MEDICAL POLICY

SUBJECT: PERCUTANEOUS VERTEBROPLASTY/
KYPHOPLASTY/Mechanical VERTEBRAL AUGMENTATION

POLICY NUMBER: 6.01.17
CATEGORY: Technology Assessment

EFFECTIVE DATE: 10/18/01
REVISED DATE: 11/21/02, 09/18/03, 06/16/05,
05/18/06, 05/17/07, 4/17/08, 3/19/09,
02/18/10, 01/20/11, 01/19/12,
01/17/13, 01/16/14, 03/19/15, 09/15/16

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- If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.
- Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.

POLICY STATEMENT:

I. Based upon our criteria and review of the peer-reviewed literature, percutaneous vertebroplasty and kyphoplasty have been medically proven to be effective and therefore medically appropriate for the following indications:

A. Osteoporotic vertebral collapse with pain for at least six weeks that has not responded to conservative measures such as physical therapy, bed rest, bracing and analgesia; and is severe enough to cause significant immobility and impairment of activities of daily living and/or to require maximal pain management; or

B. Osteolytic vertebral metastasis or myeloma with severe back pain for at least two weeks related to destruction of a vertebral body that does not involve the major part of the cortical bone (particularly the posterior wall) and has not responded to conservative measures, such as physical therapy, bed rest, bracing, and analgesia; and is severe enough to cause significant immobility and impairment of activities of daily living and/or to require maximal pain management.

II. Based upon our criteria and assessment of the peer-reviewed literature, percutaneous vertebroplasty and kyphoplasty have not been medically proven to be effective and therefore, are considered investigational for all other indications, including acute fractures.

III. Based upon our criteria and assessment of peer-reviewed literature, percutaneous mechanical vertebral augmentation using any other device, including but not limited to Kiva® and vertebral body stenting, has not been medically proven to be effective and is therefore 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:

The Federal Employee Health Benefit Program (FEHB/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.

RATIONAL:

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.

The Kiva® VCF Treatment System (Benvenue Medical) received FDA 510(k) marketing clearance in January 2014 (FDA product code NDN).

Kiva® System as Vertebral Augmentation Treatment (KAST) is an industry-sponsored multicenter phase 3 randomized IDE trial (NCT01123512). Vertebral augmentation with the Kiva® VCF System® was compared with balloon kyphoplasty in 300 patients with 1 or 2 osteoporotic vertebral compression fractures. The study was completed in May 2013. Preliminary results of this study were presented at the Society for Interventional Radiology Annual Scientific Meeting in March 2014, reporting noninferiority of KIVA® compared with kyphoplasty. Evidence to date of the Kiva® System includes a preliminary report of a large industry-sponsored, multicenter IDE trial, a large independent randomized
trial, and a retrospective matched pair comparison. 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.

There is insufficient evidence in the peer-reviewed literature to demonstrate that the use of the Kiva® system or vertebral body stenting improve the overall health outcomes of patients suffering compression fractures. While preliminary studies show promising short-term outcomes, further studies are necessary.

There is insufficient 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.

**CODES:**

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<tr>
<th>Number</th>
<th>Description</th>
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<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>
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<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>
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<tr>
<td>22512</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>
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<td>22513</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; thoracic</td>
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<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>
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<td>22515</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; each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)</td>
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**HCPCS:**

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<tbody>
<tr>
<td>S2360</td>
<td>Percutaneous vertebroplasty, one vertebral body, unilateral or bilateral injection; cervical</td>
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S2361 each additional cervical vertebral body (list separately in addition to code for primary procedure)

ICD9:  
170.2 Malignant neoplasm of bone and articular cartilage; vertebral column excluding sacrum and coccyx
198.5 Secondary malignant neoplasm of bone and bone marrow
203.00 Multiple myeloma and immunoproliferative neoplasms; without mention of remission
203.01 Multiple myeloma immunoproliferative neoplasms; in remission
733.13 Pathologic fracture of vertebrae

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)
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 neoplastic disease, vertebrae, initial encounter for fracture

REFERENCES:


Proprietary Information of YourCare Health Plan


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* key article

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