BlueCross BlueShield of North Carolina

Medicare Part C Medical Coverage Policy

Vertebroplasty and Percutaneous Vertebral Augmentation

Origination Date: December 16, 2002 Vertebroplasty
August 20, 2003 Kyphoplasty
Review Date: January 19, 2022
Next Review: January, 2024

******This policy applies to all Blue Medicare HMO, Blue Medicare PPO, Blue Medicare Rx members, and members of any third-party Medicare plans supported by Blue Cross NC through administrative or operational services. ******

DESCRIPTION OF PROCEDURE OR SERVICE

Percutaneous Vertebroplasty (PVP)

Percutaneous vertebroplasty is a therapeutic, interventional radiologic procedure, which consists of the injection of a biomaterial (usually polymethylmethacrylate- bone cement) under imaging guidance (either fluoroscopy or CT) into a cervical, thoracic or lumbar vertebral body lesion for the relief of pain and the strengthening of bone.

Percutaneous Vertebral Augmentation (PVA)

This is also known as balloon-assisted Percutaneous Vertebroplasty or Kyphoplasty. The procedure is similar to percutaneous vertebroplasty in that stabilization of the collapsed vertebra is accomplished by the injection of the same biomaterial into the body of the vertebra.

The primary difference is that the fracture is partially reduced with the insertion of an inflatable balloon tamp. Once inflated, the balloon tamp (plug) restores some height to the vertebral body, while creating a cavity that is filled with bone cement.

POLICY STATEMENT

Coverage will be provided for Percutaneous Vertebroplasty or Percutaneous Vertebral Augmentation when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

BENEFIT APPLICATION

Please refer to the member's individual Evidence of Coverage (EOC) for benefits.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations (NCDs);

- General coverage guidelines included in Original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (EOC), the EOC always governs the determination of benefits.

INDICATIONS FOR COVERAGE

A. Osteoporotic Conditions

Painful, debilitating, osteoporotic vertebral collapse/compression fractures, that have not responded to non-surgical management (e.g., narcotic and/or non-narcotic medication, physical therapy modalities) with or without methods of immobility (e.g., bed rest, bracing).

Both PVP and PVA will be considered reasonable and necessary for osteoporotic conditions when **ALL** of the following criteria are met:

1. Acute (< 6 weeks) or subacute (6-12 weeks) osteoporotic Vertebral Compression Fracture (VCF) (T5 – L5) based on symptom onset, and documented by recent (within 30 days) advanced imaging (bone marrow edema on MRI or bone-scan/SPECT/CT uptake) **and**
2. The member is symptomatic and is hospitalized with severe pain (Numeric Rating Scale [NRS] or visual Analog Scale [VAS] pain score ≥ 8) (4-7) or is non-hospitalized with moderate to severe pain (NRS or VAS ≥ 5) despite optimal non-surgical management (NSM) with **one** of the following:
    i. Worsening pain or
    ii. Stable to improved pain (but NRS or VAS ≥ 5) when 2 or more of the following are present:
        a. Progression of vertebral body height loss
        b. >25% vertebral body height reduction
        c. Kyphotic deformity
        d. Severe impact of VCF on daily functioning (Roland Morris Disability Questionnaire (RDQ) > 17)
        e. Steroid-induced fractures
        f. Reinforcement or stabilization of vertebral body prior to surgery

B. Malignant Vertebral Fractures

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. Painful osteolytic metastasis
2. Multiple myeloma with painful vertebral body involvement

C. Trauma Compression Fractures

Trauma, even minor falls, can produce a spine fracture. Many of these injuries will never require surgery, but major fractures can result in serious long-term problems unless treated promptly and properly. These severe injuries frequently result in spinal instability, with a high risk of spinal cord injury and pain, which can produce a spine fracture. **PVA** is considered reasonable and necessary for the following traumatic conditions.

1. Stable and/or unstable burst fractures
2. Wedge compression fractures
3. Fracture-dislocations that occur following auto accidents or falls from height

For both percutaneous vertebroplasty and vertebral augmentation, the decision for treatment should take into consideration the local and general extent of the disease. This includes the spinal level involved, the severity of pain experienced by the patient, his/her neurologic condition, previous treatments and their outcomes, the general state of health and life expectancy.

Limitations:

A. **Absolute Contraindications for both procedures:**
   1. Current back pain is not primarily due to the identified acute VCF(s);
   2. Osteomyelitis, discitis or active systemic infection

B. **Relative Contraindications for both procedures:**
   1. Greater than three vertebral fractures per procedure
   2. Allergy to bone cement or opacification agents
   3. Uncorrected coagulopathy
   4. Spinal Instability
   5. Myelopathy from the fracture
   6. Neurologic deficit
   7. Fracture retropulsion/canal compromise
   8. Pregnancy

Special Notes:

A. These procedures are not considered prophylactic for osteoporosis of the spine or for chronic back pain of long-standing duration, even if associated with old compression fractures, unless pain is localized to a specific chronic fracture and medical therapy has failed.

BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

Applicable codes:
Vertebroplasty Codes: 22510; 22511; 22512; 22513; 22514; 22515; 22899

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

References:

1. Medicare Local Coverage Determination for Vertebroplasty/Vertebral Augmentation Retired (L33473) – Palmetto GBA Part A/B; Effective date: 10/01/2015: Accessed via www.cms.gov. 11/2021.
2. Medicare Local Coverage Determination for Vertebroplasty, Vertebral Augmentation including cavity creation Retired (L34592) – Wisconsin Physicians Service; Effective date: 02/01/2016. Accessed via www.cms.gov 5/16/18.
3. Medicare Local Coverage Determination for Percutaneous Vetebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L38213)- Accessed via www.cms.gov. 12/20/2021.
4. BCBSNC Corporate Medical Policy "Vertebroplasty and Kyphoplasty, Percutaneous "Effective date 8/2010; Accessed online at http://www.bcbsnc.com/content/providers/medical-policies-and-coverage/index.htm; Viewed on 12/20/21.

Policy Implementation/Update Information:

Revision Date: 8/20/03 Policy renamed to Vertebroplasty and Kyphoplasty, Percutaneous, 8/2003. Previous policy name "Vertebroplasty Percutaneous-Medicare + Choice."
Revision Date: September 2009: Code review only.
Revision Date: 1/05/11 Policy renamed to Vertebroplasty and Percutaneous Vertebral Augmentation, per new CMS policy.

- Description of Procedure/Service section: Updated with current CMS language. Replaced Kyphoplasty with Percutaneous Vertebral Augmentation.
- Indications for Coverage section: For Vertebroplasty Coverage: Bullets 3 and 5 pertaining to retired policies and Contraindications section were removed. First two bullet items added from LCD L31344.
  For Percutaneous Vertebral Augmentation: Updated language from new policy, bullet 3 pertaining to retired policies removed, and added bullet 1, from new policy.
- When Coverage Will Not Be Approved section: Removed this section and associated language pertaining to retired LCD L22552 and replaced with the Contraindications section from LCD L31344 and L17864 for clarity.
- Reference section: New CMS policy added and retired policies L22552 and L9710 removed.
- Limitations: Added this section and language to policy to mirror new CMS policy.

Revision Date: 03/15/2013: Annual review; Reformatted and to mirror NCD.
Revision Date: 08/20/2014: This policy was revised to eliminate the time frame for conservative therapy for criteria B.2. Also, multidisciplinary was deleted regarding the decision for treatment. No changes in LCD or NCD noted.
Revision Date: 1/21/15; Updated codes and added to policy; no other revisions required. October 29, 2015 updated LCD due to ICD-10 update only.
Revision Date: 9/21/2016: Policy Revised by removing Sub point (A) from the Limitations Section to reflect changes on the updated LCD (L33473). No other changes. Minor revisions only.
Revision Date: 5/16/18; Annual Review. No CMS Updates. Minor Revisions Only.
Revision Date: 10/16/19; Staff Clarification; Added: Limitations Section: D. If vertebroplasty is being performed to the sacral region (sacroplasty), this is a non-covered service even when billed with a covered code (ex. 22511).
Revision Date: 6/17/20; Annual Review; CMS Updates to LCD. Minor revisions only. Criteria still current with Part B LCD.
Revision Date: 12/20/21; Retired LCD L33473, Reformatted policy to align with LCD L38213.

Approval Dates:

Medical Coverage Policy Committee: January 19, 2022

Policy Owner: Carolyn Wisecarver, RN, BSN
Medical Policy Coordinator