Local Coverage Determination (LCD)

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

L34106

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
Noridian Healthcare Solutions, LLC	A and B MAC	02101 - MAC A	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02102 - MAC B	J - F	Alaska
Noridian Healthcare Solutions, LLC	A and B MAC	02201 - MAC A	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02202 - MAC B	J - F	Idaho
Noridian Healthcare Solutions, LLC	A and B MAC	02301 - MAC A	J - F	Oregon
Noridian Healthcare Solutions, LLC	A and B MAC	02302 - MAC B	J - F	Oregon

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
Noridian Healthcare Solutions, LLC	A and B MAC	02401 - MAC A	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	02402 - MAC B	J - F	Washington
Noridian Healthcare Solutions, LLC	A and B MAC	03101 - MAC A	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03102 - MAC B	J - F	Arizona
Noridian Healthcare Solutions, LLC	A and B MAC	03201 - MAC A	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03202 - MAC B	J - F	Montana
Noridian Healthcare Solutions, LLC	A and B MAC	03301 - MAC A	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03302 - MAC B	J - F	North Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03401 - MAC A	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03402 - MAC B	J - F	South Dakota
Noridian Healthcare Solutions, LLC	A and B MAC	03501 - MAC A	J - F	Utah

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
Noridian Healthcare Solutions, LLC	A and B MAC	03502 - MAC B	J - F	Utah
Noridian Healthcare Solutions, LLC	A and B MAC	03601 - MAC A	J - F	Wyoming
Noridian Healthcare Solutions, LLC	A and B MAC	03602 - MAC B	J - F	Wyoming

LCD Information

Document Information

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

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N/A

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N/A

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11/26/2020

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01/09/2021

CMS National Coverage Policy

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

CMS Transmittal No. 423, Publication 100-04, *Medicare Claims Processing Manual*, Change Request #3632, January 6, 2005. Update of the Hospital Outpatient Prospective Payment, includes Kyphoplasty.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Provisions in this LCD and related coding article only address Vertebral Augmentation for Osteoporotic Vertebral Compression Fracture (VCF). Coverage will remain available for medically necessary procedures for other conditions not included in this LCD.

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) or subacute (6-12 weeks) osteoporotic VCF (T1 – L5) based on symptom onset, and documented by advanced imaging (bone marrow edema on MRI or bone-scan/SPECT/CT uptake) [1-3,10,25,27]
    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. Continuum of care[10] **(Both)**

i. All patients presenting with VCF should be referred for evaluation of BMD and osteoporosis education for subsequent treatment as indicated.
ii. All patients with VCF should be instructed to take part in an osteoporosis prevention/treatment program.

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

a. Absolute contraindication
i. Current back pain is not primarily due to the identified acute or subacute VCF(s).
ii. Osteomyelitis, discitis or active systemic or surgical site infection
iii. Pregnancy
b. Relative contraindication
i. Greater than three vertebral fractures per procedure
ii. Allergy to bone cement or opacification agents
iii. Uncorrected Coagulopathy
iv. Spinal instability
v. Myelopathy from the fracture
vi. Neurologic deficit
vii. Neural impingement
viii. Fracture retropulsion/canal compromise

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,[6] 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).[10] Medicare claims data shows an 85% 10 year mortality following a VCF diagnosis.[11] Under-diagnosis and under-treatment may exacerbate morbidity and mortality.[10]

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,[21] the Fracture Reduction Evaluation (FREE) trial,[22,23] VERTOS II,[14] 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).[14] 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.[15] 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.[15]

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).[12,13] Ever since, there has been a lack of consensus on the appropriate management of osteoporotic VCF, particularly the role of PVA. [6,10] 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. [11] Lower PVA utilization was associated with a 4% increase in propensity-adjusted mortality risk ($p < 0.001$). A secondary analysis gave a number needed to treat (NNT) at one year to save a life of 22.8 and 14.8 for vertebroplasty and kyphoplasty, respectively.[26] Both studies noted the potential for selection bias despite propensity scoring. 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).[5] 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).[7] 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.[24] 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)[6] or severely curbed (American Academy of Orthopaedic Surgeons)[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".[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.[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".[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,[17] "though its methodology has been criticized.[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".[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".[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.[11] In a recent systematic review of evidence-based guidelines for the management of osteoporotic VCF, three of four guidelines recommended PVA.[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).[10] Whether subgroups of patients might benefit more from vertebroplasty or kyphoplasty, requires further study.[6] A review of the 14 published RCTs that examined the role of VA in osteoporotic VCF concluded: “While the RCT data are conflicting, there are patients with acute fractures causing significant pain and disability who can derive benefit with respect to improvement in pain outcomes, reduction in narcotic usage and reduced length of hospital stay”. [27] In a meta-analysis of 16 studies with mortality as an outcome, eight reported mortality benefit in VA, seven reported no benefit, and one reported mixed results.[28] The analysis found that VA provided a 22% mortality benefit over NSM at 10 years. However, the authors note the potential for “a strong selection bias in the selection of healthier patients for VA that was not captured by the analysis.” They conclude that VA “remains a controversial treatment” and “should be offered in carefully selected patients.”

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). However, in addition to timely fracture treatment, also warranted is increased emphasis on ensuring the continuum of care, and preventing medical undertreatment of the overarching systemic disease, of which VCF is a symptom.[29]

General Information

Associated Information

N/A

Sources of Information

N/A

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Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
01/10/2021	R12	Under Coverage Indications, Limitations and/or Medical Necessity - typographical error - changed (T5-L5) to (T1-L5).	• Typographical Error
01/10/2021	R11	The LCD and Billing and Coding Article were returned for comment from May 28 - July 13, 2020. Changes were made to Inclusion and Exclusion criteria in the Indications section, and Sources were added to the Bibliography.	• Provider Education/Guidance

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
02/19/2020	R10	The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.	• Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
02/19/2020	R9	LCD was revised to add Notice Period Start date of 1/3/2020 and Notice Period End Date of 2/18/2020. At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy	• Other (Added Notice Period Start and End dates.)
02/19/2020	R8	11/24/2019 - This LCD version was created as a result of DL34106 being released to a Final LCD.	• Creation of Uniform LCDs With Other MAC Jurisdiction
12/01/2019	R7	12/01/2019: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the	• Provider Education/Guidance • Revisions Due To Code Removal

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
		fields included on the LCD are applicable as noted in this policy. As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD.	
10/01/2015	R6	01/18/18-At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy. In Coverage Indications, Limitations and/or Medical Necessity, removal of: • The medical record must contain assessment of patient condition and response to treatment at one	• Other (New/Change to audit direction)

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
		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 moth 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	

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
		established in the 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/VCFRegistry/ This homepage describes the registry as well as registration resources.	
10/01/2015	R5	This final LCD, effective 10/01/2015, combines JFA L34168 into the JFB LCD so that both JFA and JFB contract numbers will have the same final MCD LCD number.	• Other (This final LCD, effective 10/01/2015, combines JFA L34168 into the JFB LCD so that both JFA and JFB contract numbers will have the same final MCD LCD number.)

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
10/01/2015	R4	LCD revised to add 178 ICD codes in Group 1 to be consistent with this policy in JFA. Information in the Coverage Indications, Limitations and/or Medical Necessity and in the Documentation Requirements portions of the LCD was not changed.	• Revisions Due To ICD-10-CM Code Changes
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,	• Provider Education/Guidance • Creation of Uniform LCDs Within a MAC Jurisdiction

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
		Vertebral Augmentation; Percutaneous".	

Associated Documents

Attachments
N/A

Related Local Coverage Documents
Articles

A56573 - Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)

A58535 - Response to Comments: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)

LCDs

DL34106 - Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (MCD Archive Site)

Related National Coverage Documents
NCDs

N/A

Public Versions

Updated On	Effective Dates	Status	
08/04/2021	01/10/2021 - N/A	Currently in Effect	You are here
11/18/2020	01/10/2021 - N/A	Superseded	View

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

N/A