POLICY STATEMENT:

I. Based upon our criteria and assessment of peer-reviewed literature, vertebral augmentation (injection of methylmethacrylate cement under imaging guidance) with confirmatory recent (within 3 months) imaging findings has been medically proven effective and is considered medically appropriate for any of the following:

A. Osteolytic or osteoporotic compression fracture with persistent and debilitating pain;
B. Osteolytic metastases including destruction of a vertebral body by multiple myeloma;
C. Primary malignant neoplasm of bone or bone marrow;
D. Painful and/or aggressive space occupying lesions of a vertebral body (e.g., hemangioma/eosinophilic granuloma);
E. Pre-surgical stabilization of a vertebral body to facilitate a fusion operation;
F. Painful osteonecrotic (e.g., Kummell disease) vertebral compression fracture; or
G. Steroid-induced vertebral compression fracture.

When ALL of the following criteria are met:

A. Acute (0-6 weeks) axial back pain that correlates with the level of the fracture
   1. No contraindications
   2. Compression fractures of the thoracic or lumbar vertebrae resulting in persistent or debilitating pain are treated conservatively;
B. Subacute (greater than 6 weeks) axial pain in the thoracic/lumbar spine for at least 6 weeks (ALL of the following):
   1. No contraindications
   2. Persistent debilitating pain defined as:
      i. Level of pain on a Visual Analog Scale (VAS) greater than 4 on a daily basis, or
      ii. Pain on a daily basis that has a documented impact on activities of daily living (IADL) (at least 2 ADL’s or IADL’s)
3. Failure of conservative treatment (All of the following):
   i. Less than clinically meaningful improvement* from prescription strength analgesics, steroids, and/or NSAIDs for 6 weeks; and
   ii. Less than clinically meaningful improvement* from an active program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 6 weeks; and
4. Recent (within 6 weeks) imaging studies to document a recent compression fracture (one of the following):
   i. Uptake on a nuclear medicine bone scan;
   ii. Increased intensity on fluid sensitive MRI sequences;
   iii. Plain x-ray; or
   iv. CT.
II. Based upon our criteria and assessment of peer-reviewed literature, the presence of alternative causes of axial back pain makes vertebral augmentation/kyphoplasty **not medically necessary** with any of the following:
   A. Lumbar/thoracic radiculopathy;
   B. Lumbar/thoracic facet disease;
   C. Lumbar/thoracic/sacral trigger points; or
   D. SI joint pain.

III. Based upon our criteria and assessment of peer-reviewed literature, percutaneous vertebroplasty or mechanical vertebral augmentation is considered **investigational** for the following:
   A. Non-painful/non-aggressive vertebral hemangioma;
   B. Acute vertebral fractures due to osteoporosis or trauma;
   C. Vertebrae of the cervical spine and thoracic levels T1-T4;
   D. Stabilization of insufficiency fractures or lesions of the sacrum (sacroplasty) or coccyx (coccygeoplasty);
   E. Prophylactic treatment for osteoporosis of the spine;
   F. Prophylactic treatment for chronic back pain of longstanding duration (greater than 6 months), even if associated with old compression fracture(s);
   G. Percutaneous mechanical vertebral augmentation using any device other than a balloon device, including but not limited to use of the Kiva system and radiofrequency-assisted vertebral augmentation.

IV. Based upon our criteria and assessment of peer-reviewed literature, Spineoplasty (e.g., OptiMesh® 1500E Polyethylene Terephthalate (PET) mesh pouch) is considered **investigational**;

V. Based upon our criteria and assessment of peer-reviewed literature, is considered **investigational**.

Refer to Corporate Medical Policy #7.01.17 regarding Percutaneous Intradiscal Electrothermal Annuloplasty (IDET/IDTA, PIRFT, biacuplasty).

Refer to Corporate Medical Policy #7.01.62 regarding Intervertebral Disc Decompression: Laser and Radiofrequency Coblation Techniques.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

**POLICY GUIDELINES:**

I. **URGENT/EMERGENT CONDITIONS**
   All patients being evaluated for spine surgery should be screened for indications of a medical condition that requires urgent/emergent diagnosis. The presence of such indications/conditions warrants definitive surgical treatment in lieu of conservative pain management treatment. If any of the following are part of the clinical presentation with a request for precertification of the CPT code, the request will go to medical review. Severe neck pain associated with any of the following will still need confirmatory imaging, such as a CT or MRI scan:
   A. Acute/Unstable Traumatic Spinal Fractures or Dislocations with or without neural compression;
   B. Infection (e.g. discitis, epidural abscess, osteomyelitis);
   C. Primary or metastatic tumor causing pathologic fracture, cord compression, or instability;
   D. Epidural hematoma;
   E. Severe or rapidly progressive symptoms of motor loss, bowel or bladder dysfunction;
   F. Documented progressive neurological deficit on two separate physical exams;
   G. Cauda equina syndrome (CES); or
   H. Hospitalization* secondary to severe debilitating pain and/or dysfunction to the point of being incapacitated.

II. The following contraindications apply to vertebral augmentation procedures:
   A. Allergy to materials used in the procedure;
   B. Uncorrected coagulation disorders or anticoagulation therapy;
   C. Myelopathy associated with a bone fragment in the spinal canal or cord compression from a tumor;

*Proprietary Information of Excellus Health Plan, Inc.*
D. Extensive vertebral destruction;
E. Burst fracture associated with widened pedicles and/or retropulsed bone fragments;
F. Potential space occupying lesions causing cord compression (tumor, bone fragment);
G. Collapse of vertebral body to less than the level of the vertebra plana;
H. The use of Norian XR cement and Norian SRS cement products is prohibited because they are not FDA approved;
I. Radiculopathy from a herniated intervertebral disc;
J. Untreated symptomatic foraminal or canal stenosis, facet arthropathy, or other significant coexistent spinal or bony pain generators;
K. Unstable fracture or requirement for stabilization procedure in same or adjacent spinal region
L. Any active infection (including urinary tract infection [UTI]);
M. Presence of painful metastases to areas other than the spine, spinal cord compression, primary bone and osteoblastic tumors, solitary plasmacytomas;
N. Severe cardiopulmonary disease;
O. Lack of neurosurgical backup for emergency decompression in the event a neurological deficit develops during the injection of PMMA.

III. There should be no more than 2 levels of the T5-L5 (L4/L5, not L5/S1) spine/single date of service.

IV. Cervical Vertebroplasty will NOT be separately paid when combined with any open spine procedure.

V. Percutaneous Vertebral Augmentation will NOT be separately paid when combined with any open spine procedure.

VI. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus, these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity for those contracts.

DESCRIPTION:
Percutaneous vertebroplasty and kyphoplasty are procedures performed for persistent pain or instability from osteoporotic or neoplastic vertebral compression fractures and aggressive hemangiomas. Bone cement, usually polymethylmethacrylate, is injected percutaneously into the partially collapsed vertebral body under fluoroscopic guidance. In the vertebroplasty procedure the cement is injected in a semi-fluid state. In kyphoplasty, an inflatable bone tamp is introduced into the vertebra. The balloon is inflated partially restoring vertebral height, then withdrawn and the cement injected into the space. The injected cement may be more viscous and injected under lower pressure than in the vertebroplasty procedure.

The Crosstrees® PVA Pod device is designed to deliver bone cement to the fractured vertebral body in a controlled manner without the need for an additional permanent implant other than the bone cement. The device consists of a shaft assembly for delivery of PMMA cement to a fabric barrier. Following cement delivery, the fabric barrier is opened and withdrawn from the vertebral body. The Crosstrees® Pod technology was designed to address the need for improved vertebral fracture repair devices by taking a novel approach to controlling the delivery of PMMA to the site of fracture and subsequently reducing the risk of complications caused by PMMA leakage, such as nerve root compression, pulmonary embolism, and additional adverse events.

Kiva® is another mechanical vertebral augmentation technique that uses an implant for structural support of the vertebral body and to provide a reservoir for bone cement. The implant is made from PEEK-OPTIMA®, a biocompatible polymer, and is inserted into the vertebral body over a guide wire. The implant can be customized by changing the coil stack height, with a maximum height of 12 mm. PMMA is injected through the lumen of the implant,
which fixes the implant to the vertebral body and contains the PMMA in a cylindrical column. The proposed advantage of the Kiva system is a reduction in cement leakage.

Another variant of kyphoplasty is vertebral body stenting, which utilizes an expandable scaffold instead of a balloon to restore vertebral height. The proposed advantages of vertebral body stenting are to reduce the risk of cement leakage by formation of a cavity for cement application and to prevent the loss of correction that is seen following removal of the balloon used for balloon kyphoplasty. Vertebral body stenting (VBS™; Synthes, Switzerland) is only available in Europe at this time.

Definitions:
I. Acceptable imaging modalities are CT scan, MRI and myelogram. Imaging must be performed and read by an independent radiologist. If discrepancies should arise in the interpretation of the imaging, interpretations by the radiologist will supersede.

II. Use of discography is not endorsed.

RATIONALE:
The Kyphon inflatable bone tamp was approved by the FDA with 510K status in 1998. Bone cements that have received FDA 510 K clearance, include, but are not limited to: KyphX® HV-R (Kyphon Inc.), Spineplex™ (Stryker), Symphony™ VR (Advanced Biomaterial Systems, Inc., Parallax® Acrylic Resin with TRACERS® (ArthroCare) and Osteopal® V.

The Crosstrees® PVA Pod System for vertebral augmentation received FDA clearance in September 2013. FDA clearance was based on a prospective, single-arm IDE study that enrolled 135 patients in the United States, China, Venezuela and Belgium. Patient outcomes for the Crosstrees procedure were compared to a literature control which included vertebroplasty and kyphoplasty outcomes. The IDE study met its primary endpoints of a significant reduction in pain scores and PMMA bone cement extravasation over a follow-up period of 12 months. Additionally, the Crosstrees procedure demonstrated a significant reduction in new fracture rates often found with vertebroplasty and kyphoplasty procedures.

There is sufficient evidence in the medical literature to conclude that percutaneous vertebroplasty and kyphoplasty improve health outcomes and are appropriate treatment options for patients with osteoporotic collapse or osteolytic vertebral metastasis or myeloma with persistent debilitating pain despite conservative treatment. Improved health outcomes have been obtained outside the investigational setting. There is not sufficient data reported in the medical literature to draw conclusions about the efficacy of these procedures for other indications.

Vertebral augmentation with the Kiva® VCF System® was compared with balloon kyphoplasty in a pivotal noninferiority RCT (Tutton, et al. 2015). This industry-sponsored multicenter open-label trial (KAST) was conducted in 300 patients with 1 or 2 osteoporotic vertebral compression fractures. Included were patients with VAS for back pain of at least 70 mm of 100 after 2 to 6 weeks of conservative care or a VAS of at least 50 mm after 6 weeks of conservative care, and an ODI of at least 30%. The primary end point at 12 months was a composite of a reduction in fracture pain by at least 15 mm on VAS, maintenance or improvement in function on ODI, and absence of device-related serious adverse events. The primary end point was met for 94.5% of patients treated with Kiva® and 97.6% of patients treated with kyphoplasty (Bayesian posterior probability of 99.92% for noninferiority, using as-treated analysis). In the 285 treated patients, Kiva® resulted in a mean improvement of 70.8 points in VAS, compared with a 71.8-point improvement for kyphoplasty. There was a 38.1-point improvement in ODI for the Kiva® group, compared with a 42.2-point improvement for the kyphoplasty group. There were no device-related serious adverse events. The total volume of cement was 50% less with Kiva® and there was lower cement extravasation compared with kyphoplasty (16.9% vs 25.8%, respectively).

Evidence to date includes a large industry-sponsored, multicenter IDE trial, a large independent randomized trial, and a retrospective matched pair comparison. The 2 randomized comparative trials show similar outcomes as compared with
kyphoplasty. The matched pair comparison reported favorable outcomes for Kiva®, although this study is limited by the retrospective nature of the study and the nonconcurrent controls.

Although uncommon, symptomatic vertebral hemangiomas can be painful and can limit daily activities. A number of methods have been used in the treatment of symptomatic and aggressive vertebral hemangioma, but none of them is optimal. Case reports and numerous case series have demonstrated that treatment with cement vertebroplasty is a safe procedure that provides very good results with improvement in pain. Also, studies using percutaneous cementoplasty as an adjunct to surgical treatment suggest that the use of percutaneous cementoplasty to treat the vertebral body component of the vascular lesion (hemangioma) may contribute to avoiding the substantial blood loss that has been historically described with primary surgical resection (curettage).

There is limited evidence to permit conclusions on the overall health outcomes on the use of percutaneous vertebroplasty, kyphoplasty or mechanical vertebral augmentation in patients with acute fractures (osteoporotic or traumatic). For acute fractures, conservative therapy consisting of rest, analgesics, and physical therapy is an option and it has been demonstrated that symptoms will resolve in a large percentage of patients with conservative therapy only. However, recent RCTs (Clark, et al. 2016; Leali, et al. 2016; Yang, et al. 2016) investigated the use of vertebroplasty in patients with osteoporotic fractures of less than 6 weeks duration who had severe pain. Outcome data reported a significant benefit of vertebroplasty for the treatment of osteoporotic vertebral fractures, including significant pain reduction allowing for earlier ambulation. Given the high morbidity associated with extended bedrest in older adults, this is considered to be a significant health benefit.

**CODES:**

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>22510</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic</td>
</tr>
<tr>
<td>22511</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral</td>
</tr>
<tr>
<td>22512</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; thoracic</td>
</tr>
<tr>
<td>22513</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body (list separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>22514</td>
<td>Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar</td>
</tr>
</tbody>
</table>

Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.
22515 Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body (list separately in addition to code for primary procedure)

HCPCS:  No specific code(s)

ICD10:  C41.2 Malignant neoplasm of vertebral column
C79.51-C75.52 Secondary malignant neoplasm of bone and bone marrow
C90.00-C90.01 Multiple myeloma (code range)
D18.09 Hemangioma other sites
M48.50xA- 48.58xA Collapsed vertebra, not elsewhere classified (code range)
M80.08xA Age-related osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M80.88xA Other osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M84.58xA Pathological fracture in neoplasic disease, vertebrae, initial encounter for fracture

REFERENCES:


SUBJECT: PERCUTANEOUS VERTEBROPLASTY/MECHANICAL VERTEBRAL AUGMENTATION

POLICY NUMBER: 6.01.17
CATEGORY: Technology Assessment

EFFECTIVE DATE: 05/18/00
REVISED DATE: 10/18/01, 11/21/02, 09/18/03, 8/19/04, 06/16/05, 05/18/06, 05/17/07, 04/17/08, 03/19/09, 02/18/10, 01/20/11, 01/19/12, 01/17/13, 01/16/14, 03/19/15, 05/25/16, 08/17/17, 06/21/18

PAGE: 7 OF 11


*BlueCross BlueShield Association Technology Evaluation Center (TEC). Percutaneous kyphoplasty for vertebral fractures caused by osteoporosis and malignancy. 2004 Dec.

*BlueCross BlueShield Association Technology Evaluation Center (TEC). Percutaneous vertebroplasty or kyphoplasty for vertebral fractures caused by osteoporosis or malignancy. 2008 Sep;23(5).

*BlueCross BlueShield Association Technology Evaluation Center (TEC). Percutaneous vertebroplasty or kyphoplasty for vertebral fractures caused by osteoporosis. 2010 Apr;24(7).


Proprietary Information of Excellus Health Plan, Inc.


* key article

**KEY WORDS:**
Kiva system, Kyphon inflatable bone tamp, Kyphoplasty, vertebral augmentation, vertebral body stenting, Vertebroplasty.

### CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) for percutaneous vertebroplasty and vertebral augmentation. Please refer to the following LCD website for Medicare Members: