

LCD - Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF) (L35130)

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CMS National Coverage Policy

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Determinations (NCDs) or payment policy rules and regulations for percutaneous vertebral augmentation (PVA) for vertebral compression fracture (VCF). Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for PVA for VCF and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

IOM Citations

- CMS IOM Publication 100-04, *Medicare Claims Processing Manual*,
 - Chapter 4, Part B Hospital (Including Inpatient Hospital Part B and OPPS), Section 10 Hospital Outpatient Prospective Payment System (OPPS)
 - Chapter 13, Radiology Services and Other Diagnostic Procedures, Section 80 Supervision and Interpretation (S&I) Codes and Interventional Radiology
- CMS IOM Publication 100-08, *Medicare Program Integrity Manual*,
 - Chapter 13, Local Coverage Determinations, Section 13.5.4 Reasonable and Necessary Provision in an LCD

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Compliance with the provisions in this LCD may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

Percutaneous Vertebroplasty

Percutaneous vertebroplasty (PVP) 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.

Percutaneous Vertebral Augmentation

Percutaneous vertebral augmentation (PVA) is a minimally invasive procedure for the treatment of compression fractures of the vertebral body. The procedure includes the creation of a cavity which results in fracture reduction along with an attempt to restore vertebral body height and alignment. Using imaging guidance x-rays, incisions are made and a probe is placed into the vertebral space in the location of the fracture. 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 the bone filler (polymethylmethacrylate) (PMMA).

Covered Indications

Percutaneous vertebroplasty and percutaneous vertebral augmentation (PVA or Kyphoplasty) procedures will be considered medically reasonable and necessary for the following indications:

1. Painful, debilitating, osteoporotic vertebral collapse/compression fractures, defined as those that have not responded to non-surgical medical management (e.g. narcotic and/or non-narcotic medication, physical therapy modalities) with and without methods of immobility (e.g. rest, bracing).
 - Both **PVP** and **PVA** will be considered reasonable and necessary when **ALL** of the following criteria are met:
 - Acute (<6 wks) or subacute (6-12 wks)^{18,28,42} osteoporotic VCF (T1– L5), based on symptom onset, and documented by advanced imaging demonstrating bone marrow edema on MRI or bone-scan/SPECT/CT uptake ^{1-3,8,26,43} **and**
 - The beneficiary is symptomatic and is hospitalized with severe pain (Numeric Rating Scale [NRS] or Visual Analog Scale [VAS] pain score ≥ 8)⁴⁻⁷ **or** is non-hospitalized with moderate to severe pain (NRS or VAS ≥ 5) despite optimal non-surgical management (NSM)⁸ with one of the following:
 - Worsening Pain or
 - Stable to improved pain (but NRS or VAS ≥ 5) **when 2 or more of the following are present:**
 - Progression of vertebral body height loss
 - > 25% vertebral body height reduction
 - Kyphotic deformity
 - Severe impact of VCF on daily functioning (Roland Morris Disability Questionnaire [RDQ] >17)

Continuum of care

All patients presenting with vertebral compression fractures (VCF) should be referred for evaluation of bone mineral density and osteoporosis education for subsequent treatment as indicated and instructed to take part in an osteoporosis prevention/treatment program.⁸

2. Malignant Vertebral Fractures

Osteolytic vertebral metastasis or myeloma with severe back pain related to a destruction of the vertebral body, not involving the major part of the cortical bone.

Limitations

1. Exclusion criteria ^{2,5,8-10,28,31}

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

Notice: Services performed for any given diagnosis must meet all of the indications and limitations stated in this LCD, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS national coverage determinations, and all Medicare payment rules.

Summary of Evidence

Percutaneous Vertebroplasty (PVP) offers many benefits in the treatment of osteoporotic and malignant compression fractures. The aim of treating these fractures is to restore mobility, reduce pain and minimize the incidence of new fractures.^{1,3,4} However, the benefits of PVP do not come without risk of complications as documented in the literature. Due to the risk of complications, guidelines have been established by several specialty panels. These specialty panel guidelines include relative and absolute contraindications to surgical management of compression fractures.^{2,8,9,31} Additionally, the 2017 Cardiovascular and Interventional Radiologic Society of Europe (CIRSE) guideline² indicates complication rates for osteoporotic PVP is between 2.2 – 3.9% and at <11.5% for malignant fractures. These complications include cement leakage, infection, fractures, risk of collapse of adjacent vertebral bodies, allergic reaction, and bleeding from the puncture site. The CIRSE guidelines² suggest complications can be minimized by not injecting cement in its liquid phase, limiting the number of treated levels to not more than five, correct positioning of the needle tip, and taking extra precaution when treating highly vascular lesions.

Osteoporotic Compression Fractures

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. Vertebral compression fractures (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).⁸ Medicare claims data shows an 85% 10 year mortality following a VCF diagnosis.¹⁰ Under-diagnosis and under-treatment may exacerbate morbidity and mortality.⁸ Vertebral augmentation provides a significant mortality benefit over nonsurgical management with a low number needed to treat (NNT).⁴³

Treatment options for symptomatic osteoporotic VCF range from non-surgical management (NSM) (anti-osteoporosis therapy, analgesics, limited activity/bed rest, back brace, physical therapy) to PVA, PVP and Percutaneous kyphoplasty (PKP). A PVP involves the percutaneous injection of bone cement under image guidance into the VCF. A PKP adds balloon tamponade within the fractured vertebral body to create a low pressure cavity prior to cement

injection. Both treatments aim 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,¹¹ the Fracture Reduction Evaluation (FREE) trial,^{12,13} 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 (≥ 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.
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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).^{16,17} Ever since, there has been a lack of consensus on the appropriate management of osteoporotic VCF, particularly the role of PVA.^{6,8} 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.¹⁰ 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).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 in-patients 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.¹⁸ The authors conclude that "kyphoplasty is a safe, effective, and durable procedure for treating patients with painful VCF due to osteoporosis."

Hirsch et al⁴³ is a claims-based analysis of national registries and insurance datasets that indicates a significant mortality benefit for patients with vertebral compression fractures who receive vertebral augmentation. Both vertebroplasty and kyphoplasty modalities conferred a prominent mortality benefit over nonsurgical management in the analysis of the U.S. Medicare registry, with a low number needed to treat. The calculations based on this data base resulted in a low number needed to treat to save 1 life at 1 year and at 5 years. This analysis of >2,000,000 patients with vertebral compression fracture (VCF) revealed that only 15 patients need to be treated to save 1 life at 1 year. This large dataset analysis suggests that vertebral augmentation provides a significant mortality benefit over nonsurgical management with a low number needed to treat (NNT).

Malignant Compression Fractures

Rastogi et al¹⁹ is a peer reviewed article outlining the use of vertebral augmentation for compression fractures caused by malignant disease. Vertebroplasty or kyphoplasty is used as the principal palliative treatment for painful compression fractures caused by malignant disease. Vertebral augmentation provides rapid onset of pain relief and significant improvement in function, quality of life, and vertebral stability.

Mansoorinasab et al²⁰ is a peer reviewed article updating new methods to determine the influence and the long-term consequences of percutaneous vertebroplasty (PVP) in the treatment of painful vertebral fractures (VFs) in metastatic patients of multifarious cancer of various sites on the spine. In patients with vertebral metastasis, PVP is considered a successful method for providing fast pain control, preventing most spinal cord compression, and vertebral collapse. The results of the peer review state that PVP is safe, feasible, reliable, effective, and useful procedure, a minimally invasive treatment, and a significant tool for reduction of pain.

Health Quality Ontario performed a systematic literature search for studies on vertebral augmentation of cancer-related vertebral compression fractures.²¹ The objective was to evaluate the effectiveness and safety of percutaneous image-guided vertebroplasty and kyphoplasty for palliation of cancer-related vertebral compression fractures. The data was compiled into categories of pain intensity, analgesic use, pain-related disability and physical performance, and health-related quality of life and patient satisfaction. In all of the clinical studies researched, patients that had either vertebroplasty or kyphoplasty, had high pain intensity levels (Visual Analogue Scale [VAS] ≥ 7.0) pre-procedure which were reduced post-procedurally to mild to low pain intensity levels (VAS < 4.0). Patients that were in the vertebroplasty group, reported change in analgesics, either discontinuation or a dose reduction. Patients from the kyphoplasty group infrequently reported analgesic use after the procedure. Both groups of patients showed improvement with pain-related disability and physical performance. The number of patients that required orthopedic braces or wheelchairs was significantly reduced after the procedures, as well as the number of patients that were bedridden or immobile. The health-related quality of life for both groups of patients was improved and remained improved at 1-year follow up. Both vertebroplasty and kyphoplasty rapidly reduced pain intensity levels in cancer patients with spinal fractures that were refractory to conservative care, usually bed rest and opioids. Both of these procedures were associated with a low-risk safety profile.

Kircelli et al²² is a 12 month retrospective clinical study of 72 patients (mean age of 78.93 ± 8.77 years) with malignant vertebral compression fractures who underwent balloon kyphoplasty to investigate clinical results. Vertebral compression fractures due to bone metastases have limited treatment options which include bone-strengthening with cement and supportive care. Patients with metastatic vertebral compression fractures have reported reduced pain and improved functionability and quality of life post percutaneous kyphoplasty. In this study, the mean follow-up period was 18.91 ± 3.71 months and mean bone mineral density (BMD) values were 3.19 ± 0.46 . The kyphosis angle (KA), vertebral height ratio (VHR), visual analog scale (VAS), and Oswestry disability Index (ODI) were compared pre and post balloon kyphoplasty. The KA decreased from 13.45 ± 6.73 to 8.55 ± 1.55 , the VHR increased from $55.75 \pm 12.82\%$ to 74.27 ± 10.54 , the VAS decreased from 8.11 ± 0.83 to 2.55 ± 1.16 , and the ODI decreased from 65.51 ± 7.32 to 25.18 ± 4.37 at the 12th postoperative month, respectively ($p < 0.001$). Post-

procedural pain decreased significantly with a mean cement volume of 4.6 ± 1.3 ml. The authors conclude that percutaneous kyphoplasty is an effective method for reducing pain and disability in patients with vertebral compression fractures due to metastases thereby improving patient quality of life.

Kyriakou et al²³ is a review statement from the International Myeloma Working Group (IMWG) on the use of cement augmentation with percutaneous vertebroplasty and percutaneous kyphoplasty for the treatment of vertebral compression fractures in multiple myeloma (MM). A majority of MM patients develop spinal osteolysis which can result in painful vertebral compression fractures impacting quality of life and overall well-being. Pain associated with vertebral compression fractures can be disabling causing progressive deformities and resulting in significant chronic pain. Treatment of malignant vertebral compression fractures with balloon kyphoplasty (BKP) and percutaneous vertebroplasty (PV) is directed towards rapid pain reduction, keeping the patient ambulatory with a normal level of function in a relatively short period of time. The IMWG concludes the use of cement augmentation is an effective way to stabilize the spinal column and indicates balloon kyphoplasty (BKP) and percutaneous vertebroplasty (PV) allows the majority of patients the ability to return to a near normal level of function in a relatively short period of time by significantly reducing back pain and decreasing the use of pain relief. Further, the consensus statement from the IMWG states "multiple myeloma patients with significant pain at a fracture site should be offered a balloon kyphoplasty or percutaneous vertebroplasty procedure and the procedure should be performed within 4-8 weeks unless there are medical contraindications."

Multi-Jurisdictional Contractor Advisory Committee (CAC) Meeting

After review of highly graded evidence-based literature from the years 2004 -2018, the opinions amongst the CAC Advisory Committee (CAC) members and the Subject Matter Experts (SMEs) varied on many of the proposed questions regarding the strength of evidence for the treatment of osteoporotic vertebral compression fractures with vertebroplasty and kyphoplasty. Multiple pieces of literature were discussed to determine if osteoporotic vertebral compression fractures receiving intervention treatment during the acute or subacute timeframes were supported. Also discussed were if current literature and quality of evidence addressed an acute, subacute or chronic fracture time frame, and if highly graded evidence existed for supporting conservative, non-interventional treatment. Topics within the discussion reviewed strength of evidence regarding pain relief, overall opioid usage, quality of life, mobility as well as mortality risk. CAC members and SMEs discussed the need for further research trials to strengthen existing data as others felt the benefits of these procedures have been proven in evidence-based literature from trials that have already been performed.

Analysis of Evidence (Rationale for Determination)

After consideration of the literature, the level of compression fractures has been amended to include T1-L5. The timing of advanced imaging requirement within 30 days has been removed. The absolute contraindication of performing greater than 3 vertebral fractures in a single session has been amended to that of a relative contraindication. Based on Subject Matter Expert (SME) recommendation and review of the Cardiovascular and Interventional Radiologic Society of Europe (CIRSE) Guidelines,² Hirsch et al. 2018, the National Guideline Clearinghouse (NGC) ACR Appropriateness Criteria,⁹ and Chandra et al. 2014, the level of vertebral compression fractures has been revised to include levels (T1-L5) and will be based on symptom onset and documented by advanced imaging without a set timeframe. According to the CIRSE Guidelines² and to minimize complications associated with PVP, it is not advisable to treat more than five levels of fractures within a single session. This recommendation is due to the positive correlation between the number of fractures treated and drop in oxygen saturation. Since the guidelines suggest five levels is safe, the absolute contraindication of greater than three vertebral fractures has been moved to the relative contraindications and is clarified to reflect per procedure. In addition, the special society guidelines list active surgical site infection as an absolute contraindication. Consistent with these guidelines, active surgical site infection has been added as an absolute contraindication.

Osteoporotic Compression Fractures

Whether or not 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)²⁴ 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 Spinal 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.) non-operative 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,"²⁵ though its methodology has been criticized.²⁶ 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."³⁰ 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."²⁸

The benefit of PVA is supported by the significantly higher 5-year mortality risk for VCF in Medicare patients after a decline in utilization.¹⁰ In a recent systematic review of evidence-based guidelines for the management of osteoporotic VCF, three of four guidelines recommended PVA.²⁹ 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).⁸ 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."⁴⁵ 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.⁴⁶ 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 and malignant VCF confirmed by physical examination and advanced imaging findings).

Malignant Compression Fractures

Percutaneous vertebroplasty (PV) and balloon kyphoplasty (BKP) procedures have played a major role in the effective treatment of painful malignant compression fractures refractory to conservative care. Vertebroplasty procedures have been shown to provide rapid pain control and improved overall quality of life. After careful review of the literature, vertebral augmentation for malignant compression fractures is a reasonable and necessary procedure providing rapid pain control with a decrease in the need for analgesics, improvement in pain related disability and physical performance, and improved vertebral stability. The literature reviewed supports the clinical utility and clinical validity, and is relevant to the Medicare population. Therefore, coverage of PV and BKP will be added for the treatment of painful malignant compression fractures refractory to conservative care.

General Information

Associated Information

Please refer to the Local Coverage Article: Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF) (A57752) for documentation requirements, utilization parameters and all coding information as applicable.

Sources of Information

Other Contractor's Policies

First Coast Service Options, Inc., L29209 Vertebroplasty, Vertebral Augmentation; Percutaneous

First Coast Service Options, Inc., L29454 Vertebroplasty, Vertebral Augmentation; Percutaneous

First Coast Service Options, Inc., L34492 Vertebroplasty, Vertebral Augmentation; Percutaneous

Novitas Solutions, Inc., L35130 Vertebroplasty, Vertebral Augmentation (Kyphoplasty) Percutaneous

CGS Administrators, LLC, DL38201 Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fractures (VCF)

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
07/11/2021	R13	LCD posted for notice on 05/27/2021 to become effective 07/11/2021. 01/14/2021 - Proposed LCD posted for comment.	<ul style="list-style-type: none"> Other (revisions to ensure alignment with Other Jurisdictions)
07/12/2020	R12	LCD posted for notice on 05/28/2020. LCD becomes effective for dates of service on and after 07/12/2020. 12/26/2019 DL35130 Draft LCD posted for comment.	<ul style="list-style-type: none"> Typographical Error
11/21/2019	R11	LCD revised and published on 11/21/2019. Consistent with CMS Change Request 10901, the entire coding section has been removed from the LCD and placed into the related Billing and Coding Article, A57752. All CPT codes and coding information within the text of the LCD has been placed in the Billing and Coding Article. IOM citations have been updated.	<ul style="list-style-type: none"> Other (CMS Change Request)
04/25/2019	R10	LCD revised and published on 04/25/2019 in response to CMS Change Request (CR) 10901 to add CMS IOM Publication 100-08, Chapter 13 to the IOM Reference section and to remove the reference and language from the body of the LCD. CMS IOM reference for Publication 100-09 pertains to coding therefore it has been removed from the LCD. The references have been moved to the Bibliography. LCD standard format changes made to Documentation Requirements. There has been no change to LCD coverage with this revision.	<ul style="list-style-type: none"> Other (Changes in response to CMS change request.)
05/04/2017	R9	Corrected a typographical error in the Group 1 and Group 2 "Medical Necessity ICD-10 Codes Asterisk Explanation" notes. Added asterisks (*) at the beginning of each note for clarification.	<ul style="list-style-type: none"> Typographical Error
05/04/2017	R8	LCD posted for notice on 03/16/2017. LCD becomes effective for dates of service on and after 05/04/2017. 09/15/2016 DL35130 Draft LCD posted for comment.	<ul style="list-style-type: none"> Aberrant Local Utilization

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASONS FOR CHANGE
10/01/2015	R7	LCD revised and published on 11/13/2015 for dates of service on and after 10/01/2015 to add additional 7th characters to ICD-10 codes as covered diagnoses. Diagnosis code M48.38 was removed from Group 3 and M48.38 and M48.58XA were removed from Group 6 consistent with the limitations section of the policy that states these services are not indicated for the sacrum or coccyx.	<ul style="list-style-type: none"> Other (Clarification)
10/01/2015	R6	08/20/2015 - Revenue Code 0332 descriptor has changed. Please note that this code is included in a code range.	<ul style="list-style-type: none"> Other (Revenue Code Update)
10/01/2015	R5	LCD revised and published on 07/09/2015 to correct the L number for the reference to the Services That Are Not Reasonable and Necessary LCD.	<ul style="list-style-type: none"> Typographical Error
10/01/2015	R4	LCD published 01/23/2015 to correct the publication date of the annual CPT/HCPCS code updates incorrectly listed as 01/22/2015 in revision history below. The code updates remain as listed in the revision history below.	<ul style="list-style-type: none"> Typographical Error
10/01/2015	R3	<p>LCD revised and published on 01/22/2015 effective for dates of service to reflect the annual CPT/HCPCS code updates. CPT/HCPCS codes 22520-22525 have been deleted and replaced with CPT/HCPCS codes 22510-22515 respectively. CPT/HCPCS codes 72291 and 72292 have been deleted and therefore have been removed from the LCD.</p> <p>Reference to LCD L32691 Category III Codes has been revised to reflect reference to LCD L31686 Services That Are Not Reasonable and Necessary since L32691 has been retired.</p>	<ul style="list-style-type: none"> Revisions Due To CPT/HCPCS Code Changes
10/01/2015	R2	LCD revised 07/25/2014 to reflect annual ICD-10 code changes. The code descriptor has been updated for ICD-10 code M84.58XA.	<ul style="list-style-type: none"> Revisions Due To ICD-10-CM Code Changes
10/01/2015	R1	LCD revised to clarify that the procedures are not indicated for treatment to the sacrum or coccyx area by including the associated Category III codes and referring to LCD L32691. Typographical errors corrected. (LCD updated 05/13/2014)	<ul style="list-style-type: none"> Provider Education/Guidance Typographical Error

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

[A57752 - Billing and Coding: Percutaneous Vertebral Augmentation \(PVA\) for Vertebral Compression Fracture \(VCF\)](#)
[A58685 - Response to Comments: Percutaneous Vertebral Augmentation \(PVA\) for Vertebral Compression Fracture \(VCF\)](#)

LCDs

[DL35130 - \(MCD Archive Site\)](#)

Related National Coverage Documents

N/A

Public Versions

UPDATED ON	EFFECTIVE DATES	STATUS
05/21/2021	07/11/2021 - N/A	Currently in Effect (This Version)
Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.		

Keywords

N/A