Cohere Medicare Advantage Policy - Kyphoplasty and Vertebroplasty

Clinical Guidelines for Medical Necessity Review

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Important Notices

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Guideline Information:

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Type: [**X**] Adult (18+ years of age) | [**X**] Pediatric (0-17 years of age)

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Medical Necessity Criteria

Service: Kyphoplasty and Vertebroplasty

Benefit Category

Not applicable.

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.[1-2]

Related CMS Documents

Please refer to the CMS Medicare Coverage Database for the most current applicable CMS National Coverage.

- Local Coverage Determination (LCD). Percutaneous vertebral augmentation (PVA) for vertebral compression fracture (VCF) (L34976)
    - Billing and Coding: Percutaneous vertebral augmentation (PVA) for osteoporotic vertebral compression fracture (VCF) (A57872)
- Local Coverage Determination (LCD). Percutaneous vertebral augmentation (PVA) for osteoporotic vertebral compression fracture (VCF) (L33569)
    - Billing and Coding: Percutaneous vertebral augmentation (PVA) for osteoporotic vertebral compression fracture (VCF) (A56178)

Recommended Clinical Approach

Vertebral compression fractures (VCF) can cause debilitating back pain which may negatively impact activities of daily living. Treatments for VCF include conservative treatment (e.g., physical therapy, rest, medication management) and surgical procedures. Kyphoplasty and vertebroplasty are minimally invasive procedures that involve injecting bone cement into a vertebral body due to a VCF or a disease process that has replaced the normal bony architecture.[3] Traditionally, vertebroplasty involves instilling bone cement directly into the vertebral body, while kyphoplasty involves creating several cavities with inflatable balloons, bone tamps, or osteotomes to attempt more controlled cement delivery and improved cement interdigitation.[4] The cement provides stability to the damaged vertebra, which may result in reduced pain and improved function.

Evaluation of Clinical Harms and Benefits

Cohere Health uses the criteria below to ensure consistency in reviewing the conditions to be met for coverage of kyphoplasty and vertebroplasty. This process helps to prevent both incorrect denials and inappropriate approvals of medically necessary services. Specifically, limiting incorrect approvals reduces the risks associated with unnecessary procedures, such as complications from surgery, infections, and prolonged recovery times.

The potential clinical harms of using these criteria may include:

- Reduced life expectancy. Although rare, serious complications such as infection, loss of bone mass, deep venous thrombosis, and pulmonary embolism can occur.[5]
- Further progression of symptoms. Untreated VCF can lead to spinal deformities, increased pain scores, height loss, and nerve damage.[6]
- Increased healthcare costs and complications from the inappropriate use of emergency services and additional treatments.

The clinical benefits of using these criteria include:

- Improved function and reduction in pain scores.[6]
- Significant survival and morbidity benefits compared to nonsurgical intervention.[7]
- Reduction of narcotic use and reduced length of hospital stay.
- Reduction in complications and adverse effects from unnecessary procedures. Proper use of diagnostic criteria can prevent unnecessary surgeries and associated risks.
- Enhanced overall patient satisfaction and healthcare experience.

This policy includes provisions for expedited reviews and flexibility in urgent cases to mitigate risks of delayed access. Evidence-based criteria are employed to prevent inappropriate denials, ensuring that patients receive medically necessary care. The criteria aim to balance the need for effective treatment with the minimization of potential harms, providing numerous clinical benefits in helping avoid unnecessary complications from inappropriate care.

In addition, the use of these criteria is likely to decrease inappropriate denials by creating a consistent set of review criteria, thereby supporting optimal patient outcomes and efficient healthcare utilization.

Medical Necessity Criteria

Indications

- ➔ **Kyphoplasty and vertebroplasty** is considered appropriate if **ANY** of the following are **TRUE:**
  - ◆ Painful osteoporotic vertebral fracture(s)as evidenced by **ALL** of the following[1-2]:
    - Acute (less than 6 weeks) or subacute (6-12 weeks) osteoporotic VCF (T1 – L5), based on symptom onset, and documented by **ANY** of the following advanced imaging findings:
      - Bone marrow edema on MRI; **OR**
      - Bone scan/SPECT/CT uptake; **AND**
    - Symptomatic as evidenced by **ANY** of the following[2]:
      - Hospitalized with severe pain (Numeric Rating Scale [NRS] or Visual Analog Scale [VAS] pain score greater than or equal to 8)[8-11]; **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[5]:
        - ◆ Worsening pain noted; **OR**
        - ◆ Stable to improved pain (but NRS or VAS still greater than or equal to 5) as evidenced by **AT LEAST TWO** 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 (Roland Morris Disability Questionnaire [RDQ] of at least 17); **AND**

- Continuum of care is required and includes **ANY** of the following[5]:
    - Referral to evaluation of bone mineral density; **OR**
    - Referral to osteoporosis education for subsequent treatment as indicated; **OR**
    - Referral to an osteoporosis prevention/treatment program; **OR**

◆ The patient has **ANY** of the following:

- Osteolytic vertebral metastasis or myeloma with severe back pain related to a destruction of the vertebral body, not involving the major part of the cortical bone[1]; **OR**
- Painful and/or aggressive vertebral hemangioma.[22-25]

Non-Indications

➔ **Kyphoplasty and vertebroplasty** are not indicated if **ANY** of the following is **TRUE**[1-2]:

◆ Current back pain is not primarily due to the identified acute or subacute VCF(s)[3-9]; **OR**

◆ Pregnancy; **OR**

◆ Osteomyelitis, discitis, active systemic or surgical site infection[3-6,10,12]; **OR**

➔ **Kyphoplasty and vertebroplasty** may not be indicated if **ANY** of the following is **TRUE**[1-2]:

◆ Greater than three vertebral fractures per procedure; **OR**

◆ Neurologic deficit; **OR**

◆ Neural impingement; **OR**

◆ Retropulsion/canal compromise; **OR**

◆ Spinal instability; **OR**

◆ Uncorrectable coagulopathy[12]; **OR**

◆ Allergy to bone cement or opacification material.

Level of Care 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

Disclaimer: S Codes are non-covered per CMS guidelines due to their experimental or investigational nature.

Medical Evidence

Clark et al. (2016) performed a double-blind, randomized controlled trial (RCT) of vertebroplasty in patients with one or two osteoporotic vertebral fractures of less than 6 weeks in duration and Numeric Rated Scale (NRS) back pain greater than or equal to 7 out of 10. The goal of this RCT was to test whether vertebroplasty provides effective analgesia for patients with poorly controlled pain and osteoporotic spinal fractures. The primary outcome was the proportion of patients with NRS pain below 4 out of 10 at 14 days post-intervention. In total, 120 patients were enrolled. 61 patients were assigned to undergo vertebroplasty and 59 were assigned to the placebo group. Vertebroplasty was performed with the adequate vertebral fill technique and the placebo procedure with simulated vertebroplasty. 24 patients in the vertebroplasty group and 12 in the control group had an NRS pain score below 4 out of 10 at 14 days. In total, there were 2 serious adverse events in each group, related to the procedure (vertebroplasty group) and the fracture (placebo group). The authors concluded that vertebroplasty is superior to placebo intervention for pain reduction in patients with acute osteoporotic spinal fractures of less than 6 weeks in duration.[9]

Daher et al. (2023) conducted a meta-analysis in patients requiring treatment for osteoporotic VCF (OVCF). The goal of this analysis was to review qualified studies in order to compare balloon kyphoplasty to vertebroplasty in the management of OVCF. A total of 8 studies were included, which assessed clinical outcomes consisting of complications (cement leakage and adjacent level fractures), VAS pain scores, Oswestry disability index, kyphotic wedge angle, and vertebral body height restoration. PubMed, Cochrane, and Google Scholar were used for the literature review in accordance with PRISMA guidelines. In total, 619 subjects were involved in this study. 325 subjects were placed in the kyphoplasty group and 294 were placed in the vertebroplasty group. The authors concluded that kyphoplasty can increase postoperative vertebral body height and decrease the risk of cement leakage to a greater extent than vertebroplasty while the rest of the analyzed outcomes were not significantly different in either group.[18]

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