

Local Coverage Determination (LCD): Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L34106)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
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
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
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
L34106

Original Effective Date

For services performed on or after 10/01/2015

LCD Title

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

Proposed LCD in Comment Period

N/A

Source Proposed LCD

DL34106

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

CPT codes, descriptions and other data only are copyright 2019 American Medical Association. All Rights Reserved. Applicable FARS/HHSARS apply.

Current Dental Terminology © 2019 American Dental Association. All rights reserved.

Copyright © 2019, the American Hospital Association, Chicago, Illinois. Reproduced with permission. No portion of the AHA copyrighted materials contained within this publication may be copied without the express written consent of the AHA. AHA copyrighted materials including the UB-04 codes and descriptions may not be removed, copied, or utilized within any software, product, service, solution or derivative work without the written consent of the AHA. If an entity wishes to utilize any AHA materials, please contact the AHA at 312-893-6816. Making copies or utilizing the content of the UB-04 Manual, including the codes and/or descriptions, for internal purposes, resale and/or to be used in any product or publication; creating any modified or derivative work of the UB-04 Manual and/or codes and descriptions; and/or making any commercial use of UB-04 Manual or any portion thereof, including the codes and/or descriptions, is only authorized with an express license from the American Hospital Association. To license the electronic data file of UB-04 Data Specifications, contact Tim Carlson at (312) 893-6816 or Laryssa Marshall at (312) 893-6814. You may also contact us at ub04@healthforum.com.

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

Revision Effective Date

For services performed on or after 02/19/2020

Revision Ending Date

N/A

Retirement Date

N/A

Notice Period Start Date

01/03/2020

Notice Period End Date

02/18/2020

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

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,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 ($VAS \geq 5$).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 ($VAS \leq 3$) 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 ($p < 0.001$). 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 ($NRS \geq 7$).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 ($NRS \geq 7$) 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

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).

General Information

Associated Information

N/A

Sources of Information

N/A

Bibliography

1. Barr JD, Jensen ME, Hirsch JA, et al. Position statement on percutaneous vertebral augmentation: a consensus statement developed by the Society of Interventional Radiology (SIR), American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), American College of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spine Radiology (ASSR), Canadian Interventional Radiology Association (CIRA), and the Society of NeuroInterventional Surgery (SNIS). *J Vasc Interv Radiol*. 2014;25(2):171-181.
2. Tsoumakidou G, Too CW, Koch G, et al. CIRSE Guidelines on Percutaneous Vertebral Augmentation. *Cardiovasc Intervent Radiol*. 2017;40(3):331-342.
3. McConnell CT, Jr., Wippold FJ, 2nd, Ray CE, Jr., et al. ACR appropriateness criteria management of vertebral compression fractures. *J Am Coll Radiol*. 2014;11(8):757-763.
4. NICE 2013 Vertebral Augmentation Guidelines.
<https://www.nice.org.uk/guidance/ta279/resources/percutaneous-vertebroplasty-and-percutaneous-balloon-kyphoplasty-for-treating-osteoporotic-vertebral-compression-fractures-pdf-82600620856261>.
5. Clark W, Bird P, Gonski P, et al. Safety and efficacy of vertebroplasty for acute painful osteoporotic fractures (VAPOUR): a multicentre, randomised, double-blind, placebo-controlled trial. *Lancet*. 2016;388(10052):1408-1416.
6. Chandra RV, Maingard J, Asadi H, et al. Vertebroplasty and Kyphoplasty for Osteoporotic Vertebral Fractures: What Are the Latest Data? *AJNR Am J Neuroradiol*. 2018;39(5):798-806.
7. Firanesco CE, de Vries J, Lodder P, et al. Vertebroplasty versus sham procedure for painful acute osteoporotic vertebral compression fractures (VERTOS IV): randomised sham controlled clinical trial. *BMJ* 2018;361:k1551.
8. UpToDate- Osteoporotic thoracolumbar vertebral compression fractures: Clinical manifestations and treatment. 2018; https://www.uptodate.com/contents/osteoporotic-thoracolumbar-vertebral-compression-fractures-clinical-manifestations-and-treatment?search=vertebroplasty&source=search_result&selectedTitle=1~19&usage_type=default&display_rank=1%23H17476846#H1565673.
9. Chandra RV, Meyers PM, Hirsch JA, et al. Vertebral augmentation: report of the Standards and Guidelines Committee of the Society of NeuroInterventional Surgery. *J Neurointerv Surg*. 2014;6(1):7-15.
10. Hirsch JA, Beall DP, Chambers MR, et al. Management of vertebral fragility fractures: A clinical care pathway developed by a multispecialty panel using the RAND/UCLA Appropriateness Method. *Spine J*.
11. Ong KL, Beall DP, Frohbergh M, Lau E, Hirsch JA. Were VCF patients at higher risk of mortality following the 2009 publication of the vertebroplasty "sham" trials? *Osteoporos Int*. 2018;29(2):375-383.
12. Buchbinder R, Osborne RH, Ebeling PR, et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. *N Engl J Med*. 2009;361(6):557-568.
13. Kallmes DF, Comstock BA, Heagerty PJ, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. *N Engl J Med*. 2009;361(6):569-579.
14. Klazen CA, Lohle PN, de Vries J, et al. Vertebroplasty versus conservative treatment in acute osteoporotic vertebral compression fractures (Vertos II): an open-label randomised trial. *Lancet* 2010;376(9746):1085-1092.
15. Venmans A, Klazen CA, Lohle PN, Mali WP, van Rooij WJ. Natural history of pain in patients with conservatively treated osteoporotic vertebral compression fractures: results from VERTOS II. *AJNR Am J Neuroradiol*. 2012;33(3):519-521.
16. McGuire R. AAOS Clinical Practice Guideline: the Treatment of Symptomatic Osteoporotic Spinal Compression Fractures. *J Am Acad Orthop Surg*. 2011;19(3):183-184.
17. Buchbinder R, Johnston RV, Rischin KJ, et al. Percutaneous vertebroplasty for osteoporotic vertebral compression fracture. *Cochrane Database Syst Rev*. 2018;4:CD006349.
18. Anselmetti GC, Bernard J, Blattert T, et al. Criteria for the appropriate treatment of osteoporotic vertebral compression fractures. *Pain Physician*. 2013;16(5):E519-530.
19. Parreira PCS, Maher CG, Megale RZ, March L, Ferreira ML. An overview of clinical guidelines for the management of vertebral compression fracture: a systematic review. *Spine J*. 2017;17(12):1932-1938.
20. Ebeling PR, Akesson K, Bauer DC, et al. The Efficacy and Safety of Vertebral Augmentation: A Second ASBMR

Task Force Report. *J Bone Miner Res.* 2019;34(1):3-21.

21. Voormolen MH, Mali WP, Lohle PN, et al. Percutaneous vertebroplasty compared with optimal pain medication treatment: short-term clinical outcome of patients with subacute or chronic painful osteoporotic vertebral compression fractures. The VERTOS study. *AJNR Am J Neuroradiol.* 2007;28(3):555-560.
22. Wardlaw D, Cummings SR, Van Meirhaeghe J, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. *Lancet.* 2009;373(9668):1016-1024.
23. Boonen S, Van Meirhaeghe J, Bastian L, et al. Balloon kyphoplasty for the treatment of acute vertebral compression fractures: 2-year results from a randomized trial. *J Bone Miner Res.* 2011;26(7):1627-1637.
24. Beall DP, Chambers MR, Thomas S, et al. Prospective and Multicenter Evaluation of Outcomes for Quality of Life and Activities of Daily Living for Balloon Kyphoplasty in the Treatment of Vertebral Compression Fractures: The EVOLVE Trial. *Neurosurgery.* 2018.
25. Clark W, Bird P, Diamond T, Gonski P, Gebiski V. Cochrane vertebroplasty review misrepresented evidence for vertebroplasty with early intervention in severely affected patients. *BMJ Evid Based Med.* 2019.

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
02/19/2020	R10	<p>The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.</p> <p>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.</p>	<ul style="list-style-type: none"> Other (The LCD is revised to remove CPT/HCPCS codes in the Keyword Section of the LCD.)
02/19/2020	R9	<p>LCD was revised to add Notice Period Start date of 1/3/2020 and Notice Period End Date of 2/18/2020.</p> <p>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</p>	<ul style="list-style-type: none"> Other (Added Notice Period Start and End dates.)
02/19/2020	R8	<p>11/24/2019 - This LCD version was created as a result of DL34106 being released to a Final LCD.</p>	<ul style="list-style-type: none"> Creation of Uniform LCDs With Other MAC Jurisdiction
12/01/2019	R7	<p>12/01/2019: At this time 21st Century Cures Act will</p>	<ul style="list-style-type: none"> Provider

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>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.</p> <p>As required by CR 10901, all billing and coding information has been moved to the companion article, this article is linked to the LCD.</p>	<p>Education/Guidance</p> <ul style="list-style-type: none"> • Revisions Due To Code Removal
10/01/2015	R6	<p>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.</p> <p>In Coverage Indications, Limitations and/or Medical Necessity, removal of:</p> <ul style="list-style-type: none"> • 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 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. 	<ul style="list-style-type: none"> • Other (New/Change to audit direction)

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
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.	<ul style="list-style-type: none"> 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.)
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.	<ul style="list-style-type: none"> Revisions Due To ICD-10-CM Code Changes
10/01/2015	R3	The LCD is revised to correct the link to the VCF registry.	<ul style="list-style-type: none"> 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.	<ul style="list-style-type: none"> 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".	<ul style="list-style-type: none"> Provider Education/Guidance Creation of Uniform LCDs Within a MAC Jurisdiction

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Article(s)

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

A57820 - Response to Comments: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF)

Related National Coverage Documents

N/A

Public Version(s)

Updated on 01/29/2020 with effective dates 02/19/2020 - N/A

Updated on 12/31/2019 with effective dates 02/19/2020 - N/A

Updated on 12/19/2019 with effective dates 02/19/2020 - N/A

Updated on 11/07/2019 with effective dates 12/01/2019 - 02/18/2020

Updated on 01/24/2018 with effective dates 10/01/2015 - 11/30/2019

Updated on 07/08/2016 with effective dates 10/01/2015 - N/A

Updated on 10/21/2015 with effective dates 10/01/2015 - N/A

Updated on 10/09/2015 with effective dates 10/01/2015 - N/A

Updated on 12/15/2014 with effective dates 10/01/2015 - 01/07/2020

Updated on 07/22/2014 with effective dates 10/01/2015 - N/A

Updated on 03/31/2014 with effective dates 10/01/2015 - N/A

Keywords

N/A