Percutaneous Vertebroplasty and Kyphoplasty Clinical Coverage Criteria

Overview

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

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

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

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

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial
☒ Medicare Advantage
☒ MassHealth ACO
☒ NaviCare
☒ PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare does not have an NCD for percutaneous vertebroplasty or kyphoplasty. National Government Services, Inc. has an LCD for Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L33569) and an LCA Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (A56178**)** (MCD search 06-25-2021).

For plan members enrolled in NaviCare and PACE plans, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the

plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health will follow guidance published by MassHealth. When there is no Medicare or MassHealth guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Each PACE plan member is assigned to an Interdisciplinary Team. When there is no Medicare or MassHealth guidance, the member's Interdisciplinary Team is responsible for coverage determinations.

Prior authorization is required for these procedures.

For Medicare Advantage, NaviCare and PACE plan members, please refer to National Government Services, Inc. **LCD for Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L33569)** and **LCA Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (A56178)** for coverage criteria.

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

1. Acute (< 6 weeks) osteoporotic VCF (T1 – L5) by recent (within 30 days) advanced imaging (bone marrow edema on MRI or bone-scan/SPECT/CT uptake)
2. Symptomatic (ONE):
    a. Hospitalized with severe pain (Numeric Rating Scale (NRS) or Visual Analog Scale (VAS) pain score ≥ 8)
    b. Non-hospitalized with moderate to severe pain (NRS or VAS ≥5) despite optimal non-surgical management (NSM) including pedicle periosteal infiltration (ONE):
        i. Worsening pain
        ii. Stable to improved pain (but NRS or VAS still ≥5) (with ≥ 2 of the following):
            A. Progression of vertebral body height loss
            B. >25% vertebral body height reduction
            C. Kyphotic deformity
            D. Severe impact of VCF on daily functioning (Roland Morris Disability Questionnaire (RDQ) >17
3. Multidisciplinary team consensus (ALL are required)
    a. Referring physician (e.g., rheumatologist, endocrinologist)
    b. Treating physician (i.e., performing the PVA)
    c. Radiologist
    d. Neurologist

Exclusion criteria (Can have NONE of the following):

1. Absolute contraindication
    a. Current back pain is not primarily due to the identified acute VCF(s).
    b. Osteomyelitis, discitis or active systemic infection
    c. Pregnancy
    d. Greater than three vertebral fractures
2. Relative contraindication
    a. Allergy to bone cement or opacification agents
    b. Coagulopathy
    c. Spinal instability
    d. Myelopathy from the fracture
    e. Neurologic deficit
    f. Neural impingement
    g. Fracture retropulsion/canal compromise

Criteria in this policy only address coverage of percutaneous vertebroplasty and kyphoplasty for osteoporotic vertebral compression fracture. Requests for coverage of percutaneous

vertebroplasty and kyphoplasty for other indications will be considered on an individual case-by-case basis.

Exclusions

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

Coding

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

Code	Description
22510	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic
22511	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral
22512	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body (list separately in addition to code for primary procedure)
22513	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic
22514	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar
22515	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body (list separately in addition to code for primary procedure)

References

1. National Government Services, Inc. Local Coverage Determination: Percutaneous Vertebral Augmentation for Osteoporotic Vertebral Compression Fracture (L33569). Original Effective Date 10/1/2015. Revision Effective Date 12/1/2020. Available at: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. Accessed June 25, 2021.
2. National Government Services, Inc. Local Coverage Article: Billing and Coding: Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (A56178). Original Effective Date 12/1/2019. Revision Effective Date 12/1/2020. Available at: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx. Accessed June 25, 2021.
3. 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 Jan;34(1):3-21. doi: 10.1002/jbmr.3653.
4. Papanastassiou ID, Phillips FM, Van Meirhaeghe J, et al. Comparing effects of kyphoplasty, vertebroplasty, and non-surgical management in a systematic review of randomized and non-randomized controlled studies. *Eur Spine J*. 2012 Sep;21(9):1826-43.

5. Stevenson M, Gomersall T, Lloyd Jones M, et al. Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for the treatment of osteoporotic vertebral fractures: a systematic review and cost-effectiveness analysis. *Health Technol Assess*. 2014 Mar;18(17):1-290.
6. Kyriakou C, Molloy S, Vrionis F, et al.The role of cement augmentation with percutaneous vertebroplasty and balloon kyphoplasty for the treatment of vertebral compression fractures in multiple myeloma: a consensus statement from the International Myeloma Working Group (IMWG). *Blood Cancer J*. 2019 Feb 26;9(3):27.
7. Beall D, Lorio MP, Yun BM, et al. Review of Vertebral Augmentation: An Updated Meta-analysis of the Effectiveness. *Int J Spine Surg*. 2018 Aug 15;12(3):295-321.
8. 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 Feb;25(2):171-81.
9. Baerlocher MO, Saad WE, Dariushnia S, et al. Quality improvement guidelines for percutaneous vertebroplasty. *J Vasc Interv Radiol*. 2014 Feb;25(2):165-70.
10. Tsoumakidou G, Too CW, Koch G, et al. CIRSE Guidelines on Percutaneous Vertebral Augmentation. *Cardiovasc Intervent Radiol*. 2017 Mar;40(3):331-342.
11. Tutton SM, Pflugmacher R, Davidian M, et al. KAST study: The Kiva® system as a vertebral augmentation treatment - a safety and effectiveness trial. *J Vasc Interv Radiol*. 2014; 25(3):S111.
12. Korovessis P, Vardakastanis K, Repantis T, et al. Balloon Kyphoplasty Versus KIVA Vertebral Augmentation-Comparison of 2 Techniques for Osteoporotic Vertebral Body Fractures: A Prospective Randomized Study. *Spine (Phila Pa 1976).* 2013; 38(4):292-9.
13. Otten LA, Bornemnn R, Jansen TR, et al. Comparison of balloon kyphoplasty with the new Kiva(R) VCF system for the treatment of vertebral compression fractures. *Pain Physician.* 2013; 16(5):E505-12.
14. Jensen ME, Kallmes DE. Percutaneous vertebroplasty in the treatment of malignant spine disease. *Cancer J.* 2002;8(2):194-206.
15. Chen F, Xia YH, Cao WZ, et al. Percutaneous kyphoplasty for the treatment of spinal metastases. *Oncol Lett*. 2016;11(3):1799-1806.
16. Yang Z, Yang Y, Zhang Y, et al. Minimal access versus open spinal surgery in treating painful spine metastasis: a systematic review. *World J Surg Oncol*. 2015;13:6.
17. Saliou G, Kocheida el M, Lehmann P, et al. Percutaneous vertebroplasty for pain management in malignant fractures of the spine with epidural involvement*. Radiology*. 2010;254(3):882-890.
18. Barragán-Campos HM, Vallée JN, Lo D, et al. Percutaneous vertebroplasty for spinal metastases: complications. *Radiology*. 2006;238(1):354-362.
19. Yevich S, Tselikas L, Gravel G, de Baère T, Deschamps F. Percutaneous Cement Injection for the Palliative Treatment of Osseous Metastases: A Technical Review. *Semin Intervent Radiol*. 2018;35(4):268-280.

Policy history

Origination date:	05/01/2014
Approval(s):	Technology Assessment Committee 12/18/2013 (Adopted Interqual Criteria). 01/28/2015 (annual review), 01/27/2016 (annual review), 01/25/2017 (annual review), 01/24/2018 (annual review) 1/23/2019 (annual review); 05/27/2020 (Adopted proprietary criteria) *06/25/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section.*

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