


<p align="center">PROVIDENCE HEALTH ASSURANCE MEDICAL POLICY</p>	<p align="center">Back: Vertebroplasty and Kyphoplasty for Vertebral Fractures (Medicare Only)</p>	
<p>Effective Date: 1/1/2019</p>  <p align="right">1/1/19</p>	<p>Section: SUR</p>	<p>Policy No: 418</p>
<p>Medical Officer Date</p>	<p>Medical Policy Committee Approved Date: 12/17; 12/18</p>	

See Policy CPT CODE section below for any prior authorization requirements

APPLIES TO:

Medicare Only

POLICY CRITERIA

This policy is based on the Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCD): Percutaneous Vertebral Augmentation (L34106).¹ This CMS guidance was identified as of the last policy review date on 12/1/2017.

Coverage Indications, Limitations, and/or Medical Necessity

This LCD applies to all types of and methods involving any procedure affecting vertebral augmentation, such as balloon reduction and augmentation, vertebroplasty.

Indication

There is only one indication for these procedures: treatment of acute (< 4 months of symptoms) and painful compression fracture(s), regardless of etiology, in a patient without contraindication due to neurological deficits:

- The fracture may be demonstrated by plain film, CT or by MRI. The findings must correlate unequivocally with the site of the patient’s pain as demonstrated by physical examination.
- Acuity may be established by history, MRI and/or nuclear medicine bone scan.
- Pain must be predominantly related to the demonstrated fracture(s), of moderate to severe intensity (e.g., pain level at least 6 on VAS 1-10), such that the patient cannot perform basic activities of daily living (ADLs), such as ambulation, sitting, bathing, transfers.
- Pain must be refractory to conservative measures employed for reasonable periods of time, such as medication management with appropriate titration.
 - Generally, procedures are not medically reasonable and necessary when performed immediately after the fracture occurs. Exceptions will not be allowed unless the medical record establishes a clear rationale for the exception. For example, “adequate

pain control impairs basic ADLs” or “is associated with respiratory compromise.”

- If pain may be due to one or more conditions, **prior** to any vertebral augmentation procedure, an appropriately comprehensive pain assessment and consequent pain management treatment plan must be instituted. Other probable causes of pain must be reasonably excluded. The treatment plan must begin with the least invasive approach that addresses identified pain generators; potentially, an implantable pump for analgesia or surgical stabilization in a patient with concurrent instability.
- An interval assessment by the proceduralist is an absolute requirement if the procedure is performed by any provider other than the diagnostician who performed the pain assessment and developed the plan of care. The proceduralist must document the rationale for proceeding with treatment in the medical record.
- The medical record must contain a detailed operative procedure narrative report. “Boilerplate” or other non-specific “canned” reports does not fulfill this requirement.
- While treatment of only one to two levels would be anticipated, treatment of no more than three (3) vertebral levels within the range of T1-L5 may be covered and reimbursed during the entire episode of pain caused by or related to an acute compression fracture(s), regardless of the number of fractures. Hence, if more than three acute fractures are present, alternative therapies must be employed. Treatment of three levels may be subject to pre- or post-pay review.
 - Exceptions: steroid-induced osteoporosis and multiple myeloma when conservative measures have been demonstrated to be inadequate in the specific patient and result in the inability to perform basic ADLs.
- Procedures must be performed with real-time CT or fluoroscopic imaging guidance, Images of final trocar placement and appearance of the vertebral body at the end of the procedure must be available on request.
- The medical record **must** contain assessment of patient condition and response to treatment at one month, three months and 6 months post-procedure unless the patient is enrolled in a registry. Telephone follow-up with documentation of outcomes is acceptable. Documentation of at least two (2) unsuccessful and reasonable attempts to contact the patient may substitute for the 3 or 6 month follow-up evaluations.
- Enrollment in a registry with an outcomes documentation schedule consistent with that described in this LCD is an acceptable substitute for medical records’ follow-up documentation. Any acceptable registry must be compliant with the principles established in AHRQ’s “Registries for Evaluating Patient Outcomes: A User’s Guide”. (See bibliography.) Noridian knows of one such registry currently available for enrollment.
- The link to the registry is: <http://www.benchmarkmedical.com/VCF-Registry/> This homepage describes the registry as well as registration resources.
- No percutaneous vertebral augmentation procedure, such as sacroplasty, is indicated for treatment of lesions of the sacrum or coccyx. The CPT Category III codes, 0200T and 0201T, are non-covered.

Contraindications

- Absence of a confirmed fracture or fracture more than 4 months unless there is evidence of edema on MRI. Symptoms that cannot be directly related to a specific acute fracture(s).
- Prophylactic treatment for osteoporosis of the spine or for chronic back pain unrelated to compression fractures. All prophylactic procedures will be denied.
- Symptomatic foraminal stenosis, other spinal degenerative disease, facet arthropathy, or other significant coexistent spinal or bony pain generators that account for the predominant portion of the patient's pain. These conditions require treatment before reimbursement for vertebral augmentation procedures may be considered. Following adequate address of other pain generators accounting for most of the patient's pain, residual disabling pain localized to the compression fracture may allow payment for vertebroplasty or vertebral augmentation procedures.
- Investigational procedures such as performance of a vertebral augmentation procedure concurrent with an open spinal surgical procedure.
- Unstable fracture or requirement for stabilization procedure in same or adjacent spinal region.
- Presence of painful metastases to areas other than the spine unless radiotherapy and other conservative measures have failed to relieve the pain due to the compression fracture.
- Presence of any other condition described as a contraindication in the FDA labeling.

Special Considerations

- Bone biopsy done at the same level as Vertebral Augmentation is part of the primary procedure and is not be separately payable consistent with CPT Manual instructions.
- In and of themselves, vertebral augmentation procedures do not require inpatient admission and the procedures do not appear on the Inpatient Only list.

Provider Qualifications

- Patient safety and quality of care mandate that healthcare professionals who perform Facet Joint Injections, Medial Branch Blocks, and Facet Joint Radiofrequency Neurotomy percutaneous vertebral augmentation procedures are appropriately experienced and/or trained to provide and manage the services. The CMS Manual System, Pub. 100-8, Program Integrity Manual, Chapter 13, Section 5.1 (<http://www.cms.hhs.gov/manuals/downloads/pim83c13.pdf>) underscores this point and states that "reasonable and necessary" services must be "ordered and/or furnished by qualified personnel." Services will be considered medically reasonable and necessary only if performed by appropriately experienced and/or formally trained providers.
- The following training requirement applies only to those providers who have not provided these specific interventional pain management services on a regular basis (at least one time per month) during the ten years prior to the effective date of this LCD as may be established by claims billings.
- A basic requirement of payment is training and/or credentialing by a formal residency/fellowship program and/or other training program that is accredited by a nationally-

recognized body and whose core curriculum includes the performance and management of the procedures addressed in this policy. (Recognized accrediting bodies include only those whose program accreditation gains the trainee eligibility to sit for a healthcare-related licensing exam or licensing itself, which in turn allows the licensee to perform these procedures. At a minimum, training must cover and develop an understanding of anatomy and drug pharmacodynamics and kinetics, the technical performance of the procedure(s) and utilization of the required associated imaging modalities, and the diagnosis and management of potential complications from the intervention.

- The following credentialing requirement applies to all providers of the services addressed in this policy. If the practitioner works in a hospital facility at any time and/or is credentialed by a hospital for any procedure, the practitioner must be credentialed to perform the same procedure in the outpatient setting.

POLICY GUIDELINES

All the documentation requirements described in the Indications section of this LCD must be met. The most important clinical information – information that must be unequivocally documented in the medical record – is that one or more but less than four acute and painful vertebral compression fractures is/are present and that the patient’s pain is predominantly, if not solely, related to the demonstrated fracture(s).

CPT CODES

Medicare Only	
Prior Authorization Required	
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
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 (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 (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

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	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 (List separately in addition to code for primary procedure)
Not Covered	
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed

DESCRIPTION

In the US, more than one quarter of the population age 50 years or older experiences one vertebral fracture in the later years of life. Fractured vertebral bodies may produce intractable pain. Vertebral augmentation procedures are some of the invasive treatments that may be employed to address pain refractory to non-invasive therapeutic modalities. The percutaneous injection of medical cement or polymethylmethacrylate (PMM) or other material FDA-approved for this purpose into the vertebral body may reduce pain and improve function. One type of vertebral augmentation procedure, e .g. Kyphoplasty, also includes fracture reduction by expanding the intrabody space with a device such as a balloon. Following reduction, the bone cement is injected.

INSTRUCTIONS FOR USE

Providence Health Assurance (PHA) Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. PHA Medical Policies are reviewed annually and are based upon Centers for Medicare & Medicaid (CMS) coverage guidance available as of the last policy update. PHA reserves the right to determine the application of Medical Policies and make revisions to its Medical Policies at any time. Providers will be given at least 60-days' notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and PHA Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

REFERENCES

1. Centers for Medicare & Medicaid Services: Local Coverage Determination (LCD): Percutaneous Vertebral Augmentation (L34106). 2015; <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34106&ver=27&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&r=10&Keyword=vertebroplasty&KeywordLookUp=Doc&KeywordSearchType=Exact&kq=true&bc=IAAAACABAAA&>. Accessed 12/1/2017.