

Corporate Medical Policy

Vertebroplasty, Kyphoplasty, and Sacroplasty Percutaneous

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Description of Procedure or Service

Percutaneous Vertebroplasty

Percutaneous vertebroplasty (PVP) is an interventional radiology 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, as a technique to limit blood loss related to surgery. The technique has been used in all levels of the vertebrae, i.e., cervical, thoracic, and lumbar.

Percutaneous Kyphoplasty

Percutaneous kyphoplasty, like vertebroplasty, is an interventional radiology technique involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) through a needle inserted into a weakened vertebral body. Kyphoplasty is a variant of vertebroplasty that uses a specialized bone tamp with an inflatable balloon to expand a collapsed vertebral body as close as possible to its natural height before injection of the PMMA. 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.

It has been proposed that percutaneous vertebroplasty and kyphoplasty 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, since PMMA undergoes a heat-releasing (exothermic) reaction during its hardening process.

Vertebroplasty and kyphoplasty are surgical procedures and, as such, are not subject to U.S. Food and Drug Administration (FDA) approval. PMMA bone cement was available as a drug product prior to 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 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. The FDA issued a guidance document on July 17, 2002 (accessed September 6, 2002, at <http://www.fda.gov/cdrh/ode/guidance/668.pdf>), 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 prior to 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 pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

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Kyphoplasty requires the use of an inflatable bone tamp. One such tamp, the KyphX® inflatable bone tamp, received 510(k) marketing clearance from the FDA in July 1998. The use of PMMA in kyphoplasty represented an off-label use of an FDA-regulated product prior to July 2004. In July 2004, KyphX® HV-RTM bone cement was given 510K marketing clearance by the FDA for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a balloon kyphoplasty procedure. Subsequently, other products such as Spine-Fix® Biomimetic Bone Cement and Osteopal® V have been issued 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

The 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 www.fda.gov/cdrh/safety/bonecement.html. 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, the FDA’s voluntary reporting program.

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 polymethylmethacrylate (PMMA) through a needle inserted into the fracture zone. While first described in 2001 as of 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 excessive stress on weakened bone and are often the cause of low back pain among the elderly. Osteoporosis is the most common risk factor for SIF.

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 pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Sacroplasty was not included.

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 a 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. 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;

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however, the 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. 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 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 neurological 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.

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Percutaneous Vertebroplasty or Percutaneous Kyphoplasty when it is determined to be medically necessary and when the medical criteria and guidelines shown below are met.

Percutaneous Sacroplasty is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Vertebroplasty and Kyphoplasty are covered

Percutaneous Vertebroplasty or Percutaneous Kyphoplasty may be considered medically necessary for patients with vertebral fractures when the following criteria are met:

1. For symptomatic osteoporotic vertebral fractures with persistent debilitating pain, which has not responded to standard medical treatment including initial bed rest with progressive activity, physical therapy AND narcotic or non-narcotic analgesics.

Persistent debilitating pain is defined as:

- a) Level of pain on a Visual Analog Scale (VAS) greater than 4 on a daily basis, OR
- b) Pain on a daily basis that has a documented impact on activities of daily living (at least 2 ADL's or IADL's)

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Up to 6 weeks of standard medical treatment is required unless the pain is not significantly relieved by rest, narcotic and non-narcotic pain medications (as appropriate), or the patient is unable to tolerate narcotic and non-narcotic pain medication.

2. For treatment of severe pain in patients with osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

When Vertebroplasty, Kyphoplasty, and Sacroplasty are not covered

Percutaneous Vertebroplasty and Percutaneous Kyphoplasty are considered investigational for all indications that do not meet the medical necessity criteria listed above, including use in acute vertebral fractures due to osteoporosis or trauma.

Percutaneous Vertebroplasty and Percutaneous Kyphoplasty are contraindicated in the following conditions:

- Coagulation disorders
- Underlying infection (osteomyelitis of the involved vertebra)
- Very severe cardiopulmonary disease
- Neurological symptoms related to spinal compression
- Lack of neurosurgical backup for emergency decompression in the event a neurological deficit develops during the injection of PMMA.

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.

Policy Guidelines

The decision for treatment should be multidisciplinary and take into consideration the local and general extent of the disease. This includes the spinal level involved, the severity of pain experienced by the patient, his/her neurologic condition, previous treatments and their outcomes, the general state of health, and life expectancy. The following should be documented prior to performing Percutaneous Vertebroplasty or Percutaneous Kyphoplasty:

- There is a high degree of certainty through targeted, documented physical exam and ancillary studies (e.g., x-ray, MRI, CT, fluoroscopy, bone scan), that the pain is caused by a non-healing fracture;
- An ancillary study indicates non-healing osteoporotic or pathologic fracture, and does not indicate presence of spinal or disc fragment at the painful vertebral level;
- The procedure is not performed on a prophylactic basis, either for osteoporosis of the spine or for chronic back pain of long-standing duration even if associated with old compression fracture(s);
- The risks of an open surgical approach are greater than risks associated with a percutaneous approach.

Sacroplasty is an evolving technique with numerous methods (short axis, long axis, balloon assisted short axis, and iliosacral screws). No randomized trials of sacroplasty have been reported. Published evidence is from mostly case reports and small case series (all but one enrolling fewer than 13 patients). No consensus for best practices has been published. The largest experience is a prospective observational cohort study of 52 consecutive patients undergoing sacroplasty for sacral insufficiency fractures using the short axis technique. Patients had a mean age of 75.9 years and a mean duration of symptoms of 34.5 days (range: 4-89 days) and mean VAS score of 8.1 at baseline. Improvement on the VAS scale was measured at 30 minutes and 2, 4, 12, 24 and 52 weeks post-procedure. At each interval, statistically sig-

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nificant improvement over baseline was observed and maintained through 52 weeks. Additional literature reports are mostly consistent, reporting immediate improvement following the procedure. Due to the small size of the evidence, base harms associated with sacroplasty have not been adequately studied. There are complications of cement leakage with sacroplasty that are not observed with vertebroplasty. Leakage of PMMA into the presacral space, spinal canal, sacral foramen or sacroiliac joint may result in pelvic injection of PMMA, sacral nerve root or sacral spinal canal compromise, or sacroiliac joint dysfunction. Performing sacroplasty on Zone 1 fractures only can minimize these risks. Varying techniques, patient indications and small numbers of treated patients leaves uncertainty on the impact of sacroplasty on health outcomes, and does not permit conclusion on its use for sacral insufficiency fractures or other indication.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 22520, 22521, 22522, 22523, 22524, 22525, 72291, 72292. 0200T, 0201T, S2360, S2361

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Cyteval C, Sarrabere MP, Roux JO et al. Acute osteoporotic vertebral collapse: Open study on percutaneous injection of acrylic surgical cement in 20 patients. *AJR* 1999; 173:1685-90.

BCBSA Medical Policy Reference Manual, 10/00

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Senior Medical Director - 12/2008

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BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.25, 2/10/2010.

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.38, 2/10/2010

Bayley E, et al. Clinical outcomes of sacroplasty in sacral insufficiency fractures: a review of the literature. *Eur Spine J* (2009) 18:1266–1271.

Eck JC, et al. Comparison of vertebroplasty and balloon kyphoplasty for treatment of vertebral compression fractures: a meta-analysis of the literature. *The Spine Journal* 8 (2008) 488–497.

Frey ME, et al. Efficacy and safety of percutaneous sacroplasty for painful osteoporotic sacral insufficiency fractures. a prospective multi-center trial. *SPINE* 32(15):1635–1640.

Medical Director - 8/2010

Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Percutaneous Vertebroplasty or Kyphoplasty for Vertebral Fractures Caused by Osteoporosis. TEC Assessments 2009; Volume 24, Tab 7. Accessed 4/20/2011 online at <http://www.bcbs.com/blueresources/tec/vols/24/percutaneous-vertebroplasty.html>

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BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.25, 4/14/2011.

BCBSA Medical Policy Reference Manual [Electronic Version]. 6.01.38, 4/14/2011

Specialty Matched Consultant Advisory Panel - 5/2011

Policy Implementation/Update Information

- 1/01 Original policy issued.
- 4/01 76012, 76013 added to coding section.
- 7/01 Changed name of policy from Percutaneous Vertebroplasty to Vertebroplasty, Percutaneous.
- 9/01 Specialty Matched Consultant Advisory Panel, 8/01. Policy renamed to include Kyphoplasty. Revised sections to include Kyphoplasty as investigational.
- 9/01 Specialty Matched Consultant Advisory Panel, 7/15/2003. Benefits Application section revised. Policy reformatted to allow for indications, contraindications and guidelines for coverage of percutaneous vertebroplasty and kyphoplasty. Added HCPCS Level II codes S2360 and S2361 and CPT code 22899 to Billing/Coding section and deleted CPT codes 76012 & 76013.
- 9/03 Specialty Matched Consultant Advisory Panel, 7/15/2003. Benefits Application section revised. Policy reformatted to allow for indications, contraindications and guidelines for coverage of percutaneous vertebroplasty and kyphoplasty. Added HCPCS Level II codes S2360 and S2361 and CPT code 22899 to Billing/Coding section and deleted CPT codes 76012 & 76013.
- 8/12/04 Codes S2362 and S2363 added to Billing/Coding section.
- 8/26/04 Reference added.
- 7/21/05 Specialty Matched Consultant Advisory Panel review 6/24/2005. Created bullet # 3 under "When not covered" section to indicate that "very severe cardiopulmonary disease" as a separate contraindication. Added CPT 76012 and 76013 to "Billing/Coding" section as they are specific to this policy. Added policy number to "Key Words" section. References added.
- 1/05/06 Added CPT codes 22523, 22524 and 22525 to Billing/Coding section.
- 2/16/06 Added additional information on the findings from a recent Mayo Clinic study regarding vertebral fractures in relation to vertebroplasty to "Policy Guidelines" section. References added.
- 1/12/09 Reviewed with Senior Medical Director 12/10/08. Reworded the "When Covered" section and added "osteoporotic vertebral compression fracture" to #1. Added definition of "Persistent debilitating pain". Added #2 under "When covered" section to indicate "2. For treatment of severe pain in patients with osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies". Updated "Policy Guidelines" section and added the following comment; "Therefore, preventive treatment, including a combination of vitamin D and calcium supplementation, micalcin, and bisphosphonates is important for all patients in whom it is not other-

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wise contraindicated." References added.

- 7/6/09 Specialty Matched Consultant Advisory Panel Review 5/28/09. "Description" section revised. Combined policy statements into one statement, no change to intent. References added. (btw)
- 6/22/10 Policy Number(s) removed (amw)
- 9/28/10 Policy reviewed by Medical Director 8/26/2010. Added Sacroplasty to policy name. Added information pertaining to Percutaneous Sacroplasty to "Description" section. Added under "Policy" section; "Percutaneous Sacroplasty is considered investigational for all applications. BCBSNC does not procedures." Added comment to the "When Not Covered" section to indicate; "Percutaneous sacroplasty is considered investigational for all indications." CPT 0200T and 0201T added to the "Billing/Coding" section. "Policy Guidelines" updated. References added. (btw)
- 10/26/10 Removed "Sacroplasty" from the title of the "When Covered" section. (btw)
- 7/1/11 Specialty Matched Consultant Advisory Panel review 5/25/2011. Revised "Description" section. Added "including use in sacral insufficiency fractures due to osteoporosis and spinal lesions due to metastatic malignancies or multiple myeloma." to the "When Not Covered" statement regarding, "Percutaneous Sacroplasty is considered investigational for all indications". Updated "Policy Guidelines" section. References added. (btw)

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