Kyphoplasty and Vertebroplasty - Single Service

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

Specialty Area: Diseases & Disorders of the Musculoskeletal System (M00-M99)
Care Path Name: Kyphoplasty and Vertebroplasty - Single Service

Literature review current through: 9/29/2023
Document last updated: 9/29/2023
Type: [**X**] Adult (18+ yo) | [_] Pediatric (0-17yo)

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Medical Necessity Criteria

Service: Kyphoplasty and Vertebroplasty - Single Service

General Guidelines

- **Units, Frequency, & Duration:** None.
- **Criteria for Subsequent Requests:** None.
- **Recommended Clinical Approach:** Kyphoplasty and vertebroplasty (or balloon-assisted vertebroplasty) involves injecting a bone cement (typically polymethylmethacrylate [PMMA]) into a vertebral body due toa vertebral compression fracture (VCF) or a disease process that has replaced the normal bony architecture. The cement provides stability to the damaged vertebra to reduce pain and improve function.
- **Exclusions:** Absolute exclusions include active infection at the surgical site or other systemic infection, allergies to bone cement, asymptomatic compression fractures, retropulsed bone fragment with spinal compromise, or nerve impingement.

Medical Necessity Criteria

Indications

➔ **Kyphoplasty and Vertebroplasty for Vertebral Compression Fractures (VCF)** is considered appropriate if **ALL** of the following are **TRUE:**

- ◆ Failure of conservative therapy, including **ANY** of the following:
  - Analgesics; **OR**
  - External orthosis; **OR**
  - Physical therapy; **OR**
  - Bed rest[1]; **AND**
- ◆ Acute (less than 6 weeks) or subacute (6-12 weeks) osteoporotic VCF (T1 – L5) as evidenced by **ALL** of the following:
  - Symptom onset; **AND**
  - Documented by advanced imaging (e.g., bone marrow edema on MRI or bone-scan/SPECT/CT uptake)[2-9]; **AND**
- ◆ Symptomatic as evidenced by **ANY** of the following:[3]
  - Hospitalized with severe pain (Numeric Rating Scale [NRS] or Visual Analog Scale [VAS] pain score greater than or equal to 8)[10-13]; **OR**
  - Non-hospitalized with moderate to severe pain (NRS or VAS greater than or equal to 5) despite optimal non-surgical management (NSM) as evidenced by **ANY** of the following:[7]
    - Worsening pain; **OR**

        - Stable to improved pain (but NRS or VAS still greater than or equal to 5) as evidenced by **TWO or more** of the following:
            - Progression of vertebral body height loss; **OR**
            - More than 25% vertebral body height reduction; **OR**
            - Kyphotic deformity; **OR**
            - Severe impact of VCF on daily functioning; **OR**
            - Roland Morris Disability Questionnaire (RDQ) greater than 17; **AND**
- The patient has **ANY** of the following indications:
    - Painful osteoporotic vertebral fracture(s) as evidenced by **ALL** of the following:[14]
        - Medically refractory pain (e.g., opioid intolerance); **AND**
        - Pain requiring a reduction in activities of daily living (ADLs); **AND**
        - Within 12 weeks of pain onset; **AND**
        - Remaining affected vertebra is more than one-third of the original vertebral height; **OR**
    - Vertebral bodies weakened by neoplasm[14]; **OR**
    - Symptomatic vertebral body microfracture as documented by advanced imaging without obvious loss of vertebral body height[14]; **OR**
    - Benign painful lesion of bone[14]; **OR**
    - Rapidly progressive fracture, with or without pseudoarthrosis potentially leading to kyphosis[14]; **OR**
    - Severe kyphosis resulting in decreased pulmonary function[14]; **OR**
    - Steroid-induced fracture; **OR**
    - Painful and/or aggressive hemangioma; **OR**
    - Painful multiple myeloma involving the vertebral body; **OR**
    - Painful osteolytic vertebral body metastatic disease; **OR**
- Continuum of care as evidenced by **ALL** of the following:[2-3,7]
    - Referral for evaluation of a bone mineral density; **AND**
    - Referral to osteoporosis education for subsequent treatment as indicated; **AND**
    - Referral to an osteoporosis prevention/treatment program.

Non-Indications

- ➔ **Kyphoplasty and Vertebroplasty for Vertebral Compression Fractures (VCF)** are not indicated if **ANY** of the following is **TRUE**:
  - ◆ Osteoporotic VCF on imaging with correlating signs and symptoms and are neurologically not intact[15]; **OR**
  - ◆ Patient has **ANY** of the following absolute contraindications:
    - Current back pain is not primarily due to the identified acute or subacute VCF(s)[2-3,5,7,11-12]; **OR**
    - Osteomyelitis, discitis, active systemic or surgical site infection[3,5,7,11-12,14] ; **OR**
    - Infection along the intended trajectory of access[14]; **OR**
    - Septicemia[14]; **OR**
    - Uncorrectable coagulopathy[14]; **OR**
    - Asymptomatic compression fracture[1]; **OR**
    - Allergy to cement or components of fill material; **OR**
    - Pregnancy; **OR**
  - ◆ Patient has **ANY** of the following relative contraindications that have been evaluated and indicate that the procedure is not recommended:[3,5,7,11,12]
    - Greater than three vertebral fractures per procedure; **OR**
    - Allergy to bone cement or opacification agents; **OR**
    - Uncorrected coagulopathy; **OR**
    - Spinal instability; **OR**
    - Myelopathy from the fracture; **OR**
    - Neurologic deficit; **OR**
    - Neural impingement; **OR**
    - Fracture retropulsion with canal compromise; **OR**
    - Radiculopathy, caused by a compressive syndrome unrelated to vertebral body fracture[14]; **OR**
    - Retropulsion of a fracture fragment with signs and/or symptoms of neurological compromise up to and including myelopathy or cauda equina syndrome[14]; **OR**
    - Epidural tumor extension with significant encroachment on the spinal canal[14]; **OR**
    - Fracture extension into the posterior vertebral body wall (risk of cement extravasation into the spinal canal)[1]; **OR**
    - Patient with apparently stable fracture on imaging who is clinically improving[14]; **OR**

- Severe compression fractures or deformity[1]; **OR**
- Prophylactic treatment for osteoporosis to prevent future fractures; **OR**
- Pregnancy.[14]

Site of Service Criteria

Inpatient or Outpatient.

Procedure Codes (HCPCS/CPT)

HCPCS Code	Code Description/Definition
01941	Anesthesia for percutaneous image-guided neuromodulation or intravertebral procedures (e.g., kyphoplasty, vertebroplasty) on the spine or spinal cord; cervical or thoracic
01942	Anesthesia for percutaneous image-guided neuromodulation or intravertebral procedures (e.g., kyphoplasty, vertebroplasty) on the spine or spinal cord; lumbar or sacral
22510	Percutaneous vertebroplasty of single cervicothoracic vertebral body with bilateral injection
22511	Percutaneous vertebroplasty of single lumbosacral vertebral body with bilateral injection
22512	Percutaneous vertebroplasty of each additional cervicothoracic vertebral body with bilateral injection
22513	Percutaneous augmentation of single thoracic vertebral body with insertion of mechanical device using cannula, including cavity creation
22514	Percutaneous augmentation of single lumbar vertebral body with insertion of mechanical device using cannula, including cavity creation
22515	Percutaneous augmentation of each additional lumbar vertebral body with insertion of mechanical device using cannula, including cavity creation

Medical Evidence

National and Professional Organizations

The **American Academy of Orthopaedic Surgeons (AAOS)** published a clinical practice guideline on the *Treatment of Symptomatic Osteoporotic Spinal Compression Fractures.* Kyphoplasty is for neurologically intact patients with an osteoporotic spinal compression fracture, as evidenced by imaging with clinical symptoms. The AAOS does provide a recommendation of support or non-support regarding the improvement of kyphosis angle in patients with an osteopathic spinal compression fracture.[16]

The **American College of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spine Radiology (ASSR), Society of Interventional Radiology (SIR),** and the **Society of NeuroInterventional Surgery (SNIS)** published a *Practice Parameter for the Performance of Vertebral Augmentation*. The document includes indications, contraindications, and specifications of the procedure.[14] The **ACR** also published *Appropriateness Criteria: Management of Vertebral Compression Fractures.*[17]

The **Society of Interventional Radiology (SIR)** issued a position statement on percutaneous vertebral augmentation in collaboration with the **American Association of Neurological Surgeons (AANS), 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 **Society of NeuroInterventional Surgery (SNIS).** The Societies support percutaneous vertebral augmentation (PVA) with the use of vertebroplasty or kyphoplasty as a safe, effective, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures.[4]

The **National Comprehensive Cancer Network (NCCN)** published a clinical practice guideline on *Multiple Myeloma*. Vertebroplasty or kyphoplasty is indicated for vertebral compression fractures.[18]

The **International Society for the Advancement of Spine Surgery (ISASS)** published a policy on *Vertebral Augmentation.* Vertebroplasty and kyphoplasty are supported for the early treatment of painful VCFs. The ISASS does not endorse any specific vertebroplasty/ kyphoplasty system.[19]

The **National Institute for Health and Care Excellence (NICE)** published the *Technology Appraisal Guidance*: *Percutaneous Vertebroplasty and Percutaneous Balloon Kyphoplasty for Treating Osteoporotic Vertebral Compression Fractures.* Percutaneous vertebroplasty and percutaneous balloon kyphoplasty without stenting are recommended to treat osteoporotic vertebral compression fractures in patients:[10]

- "Who have severe ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management; and
- In whom the pain has been confirmed to be at the level of the fracture by physical examination and imaging."

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