

# Protocol

## Percutaneous Vertebroplasty and Sacroplasty

(60125)

<b>Medical Benefit</b>		<b>Effective Date:</b> 10/01/17	<b>Next Review Date:</b> 07/19
<b>Preauthorization</b>	No	<b>Review Dates:</b> 04/07, 05/08, 01/09, 01/10, 09/10, 07/11, 07/12, 07/13, 07/14, 07/15, 07/16, 07/17, 07/18	

### **Preauthorization is not required.**

*The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Populations	Interventions	Comparators	Outcomes
Individuals: • With symptomatic osteoporotic vertebral fractures between six weeks and one year old	Interventions of interest are: • Vertebroplasty	Comparators of interest are: • Conservative management	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Hospitalizations • Medication use • Treatment-related morbidity
Individuals: • With symptomatic osteoporotic vertebral fractures less than six weeks old	Interventions of interest are: • Vertebroplasty	Comparators of interest are: • Conservative management	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Hospitalizations • Medication use • Treatment-related morbidity
Individuals: • With sacral insufficiency fractures	Interventions of interest are: • Sacroplasty	Comparators of interest are: • Conservative management	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Hospitalizations • Medication use • Treatment-related morbidity

### **DESCRIPTION**

Percutaneous vertebroplasty is an interventional technique involving the fluoroscopically guided injection of polymethylmethacrylate 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 (e.g., multiple myeloma, metastatic malignancies); as a treatment for sacral insufficiency fractures; and as a technique to limit blood loss related to surgery.

## SUMMARY OF EVIDENCE

For individuals who have symptomatic osteoporotic vertebral fractures of 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 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 two with sham controls, the efficacy of vertebroplasty for painful osteoporotic compression fractures remains uncertain. Two meta-analysis studies which included the two 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 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 less than six 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 fewer than six 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 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 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 the effects of the technology on health outcomes.

## POLICY

Percutaneous vertebroplasty may be considered **medically necessary** for the treatment of symptomatic osteoporotic vertebral fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy, rest) for at least six weeks.

Percutaneous vertebroplasty may be considered **medically necessary** for the treatment of symptomatic osteoporotic vertebral fractures that are less than six 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 metastatic malignancies or multiple myeloma.

## MEDICARE ADVANTAGE

Percutaneous vertebroplasty is considered **medically necessary** for the following indications:

1. An osteoporotic or osteopenic compression fracture of the lumbar or thoracic vertebrae with persistent debilitating pain that has not responded to accepted standard medical treatment generally within six (6) weeks to three months;
2. Osteolytic metastasis with severe back pain related to a destruction of the vertebral body;
3. Multiple myeloma with severe back pain related to a destruction of the vertebral body;
4. Painful and/or aggressive vertebral hemangiomas (or eosinophilic granulomas of the spine);
5. Painful vertebral fracture associated with osteonecrosis (Kummell Disease); and
6. Reinforcement, or stabilization, of vertebral body prior to surgery.

Percutaneous vertebroplasty is considered **not medically necessary** as a prophylactic procedure for osteoporosis of the spine or kyphosis without fracture. It also should not be used for chronic back pain of long-standing duration, even if associated with old compression fractures, unless pain is localized to a specific chronic fracture and medical therapy has failed.

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.

## 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 reach clinical diagnosis, and most symptomatic fractures will heal within a few weeks or one month. Nonetheless, some individuals with acute fractures will have severe pain and decreased function that interferes with the ability to ambulate and is not responsive to usual medical management. Also, a minority of patients will exhibit chronic pain following osteoporotic compression fracture that presents challenges for 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.<sup>1</sup> Osteoporosis is the most common risk factor for SIF. Spontaneous fracture of the

sacrum in patients with osteoporosis was described by Lourie (1982) and presents as lower back and buttock pain with or without referred pain in the legs.<sup>2</sup> 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 nine to 12 months.<sup>1,3</sup>

#### Vertebral and Sacral Body Metastasis

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

#### *Treatment*

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

Vertebroplasty is a surgical procedure that involves the injection of synthetic cement (e.g., polymethylmethacrylate [PMMA], bis-glycidal dimethacrylate [Cortoss]<sup>4</sup>) 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

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 PMMA through a needle inserted into the fracture zone. While first described in 2000 as a treatment for symptomatic sacral metastatic lesions,<sup>5,6</sup> it is most often described as a minimally invasive alternative to conservative management<sup>7-9</sup> 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 events 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.<sup>4</sup>

#### **REGULATORY STATUS**

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

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 the 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.

## RELATED PROTOCOLS

Diagnosis and Treatment of Sacroiliac Joint Pain

Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

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