

## Medical Policy



### Title: Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation

**Professional**

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Populations	Interventions	Comparators	Outcomes
Individuals: • With osteoporotic vertebral compression fractures	Interventions of interest are: • Balloon kyphoplasty or mechanical vertebral augmentation (Kiva)	Comparators of interest are: • Conservative care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Hospitalizations • Treatment-related morbidity
Individuals: • With osteolytic vertebral compression fractures	Interventions of interest are: • Balloon kyphoplasty or mechanical vertebral augmentation (Kiva)	Comparators of interest are: • Conservative care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Hospitalizations • Treatment-related morbidity

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> <li>• With osteoporotic or osteolytic vertebral compression fractures</li> </ul>	Interventions of interest are: <ul style="list-style-type: none"> <li>• Radiofrequency kyphoplasty</li> </ul>	Comparators of interest are: <ul style="list-style-type: none"> <li>• Conservative care</li> </ul>	Relevant outcomes include: <ul style="list-style-type: none"> <li>• Symptoms</li> <li>• Functional outcomes</li> <li>• Quality of life</li> <li>• Hospitalizations</li> <li>• Treatment-related morbidity</li> </ul>

## **DESCRIPTION**

Percutaneous balloon kyphoplasty, radiofrequency kyphoplasty, and mechanical vertebral augmentation with Kiva 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 or metastatic malignancies.

## **OBJECTIVE**

The objective of this policy is to determine whether the use of balloon kyphoplasty, radiofrequency kyphoplasty, or mechanical vertebral augmentation improves the net health outcome for individuals who have osteoporotic vertebral compression fractures or osteolytic vertebral compression fractures.

## **BACKGROUND**

### **Osteoporotic Vertebral Compression Fracture**

Osteoporotic compression fractures are a common problem, and it is estimated that up to one half of women and approximately one quarter of men will have a vertebral fracture at some point in their lives. However, only about one third of vertebral fractures actually reach clinical diagnosis, and most symptomatic fractures will heal within a few weeks or 1 month. However, a minority of patients will exhibit chronic pain following osteoporotic compression fracture that presents challenges for medical management.

### Treatment

Chronic symptoms do not tend to respond to the management strategies for acute pain such as bedrest, immobilization/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 Fractures**

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.

### Treatment

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.

### Kyphoplasty

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 polymethylmethacrylate (PMMA). Radiofrequency kyphoplasty (also known as radiofrequency targeted vertebral augmentation) is a modification of balloon kyphoplasty. In this procedure, a small diameter articulating osteotome creates paths across the vertebra. An ultra-high viscosity cement is injected into the fractured vertebral body and radiofrequency is used to achieve the desired consistency of the cement. The ultra-high 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.

### Vertebral Augmentation

Kiva is another mechanical vertebral augmentation technique that uses an implant for structural support of the vertebral body to provide a reservoir for bone cement. The Kiva VCF Treatment System consists of a shaped memory coil and an implant, which is filled with bone cement. The coil is inserted into the vertebral body over a removable guidewire. 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.

### Outcome Measures

For treatment of osteoporosis and malignancy with percutaneous kyphoplasty, the primary beneficial outcomes of interest are relief of pain and improvement in the 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 may be associated with lower health-related quality of life.

### **REGULATORY STATUS**

Kyphoplasty is a surgical procedure and, as such, is not subject to FDA approval. Balloon kyphoplasty requires the use of an inflatable bone tamp. One such tamp, the KyphX® inflatable bone tamp, received 510(k) marketing clearance from FDA in July 1998. Other devices with FDA 510(k) marketing clearance include AVAmax® Vertebral Balloon system (Carefusion), NeuroTherm Parallax® Balloon Inflatable Bone Tamp (NeuroTherm), Stryker iVAS® Balloon catheter, and Synthes Synflate™ Vertebral Balloon System, (Synthes). StabiliT® Vertebral Augmentation System (Merit Medical) for radiofrequency vertebral augmentation was cleared for marketing in 2009. FDA product code NDN.

The Kiva® VCF Treatment System (Benvenue Medical) received FDA 510(k) marketing clearance in 2014. FDA product code NDN.

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 given 510(k) marketing clearance by FDA 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 and Osteopal® V have been issued 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. FDA product code: NDN.

### **POLICY**

- A. Percutaneous balloon kyphoplasty and Kiva may be considered **medically necessary** for:
1. The treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies; **OR**
  2. The treatment of MRI documented acute osteoporotic vertebral compression fractures with persistent debilitating pain that have failed to respond to conservative treatment (eg, rest with graduated activity, back bracing, analgesics, physical therapy, and calcitonin) for at least 6 weeks or these treatments are contraindicated; **OR**

3. The treatment of MRI / bone scan documented acute osteoporotic vertebral compression fractures with persistent debilitating pain requiring hospital admission and parenteral narcotics for treatment.
- B. Percutaneous balloon kyphoplasty and Kiva are considered **experimental / investigational** for all other indications, including use in acute vertebral fractures due to trauma.
- C. Percutaneous radiofrequency kyphoplasty or mechanical vertebral augmentation using any other device is considered **experimental / investigational**.

## **RATIONALE**

The most recent literature review was performed through February 22, 2018.

This review has been informed by a 2000 TEC Assessment,<sup>1</sup> updated with TEC Assessments in 2004,<sup>2</sup> 2005,<sup>3</sup> 2008,<sup>4</sup> 2009,<sup>5</sup> and 2010.<sup>6</sup>

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

The natural history of pain and disability associated with these conditions vary. Also, 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.<sup>7,8</sup> The placebo effect may be on the order of 6 to 7 mm on a 100-mm scale, for invasive procedures,<sup>7-10</sup> and even larger effects (10%) have been observed in the sham-controlled vertebroplasty trials.<sup>11,12</sup> 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.

### **Osteoporotic Vertebral Compression Fractures**

#### Balloon Kyphoplasty vs Conservative Care

Wardlaw et al (2009) reported on the FREE trial, a nonblinded industry-sponsored, multisite RCT in which 300 adults with 1 to 3 painful osteoporotic vertebral compression fractures (VCFs) of less than 3 months in duration were assigned to kyphoplasty or conservative care.<sup>13</sup> Twenty-four-month results were reported by Boonen et al (2011) and by Van Meirhaeghe et al (2013).<sup>14,15</sup> Scores for the primary outcome, 1-month change in 36-Item Short-Form Health Survey Physical Component Summary score, were significantly higher for those in the kyphoplasty group. The difference between groups was 5.2 points (95% confidence interval [CI], 2.9 to 7.4 points;  $p < 0.001$ ). Kyphoplasty was associated with greater improvements in 36-Item Short-Form Health Survey Physical Component Summary 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.

Eddin et al (2011) reported on mortality risk in Medicare patients who had VCFs and had been treated with vertebroplasty, kyphoplasty, or nonoperatively.<sup>16</sup> This study was industry-funded. Using the U.S. Medicare dataset, the authors identified 858,978 patients who had VCFs between 2005 and 2008. The dataset 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 vs Vertebroplasty

Chang et al (2015) reported on a meta-analysis of prospective studies that compared vertebroplasty with kyphoplasty.<sup>17</sup> Included were 6 RCTs and 14 prospective comparative studies (total N=1429 patients). Outcomes were compared for the short ( $\leq 1$  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, an RCT by Dohm et al (2014; 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 ( $p=0.047$ ).<sup>18</sup> 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 occurrences of device-related cement embolism were similar, with 1 (0.5%) case in each group. Kyphosis correction was better in the kyphoplasty group by  $1.42^\circ$  ( $p=0.036$ ). Pain and function improvements were similar for both procedures.

In a Bayesian network meta-analysis, Zhao et al (2017) examined the efficacy and safety of vertebroplasty, kyphoplasty, and conservative treatment for the treatment of osteoporotic vertebral compression fractures.<sup>19</sup> Sixteen RCTs were identified (total  $N=2046$  participants; vertebroplasty, 816; kyphoplasty, 478; conservative treatment, 752). Eleven of the RCTs compared vertebroplasty with conservative treatment; 2 RCTs compared kyphoplasty with conservative treatment, and 3 RCTs compared kyphoplasty with vertebroplasty. Each trial assessed at least one of the following: VAS, the RMDQ, the European Quality of Life-5 Dimensions, and the observance of any new fractures. Network meta-analysis demonstrated that kyphoplasty was superior to conservative therapy as assessed by VAS (mean difference, 0.94; 95% CI, -0.40 to 2.39), European Quality of Life-5 Dimensions (mean difference -0.10; 95% CI, -0.17 to -0.01), and RMDQ (mean difference, 5.72; 95% CI, 1.05 to 10.60). Insufficient data were present to complete pairwise comparison of kyphoplasty with conservative treatment for some metrics. No significant differences were found between vertebroplasty and kyphoplasty for pain relief, daily function, and quality of life. Kyphoplasty was associated with the lowest risk of new fractures, while vertebroplasty was the most effective treatment for pain relief. This review was limited by significant heterogeneity across measured outcomes and length of follow-up in studies; the presence of performing and reporting bias in studies was also a concern.

#### Mechanical Vertebral Augmentation With Kiva vs Balloon Kyphoplasty

Vertebral augmentation with the Kiva VCF System was compared with balloon kyphoplasty in a pivotal noninferiority RCT reported by Tutton et al (2015).<sup>20</sup> 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 VAS scores of at least 50 mm after 6 weeks of conservative care, and ODI scores of at least 30%. The primary composite end point at 12 months was 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 by 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%).

Korovessis et al (2013) reported on a randomized trial comparing mechanical vertebral augmentation with the Kiva device with balloon kyphoplasty in 180 patients with osteoporotic VCFs.<sup>21</sup> The groups showed similar improvements in VAS scores for back pain, 36-Item Short-Form Health Survey 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 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.

#### *Section Summary: Osteoporotic Vertebral Compression Fractures*

A moderately sized unblinded RCT reported short-term benefits of kyphoplasty for pain and other outcomes in patients with painful osteoporotic fractures compared with conservative care. Other relevant studies, including additional RCTs and meta-analysis studies, found similar outcomes for kyphoplasty and vertebroplasty.

For mechanical vertebral augmentation with Kiva, evidence includes a large industry-sponsored, multicenter investigational device exemption trial and a large independent randomized trial. These randomized comparative trials showed outcomes similar to kyphoplasty.

#### **Osteolytic Vertebral Compression Fractures**

Health Quality Ontario (2016) assessed vertebral augmentation for cancer-related VCFs.<sup>22</sup> The assessment identified 33 reports with 1690 patients who were treated with kyphoplasty for spinal metastatic cancers, multiple myeloma, or hemangiomas. For cancer-related VCFs there were 5 case series (110 patients) on multiple myeloma and 6 reports (2 RCTs, 4 case series; 308 patients) on mixed cancers with spinal metastases. Vertebral augmentation resulted in reductions in pain intensity scores, opioid or other analgesic use, and disability scores. One RCT (N=129) compared kyphoplasty with nonsurgical management for cancer-related VCFs, reporting that pain scores, pain-related disability, and health-related quality of life were significantly improved in the kyphoplasty group than in the usual care group. The second RCT compared the Kiva device with kyphoplasty in 47 patients with cancer-related compression fractures, finding no significant differences between groups for improvements in VAS pain and ODI scores.

Berenson et al (2011) reported on the results of an international multicenter RCT.<sup>23</sup> 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. Reviewers 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,  $p < 0.001$ ).

*Section Summary: Osteolytic Vertebral Compression Fractures*

Results of RCTs and case series would suggest vertebral augmentation reduces pain, disability, and analgesic use in patients with cancer-related compression fractures. However, because the results of the comparative studies of vertebroplasty have also suggested possible placebo or natural history effects, the evidence provided is insufficient to warrant conclusions about the effect of kyphoplasty on health outcomes.

**Radiofrequency Kyphoplasty**

Petersen et al (2016) reported on an RCT with 80 patients that compared radiofrequency kyphoplasty (RFK) with balloon kyphoplasty.<sup>24</sup> Patients had been admitted to the hospital for severe back pain and met criteria for surgery after failed conservative treatment. All had osteoporotic compression fractures. Before treatment, VAS pain scores on movement were similar in both groups (8.4 in the balloon kyphoplasty group vs 8.0 in the RFK group). Postoperatively, VAS scores improved by 4.6 after balloon kyphoplasty and 4.4 after RFK ( $p=NS$ ). Pain at 12 months also did not differ significantly between both groups, with 58% of patients in the balloon kyphoplasty group and 66% of patients in the RFK group reporting no to mild pain on movement ( $p=NS$ ). There was a trend for greater restoration of the kyphosis angle.

Feng et al (2017) performed a meta-analysis comparing radiofrequency kyphoplasty with BK in patients with VCFs.<sup>25</sup> Six studies (total N=833 patients) evaluating VCFs were identified. The main outcomes were pain relief (VAS), functionality improvement (ODI), operation time, reduction of deformity (ie, the restoration of vertebral height and kyphosis angle), and incidence of cement leakage. VAS scores improved for both groups after the respective procedure; however, VAS score dropped 3.96 points more in the radiofrequency kyphoplasty group (95% CI, 1.67 to 6.24;  $p=0.001$ ), with improvement persisting until the 12-month mark. While functionality improvement was initially improved more after RFK than BK ( $p=0.04$ ), the difference between the 2 groups was not significant after a year ( $p=0.6$ ). No significant difference in cement leakage between groups was observed. This review was limited by the small number of studies included as well as the presence of significant bias within these studies.

Adverse Events

Yi et al (2014) assessed the occurrence of new VCFs after treatment with cement augmenting procedures (vertebroplasty or kyphoplasty) vs conservative treatment in an RCT with 290 patients (363 affected vertebrae).<sup>26</sup> 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 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: Radiofrequency Kyphoplasty*

For RFK, the evidence includes a meta-analysis study and an RCT. While the RCT showed similar results compared with balloon kyphoplasty, an improvement in immediate pain relief after RCT was noted in the meta-analysis. Further high-quality studies are needed to determine with greater certainty whether RFK has outcomes similar to balloon kyphoplasty.

The major limitation of all 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 is 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.

### **SUMMARY OF EVIDENCE**

For individuals who have osteoporotic vertebral compression fractures who receive balloon kyphoplasty, or mechanical vertebral augmentation (Kiva), the evidence includes RCTs and meta-analyses. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. A meta-analysis and moderately sized unblinded RCT have compared kyphoplasty with conservative care and found short-term benefits in pain and other outcomes. Other RCTs, summarized in a meta-analysis, have reported similar outcomes for kyphoplasty and vertebroplasty. Two randomized trials that compared mechanical vertebral augmentation (Kiva) with kyphoplasty have reported similar outcomes for both 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, whether these improvements represent a true treatment effect is uncertain. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have osteolytic vertebral compression fractures who receive balloon kyphoplasty or mechanical vertebral augmentation (Kiva), the evidence includes RCTs, case series, and a systematic review of these studies. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. Two RCTs have compared balloon kyphoplasty with conservative management, and another has compared Kiva with balloon kyphoplasty. Results of these trials, along with case series, would suggest a reduction in pain, disability, and analgesic use in patients with cancer-related compression fractures. However, because the results of the comparative studies of vertebroplasty have suggested possible placebo or natural history effects, the evidence these studies provide is insufficient to warrant conclusions about the effect of kyphoplasty on health outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have osteoporotic or osteolytic vertebral compression fractures who receive radiofrequency kyphoplasty, the evidence includes a systematic review and an RCT. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. The only RCT (N=80) identified showed similar results between radiofrequency kyphoplasty and balloon kyphoplasty. The systematic review suggested that radiofrequency kyphoplasty is superior to balloon kyphoplasty in pain relief, but the review itself was limited by the inclusion of a small number of studies as well as possible bias. Corroboration of these results in a larger number of patients would be needed to determine with greater certainty whether

radiofrequency kyphoplasty provides outcomes similar to balloon kyphoplasty. The evidence is insufficient to determine the effects of the technology on health outcomes.

### **CLINICAL INPUT RECEIVED 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 there is severe pain that 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 support 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.<sup>27</sup> 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.<sup>28</sup> Failure of medical therapy includes the following situations:

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";
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 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.<sup>29</sup>

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.<sup>30</sup>

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.<sup>31</sup>

**U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS**

Not applicable.

**ONGOING AND UNPUBLISHED CLINICAL TRIALS**

Some currently unpublished trials that might influence this review are listed in Table 1.

**Table 1.** Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
NCT02461810 <sup>a</sup>	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	152	Mar 2018 (ongoing)

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

## **CODING**

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

### CPT/HCPCS

- 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
- 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)

### ICD-10 Diagnoses

- C41.2 Malignant neoplasm of vertebral column
- C79.51 Secondary malignant neoplasm of bone
- C79.52 Secondary malignant neoplasm of bone marrow
- C90.00 Multiple myeloma not having achieved remission
- C90.01 Multiple myeloma in remission
- D18.09 Hemangioma of other sites
- D47.Z9 Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
- M48.50XA Collapsed vertebra, not elsewhere classified, site unspecified, initial encounter for fracture
- M48.51XA Collapsed vertebra, not elsewhere classified, occipito-atlanto-axial region, initial encounter for fracture
- M48.52XA Collapsed vertebra, not elsewhere classified, cervical region, initial encounter for fracture
- M48.53XA Collapsed vertebra, not elsewhere classified, cervicothoracic region, initial encounter for fracture
- M48.54XA Collapsed vertebra, not elsewhere classified, thoracic region, initial encounter for fracture
- M48.55XA Collapsed vertebra, not elsewhere classified, thoracolumbar region, initial encounter for fracture

- M48.56XA Collapsed vertebra, not elsewhere classified, lumbar region, initial encounter for fracture
- M48.57XA Collapsed vertebra, not elsewhere classified, lumbosacral region, initial encounter for fracture
- M48.58XA Collapsed vertebra, not elsewhere classified, sacral and sacrococcygeal region, initial encounter for fracture
- M80.08XA Age-related osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
- M80.88XA Other osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
- M81.0 Age-related osteoporosis without current pathological fracture
- M81.8 Other osteoporosis without current pathological fracture
- M84.48XA Pathological fracture, other site, initial encounter for fracture
- M84.58XA Pathological fracture in neoplastic disease, vertebrae, initial encounter for fracture
- M84.68XA Pathological fracture in other disease, other site, initial encounter for fracture

## REVISIONS

10-21-2015	This policy was created following removal of information on kyphoplasty from an existing policy titled "Percutaneous Vertebroplasty, Kyphoplasty and Sacroplasty."
	Effective for Professional and Institutional providers 30 days after the publication date.
02-03-2017	Updated Description section.
	In Policy section: <ul style="list-style-type: none"> <li>▪ Removed Item A 2, "Vertebral hemangiomas with pain, nerve compression, or aggressive radiologic signs, and radiation therapy has failed to relieve symptoms; OR"</li> <li>▪ Removed Item A 3, "Painful vertebral eosinophilic granuloma; OR"</li> </ul>
	Updated Rationale section.
	Updated References section.
10-28-2017	Revised policy title from "Percutaneous Balloon Kyphoplasty and Mechanical Vertebral Augmentation"
	Updated Description section.
	In Policy section: <ul style="list-style-type: none"> <li>▪ In Item C, added "radiofrequency kyphoplasty, or" and removed "including, but not limited to, vertebral body stenting," to read, "Percutaneous radiofrequency kyphoplasty or mechanical vertebral augmentation using any other device is considered experimental / investigational."</li> </ul>
	Updated Rationale section.
	Updated References section.
05-23-2018	Updated Description section.
	Updated Rationale section.
	In Coding section: <ul style="list-style-type: none"> <li>▪ Removed ICD-9 codes.</li> </ul>
	Updated References section.

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