BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Percutaneous Vertebroplasty and Sacroplasty

Policy #: 004
Category: Radiology/Surgical

Latest Review Date: June 2021
Policy Grade: B

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 for dates of service on or after March 24, 2020:

Blue Advantage will treat **percutaneous vertebroplasty** as a **covered benefit** for the treatment of symptomatic osteoporotic vertebral fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy, and rest) for at least six (6) weeks.

Blue Advantage will treat **percutaneous vertebroplasty** as a **covered benefit** for the treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

Blue Advantage will treat **percutaneous vertebroplasty** as a **covered benefit** for the treatment of vertebral hemangiomas with severe pain or nerve compression.

Blue Advantage will treat **percutaneous vertebroplasty** as a **non-covered benefit** and as **investigational** for all other indications.

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 or multiple myeloma.

For dates of service February 26, 2018, through March 23, 2020, refer to LCD L34555.

Effective for dates of service prior to February 26, 2018:

Blue Advantage will treat **Percutaneous vertebroplasty** as a **covered** benefit when one of the following criteria are met:

- Acute and sub-acute (age of fracture must be 6 months or less) osteoporotic vertebral collapse with pain for at least 6 weeks that has not responded to conservative management (rest, external support, treatment with analgesics, physical therapy and calcium) and is severe enough to cause significant immobility and impairment of activities of daily living and/or require maximal pain management, **and** notable height loss with negative consequences (e.g., reduction of vital capacity in patients with impaired pulmonary function).

- Osteolytic vertebral metastasis or myeloma with severe back pain for at least 2 weeks related to destruction of a vertebral body that does not involve the major part of the cortical bone and has not responded to conservative measures and/or require maximal pain management.

Blue Advantage will treat **Kyphoplasty** as a **covered** benefit when one of the following criteria are met:

- Acute and sub-acute (age of fracture must be 6 months or less) osteoporotic vertebral collapse with pain for at least 6 weeks that has not responded to conservative

management (rest, external support, treatment with analgesics, physical therapy and calcium) and is severe enough to cause significant immobility and impairment of activities of daily living and/or require maximal pain management, **and** notable height loss with negative consequences (e.g., reduction of vital capacity in patients with impaired pulmonary function).

- Osteolytic vertebral metastasis or myeloma with severe back pain for at least 2 weeks related to destruction of a vertebral body that does not involve the major part of the cortical bone and has not responded to conservative measures and/or require maximal pain management.

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 Vertebroplasty
Vertebroplasty is a surgical procedure that involves the injection of synthetic cement (e.g., polymethylmethacrylate [PMMA], bis-glycidal dimethacrylate [Cortoss]) 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.

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.

Kyphoplasty and mechanical vertebral augmentation are addressed separately in medical policy, #648- Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty and Mechanical Vertebral Augmentation.

KEY POINTS:
The most recent literature update for this policy was performed through February 24, 2021.

Summary of Evidence
For individuals who have symptomatic osteoporotic vertebral fractures of 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 systematic reviews of these RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, hospitalizations, medication use, and treatment-related morbidity. Despite the completion of numerous 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 effect of the sham procedure having 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. Overall, conclusions about the effect of vertebroplasty remain unclear. However, clinical input in 2008 provided uniform support for the use of vertebroplasty in painful osteoporotic fractures. After consideration of the available evidence and input, the consistent results of numerous case series, including large prospective reports, were sufficient to determine that vertebroplasty was a reasonable treatment option in patients with vertebral fractures who have failed to respond to conservative treatment (at least 6 weeks with analgesics, physical therapy, and rest). It is also

clinically reasonable to consider the evidence supporting the clinical benefit of vertebroplasty in osteoporotic vertebral fracture to support its use in osteolytic lesions of the spine (e.g., multiple myeloma, metastatic malignancies).

For individuals with symptomatic osteoporotic vertebral fractures less than 6 weeks old who receive vertebroplasty, the evidence includes a randomized sham-controlled trial and other 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 less 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 bedrest. Given the high morbidity associated with extended bedrest in older adults, this procedure is considered to have a significant health benefit. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

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 available evidence includes a prospective cohort study and a retrospective series with 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 the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
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. 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
"New symptomatic compression fracture identified on radiographs or CT. No known malignancy."	May Be Appropriate

Variants	Appropriateness Category
"Osteoporotic compression fracture, with or without edema on MRI and no '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

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

n 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 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."

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

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. The device creates 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:

01936	Anesthesia for percutaneous image guided procedures on the spine and spinal cord; therapeutic
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
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 cervicothoracic or lumbosacral vertebral body (List separately in addition to code for primary procedure)
64999	Unlisted procedure, nervous system

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POLICY HISTORY:

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