

## Medical Policy



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### **Title: Percutaneous Vertebroplasty, Kyphoplasty and Sacroplasty**

#### **Professional**

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#### **Institutional**

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#### **DESCRIPTION**

Percutaneous vertebroplasty and kyphoplasty 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 techniques have 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. Vertebroplasty has been used in all levels of the vertebrae, i.e. cervical, thoracic, and lumbar.

It has been proposed that 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. 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.

PMMA is a bone cement. 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 510k marketing clearance for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

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.

Metastatic malignant disease involving the spine generally involves the vertebral bodies, 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 vertebral body strength, which may necessitate supportive bracing to minimize the risk of vertebral body collapse during healing.

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 cementoplasty 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.

Sacroplasty is a variation of vertebroplasty for sacral fractures. This procedure is used as an alternative treatment in patients with sacral insufficiency fractures related to osteoporosis. These fractures produce pain in the low back, hip, buttock or groin. Standard treatment includes bed rest, limited weight bearing, oral analgesics and sacral corsets. Improvement in symptoms may take as long as 12 months.

**POLICY**

Percutaneous vertebroplasty and kyphoplasty may be considered **medically necessary** for the treatment of:

- A. severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies
- B. vertebral hemangiomas with pain, nerve compression or aggressive radiologic signs, and radiation therapy has failed to relieve symptoms
- C. painful vertebral eosinophilic granuloma
- D. osteoporotic vertebral compression fracture with persistent debilitating pain

Sacroplasty may be considered **medically necessary** for the treatment of sacral insufficiency fractures that have failed to respond to conservative treatment.

Percutaneous vertebroplasty, kyphoplasty and sacroplasty are considered **experimental / investigational** for all other indications.

**RATIONALE**

This Policy was originally based on a 2000 TEC Assessment (1) and updated with 2004, 2005 and 2008 TEC Assessments. (2, 3, 26)

In response to requests, input was received from 6 physician specialty societies (1 unsolicited) and 2 academic medical centers while this policy was under review. Unsolicited input was received from another physician specialty society. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. All reviewers disagreed with the proposed policy, referring to a body of evidence from uncontrolled studies that support use of kyphoplasty.

After consideration of the uniform clinical input, it was concluded that although comparative studies with long-term outcomes are lacking, numerous case series, including large prospective reports, consistently show that vertebroplasty or kyphoplasty may alleviate pain and improve function in patients with vertebral fractures who fail to respond to conservative treatment (at least 6 weeks) with analgesics, physical therapy, and rest. Given the absence of alternative treatment options and the morbidity associated with extended bedrest, vertebroplasty and kyphoplasty may be considered a reasonable treatment option in patients with vertebral fractures who fail to improve after 6 weeks of conservative therapy.

## **Guidelines and Position Statements**

An updated 2008 TEC Assessment found that although many case series had been published, there was a lack of rigorous comparative trials of vertebroplasty and kyphoplasty. (26) Since case series studies are subject to many sources of bias and are generally not reliable evidence of efficacy, it was concluded that the evidence for kyphoplasty did not meet TEC criteria.

2006 Guidance from United Kingdom's National Institute for Health and Clinical Excellence (NICE) concluded that the current evidence on the safety and efficacy of balloon kyphoplasty for vertebral compression fractures appears adequate to support the use of this procedure provided that normal arrangements are in place for consent, audit, and clinical governance. (27) NICE also concluded that current evidence on the safety and efficacy of percutaneous cementoplasty for the palliative treatment of bony malignancies is limited, but appears adequate to support the use of this procedure in patients for whom other treatments have failed, provided that the normal arrangements are in place for consent, audit, and clinical governance. The aim of the procedure is to reduce pain and stabilize bones. (28)

A position statement from the American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, American Association of Neurological Surgeons/Congress of Neurological Surgeons, and American Society of Spine Radiology ("the Societies") from 2007 states that "percutaneous vertebral augmentation with vertebroplasty and kyphoplasty is a safe, efficacious, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures when performed in a manner in accordance with published standards. These procedures are offered only when traditional medical therapy has not provided pain relief or pain is substantially altering the patient's lifestyle." (29) The societies determined that the clinical response rate in individuals treated with kyphoplasty is equivalent to that seen in patients treated with vertebroplasty, and that there is no proven advantage of kyphoplasty relative to vertebroplasty with regard to pain relief, vertebral height restoration, or complication rate.

## **CODING**

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

### CPT/HCPCS

22520 Percutaneous vertebroplasty, 1 vertebral body, unilateral or bilateral injection; thoracic  
22521 Percutaneous vertebroplasty, 1 vertebral body, unilateral or bilateral injection; lumbar

- 22522 Percutaneous vertebroplasty, 1 vertebral body, unilateral or bilateral injection; each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)
- 22523 Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); thoracic
- 22524 Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); lumbar
- 22525 Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)
- 72291 Radiological supervision and interpretation, percutaneous vertebroplasty or vertebral augmentation including cavity creation, per vertebral body; under fluoroscopic guidance
- 72292 Radiological supervision and interpretation, percutaneous vertebroplasty or vertebral augmentation including cavity creation, per vertebral body; under CT guidance
- 0200T Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device (if utilized), 1 or more needles
- 0201T Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device (if utilized), 2 or more needles
- S2360 Percutaneous vertebroplasty, one vertebral body, unilateral or bilateral injection; cervical
- S2361 Each additional cervical vertebral body (list separately in addition to code for primary procedure)

### DIAGNOSIS

- 170.2 Malignant neoplasm of bone and articular cartilage; vertebral column, excluding sacrum and coccyx
- 198.5 Secondary malignant neoplasm of other specifies sites; bone and bone marrow
- 203.00 Multiple myeloma and immunoproliferative neoplasms; multiple myeloma
- 203.01 Multiple myeloma and immunoproliferative neoplasms; plasma cell leukemia
- 228.09 Hemangioma, of other sites
- 238.6 Neoplasm of uncertain behavior or other and unspecified sites and tissues; plasma cells
- 733.00 Osteoporosis, unspecified
- 733.01 Senile osteoporosis
- 733.02 Idiopathic osteoporosis
- 733.03 Disuse osteoporosis
- 733.13 Pathologic fracture of vertebrae

**REVISIONS**

04-21-2005	Added "or kyphoplasty" to policy #C.
12-14-2005	In "Policy" section, #C., added 'and cervical percutaneous vertebroplasty and kyphoplasty' based on Radiology Liaison Committee recommendations from 02-12-2002.
	In "Coding" CPT/HCPCS section, added CPT codes 22523, 22524, and 22525, and added "or vertebral augmentation including cavity creation" to CPT code 76012 to reflect changes in CPT book.
	In "Coding" CPT/HCPCS section, deleted HCPCS codes S2360 and S2361 because 'cervical' is considered E/I by the Radiology Liaison Committee 02-12-2002.
12-21-2006	In "Coding", Covered Diagnosis section, added Percutaneous vertebroplasty or Kyphoplasty – CPT Codes – 22520, 22521, 22522, 22523, 22524, 22525, 76012, 76013, S2362, S2363 to the current listing of diagnosis codes.
07-27-2006 effective 10-01-2006	Deleted S2362 and S2363, the codes were deleted from HCPCS 4-1-06.
10-31-2006 effective 01-01-2007	In "Coding", CPT/HCPCS deleted CPT codes 76012 and 76013 and added CPT codes 72291 and 72292 due to the 2007 CPT changes.
07-23-2009	<ul style="list-style-type: none"> <li>▪ Removed percutaneous vertebroplasty and kyphoplasty policy language from the policy entitled: Minimally Invasive Procedures for Spine Pain creating a free-standing policy entitled: Percutaneous Vertebroplasty, Kyphoplasty and Sacroplasty.</li> </ul> <p>Description section:</p> <ul style="list-style-type: none"> <li>▪ Updated description to reflect discussion of percutaneous vertebroplasty, kyphoplasty and sacroplasty</li> </ul>

	<p>Policy section:</p> <ul style="list-style-type: none"> <li>▪ Revised policy language from:</li> </ul> <p>C. Percutaneous vertebroplasty or kyphoplasty is considered medically necessary after failure of standard medical therapy in patients when any of the following criteria is met. Medical conditions not listed and cervical percutaneous vertebroplasty and kyphoplasty will be denied experimental/investigational.</p> <ol style="list-style-type: none"> <li>1. Osteolytic vertebral metastasis or myeloma with severe back pain related to destruction of the vertebral body not involving the major part of the cortical bone, and chemotherapy and radiation therapy have failed to relieve symptoms; or</li> <li>2. Vertebral hemangiomas with aggressive clinical signs (severe pain or nerve compression) and/or aggressive radiological signs, and radiation therapy has failed to relieve symptoms; or</li> <li>3. Osteoporotic vertebral collapse with persistent debilitating pain that has not responded to accepted standard medical therapy as documented in the medical records. Standard medical therapy may include initial bed rest with progressive activity, analgesics, physical therapy, bracing and exercises to correct postural deformity and increase muscle tone, salmon calcitonin, bisphosphonates and calcium supplementation; or</li> <li>4. Painful vertebral eosinophilic granuloma with spinal instability.</li> </ol> <p>To:</p> <p>Percutaneous vertebroplasty and kyphoplasty may be considered medically necessary for the treatment of:</p> <ol style="list-style-type: none"> <li>A. severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies</li> <li>B. vertebral hemangiomas with pain, nerve compression or aggressive radiologic signs, and radiation therapy has failed to relieve symptoms</li> <li>C. painful vertebral eosinophilic granuloma</li> <li>D. vertebral compression fracture with persistent debilitating pain</li> </ol> <p>Sacroplasty may be considered medically necessary for the treatment of sacral insufficiency fractures that have failed to respond to conservative treatment.</p> <p>Percutaneous vertebroplasty, kyphoplasty and sacroplasty are considered experimental / investigational for all other indications.</p>
	<p>Rationale section:</p> <ul style="list-style-type: none"> <li>▪ Added Rationale section.</li> </ul>
	<p>Coding section:</p> <ul style="list-style-type: none"> <li>▪ Added CPT/HCPCS Codes: 0200T, 0201T, S2360, S2361.</li> <li>▪ Deleted ICD-9 Code: 213.2.</li> <li>▪ Added ICD-9 Codes: 203.01, 238.6.</li> </ul>

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