Percutaneous Vertebroplasty and Kyphoplasty
Clinical Coverage Criteria

Overview
As currently practiced, vertebral augmentation includes either percutaneous vertebroplasty, where bone cement (polymethylmethacrylate, PMMA) is injected percutaneously into the vertebral body, and kyphoplasty, where a balloon or bone tamp is introduced into the vertebral body, inflated, and then injected with PMMA. The latter procedure has the added potential benefit of restoring vertebral height and reducing spinal deformity.

Vertebral compression fractures (VCFs) are extremely prevalent and are a hallmark of osteoporosis. These fractures result in pronounced pain in addition to a negative impact on function and quality of life. Osteoporosis is the most frequent cause for VCFs and is the most important potentially modifiable risk factor for VCFs. Other etiologies, such as neoplasm, trauma, or underlying infection, may also predispose patients to fractures.

The principal goal of vertebral augmentation is to fill the fracture cleft with cement to provide vertebral body mechanical stability. It is this mechanical stability that provides pain relief. The second goal of performing an augmentation procedure is to improve the sagittal alignment and biomechanics of the functional spinal unit (complex of adjacent vertebra). This optimization decreases the probability of refracture within the vertebral body and adjacent-level fractures.

Vertebral compression fracture (VCF) is the reduction in the height of the individual vertebra by 20% or 4 mm.

Policy
This Policy applies to the following Fallon Health products:
- Commercial
- Medicare Advantage
- MassHealth ACO
- NaviCare
- PACE

Prior authorization is required.

Fallon Health covers percutaneous vertebroplasty or kyphoplasty for osteoporotic vertebral compression fracture (VCF) when all of the following criteria are met:

1. Acute (< 6 weeks) osteoporotic VCF (T5 – L5) by recent (within 30 days) advanced imaging (bone marrow edema on MRI or bone-scan/SPECT/CT uptake)
2. Symptomatic (ONE):
   a. Hospitalized with severe pain (Numeric Rating Scale (NRS) or Visual Analog Scale (VAS) pain score ≥ 8)
   b. Non-hospitalized with moderate to severe pain (NRS or VAS ≥5) despite optimal non-surgical management (NSM) including pedicle periosteal infiltration (ONE):
      i. Worsening pain
      ii. Stable to improved pain (but NRS or VAS still ≥5) (with ≥ 2 of the following):
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

3. Multidisciplinary team consensus (ALL are required)
   a. Referring physician (e.g., rheumatologist, endocrinologist)
   b. Treating physician (i.e., performing the PVA)
   c. Radiologist
   d. Neurologist

Exclusion criteria (Can have NONE of the following):

1. Absolute contraindication
   a. Current back pain is not primarily due to the identified acute VCF(s).
   b. Osteomyelitis, discitis or active systemic infection
   c. Pregnancy
   d. Greater than three vertebral fractures

2. Relative contraindication
   a. Allergy to bone cement or opacification agents
   b. Coagulopathy
   c. Spinal instability
   d. Myelopathy from the fracture
   e. Neurologic deficit
   f. Neural impingement
   g. Fracture retropulsion/canal compromise

Criteria in this policy only address coverage of percutaneous vertebroplasty and kyphoplasty for osteoporotic vertebral compression fracture. Requests for coverage of percutaneous vertebroplasty and kyphoplasty for other indications will be considered on an individual case-by-case basis.

Exclusions

- Percutaneous mechanical vertebral augmentation using any device, including but not limited to Kiva® and vertebral body stenting, is considered investigational.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage.

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>22510</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic</td>
</tr>
<tr>
<td>22511</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral</td>
</tr>
<tr>
<td>22512</td>
<td>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)</td>
</tr>
<tr>
<td>22513</td>
<td>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</td>
</tr>
<tr>
<td>22514</td>
<td>Percutaneous vertebral augmentation, including cavity creation (fracture...</td>
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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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<tr>
<td>22515</td>
<td>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)</td>
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References


Policy history
Origination date: 05/01/2014
Approval(s): Technology Assessment Committee 12/18/2013 (Adopted Interqual Criteria).
01/28/2015 (annual review), 01/27/2016 (annual review), 01/25/2017 (annual review), 01/24/2018 (annual review) 1/23/2019 (annual review); 05/27/2020 (Adopted proprietary criteria)

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product’s Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member’s benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans. For Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this policy.