Kyphoplasty and Vertebroplasty

Date of Origin: 10/2003 **Last Review Date: 02/28/2024** **Effective Date: 03/01/2024**

Dates Reviewed: 10/2004, 10/2005, 11/2006, 11/2007, 11/2008, 07/2010, 06/2012, 04/2013, 04/2014, 04/2015, 12/2015, 02/2019, 02/2020, 03/2021, 02/2022, 02/2023, 02/2024

Developed By: Medical Necessity Criteria Committee

I. Description

Percutaneous vertebroplasty is a therapeutic, interventional radiologic procedure performed under imaging guidance that consists of the injection of medical grade cement through a needle into a painful fractured cervical, thoracic or lumbar vertebral body to stabilize the fracture. Vertebroplasty is performed in an attempt to relieve pain and strengthen the spine.

Percutaneous kyphoplasty is similar to vertebroplasty in that stabilization of a collapsed vertebra is accomplished by the injection of bone cement. Under fluoroscopic guidance, an inflatable balloon is inserted to expand a collapsed vertebral body to its natural height prior to the injection of the cement. With kyphoplasty, some of the bony deformity and resulting kyphosis may be reduced which will often significantly improve a patient's pain.

II. Criteria: CWQI HCS-0049A

A. For the following **urgent/emergent indications/conditions**, vertebroplasty or kyphoplasty will be covered to plan limitations WITHOUT a trial of conservative treatment and WITHOUT submission of imaging:
   a. Primary metastatic neoplastic disease-causing pathological fracture
   b. Documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated

B. For **non-urgent/non-emergent, indications/conditions,** vertebroplasty or kyphoplasty will be covered to plan limitations when **ALL** of the following have been met:
   a. Patients with acute (< 4 months of symptoms) vertebral collapse and persistent, debilitating pain in the cervical, thoracic or lumbar vertebral bodies confirmed by plain film, CT or by MRI resulting from **1 or more** of the following:
      i. Painful osteoporotic or osteolytic vertebral collapse/compression fractures (e.g. Kummell's disease)
      ii. Osteolytic metastases including destruction of a vertebral body by multiple myeloma
      iii. Painful and aggressive space occupying lesions of a vertebral body (hemangioma/eosinophilic granuloma)
      iv. Primary malignant neoplasm of bone or bone marrow
      v. Pre-surgical stabilization of a vertebral body to facilitate a fusion operation

vi. Steroid induced fractures
vii. Secondary osteolytic metastasis, excluding sacrum and coccyx

b. Persistent debilitating pain including **both** of the following:
    i. Pain level at least 7 on Visual Analog Scale (VAS/Number Rating Scale (NRS) on a daily basis
    ii. Clinically significant functional impairment (e.g. inability to perform basic activities of daily living [ADLs], such as ambulation, sitting, bathing, transfers).

c. Either of the following:
    i. Acute (0-6 weeks) axial back pain that persists at a level that prevents independent transfers and/or ambulation and correlates with the level of the fracture
    ii. Subacute (more than 6 weeks) axial pain in the thoracic/lumbar spine
        1. Failure of clinically significant improvement after at least 4 weeks of BOTH of the following (unless contraindicated):
            a. Prescription strength analgesics, steroids, and/or NSAIDS
            b. Physical therapy or chiropractic therapy

C. Moda Health considers Vertebral Augmentation (Percutaneous Vertebroplasty/Kyphoplasty) **NOT** medically necessary for ANY of the following:

a. The presence of any of the following contraindications:
    i. Uncorrected coagulation disorders or anticoagulation therapy
    ii. Active osteomyelitis of the affected vertebra
    iii. Neurological symptoms related to spinal decompression
    iv. Lack of neurological backup for emergency decompression in the event a neurological deficit develops during the injections of PMMA
    v. Absence of a confirmed acute or subacute fracture
    vi. Unstable fracture or requirement for stabilization procedure in the same or adjacent spinal region
    vii. Asymptomatic vertebral compression fracture
    viii. Burst fracture with retropulsed fragments
    ix. Known allergy to materials used in either procedure
    x. Myelopathy associated with a bone fragment in the spinal canal or cord compression from a tumor
    xi. Extensive vertebral destruction
    xii. Potential space occupying lesions causing cord compression (tumor, bone fragment)
    xiii. Collapse of the vertebral body to less than the level of the vertebra plana
    xiv. The use of Norian XR cement and Norian SRS cement products is prohibited because they are not FDA approved
    xv. Radiculopathy from a herniated intervertebral disc
    xvi. Untreated symptomatic foraminal or canal stenosis, facet arthropathy, or other significant coexistent spinal or bony pain generators
    xvii. Septicemia and any active infection (including UTI)
    xviii. Presence of painful metastases to areas other than the spine, spinal cord compression, primary bone and osteoblastic tumors, solitary plasmacytomas
    xix. Severe cardiopulmonary disease
    xx. Applications in the cervical spine

b. The presence of ANY of the following alternative causes of axial back pain:
    i. Lumbar/thoracic radiculopathy or facet disease
    ii. Lumbar/thoracic/sacral trigger points
    iii. Sacral insufficiency fractures

D. Moda Health considers Vertebral Augmentation (Percutaneous Vertebroplasty/Kyphoplasty) experimental or investigational for EITHER of the following:
    a. Percutaneous vertebral augmentation for ANY of the following:
        i. Non-painful/non-aggressive vertebral hemangioma
        ii. Vertebrae of the cervical spine and thoracic levels T1-T4
        iii. Stabilization of insufficiency fractures or lesions of the sacrum (sacroplasty) or coccyx (coccygeoplasty)
        iv. Prophylactic treatment for osteoporosis of the spine
        v. Prophylactic treatment for chronic back pain of longstanding duration (> 6 months), even if associated with an old compression fracture(s)
        vi. Percutaneous mechanical vertebral augmentation using any device other than a balloon device, including, but not limited to use of the Kiva system and radiofrequency-assisted vertebral augmentation
    b. Spinoplasty (e.g. OptiMesh® 1500E Polyethylene Terephthalate [PET] mesh pouch)

III. Information Submitted with the Prior Authorization Request:

1. Medical records from the treating physician documenting the spinal level involved, the severity of pain, previous treatments tried, and the patient's neurologic condition
2. X-Ray, CT, or MRI report documenting vertebral collapse

IV. Applicable CPT or HCPC codes covered:

Codes	Description
22510	Percutaneous vertebroplasty, 1 vertebral body, unilateral or bilateral injection; thoracic
22511	Percutaneous vertebroplasty, 1 vertebral body, unilateral or bilateral injection; lumbar
22512	Percutaneous vertebroplasty, 1 vertebral body, unilateral or bilateral injection; each additional thoracic or lumbar 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, one vertebral body, unilateral or bilateral cannulation (e.g., kyphoplasty), including of all imaging guidance; thoracic
22514	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, one vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty), including all imaging guidance; lumbar
22515	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, one vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)

V. Annual Review History

Review Date	Revisions	Effective Date
04/2013	Annual Review: Added table with review date, revisions, and effective date	04/24/2013
04/2014	Annual Review: No change	04/30/2014
04/2015	Annual Review: No change	04/25/2015
07/2015	Added ICD-9 and ICD-10 Codes	07/2015
12/1/15	Edited with new LCD- Deleted ICD-9 codes	12/2/2015
03/2017	Annual Review: Updated to new template	03/22/2017
02/27/2019	Annual Review: Updated reference to Medicare resource; Updated to include more specific criteria	03/01/2019
02/26/20	Annual Review: removed deleted codes, no content change	03/01/2020
03/24/21	Annual Review: no content change	04/01/2021
02/2022	Annual Review: No changes	03/01/2022
02/2023	Annual Review: Grammar updates	03/01/2023
02/2024	Annual Review: No changes	03/01/2024

VI. References

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26. Physician Advisors

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
M48.50XA	Collapsed vertebra, not elsewhere classified, site unspecified, initial encounter for fracture
M80.08XA	Age-related osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M81.0	Age-related osteoporosis without current pathological fracture
M81.0	Age-related osteoporosis without current pathological fracture
M81.8	Other osteoporosis without current pathological fracture
M84.48XA	Pathological fracture, other site, initial encounter for fracture
M84.68XA	Pathological fracture in other disease, other site, initial encounter for fracture
M89.00	Algoneurodystrophy, unspecified site
S12.200A	Unspecified displaced fracture of third cervical vertebra, initial encounter for closed fracture
S12.201A	Unspecified nondisplaced fracture of third cervical vertebra, initial encounter for closed fracture
S12.300A	Unspecified displaced fracture of fourth cervical vertebra, initial encounter for closed fracture
S12.301A	Unspecified nondisplaced fracture of fourth cervical vertebra, initial encounter for closed fracture
S12.400A	Unspecified displaced fracture of fifth cervical vertebra, initial encounter for closed fracture
S12.401A	Unspecified nondisplaced fracture of fifth cervical vertebra, initial encounter for closed fracture
S12.500A	Unspecified displaced fracture of sixth cervical vertebra, initial encounter for closed fracture
S12.501A	Unspecified nondisplaced fracture of sixth cervical vertebra, initial encounter for closed fracture
S12.600A	Unspecified displaced fracture of seventh cervical vertebra, initial encounter for closed fracture
S12.601A	Unspecified nondisplaced fracture of seventh cervical vertebra, initial encounter for closed fracture
S12.9XXA	Fracture of neck, unspecified, initial encounter
S22.009A	Unspecified fracture of unspecified thoracic vertebra, initial encounter for closed fracture
S32.009A	Unspecified fracture of unspecified lumbar vertebra, initial encounter for closed fracture
S32.10XA	Unspecified fracture of sacrum, initial encounter for closed fracture
SS32.2XXA	Fracture of coccyx, initial encounter for closed fracture

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): J	**NCD/LCD Document (s): L34106**
Noridian Local Coverage Determination (LCD) Percutaneous Vertebral Augmentation (L34106)	

NCD/LCD Document (s):
https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34106&ver=27&Date=&DocID=L34106&SearchType=Advanced&bc=KAAAABAAAAAA&

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC