MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Percutaneous Vertebroplasty/Mechanical Vertebral Augmentation and Percutaneous Sacroplasty**
Policy Number	**6.01.17**
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Product Disclaimer	• *Services are contract dependent; 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 or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, Vertebral Augmentation (e.g., injection of polymethylmethacrylate [PMMA] cement under imaging guidance) has been medically proven to be effective and, therefore, is considered **medically necessary** for the following indications:
   A. Associated Surgical Procedure:
      1. When **ALL** of the following criteria are met:
         a. Performed as a prophylactic vertebroplasty (including adjacent vertebrae if needed) to facilitate fusion surgery;
            AND
         b. Performed at no more than two (2) levels of the T5-L5 spine on the same date of service.
   B. Malignant Conditions:
      1. When **ALL** of the following criteria are met:
         a. Imaging that is concordant with the individual's symptoms and physical exam findings and shows **ANY** of the following:
            i. Osteolytic metastases, including destruction of a vertebral body by multiple myeloma; **or**
            ii. Primary malignant neoplasm of bone or bone marrow;
            AND
         b. Subjective symptoms include:
            i. Significant level of pain on a daily basis defined as clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing, etc.)**;**
            AND

c. Significant functional limitations have resulted in diminished quality of life and impaired, age-appropriate activities of daily living.

C. Non-Malignant Conditions:
1. When **ALL** of the following criteria are met:
a. Imaging that is concordant with the individual's symptoms and physical exam findings and shows **ANY** of the following:
i. Osteoporotic vertebral compression fracture;
ii. Osteolytic vertebral compression fracture;
iii. Aggressive space occupying lesions of a vertebral body (hemangioma/eosinophilic granuloma);
iv. Osteonecrotic (i.e., Kummel disease) vertebral compression fracture; **or**
v. Steroid-induced vertebral compression fracture;

AND

b. Performed at no more than two (2) levels of the T5-L5 spine on the same date of service;

AND

c. Subjective symptoms include:
i. Significant level of pain on a daily basis defined as clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing, etc.);

AND

i. Significant functional limitations have resulted in diminished quality of life and impaired, age-appropriate activities of daily living;

AND

d. **EITHER** of the following:
i. Acute (0-6 weeks) axial pain in the thoracic/lumbar spine that persists at a level which prevents independent transfers and/or ambulation and correlates with the level of fracture; **or**
ii. Subacute (greater than six (6) weeks) axial pain in the thoracic/lumbar spine with less than clinically meaningful improvement with **BOTH** of the following (unless contraindicated):
a) Prescription strength analgesics, steroids and/or NSAIDS for four (4) weeks; and
b) Provider-directed exercise program for four (4) weeks;

AND

e. For osteoporotic compression fractures, the individual is enrolled in an osteoporosis treatment and prevention program after an osteoporotic vertebral compression fracture.

II. Vertebral Augmentation (Percutaneous Vertebroplasty/Kyphoplasty) is considered **not medically necessary**, when there is presence of **ANY** of the following contraindications:
A. Allergy to materials used in the procedure;
B. Uncorrected coagulation disorder 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 retro-pulsed 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. Radiculopathy from a herniated intervertebral disc;
I. Untreated symptomatic foraminal or canal stenosis, facet arthropathy, or other significant coexistent spinal or bony pain generators;
J. Unstable fracture or requirement for stabilization procedure in same or adjacent spinal region;
K. Septicemia and any active infection (including urinary tract infection [UTI]);
L. Active osteomyelitis of the target vertebra;
M. Severe cardiopulmonary disease.

III. Based upon our criteria and assessment of the peer-reviewed literature, Vertebral Augmentation (Percutaneous Vertebroplasty/Kyphoplasty) is considered **not medically necessary** for **ANY** of the following alternative causes of axial back pain:
   A. Lumbar/thoracic radiculopathy or facet disease;
   B. Lumbar/thoracic/sacral trigger points;
   C. Insufficiency fractures or lesions of the sacrum or coccyx.

IV. Based upon our criteria and assessment of the peer-reviewed literature, Primary Vertebral Augmentation (Percutaneous Vertebroplasty/Kyphoplasty) has not been medically proven to be effective and, therefore, is considered **investigational** for **ANY** of the following:
   A. Non-painful/non-aggressive vertebral hemangioma;
   B. Vertebrae of the cervical spine and thoracic levels T1-T4;
   C. Prophylactic treatment for osteoporosis of the spine;
   D. Prophylactic treatment for chronic back pain of long-standing duration (greater than six (6) months), even if associated with old compression fracture(s);
   E. Spinoplasty (e.g., OptiMesh 1500E Polyethylene Terephthalate (PET) mesh pouch);
   F. The use of any cement, cement products or devices that are not U.S. Food and Drug Administration (FDA) approved for vertebral augmentation (e.g., Norian XR cement and Norian SRS cement products);
   G. Radiofrequency Kyphoplasty (e.g., StabiliT System);
   H. Vertebral body stenting.

V. Based upon our criteria and assessment of the peer-reviewed literature, percutaneous sacroplasty is considered **investigational** for all indications.

Refer to Corporate Medical Policy #7.01.112 Intradiscal Procedures

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINES

I. Urgent/Emergent Conditions

All individuals being evaluated for spine surgery should be screened for the presence of urgent/emergent indications/conditions that warrant definitive surgical treatment. Provider-directed, non-surgical management is not required for confirmed urgent/emergent conditions. Imaging findings noted in the applicable procedure policy statement are required.

Urgent/emergent conditions for vertebral augmentation procedure include **EITHER** of the following:
   A. Primary or metastatic neoplastic disease which is causing pathologic fracture; or
   B. A condition otherwise meeting criteria listed in the applicable procedure policy statement with documentation of severe debilitating, crippling pain or dysfunction to the point of being incapacitated.

II. Minimum documentation requirements needed to complete a spinal surgery prior authorization request include **ALL** of the following:
   A. CPT codes, ICD-10 codes, and disc levels or motion segments involved for planned surgery must be provided;
   B. Detailed documentation of the type, duration, and frequency of provider-directed non-surgical treatment (e.g., interventional pain management, manual therapy or provider-directed active exercise program, etc.) that includes response to each treatment:
      1. Detailed documentation explaining why a sufficient trial of non-surgical treatment was contraindicated (if applicable);
      2. Detailed documentation of less than clinically meaningful improvement for each treatment;
   C. Written reports/interpretations of the most recent advanced diagnostic imaging reports (e.g., computed tomography [CT] scan, magnetic resonance imaging [MRI], or Myelography) performed, read, and interpreted

by an independent radiologist. Clinically significant discrepancies in interpretation between the surgeon and the radiologist need to be reconciled prior to the documentation submission;

D. Documentation of nicotine-free status including **EITHER** of the following (unless this is an urgent/emergent request for fusion/ disc arthroplasty or when myelopathy is present):
   1. Individual is a never smoker; or
   2. Individual has refrained from smoking, use of smokeless tobacco products, and/or nicotine replacement therapy for at least six (6) weeks prior to planned surgery as evidenced by blood cotinine lab results of < 10ng/mL.

III. Use of discography or magnetic resonance spectroscopy (MRS) is not endorsed.

IV. Percutaneous vertebroplasty will **NOT** be separately reimbursed when combined with any open spine procedure.

V. Mechanical vertebral augmentation will **NOT** be separately reimbursed when combined with any open spine procedure.

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. Sacroplasty or coccygeoplasty are the terms used when vertebroplasty or kyphoplasty is used to treat insufficiency fractures of the sacrum or coccyx, respectively.

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, consequently, 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.

SpineJack is a percutaneous kyphoplasty technique using an expandable intervertebral body implant to restore vertebral height followed by injection of PMMA cement to keep the implant in place.

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 (Synthes, Switzerland) is only available in Europe at this time.

Percutaneous sacroplasty, a variation of vertebroplasty, is an evolving technique that has been proposed for the treatment of sacral insufficiency fractures. The treatment goal of sacroplasty is to restore stability and integrity of the sacral spine, relieve pain and restore mobility. Sacral insufficiency fractures have traditionally been treated with conservative measures, including bed rest, analgesics, orthoses/corsets and physical therapy. In some cases, pain persists and is

refractory to these measures. These patients are predominately elderly, and hardware implantation may not be possible in weakened bone. Percutaneous sacroplasty is a minimally invasive procedure, in which PMMA is injected through a needle inserted into the sacrum at the fracture site under fluoroscopic guidance.

RATIONALE

The Kyphon inflatable bone tamp was approved by the U.S. Food and Drug Administration (FDA) under Section 510(k) in 1998. Bone cements that have received FDA Section 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 (Heraeus Medical).

The Crosstrees PVA Pod System for vertebral augmentation received FDA clearance under the investigational device exemption (IDE) 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, non-inferiority randomized, controlled trial (RCT) conducted by Tutton et al. in 2015. This industry-sponsored, multi-center, open-label trial, known as KAST, was conducted in 300 patients with one or two osteoporotic vertebral compression fractures. Included were patients with VAS for back pain of at least 70 mm of 100 after two to six weeks of conservative care or a VAS of at least 50 mm after six weeks of conservative care, and an Oswestry Disability Index (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 (SAEs). 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 non-inferiority, 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 SAEs. The total volume of cement was 50% less with Kiva, and there was lower cement extravasion, compared with kyphoplasty (16.9% versus 25.8%, respectively).

Evidence to date includes a large, industry-sponsored, multi-center IDE trial, a large, independent randomized trial, and a retrospective matched-pair comparison. The two 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 non-concurrent 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, several 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 six 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.

Frey et al. (2017) reported the results of a prospective observational cohort of subjects treated for sacral insufficiency fractures using either sacroplasty (n=210) or non-surgical management (n=34). The non-surgical group consisted of subjects who did not meet inclusion criteria for sacroplasty. Follow-up occurred at various intervals from pretreatment to two years post treatment; the experimental group was also contacted at 10 years post treatment ; the control group was not. Both groups had statistically significant decreases in VAS scores from pretreatment to two-year follow-up ($p<0.001$). The experimental group had more significant decreases from follow-up to follow-up extending out to one year, the control group had significant decrease in mean VAS only at the pre-treatment to two-week follow-up. Additionally, the authors reported decreased use of opioid and non-opioid medications from preoperatively to postoperatively in the experimental group, which was sustained at the 10-year follow-up. Limitations of the study include small sample populations and lack of outcomes at 10-year follow-up for the control group.

Mahmood et al. (2019) published results of a systematic review evaluating sacroplasty as treatment of sacral insufficiency fractures. The authors reviewed 31 studies that met inclusion criteria; the studies consisted of eight prospective trials, 11 retrospective studies, and 12 case series; only one study included a control group. Sample populations ranged from 3 to 243 subjects. Sacroplasty was performed using different methods, the amount of PMMA injected varied, and a majority of the studies included the VAS score as the primary outcome, eight studies did not use VAS. Of the studies that used VAS, all reported a mean reduction of VAS at follow-up (68-94% reduction). Follow-up ranged from one month to one year with the exception of one study that followed subjects for 10 years (Frey, et al., 2017 described above). Nine studies reported cement extravasation, although clinically insignificant. Two studies had patients with persistent pain that required reoperation. In the author's opinion, sacroplasty as a treatment of sacral insufficiency fractures is a safe and effective procedure, in terms of pain relief with early return to function.

The published evidence evaluating sacroplasty is conflicting and insufficient to support improved clinical outcomes. A majority of the studies lack control groups, large sample populations, and measurement of long-term outcomes, therefore no conclusions can be made regarding the safety and efficacy of sacroplasty.

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.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

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

Code	Description
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 (e.g., 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 (e.g., 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 (e.g., 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)
0200T **(E/I)**	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed
0201T **(E/I)**	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed

HCPCS Codes

Code	Description
C1062	Intravertebral body fracture augmentation with implant (e.g., metal, polymer)
C7504	Percutaneous vertebroplasties (bone biopsies included when performed), first cervicothoracic and any additional cervicothoracic or lumbosacral vertebral bodies, unilateral or bilateral injection, inclusive of all imaging guidance
C7505	Percutaneous vertebroplasties (bone biopsies included when performed), first lumbosacral and any additional cervicothoracic or lumbosacral vertebral bodies, unilateral or bilateral injection, inclusive of all imaging guidance
C7507	Percutaneous vertebral augmentations, first thoracic and any additional thoracic or lumbar vertebral bodies, including cavity creations (fracture reductions and bone biopsies included when performed) using mechanical device (e.g., kyphoplasty), unilateral or bilateral cannulations, inclusive of all imaging guidance
C7508	Percutaneous vertebral augmentations, first lumbar and any additional thoracic or lumbar vertebral bodies, including cavity creations (fracture reductions and bone biopsies included when performed) using mechanical device (e.g., kyphoplasty), unilateral or bilateral cannulations, inclusive of all imaging guidance

ICD10 Codes

Code	Description
C41.2	Malignant neoplasm of vertebral column
C79.51-C75.52	Secondary malignant neoplasm of bone and bone marrow (code range)
C90.00-C90.02	Multiple myeloma (code range)
D18.09	Hemangioma other sites
M48.50XA-M48.58XS	Collapsed vertebra, not elsewhere classified (code range)
M80.08XA-M80.08XS	Age-related osteoporosis with current pathological fracture, vertebra(e) (code range)
M80.88XA-M80.88XS	Other osteoporosis with current pathological fracture, vertebra(e) (code range)
M84.58XA-M84.58XS	Pathological fracture in neoplastic disease, vertebrae (code range)

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*Key Article

KEY WORDS

Kiva system, Kyphon inflatable bone tamp, SpineJack, kyphoplasty, vertebral augmentation, vertebral body stenting, vertebroplasty.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) (L33569) for Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF). Please refer to the following LCD website for Medicare Members:

[https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=33569&ver=28] accessed 09/05/24.