PREMERA | BLUE CROSS

An Independent Licensee of the Blue Cross Blue Shield Association

MEDICAL POLICY – 6.01.25

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

BCBSA Ref. Policy:	6.01.25
Effective Date:	Jul. 1, 2025
Last Revised:	Jun. 9, 2025
Replaces:	6.01.520

RELATED MEDICAL POLICIES:

6.01.527 Diagnosis and Treatment of Sacroiliac Joint Pain

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

Clicking this icon returns you to the hyperlinks menu above.

Introduction

Osteoporosis or cancer in the bones can cause the vertebrae (the bone in the spine) to weaken. They may become so weak that they collapse. This is known as a compression fracture. The collapse usually happens at the front side of the vertebra, creating a vertebra that looks a bit like a wedge. Vertebral augmentation procedures, such as percutaneous vertebroplasty or kyphoplasty, are minimally invasive procedures intended to stabilize spinal compression fractures. The procedures involve inserting a hollow needle through the skin and into the damaged bone. Bone cement is then injected into the bone. In some cases, a small balloon or coil device is used to make space in the bone before the cement is injected. This policy describes when these procedures may be considered medically necessary. Percutaneous sacroplasty is a similar procedure, but the bone cement is placed in the sacrum. The sacrum is the bone at the bottom of the spine and forms the back of the pelvis. Using this technique for the sacrum is investigational. There are not yet enough medical studies to show whether percutaneous sacroplasty is effective.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Service	Medical Necessity
Percutaneous vertebroplasty	**Percutaneous vertebroplasty may be considered medically necessary for the treatment of the following:** • Symptomatic osteoporotic vertebral fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy, and rest) for at least 6 weeks **OR** • Symptomatic osteoporotic vertebral fractures that happened less than 6 weeks ago and have led to hospitalization or persist at a level that prevents ambulation **OR** • Severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies **Note:** There is considerable variability in pain scores based on the literature review. If the individual is in intractable pain that cannot be managed safely with conservative treatment for at least 1 week, then percutaneous vertebroplasty surgery may be considered sooner than 6 weeks. **Percutaneous vertebroplasty is considered investigational for all other indications, including use in acute vertebral fractures due to osteoporosis or trauma that have not led to hospitalization or prevent ambulation.**

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

Service	Medical Necessity
Percutaneous balloon kyphoplasty or mechanical vertebral augmentation	**Percutaneous balloon kyphoplasty or 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 at least 6 weeks of conservative treatment (e.g., analgesics, physical therapy, rest).** **Percutaneous balloon kyphoplasty or 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.** **Note:** *See Table 3 for list of FDA-cleared devices

Service	Investigational
Percutaneous balloon kyphoplasty or mechanical vertebral augmentation	**Percutaneous 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.** **Percutaneous radiofrequency kyphoplasty or percutaneous mechanical vertebral augmentation using any other device is considered investigational.** **Note:** *See Table 3 for list of FDA-cleared devices

Documentation Requirements
The individual's medical records submitted for review for all percutaneous vertebroplasty should document that medical necessity criteria are met. The record should include the following: • Symptomatic osteoporotic vertebral fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy, and rest) for at least 6 weeks **OR**

Documentation Requirements

- Symptomatic osteoporotic vertebral fractures that happened less than 6 weeks ago and have led to hospitalization or persist at a level that prevents walking

OR

- Severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies

The individual's medical records submitted for review for all percutaneous balloon kyphoplasty or mechanical vertebral augmentation should document that medical necessity criteria are met. The record should include the following:

- Relevant history and physical supporting painful osteoporotic thoracolumbar vertebral compression fractures that have failed to respond to at least 6 weeks of conservative treatment (e.g., analgesics, physical therapy, rest)

OR

- Severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies

AND

- Use of an FDA-cleared device

Coding

Code	Description
CPT	
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed
22510	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic
22511	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral
22512	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional

Code	Description
	cervicothoracic or lumbosacral vertebral body (List separately in addition to code for primary procedure)
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)
Code	**Description**
HCPC	
C1062	Intravertebral body fracture augmentation with implant (e.g., metal, polymer)
C7504	Percutaneous vertebroplasties (bone biopsies included when performed), first cervicothoracic and any additional cervicothoracic or lumbosacral vertebral bodies, unilateral or bilateral injection, inclusive of all imaging guidance
C7505	Percutaneous vertebroplasties (bone biopsies included when performed), first lumbosacral and any additional cervicothoracic or lumbosacral vertebral bodies, unilateral or bilateral injection, inclusive of all imaging guidance
C7507	Percutaneous vertebral augmentations, first thoracic and any additional thoracic or lumbar vertebral bodies, including cavity creations (fracture reductions and bone biopsies included when performed) using mechanical device (e.g., kyphoplasty), unilateral or bilateral cannulations, inclusive of all imaging guidance
C7508	Percutaneous vertebral augmentations, first lumbar and any additional thoracic or lumbar vertebral bodies, including cavity creations (fracture reductions and bone biopsies included when performed) using mechanical device (e.g., kyphoplasty), unilateral or bilateral cannulations, inclusive of all imaging guidance

Related Information

Benefit Application

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

Percutaneous vertebroplasty, kyphoplasty, and sacroplasty are specialized procedures, and thus some individuals may seek out of network referral.

Evidence Review

Description

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 individuals with osteoporotic vertebral compression fractures or those with osteolytic lesions of the spine (e.g., multiple myeloma, metastatic malignancies); as a treatment for sacral insufficiency fractures; and as a technique to limit blood loss related to surgery.

Background

Treatment of Vertebral Compression Fracture

Chronic symptoms do not tend to respond to the management strategies for acute pain, such as bed rest, immobilization or bracing device, and analgesic medication, sometimes including narcotic analgesics. The source of chronic pain after a 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 does not improve with analgesics and may be better addressed through exercise or physical therapy. Improvements in pain and ability to function are the principal outcomes of interest for treatment of osteoporotic fractures.

Treatment of Sacral Insufficiency Fractures

Similar interventions are used for sacral fractures and include bed rest, bracing, and analgesics. Initial clinical improvements may occur quickly; however, resolution of all symptoms may not occur for 9 to 12 months.[1,2]

Vertebral and Sacral Body Metastasis

Metastatic malignant disease of the spine generally involves the vertebrae/sacrum, with pain being the most frequent complaint.

Treatment Vertebral and Sacral Body Metastasis

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 strength in the vertebrae/sacrum, which may necessitate supportive bracing to minimize the risk of vertebral/sacral collapse during healing. Improvements in pain and function are the primary outcomes of interest for treatment of bone malignancy with percutaneous vertebroplasty or sacroplasty.

Surgical Treatment Options

Percutaneous Vertebroplasty and Kyphoplasty

Vertebroplasty is a surgical procedure that involves the injection of synthetic cement (e.g., polymethylmethacrylate [PMMA], bis-glycidal dimethacrylate [Cortoss][3]) into a fractured vertebra. It has been suggested that vertebroplasty may provide an analgesic effect through mechanical stabilization of a fractured or otherwise weakened vertebral body. However, other mechanisms of effect have been postulated, including thermal damage to intraosseous nerve fibers.

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.

Percutaneous Sacroplasty

Sacroplasty evolved from the treatment of insufficiency fractures in the thoracic and lumbar vertebrae with vertebroplasty. The procedure, essentially identical to vertebroplasty, entails guided injection of polymethylmethacrylate (PMMA) through a needle inserted into the fracture zone. Although first described in 2000 as a treatment for symptomatic sacral metastatic lesions,[4,5] it is most often described as a minimally invasive alternative to conservative management[6,7,8] for sacral insufficiency fractures.

Mechanical Vertebral Augmentation

Kiva is a 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.

Pain and function are subjective outcomes and, thus, may be susceptible to placebo effects. Furthermore, the natural history of pain and disability associated with these conditions may vary.

Therefore, controlled comparison studies would be valuable to demonstrate the clinical effectiveness of vertebroplasty and sacroplasty over any associated nonspecific or placebo effects and to demonstrate the effect of treatment compared with alternatives such as continued medical management.

In all clinical situations, adverse events related to complications from vertebroplasty, kyphoplasty, sacroplasty, and mechanical vertebral augmentation are the primary harms to be considered. Principal safety concerns relate to the incidence and consequences of leakage of the injected PMMA or another injectate.

Summary of Evidence

For individuals who have symptomatic osteoporotic vertebral fractures that are between six weeks and one year old who receive vertebroplasty, the evidence includes two randomized sham-controlled trials, nonblinded randomized controlled trials (RCTs) comparing vertebroplasty with conservative management, and several meta-analyses. The relevant outcomes are symptoms, functional outcomes, quality of life, hospitalizations, medication use, and treatment-related morbidity. Despite the completion of multiple RCTs, including two 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 two 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 individuals screened who participated in the trial, the volume of polymethylmethacrylate injected, and the inclusion of individuals 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 that are less than six weeks old who receive vertebroplasty, the evidence includes a randomized sham-controlled trial and nonblinded RCTs comparing vertebroplasty with conservative management. The 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

individuals with conservative treatment only. However, a sham-controlled randomized trial in individuals who had severe pain of fewer than six weeks in duration found a significant benefit of vertebroplasty for the treatment of osteoporotic vertebral fractures 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 three prospective cohort studies and a case series. The 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 individuals 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 individuals 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 individuals with vertebral compression fracture at up to one month and may be more effective at greater than one month to one 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 in pain and disability scores. Other RCTs, summarized in a meta-analysis, have reported similar outcomes for kyphoplasty and vertebroplasty. A systematic review that compared mechanical vertebral augmentation (Kiva or SpineJack) with kyphoplasty have reported similar outcomes for both procedures. A major

limitation of the available 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 individuals 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 individuals 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.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06141187	Percutaneous Vertebroplasty vs. Sham for Osteoporotic Vertebral Compression Fractures Focusing on Pain and Economy: A Single-center, Double-blind Randomized Controlled Clinical Trial	240	Dec 2030
Unpublished			
NCT04795765	Prospective SpineJack System Registry	261	Nov 2024
NCT02902250	The Comparative Study About the Effect of Vertebral Body Decompression Procedure and Conservative Treatment for Benign Vertebral Compression Fracture - Prospective Randomized Control Study	80	Feb 2022
NCT03617094	Early Percutaneous Vertebroplasty Versus Standard Conservative Treatment in Thoracolumbar Vertebral Fractures. Monocentric, Prospective, Randomised and Compared Clinical Study	42	Oct 2020
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

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 two physician specialty societies and three academic medical centers while this policy was under review in 2014. Input was sought on the treatment of acute vertebral fractures when there is severe pain that has led to hospitalization or persists at a level that prevents ambulation, and on the treatment of traumatic fractures that have remained symptomatic after six weeks of conservative treatment. Input on these issues was mixed.

2008 Input

In response to requests, input was received from five physician specialty societies and two academic medical centers while this policy was under review in 2008. Unsolicited input was received from a sixth physician specialty society. All reviewers disagreed with the proposed policy and provided references in support of the use of vertebroplasty. Vertebroplasty has been investigated as an intervention to provide mechanical support and symptomatic relief in individuals with an osteoporotic vertebral compression fracture and in those with osteolytic lesions of the spine (i.e., multiple myeloma, metastatic malignancies). Clinical input obtained in 2008 provided uniform support for the use of vertebroplasty in painful osteoporotic fractures. Reconsideration of the available evidence (consistent results of numerous case series, including large prospective reports) and evaluation of the input led to a conclusion that the evidence was sufficient to determine that vertebroplasty is a reasonable treatment option in individuals with vertebral fractures who have failed to respond to conservative treatment (at least six weeks with analgesics, physical therapy, and rest). It is also clinically reasonable to consider the evidence supporting the clinical benefit of vertebroplasty in the osteoporotic vertebral fracture to support its use in osteolytic lesions of the spine (e.g., multiple myeloma, metastatic malignancies).

Practice Guidelines and Position Statements

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

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or the 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.[72] 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 individuals 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 individual's quality of life.

A joint practice parameter for the performance of vertebral augmentation was updated in 2017.[73]

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.[74] **Table 2** shows the appropriateness categories for each variant.

Table 2. American College of Radiology 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

VCF: vertebral compression fracture.

Society of Interventional Radiology

In a 2014 quality improvement guideline for percutaneous vertebroplasty from the Society for Interventional Radiology, failure of medical therapy was defined as follows[72]:

1. For an individual rendered non-ambulatory 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 an individual 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 individual 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.[75] The AAOS approved a strong recommendation against the use of vertebroplasty for individuals 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…"[76] The guidance also recommended that the procedure be limited to patients whose pain is refractory to more conservative treatment. In 2023, NICE issued guidance on the diagnosis and management of adults with spinal metastases and metastatic spinal cord compression.[77] This guidance indicated that vertebroplasty or kyphoplasty should be considered for "patients who have spinal metastases and no evidence of metastatic spinal cord compression if they have: suspected or confirmed spinal instability, or pain uncontrolled by analgesia." Other options for

this population include radiofrequency ablation, surgical stabilization, or spinal surgery to prevent metastatic spinal cord compression.

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.[78] 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.[79] The guideline included a best practice statement that stated, "vertebral augmentation should be strongly considered for individuals 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.

Medicare National Coverage

There is no national coverage determination.

Regulatory Status

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

Polymethylmethacrylate (PMMA) 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, PMMA 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 PMMA in vertebroplasty represented an off-label use of an FDA-

regulated product before 2005. In 2005, PMMA 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 PMMA 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 FDA through the 510(k) process. Cortoss is a nonresorbable synthetic material that is a composite resin-based, bis-glycidal dimethacrylate. FDA classifies this product as a PMMA 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 (e.g., Balex Bone Expander System, Arcadia Balloon 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 US 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, Osteopal V (Heraeus), VertehighFix (Xelite Biomed) and 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 3**.

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 3.**

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

Table 3. Kyphoplasty and Mechanical Vertebral Augmentation Devices Cleared by the US Food and Drug Administration

(Note: This list is not all inclusive)

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

Device	Manufacturer	Date Cleared	510(k) No.	Indication
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

References

1. Gotis-Graham I, McGuigan L, Diamond T, et al. Sacral insufficiency fractures in the elderly. J Bone Joint Surg Br. Nov 1994; 76(6): 882-6. PMID 7983111
2. Lin J, Lachmann E, Nagler W. Sacral insufficiency fractures: a report of two cases and a review of the literature. J Womens Health Gend Based Med. Sep 2001; 10(7): 699-705. PMID 11571100
3. Bae H, Hatten HP, Linovitz R, et al. A prospective randomized FDA-IDE trial comparing Cortoss with PMMA for vertebroplasty: a comparative effectiveness research study with 24-month follow-up. Spine (Phila Pa 1976). Apr 01 2012; 37(7): 544-50. PMID 21738093
4. Dehdashti AR, Martin JB, Jean B, et al. PMMA cementoplasty in symptomatic metastatic lesions of the S1 vertebral body. Cardiovasc Intervent Radiol. 2000; 23(3): 235-7. PMID 10821903
5. Marcy PY, Palussière J, Descamps B, et al. Percutaneous cementoplasty for pelvic bone metastasis. Support Care Cancer. Nov 2000; 8(6): 500-3. PMID 11094996

6. Aretxabala I, Fraiz E, Pérez-Ruiz F, et al. Sacral insufficiency fractures. High association with pubic rami fractures. Clin Rheumatol. 2000; 19(5): 399-401. PMID 11055834

7. Leroux JL, Denat B, Thomas E, et al. Sacral insufficiency fractures presenting as acute low-back pain. Biomechanical aspects. Spine (Phila Pa 1976). Dec 1993; 18(16): 2502-6. PMID 8303454

8. Newhouse KE, el-Khoury GY, Buckwalter JA. Occult sacral fractures in osteopenic patients. J Bone Joint Surg Am. Dec 1992; 74(10): 1472-7. PMID 1364816

9. 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

10. 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

11. 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

12. 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

13. 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

14. 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

15. Stratford PW, Binkley J, Solomon P, et al. Defining the minimum level of detectable change for the Roland-Morris questionnaire. Phys Ther. Apr 1996; 76(4): 359-65; discussion 366-8. PMID 8606899

16. Katz J, Melzack R. Measurement of pain. Surg Clin North Am. Apr 1999; 79(2): 231-52. PMID 10352653

17. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Percutaneous vertebroplasty or kyphoplasty for vertebral fractures caused by osteoporosis. TEC Assessments. 2010;Volume 25:Tab 9.

18. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Percutaneous vertebroplasty or kyphoplasty for vertebral fractures caused by osteoporosis. TEC Assessments. 2009;Volume 24:Tab 7.

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

20. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Percutaneous kyphoplasty for vertebral fractures caused by osteoporosis or malignancy. TEC Assessments. 2005;Volume 20:Tab 7.

21. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Percutaneous kyphoplasty for vertebral fractures caused by osteoporosis and malignancy. TEC Assessments. 2004;Volume 19:Tab 12.

22. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Percutaneous Vertebroplasty. TEC Assessments. 2000;Volume 15:Tab 21.

23. Barr JD, Jensen ME, Hirsch JA, et al. Position statement on percutaneous vertebral augmentation: a consensus statement developed by the Society of Interventional Radiology (SIR), American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), American College of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spine Radiology (ASSR), Canadian Interventional Radiology Association (CIRA), and the Society of NeuroInterventional Surgery (SNIS). J Vasc Interv Radiol. Feb 2014; 25(2): 171-81. PMID 24325929

24. Buchbinder R, Johnston RV, Rischin KJ, et al. Percutaneous vertebroplasty for osteoporotic vertebral compression fracture. Cochrane Database Syst Rev. Apr 04 2018; 4(4): CD006349. PMID 29618171

25. Staples MP, Kallmes DF, Comstock BA, et al. Effectiveness of vertebroplasty using individual patient data from two randomised placebo controlled trials: meta-analysis. BMJ. Jul 12 2011; 343: d3952. PMID 21750078

26. Xie L, Zhao ZG, Zhang SJ, et al. Percutaneous vertebroplasty versus conservative treatment for osteoporotic vertebral compression fractures: An updated meta-analysis of prospective randomized controlled trials. Int J Surg. Nov 2017; 47: 25-32. PMID 28939236

27. 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

28. Zhang L, Zhai P. A Comparison of Percutaneous Vertebroplasty Versus Conservative Treatment in Terms of Treatment Effect for Osteoporotic Vertebral Compression Fractures: A Meta-Analysis. Surg Innov. Feb 2020; 27(1): 19-25. PMID 31423902

29. Chang M, Zhang C, Shi J, et al. Comparison Between 7 Osteoporotic Vertebral Compression Fractures Treatments: Systematic Review and Network Meta-analysis. World Neurosurg. Jan 2021; 145: 462-470.e1. PMID 32891841

30. Liu Y, Liu J, Suvithayasiri S, et al. Comparative Efficacy of Surgical Interventions for Osteoporotic Vertebral Compression Fractures: A Systematic Review and Network Meta-analysis. Neurospine. Dec 2023; 20(4): 1142-1158. PMID 38171285

31. Kroon F, Staples M, Ebeling PR, et al. Two-year results of a randomized placebo-controlled trial of vertebroplasty for acute osteoporotic vertebral fractures. J Bone Miner Res. Jun 2014; 29(6): 1346-55. PMID 24967454

32. Ostelo RW, Deyo RA, Stratford P, et al. Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. Spine (Phila Pa 1976). Jan 01 2008; 33(1): 90-4. PMID 18165753

33. Comstock BA, Sitlani CM, Jarvik JG, et al. Investigational vertebroplasty safety and efficacy trial (INVEST): patient-reported outcomes through 1 year. Radiology. Oct 2013; 269(1): 224-31. PMID 23696683

34. Firanescu CE, de Vries J, Lodder P, et al. Vertebroplasty versus sham procedure for painful acute osteoporotic vertebral compression fractures (VERTOS IV): randomised sham controlled clinical trial. BMJ. May 09 2018; 361: k1551. PMID 29743284

35. Chen D, An ZQ, Song S, et al. Percutaneous vertebroplasty compared with conservative treatment in patients with chronic painful osteoporotic spinal fractures. J Clin Neurosci. Mar 2014; 21(3): 473-7. PMID 24315046

36. Farrokhi MR, Alibai E, Maghami Z. Randomized controlled trial of percutaneous vertebroplasty versus optimal medical management for the relief of pain and disability in acute osteoporotic vertebral compression fractures. J Neurosurg Spine. May 2011; 14(5): 561-9. PMID 21375382

37. 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

38. Edidin AA, Ong KL, Lau E, et al. Morbidity and Mortality After Vertebral Fractures: Comparison of Vertebral Augmentation and Nonoperative Management in the Medicare Population. Spine (Phila Pa 1976). Aug 01 2015; 40(15): 1228-41. PMID 26020845

39. Lin JH, Chien LN, Tsai WL, et al. Early vertebroplasty associated with a lower risk of mortality and respiratory failure in aged patients with painful vertebral compression fractures: a population-based cohort study in Taiwan. Spine J. Sep 2017; 17(9): 1310-1318. PMID 28483705

40. Clark W, Bird P, Gonski P, et al. Safety and efficacy of vertebroplasty for acute painful osteoporotic fractures (VAPOUR): a multicentre, randomised, double-blind, placebo-controlled trial. Lancet. Oct 01 2016; 388(10052): 1408-1416. PMID 27544377

41. Klazen CA, Lohle PN, de Vries J, et al. Vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures (Vertos II): an open-label randomised trial. Lancet. Sep 25 2010; 376(9746): 1085-92. PMID 20701962

42. 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

43. Leali PT, Solla F, Maestretti G, et al. Safety and efficacy of vertebroplasty in the treatment of osteoporotic vertebral compression fractures: a prospective multicenter international randomized controlled study. Clin Cases Miner Bone Metab. 2016; 13(3): 234-236. PMID 28228788

44. Yang EZ, Xu JG, Huang GZ, et al. Percutaneous Vertebroplasty Versus Conservative Treatment in Aged Patients With Acute Osteoporotic Vertebral Compression Fractures: A Prospective Randomized Controlled Clinical Study. Spine (Phila Pa 1976). Apr 2016; 41(8): 653-60. PMID 26630417

45. Lourie H. Spontaneous osteoporotic fracture of the sacrum. An unrecognized syndrome of the elderly. JAMA. Aug 13 1982; 248(6): 715-7. PMID 7097924

46. Frey ME, Depalma MJ, Cifu DX, et al. Percutaneous sacroplasty for osteoporotic sacral insufficiency fractures: a prospective, multicenter, observational pilot study. Spine J. 2008; 8(2): 367-73. PMID 17981097

47. Kortman K, Ortiz O, Miller T, et al. Multicenter study to assess the efficacy and safety of sacroplasty in patients with osteoporotic sacral insufficiency fractures or pathologic sacral lesions. J Neurointerv Surg. Sep 01 2013; 5(5): 461-6. PMID 22684691

48. Frey ME, Warner C, Thomas SM, et al. Sacroplasty: A Ten-Year Analysis of Prospective Patients Treated with Percutaneous Sacroplasty: Literature Review and Technical Considerations. Pain Physician. Nov 2017; 20(7): E1063-E1072. PMID 29149151

49. Beall DP, Shonnard NH, Shonnard MC, et al. An Interim Analysis of the First 102 Patients Treated in the Prospective Vertebral Augmentation Sacroplasty Fracture Registry. J Vasc Interv Radiol. Sep 2023; 34(9): 1477-1484. PMID 37207812

50. Sarigul B, Ogrenci A, Yilmaz M, et al. Sacral insufficiency fracture: a single-center experience of 185 patients with a minimum 5-year follow-up. Eur Spine J. Apr 2024; 33(4): 1511-1517. PMID 37955749

51. Dougherty RW, McDonald JS, Cho YW, et al. Percutaneous sacroplasty using CT guidance for pain palliation in sacral insufficiency fractures. J Neurointerv Surg. Jan 2014; 6(1): 57-60. PMID 23345629

52. Zaman FM, Frey M, Slipman CW. Sacral stress fractures. Curr Sports Med Rep. Feb 2006; 5(1): 37-43. PMID 16483515

53. Denis F, Davis S, Comfort T. Sacral fractures: an important problem. Retrospective analysis of 236 cases. Clin Orthop Relat Res. Feb 1988; 227: 67-81. PMID 3338224

54. 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

55. 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

56. 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

57. 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

58. 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

59. 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

60. 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

61. 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

62. Macciacchera M, McDonnell JM, Amir A, et al. Mechanical Vertebral Body Augmentation Versus Conventional Balloon Kyphoplasty for Osteoporotic Thoracolumbar Compression Fractures: A Systematic Review and Meta-Analysis of Outcomes. Global Spine J. Mar 2025; 15(2): 1356-1366. PMID 38889443

63. 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

64. 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

65. 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

66. 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

67. 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

68. 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

69. 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

70. 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

71. 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

72. 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

73. ACR-ASNR-ASSR-SIR-SNIS Practice Parameter for the Performance of Vertebral Augmentation. Available at **https://www.sirweb.org/practice-resources/clinical-practice/guidelines-and-statements/neuro-and-spine/collaboration_endorsements/acr_sir-vertebral-augment/**. Accessed May 12, 2025.

74. American College of Radiology. Management of vertebral compression fractures. **https://acsearch.acr.org/docs/70545/Narrative/**. Published 2022. Accessed May 12, 2025.

75. McGuire R. AAOS Clinical Practice Guideline: the Treatment of Symptomatic Osteoporotic Spinal Compression Fractures. J Am Acad Orthop Surg. Mar 2011; 19(3): 183-4. PMID 21368100

76. National Institute for Health and Care Excellence (NICE). Percutaneous vertebroplasty [IPG12]. 2003; **https://www.nice.org.uk/guidance/ipg12**. Accessed May 12, 2025.

77. National Institute for Health and Care Excellence (NICE). Spinal metastases and metastatic spinal cord compression [NG234]. 2023; **https://www.nice.org.uk/guidance/ng234**. Accessed May 12, 2025.

78. 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 May 12, 2025.

79. Aman MM, Mahmoud A, Deer T, et al. The American Society of Pain and Neuroscience (ASPN) Best Practices and Guidelines for the Interventional Management of Cancer-Associated Pain. J Pain Res. 2021; 14: 2139-2164. PMID 34295184

History

Date	Comments
06/12/12	New policy, add to Radiology section. Policy replaces 6.01.520 in conjunction with 6.01.38.
09/25/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
07/24/13	Replace policy. Rationale updated based on a literature review through March 2013. ACR 2012 practice guideline added. References 31, 33, 34, 37 added; others renumbered or removed. Policy statements unchanged.
06/19/14	Annual Review. Policy updated with literature review through March 25, 2014; references 22, 31, 40-42, and 45-46 added; policy statements unchanged. ICD-9 procedure code 81.65 removed; this is performed outpatient – ICD-10 procedure codes also removed, along with both sets of diagnosis codes.
01/12/15	Coding update. New CPT codes 22510-22515, effective 1/1/15, added to policy; notation made regarding CPT codes 22520-22522 and 72291-72292, deleted as of 12/31/14.
08/11/15	Annual Review. Policy updated with literature review through March 3, 2015; references 18 and 27 added; Reworded the third policy statement for clarity: Percutaneous vertebroplasty is considered investigational for all other indications not listed above.
08/01/16	Annual Review, approved July 12, 2016. No change to policy statements. No new RCTs identified.
06/06/17	Coding update, removed HCPCS codes S2360 and S2361 as they were terminated 01/01/16.
08/01/17	Annual Review, approved July 18, 2017. Policy moved into the new format. 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.
07/01/18	Annual Review, approved June 22, 2018. Policy updated with literature review through February 2018; references 20, 28, and 36 added. Policy statements unchanged.
07/01/19	Annual Review, approved June 4, 2019. Policy updated with literature review through February 2019; references added. Policy statements unchanged.
04/01/20	Delete policy, approved March 10, 2020. This policy will be deleted effective July 2, 2020, and replaced with InterQual criteria for dates of service on or after July 2, 2020.
06/10/20	Interim Review, approved June 9, 2020, effective June 10, 2020. This policy is reinstated immediately and will no longer be deleted or replaced with InterQual criteria on July 2, 2020.

Date	Comments
06/30/2020	Coding update. Removed 0200T and 0201T.
08/01/20	Annual Review, approved July 23, 2020. Policy updated with literature review through February, 2020; references updated. Policy statements unchanged. Coding update, removed CPT codes 22513, 22514, 22515.
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through February 24, 2021; references added. Investigational policy statement edited for clarity. Policy statements otherwise unchanged.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through February 21, 2022; references updated. Policy statements unchanged. Added CPT codes 0200T and 0201T.
01/01/23	Coding update. Added new HCPC codes C7504 and C7505.
07/01/23	Annual Review, approved June 12, 2023. Policy updated with literature review through March 6, 2023; references updated. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
07/01/24	Annual Review, approved June 11, 2024. Policy updated with literature review through February 16, 2024; policy merged with 6.01.38 Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation. Title changed from Percutaneous Vertebroplasty and Sacroplasty to Minimally Invasive Approaches to Vertebral Fractures and Osteolytic Lesions of the Spine. References updated. Policy statements unchanged.
04/03/25	Minor update. Adding history information to correct the entry of 08/01/20 pertaining to the removal of CPT codes 22513, 22514, and 22515. These CPT codes were not removed from this policy and continued to be valid and applicable.
07/01/25	Annual Review, approved June 9, 2025. Policy updated with literature review through February 14, 2025; references added. Policy statements unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.