES AND POSITION STATEMENTS

American College of Radiology et al
The American College of Radiology (ACR) and 7 other surgical and radiologic specialty associations published a joint position statement on percutaneous vertebral augmentation in 2014.(26) This document stated that percutaneous vertebral augmentation, using vertebroplasty or kyphoplasty and performed in a manner consistent with public standards, is a safe, efficacious, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures. The document also indicated that these procedures be offered only when nonoperative medical therapy has not provided adequate pain relief or pain is significantly altering the patient’s quality of life.

Society of Interventional Radiology
In a 2014 quality improvement guideline on percutaneous vertebroplasty from the Society of Interventional Radiology, vertebral augmentation was recommended for compression fractures refractory to medical therapy. Failure of medical therapy includes the following situations(27):

1. Patients who are “rendered nonambulatory as a result of pain from a weakened or fractured vertebral body, pain persisting at a level that prevents ambulation despite 24 hours of analgesic therapy”;

Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation 6.01.38
2. Patients with “sufficient pain from a weakened or fractured vertebral body that physical therapy is intolerable, pain persisting at that level despite 24 hours of analgesic therapy”; or
3. Patients with “a weakened or fractured vertebral body, and unacceptable side effects such as excessive sedation, confusion, or constipation as a result of the analgesic therapy necessary to reduce pain to a tolerable level”.

American College of Radiology
In 2013, ACR updated its appropriateness criteria on the management of compression fractures. The criteria for management of these fractures indicated that most vertebral compression fractures resolve within 4 to 6 weeks with more conservative first-line treatment using nonsteroidal anti-inflammatory drugs (NSAIDs) and possibly narcotic medications. However, due to expanded use of percutaneous vertebroplasty and balloon-assisted vertebroplasty by the medical community, the rapidity of clinical response, and the relatively low procedural risk, the threshold for performing these procedures has declined. There has been an increased number of studies describing successful results using vertebral augmentation for painful malignant fractures and symptomatic myelomatous vertebral replacement. The criteria indicate that vertebroplasty should be reserved for patients who either have failed or cannot tolerate traditional conservative treatment. Failure was defined as pain refractory to oral medications (NSAIDs and/or narcotic) over 6 to 12 weeks. However, failure can also be defined as contraindications to such medications or a requirement for parenteral narcotics and hospital admission.(28) Table 1 provides examples of patient scenarios and the recommendations for vertebroplasty and kyphoplasty.

Table 1. ACR Recommendations for Management of Compression Fractures

<table>
<thead>
<tr>
<th>Conditions</th>
<th>Treatments</th>
<th>Ratinga</th>
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<tbody>
<tr>
<td>Elderly woman, recent recurring benign painful 25% loss of height compression fracture; previous compression healed spontaneously with conservative management</td>
<td>▪ Vertebroplasty</td>
<td>4</td>
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<tr>
<td></td>
<td>▪ Kyphoplasty</td>
<td>4</td>
</tr>
<tr>
<td>Elderly male, painful first spontaneous compression fracture, limited ADL; no neurologic symptoms</td>
<td>▪ Vertebroplasty</td>
<td>5b</td>
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<tr>
<td></td>
<td>▪ Kyphoplasty</td>
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<td>Middle-aged active man, T7 burst fracture, history of recent trauma; new fracture impeding ADL; complaints of new-onset right lower-limb tingling</td>
<td>▪ Vertebroplasty</td>
<td>3</td>
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<tr>
<td></td>
<td>▪ Kyphoplasty</td>
<td>3</td>
</tr>
<tr>
<td>Elderly female, painful subacute, hyperkyphotic compression fracture unresponsive to conservative treatment (NSAIDs); continued loss of ADL</td>
<td>▪ Vertebroplasty</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>▪ Kyphoplasty</td>
<td>7</td>
</tr>
<tr>
<td>Elderly independent female, new painful fracture limiting ADL; previous successful vertebroplasty</td>
<td>▪ Vertebroplasty</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>▪ Kyphoplasty</td>
<td>5</td>
</tr>
<tr>
<td>Elderly chronically bedridden man with a painful compression fracture that has failed conservative management</td>
<td>▪ Vertebroplasty</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>▪ Kyphoplasty</td>
<td>7</td>
</tr>
<tr>
<td>Elderly female, malignant subacute, painful compression fracture refractory to conservative treatment</td>
<td>▪ Vertebroplasty</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>▪ Kyphoplasty</td>
<td>8</td>
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</tbody>
</table>

a Rating scale: 1, 2, 3: usually not appropriate; 4, 5, 6: may be appropriate; 7, 8, 9: usually appropriate.
b Recommended if the patient fails conservative management.
American Academy of Orthopaedic Surgeons
In 2010 the American Academy of Orthopaedic Surgeons (AAOS) approved a new clinical practice guideline on the treatment of osteoporotic spinal compression fractures, which had a weak recommendation for offering kyphoplasty to patients who “present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.” AAOS indicated that future evidence could overturn existing evidence and that the quality of the current literature is poor. These recommendations were based on literature reviewed through September 2009.(29)

National Institute for Health and Care Excellence
The National Institute for Health and Care Excellence (NICE) issued a 2013 technology appraisal guidance that recommended percutaneous vertebroplasty and percutaneous balloon kyphoplasty as treatment options for treating osteoporotic vertebral compression fractures in persons having severe, ongoing pain after a recent unhealed vertebral fracture, despite optimal pain management, and whose pain has been confirmed through physical exam and imaging at the level of the fracture. This guidance did not address balloon kyphoplasty with stenting, because the manufacturer of the stenting system (Synthes) stated there is limited evidence for vertebral body stenting given that the system had only recently become available.(30)

In 2008, NICE issued guidance on the diagnosis and management of adults with metastatic spinal cord compression. It was last reviewed in 2014, and placed on the static list (no major ongoing studies identified, with the next review in 5 years). The guidance stated that vertebroplasty or kyphoplasty should be considered for patients who have vertebral metastases, and no evidence of spinal cord compression or spinal instability, if they have mechanical pain resistant to conventional pain management and vertebral body collapse. Surgery should only be performed when all appropriate specialists, including the oncologist, interventional radiologist, and spinal surgeon, agree. At present, relatively few patients in England receive surgery; however, evidence suggests that in a select subset of patients, early surgery may be more effective at maintaining mobility than radiotherapy.(31)

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS
Not applicable.

MEDICARE NATIONAL COVERAGE
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

ONGOING AND UNPUBLISHED CLINICAL TRIALS
Some currently unpublished trials that might influence this review are listed in Table 2.
Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td>A Prospective, Multicenter, Randomized, Comparative Clinical Study to Compare the Safety and Effectiveness of Two Vertebral Compression Fracture (VCF) Reduction Techniques: the SpineJack® and the KyphX Xpander® Inflatable Bone Tamp</td>
<td>160</td>
<td>Dec 2017</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
a Denotes industry-sponsored or cosponsored trial.

References:
4. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Percutaneous vertebroplasty or kyphoplasty for vertebral fractures caused by osteoporosis or malignancy. TEC Assessments. 2008;Volume 23:Tab 5.


**Billing Coding/Physician Documentation Information**

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

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

**ICD-10 Codes**

- **C41.2** Malignant neoplasm of vertebral column
- **C79.51-C75.52** Secondary malignant neoplasm of bone and bone marrow; code range
- **C90.00-C90.02** Multiple myeloma; code range
- **D18.09** Hemangioma of other sites
- **D47.Z9** Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related issues
- **M48.50-M48.58** Collapsed vertebra, not elsewhere classified; code range
- **M80.08** Age related osteoporosis with current pathological fracture, vertebra(e)
- **M84.48** Pathological fracture, other site
- **M84.58** Pathological fracture in neoplastic disease, vertebrae
- **M84.68** Pathological fracture in other disease, other site

Codes 22523, 22524, 22525, 72291 and 72292 were deleted effective 12/31/2014.

**Additional Policy Key Words**

N/A

**Policy Implementation/Update Information**

<table>
<thead>
<tr>
<th>Date</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>6/1/04</td>
<td>New indication added to the Percutaneous Vertebroplasty medical policy. Considered investigational.</td>
</tr>
<tr>
<td>2/1/05</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>2/1/06</td>
<td>Policy changed to address only percutaneous kyphoplasty. Previously was combined with the percutaneous vertebroplasty policy. Remains investigational. Added new CPT codes for kyphoplasty.</td>
</tr>
<tr>
<td>8/1/06</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>2/1/07</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>8/1/07</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>2/1/08</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>8/1/08</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>10/7/08</td>
<td>Policy statement revised to indicate may be medically necessary if conservative treatment has failed.</td>
</tr>
<tr>
<td>11/1/09</td>
<td>No policy statement changes.</td>
</tr>
<tr>
<td>11/1/10</td>
<td>Policy statement revised to indicate use in acute vertebral fractures as</td>
</tr>
</tbody>
</table>
investigational.

11/1/11  No policy statement changes.
11/1/12  No policy statement changes.
11/1/13  Added to policy: Percutaneous mechanical vertebral augmentation using any other device, including but not limited to Kiva, is considered investigational.

9/1/14  Vertebral body stenting added to investigational statement.
9/1/15  Kiva considered medically necessary. Added notations that CPT 22523, 22524, 22525, 72291, 72292 were deleted 12/31/2014.
9/1/16  No policy statement changes.
9/1/17  The last investigational policy statement was revised to delete the wording, “including but not limited to vertebral body stenting”.
10/1/17  Radiofrequency kyphoplasty was added to the investigational statement and policy title

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