

Protocol

Percutaneous Vertebroplasty and Sacroplasty

(60125)

Medical Benefit	Effective Date: 10/01/13	Next Review Date: 07/15
Preauthorization	No	Review Dates: 04/07, 05/08, 01/09, 01/10, 09/10, 07/11, 07/12, 07/13, 07/14

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required.** 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.*

Description

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. Injection of PMMA is also being investigated for the treatment of sacral insufficiency fractures.

Background

Percutaneous Vertebroplasty

It has been proposed that vertebroplasty may provide an analgesic effect through mechanical stabilization of a fractured or otherwise weakened vertebral body. However, other possible mechanisms of effect have been postulated, including thermal damage to intraosseous nerve fibers, because PMMA undergoes a heat-releasing (exothermic) reaction during its hardening process.

Percutaneous Sacroplasty

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 2001 as a treatment for symptomatic sacral metastatic lesions, (1, 2) it is most often described as a minimally invasive procedure employed as an alternative to conservative management (3-5) for sacral insufficiency fractures (SIFs). SIFs are the consequence of excessive stress on weakened bone and are often the cause of low back pain in the elderly population. Osteoporosis is the most common risk factor for SIF.

Osteoporotic Vertebral Compression Fracture

Osteoporotic compression fractures are a common problem, and 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 one month. However, a minority of patients will exhibit chronic pain following osteoporotic compression fracture that presents challenges for medical management. Chronic symptoms do not tend to respond to the management strategies for acute pain such as bed rest, immobilization/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 is not improved with analgesics and may be better addressed through exercise.

Sacral Insufficiency Fractures

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. (6, 7) Although common, SIFs can escape detection due to low provider suspicion and poor sensitivity on plain radiographs, slowing the application of appropriate intervention. Similar interventions are used for sacral and vertebral fractures including bed rest, bracing, and analgesics. Initial clinical improvements may occur quickly; however, the resolution of all symptoms may not occur for nine to 12 months. (6, 8)

Vertebral/Sacral Body Metastasis

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

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 radiation therapy 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.

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 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. FDA issued a guidance document on July 17, 2002 (last accessed September 2002, available at: <http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm072795.htm>) that outlines the types of special controls required and describes the recommended labeling information.

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 or kyphoplasty procedures.

FDA also issued a "Public Health Web Notification: Complications related to the use of bone cement in vertebroplasty and kyphoplasty procedures," which is available at: <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062126.htm>. This notification is intended to inform the public about reports on safety and to encourage hospitals and other user

facilities to report adverse events related to bone cement malfunctions, either directly to manufacturers or to MedWatch, FDA's voluntary reporting program.

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 and Osteopal® V), as the 510(k) marketing clearance was for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Sacroplasty was not included.

ArthroCare received FDA clearance for the Parallax® Contour® Vertebral Augmentation Device in 2010. The device creates a void in cancellous bone that can then be filled with bone cement.

Vesselplasty using Vessel-X®, (MAXXSPINE) and a similar procedure from A-Spine, are variations of vertebroplasty that are reported to eliminate leakage of bone cement by containing the filler in an inflatable vessel. These devices do not have clearance for marketing by FDA.

Related Protocols

Diagnosis and Treatment of Sacroiliac Joint Pain

Percutaneous Balloon Kyphoplasty and Mechanical Vertebral Augmentation

Policy (Formerly Corporate Medical Guideline)

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, and rest) for at least six weeks.

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 are 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 spinal lesions due to metastatic malignancies or multiple myeloma.

Medicare Advantage

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

1. An osteoporotic compression fracture of the lumbar or thoracic vertebrae with persistent debilitating pain, which 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);
6. Reinforcement or stabilization of vertebral body prior to surgery.

Percutaneous vertebroplasty is **not considered medically necessary** as a prophylactic procedures 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.

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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We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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