Cigna Medical Coverage Policies – Musculoskeletal Primary Vertebral Augmentation (Percutaneous Vertebroplasty-Kyphoplasty) and Sacroplasty Guidelines

Effective November 1, 2024

Instructions for use

The following coverage policy applies to health benefit plans administered by Cigna. Coverage policies are intended to provide guidance in interpreting certain standard Cigna benefit plans and are used by medical directors and other health care professionals in making medical necessity and other coverage determinations. Please note the terms of a customer's particular benefit plan document may differ significantly from the standard benefit plans upon which these coverage policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a coverage policy.

In the event of a conflict, a customer's benefit plan document always supersedes the information in the coverage policy. In the absence of federal or state coverage mandates, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of:

1. The terms of the applicable benefit plan document in effect on the date of service
2. Any applicable laws and regulations
3. Any relevant collateral source materials including coverage policies
4. The specific facts of the particular situation

Coverage policies relate exclusively to the administration of health benefit plans. Coverage policies are not recommendations for treatment and should never be used as treatment guidelines.

This evidence-based medical coverage policy has been developed by eviCore, Inc. Some information in this coverage policy may not apply to all benefit plans administered by Cigna.

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

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CMM-607.1: General Guidelines

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 procedure 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 or crippling pain and/or dysfunction to the point of being incapacitated

Definitions

- **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.
  - Vertebroplasty: a percutaneous augmentation procedure that involves image-guided injection of polymethylmethacrylate [PMMA] cement.
  - Kyphoplasty: a percutaneous 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.

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

- Mechanical Kyphoplasty: a percutaneous augmentation technique using a device other than a balloon to expand collapsed vertebrae. Types of mechanical kyphoplasty techniques include, but are not limited to, the following:

- Radiofrequency Kyphoplasty: a percutaneous 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.
- Kiva® VCF System: a percutaneous kyphoplasty technique using a cannula-deployed Kiva® coil to insert a spiral PolyEtherEtherKetone (PEEK) implant which serves as a conduit for PMMA cement placement.
- SpineJack®: 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.
- Vertebral Body Stenting: a percutaneous kyphoplasty technique using an expandable metal stent with PMMA cement resulting in a stent-reinforced cement implant that restores vertebral height.

CMM-607.2: Indications

Vertebral augmentation (e.g., injection of polymethylmethacrylate [PMMA] cement under imaging guidance) is considered **medically necessary** for **ANY** of the following when **ALL** of the associated criteria are met:

Associated Surgical Procedure

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

Malignant Conditions

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

Non-Malignant Conditions

- Imaging that 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 (i.e., Kummel disease) vertebral compression fracture
- Steroid-induced vertebral compression fracture

- Performed at no more than 2 levels of the T5-L5 spine on the same date of service
- Subjective symptoms include clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing)
- **EITHER** of the following:
  - 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 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 NSAIDs for 4 weeks
    - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician for 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

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/thoracic radiculopathy or facet disease
  - Lumbar/thoracic/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 and thoracic 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)
- The 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) 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

Procedure (CPT®) Codes (CMM-607)

This guideline relates to the CPT® code set below. Codes are displayed for informational purposes only. Any given code's inclusion on this list does not necessarily indicate prior authorization is required.

CPT®	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)
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

This list may not be all-inclusive and is not intended to be used for coding/billing purposes. The final determination of reimbursement for services is the decision of the health plan and is based on the individual's policy or benefit entitlement structure as well as claims processing rules.

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