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FEP Medical Policy Manual

FEP 6.01.25 Minimally Invasive Approaches to Vertebral Fractures and Osteolytic Lesions of the Spine

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None

Minimally Invasive Approaches to Vertebral Fractures and Osteolytic Lesions of the Spine

Description

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Percutaneous vertebroplasty, percutaneous balloon kyphoplasty, radiofrequency kyphoplasty, and mechanical vertebral augmentation are interventional techniques involving the fluoroscopically guided injection of polymethyl methacrylate into a weakened vertebral body or a cavity created in the vertebral body with a balloon or mechanical device. The techniques have been investigated to provide mechanical support and symptomatic relief in patients with osteoporotic vertebral compression fractures or those with osteolytic lesions of the spine (eg, multiple myeloma, metastatic malignancies); as a treatment for sacral insufficiency fractures; and as a technique to limit blood loss related to surgery.

OBJECTIVE

The objective of this evidence review is to evaluate whether vertebroplasty, sacroplasty, balloon kyphoplasty, radiofrequency kyphoplasty, or mechanical vertebral augmentation, improve the net health outcome in individuals with osteoporotic or osteolytic vertebral compression fractures or sacral insufficiency fractures.

POLICY STATEMENT

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

Percutaneous vertebroplasty may be considered **medically necessary** for the treatment of symptomatic osteoporotic vertebral fractures that are less than 6 weeks in duration that have led to hospitalization or persist at a level that prevents ambulation.

Percutaneous vertebroplasty 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.

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

Percutaneous sacroplasty is considered **investigational** for all indications, including use in sacral insufficiency fractures due to osteoporosis and sacral lesions due to multiplemyeloma or metastatic malignancies.

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 (eg, analgesics, physical therapy, rest) for at least 6 weeks.

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 (eg, analgesics, physical therapy, rest) for at least 6 weeks.

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.

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.

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.

Radiofrequency kyphoplasty is considered **investigational**.

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

POLICY GUIDELINES

See Table 1 for FDA-cleared devices.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

State or federal mandates (eg, Federal Employee Program) may dictate that certain U.S. Food and Drug Administration (FDA) approved devices, drugs, or biologics may not be considered investigational. However, this policy considers specific applications of an FDA-approved device as investigational. Alternatively, FDA-approved devices may be assessed only by their medical necessity.

Percutaneous vertebroplasty, kyphoplasty, and sacroplasty may be performed by interventional radiologists or orthopedic surgeons.

Percutaneous vertebroplasty, kyphoplasty, and sacroplasty is a specialized procedure, and thus some patients may seek out of network referral.

FDA REGULATORY STATUS

Vertebroplasty is a surgical procedure and, as such, is not subject to U.S. Food and Drug Administration (FDA) approval.

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 terms a "transitional device." It was transitioned to a class III device requiring premarketing applications. Several orthopedic companies have received approval of their bone cement products since 1976. In 1999, polymethylmethacrylate was reclassified from class III to class II, which requires future 510(k) submissions to meet "special controls" instead of "general controls" to assure safety and effectiveness. Thus, use of polymethylmethacrylate in vertebroplasty represented an off-label use of an FDA-regulated product before 2005. In 2005, polymethylmethacrylate bone cements such as Spine-Fix Biomimetic Bone Cement and Osteopal V were cleared for marketing by the FDA through the 510(k) process for the fixation of pathologic fractures of the vertebral body using vertebroplasty procedures.

The use of polymethylmethacrylate in sacroplasty is an off-label use of an FDA-regulated product (bone cements such as Spine-Fix Biomimetic Bone Cement [Teknimed] and Osteopal V [Heraeus]) because the 510(k) approval was for the fixation of pathologic fractures of the vertebral body using vertebroplasty procedures. Sacroplasty was not included. FDA product code: NDN.

In 2009, Cortoss (Stryker) Bone Augmentation Material was cleared for marketing by the FDA through the 510(k) process. Cortoss is a nonresorbable synthetic material that is a composite resin-based, bis-glycidyl dimethacrylate. The FDA classifies this product as a polymethylmethacrylate bone cement.

In 2010, the Parallax Contour Vertebral Augmentation Device (ArthroCare) was cleared for marketing by FDA through the 510(k) process. There have been several other augmentation and bone expander devices (eg, Balex Bone Expander System, Arcadia Ballon Catheter, Kyphon Element Inflatable Bone Tamp) that were also cleared for marketing by FDA through the 510(k) process. These devices create a void in cancellous bone that can then be filled with bone cement. FDA product code: HXG.

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, KYPHON™ VuE™ 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				
Balloon Inflation System	Ningbo Biotechnology Co. Ltd	2/29/2024	K232842	Reduction of fractures and/or creation of a void
Renova Spine Baloon Catheter	Biopsybell S.R.L.	10/30/2023	K231340	Reduction of fractures and/or creation of a void
TRACKER Plus Kyphoplasty System	GS Medical Co., Ltd	10/28/2021	K211797	Reduction of fractures and/or creation of a void
Joline Kyphoplasty System Allevo	Joline GmbH & Co.	5/27/2020	K192449	To repair vertebral compression fractures
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

RATIONALE

Summary of Evidence

For individuals who have symptomatic osteoporotic vertebral fractures between 6 weeks and 1 year old who receive vertebroplasty, the evidence includes 2 randomized sham-controlled trials, nonblinded randomized controlled trials (RCTs) comparing vertebroplasty with conservative management, and several meta-analyses. Relevant outcomes are symptoms, functional outcomes, quality of life, hospitalizations, medication use, and treatment-related morbidity. Despite the completion of multiple RCTs, including 2 with sham controls, the efficacy of vertebroplasty for painful osteoporotic compression fractures remains uncertain. Two meta-analysis studies, which included the 2 sham-controlled trials, have demonstrated mixed results. The 2 studies had methodologic issues, including the choice of sham procedure and the potential of the sham procedure to have a therapeutic effect by reducing pain. Questions have also been raised about the low percentage of patients screened who participated in the trial, the volume of polymethylmethacrylate injected, and the inclusion of patients with chronic pain. One network meta-analysis found that relative to conservative treatment, vertebroplasty provided short-term and long-term improvements to pain relief and disability scores. Other meta-analyses had numerous limitations due to the heterogeneity of included studies or not specifying the timeframe for osteoporotic vertebral compression fractures. Overall, conclusions about the effect of vertebroplasty remain unclear. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with symptomatic osteoporotic vertebral fractures less than 6 weeks old who receive vertebroplasty, the evidence includes a randomized sham-controlled trial and nonblinded RCTs comparing vertebroplasty with conservative management. Relevant outcomes are symptoms, functional outcomes, quality of life, hospitalizations, medication use, and treatment-related morbidity. For acute fractures, conservative therapy consisting of rest, analgesics, and physical therapy is an option, and symptoms will resolve in a large percentage of patients with conservative treatment only. However, a sham-controlled randomized trial in patients who had severe pain of fewer than 6 weeks in duration found a significant benefit of vertebroplasty for the treatment of osteoporotic vertebral fracture at the thoracolumbar junction. Other RCTs without sham controls have reported that vertebroplasty is associated with significant improvements in pain and reductions in the duration of bed rest. Given the high morbidity associated with extended bed rest in older adults, this procedure is considered to have a significant health benefit. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with sacral insufficiency fractures who receive sacroplasty, the evidence includes 3 prospective cohort studies and a case series. Relevant outcomes are symptoms, functional outcomes, quality of life, hospitalizations, medication use, and treatment-related morbidity. No RCTs have been reported. The prospective cohort studies and retrospective series of 243 patients have reported rapid and sustained decreases in pain following percutaneous sacroplasty. Additional literature has mostly reported immediate improvements following the procedure. However, due to the small size of the evidence base, the harms associated with sacroplasty have not been adequately studied. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have osteoporotic vertebral compression fracture who receive balloon kyphoplasty or mechanical vertebral augmentation, the evidence includes an Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness review, RCTs, and meta-analyses. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. The AHRQ review concluded that vertebroplasty was probably more effective at reducing pain and improving function in patients greater than 65 years of age, but benefits were small. Kyphoplasty 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 greater than 1 month to 1 year or more, but has not been compared against sham therapy. A meta-analysis and moderately-sized unblinded RCT have compared kyphoplasty with conservative care and found short-term benefits in pain and other outcomes. 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. A network meta-analysis found that relative to conservative treatment, kyphoplasty provided short-term and long-term improvements to pain and disability scores. Other RCTs, summarized in a meta-analysis, have reported similar outcomes for kyphoplasty and vertebroplasty. Three RCTs 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 that the technology results in an improvement in the net health outcome.

For individuals who have osteolytic vertebral compression fracture who receive balloon kyphoplasty or mechanical vertebral augmentation, the evidence includes RCTs, case series, and systematic reviews 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 that these studies provide is insufficient to warrant conclusions about the effect of kyphoplasty on health outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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

SUPPLEMENTAL INFORMATION

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

The American College of Radiology (2014) and 7 other surgical and radiologic specialty associations published a joint position statement on percutaneous vertebral augmentation.[71,] 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.[72,]

In 2022, the American College of Radiology (ACR) revised its Appropriateness Criteria for the use of percutaneous vertebral augmentation in the management of vertebral compression fractures.[73,] Table 2 shows the appropriateness categories for each variant.

Table 2. ACR Appropriateness Criteria for the Use of Percutaneous Vertebral Augmentation for the Management of Vertebral Compression Fractures

Variants	Appropriateness Category
"Asymptomatic, osteoporotic VCF. Initial treatment"	Usually Not Appropriate
"Symptomatic osteoporotic VCF with bone marrow edema or intravertebral cleft. Initial treatment"	Usually Appropriate
"New symptomatic VCF. History of prior vertebroplasty or surgery. Initial treatment."	Usually Appropriate
"Benign VCF with worsening pain, deformity, or pulmonary dysfunction. Initial treatment"	Usually Appropriate
"Pathological VCF with ongoing or increasing mechanical pain. Initial treatment"	Usually Appropriate

ACR: American College of Radiology; CT: computed tomography; MRI: magnetic resonance imaging; VCF: vertebral compression fracture.

Society of Interventional Radiology

In a 2014 quality improvement guideline for percutaneous vertebroplasty from the Society of Interventional Radiology, failure of medical therapy was defined as follows[71,]:

1. "For a patient 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. For a patient 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. For any patient 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

In 2011, the American Academy of Orthopaedic Surgeons (AAOS) published practice guidelines on the treatment of osteoporotic spinal compression fractures.[74,] The AAOS approved "a strong recommendation against the use of vertebroplasty for patients who present with an acute osteoporotic spinal compression fracture and are neurologically intact."

National Institute for Health and Care Excellence

In 2003, NICE concluded in its guidance on percutaneous vertebroplasty that the current evidence on the safety and efficacy of vertebroplasty for vertebral compression fractures appeared "adequate to support the use of this procedure" to "provide pain relief for people with severe painful osteoporosis with loss of height and/or compression fractures of the vertebral body...." The guidance also recommended that the procedure be limited to patients whose pain is refractory to more conservative treatment. A 2013 NICE guidance, which was reaffirmed in 2016, indicated that percutaneous vertebroplasty and percutaneous balloon kyphoplasty "are recommended as 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 to be at the level of the fracture by physical examination and imaging." In 2008, NICE issued guidance on the diagnosis and management of adults with metastatic spinal cord compression.[75,] This guidance indicated that vertebroplasty or kyphoplasty should be considered for "patients who have vertebral metastases and no evidence of metastatic spinal cord compression or spinal instability if they have: mechanical pain resistant to conventional pain management, or vertebral body collapse." 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."[76,] 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.

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.[76,] 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.

American Society of Pain and Neuroscience

In 2021, the American Society of Pain and Neuroscience (ASPN) published practice guidelines for the interventional management of cancer-associated pain. [77,] The guideline included a best practice statement that stated "vertebral augmentation should be strongly considered for patients with symptomatic vertebral compression fractures from spinal metastases (evidence level 1-A)." However, ASPN noted that there is little data to suggest the superiority of either vertebroplasty or kyphoplasty when treating malignant vertebral compression fractures.

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.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
December 2011	New policy	
June 2013	Replace policy	Policy updated with literature review, References added, reordered and some removed. Policy statements unchanged.
June 2014	Replace policy	Policy updated with literature review; references 22, 31, 40-42, 45, and 46 added; policy statements unchanged.
June 2015	Replace policy	Policy updated with literature review; references 18 and 27 added; policy statements unchanged.
March 2018	Archive policy	Policy updated with literature review through March 23, 2017; references 9, 16, 26-27, and 30-31 added; vertebroplasty may be medically necessary in vertebral fractures of less than 6 weeks in duration that prevent ambulation.
June 2020	Reactivate policy	Policy updated with literature review through February 11, 2020; references updated. Policy statements unchanged.
June 2021	Replace policy	Policy updated with literature review through February 24, 2021; references added. Investigational policy statement edited for clarity. Policy statements otherwise unchanged.
June 2022	Replace policy	Policy updated with literature review through February 21, 2022; references updated. Policy statements unchanged.
June 2023	Replace policy	Policy updated with literature review through March 6, 2023; references updated. Policy statements unchanged.
June 2024	Replace policy	Policy updated with literature review through February 16, 2024; policy merged with 6.01.38 and title changed; references updated. Policy statements unchanged