

## 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	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	Comparators of interest are: • Conservative care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Hospitalizations • Treatment-related morbidity
Individuals: • With osteoporotic or osteolytic vertebral compression fractures	Interventions of interest are: • Radiofrequency kyphoplasty	Comparators of interest are: • Conservative care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Hospitalizations • Treatment-related morbidity

## **DESCRIPTION**

Percutaneous balloon kyphoplasty, radiofrequency kyphoplasty (RFK), and mechanical vertebral augmentation 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 those with osteolytic lesions of the spine (i.e., multiple myeloma, metastatic malignancies).

### **Objective**

The objective of this evidence review 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 common. 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 reach clinical diagnosis, and most symptomatic fractures will heal within a few weeks or one month. 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 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. Conventional vertebroplasty surgical intervention may be required in severe cases not responsive to conservative measures.

#### **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 radiotherapy 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). Polymethyl methacrylate bone cement was available as a drug product before enactment of the FDA's device regulation and was at first considered what the FDA termed 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 the 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 (Heraeus) have received 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

Balloon kyphoplasty requires the use of an inflatable bone tamp. In July 1998, one such tamp, the KyphX® inflatable bone tamp (Medtronic), was cleared for marketing by the FDA through the 510(k) process. Additional devices for balloon kyphoplasty are listed in Table 1.

There are several mechanical vertebral augmentation devices that have received marketing clearance by the FDA through the 510(k) process; these are listed in Table 1.

StabiliT® Vertebral Augmentation System (Merit Medical) for radiofrequency vertebral augmentation was cleared for marketing in 2009.

FDA product code NDN.

**Table 1. Kyphoplasty and Mechanical Vertebral Augmentation Devices Cleared by the U.S. Food and Drug Administration**

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Balloon Kyphoplasty				
TRACKER Kyphoplasty System	GS Medical Co., Ltd	12/4/2019	K192335	Reduction of fractures or creation of a void
Stryker iVAS Elite Inflatable Vertebral Augmentation System (Stryker iVAS Elite Balloon Catheter)	Stryker Corporation	12/21/2018	K181752	To repair vertebral compression fractures
SpineKure Kyphoplasty System	Hanchang Co. Ltd.	5/29/2018	K172871	To repair vertebral compression fractures
Modified Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters	G-21 s.r.l.	8/23/2017	K172214	To repair vertebral compression fractures
13G InterV Kyphoplasty Catheter (Micro) and 11G InterV Kyphoplasty Catheter (Mini-Flex)	Pan Medical Ltd.	11/1/2016	K162453	To repair vertebral compression fractures
MEDINAUT Kyphoplasty System	Imedicom Co. Ltd.	7/29/2016	K153296	To repair vertebral compression fractures
AVAflex Vertebral Balloon System	Carefusion	11/24/2015	K151125	To repair vertebral compression fractures

Osseoflex SB Straight Balloon 10g/4ml Osseoflex SB Straight Balloon 10g/2ml	Osseon LLC	4/9/2015	K150607	To repair vertebral compression fractures
InterV Kyphoplasty Catheter (Balloon Length: 1015 and 20mm) InterV Kyphoplasty Catheter (Mini) (Balloon Length: 10 15 and 20mm)	Pan Medical Ltd.	3/6/2015	K150322	To repair vertebral compression fractures
GUARDIAN-SG Inflatable Bone Expander System	BM Korea Co. Ltd.	1/16/2015	K143006	To repair vertebral compression fractures
ZVPLASTY	Zavation LLC	9/12/2014	K141419	To repair vertebral compression fractures
Mechanical Vertebral Augmentation				
Kiva VCF Treatment System	Benvenue Medical Inc.	8/14/2014	K141141	To repair vertebral compression fractures
SpineJack Expansion Kit	Vexim SA	8/30/2018	K181262	To repair vertebral compression fractures
V-Strut Vertebral Implant	Hyprevention SAS	3/5/2020	K191709	Treatment of vertebral fractures in the thoracic and lumbar spine

## **POLICY**

- A. Percutaneous balloon kyphoplasty or Mechanical vertebral augmentation with an FDA cleared device 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 (e.g., 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 or mechanical vertebral augmentation with an FDA cleared device 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**

This evidence review has been updated regularly with searches of the PubMed database. The most recent literature update was performed through February 18, 2020.

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 technology improves the net health outcome. Broadly defined, health outcomes are the 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 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 technology, two domains are examined: the relevance, and 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>7,8,9,10</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 polymethyl methacrylate.

## **OSTEOPOROTIC VERTEBRAL COMPRESSION FRACTURES**

### **Clinical Context and Therapy Purpose**

The purpose of balloon kyphoplasty or mechanical vertebral augmentation is to provide a treatment option that is an alternative to or an improvement on existing therapies in patients with osteoporotic vertebral compression fractures.

The question addressed in this evidence review is: Does the use of balloon kyphoplasty or mechanical vertebral augmentation improve the net health outcome for individuals who have osteoporotic vertebral compression fracture?

The following PICO was used to select literature to inform this review.

### ***Patients***

The relevant population of interest is individuals with osteoporotic vertebral compression fracture.

### ***Interventions***

The therapy being considered is balloon kyphoplasty or mechanical vertebral augmentation. The intervention involves the fluoroscopically guided injection of polymethyl methacrylate into a cavity created in the vertebral body with a balloon or mechanical device to provide support and symptomatic relief in patients.

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 polymethyl methacrylate. 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.

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 vertebral compression fractures 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 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 polymethyl methacrylate is injected through the lumen of the implant. The polymethyl methacrylate cement flows through small slots in the center of the implant, which fixes the implant to the vertebral body and contains the polymethyl methacrylate in a cylindrical column. The proposed advantage of the Kiva system is a reduction in cement leakage.

SpineJack is a mechanical vertebral augmentation technique that utilizes bipedicular 4.2 mm to 5.0 mm self-expanding jacks to restore vertebral height. Placement of the titanium devices are verified in anteroposterior and lateral view prior to expansion. Once the devices are expanded, the proprietary bone cement is injected. The proposed benefit is greater control over expansion and greater restoration of vertebral height compared to balloon kyphoplasty. The procedure requires good bone quality.

### ***Comparators***

Comparators of interest include conservative care. Treatment includes bed rest, local and systemic analgesia, and bracing, in a home setting as well as an outpatient clinical setting. Conventional vertebroplasty procedures may also be used to treat this condition.

### ***Outcomes***

The general outcomes of interest are symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. 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 (e.g., European Quality of Life-5 Dimensions).

The existing literature evaluating balloon kyphoplasty or mechanical vertebral augmentation as a treatment for osteoporotic vertebral compression fractures has varying lengths of follow-up, ranging from one month to four years.

### **Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

- a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- d. Studies with duplicative or overlapping populations were excluded.

## Review of Evidence

### Network Meta-analysis

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 fracture.<sup>13</sup> Sixteen RCTs were identified (total n=2,046 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: visual analog scale, the Roland-Morris Disability Questionnaire, the European Quality of Life-5 Dimensions, and the observance of any new fractures. No significant difference was found between kyphoplasty and vertebroplasty for pain relief, daily function, and quality of life. Network meta-analysis demonstrated that kyphoplasty was superior to conservative therapy as assessed by visual analog scale (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 Roland-Morris Disability Questionnaire (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. Kyphoplasty was associated with the lowest risk of new fractures. 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.

**Table 2. Systematic Reviews & Meta-Analysis Characteristics**

Study	Dates	Trials	Participants	N (Range)	Design
Zhao (2017) <sup>13</sup> ,	2006-2016	16	Patients with osteoporotic vertebral compression fracture	2046 (34 - 381)	RCT

RCT: randomized controlled trial; NR: no response.

**Table 3. Systematic Reviews & Meta-Analysis Results**

Study	VAS	EQ-5D	RMDQ	New Fractures
Zhao (2017) <sup>13</sup> ,				
MD (95% CI) CT vs KP	0.94 (-0.40 to 2.39)	-0.10 (-0.17 to -0.01)	5.72 (1.05 to 10.60)	1.11 (0.46 to 2.86)
MD (95% CI) KP vs Vertebroplasty	0.05 (-0.18 to 0.27)	-0.02 (-0.06 to 0.02)	-2.50 (-3.40 to -1.60)	1.29 (0.84 to 1.99)

CI: confidence interval; CT: conservative therapy; EQ-5D; European Quality of Life-5 Dimensions; KP: kyphoplasty; SMD: standard mean difference; MD: mean difference; VAS: visual analog score.

### Mortality Risk

Edidin et al (2011) reported on mortality risk in Medicare patients who had osteoporotic vertebral compression fractures and had been treated with vertebroplasty, kyphoplasty, or nonoperatively.<sup>14</sup> Using the U.S. Medicare dataset, the authors identified 85,8978 patients who had vertebral compression fractures 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.

An industry-sponsored analysis by Ong et al (2018) evaluated the effect of the sham-controlled vertebroplasty trials (see evidence review #6.01.25) on utilization of kyphoplasty/vertebroplasty, morbidity, and mortality in the Medicare population.<sup>15,12,11</sup> Using the complete inpatient/outpatient U.S. Medicare data set from 2005 to 2014, the investigators evaluated utilization of vertebral augmentation procedures in patients with osteoporotic vertebral compression fractures who were treated in the 5 year period before 2009 and those who were treated in the 5 years after the sham-controlled trials were published. Use of the 2 procedures peaked at 24% of the osteoporotic vertebral compression fracture population in 2007 - 2008, then declined to 14% of osteoporotic vertebral compression fracture patients in 2014. Compared to patients with osteoporotic vertebral compression fractures treated non-surgically, the kyphoplasty cohort (n=261,756) had a 19% (95% CI 19-19%) lower propensity-adjusted 10 year mortality risk. Compared to patients with osteoporotic vertebral compression fracture treated with vertebroplasty (n=117,232), the kyphoplasty cohort had a 13% (95% CI, 12-13%) lower propensity-adjusted 10 year mortality risk. The study also found that patients treated with non-surgical management were more likely to be discharged to nursing facilities. Although the analysis did adjust for possible confounding factors, the observational nature of the study precludes any inference of causality.

### **Balloon Kyphoplasty Versus Conservative Care**

The largest trial of kyphoplasty vs conservative care is by Wardlaw et al (2009), who reported the Fracture Reduction Evaluation (FREE) trial, a nonblinded industry-sponsored, multisite RCT in which 300 adults with 1 to 3 painful osteoporotic vertebral compression fractures of less than 3 months in duration.<sup>16</sup> Twenty-four-month results were reported by Boonen et al (2011) and by Van Meirhaeghe et al (2013).<sup>17,18</sup> Scores for the primary outcome, 1-month change in the 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 the 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 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.

**Table 4. Summary of Key RCT Characteristics**

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Wardlaw (2009), Boonen (2011), Van Meirheghe (2013) <sup>16,17,18</sup>	EU	21	2003-2005	Patients with 1-3 vertebral fractures	Balloon kyphoplasty (n=149)	Non-surgical care (n=151)

**Table 5. Summary of Key RCT Results**

Study	Mean SF 36 PCS Score Improvement at 1 mo (95% CI)	Difference in SF 36 Scores between Groups at 24 mo (95% CI)	Serious Adverse Events within 30 days	Serious Adverse Events within 12 mo.	Serious Adverse Events within 24 mo
Wardlaw (2009), Boonen (2011), Van Meirheghe (2013) <sup>16,17,18</sup>					
Kyphoplasty	7.2 (5.7 to 8.8)		24 (16.1%)	58 (38.9%)	74 (49.7%)
Control	2 (0.4 to 3.6)		17 (11.3%)	54 (35.8%)	73 (48.3%)
Mean Diff		3.24 (1.47 to 5.01)			
P value	<0.0001	0.0004			

CI: confidence interval; RCT: randomized controlled trial; SF-36 PCS: 36-Item Short-Form Physical Component Score.

**Table 6. Study Relevance Limitations**

Study	Population <sup>a</sup>	Intervention <sup>b</sup>	Comparator <sup>c</sup>	Outcomes <sup>d</sup>	Follow-Up <sup>e</sup>
Wardlaw (2009), Boonen (2011), Van Meirheghe (2013) <sup>16,17,18</sup>			3. Non-surgical treatment was not standardized		2. 24 mo. follow-up

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.

a Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.

b Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest.

c Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

d Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.

e Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

**Table 7. Study Design and Conduct Limitations**

Study	Allocation <sup>a</sup>	Blinding <sup>b</sup>	Selective Reporting <sup>c</sup>	Follow Up <sup>d</sup>	Power <sup>e</sup>	Statistical <sup>f</sup>
Wardlaw (2009), Boonen (2011), Van Meirheghe (2013) <sup>16,17,18</sup>	3. Allocation concealment unclear	1,2. Not blinded				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.

a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.

b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

d Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

f Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

**Mechanical Vertebral Augmentation (e.g., Kiva or SpineJack) vs Balloon Kyphoplasty**

Vertebral augmentation with the Kiva vertebral compression fractures System was compared with balloon kyphoplasty in a pivotal noninferiority RCT reported by Tutton et al (2015).<sup>19</sup> This industry-sponsored, multicenter open-label Kiva Safety and Effectiveness Trial was conducted in 300 patients with 1 or 2 osteoporotic vertebral compression fractures. Included were patients with visual analog scale scores for back pain of at least 70 mm (/100 mm) after 2 to 6 weeks of conservative care or visual analog scale scores of at least 50 mm after 6 weeks of conservative care, and Oswestry Disability Index scores of at least 30%. The primary composite endpoint at 12 months was a reduction in fracture pain by at least 15 mm on the visual analog scale, maintenance or improvement in function on the Oswestry Disability Index, and absence of device-related serious adverse events. The primary endpoint 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 visual analog scale scores, compared with a 71.8-point improvement for kyphoplasty. There was a 38.1-point improvement in Oswestry Disability Index 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 extravasation (16.9%) compared with kyphoplasty (25.8%).

Korovessis et al (2013) reported a randomized trial of 180 patients with osteoporotic vertebral compression fractures that compared mechanical vertebral augmentation with the Kiva device with balloon kyphoplasty in 180 patients with osteoporotic vertebral compression fractures.<sup>20</sup> The groups showed similar improvements in visual analog scale scores for back pain, 36-Item Short-Form Health Survey scores, and Oswestry Disability Index scores. For example, there was a more than 5.5 point improvement in visual analog scale 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 two patients treated with balloon kyphoplasty, necessitating decompression, compared with none following the Kiva procedure.

Noriega et al (2019) reported the pivotal multicenter non-inferiority trial of the SpineJack vertebral augmentation system.<sup>21</sup> Patients (n=152) with osteoporotic vertebral compression fractures less than 3 mo old were randomized to treatment with SpineJack or balloon kyphoplasty. The primary outcome was a composite measure that included improvement in visual analog scale for pain of greater than 20 mm, maintenance or improvement in Oswestry Disability Index, and lack of adverse events. Vertebral height was prespecified to be included if the primary outcome was achieved. Non-inferiority was achieved with 89.8% of SpineJack patients achieving the composite of clinical success compared to 87.3% for balloon kyphoplasty (see Table 9). When including the restoration of vertebral body height, the SpineJack procedure was found to be superior to balloon kyphoplasty at 6 months (88.1% vs. 60.9%) and at 12 months (79.7% vs. 59.3%, p<0.001). There was also a reduction in adjacent vertebral fractures with the mechanical augmentation system (12.9% vs. 27.3%; p=0.043). Interpretation of this study is limited by the lack of a sham control group.

**Table 8. Summary of Key RCT Characteristics**

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Tutton (2015) <sup>19</sup> ,	US, EU	21	2010-2013	Patients with OVCF	Kiva (n=153)	BK (n=147)
Korovessis (2013) <sup>20</sup> ,	Greece	1	2010-2011	Patients with OVCF	Kiva (n=82 patients, 133 fractures)	BK (n=86 patients, 122 fractures)
Noriega et al (2019) <sup>21</sup> ,	EU	13	2015-2017	Patients with OVCF aged <3 mo and loss of height ≥15% but ≤40%, VAS ≥ 50 mm and ODI ≥30%	SpineJack (n=77, 68 in mITT)	BK (n=75, 73 in mITT)

BK: balloon kyphoplasty; mITT; modified intention-to-treat; ODI: Oswestry Disability Index; OVCF: osteoporotic vertebral compression fracture; RCT: randomized controlled trial; visual analog score.

**Table 9. Summary of Key RCT Results**

Study	Improvement in VAS Score at 12 mo.	Improvement in ODI at 12 mo		Restoration of VBH	Percent Success
				Anterior	VAS Improvement of 5.5 Points
Tutton (2015) <sup>19</sup> ,					
Kiva	70.8	38.1			
BK	71.8	42.2			

Study	Improvement in VAS Score at 12 mo.	Improvement in ODI at 12 mo		Restoration of VBH	Percent Success
Korovessis (2013) <sup>20</sup> ,					
Kiva				24%	44 (54%)
BK				23%	37 (43%)
P-value				0.97	
	Improvement in VAS at 1 mo + SD	Improvement in ODI at 1 mo + SD	Improvement in EQ-5D at 1 mo + SD	Midline + SD	Percent Achieving CCS (95% CI)
Noriega et al (2019) <sup>21</sup> ,					
Spine-Jack	56.4 + 20.3	44.2 + 21.2	0.45 + 0.29	1.31 + 2.58	89.8% (82.1%–97.5%)
BK	47.8 + 25.7	39.9 + 23.7	0.42 + 0.29	0.10 + 2.34	87.3% (78.5%–96.1%)
p-Value	0.029	0.321	0.598	0.0035	0.0016

AE: adverse events; BK: balloon kyphoplasty; CCS: composite clinical success; CI: confidence interval; EQ-5D: EuroQol 5-domain questionnaire; ODI: Oswestry Disability Index; RCT: randomized controlled trial; SD: standard deviation; VAS: visual analog scale; VBHr: vertebral body height.

Composite clinical success included greater than 20 mm improvement in visual analog score, maintenance or improvement in ODI, and absence of adverse events.

**Table 10. Study Design and Conduct Limitations**

Study	Allocation <sup>a</sup>	Blinding <sup>b</sup>	Selective Reporting <sup>c</sup>	Follow-Up <sup>d</sup>	Power <sup>e</sup>	Statistical <sup>f</sup>
Tutton (2015) <sup>19</sup> ,	2. Allocation not concealed throughout study	1,2. Patients only blinded prior to procedure performance			2. Study not powered for primary or secondary endpoint	
Korovessis (2013) <sup>20</sup> ,		1,2. Not blinded				
Noriega et al (2019) <sup>21</sup> ,		1. Not blinded for patient-reported outcomes. Radiographic assessments were blinded.				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.

a Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear;

4. Inadequate control for selection bias.

b Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.

c Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.

d Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).

e Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.

f Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

### **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 and SpineJack, evidence includes industry-sponsored, multicenter investigational device exemption trials and a large independent randomized trial. These randomized comparative trials showed outcomes similar between Kiva and kyphoplasty. Mechanical vertebral augmentation with SpineJack was found to be non-inferior to balloon kyphoplasty for success on a composite outcome measure and superior to BK when vertebral height restoration was included in the composite. A major limitation of all these RCTs is the lack of a sham procedure. Due to the possible sham effect observed in the 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.

## **OSTEOLYTIC VERTEBRAL COMPRESSION FRACTURES**

### **Clinical Context and Therapy Purpose**

The purpose of balloon kyphoplasty or mechanical vertebral augmentation (Kiva) is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative care, in patients with osteolytic vertebral compression fractures.

The question addressed in this evidence review is: Does the use of balloon kyphoplasty or mechanical vertebral augmentation improve the net health outcome for individuals who have osteoporotic vertebral compression fracture or osteolytic vertebral compression fractures?

The following PICO was used to select literature to inform this review.

### ***Patients***

The relevant population of interest are individuals with osteolytic vertebral compression fractures.

### ***Interventions***

The therapy being considered is balloon kyphoplasty or mechanical vertebral augmentation. The intervention involves the fluoroscopically guided injection of polymethyl methacrylate po into a cavity created in the vertebral body with a balloon or mechanical device to provide support and symptomatic relief in patients.

**Comparators**

Comparators of interest include conservative care. Treatment includes bed rest, local and systemic analgesia, and bracing, in a home setting as well as an outpatient clinical setting by a primary care provider.

**Outcomes**

The general outcomes of interest are symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity.

**Table 11. Outcomes of Interest for Individuals with osteolytic vertebral compression fractures**

Outcomes	Details
Quality of Life	reduced pain, disability, and analgesic use in patients

The existing literature evaluating balloon kyphoplasty or mechanical vertebral augmentation (Kiva) as a treatment for osteolytic occipital condyle fracture has varying lengths of follow-up. At least one year of follow-up for the primary outcome is necessary to adequately assess outcomes.

**Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

- a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- d. Studies with duplicative or overlapping populations were excluded.

**Review of Evidence**

**Systematic Reviews**

In a systematic review, Health Quality Ontario (2016) assessed vertebral augmentation for cancer-related vertebral compression fractures.<sup>22</sup> The assessment identified 33 reports with 1,690 patients who were treated with kyphoplasty for spinal metastatic cancers, multiple myeloma, or hemangiomas. For cancer-related vertebral compression fractures 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 vertebral compression fractures, 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 visual analog scale pain and Oswestry Disability Index scores.

**Randomized Controlled Trials**

The only RCT to compare kyphoplasty to non-surgical management was an international multicenter study reported by Berenson et al (2011).<sup>23</sup> The trial enrolled 134 patients with cancer

who had at least 1 and not more than 3 painful osteolytic vertebral compression fractures. The primary outcome was change in functional status from baseline at 1 month as measured by the Roland-Morris Disability Questionnaire. 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-up (between-group difference in scores,  $p < 0.001$ ).

Korovessis et al (2014) compared efficacy of Kiva and kyphoplasty in an RCT with 47 participants with osteolytic vertebral compression fractures.<sup>24</sup> Oswestry Disability Index scores improved by 42 and 43 points in the kyphoplasty and Kiva groups, respectively. Pain scores improved by 5.1 points in both groups, from baseline mean scores of 8.1 (kyphoplasty) and 8.3 (Kiva).

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

Results of an RCT and case series 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 effect, the evidence provided is insufficient to warrant conclusions about the effect of kyphoplasty on health outcomes.

## **RADIOFREQUENCY KYPHOPLASTY**

### **Clinical Context and Therapy Purpose**

The purpose of radiofrequency kyphoplasty is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative care, in patients with osteoporotic or osteolytic vertebral compression fractures.

The question addressed in this evidence review is: Does the use of radiofrequency kyphoplasty improve the net health outcome for individuals who have osteoporotic vertebral compression fracture or osteolytic vertebral compression fractures?

The following PICO was used to select literature to inform this review.

#### ***Patients***

The relevant population of interest is individuals with osteoporotic or osteolytic vertebral compression fractures.

#### ***Interventions***

The therapy being considered is radiofrequency kyphoplasty. The intervention uses radiofrequency energy to ablate metastatic malignant lesions in a vertebral body to provide symptomatic relief.

#### ***Comparators***

Comparators of interest include conservative care. Treatment includes bed rest, local and systemic analgesia, and bracing, in a home setting as well as an outpatient clinical setting by a primary care provider.

### Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity.

**Table 12. Outcomes of Interest for Individuals with osteoporotic or osteolytic vertebral compression fractures**

Outcomes	Details
Quality of Life	reduced pain, disability, and analgesic use in patients

The existing literature evaluating radiofrequency kyphoplasty as a treatment for osteoporotic or osteolytic vertebral compression fractures has varying lengths of follow-up, ranging from 36-80 months. While studies described below all reported at least one outcome of interest, longer follow-up is necessary to fully observe outcomes.

### Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- c. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- d. Studies with duplicative or overlapping populations were excluded.

### Review of Evidence

Petersen et al (2016) reported on an RCT with 80 patients that compared radiofrequency kyphoplasty with balloon kyphoplasty.<sup>25</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, visual analog scale pain scores on movement were similar in both groups (8.4 in the balloon kyphoplasty group vs 8.0 in the radiofrequency kyphoplasty group). Postoperatively, visual analog scores improved by 4.6 after balloon kyphoplasty and 4.4 after radiofrequency kyphoplasty ( $p=NS$ ). 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 radiofrequency kyphoplasty 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 balloon kyphoplasty in patients with vertebral compression fractures.<sup>26</sup> Six studies (total  $n=833$  patients) evaluating vertebral compression fractures were identified. The main outcomes were pain relief (visual analog scale), functionality improvement (Oswestry Disability Index), operation time, reduction of deformity (i.e., the restoration of vertebral height and kyphosis angle), and incidence of cement leakage. Visual analog score improved for both groups after the respective procedure; however, visual analog scale 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 radiofrequency kyphoplasty than balloon kyphoplasty ( $p=0.04$ ), 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 vertebral compression fractures after treatment with cement augmenting procedures (vertebroplasty or kyphoplasty) vs conservative treatment in an RCT with 290 patients (363 affected vertebrae).<sup>27</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 six 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 vertebral compression fractures. 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 radiofrequency kyphoplasty, the evidence includes a meta-analysis study and a 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 radiofrequency kyphoplasty 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 fracture who receive balloon kyphoplasty, or mechanical vertebral augmentation (Kiva), the evidence includes randomized control trials and meta-analyses. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. A meta-analysis and moderately sized unblinded randomized control trial (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. Three randomized trials that compared mechanical vertebral augmentation (Kiva or SpineJack) 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 fracture who receive balloon kyphoplasty or mechanical vertebral augmentation, 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 fracture who receive radiofrequency kyphoplasty, the evidence includes a systematic review and an RCT. The 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.

## **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. 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 six 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 the use of kyphoplasty.

## **Practice Guidelines and Position Statements**

### **American College of Radiology et al**

The American College of Radiology (2014) and 7 other surgical and radiologic specialty associations published a joint position statement on percutaneous vertebral augmentation.<sup>28</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 statement 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.

A joint practice parameter for the performance of vertebral augmentation was updated in 2017.<sup>29</sup>

### **Society of Interventional Radiology**

In a quality improvement guideline on percutaneous vertebroplasty from the Society of Interventional Radiology (2014) 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, 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**

The American Academy of Orthopaedic Surgeons (2010) approved clinical guidelines 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."<sup>30</sup> The American Academy of Orthopaedic Surgeons indicated that future evidence could overturn existing evidence and that the quality of the current literature is poor. These recommendations were based on the literature reviewed through September 2009.

### **National Institute for Health and Care Excellence**

The National Institute for Health and Care Excellence (2013) issued a 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.<sup>31</sup> 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.

The Institute (2008) 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).<sup>32</sup> 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, agree. Despite a relatively small sample base, the Institute concluded the evidence suggests, in a select subset of patients, that early surgery may be more effective at maintaining mobility than radiotherapy.

**U.S. Preventive Services Task Force Recommendations**

Not applicable.

**Table 13. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT03730207 <sup>a</sup>	A Prospective, 1: 1 Randomized, Single Blind, Multi-center Human Clinical Trial	180	Oct 2020

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 (e.g., 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 (e.g., 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 (e.g., 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.
05-21-2019	Updated Description section.
	Updated Rationale section.
	Updated References section.
04-23-2021	Updated Description section
	In Policy section: <ul style="list-style-type: none"> <li>• Replaced "and Kiva" with " or mechanical vertebral augmentation with an FDA cleared device" in Items A and B</li> </ul>
	Updated Rationale section.
	Updated References section.

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