



CLINICAL GUIDELINES

CMM-607: Primary Vertebral Augmentation (Percutaneous Vertebroplasty-Kyphoplasty) and Sacroplasty

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EviCore

By ~~EVERNORTH~~

EviCore healthcare Clinical Decision Support Tool Diagnostic Strategies: This tool addresses common symptoms and symptom complexes. Imaging requests for individuals with atypical symptoms or clinical presentations that are not specifically addressed will require physician review. Consultation with the referring physician, specialist, and/or individual's Primary Care Physician (PCP) may provide additional insight.

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General Guidelines

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Application of Guideline

- The determination of medical necessity for the performance of vertebral augmentation (percutaneous vertebroplasty/kyphoplasty) and sacroplasty is always made on a case-by-case basis.
- For additional timing and documentation requirements, see **CMM-600.1: Prior Authorization Requirements**.

Urgent/Emergent Indications/Conditions

The presence of urgent/emergent indications/conditions warrants definitive surgical treatment. **Imaging findings noted in the applicable procedure section(s) are required.**

- Provider-directed non-surgical management is NOT required for confirmed urgent/emergent conditions.
- Urgent/emergent conditions for vertebral augmentation include EITHER of the following:
 - primary or metastatic neoplastic disease causing pathologic fracture
 - a condition otherwise meeting criteria listed in the applicable procedure section(s) with documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated

Definitions

Balloon Kyphoplasty a percutaneous kyphoplasty technique that involves the use of a specialized balloon to expand collapsed vertebrae, which then allows injection of PMMA.

Kiva® VCF System a percutaneous mechanical kyphoplasty technique using a cannula-deployed Kiva® coil to insert a spiral PolyEtherEtherKetone (PEEK) implant which serves as a conduit for PMMA cement placement.

Kyphoplasty	a percutaneous vertebral augmentation procedure that is a variant of vertebroplasty. This procedure uses instrumentation or a device to re-establish vertebral height. Kyphoplasty techniques include balloon kyphoplasty and mechanical kyphoplasty.
Mechanical Kyphoplasty	a percutaneous kyphoplasty technique using a device other than a balloon to expand collapsed vertebrae. Types of mechanical kyphoplasty techniques include, but are not limited to, radiofrequency kyphoplasty, Kiva® VCF system, SpineJack®, and vertebral body stenting.
Radiofrequency Kyphoplasty	a percutaneous mechanical kyphoplasty technique utilizing the StabiliT® Vertebral Augmentation System (StabiliT®). This technique uses radiofrequency energy to modify ultra-high viscosity cement to a desired consistency. This ultra-high viscosity cement is introduced into the vertebral body to expand the collapsed vertebrae.
SpineJack®	a percutaneous mechanical kyphoplasty technique using an expandable intervertebral body implant to restore vertebral height followed by injection of PMMA cement to keep the implant in place.
Vertebral Augmentation	a minimally invasive procedure for stabilization and restoration of a vertebra to treat painful, pathologic fractures. The more common techniques in current use are vertebroplasty, kyphoplasty. Sacroplasty or coccygeoplasty are the terms used when vertebroplasty or kyphoplasty is used to treat insufficiency fractures of the sacrum or coccyx, respectively.
Vertebral Body Stenting	a percutaneous mechanical kyphoplasty technique using an expandable metal stent with PMMA cement resulting in a stent-reinforced cement implant that restores vertebral height.
Vertebroplasty	a percutaneous vertebral augmentation procedure that involves image-guided injection of polymethylmethacrylate [PMMA] cement.

Health Equity Considerations

Health equity is the highest level of health for all individuals; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which individuals are born, grow, live, work, and age. Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include the following: safe housing, transportation, and neighborhoods; racism, discrimination, and violence; education, job opportunities, and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

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CMM-607.2: Indications

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Vertebral augmentation is considered **medically necessary** for ANY of the following when ALL of the associated criteria have been met:

Associated Surgical Procedure

- Performed as a prophylactic vertebroplasty (including adjacent vertebrae if needed) to facilitate fusion surgery
- Performed at no more than two (2) levels of the T5-L5 spine on the same date of service

Malignant Conditions

- Imaging is concordant with the individual's symptoms and physical exam findings and that shows EITHER of the following:
 - osteolytic metastases including destruction of a vertebral body by multiple myeloma
 - primary malignant neoplasm of bone or bone marrow
- Symptoms include significant level of pain on a daily basis defined as clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing, etc.)

Non-Malignant Conditions

- Imaging is concordant with the individual's symptoms and physical exam findings and that shows ANY of the following:
 - osteoporotic vertebral compression fracture
 - osteolytic vertebral compression fracture
 - aggressive space occupying lesions of a vertebral body (hemangioma/eosinophilic granuloma)
 - osteonecrotic vertebral compression fracture (i.e., Kummel disease)
 - steroid-induced vertebral compression fracture
- Performed at no more than two (2) levels of the T5-L5 spine on the same date of service
- Symptoms include significant level of pain on a daily basis defined as clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing, etc.)
- EITHER of the following:

- acute (0-6 weeks) axial pain in the thoracic/lumbar spine that persists at a level which prevents independent transfers or ambulation and correlates with the level of the fracture
- subacute (> 6 weeks) axial pain in the thoracic/lumbar spine with less than clinically meaningful improvement with BOTH of the following (unless contraindicated):
 - prescription strength analgesics, steroids, and/or nonsteroidal anti-inflammatory drugs (NSAIDs) for four (4) weeks
 - provider-directed exercise program (prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician) for four (4) weeks
- For osteoporotic compression fractures, the individual is enrolled in an osteoporosis treatment and prevention program after an osteoporotic vertebral compression fracture.

CMM-607.3: Non-Indications

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CMM-607.3: Non-Indications

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Not Medically Necessary

- Vertebral augmentation (percutaneous vertebroplasty/kyphoplasty) performed without meeting the criteria in the **General Guidelines** (when applicable for urgent/emergent conditions) and the criteria in the applicable procedure-specific **Indications** section (**associated surgical procedure; malignant conditions; non-malignant conditions**) is considered **not medically necessary**.
- Vertebral augmentation (percutaneous vertebroplasty/kyphoplasty) is considered **not medically necessary** when there is presence of ANY of the following alternative causes of axial back pain:
 - lumbar or thoracic radiculopathy or facet disease
 - lumbar, thoracic, or sacral trigger points
 - insufficiency fractures or lesions of the sacrum or coccyx
- Sacroplasty and coccygeoplasty are considered **not medically necessary**.
- Primary vertebral augmentation (percutaneous vertebroplasty/kyphoplasty) is considered **not medically necessary** for ANY of the following:
 - non-painful/non-aggressive vertebral hemangioma
 - vertebrae of the cervical spine at any level
 - vertebrae of the thoracic spine at levels T1-T4
 - prophylactic treatment for osteoporosis of the spine
 - prophylactic treatment for chronic back pain of longstanding duration (>6 months), even if associated with old compression fracture(s)
 - spinoplasty (e.g., OptiMesh® 1500E Polyethylene Terephthalate (PET) mesh pouch)
 - use of any cement, cement products, or devices that are not FDA-approved for vertebral augmentation (e.g., Norian XR cement and Norian SRS cement products)
 - radiofrequency kyphoplasty (e.g., StabiliT® System)
 - vertebral body stenting
- Vertebral augmentation (percutaneous vertebroplasty/kyphoplasty) is considered **not medically necessary** when there is a presence of ANY of the following contraindications:
 - allergy to materials used in the procedure
 - uncorrected coagulation disorders or anticoagulation therapy
 - myelopathy associated with a bone fragment in the spinal canal or cord compression from a tumor

- extensive vertebral destruction
- burst fracture associated with widened pedicles and/or retropulsed bone fragments
- potential space occupying lesions causing cord compression (tumor, bone fragment)
- collapse of vertebral body to less than the level of the vertebra plana
- radiculopathy from a herniated intervertebral disc
- untreated symptomatic foraminal or canal stenosis, facet arthropathy, or other significant coexistent spinal or bony pain generators
- unstable fracture or requirement for stabilization procedure in the same or adjacent spinal region
- septicemia and any active infection (including urinary tract infection [UTI])
- active osteomyelitis of the target vertebra
- severe cardiopulmonary disease

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Codes (CMM-607)

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The inclusion of any code in this table does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for management details. Prior authorization of a code listed in this table is not a guarantee of payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's health insurance policy.

Code	Code Description/Definitions
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, (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)

CMM-607: Primary Vertebral Augmentation and Sacroplasty

Code	Code Description/Definitions
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, one or more needles, includes imaging guidance and bone biopsy, when performed
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, two or more needles, includes imaging guidance and bone biopsy, when performed

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