Protocol

Percutaneous Vertebroplasty and Sacroplasty

(60125)

Medical Benefit		**Effective Date**: 10/01/20	**Next Review Date**: 07/23
Preauthorization	No	**Review Dates**: 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, 07/19, 07/20, 07/21, 07/22	

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.

RELATED PROTOCOLS

Diagnosis and Treatment of Sacroiliac Joint Pain

Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation

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

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 (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 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 that 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 polymethyl methacrylate 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 prospective cohort studies and retrospective series of 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 that the technology results in an improvement in the net health outcome.

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 multiple myeloma or metastatic malignancies.

MEDICARE ADVANTAGE

The following only addresses Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF). See above for other indications.

PVA [percutaneous vertebroplasty (PVP)] is considered **medically necessary** with BOTH the following:

1. Inclusion criteria (ALL are required):
    a. Acute* (less than six weeks) osteoporotic Vertebral Compression Fracture (VCF) (T5 – L5) by recent (within 30 days) advanced imaging (bone marrow edema on MRI or bone-scan/SPECT/CT uptake)
    b. Symptomatic (ONE):
        i. Hospitalized with severe pain (Numeric Rating Scale (NRS) or Visual Analog Scale (VAS) pain score ≥8)
        ii. Non-hospitalized with moderate to severe pain (NRS or VAS ≥5) despite optimal non-surgical management** (ONE):
            1. Worsening pain
            2. Stable to improved pain (but NRS or VAS still ≥5) (with two or more of the following)**:**
                A. Progression of vertebral body height loss
                B. More than 25% vertebral body height reduction
                C. Kyphotic deformity
                D. Severe impact of VCF on daily functioning (Roland Morris Disability Questionnaire (RDQ)) >17
    c. Multidisciplinary team consensus (ALL are required)
        i. Referring physician (e.g., rheumatologist, endocrinologist)
        ii. Treating physician (i.e., performing the PVA)
        iii. Radiologist
        iv. Neurologist
2. Exclusion criteria (Can have NONE of the following):
    a. Absolute contraindication
        i. Current back pain is not primarily due to the identified acute VCF(s)

ii. Osteomyelitis, discitis or active systemic infection

iii. Pregnancy

iv. Greater than three vertebral fractures

b. Relative contraindication

i. Allergy to bone cement or opacification agents

ii. Coagulopathy

iii. Spinal instability

iv. Myelopathy from the fracture

v. Neurologic deficit

vi. Neural impingement

vii. Fracture retropulsion/canal compromise

*at least an acute component (e.g., acute on chronic)

**consider including pedicle periosteal infiltration

Percutaneous sacroplasty is considered **not medically necessary**.

BACKGROUND

TREATMENT OF VERTEBRAL COMPRESSION FRACTURE

Chronic symptoms do not tend to respond to the management strategies for acute pain such as bed rest, 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 or physical therapy. Improvements in pain and ability to function are the principal outcomes of interest for the treatment of osteoporotic fractures.

Treatment of Sacral Insufficiency Fractures

Similar interventions are used for sacral fractures and include bed rest, bracing, and analgesics. Initial clinical improvements may occur quickly; however, resolution of all symptoms may not occur for 9 to 12 months.[1,2]

VERTEBRAL AND SACRAL BODY METASTASIS

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

Treatment of Vertebral and Sacral Body Metastasis

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, bis-glycidal dimethacrylate [Cortoss][3]) 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 polymethylmethacrylate through a needle inserted into the fracture zone. Although first described in 2000 as a treatment for symptomatic sacral metastatic lesions,[4,5] it is most often described as a minimally invasive alternative to conservative management[6,7,8] for sacral insufficiency fractures.

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 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 polymethyl methacrylate or another injectate.

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. 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. FDA product code: HXG.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services 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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We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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53. National Government Services, Inc. (Primary Geographic Jurisdiction 06 & K - Illinois, Minnesota, Wisconsin, Connecticut, New York - Entire State, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont) Local Coverage Determination (LCD): Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L33569), Revision Effective Date For services performed on or after 12/01/2020.