I. Policy: Vertebroplasty and Percutaneous Kyphoplasty

II. Purpose/Objective:
   To provide a policy of coverage regarding Vertebroplasty and Percutaneous Kyphoplasty

III. Responsibility:
   A. Medical Directors
   B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member’s condition, illness, disease or injury;

b. provided for the diagnosis, and the direct care and treatment of the Member’s condition, illness disease or injury;

c. in accordance with current standards of good medical treatment practiced by the general medical community.

d. not primarily for the convenience of the Member, or the Member’s Health Care Provider; and

e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member’s condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.
DESCRIPTION:
Vertebroplasty is an interventional radiology technique that has been investigated as a therapy for pain relief and bone strengthening in vertebral collapse secondary to osteoporosis, painful vertebral hemangioma, osteolytic metastases and multiple myeloma. Polymethylmethacrylate is inserted through a fluoroscopically guided needle into the weakened vertebral body. Percutaneous sacroplasty, a variation of vertebroplasty, is an evolving technique that has been proposed for the treatment of sacral insufficiency fractures. Kyphoplasty (also known as Percutaneous Vertebral Augmentation) is a minimally invasive procedure used in the treatment of vertebral fractures. This technique involves the use of an inflatable bone tamp (i.e. KyphX™) inserted into a weakened or collapsed vertebral body. This procedure, used in conjunction with vertebroplasty, is used to restore vertebral body height after vertebral collapse related to osteoporosis, reduce pain, and restore mobility in affected persons.

INDICATIONS:
Requests for this service should be accompanied by medical record documentation including clinical presentation, previous conventional non-invasive treatments (trial of bed rest and analgesics), radiographic imaging to differentiate covered indications from other etiologies of back pain such as but not limited to disc herniation, spinal cord or nerve root compression, discogenic back pain, facet arthropathy or spinal stenosis.
Vertebroplasty and Kyphoplasty of the cervical, lumbar and thoracic region is covered for ANY of the following indications:

- Acute osteoporotic vertebral collapse (age of fracture must be 6 months or less) with persistent debilitating pain which is refractory to conservative medical treatment
- Vertebral metastasis
- Vertebral Myeloma
- Vertebral plasmacytoma
- Painful and/or aggressive vertebral hemangiomas
- Steroid induced vertebral fracture
- Painful vertebral eosinophilic granuloma with spinal instability
- Traumatic vertebral compression fracture*

*At present, vertebroplasty for treatment of traumatic compression fractures in young, otherwise healthy patients is not recommended because the long-term effects of vertebral PMMA injection are unknown. The majority of these patients have the normal capacity to heal the fracture within 4-6 weeks; in the interim, symptomatic relief can be obtained with oral analgesics, bedrest and bracing. (Stallmeyer, Zoarski, Obuchowski 2003)

FOR MEDICARE BUSINESS SEGMENT:
Please see Novitas Solutions, Inc. L35130 Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)

LIMITATIONS:
Coverage for vertebroplasty and kyphoplasty is limited to 2 vertebral levels on the same date of service.

Complications related to the use of polymethylmethacrylate bone cement such as soft tissue damage, pulmonary embolism, nerve root pain and compression, respiratory and cardiac failure, and death have been reported in the medical literature and to the FDA. Coverage for vertebroplasty and kyphoplasty is dependent upon any FDA decisions related to the bone cement used in this procedure.

Coverage is limited to painful osteoporotic vertebral fractures. Coverage will not be approved for fractures caused by high velocity injury, fractures associated with retropulsion of bone as in burst fracture, asymptomatic fractures, fractures healing by conservative methods, kyphosis without fracture, or as a treatment of pulmonary function or gastrointestinal complications secondary to kyphosis.

CONTRAINDICATIONS:
- Uncorrected coagulation disorders
- Significant vertebral collapse (greater than 70%) or extensive vertebral destruction (relative contraindication)
- Neurologic symptoms related to compression (relative contraindication)
- Active infection, osteomyelitis, discitis or epidural abscess
- Asymptomatic compression fracture
- Prophylaxis in osteoporotic patients
- Retropulsed bone fragment resulting in myelopathy
- Allergy to contrast material or components of the bone cement
- Systemic or local infections

**EXCLUSION:** The Plan does **NOT** provide coverage for Percutaneous Sacroplasty because it is considered experimental, investigational or unproven. There is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes when compared to established treatments or technologies.

**Note:** A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment.**

**CODING ASSOCIATED WITH:** Vertebroplasty

*The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services.*

- 22510 Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic
- 22511 Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral [when specified as lumbar]
- 22512 Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body [when specified as other than sacral]
- 22513 Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic
- 22514 Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar
- 22515 Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body
- 22899 Unlisted procedure, spine
- 0200T Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles
- 0201T Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 2 or more needles

**LINE OF BUSINESS:**

Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supersede this policy. For PA Medicaid Business segment, this policy applies as written.
REFERENCES:

Technology Evaluation Center, TEC Review. Percutaneous Vertebroplasty, 15(21), March 2001


BlueCross BlueShield Association (BCBSA), Technology Evaluation Center (TEC). Percutaneous vertebroplasty or kyphoplasty for vertebral fractures caused by osteoporosis. TEC Assessment Program. Chicago, IL: BCBSA; April 2010; 24(7).


Mukherjee, S., Yeh, J., Ellamushi, H. Pain and functional outcomes following vertebroplasty for vertebral compression fractures – a tertiary centre experience. Brit J Neurosurg. 2015


Novitas Solutions, Inc. L35130 Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF)

This policy will be revised as necessary and reviewed no less than annually.

Devised: 8/03

Revised: 5/04; 5/05 (grammatical); 7/10 (exclusions and coding); 2/11(removal of PA); 7/15 (added indication), 7/16, 6/20 (Medicare coverage citation)

Reviewed: 5/06; 5/07; 5/08; 5/09; 6/11, 7/12, 7/13, 7/14, 6/17, 6/18, 6/19

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.