Vertebroplasty, Vertebral Augmentation; Percutaneous

FIRST COAST SERVICE OPTIONS
MAC - PART A/B
LOCAL COVERAGE DETERMINATION

LCD Database ID Number
L34976

Contractor Name
First Coast Service Options, Inc.

Contractor Number
09101 – Florida
09201 – Puerto Rico/Virgin Islands
09102 – Florida
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type
MAC – Part A and B

LCD Title
Vertebroplasty, Vertebral Augmentation; Percutaneous

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 Unless otherwise specified, italicized text represents quotation from one or more of the following CMS sources:

N/A
Vertebral Augmentation; Percutaneous

Primary Geographic Jurisdiction
Florida
Puerto Rico/Virgin Islands

Oversight Region
Region I

Original Determination Effective Date
10/01/2015

Original Determination Ending Date
N/A

Revision Effective Date
N/A

Revision Ending Date
N/A

Indications and Limitations of Coverage and/or Medical Necessity

Indications

Percutaneous Vertebroplasty

Percutaneous vertebroplasty is a therapeutic, interventional neurosurgical and radiological procedure that consists of the percutaneous injection of a biomaterial, methyl methacrylate, into a lesion of a thoracic or lumbar vertebral body. The procedure is utilized for pain relief and bone strengthening of weakened vertebral bodies.

The procedure is performed under fluoroscopic guidance, although some prefer the use of computed tomography (CT) with fluoroscopy for needle positioning and injection assessment. An intraosseous venogram is sometimes performed before cement injection to determine whether the needle is positioned within a direct venous anastomosis to the central or epidural veins, to minimize extravasation into venous structures. Conscious sedation with additional local anesthesia (1% lidocaine) is generally utilized; however, patients who experience difficulties with ventilation or are unable to tolerate prone position during the procedure may require general anesthesia or deep sedation with airway and ventilation support. The methyl methacrylate is injected into the vertebral body until resistance is met or until cement reaches the posterior wall. The procedure usually lasts from 1 to 2 hours, unless cement is injected into two or more vertebral bodies.

Percutaneous vertebroplasty procedure will be considered medically reasonable and necessary for the following indications:

- Painful osteolytic vertebral body metastatic disease;
- Painful multiple myeloma involving the vertebral body;
- Painful and/or aggressive hemangioma; or
- Painful, debilitating, osteoporotic vertebral collapse/compression fractures that have not responded to non-surgical medical management. (i.e., weeks to months of conservative management (e.g. narcotic and/or non-narcotic
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medication, physical therapy modalities) with and without methods of immobility (e.g. rest, bracing)), or in the rare exception to weeks to months of non-surgical medical management see “Limitation of Coverage”

Percutaneous Vertebral Augmentation

Percutaneous vertebral augmentation (vertebral augmentation) is a minimally invasive procedure for the treatment of compression fractures of the vertebral body. The procedure includes a cavity creation which results in fracture reduction along with an attempt to restore vertebral body height and alignment. Using image guidance x-rays, incisions are made and a probe is placed into the vertebral space where the fracture is located. The collapsed vertebral body is drilled and a device which displaces, removes or compacts the compressed area of the vertebrae is used to create a cavity prior to injection of bone filler (polymethylmethacrylate) (PMMA).

Vertebral augmentation procedure will be considered medically reasonable and necessary for the following indications:

- Painful osteolytic vertebral body metastatic disease;
- Painful multiple myeloma involving the vertebral body; or
- Painful, debilitating osteoporotic vertebral collapse/compression fractures that have not responded to non-surgical medical management. (i.e., weeks to months of conservative management (e.g. narcotic and/or non-narcotic medication, physical therapy modalities) with and without methods of immobility (e.g. rest, bracing)), or in the rare exception to weeks to months of non-surgical medical management see “Limitation of Coverage”

The decision to perform these procedures should take into consideration the following factors: the local and general extent of the disease, the spinal level involved, the severity of pain experienced by the patient, previous treatments and their outcomes, as well as the patient’s neurological condition, general state of health, and life expectancy. It is expected that only those skilled in this procedure/technique will perform it. Rapid access to emergency equipment and personnel is required for both percutaneous vertebroplasty and percutaneous vertebral augmentation.

Limitations of Coverage

Percutaneous vertebroplasty and percutaneous vertebral augmentation are not to be considered prophylactic for osteoporosis of the spine or for chronic back pain of long-standing duration, even if associated with old compression fractures.

In the rare exceptions to providing weeks to months of non-surgical medical management, the documentation must support that one or more vertebral compression fractures are present (confirmed by MRI or CT/bone scan if MRI is contraindicated) and that the patient’s pain is predominantly, if not solely, related to the demonstrated fracture(s). Complete assessment of the patient by the physician who performs the procedure is an absolute requirement. The History and Physical exam must be present in the medical record prior to performance of the procedure. The documentation must support the patient has severe debilitating pain unresponsive to adequate pain control and the rationale of proceeding to treatment within a brief period of time after the vertebral fracture has occurred. The medical record must document that appropriate imaging has been performed preoperatively and that the findings of the imaging performed correlate unequivocally with the patient’s pain.

Absolute Contraindications for both Percutaneous Vertebroplasty and Percutaneous Vertebral Augmentation

- Absence of confirmed acute or subacute fracture;
- Symptoms that cannot be related to a fracture;
- Radicular symptoms that are explained by bone impinging on nerves or another anatomic lesion;
- Unstable fracture;
- Asymptomatic vertebral compression fracture;
- Spinal canal compromise secondary to tumor resulting in myelopathy;
- Active osteomyelitis, whether fungal bacterial or mycobacterial;
- Symptomatic spinal stenosis with cauda equine symptoms or signs of cord compression;
- Uncorrected coagulation disorders; and
- Known allergy to any material used in the procedure (i.e. PMMA)
Absolute contraindications for Vertebral Augmentation

- Compression fractures without radiographic evidence of edema shown by medical record to be more than one year old;
- Retropulsed fracture fragment(s) or tumor mass causing significant spinal canal compromise (i.e. long tract or neurological symptom); and
- When it is technically not feasible (e.g., vertebra plana).

Relative Contraindications to Percutaneous Vertebroplasty

- significant vertebral collapse (i.e., vertebra reduced to less than one-third its original height); and
- extensive vertebral destruction

Sacroplasty (0200T, 0201T and 22899) performed for sacral insufficiency fractures due to osteoporosis or other conditions have been suggested as an extension of thoracic/lumbar procedures. The peer reviewed literature is incomplete. Sacroplasty is not the subject of this LCD. This coverage decision is limited to lesions of a thoracic or lumbar vertebral body. Therefore, claims for this procedure will continue to be evaluated on a case by case basis.

Type of Bill Code

012x Hospital Inpatient (Medicare Part B only)
013x Hospital Outpatient
021x Skilled Nursing - Inpatient (Including Medicare Part A)
083x Ambulatory Surgery Center
085x Critical Access Hospital

Revenue Codes

033X Radiology - Therapeutic and/or Chemotherapy Administration - General Classification
036X Operating Room Services - General Classification
049X Ambulatory Surgical Care - General Classification
076X Specialty Services - General Classification

CPT/HCPCS Codes

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 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar
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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)

76380  Computed tomography, limited or localized follow-up study

**ICD-10 Codes that Support Medical Necessity**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C41.2</td>
<td>Malignant neoplasm of vertebral column</td>
</tr>
<tr>
<td>C79.51-C79.52</td>
<td>Secondary malignant neoplasm of bone and bone marrow</td>
</tr>
<tr>
<td>C90.00-C90.02</td>
<td>Multiple myeloma</td>
</tr>
<tr>
<td>D18.09</td>
<td>Hemangioma of other sites</td>
</tr>
<tr>
<td>D47.Z9</td>
<td>Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue</td>
</tr>
<tr>
<td>M80.08XA-M80.08XS</td>
<td>Age-related osteoporosis with current pathological fracture, vertebra(e)</td>
</tr>
<tr>
<td>M80.88XA-M80.88XS</td>
<td>Other osteoporosis with current pathological fracture, vertebra(e)</td>
</tr>
<tr>
<td>M84.58XA-M84.58XS</td>
<td>Pathological fracture in neoplastic disease, other specified site</td>
</tr>
<tr>
<td>M84.68XA-M84.68XS</td>
<td>Pathological fracture in other disease, other site</td>
</tr>
<tr>
<td>S22.000A-S22.089S</td>
<td>Fracture of thoracic vertebra</td>
</tr>
<tr>
<td>S32.000A-S32.059S</td>
<td>Fracture of lumbar vertebra</td>
</tr>
</tbody>
</table>

**Diagnoses that Support Medical Necessity**

N/A

**ICD-10 Codes that DO NOT Support Medical Necessity**

N/A

**Diagnoses that DO NOT Support Medical Necessity**

N/A

**Associated Information**

**Documentation Requirements**

Medical record documentation (e.g., office/progress notes, history and physical, procedure notes) must indicate the medical necessity for performing this service. The documentation must also support that the service was performed. In addition the medical record documentation should indicate the local and general extent of the disease, the spinal level involved, the severity of pain experienced by the patient, previous treatments and their outcomes, as well as the patient’s neurological condition and general state of health.

The History and Physical exam must be present in the medical record prior to performance of the procedure. The documentation must support the patient has severe debilitating pain unresponsive to adequate pain control and the rationale of proceeding to treatment within a brief period of time after the vertebral fracture has occurred. The medical record must document that appropriate imaging has been performed preoperatively and that the findings of the imaging performed correlate unequivocally with the patient’s pain.]

When the service is performed for painful, debilitating, osteoporotic vertebral collapse/compression fractures, documentation must support that fractures have not responded to non-surgical medical management. (i.e., weeks to months of conservative
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management (e.g. narcotic and/or non-narcotic medication, physical therapy modalities) with and without methods of immobility (e.g. rest, bracing)). In the rare exceptions to providing weeks to months of non-surgical medical management, the documentation must support that one or more vertebral compression fractures are present (confirmed by MRI or CT/bone scan if MRI is contraindicated) and that the patient’s pain is predominantly, if not solely, related to the demonstrated fracture(s).

Documentation of the necessity of percutaneous vertebroplasty or vertebral augmentation in more than two levels should be maintained in patient’s medical record and made available upon request. If a repeat procedure on a single vertebra is to be performed, medical record documentation must support the medical necessity of the repeat procedure.

The Centers for Medicare & Medicaid Services (CMS) Online Manual System, Publication 100-08, Medicare Program Integrity Manual, Chapter 13, Section 13.5.1 outlines that “reasonable and necessary” services are “ordered and/or furnished by qualified personnel.” Services will be considered medically reasonable and necessary only if performed by appropriately trained providers. This training and expertise must have been acquired within the framework of an accredited residency and/or fellowship program in the applicable specialty/subspecialty or must reflect extensive continued medical education activities. If these skills have been acquired by way of continued medical education, the courses must be comprehensive, offered or sponsored or endorsed by an academic institution in the United States and/or by the applicable specialty/subspecialty society in the United States, and designated by the American Medical Association (AMA) as Category 1 Credit.

Utilization Guidelines

The use of percutaneous vertebroplasty or vertebral augmentation in more than two vertebral levels is rarely justified. Documentation of the necessity of use in more than two levels should be maintained in patient’s medical record and made available upon request. Coverage for any procedure is limited to no more than three (3) vertebral levels on any date of service if there is radiographic evidence to support acute fracture. Payable levels are only within the range of T5–L-5.

One procedure per lifetime per vertebra will be allowed. If a repeat procedure on a single vertebra is to be performed, medical record documentation must support the medical necessity of the repeat procedure.

Payment of vertebroplasty and vertebral augmentation will be all-inclusive for the entire procedure (i.e. injection, intraosseous venography, etc.)

Bone biopsy done at the same level as percutaneous vertebroplasty and percutaneous vertebral augmentation (CPT codes 20225, 20250, and 20251 is considered integral to both procedures and should not be separately billed.

Sources of Information and Basis for Decision

FCSO reference LCD number(s) – L29209, L29454, L34492


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LCDs and policies from other Medicare contractors and private insurers, accessed September, 2013.


Start Date of Comment Period
N/A

End Date of Comment Period
N/A

Start Date of Notice Period
04/10/2014
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**Revision Number:** Original

This LCD replaces all previous LCD versions (refer to “Sources of Information and Basis for Decision” section of the LCD) and publications on this subject to comply with ICD-10-CM based on Change Request 8112. The effective date of this LCD is based on date of service.

**Related Documents**

N/A

**LCD Attachments**

Coding guidelines

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