BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Percutaneous Vertebroplasty and Sacroplasty

Policy #: 004
Latest Review Date: May 2023
Category: Radiology/Surgical

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective November 28, 2021, and after:

For percutaneous vertebroplasty, refer to LCD L38737.

Blue Advantage will treat **percutaneous sacroplasty** as a **non-covered benefit** and **investigational** for all indications, including use in sacral insufficiency fractures due to osteoporosis and spinal lesions due to metastatic malignancies.

Effective May 1, 2018, through November 27, 2021:

For percutaneous vertebroplasty, refer to LCD L33473.

Blue Advantage will treat **percutaneous sacroplasty** as a **non-covered benefit** and **investigational** for all indications, including use in sacral insufficiency fractures due to osteoporosis and spinal lesions due to metastatic malignancies.

The purpose of Blue Advantage's medical policy is to provide a guide to coverage. Medical policy is not intended to dictate to physicians how to practice medicine. Physicians should exercise their medical judgment in providing the care they feel is most appropriate for their patients.

DESCRIPTION OF PROCEDURE OR SERVICE:

Percutaneous vertebroplasty is an interventional technique involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) through a needle inserted into a weakened vertebral body. The technique has been investigated as an option to provide mechanical support and symptomatic relief in patients with osteoporotic vertebral compression fracture or in those with osteolytic lesions of the spine, i.e., multiple myeloma or metastatic malignancies. Percutaneous vertebroplasty has also been investigated as an adjunct to surgery for aggressive vertebral body hemangiomas, and as a technique to limit blood loss related to surgery.

Osteoporotic Fracture

Vertebral Compression Fracture

Osteoporotic compression fractures are common. It is estimated that up to one-half of women and approximately one-quarter of men will have a vertebral fracture at some point in their lives. However, only about one-third of vertebral fractures actually reach clinical diagnosis, and most symptomatic fractures will heal within a few weeks or 1 month. Nonetheless, some individuals with acute fractures will have severe pain and decreased function that interferes with ability to ambulate and is not responsive to usual medical management.

Treatment

Chronic symptoms do not tend to respond to the management strategies for acute pain such as bedrest, immobilization or bracing device, and analgesic medication, sometimes including narcotic analgesics. The source of chronic pain after vertebral compression fracture may not be from the vertebra itself but may be predominantly related to strain on muscles and ligaments

secondary to kyphosis. This type of pain frequently does not improve with analgesics and may be better addressed through exercise. Improvements in pain and ability to function are the principal outcomes of interest for treatment of osteoporotic fractures.

Sacral Insufficiency Fractures
Sacral insufficiency fractures (SIFs) are the consequence of stress on weakened bone and often cause low back pain in the elderly population. Osteoporosis is the most common risk factor for SIF. Spontaneous fracture of the sacrum in patients with osteoporosis was described by Lourie in 1982 and presents as lower back and buttock pain with or without referred pain in the legs. Although common, SIFs can escape detection due to low provider suspicion and poor sensitivity on plain radiographs, slowing the application of appropriate intervention.

Treatment
Similar interventions are used for sacral and vertebral fractures and include bedrest, bracing, and analgesics. Initial clinical improvements may occur quickly; however, resolution of all symptoms may not occur for 9 to 12 months.

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

Treatment
While radiation 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.

Percutaneous Sacroplasty
Percutaneous sacroplasty evolved from the treatment of insufficiency fractures in the thoracic and lumbar vertebrae with vertebroplasty. The procedure, essentially identical, entails guided injection of PMMA through a needle inserted into the fracture zone. While first described in 2000 as a treatment for symptomatic sacral metastatic lesions, it is most often described as a minimally invasive procedure employed as an alternative to conservative management for sacral insufficiency fractures (SIFs). SIFs are the consequence of stress on weakened bone and are often the cause of low back pain among the elderly population. Osteoporosis is the most common risk factor for SIF.

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 and above 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 effects related to complications from vertebroplasty and sacroplasty 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.

Vertebral Hemangiomas
Vertebral hemangiomas are relatively common lesions noted in up to 12% of the population based on autopsy series; however, only rarely do these lesions display aggressive features and produce neurologic compromise and/or pain. Treatment of aggressive vertebral hemangiomas has evolved from radiotherapy to surgical approaches using anterior spinal surgery for resection and decompression. There is the potential for large blood loss during surgical resection, and vascular embolization techniques have been used as adjuncts to treatment to reduce blood loss. Percutaneous vertebroplasty has been proposed as a way to treat and stabilize some hemangioma to limit the extent of surgical resection and as an adjunct to reduce associated blood loss from the surgery.

KEY POINTS:
The most recent literature update for this policy was performed through March 6, 2023.

Summary of Evidence
For individuals with sacral insufficiency fractures who receive sacroplasty, the evidence includes two prospective cohort studies, several retrospective reviews, 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 with 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 the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
American College of Radiology
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. The table below shows the appropriateness categories for each variant.

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

Variants	Appropriateness Category
"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

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

In 2014, the ACR and 7 other medical specialty associations, including the Society for Radiology, updated a 2012 joint position statement on percutaneous vertebral augmentation. 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 public standards. The document also stated that these procedures are offered only when nonoperative medical therapy has not provided adequate pain relief, or pain is significantly altering patients' quality of life.

Society for 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:

1. 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. 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. 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. 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
The U.K.'s National Institute for Health and Care Excellence (NICE) concluded in its 2003 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 o 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. This guidance indicated that vertebroplasty or kyphoplasty should be considered for "patients who have vertebral metastases and no evidence of MSCC [metastatic spinal cord compression] or spinal instability if they have: mechanical pain resistant to conventional pain management, or vertebral body collapse."

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. 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.

KEY WORDS:
Percutaneous vertebroplasty, vertebroplasty, polymethylmethacrylate, PMMA, osteoporosis, vertebral body compression fracture, vertebral fracture, vertebral compression fracture, PV, VCF, optiplasty, OptiMesh, Arcuate XP device, Arcuplasty, ARCUATE™ Vertebral Augmentation System, sacroplasty, Cortoss Bone Augmentation Material, Osteopal, SpineFix, Parallax Contour Vertebral Augmentation device, Balex Bone Expander System, Arcadia Balloon Catheter, Kyphon Element Inflatable Bone Tamp

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

Polymethylmethacrylate (PMMA) bone cement was available as a drug product before enactment of FDA's device regulation and was at first considered what 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 October 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 issued 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty procedures.

The use of PMMA in sacroplasty represents an off-label use of an FDA-regulated product (bone cements such as Spine-Fix® Biomimetic Bone Cement [Teknimed] and Osteopal® V [Heraeus]), as the 510(k) marketing clearance was for the fixation of pathologic fractures of the vertebral body using vertebroplasty procedures. Sacroplasty was not included.

In May 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 February 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® 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.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, one or more needles, includes imaging guidance and bone biopsy, when performed
0201T	; two or more needles includes imaging guidance and bone biopsy, when performed

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POLICY HISTORY:

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Medical Policy Group, April 2020: Reinstated policy effective March 24, 2020.
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Medical Policy Group, December 2021
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