6.01.38	Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation		
Original Policy Date:	February 14, 2001	**Effective Date:**	June 1, 2023
Section:	6.0 Radiology	**Page:**	Page 1 of 27

Policy Statement

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

II. Mechanical vertebral augmentation with an FDA-cleared device may be considered **medically necessary** for the treatment of symptomatic thoracolumbar osteoporotic vertebral compression fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy, rest) for at least 6 weeks.

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

IV. Mechanical vertebral augmentation with an FDA-cleared device may be considered **medically necessary** for the treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

V. Balloon kyphoplasty or mechanical vertebral augmentation with an FDA-cleared device is considered **investigational** for all other indications, including use in acute vertebral fractures due to osteoporosis or trauma.

VI. Radiofrequency kyphoplasty is considered **investigational**.

VII. Mechanical vertebral augmentation using any other device is considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

There are CPT codes that combine the kyphoplasty procedure with all of the necessary imaging guidance:

- **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)

Description

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

Related Policies

- Percutaneous Vertebroplasty and Sacroplasty

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. 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.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Kyphoplasty is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration (FDA). Balloon kyphoplasty requires the use of an inflatable bone tamp. In July 1998, one such tamp, the KyphX® inflatable bone tamp (Medtronic), was cleared for marketing by the FDA through the 510(k) process. Other devices with the FDA 510(k) marketing clearance include the AVA*max*® Vertebral Balloon system (CareFusion), NeuroTherm Parallax® Balloon Inflatable Bone Tamp (NeuroTherm), Stryker iVAS® Balloon catheter, and Synthes Synflate™ Vertebral Balloon System (Synthes [West Chester, PA]). StabiliT® Vertebral Augmentation System (Merit Medical) for radiofrequency vertebral augmentation was cleared for marketing in 2009. FDA product code NDN.

In 2014, the Kiva® VCF Treatment System (Benvenue Medical) was cleared for marketing by the FDA through the 510(k) process. FDA product code NDN.

Polymethylmethacrylate 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 issued 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. FDA product code: NDN.

Table 1 lists examples of FDA-cleared devices for kyphoplasty and vertebral augmentation.

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

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Stryker iVAS Elite Inflatable Vertebral Augmentation System (Stryker iVAS Elite Balloon Catheter)	Stryker Corporation	12/21/2018	K181752	To repair vertebral compression fractures
SpineJack Expansion Kit	Vexim SA	8/30/2018	K181262	To repair vertebral compression fractures
SpineKure Kyphoplasty System	Hanchang Co. Ltd.	5/29/2018	K172871	To repair vertebral compression fractures
KYPHON HV-R Bone Cement	Medtronic Sofamor Danek USA Inc.	5/18/2018	K180700	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
Kyphon HV-R Bone Cement	MEDTRONIC INC	8/24/2016	K160983	To repair vertebral compression fractures
MEDINAUT Kyphoplasty System	IMEDICOM Co. Ltd.	7/29/2016	K153296	To repair vertebral compression fractures
OSTEOPAL plus	HERAEUS MEDICAL GMBH	4/22/2016	K153737	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 KyphoplastyCatheter (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

Device	Manufacturer	Date Cleared	510(k) No.	Indication
				compression fractures
KIVA VCF TREATMENT SYSTEM	BENVENUE MEDICAL INC.	8/14/2014	K141141	To repair vertebral compression fractures

Rationale

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.

Literature Review

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, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 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. Randomized controlled trials 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.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

The natural history of pain and disability associated with vertebral compression fractures 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.[2,3,] The placebo effect may be on the order of 6 to 7 mm on a 100-mm scale, for invasive procedures,[2,3,4,5,] and even larger effects (10%) have been observed in the sham-controlled vertebroplasty trials.[6,7,] 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 individuals with osteoporotic vertebral compression fractures.

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

Populations

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, a 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. 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 1 month to 4 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

The Agency for Healthcare Research and Quality (AHRQ) published a comparative effectiveness review on selected interventional treatments for acute and chronic pain in September 2021.[8,] The review included 37 RCTs for 10 interventional procedures and conditions that evaluated pain, function, health status, quality of life, medication use, and harm. Results of the review concluded that vertebroplasty (13 trials) was probably more effective at reducing pain and improving function in patients >65 years of age, but benefits were small (<1 point on a 10 point pain scale). Benefits of vertebroplasty appeared smaller in sham-controlled trials compared with trials involving usual care as a control and larger in trials involving patients with more acute symptoms. Vertebroplasty was also found to be probably not associated with an increased risk of incident vertebral fracture. Kyphopasty (2 trials) was concluded to probably be more effective than usual care for pain and function in older patients with vertebral compression fracture at up to 1 month and may be more effective at >1 month to ≥1 year but has not been compared against sham therapy. The evidence

regarding the risk of incident fracture with kyphoplasty was conflicting. The overall evidence base for vertebroplasty had several limitations including variations in patient selection criteria, technical factors such as volume of polymethyl methacrylate , and sham interventions. Usual care interventions were also not well standardized or defined, and the majority of results were based on mean differences in outcomes. Few trials reported the likelihood of achieving a clinically relevant response and data on long-term outcomes were limited. For kyphoplasty, a major limitation is the absence of sham-controlled trials.

Kyphoplasty or Vertebroplasty versus Conservative Treatment

Meta-analyses

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.[9,] Sixteen RCTs were identified (N=2 046 participants: vertebroplasty, n=816; kyphoplasty, n=478; conservative treatment, n=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 1 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% confidence interval [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.

Hinde et al (2020) performed a meta-analysis of 7 studies on the effect of vertebral augmentation (either vertebroplasty and/or balloon kyphoplasty) compared with nonsurgical management in over 1.5 million patients with osteoporotic vertebral compression fractures.[10,] Compared with nonsurgical management, vertebral augmentation reduced risk of mortality (hazard ratio [HR], 0.78; 95% CI, 0.66 to 0.92). These benefits remained significant in stratified analyses of mortality over periods of 2 years (HR, 0.70; 95% CI, 0.69 to 0.71) and 5 years (HR, 0.79; 95% CI, 0.62 to 1.00). Most studies were rated with scores of 7 to 9 on the Newcastle-Ottawa rating scale.

Sun et al (2020) performed a meta-analysis of 32 studies (N=945) in patients with osteoporotic vertebral compression fracture treated with vertebral augmentation or conservative treatment.[11,] No significant differences were observed in the risk of clinical fracture (risk ratio [RR], 1.22; 95% CI, 0.70 to 2.12) or radiological fracture (RR, 0.91; 95% CI, 0.71 to 2.12). Overall, 10 studies were rated as high quality, and the remainder were rated as low quality. Results remained consistent when stratified by RCTs and non-RCTs.

Halvachizadeh et al (2021) conducted a systematic review and meta-analysis comparing vertebroplasty, kyphoplasty, and nonoperative management in patients with osteoporotic vertebral compression fractures.[12,] A total of 16 RCTs (N=2731 patients) were included with 11 trials comparing vertebroplasty to nonoperative management, 1 trial comparing kyphoplasty to nonoperative management, and 4 comparing kyphoplasty and vertebroplasty. Surgical intervention was associated with greater improvement of pain as compared to nonoperative management and was unrelated to the development of adjacent level fractures or quality of life. Of the trials comparing kyphoplasty and vertebroplasty, no significant differences in outcome measures were observed. Fourteen of the 16 trials provided some concern for bias, and the remaining 2 trials provided a high concern for bias. The authors noted the heterogeneity of the included studies as a limitation.

Nonoperative management was not standardized and the majority of studies failed to provide evidence of osteoporosis despite indicating that the treated fractures were osteoporotic vertebral fractures. Tables 2, 3, and 4 present a comparison of studies included in the systematic reviews, review characteristics, and results, respectively.

Table 2. Comparison of Studies Included in Systematic Reviews & Meta-analyses

Study	Zhao (2017)[9]	Hinde (2020)[10]	Sun (2020)[11]	Halvachizadeh (2021)[12]
Chen (2013)	●	●	●	
Blasco (2012)	●		●	●
Boonen (2011)	●			
Farrokhi (2011)	●		●	●
Klazen (2010a)	●		●	●
Klazen (2010b)			●	
Rousing (2009)	●		●	●
Kallmes (2009)	●			●
Buchbinder (2009)	●		●	●
Voormolen (2006)	●			●
Liu (2009)	●			
Endres (2012)	●			
Dohm (2014)	●			●
Clark (2016)	●		●	●
Staples (2015)	●		●	
Yang (2015)	●			
Berenson (2011)	●			
Ong (2018)		●		
Edidin (2015)		●		
Edidin (2011)		●		
McCullough (2013)		●		
Lin (2017)		●		
Zampini (2010)		●		
Lange (2014)		●		
McDonald (2011)		●		
Lavelle (2008)		●		
Gerling (2011)		●		
Becker (2011)		●		
Levy (2012)		●		
Diamond (2016)		●		

Study	Zhao (2017)[9],	Hinde (2020)[10],	Sun (2020)[11],	Halvachizadeh (2021)[12],
Klezl (2012)		●		
Liu (2015)		●		
Bornemann (2012)			●	
Kroon (2013)			●	
Diamond (2003)			●	
Firanescu (2018)			●	●
Giannotti (2012)			●	
Grafe (2005)			●	
Kasperk (2010)			●	
Klazen (2010)			●	
Lee (2012)			●	
Rousing (2010)			●	
Voormolen (2007)			●	
Wang (2016)			●	●
Wang (2010)			●	
Wardlaw (2009)			●	●
Boonen (2011)			●	
Van Meirhaeghe (2013)			●	
Yang (2016)			●	
Yi (2014)			●	
Martinez-Ferrer (2013)			●	
Kroon (2013)			●	
Diamond (2006)			●	
Kasperk (2005)			●	
Lee (2012)			●	
Chen (2014)			●	●
Du (2018)			●	
Firanescu (2019)			●	
Kroon (2014)			●	
Movrin (2012)			●	
Voormolen (2007)			●	
Evans (2016)				●
Korovessis (2013)				●
Liu (2010)				●

Table 3. Systematic Reviews & Meta-Analyses Characteristics

Study	Dates	Trials	Participants	N (Range)	Design
Zhao (2017)[9],	2006-2016	16	Patients with osteoporotic vertebral compression fracture	2046 (34 to 381)	RCTs
Hinde (2020)[10],	2010-2018	7	Patients with osteoporotic vertebral compression fracture	1,649,247 (40 to 378,988)	Retrospective and prospective
Sun (2020)[11],	2005-2019	32	Patients with osteoporotic vertebral compression fracture	945 (34 to 300)	Prospective and RCTs
Halvachizadeh (2021)[12],	2006-2019	16	Patients with osteoporotic vertebral compression fracture	2731 (34 to 381)	RCTs

RCT: randomized controlled trial.

Table 4. Systematic Reviews & Meta-Analyses Results

Study	VAS	EQ-5D	RMDQ	New Fractures	Mortality
Zhao (2017)[9],					
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)	
Hinde (2020)[10],					
HR (95% CI) VA vs. CT					0.78 (0.66 to 0.92)
HR (95% CI) Balloon KP vs. Vertebroplasty					0.77 (0.77 to 0.78)
Sun (2020)[11],					
RR (95% CI) VA vs. CT				Clinical fracture: 1.22 (0.70 to 2.12) Radiological fracture: 0.91 (0.71 to 2.12)	
Halvachizadeh (2021)[12],		Adjacent level fractures			
VAS change: short-term; long-term (95% CI) Vertebroplasty or KP vs. CT	1.31 (0.41 to 2.21); 0.89 (0.16 to 1.62)				
p value	<.0001; <.0001				
I^2	99.8%; 99.2%				
VAS change: short-term; long-term (95% CI) KP vs. Vertebroplasty	-0.20 (-0.34 to -0.05); -0.30 (-0.98 to 0.37)				
p value	.90;.02				
I^2	0%; 81.9%				

Study	VAS	EQ-5D	RMDQ	New Fractures	Mortality
log OR (95% CI) Vertebroplasty or KP vs. CT		-0.16 (-0.83 to 0.50)			
MD (95% CI) Vertebroplasty or KP vs. CT			1.7 (0.01 to 3.47)		

CI: confidence interval; CT: conservative therapy; EQ-5D: European Quality of Life-5 Dimensions; HR: hazard ratio; KP: kyphoplasty; MD: mean difference; OR: odds ratio; RMDQ: Roland–Morris Disability Questionnaire; RR: relative risk; VA: vertebral augmentation; VAS: visual analog score.

Observational Studies

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.[13], Using the U.S. Medicare dataset, the authors identified 858,978 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 relationship 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. [14,7,6,] 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 to 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 to 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 to 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 versus conservative care is by Wardlaw et al (2009), who reported the Fracture Reduction Evaluation (FREE) trial, a nonblinded, industry-sponsored, multisite RCT involving 300 adults with 1 to 3 painful osteoporotic vertebral compression fractures of less than 3 months in duration.[15,] Twenty-four-month results were reported by Boonen et al (2011) and by Van Meirhaeghe et al (2013).[16,17,] 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% CI, 2.9 to 7.4 ; p<.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. Tables 5 and 6 summarize the key characteristics and results of the FREE trial. Tables 7 and 8 detail the relevance and design/conduct limitations of the study.

Table 5. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Wardlaw (2009), Boonen (2011), Van Meirheghe (2013) [15,16,17,]	EU	21	2003-2005	Patients with 1 to 3 vertebral fractures	Balloon kyphoplasty (n=149)	Non-surgical care (n=151)

EU: European Union; RCT: randomized controlled trial.

Table 6. 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	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) [15,16,17,]					
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%)
MD (95% CI)		3.24 (1.47 to 5.01)			
p value	<.0001	.0004			

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

Table 7. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Follow.Up[e]
Wardlaw (2009), Boonen (2011), Van Meirheghe (2013) [15,16,17,]			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 gaps 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 8. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Wardlaw (2009), Boonen (2011), Van Meirheghe (2013) [15,16,17,]	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 gaps 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 Data Completeness 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) versus 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).[18,] 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 on 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.[19,] 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 2 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.[20,] Patients (N =152) with osteoporotic vertebral compression fractures less than 3 months 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 (Table 10). 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 12 months (79.7% vs. 59.3%, p<.001). There was also a reduction in adjacent vertebral fractures with the mechanical augmentation system (12.9% vs. 27.3%; p=.043). Interpretation of this study is limited by the lack of a sham control group.

Tables 9 and 10 summarize the key characteristics and results of these RCTs. Table 11 details study design and conduct limitations.

Table 9. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Tutton (2015)[18,]	US, EU	21	2010-2013	Patients with OVCF	Kiva (n=153)	BK (n=147)
Korovessis (2013)[19,]	Greece	1	2010-2011	Patients with OVCF	Kiva (n=82 patients, 133 fractures)	BK (n=86 patients, 122 fractures)
Noriega et al (2019) [20,]	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; EU: European Union; mITT: modified intention-to-treat; ODI: Oswestry Disability Index; OVCF: osteoporotic vertebral compression fracture; RCT: randomized controlled trial; VAS: visual analog score.

Table 10. 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)[18,]					
Kiva	70.8	38.1			
BK	71.8	42.2			
Korovessis (2013)[19,]					
Kiva				24%	44 (54%)
BK				23%	37 (43%)
p value				.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) [20,]					
Spine-Jack	56.4 ± 20.3	44.2 ± 21.2	0.45 ± 0.29	1.31 ± 2.58	89.8% (82.1 to 97.5)
BK	47.8 ± 25.7	39.9 ± 23.7	0.42 ± 0.29	0.10 ± 2.34	87.3% (78.5 to 96.1)
p value	.029	.321	.598	.0035	.0016

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; VBH: vertebral body height.
Composite clinical success included greater than 20 mm improvement in VAS, maintenance or improvement in ODI, and absence of adverse events.

Table 11. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Tutton (2015)[18,]	2. Allocation not concealed throughout study	1,2. Patients only blinded prior to procedure performance			2. Study not powered for primary or	

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
					secondary endpoint	
Korovessis (2013)[19],		1,2. Not blinded				
Noriega et al (2019) [20],		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 gaps 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 Data Completeness 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

An AHRQ review concluded that vertebroplasty was probably more effective at reducing pain and improving function in patients >65 years of age, but benefits were small (<1 point on a 10 point pain scale). Kyphopasty was found to be probably more effective than usual care for pain and function in older patients with vertebral compression fracture at up to 1 month, and may be more effective at >1 month to ≥1 year, but has not been compared against sham therapy. The review found that the overall evidence base for vertebroplasty had several limitations while the absence of sham-controlled trials is a major limitation for kyphoplasty.

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. One systematic review of RCTs found no significant difference in subsequent fracture between vertebroplasty and conservative treatment, and another systematic review of prospective and retrospective studies reported improved mortality with either vertebroplasty or balloon kyphoplasty compared with conservative treatment. Other relevant studies, including additional RCTs and meta-analyses , found similar outcomes for kyphoplasty and vertebroplasty.

For mechanical vertebral augmentation with Kiva and SpineJack, the 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 balloon kyphoplasty 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 is to provide a treatment option that is an alternative to or an improvement on existing therapies, such as conservative care, in individuals with osteolytic vertebral compression fractures.

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

Populations
The relevant population of interest is 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 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.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, quality of life (Table 12), hospitalizations, and treatment-related morbidity.

Table 12. 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 as a treatment for osteolytic vertebral compression fracture has varying lengths of follow-up. At least 1 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.[21,] 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.

Mattie et al (2021) conducted a systematic review and meta-analysis of 7 RCTs (N=476) that compared the magnitude and duration of pain relief with vertebral augmentation (ie, balloon kyphoplasty or percutaneous vertebroplasty), with or without additional therapy, to any other intervention or placebo/sham for the treatment of cancer-related vertebral compression fractures.[22,] In 5 of the 7 studies, vertebral augmentation alone comprised 1 group; comparative treatments included nonsurgical management, Kiva implantation, and combinations of percutaneous vertebroplasty and radiofrequency therapy, chemotherapy, instrasomatic steroid injection, or ^{125}I seeds. Results revealed an overall positive and statistically significant effect of vertebral augmentation for the management of cancer-related vertebral compression fractures. This effect was particularly pronounced when comparing vertebral augmentation to nonsurgical management, radiofrequency ablation, or chemotherapy alone. The authors noted that there was much heterogeneity among the included studies regarding the treatment methods in the control groups, and 1 study allowed patients to crossover to the intervention group, potentially leading to biased results.

Randomized Controlled Trials

The only RCT to compare kyphoplasty to non-surgical management was an international multicenter study reported by Berenson et al (2011).[23,] 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 9.1 and 18.0 at 1-month follow-up (between-group difference in scores, p<.001).

Korovessis et al (2014) compared the efficacy of Kiva and kyphoplasty in an RCT with 47 participants with osteolytic vertebral compression fractures.[24,] 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, systematic reviews, 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 a possible placebo effect, the evidence 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 individuals with osteoporotic or osteolytic vertebral compression fractures.

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

Populations

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.

Outcomes

The general outcomes of interest are symptoms, functional outcomes, quality of life (Table 13), hospitalizations, and treatment-related morbidity.

Table 13. 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 to 80 months. While studies described below all reported at least 1 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

Meta-analysis

Feng et al (2017) performed a meta-analysis comparing radiofrequency kyphoplasty with balloon kyphoplasty in patients with vertebral compression fractures.[25,] Six studies (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 (ie, the restoration of vertebral height and kyphosis angle), and incidence of cement leakage. Visual analog scale 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=.001), with improvement persisting until the 12-month mark. While functionality improvement was initially improved more after radiofrequency kyphoplasty than balloon kyphoplasty (p=.04), the difference between the 2 groups was not significant after a year (p=.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.

Randomized Controlled Trials

Petersen et al (2016) reported on an RCT with 80 patients that compared radiofrequency kyphoplasty with balloon kyphoplasty.[26,] Patients had been admitted to the hospital for severe back pain and met the 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=not significant). 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=not significant). There was a trend for greater restoration of the kyphosis angle.

Section Summary: Radiofrequency Kyphoplasty

For radiofrequency kyphoplasty, the evidence includes a meta-analysis 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 radiofrequency kyphoplasty has outcomes similar to balloon kyphoplasty.

Adverse Events

Yi et al (2014) assessed the occurrence of new vertebral compression fractures after treatment with cement augmenting procedures (vertebroplasty or kyphoplasty) versus conservative treatment in an RCT with 290 patients (363 affected vertebrae).[27,] Surgically treated patients were discharged the next day. Patients treated conservatively (pain medication, bed rest, 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 to 80), 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).

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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 6 weeks of conservative treatment. Clinical input on these issues was mixed.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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.[28,] 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.[29,]

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.[28,] 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."

National Institute for Health and Care Excellence

The NICE (2013) issued a guidance that recommended percutaneous vertebroplasty and percutaneous balloon kyphoplasty as treatment options for 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.[30,] 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 NICE (2008) issued guidance on the diagnosis and management of adults with metastatic spinal cord compression. It was last reviewed in 2019, and a decision was made that the guideline required updating as "since its publication, there have been advances in the diagnosis and management of metastatic spinal cord compression." [31,] The guidance currently still states 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.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 14.

Table 14. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
Unpublished			

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT02700308	A Randomized, Multicenter, Open-label, Bayesian-based Phase II Study of the Feasibility of Kyphoplasty in the Local Treatment of Spine Metastases From Solid Tumors	60	Sep 2022
NCT04581707	Evaluation of Surgical Therapy of Vertebral Compression Fractures With the Kyphoplasty Single Balloon Catheter Allevo (Joline®) and the Quattroplasty Double Balloon Catheter Stop'n GO (Joline®) With BonOs® Inject Bone Cement	80	Oct 2021

NCT: national clinical trial.

References

1. Alsoof D, Anderson G, McDonald CL, et al. Diagnosis and Management of Vertebral Compression Fracture. Am J Med. Jul 2022; 135(7): 815-821. PMID 35307360
2. Jarvik JG, Deyo RA. Cementing the evidence: time for a randomized trial of vertebroplasty. AJNR Am J Neuroradiol. Sep 2000; 21(8): 1373-4. PMID 11003266
3. Moerman DE, Jonas WB. Deconstructing the placebo effect and finding the meaning response. Ann Intern Med. Mar 19 2002; 136(6): 471-6. PMID 11900500
4. Hróbjartsson A, Gøtzsche PC. Is the placebo powerless? An analysis of clinical trials comparing placebo with no treatment. N Engl J Med. May 24 2001; 344(21): 1594-602. PMID 11372012
5. Vase L, Riley JL, Price DD. A comparison of placebo effects in clinical analgesic trials versus studies of placebo analgesia. Pain. Oct 2002; 99(3): 443-452. PMID 12406519
6. Buchbinder R, Osborne RH, Ebeling PR, et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. N Engl J Med. Aug 06 2009; 361(6): 557-68. PMID 19657121
7. Kallmes DF, Comstock BA, Heagerty PJ, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. N Engl J Med. Aug 06 2009; 361(6): 569-79. PMID 19657122
8. Chou R, Fu R, Dana T, et al. Interventional treatments for acute and chronic pain: systematic review [Internet]. AHRQ Comparative Effectiveness Reviews. Rockville (MD): Agency for Healthcare Research and Quality; 2021 Sep. Report No.: 21-EHC030
9. Zhao S, Xu CY, Zhu AR, et al. Comparison of the efficacy and safety of 3 treatments for patients with osteoporotic vertebral compression fractures: A network meta-analysis. Medicine (Baltimore). Jun 2017; 96(26): e7328. PMID 28658144
10. Hinde K, Maingard J, Hirsch JA, et al. Mortality Outcomes of Vertebral Augmentation (Vertebroplasty and/or Balloon Kyphoplasty) for Osteoporotic Vertebral Compression Fractures: A Systematic Review and Meta-Analysis. Radiology. Apr 2020; 295(1): 96-103. PMID 32068503
11. Sun HB, Jing XS, Tang H, et al. Clinical and radiological subsequent fractures after vertebral augmentation for treating osteoporotic vertebral compression fractures: a meta-analysis. Eur Spine J. Oct 2020; 29(10): 2576-2590. PMID 32776263
12. Halvachizadeh S, Stalder AL, Bellut D, et al. Systematic Review and Meta-Analysis of 3 Treatment Arms for Vertebral Compression Fractures: A Comparison of Improvement in Pain, Adjacent-Level Fractures, and Quality of Life Between Vertebroplasty, Kyphoplasty, and Nonoperative Management. JBJS Rev. Oct 25 2021; 9(10). PMID 34695056
13. Edidin AA, Ong KL, Lau E, et al. Mortality risk for operated and nonoperated vertebral fracture patients in the medicare population. J Bone Miner Res. Jul 2011; 26(7): 1617-26. PMID 21308780
14. Ong KL, Beall DP, Frohbergh M, et al. Were VCF patients at higher risk of mortality following the 2009 publication of the vertebroplasty "sham" trials?. Osteoporos Int. Feb 2018; 29(2): 375-383. PMID 29063215
15. Wardlaw D, Cummings SR, Van Meirhaeghe J, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. Lancet. Mar 21 2009; 373(9668): 1016-24. PMID 19246088

16. Boonen S, Van Meirhaeghe J, Bastian L, et al. Balloon kyphoplasty for the treatment of acute vertebral compression fractures: 2-year results from a randomized trial. J Bone Miner Res. Jul 2011; 26(7): 1627-37. PMID 21337428
17. Van Meirhaeghe J, Bastian L, Boonen S, et al. A randomized trial of balloon kyphoplasty and nonsurgical management for treating acute vertebral compression fractures: vertebral body kyphosis correction and surgical parameters. Spine (Phila Pa 1976). May 20 2013; 38(12): 971-83. PMID 23446769
18. Tutton SM, Pflugmacher R, Davidian M, et al. KAST Study: The Kiva System As a Vertebral Augmentation Treatment-A Safety and Effectiveness Trial: A Randomized, Noninferiority Trial Comparing the Kiva System With Balloon Kyphoplasty in Treatment of Osteoporotic Vertebral Compression Fractures. Spine (Phila Pa 1976). Jun 15 2015; 40(12): 865-75. PMID 25822543
19. Korovessis P, Vardakastanis K, Repantis T, et al. Balloon kyphoplasty versus KIVA vertebral augmentation--comparison of 2 techniques for osteoporotic vertebral body fractures: a prospective randomized study. Spine (Phila Pa 1976). Feb 15 2013; 38(4): 292-9. PMID 23407406
20. Noriega D, Marcia S, Theumann N, et al. A prospective, international, randomized, noninferiority study comparing an implantable titanium vertebral augmentation device versus balloon kyphoplasty in the reduction of vertebral compression fractures (SAKOS study). Spine J. Nov 2019; 19(11): 1782-1795. PMID 31325625
21. Pron G, Holubowich C, Kaulback K. Vertebral Augmentation Involving Vertebroplasty or Kyphoplasty for Cancer-Related Vertebral Compression Fractures: A Systematic Review. Ont Health Technol Assess Ser. 2016; 16(11): 1-202. PMID 27298655
22. Mattie R, Brar N, Tram JT, et al. Vertebral Augmentation of Cancer-Related Spinal Compression Fractures: A Systematic Review and Meta-Analysis. Spine (Phila Pa 1976). Dec 15 2021; 46(24): 1729-1737. PMID 33958537
23. Berenson J, Pflugmacher R, Jarzem P, et al. Balloon kyphoplasty versus non-surgical fracture management for treatment of painful vertebral body compression fractures in patients with cancer: a multicentre, randomised controlled trial. Lancet Oncol. Mar 2011; 12(3): 225-35. PMID 21333599
24. Korovessis P, Vardakastanis K, Vitsas V, et al. Is Kiva implant advantageous to balloon kyphoplasty in treating osteolytic metastasis to the spine? Comparison of 2 percutaneous minimal invasive spine techniques: a prospective randomized controlled short-term study. Spine (Phila Pa 1976). Feb 15 2014; 39(4): E231-9. PMID 24253785
25. Feng L, Shen JM, Feng C, et al. Comparison of radiofrequency kyphoplasty (RFK) and balloon kyphoplasty (BKP) in the treatment of vertebral compression fractures: A meta-analysis. Medicine (Baltimore). Jun 2017; 96(25): e7150. PMID 28640091
26. Petersen A, Hartwig E, Koch EM, et al. Clinical comparison of postoperative results of balloon kyphoplasty (BKP) versus radiofrequency-targeted vertebral augmentation (RF-TVA): a prospective clinical study. Eur J Orthop Surg Traumatol. Jan 2016; 26(1): 67-75. PMID 26482590
27. Yi X, Lu H, Tian F, et al. Recompression in new levels after percutaneous vertebroplasty and kyphoplasty compared with conservative treatment. Arch Orthop Trauma Surg. Jan 2014; 134(1): 21-30. PMID 24287674
28. Baerlocher MO, Saad WE, Dariushnia S, et al. Quality improvement guidelines for percutaneous vertebroplasty. J Vasc Interv Radiol. Feb 2014; 25(2): 165-70. PMID 24238815
29. ACR-ASNR-ASSR-SIR-SNIS Practice Parameter for the Performance of Vertebral Augmentation. Available at https://www.acr.org/-/media/ACR/Files/Practice-Parameters/VerebralAug.pdf. Accessed February 16, 2023.
30. National Institute for Health and Care Excellence (NICE). Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures [TA279]. 2013; https://www.nice.org.uk/guidance/ta279. Accessed February 17, 2023.

31. National Institute for Health and Care Excellence (NICE). Metastatic spinal cord compression in adults: risk assessment, diagnosis and management [CG75]. 2008; https://www.nice.org.uk/guidance/cg75/chapter/1- Guidance. Accessed February 16, 2023.

Documentation for Clinical Review

Please provide the following documentation:

- History and physical and/or consultation notes including:
- Reason for procedure
- Description of prior treatment and response (including time frame of treatment)
- Imaging report(s)

Post Service (in addition to the above, please include the following):

- Procedure report

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	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)
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
02/14/2001	New Policy Adoption Policy for Vertebroplasty
10/24/2001	New Policy Adoption Policy for Kyphoplasty

Effective Date	Action
11/05/2002	Policy Revision Addition of FDA notification to description
03/01/2005	Policy Revision MPC Adoption CTAF Consent review of BCBSA TEC 2004 Vol. 24, No. 12 & 13. Policy Updated.
10/01/2005	Policy Name Change Policy review, title modifications
12/01/2005	Policy Revision MPC Adoption CTAF Consent review of BCBSA TEC Vol.20, No. 6 & 7. Policy Updated.
12/01/2006	BCBSA Medical Policy adoption MPC adopted BCBSA MPP review for Percutaneous Vertebroplasty 4:2006 & Percutaneous Kyphoplasty
10/15/2007	Policy Revision Policy changed based on expert input and evidence review. Approved under certain conditions (see policy for details).
06/19/2009	Policy Revision
03/30/2012	Policy Name Change Combination of two BCBSA medical policies: Percutaneous Vertebroplasty and Sacroplasty (6.01.25) and Percutaneous Kyphoplasty (6.01.38)
07/06/2012	Policy title change from Percutaneous Kyphoplasty and Vertebroplasty with position change
07/13/2012	Coding Update
12/15/2014	Policy title change from Percutaneous Kyphoplasty, Vertebroplasty and Sacroplasty Policy revision with position change
04/08/2015	Coding update
08/31/2015	Policy revision with position change
01/01/2017	Policy revision without position change
10/01/2017	Policy title change from Percutaneous Balloon Kyphoplasty and Mechanical Vertebral Augmentation Policy revision without position change
06/01/2018	Policy revision without position change
06/01/2019	Policy revision without position change
06/01/2023	Policy reactivated. Previously archived from 06/01/2020 to 05/31/2023.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** Blue font: Verbiage Changes/Additions
Reactivated Policy **Policy Statement:** N/A	**Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation 6.01.38** **Policy Statement:** I. Balloon kyphoplasty may be considered **medically necessary** for the treatment of symptomatic thoracolumbar osteoporotic vertebral compression fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy, rest) for at least 6 weeks. II. Mechanical vertebral augmentation with an FDA-cleared device may be considered **medically necessary** for the treatment of symptomatic thoracolumbar osteoporotic vertebral compression fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy, rest) for at least 6 weeks. III. Balloon kyphoplasty may be considered **medically necessary** for the treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies. IV. Mechanical vertebral augmentation with an FDA-cleared device may be considered **medically necessary** for the treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies. V. Balloon kyphoplasty or mechanical vertebral augmentation with an FDA-cleared device is considered **investigational** for all other indications, including use in acute vertebral fractures due to osteoporosis or trauma. VI. Radiofrequency kyphoplasty is considered **investigational**.

POLICY STATEMENT	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
	VII. Mechanical vertebral augmentation using any other device is considered **investigational**.