



Cohere Medical Policy - Kyphoplasty and Vertebroplasty

Clinical Guidelines for Medical Necessity Review

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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: 8/19/2024

Document last updated: 8/19/2024

Type: Adult (18+ yo) | Pediatric (0-17 yo)

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Medical Necessity Criteria

Service: Kyphoplasty and Vertebroplasty

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 to a 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, retracted bone fragment with spinal compromise, or nerve impingement.

Medical Necessity Criteria

Indications

- **Kyphoplasty and Vertebroplasty for Vertebral Compression Fractures (VCF)** is considered appropriate if **ANY** of the following is **TRUE**:
- ◆ Painful osteoporotic vertebral fracture(s) as evidenced by **ALL** of the following:¹⁴
 - Low energy injury; **AND**
 - Acute (less than 6 weeks) or subacute (6-12 weeks) osteoporotic VCF (T1 – L5) as evidenced by **ALL** of the following:
 - Symptomatic onset; **AND**
 - Documented by advanced imaging (e.g., bone marrow edema on MRI or bone-scan/SPECT/CT uptake)²⁻⁹; **AND**
 - Failure of conservative management for greater than 4 weeks, including **ANY** of the following:
 - Oral steroids, anti-inflammatory medications, or analgesics; **OR**
 - External orthosis; **OR**
 - Physical therapy; **OR**
 - Bed rest¹; **AND**

- Pain requiring a reduction in activities of daily living (ADLs); **AND**
- Procedure performed within 12 weeks of pain onset; **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 patients 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 noted (NRS or VAS 6 or higher); **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 but not flattened (vertebra plana); **OR**
 - New Kyphotic deformity; **OR**
 - Severe impact of VCF on daily functioning; **OR**
- ◆ The patient has **ANY** of the following indications:
 - Trauma resulting in acute osteoporotic fracture
 - Vertebral bodies weakened by neoplasm (primary or metastatic)¹⁴; **OR**
 - Painful multiple myeloma involving the vertebral body; **OR**
 - Severe kyphosis from osteoporotic VCF resulting in decreased pulmonary function¹⁴; **OR**
 - Painful and/or aggressive vertebral hemangioma; **OR**
- ◆ Continuum of care for recurrent or subsequent fractures 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 vertebral compression fracture in patients who are not intact neurologically¹⁵; **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 access¹⁴; **OR**
 - Septicemia¹⁴; **OR**
 - Uncorrectable coagulopathy¹⁴; **OR**
 - Asymptomatic compression fracture¹; **OR**
 - Allergy to cement or components of fill material; **OR**
 - Pregnancy; **OR**
- ◆ The 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**
 - Radiculopathy, caused by a compressive syndrome unrelated to vertebral body fracture¹⁴; **OR**
 - Retropulsion of a fracture fragment with signs and/or symptoms of neurological compromise up to and including myelopathy or cauda equina syndrome¹⁴; **OR**
 - Epidural tumor extension with significant encroachment on the spinal canal¹⁴; **OR**
 - Fracture extension into the posterior vertebral body wall (risk of cement extravasation into the spinal canal)¹; **OR**
 - Patient with an apparently stable fracture on imaging who is clinically improving¹⁴; **OR**
 - Severe compression fractures or deformity¹; **OR**

- Burst Fracture; **OR**
- Vertebra Plana; **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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Clinical Guideline Revision History/Information

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Review History

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