MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**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, 4/17/08, 3/19/09, 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, 12/20/18**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT

I. Based upon our criteria and assessment of peer-reviewed literature, vertebral augmentation (percutaneous vertebroplasty/kyphoplasty) (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** when ALL of the following criteria are met:

A. Performed for ANY of the following conditions which is concordant with recent (within 3 months) confirmatory imaging:
   1. Osteolytic or osteoporotic compression fracture with persistent and debilitating pain;
   2. Osteolytic metastases including destruction of a vertebral body by multiple myeloma;
   3. Primary malignant neoplasm of bone or bone marrow;
   4. Painful and/or aggressive space occupying lesions of a vertebral body (e.g., hemangioma/ eosinophilic granuloma)
   5. re-surgical stabilization of a vertebral body to facilitate a fusion operation;
   6. Painful osteonecrotic (e.g., Kummell disease) vertebral compression fracture; or
   7. Steroid-induced vertebral compression fracture.

B. Persistent debilitating pan including BOTH of the following:
   1. Level of pain on a Visual Analog Scale (VAS)/Number Rating Scale (NRS) greater than or equal to 7 on a daily basis; and
   2. Clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing or essential job functions).

C. EITHER of the following:
   1. Acute (0-6 weeks) axial back pain that persists at a level which prevents independent transfers and/or ambulation and correlates with the level of the fracture; or
   2. Subacute (greater than 6 weeks) axial pain in the thoracic/lumbar spine for at least 4 weeks with less than clinically meaningful improvement woth BOTH of the following unless contraindicated:
      a. Prescription strength analgesics, steroids and/or NSAIDs for 4 weeks; and
      b. Provider-directed exercise program prescribed by a physical therapist, chiropratic provider, osteopathic or allopathic physician for 4 weeks.

D. Documentation of a recent (within 3 months) compression fracture with ANY of the following:
   1. Uptake on a nuclear medicine bone scan;
   2. Increased intensity on fluid sensitive MRI sequences;
   3. Plain x-ray;

4. CT.

E. Performed at no more than two levels of the T5-L5 spine on the same date of service

II. Based upon our criteria and assessment of peer-reviewed literature, the presence of alternative causes of axial back pain makes vertebral augmentation **not medically necessary** with any of the following:
   A. Lumbar/thoracic radiculopathy or facet disease;
   B. Lumbar/thoracic/sacral trigger points; or
   C. Sacral insufficiency fractures.

III. Based upon our criteria and assessment of peer-reviewed literature, Vertebral Augmentation (percutaneous vertebroplasty/kyphoplasty) is considered **investigational** for EITHER of the following:
   A. Percutaneous vertebral augmentation for ANY of the following:
      1. Non-painful/non-aggressive vertebral hemangioma;
      2. Vertebrae of the cervical spine and thoracic levels T1-T4;
      3. Stabilization of insufficiency fractures or lesions of the sacrum (sacroplasty) or coccyx (coccygeoplasty);
      4. Prophylactic treatment for osteoporosis of the spine;
      5. Prophylactic treatment for chronic back pain of longstanding duration (greater than 6 months), even if associated with old compression fracture(s); or
      6. 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. AND
   B. Spineoplasty (e.g., OptiMesh® 1500E Polyethylene Terephthalate (PET) mesh pouch)

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. Urgent/emergent conditions for vertebral augmentation procedure include EITHER of the following:

   A. Primary or metastatic neoplastic disease causing pathologic fracture;
   B. Documented 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;
   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. Septicemia and any active infection (including urinary tract infection [UTI]);
   M. Active osteomyelitis of the target vertebra;

N. Presence of painful metastases to areas other than the spine, spinal cord compression, primary bone and osteoblastic tumors, solitary plasmacytomas;
O. Severe cardiopulmonary disease;
P. 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 on a single date of service.

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

V. Mechanical 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 extravasion 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

- *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.*

CPT Codes

Code	Description
22510	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic
22511	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral
22512	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)
22513	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
22514	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
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 Codes

Code	Description
No specific code(s)	

ICD10 Codes

Code	Description

Code	Description
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 neoplastic disease, vertebrae, initial encounter for fracture

REFERENCES

*American Academy of Orthopedic Surgeons. The treatment of symptomatic osteoporotic spinal compression fractures. Guideline and evidence report. 2010 Sep 24 [http://www.aaos.org/research/guidelines/guide.asp] accessed 4/13/17.

American College of Radiology. Practice guideline for the performance of percutaneous vertebroplasty. Revised 2011 [http://www.acr.org/SecondaryMainMenuCategories/quality_safety/guidelines/dx/head-neck/Vertebral_Augmentation.aspx] accessed 4/13/17.

Baerlocher MO, et al. Quality improvement guidelines for percutaneous vertebroplasty. J Vasc Interv Radiol 2014 Feb;25(2):165-70.

Barr JD, et al. Position statement on percutaneous vertebral augmentation: a consensus statement developed by the Society of Interventional Radiology (SIR), American Association of neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), American College of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spine Radiology (ASSR), Canadian Interventional Radiology association (CIRA), and the Society of Neurointerventional Surgery (SNIS). J Vasc Interv Radiol 2014 Feb;25(2):171-81.

*Bastian L, et al. A randomized trial comparing 2 techniques of balloon kyphoplasty and curette use for obtaining vertebral body height restoration and angular-deformity correction in vertebral compression fractures due to osteoporosis. AJNR Am J Neuroradiol 2012 Nov 22 [Epub ahead of print].

Beall DP, et al. Economic analysis of Kiva VCF Treatment System compared to balloon kyphoplasty using randomized Kiva Safety and Effectiveness Trial (KAST) data. Pain Physician 2015 May-Jun;18(3):E299-306.

*Berenson J, et al. Balloon kyphoplasty versus non-surgical fracture management for treatment of painful vertebral body compression fractures in patients with cancer: a multicenter, randomized controlled trial. Lancet Oncol 2011 Mar;12(3):225-35.

BlueCross BlueShield Association. Percutaneous Balloon Kyphoplasty and Mechanical Vertebral Augmentation. Medical Policy Reference Manual. Policy #6.01.38. 2016 Nov 10.

BlueCross BlueShield Association. Percutaneous Vertebroplasty and Sacroplasty. Medical Policy Reference Manual. Policy #6.01.25. 2015 Apr 23.

*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).

*Boonen S, et al. Balloon kyphoplasty for the treatment of acute vertebral compression fractures: 2-year results from a randomized trial. J Bone Miner Res 2011 Jul;26(7):1627-37.

Bornemann R, et al. Comparison of radiofrequency-targeted vertebral augmentation with balloon kyphoplasty for the treatment of vertebral compression fractures: 2-year results. J Spinal Disord Tech 2013 Nov 15 [Epub ahead of print].

Bousa C, et al. Safety of balloon kyphoplasty in the treatment of osteoporotic vertebral compression fractures in Europe: a meta-analysis of randomized controlled trials. Eur Spine J 2015 Apr;24(4):715-23.

*Buchbinder R, et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. NEJM 2009 Aug 6;361(6):557-67.

Buchbinder R, et al. Percutaneous vertebroplasty for osteoporotic vertebral compression fracture. Cochrane Database Syst Rev 2015 Apr 30;4:CD006349.

Chang X, et al. Vertebroplasty versus kyphoplasty in osteoporotic vertebral compression fracture: a meta-analysis of prospective comparative studies. Int Orthop 2015 Mar;39(3):491-500.

Chen AT, et al. Impact of nonoperative treatment, vertebroplasty, and kyphoplasty on survival and morbidity after vertebral compression fracture in the Medicare population. J Bone Joint Surg Am 2013 Oct 2;95(19):1729-36.

Chen D, et al. Percutaneous vertebroplasty compared with conservative treatment in patients with chronic painful osteoporotic spinal fractures. J Clin Neurosci 2014 Mar;21(3):473-7.

Chen LX, et al. Comparative efficacy and tolerability of three treatments in old people with osteoporotic vertebral compression fracture: a network meta-analysis and systematic review. PLoS One 2015 Apr 13;10(4):e0123153.

Chen C, et al. Safety and efficacy studies of vertebroplasty, kyphoplasty, and mesh-container-plasty for the treatment of vertebral compression fractures: preliminary report. PLoS One 2016 March 10’11(3):e0151492.

Civelek E, et al. The retrospective analysis of the effect of balloon kyphoplasty to the adjacent-segment fracture in 171 patients. J Spinal Disord Tech 2014 Apr;27(2):98-104.

Clarencon F, et al. Safety and clinical effectiveness of percutaneous vertebroplasty in the elderly (>80 years). Eur Radiol 2016 July;26(7):2352-2358.

Clark W, et al. Safety and efficacy of vertebroplasty for acute painful osteoporotic fractures (VAPOUR): a multicenter, randomized, double-blind, placebo-controlled trial. Lancet 2016 Oct 1;388(10052):1408-1416.

Comstock BA, et al. Investigational vertebroplasty safety and efficacy trial (INVEST): patient-reported outcomes through 1 year. Radiology 2013 Oct;269(1):224-31.

de Falco R, et al. Balloon kyphoplasty for pure traumatic thoracolumbar fractures: retrospective analysis of 61 cases focusing on restoration of vertebral height. Eur Spine J 2014 Oct 23 Suppl 6:664-70.

Diel P, et al. Safety, effectiveness and predictors for early reoperation in therapeutic and prophylactic vertebroplasty: short-term results of a prospective case series of patients with osteoporotic vertebral fractures. Eur Spine J 2012 Aug;21 Suppl 6;S792-799.

Dohm M, et al. A randomized trial comparing balloon kyphoplasty and vertebroplasty for vertebral compression fractures due to osteoporosis. AJNR Am J Neuroradiol 2014 Oct 9 [Epub ahead of print].

*Farrokhi MR, eta l. Randomized controlled trial of percutaneous vertebroplasty versus optimal medical management for the relief of pain and disability in acute osteoporotic vertebral compression fractures. J Neurosurg Spine 2011 May;14(5):561-9.

Feng H, et al. Unilateral versus bilateral percutaneous kyphoplasty for osteoporotic vertebral compression fractures: a systematic review and meta-analysis. J Orthop Res 2015 Nov;33(11):1713-23.

*Han S, et al. percutaneous vertebroplasty versus balloon kyphoplasty for treatment of osteoporotic vertebral compression fracture: a meta-analysis of randomised and non-randomised trials. Int Orthop 2011 Sep;35(9):1349-58.

Hazzard MA, et al. Comparison of vertebroplasty, kyphoplasty, and nonsurgical management of vertebral compression fractures and impact on US Healthcare Resource Utilization. Asian Spine J 2014 Oct;8(5):605-14.

Health Quality Ontario. Vertebral augmentation involving vertebroplasty or kyphoplasty for cancer-related vertebral compression fractures: a systematic review. Ont Health Technol Assess Ser 2016 May1;16(11):1-202.

Huang Z, et al. Is unilateral kyphoplasty as effective and safe as bilateral kyphoplasties for osteoporotic vertebral compression fractures? A meta-analysis. Clin Orthop Relat Res 2014 Sep;472(9):2833-42.

Itshayek E, et al. Efficacy and safety of vertebral stenting for painful vertebral compression fractures in patients with metastatic disease. Neurol Res 2014 Dec;36(12):1086-93.

Jensen ME, et al. Position statement on percutaneous vertebral augmentation: a consensus statement developed by the American Society of Interventional and Therapeutic Neuroradiology, Society of International Radiology, American Association of Neurological Surgeons/Congress of Neurological Surgeons, and American Society of Spine Radiology. [http://guideline.gov/content.aspx?f=rss&id=25723] accessed 4/13/17.

Jian W. Symptomatic cervical vertebral hemangioma treated by percutaneous vertebroplasty. Pain Physician 2013 Jul-Aug;16(4):E419-25.

Jiang L, et al. Diagnosis and treatment of vertebral hemangiomas with neurologic deficit: a report of 29 cases and literature review. Spine J 2014 Jun 1;14(6):944-54.

Julka A, et al. Functional outcomes and height restoration for patients with multiple myeloma-related osteolytic vertebral compression fractures treated with kyphoplasty. J Spinal Disord Tech 2014 Aug;27(6):342-6.

Jurczszyn A, et al. percutaneous vertebroplasty for pathological vertebral compression fractures secondary to multiple myeloma--medium-term and long-term assessment of pain relief and quality of life. Adv Clin Exp Med 2015 Jul-Aug;24(4):651-6.

*Kallmes DF, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. NEJM 2009 Aug 2;361(6):569-79.

*Kasperk C, et al. Three-year outcomes after kyphoplasty in patients with osteoporosis with painful vertebral fractures. J Vasc Interv Radiol 2010 May;21(5):702-9.

*Klazen CA, et al. Vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures (Vertos II): an open-label randomized trial. Lancet 2010 Sep 25;376(9746):1085-92.

*Korovessis P, et al. Balloon kyphoplasty versus KIVA vertebral augmentation- comparison of 2 techniques for osteoporotic vertebral body fractures: a prospective randomized study. Spine 2013 Feb 15;38(4):292-9.

Korovessis P, et al. Is KIVA implant advantageous to balloon kyphoplasty in treating osteolytic metastasis to the spine? Comparison to tow percutaneous MIS techniques: a prospective randomized controlled short-term study. Spine 2014 Feb 15;39(4):E231-239.

Leali PT, et al. Safety and efficacy of vertebroplasty in the treatment of osteoporotic vertebral compression fractures: a prospective multicenter international randomized controlled study. Clin Cases Miner Bone Metab 2016 Sept-Dec;13(3):234-236.

Lee JH, et al. Comparison of radiological and clinical results of balloon kyphoplasty according to anterior height loss in the osteoporotic vertebral fracture. Spine J 2014 Oct 1;14(10):2281-9.

Liu J, et al. Comparing pain reduction following vertebroplasty and conservative treatment for osteoporotic vertebral compression fractures: a meta-analysis of randomized controlled trials. Pain Physician 2013 Sep-Oct;16(5):455-64.

Liu XW, et al. Vertebroplasty in the treatment of symptomatic vertebral haemangiomas without neurological deficit. Eur Radiol 2013 Sep;23(9):2575-81.

Liu JT, et al. Long-term follow-up study of osteoporotic vertebral compression fracture treated using balloon kyphoplasty and vertebroplasty. J Neurosurg Spine 2015 Jul;23(1):94-8.

Marcias-Hernandez SI, et al. Percutaneous vertebroplasty versus conservative treatment and rehabilitation in women with vertebral fractures due to osteoporosis: A prospective comparative study. Rev Onvest Clin 2015 Mar-Apr;67(2):98-103.

Mattie R, et al. Comparing percutaneous vertebroplasty and conservative therapy for treating osteoporotic compression fractures in the thoracic and lumbar spine: a systematic review and meta-analysis. J Bone Joint Surg Am 2016 June 15;98(12):1041-1051.

McCullough BJ, et al. major medical outcomes with spinal augmentation vs conservative therapy. JAMA Intern Med 2013 Sep 9;173(16):1514-21.

Mukherjee S, et al. Pain and functional outcomes following vertebroplasty for vertebral compression fractures- a tertiary centre experience. Br J Neurosurg 2015 Oct 20:1-7.

Nakano M, et al. Transpedicular vertebroplasty after intravertebral cavity formation versus conservative treatment for osteoporotic burst fractures. Spine J 2014 Jan 1;14(1):39-48.

Narayana R, et al. Percutaneous vertebroplasty in painful refractory vertebral hemangiomas. Indian J Orthop 2014 Mar;48(2):163-7.

National Institute for Health and Care Excellence. Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures. NICE technology appraisal guidance 279. 2013 Apr [www.nice.org/uk] accessed 4/13/17.

Niu J, et al. factors affecting recompression of augmented vertebrae after successful percutaneous balloon kyphoplasty: a retrospective analysis. Acta Radiol 2014 Nov 18 [Epub ahead of print].

Otten LA, et al. Comparison of balloon kyphoplasty with the new KIVA® VCF system for the treatment of vertebral compression fractures. Pain Physician 2013 Sep-Oct;16(5):E505-12.

*Rousing R, et al. Percutaneous vertebroplasty compared to conservative treatment in patients with painful acute or subacute osteoporotic vertebral fractures: three-months follow-up in a clinical randomized study. Spine 2009 Jun 1;34(13):1349-54.

*Saad WEA , et al. ACR Appropriateness criteria radiologic management of vertebral compression fractures. 2010. [http://www.acr.org/~/media/ACR/Documents/AppCriteria/Interventional/RadiologicManagement VertebralCompressionFractures.pdf] accessed 4/13/17.

Saracen A, et al. Complications of percutaneous vertebroplasty: an analysis of 1100 procedures performed in 616 patients. Medicine 2016 June;95(24):e3850.

Shi-Ming G, et al. Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for osteoporotic vertebral compression fracture: a meta-analysis. Indian J Orthop 2015 Jul-Aug;49(4):377-87.

Society of International Radiology. Quality improvement guidelines for percutaneous vertebroplasty. [http://www.sirweb.org/clinical/cpg/S311.pdf] accessed 4/13/17.

Song D, et al. The incidence of secondary vertebral fracture of vertebral augmentation techniques versus conservative treatment for painful osteoporotic vertebral fractures: a systematic review and meta-analysis. Acta Radiol 2015 Aug;56(8):970-9.

Stevenson M, et al. percutaneous vertebroplasty and percutaneous balloon kyphoplasty for the treatment of osteoporotic vertebral fractures: a systematic review and cost-effectiveness analysis. Health Technol Assess 2014 Mar;18(17):1-290.

Tan HY, et al. A prospective study of percutaneous vertebroplasty for chronic painful osteoporotic vertebral compression fracture. Pain Res Manag 2015 Jan-Feb;20(1):e8-e11.

Van Meirhaeghe J, et al. A randomized trial of balloon kyphoplasty and non-surgical management for treating acute vertebral compression fractures: vertebral body kyphosis correction and surgical parameters. Spine 2013 Mar 5 [Epub ahead of print].

Vanni D, et al. Third-generation percutaneous vertebral augmentation systems. J Spine Surg 2016 March;2(1):13-20.

Vogl TJ, et al. Cement directed kyphoplasty reduces cement leakage as compared with vertebroplasty: results of a controlled, randomized trial. Spine 2013 Sep 15;38(20):1730-6.

Wang CH, et al. Comparison of high viscosity cement vertebroplasty and balloon kyphoplasty for the treatment of osteoporotic vertebral compression fractures. Pain Physician 2015 Mar-Apr;18(2):E187-94.

Wanh H, et al. Comparison of percutaneous vertebroplasty and balloon kyphoplasty for the treatment of single level vertebral compression fractures: a meta-analysis of the literature. Pain Physician 2015 May-Jun;18(3):209-22.

Wang Y, et al. Clinical evaluation of percutaneous kyphoplasty in the treatment of osteolytic and osteoblastic metastatic vertebral lesions. Int J Surg 2016 June 30:161-165.

*Wardlaw D, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomized controlled trial. Lancet 2009 Mar 21;373(9668):1016-24.

Werner CM, et al. vertebral body stenting versus kyphoplasty for the treatment of osteoporotic vertebral compression fractures: a randomized trial. J Bone Joint Surg Am 2013 Apr 3;95(7):577-84.

Xie W, et al. The incidence of new vertebral fractures following vertebral augmentation: a met-analysis of randomized controlled trials. Medicine 2015 Sep;94(37):e1532.

Yang EZ, et al. Percutaneous vertebroplasty versus conservative treatment in aged patients with acute osteoporotic vertebral compression fractures: a prospective randomized controlled clinical study. Spine 2016 April;41(8):653-660.

Yang S, et al. Risk factors and correlation of secondary adjacent vertebral compression fracture in percutaneous kyphoplasty. Int J Surg 2016 Dec;36(PtA):138-142.

Hi HJ, et al. percutaneous vertebroplasty versus conservative treatment for one-level thoracolumbar osteoporotic compression fracture: results of an over 2-year follow-up. Pain Physician 2016 July;19(5):E743-750.

Yi X, et al. Recompression in new levels after percutaneous vertebroplasty and kyphoplasty compared with conservative treatment. Arch Orthop Trauma Surg 2014 Jan;134(1):21-30.

Yimin Y, et al. Current status of percutaneous vertebroplasty and percutaneous kyphoplasty- a review. Med Sci Monit 2013 Oct 7;19:826-36.

Yokouama K, et al. Long-term therapeutic effects of vertebroplasty for painful vertebral compression fracture: a retrospective comparative study. Br J Neurosurg 2017 April;31(2):184-188.

Yu CW, et al. Percutaneous balloon kyphoplasty for the treatment of vertebral compression fractures. BMC Surg 2014 Jan 14;14:3

*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:
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33569&ContrId=298&ver=16&ContrVer=1&CntrctrSelected=298*1&Cntrctr=298&name=National+Government+Services%2c+Inc.+(13201%2c+A+and+B+and+HHH+MAC%2c+J+-+K)&s=All&DocType=Active&bc=AggAAAIAAAAAAA%3d%3d&.