Clinical Policy Title: Percutaneous vertebroplasty, kyphoplasty, sacroplasty

Clinical Policy Number: 03.02.08

Effective Date: August 1, 2016
Initial Review Date: July 20, 2016
Most Recent Review Date: June 5, 2018
Next Review Date: June 2019

Related policies:
- CP# 03.03.08 Intravenous lidocaine for chronic regional pain
- CP# 03.02.02 Radiofrequency ablation treatment for spine pain
- CP# 03.03.01 Spinal cord stimulators for chronic pain
- CP# 03.03.02 Intrathecal opioid therapy for chronic pain
- CP# 03.03.03 Spinal surgeries
- CP# 03.03.04 Spine pain — epidural pain
- CP# 03.03.06 Biofeedback for chronic pain
- CP# 03.02.07 Spine pain — facet joint injection
- CP# 03.03.05 Spine pain — trigger point injection

ABOUT THIS POLICY: AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’ clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas’ clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas’ clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’ clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers the use of percutaneous vertebroplasty (PVP), percutaneous kyphoplasty (PKP), or percutaneous sacroplasty (PSP) to be clinically proven and, therefore, medically necessary when the following criteria are met (Zhang 2017, Knavel 2009, Schmelzer-Schmied 2009, Barr 2014, Bayley 2009):

Persistent, debilitating pain in the cervical, thoracic, or lumbo/sacral vertebral bodies resulting from any of the following conditions:
- Multiple myeloma.
- Painful and/or aggressive hemangiomas.
- Painful vertebral eosinophilic granuloma.
- Painful, debilitating osteoporotic collapse and non-osteotic compression fractures.
- Primary malignant neoplasm of bone or bone marrow.
- Secondary osteolytic metastasis.
- Steroid-induced fractures.

and the following criteria are met:
- Presence of severe debilitating pain or loss of mobility that cannot be relieved by optimal medical therapy (e.g., acetaminophen, non-steroid anti-inflammatory drugs [NSAIDS], narcotic analgesics, braces, physical therapy) for a duration no less than two weeks.
- The affected vertebra has not been extensively destroyed and is at least one-third of its original height.
- Other causes of pain such as herniated intervertebral disk have been ruled out by computed tomography or magnetic resonance imaging.

Limitations:

All other uses of percutaneous vertebroplasty, percutaneous kyphoplasty, or percutaneous sacroplasty are not medically necessary.
- Vertebroplasty, kyphoplasty, and sacroplasty may not be covered for prophylaxis of osteoporosis.
- Vertebroplasty, kyphoplasty, and sacroplasty may not be covered for treatment of chronic or old compression fractures.
- Contraindications to use include osteomyelitis, tuberculosis of the spine, spinal stenosis, anti-coagulant prescription or coagulopathy, and allergy to the cement.

Alternative covered services:

- Facet joint injection.
- Chiropractic manipulation in the first four weeks if there is no radiculopathy.
- Exercise programs.
- Heat/cold modalities for home use.
- Low-impact exercise as tolerated (e.g., stationary bike, swimming, walking).
- Pharmacotherapy (e.g., non-narcotic analgesics, non-steroidal anti-inflammatory drugs).
- Trigger point injections.
- Epidural injections.

Background
Percutaneous vertebroplasty (PVP, or cementoplasty, or simply vertebroplasty) is a percutaneous minimally invasive technique developed in the late 1980s as a pain-mitigating and stabilizing treatment in patients affected by symptomatic vertebral fracture due to osteoporotic disease, traumatic injury, and primary or secondary vertebral spine tumors. The technique consists of a simple percutaneous injection of an inert cement (poly-methyl-methacrylate [PMMA]) through a needle by trans-peduncular, parapeduncular, or trans-somatic approach with the aim of obtaining a vertebral augmentation and stabilization effect associated with pain relief.

Percutaneous kyphoplasty (PKP) is a similar therapeutic procedure that aims to reduce the pain of vertebral compression fractures that are the result of osteoporosis, osteolytic vertebral metastases, multiple myeloma, or vertebral hemangioma. Bone cement is injected into the fracture site under fluoroscopic or computerized tomographic (CT) guidance after the fracture has been reduced or elevated with a bone tamp device or balloon. Percutaneous sacroplasty (PSP) involves the same techniques for reduction of pain from sacral fractures (i.e., the injection of cement into the fractured sacrum).

The treatment goals of this percutaneous minimally invasive approach are (Guarnieri, 2015):

- Pain relief in order to facilitate daily activity and improve quality of life.
- Stability to restore biomechanics and alleviate further stress on the spine.

It is important to note that chronic spinal pain may display a waxing and waning pattern of severity, and pain from benign compression fractures may improve over time without intervention as the fracture heals. As a result, it is often difficult to assign specific gain in either functionality or pain relief to percutaneous technique versus simple cyclic symptomatic and asymptomatic periods occurring over the course of chronic disease, or the natural healing effects of time.

Complications of this procedure include cement leaks, with or without any clinical symptoms, bleeding, pulmonary embolus (rare), congestive heart failure (rare), myocardial infarction (rare), and rib fracture (rare).

**Searches**

AmeriHealth Caritas searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on April 9, 2018. Search terms were: "percutaneous vertebroplasty (MeSH)," "percutaneous kyphoplasty (MeSH)," and "sacroplasty."

We included:
• **Systematic reviews,** which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.

• **Guidelines based on systematic reviews.**

• **Economic analyses,** such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Knavel (2009) retrospectively reviewed the records of 819 patients (982 procedures) who underwent percutaneous procedures for traumatic compression fracture failing conservative medical therapy, selectively studying patients who had normal bone mineral densitometry scores and no previous diagnosis of osteoporosis, multiple myeloma, or history of long-term steroid use. Follow-up evaluations included pain at rest and with activity, medication use, and mobility at one week, one month, six months, and one year. Disability scores were also collected. Statistical analysis included a two-tailed t test comparing post-procedure outcomes with baseline values. Significant durable improvements in the pain scores, both at rest and with activity (p=0.0006), and in disability scores (p=0.001) were found. Additionally, there was a marked decrease in pain medication use in patients treated by PVP and PKP with substantial concomitant improvement in mobility. The complication rate was low and consisted primarily of asymptomatic extravasation of cement.

Schmelzer-Schmied (2009) in a prospective study of 42 patients with stable traumatic vertebral fractures compared those treated conservatively with back-braces versus those who underwent kyphoplasty. Patients of the kyphoplasty group showed an immediate beneficial and significant effect postoperatively, and better outcomes at one and three months after operation compared to the conservatively treated group in degree of pain, mobility, and vertebral body height (p<0.05). However, after 12 months the difference between both groups was not significant excepting the vertebral body height. There were also clinically asymptomatic cement leakages in up to 45 percent. The authors summed up their experience as one of short-term superiority with eventual regression to mean, in the presence of uncertain implications of long-term cement extravasation and migration.

Bayley (2009) described in a narrative review sacral insufficiency fractures (n=108) treated with sacroplasty. The authors found significant reduction in pain score from 8.9 to 2.6 (p<0.001, paired Student’s t test) following the PSP procedure. The authors concluded that sacral cement augmentation techniques with or without iliosacral screw fixation can produce significant pain relief, and offer a suitable alternative to analgesics and rehabilitation.

There is a general scientific consensus supported by many international societies (Cardiovascular and Interventional Radiological Society of Europe [CIRSE], American Society of Neuroradiology [ASNR], American College of Radiology [ACR], Societe Francaise de Radiologie [SFR]) that percutaneous vertebral
cementoplasty represents a successful, safe, and effective minimally invasive procedure in selected patients for pain relief, performed with the correct medical indications (Barr, 2014):

“It is the position of the Societies that percutaneous vertebral augmentation (PVA) with the use of vertebroplasty or kyphoplasty is a safe, efficacious, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures. These procedures are offered when nonoperative medical therapy has not provided adequate pain relief, or pain is significantly altering the patient’s quality of life, as they have shown statistically significant improvement in pain and function, particularly ambulation.”

Policy updates:

During the past twelve months (July, 2017 to June, 2018) there has been no further information published regarding of percutaneous vertebroplasty, percutaneous kyphoplasty, or percutaneous sacroplasty of material impact on this policy. Previous updates have noted the following:

A systematic review (n=1,328) sought to understand the new-level fracture risk after PVP compared with conservative (non-operative) treatment (Zhang 2017). There was no significant difference between the 2 methods, including total new fractures (P = 0.55) and adjacent fractures (P = 0.5). For pre-existing vertebral fractures, there was no significant difference between the 2 groups (operative and non-operative groups) (P = 0.24). Additionally, there was no significant difference in bone mineral density, both in the lumbar (P = 0.13) and femoral neck regions (P = 0.37). The authors concluded that there is not an increased risk of fracture of vertebral bodies, especially those adjacent to the treated vertebrae, following augmentation compared with conservative treatment.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td><strong>Zhang (2017)</strong></td>
<td><strong>Key points:</strong></td>
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<td>Does Percutaneous Vertebroplasty</td>
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<td>or Balloon Kyphoplasty for</td>
<td>compared with conservative (non-operative) treatment.</td>
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<td>Compression Fractures Increase</td>
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<td>conservative treatment.</td>
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<td><strong>Key points:</strong></td>
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treatment of traumatic nonosteoporotic compression fractures

procedures for traumatic compression.

- Follow-up evaluations included pain at rest and with activity, medication use, and mobility at one week, one month, six months, and one year.
- Significant durable improvements in the pain scores, both at rest and with activity (p=0.0006), and in disability scores (p=0.001) were found.
- Authors noted a marked decrease in pain medication use in patients treated by PVP and PKP.
- The complication rate was low: primarily extravasation of cement.

Schmelzer-Schmied (2009)

Comparison of kyphoplasty with use of a calcium phosphate cement and non-operative therapy in patients with traumatic non-osteoporotic vertebral fractures

Key points:

- Prospective study of 42 patients with stable traumatic vertebral fractures treated conservatively with back-braces vs. those who underwent kyphoplasty.
- Kyphoplasty created an immediate beneficial effect and better outcomes at one and three months in degree of pain, mobility, and vertebral body height (p<0.05).
- At 12 months, the difference between both groups was not significant but for vertebral body height.
- There were also clinically asymptomatic cement leakages in up to 45%.

Barr (2014)

Position statement on percutaneous vertebral augmentation

Key points:

- Position paper from eight North American and international clinical societies stated that PVP and PKP are “a safe, efficacious, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures.”

Bayley (2009)

Clinical outcomes of sacroplasty in sacral insufficiency fractures: a review of the literature

Key points:

- Narrative review of various techniques used in the surgical treatment of sacral insufficiency fractures and their outcome.
- 108 patients who underwent PSP were included.
- There was significant improvement in mean pain score from 8.9 to 2.6 (p<0.001, paired Student’s t test).

References

Professional society guidelines/other:


Peer-reviewed references:


**CMS National Coverage Determinations (NCDs):**

No NCDs identified as of the writing of this policy.

**Local Coverage Determinations (LCDs):**

L34592 VERTEBROPLASTY (PERCUTANEOUS) and Vertebral Augmentation including cavity creation. CMS Medicare Coverage Database Web site. https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34592&ver=20&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=All&KeyWord=percutaneous+vertebroplasty&KeyWordLookUp=Title&KeyWordSearchType=And&bc=gAAAABABAAAA&. Accessed April 9, 2018.


Commonly submitted codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
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<tr>
<td>22510</td>
<td>Percutaneous vertebroplasty (bone bx included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of imaging guidance; cervicothoracic</td>
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<td>22511</td>
<td>Percutaneous vertebroplasty (bone bx included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of imaging guidance; lumbosacral</td>
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<td>+22512</td>
<td>Each additional cervicothoracic or lumbosacral vertebral body (list in addition to primary procedure)</td>
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<td>22513</td>
<td>Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone bx included when performed) using mechanical device (eg, kyphoplasty) 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance, thoracic</td>
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<tr>
<td>22514</td>
<td>Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone bx included when performed) using mechanical device (eg, kyphoplasty) 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance, lumbar</td>
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<td>+22515</td>
<td>Each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)</td>
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<td>0200T</td>
<td>Percutaneous sacral augmentation (sacroplasty) unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging device or bone biopsy, when performed</td>
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<td>0201T</td>
<td>Percutaneous sacral augmentation (sacroplasty) bilateral injection(s), including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging device or bone biopsy, when performed</td>
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<tr>
<th>ICD-10 Code</th>
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<td>C40.0-C41.9</td>
<td>Primary malignant neoplasm of bone or bone marrow</td>
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<td>C41.2</td>
<td>Malignant neoplasm vertebra</td>
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<td>C79.51</td>
<td>Secondary malignant neoplasm bone</td>
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<td>C79.52</td>
<td>Secondary malignancy, bone marrow</td>
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<td>C90.00-C90.02</td>
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<td>C96.6</td>
<td>Eosinophilic granuloma</td>
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<td>Hemangioma vertbra</td>
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<td>M48.50XA-M48.58XS</td>
<td>Compression fractures</td>
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<td>M80.88XA-M80.88XS</td>
<td>Osteoporotic collapse</td>
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<td>M81.8</td>
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