BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 6.01.25 Percutaneous Vertebroplasty and Sacroplasty

Effective Policy Date: July 1, 2021

Original Policy Date: December 2011

Related Policies:

6.01.38 - Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation

Percutaneous Vertebroplasty and Sacroplasty

Description

Description

Percutaneous vertebroplasty is an interventional technique involving the fluoroscopically guided injection of polymethyl methacrylate into a weakened vertebral body. The technique has 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 or sacroplasty improves the net health outcome in individuals with osteoporotic 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 multiple myeloma or metastatic malignancies.

POLICY GUIDELINES

None

BENEFIT APPLICATION

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

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

Percutaneous vertebroplasty 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. The device creates a void in cancellous bone that can then be filled with bone cement. FDA product code: HXG.

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. 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 2 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 available evidence includes a prospective cohort study and a retrospective series of 243 patients. These studies 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.

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

In 2020 , the American College of Radiology (ACR) revised its Appropriateness Criteria for the use of percutaneous vertebral augmentation in the management of vertebral compression fractures.[46.] Table 1 shows the appropriateness categories for each variant.

Table 1. ACR Appropriateness Criteria for the Use of Percutaneous Vertebral Augmentation for the Management of Vertebral Compression Fractures

Variants	Appropriateness Category
"New symptomatic compression fracture identified on radiographs or CT. No known malignancy."	May Be Appropriate
"Osteoporotic compression fracture, with or without edema on MRI and no <91>red flags.' With or without spinal deformity, worsening symptoms, or pulmonary dysfunction."	Usually Appropriate
"Asymptomatic pathologic spinal fracture with or without edema on MRI."	May Be Appropriate
"Pathologic spinal fracture with severe and worsening pain."	Usually Appropriate
"Pathologic spinal fracture with spinal deformity or pulmonary dysfunction."	Usually Appropriate

ACR: American College of Radiology; CT: computed tomography; MRI: magnetic resonance imaging.

In 2014, the ACR and 7 other medical specialty associations, including the Society for Interventional Radiology, updated a 2012 joint position statement on percutaneous vertebral augmentation.[11,] The statement indicated that "percutaneous vertebral augmentation with the use of vertebroplasty or kyphoplasty is a safe, efficacious, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures, when performed in accordance with published standards...only when nonoperative medical therapy has not provided adequate pain relief or pain is significantly altering the patient's quality of life. "

Society of Interventional Radiology

In a 2014 quality improvement guideline for percutaneous vertebroplasty from the Society of Interventional Radiology, failure of medical therapy was defined as follows[47,]:

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.[48,] 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, the National Institute for Health and Care Excellence (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...."[49.] The guidance also recommended that the procedure be limited to patients whose pain is refractory to more conservative treatment. A 2013 NICE guidance 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."[50.]

In 2008, NICE issued guidance on the diagnosis and management of adults with metastatic spinal cord compression.[51.] 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."

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.