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. Percutaneous vertebroplasty is a non-surgical procedure to stabilize a spinal compression fracture. A hollow needle is inserted through the skin and into the damaged bone. Bone cement is then injected into the bone. This policy describes when this procedure 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.
### Service | Medical Necessity
--- | ---
**Percutaneous vertebroplasty** | 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, 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 patient 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 spinal lesions due to metastatic malignancies or multiple myeloma.

### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>CPT</td>
<td>Percutaneous vertebroplasty of thoracic or lumbar vertebrae</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>22510</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic</td>
</tr>
<tr>
<td>22511</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral</td>
</tr>
<tr>
<td>22512</td>
<td>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)</td>
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<tr>
<td>22513</td>
<td>Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic</td>
</tr>
<tr>
<td>22514</td>
<td>Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar</td>
</tr>
<tr>
<td>22515</td>
<td>Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, 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)</td>
</tr>
</tbody>
</table>

**Category III codes for sacroplasty**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0200T</td>
<td>Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles</td>
</tr>
<tr>
<td>0201T</td>
<td>Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles</td>
</tr>
</tbody>
</table>

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**Related Information**

**Benefit Application**

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

Percutaneous vertebroplasty is an interventional technique involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) 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 in those with osteolytic lesions of the spine (eg, multiple myeloma, metastatic malignancies). Percutaneous vertebroplasty has also been investigated as a technique to limit blood loss often seen with other types of back surgery. Injection of PMMA is also being investigated as a treatment for sacral insufficiency fractures.

Background

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 month. Nonetheless, some individuals with acute fractures will have severe pain and decreased function that interferes with their ability to ambulate and is not responsive to the usual medical management. In addition, a minority of patients with osteoporotic compression fractures will exhibit chronic pain that is difficult to medically manage. Chronic pain often does not respond to the same management strategies that are used for acute pain, such as bed rest, immobilization or bracing device, and analgesic medication, even narcotic analgesics. Chronic pain after a vertebral compression fracture may not come from the vertebra itself. Rather, the compression fracture may cause spinal kyphosis, which puts a strain on surrounding muscles and ligaments. This type of pain frequently does not improve with analgesics and may be better treated with exercise. Reduction of pain and an improved ability to function are the goals of treating osteoporotic fractures.
Sacral Insufficiency Fractures

Sacral insufficiency fractures (SIFs) are caused by stress on the weakened sacrum and often lead to 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. These fractures often present as lower back and buttock pain, with or without referred pain into the legs.\textsuperscript{1,2} Although common, SIFs are often not diagnosed because of low provider suspicion and poor sensitivity on plain radiographs. As a result, appropriate treatments and interventions are often delayed. Treatments for sacral and vertebral fractures are similar and include bed rest, bracing, and analgesics. Clinical improvement may soon be seen, but it may take up to 12 months for all symptoms to disappear.\textsuperscript{1,3}

Vertebral and Sacral Body Metastasis

Cancer can spread to the bone, and often targets the spine and pelvis. Pain is the most frequent complaint. Radiation and chemotherapy are frequently effective in reducing tumor burden and associated symptoms, but pain relief may be delayed days to weeks. Additionally, effective treatment may rely on bone remodeling to regain strength in the vertebrae/sacrum, which may require supportive bracing to minimize the risk of vertebral/sacral collapse during healing. Reduction of pain and an improved ability to function are the goals of treating bone malignancy with percutaneous vertebroplasty or sacroplasty.

Treatment

Percutaneous Vertebroplasty

It has been proposed that vertebroplasty may reduce pain by 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

Sacroplasty evolved from using vertebroplasty to treat insufficiency fractures in the thoracic and lumbar vertebrae. The procedure is essentially identical to vertebroplasty and involves the injection of polymethylmethacrylate (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 used as a minimally invasive alternative to conservative management for SIFs.

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 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. Use of a bis-glycidal dimethacrylate (Bis-GMA) composite material (Cortoss) for vertebroplasty has also been reported.

**Summary of Evidence**

For individuals who have symptomatic osteoporotic vertebral fractures that are 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. A 2016 meta-analysis, which included the 2 sham-controlled trials, found that vertebroplasty showed no significant benefit above sham for painful osteoporotic fractures, although alternative interpretations are possible. These studies have some methodologic issues, including the choice of sham procedure and the potential effect of the sham procedure actually 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with symptomatic osteoporotic vertebral fractures that are less than 6 weeks old who undergo 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, symptoms will resolve in a large percentage of patients using only conservative therapy consisting of rest, analgesics, and physical therapy. However, a sham-controlled randomized trial in patients who had severe pain of less than 6 weeks duration found a significant benefit using vertebroplasty to treat 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 a meaningful improvement in the net health outcome.

For individuals with sacral insufficiency fractures who receive sacroplasty, the evidence includes a prospective cohort study 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, possible harms associated with sacroplasty have not been adequately studied. The evidence is insufficient to determine the effects of the technology on health outcomes.

**Ongoing and Unpublished Clinical Trials**

Ongoing trials that might influence this policy are listed in Table 1.

**Table 1. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
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<tr>
<td>NCT02370628</td>
<td>Vertebroplasty in the treatment of acute fracture trial (The VITTA Trial)</td>
<td>495</td>
<td>Apr 2018</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may provide appropriate reviewers who collaborate with and make recommendations during this process, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2008 Input

In response to requests, input was received from 5 physician specialty societies and 2 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.

2014 Input

In response to requests, input was received from 2 physician specialty societies and 3 academic medical centers while this policy was under review in 2014. Focused 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 6 weeks of conservative treatment. Clinical input on these issues was mixed.

Practice Guidelines and Position Statements

American College of Radiology et al

In 2012, joint practice guidelines on the performance of vertebral augmentation were published by the American College of Radiology (ACR), the American Society of Neuroradiology (ASN), the American Society of Spine Radiology (ASSR), the Society of Interventional Radiology (SIR), and the Society of Neurointerventional Surgery (SNIS). Methods to achieve internal vertebral body stabilization included vertebroplasty, balloon kyphoplasty, radiofrequency ablation and coblation, mechanical void creation, and injection of bone graft material or bone substitutes. ACR, ASN, ASSR, SIR, and SNIS considered vertebral augmentation to be an established and safe
procedure. They provided guidelines for appropriate patient selection, qualifications and responsibilities of personnel, specifications of the procedure, equipment quality control, and quality improvement and documentation. These guidelines addressed vertebral augmentation in general and referred to all percutaneous techniques used.\(^{37}\)

These 5 societies also published a joint position statement on percutaneous vertebral augmentation in 2014.\(^ {38}\) The statement indicated that percutaneous vertebral augmentation using 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 the patients’ quality of life.

In a 2014 quality improvement guideline from SIR, failure of medical therapy is defined as follows\(^ {39}\):

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 2010, the American Academy of Orthopaedic Surgeons (AAOS) approved practice guidelines on the treatment of osteoporotic spinal compression fractures.\(^ {40}\) AAOS approved a strong recommendation against the use of vertebroplasty for patients who “present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.” With this recommendation, AAOS expressed its confidence that future evidence is unlikely to overturn the existing evidence. As a note, these recommendations were based on a literature review through September 2009; therefore, the 2010 Klazen trial was not included in the systematic review.
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 to be at the level of the fracture by physical examination and imaging.”

In 2008, NICE issued guidance on the diagnosis and management of adults with metastatic spinal cord compression. 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.”

**Medicare National Coverage**

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**Regulatory Status**

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 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
In 2005, PMMA bone cements such as Spine-Fix® Biomimetic Bone Cement and Osteopal® V were cleared for marketing by FDA through the 510(k) process for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty 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 and Osteopal® V), because the 510(k) approval was for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Sacroplasty was not included. FDA product code: NDN.

In May 2009, Cortoss® 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.

FDA product code: HXG.

References

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


<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>06/12/12</td>
<td>New policy, add to Radiology section. Policy replaces 6.01.520 in conjunction with 6.01.38.</td>
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<tr>
<td>09/25/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
</tr>
<tr>
<td>07/24/13</td>
<td>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.</td>
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<tr>
<td>06/19/14</td>
<td>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.</td>
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<tr>
<td>01/12/15</td>
<td>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.</td>
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<tr>
<td>08/11/15</td>
<td>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.</td>
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<tr>
<td>08/01/16</td>
<td>Annual Review, approved July 12, 2016. No change to policy statements. No new RCTs identified.</td>
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<tr>
<td>06/06/17</td>
<td>Coding update, removed HCPCS codes S2360 and S2361 as they were terminated 01/01/16.</td>
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<tr>
<td>08/01/17</td>
<td>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.</td>
</tr>
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</table>

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Email AppealsDepartmentInquiries@Premera.com

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200 Independence Avenue SW, Room 509F, HHH Building
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