Local Coverage Determination (LCD): Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L34228)

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## Contractor Information

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## LCD Information

## Document Information

Created on 02/20/2020. Page 1 of 11
LCD ID
L34228

LCD Title
Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)

Proposed LCD in Comment Period
N/A

Source Proposed LCD
DL34228

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CMS National Coverage Policy
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Language quoted from Centers for Medicare and Medicaid Services (CMS), National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals is italicized throughout the policy. NCDs and coverage provisions in interpretive manuals are not subject to the Local Coverage Determination (LCD) Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.

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

**Title XVIII of the Social Security Act (SSA):**

Section 1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

**CMS Publications:**

CMS Publication 100-04; *Medicare Claims Processing Manual*, Chapter 13:

80 Supervision and Interpretation (S & I) Codes and Interventional Radiology


**Coverage Guidance**

**Coverage Indications, Limitations, and/or Medical Necessity**

PVA (percutaneous vertebroplasty (PVP) or kyphoplasty (PKP)) is covered in patients with BOTH the following:

1. **Inclusion criteria (ALL are required):**
   a. 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) 1-3,10,25
   b. Symptomatic (ONE):
      i. Hospitalized with severe pain (Numeric Rating Scale (NRS) or Visual Analog Scale (VAS) pain score ≥ 8) 4-7
      ii. Non-hospitalized with moderate to severe pain (NRS or VAS ≥5) despite optimal non-surgical management (NSM) (10)** (ONE):
         1. Worsening pain
         2. 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
   c. Multidisciplinary team consensus (2) (ALL are required)
      i. Referring physician (e.g., rheumatologist, endocrinologist)
      ii. Treating physician (i.e., performing the PVA)
      iii. Radiologist
iv. Neurologist

2. Exclusion criteria 2,5,8-10 (Can have NONE of the following):

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

b. Relative contraindication
   1. Allergy to bone cement or opacification agents
   2. Coagulopathy
   3. Spinal instability
   4. Myelopathy from the fracture
   5. Neurologic deficit
   6. Neural impingement
   7. Fracture retropulsion/canal compromise

*at least an acute component (e.g., acute on chronic)

**consider including pedicle periosteal infiltration 7

Summary of Evidence

Osteoporosis (and low bone mass) affects 50 percent of people over 50 years of age, or over 50 million people in the United States. Its primary impact, fractures (also called fragility or low-trauma fractures), occurs secondary to normal activity (e.g., bending, coughing, lifting, fall from a standing height), and eventually occurs in 50% of women and 20% of men. VCFs constitute one-quarter of osteoporotic fractures, often at the midthoracic (T7-T8) and thoracolumbar junction (T12-L1). They may cause significant acute and chronic pain, leading to complications of impaired mobility comparable to a hip fracture (pneumonia, loss of bone and muscle mass, incidental falls, deep venous thrombosis, depression, and isolation). Medicare claims data shows an 85% 10 year mortality following a VCF diagnosis. Under-diagnosis and under-treatment may exacerbate morbidity and mortality.

Treatment options for symptomatic osteoporotic VCF range from NSM (anti-osteoporosis therapy, analgesics, limited activity/bed rest, back brace, physical therapy) to PVA (PVP and PKP). PVP involves the percutaneous injection of bone cement under image guidance into the VCF. PKP adds balloon tamponade within the fractured vertebral body to create a low pressure cavity prior to cement injection. Both treatments aimed to immobilize the fracture, reduce pain, and improve alignment.

Successful small European series introduced PVP into the United States in 1993; by 2007 encouraging preliminary observational data led to medical society endorsement and clinical acceptance in painful osteoporotic VCFs refractory to medical management. Subsequent early open-label randomized controlled trials (RCTs), including the Vertebroplasty for Painful Chronic Osteoporotic Vertebral Fractures (VERTOS) trial, the Fracture Reduction Evaluation (FREE) trial, VERTOS II, and others, found a benefit of vertebral augmentation over non-surgical management.
VERTOS II was a multicenter RCT that compared PVP and NSM of acute (< 6 weeks) osteoporotic VCF in patients with moderate to severe pain (VAS≥5). Among 202 patients, the primary endpoint of pain relief at one month and one year was greater after PVP (-5.2/-5.7) than after NSM (-2.7/-3.7) (p < 0.001). Secondary outcomes, including RDQ and Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO), were similarly improved. The main limitation in the VERTOS II trial was the lack of blinding. Subsequent analysis of the medical cohort showed that 60% achieved sufficient (VAS ≤ 3) pain relief, most within 3 months. The authors acknowledged that despite the VERTOS II results, "clinicians still do not know how to best treat their patients," but conclude that, pending further RCTs, PVP may be justified in patients with insufficient pain relief after 3 months of conservative treatment.

The lack of blinding made the early open-label RCTs, vulnerable to placebo effect. However, in 2009, two high profile, methodologically controversial (e.g., non-rigorous patient selection) double-blinded, RCTs found no benefit of PVP over a "sham" procedure (pedicle periosteal bupivacaine injection). Ever since, there has been a lack of consensus on the appropriate management of osteoporotic VCF, particularly the role of PVA. Medicare claims data shows that among over 2 million VCF patients, PVA was performed in 20% in 2005, peaked at 24% in 2007-2008, and declined to 14% in 2014, a 42% decrease. Lower PVA utilization was associated with a 4% increase in propensity-adjusted mortality risk (p < 0.001). Subsequent major RCTs, described below, have attempted to address the perceived shortcomings of these two negative studies (primarily more stringent selection criteria and choice of control).

The Vertebroplasty for Acute Painful Osteoporotic Fractures (VAPOUR) double-blinded RCT was designed to compare acute fracture (< 6 weeks) PVP with a sham procedure (subcutaneous, not periosteal, infiltration) for patients with severe pain (NRS ≥7). Among 120 randomized patients, the primary endpoint (NRS score < 4 by 14 days) was achieved in 44% and 21% of PVP and sham patients, respectively (p = 0.011), and durable to 6 months. Mean height loss at 6 months was 36% greater in the control group (63% vs. 27%). Hospital inpatients constituted 57% of study patients; among this group, median length of stay was reduced by 5.5 days in the PVP group. In addition to a focus on the acute, severely painful VCF, this study also concentrated on delivering greater cement volumes than prior studies. The authors conclude that PVP is superior to true placebo control of severe pain in VCFs of less than 6 weeks.

VERTOS IV used the same inclusion criteria as VERTOS II, but was a double-blinded comparison of PVP with a sham procedure (pedicle periosteal infiltration). Among the 180 randomized patients, although the reduction in VAS score was clinically (> 1.5 points) and statistically significant up to 12 months in both groups (5.00 at 12 months in the PVP group vs. 4.75 in the sham group), reductions in VAS scores did not differ between groups (p = 0.48). The authors conclude, "the results suggest that periosteal infiltration alone in the early phase provides enough pain relief with no need for additional cementation." They recommend the "pragmatic approach" of first use of "periosteal infiltration during natural healing" and "cementation only in a selected subgroup of patients with insufficient pain relief after this early phase." They also highlight a subgroup that may warrant earlier PVP per the VAPOUR trial (hospital inpatients with more comorbidity and severe pain).

The 2018 multicenter, prospective, uncontrolled, EVOLVE study of 354 Medicare-age patients with acute or subacute (≤ 4 mo.) painful (NRS ≥7) VCF (all but 8 osteoporotic), found statistical improvement in NRS, Oswestry Disability Index (ODI), Short Form-36 Questionnaire Physical Component Summary (SF-36v2 PCS), and EuroQol-5-Domain (EQ-SD) out to 12 months. The authors conclude that "kyphoplasty is a safe, effective, and durable procedure for treating patients with painful VCF due to osteoporosis."

**Analysis of Evidence**
(Rationale for Determination)
Whether or when to use PVA for osteoporotic VCF has been very controversial since publication of the two negative 2009 RCTs. At the time, some national organizations withdrew (Australia Medical Services Advisory Committee)\textsuperscript{6} or severely curbed (American Academy of Orthopaedic Surgeons)\textsuperscript{16} endorsement. Others continued recommending PVA in select patients. The National Institute for Health and Care Excellence (NICE) recommends PVA in patients "who have severe ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management and in whom the pain has been confirmed to be at the level of the fracture by physical examination and imaging",\textsuperscript{4} In a 2014 consensus statement, the Society of Interventional Radiology (SIR), American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), American College of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spin Radiology (ASSR), Canadian Interventional Radiology Association (CIRA), and the Society of NeuroInterventional Surgery (SNIS) considered PVA a proven medically appropriate therapy for treatment of painful VCFs refractory to brief (24 hrs.) nonoperative medical therapy.\textsuperscript{1} The 2017 Cardiovascular and Interventional Radiologic Society of Europe (CIRSE) guideline notes that while the evidence for PVP has been conflicting, based on recent data "it seems clear that PVP offers significant pain reduction in patients with acute VCFs after short (<3 wks.) failed medical therapy".\textsuperscript{2}

A 2018 Cochrane review of 21 trials of PVA for osteoporotic VCF "does not support a role for vertebroplasty for treating acute or subacute osteoporotic vertebral fractures in routine practice,"\textsuperscript{17} "though its methodology has been criticized.\textsuperscript{25} A 2019 systematic review and meta-analysis by the American Society for Bone and Mineral Research (ASBMR) Task Force concluded:"Vertebroplasty does not work to relieve pain from the fracture, and kyphoplasty should generally only be done in the context of a placebo-controlled clinical trial".\textsuperscript{20} Based on the uncertainty of benefit, citing both the recent Cochrane analysis and the VERTOS IV results, UpToDate recommends reserving PVA "for patients with incapacitating pain from acute and subacute VCFs who are unable to taper parenteral opioids or transition to oral opioids within seven days of admission or have intolerable side effects from opioid therapy".\textsuperscript{8} The benefit of PVA is supported by the significantly higher 5-year mortality risk for VCF in Medicare patients after a decline in utilization.\textsuperscript{11} In a recent systematic review of evidence-based guidelines for the management of osteoporotic VCF, three of four guidelines recommended PVA.\textsuperscript{19} In 2018, a multispecialty expert panel (orthopedic and neurosurgeons, interventional [neuro] radiologists and pain specialists), endorsed vertebral augmentation for select patients, in a clinical care pathway (developed using the RAND/UCLA Appropriateness Method), based on seven variables (pain duration and evolution, acute fracture by advanced imaging, kyphotic deformity, degree and progression of vertebral height loss, and impact on daily functioning).\textsuperscript{10} Whether subgroups of patients might benefit more from vertebroplasty or kyphoplasty, requires further study.\textsuperscript{6}

In summary, the premise of weight-bearing fracture immobilization, to limit pain and deformity, has prima facie validity on first principles. Superimposed is the recent trend toward immediate, focused, surgical immobilization, and away from prolonged, general immobilization (e.g., casting, bracing, bedrest) and prolonged systemic pain management (e.g., opioid analgesics), particularly in the elderly. The preponderance of evidence (studies, national and society guidelines, systematic reviews, multispecialty panel clinical care pathway, and Medicare claims data) favors consideration of early PVA in select patients (moderate to severe and disabling pain due to acute osteoporotic VCF confirmed by physical examination and advanced imaging findings).

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**General Information**

**Associated Information**

N/A

**Sources of Information**

N/A
Bibliography


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Revision History Information

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<td>• Creation of Uniform LCDs With Other MAC Jurisdiction</td>
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- 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 the AHRQ's "Registries for Evaluating Patient Outcomes: A User's Guide". (See...
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| 10/01/2015           | R4                      | This final LCD, effective 10/01/2015, combines JEA L34184 into the JEB LCD so that both JEA and JEB contract numbers will have the same final MCD LCD number. The CPT code section revised to show the complete description of the CPT codes listed in the LCD. | • Typographical Error  
• Other (This final LCD, effective 10/01/2015, combines JEA L34184 into the JEB LCD so that both JEA and JEB contract numbers will have the same final MCD LCD number) |
| 10/01/2015           | R3                      | The LCD is revised to correct the link to the VCF registry.                                                                                                                                                                     | • Other (Correct the link to the VCF Registry referenced in the LCD.  )                                                                                                                                                  |
| 10/01/2015           | R2                      | The LCD is revised to remove the deleted CPT codes 22520, 22521, 22522, 22523, 22524, 22525, 72291, 72292 and replaced with 22510, 22511, 22512, 22513, 22514 and 22515.                                                                 | • Revisions Due To CPT/HCPCS Code Changes                                                                                      |
| 10/01/2015           | R1                      | This LCD is renamed to "Percutaneous Vertebral Augmentation" for the comment period ending 3/4/2014. The original LCD title was "Vertebroplasty, Vertebral Augmentation; Percutaneous".                                                                 | • Provider Education/Guidance  
• Creation of Uniform LCDs Within a MAC Jurisdiction                                                                                              |

**Associated Documents**

**Attachments**

N/A

**Related Local Coverage Documents**

**Article(s)**

A56572 - Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)
A57818 - Response to Comments: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)

**Related National Coverage Documents**

N/A

**Public Version(s)**

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Updated on 07/08/2016 with effective dates 10/01/2015 - N/A
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Updated on 12/15/2014 with effective dates 10/01/2015 - N/A
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**Keywords**

N/A