

Vertebral Augmentation (Percutaneous Kyphoplasty)

Policy Number: PA-086
Last Review Date: 05/09/2019
Effective Date: 07/01/2019

Policy

Evolent Health considers **Percutaneous kyphoplasty or vertebroplasty** performed on a thoracic or lumbar fracture for severe, debilitating pain (pain level >7 on pain scale of 1-10) unresponsive to standard conservative medical/pain management of two-four weeks medically necessary for the following indications:

1. Pain from a fractured or weakened vertebral body unresponsive to conservative management defined as any one of the following:
 - Persisting at a level that prevents ambulation despite analgesic therapy.
 - Physical therapy is intolerable with pain persisting at that level despite analgesic therapy.
 - Development of unacceptable side effects such as excessive sedation, confusion, or constipation due to the analgesic therapy necessary to reduce pain to a tolerable level.
2. Debilitating osteoporotic or osteolytic compression fractures of the vertebrae (if the osteoporotic vertebral compression fracture is > eight weeks old, additional clinical and diagnostic criteria are needed to determine that the fracture is the source of pain).
3. Osteolytic vertebral metastasis and myeloma with severe back pain related to a destruction of the vertebral body.
4. Painful vertebral eosinophilic granuloma with spinal instability
5. Painful vertebral fracture associated with osteonecrosis (Kummell disease).

NOTE: These procedures are usually performed as an outpatient but occasionally require an overnight stay due to pain management or adverse events associated with the procedure. Adverse events associated with this procedure include cardiac arrhythmia, re-fracture, new fractures, pulmonary embolism and/or deep vein thrombosis.

Limitations/Exclusions:

General Limitations for Vertebral Augmentation (Percutaneous Kyphoplasty) and Vertebroplasty include all of the following:

- Treatment of more than one or two levels per session would not be anticipated and documentation should justify the treatment of each level (three levels may be performed in rare instances such as severe osteopenia in immunocompromised patients).

Vertebral Augmentation (Percutaneous Kyphoplasty)

Policy Number: PA-086
Last Review Date: 05/09/2019
Effective Date: 07/01/2019

- The procedure must be performed utilizing CT or fluoroscopic real-time imaging guidance.
- Spinal surgical services must be available for emergency decompressive surgery secondary to epidural leakage.
- Neither vertebroplasty nor percutaneous vertebral augmentation is indicated for treatment of lesions of the sacrum or coccyx.
- The bone cement, bone cement delivery systems and devices used in percutaneous kyphoplasty and vertebroplasty procedures must have Food and Drug Administration (FDA) approval for that intent.
- Not covered as prophylactic procedures of the spine for osteopenia or osteoporosis.
- Presence of a retropulsed fracture fragment or tumor mass causing significant spinal canal compromise resulting in myelopathy.
- Absence of a confirmed fracture.
- No payment allowed for procedures performed immediately following acute compression fractures or the diagnosis of them or for procedures performed in Emergency Room.
- Kyphoplasty and vertebroplasty may be considered on a case by case basis with less than two weeks of conservative therapy in elderly patients who are immunocompromised and experiencing continuous pain in spite of analgesics.
- Procedures will not be paid separately when combined with any open spine procedure.
- Bone biopsy done at the same level as vertebral augmentation is part of the primary procedure and will not be paid separately.
- Performance of these procedures should include follow-up assessment of the patient including documentation of patient comfort/activity and pain scores.

Background

Percutaneous vertebroplasty (PVP) is a minimally invasive treatment involving percutaneous needle injection of bone cement into a diseased vertebral body. PVP may provide an analgesic effect through mechanical stabilization of a fractured or otherwise weakened vertebral body. PVP involves injection of a cement-like substance, most commonly Polymethylmethacrylate (PMMA), into a diseased vertebral body. PMMA is made radiopaque by the addition of barium sulfate powder and tantalum powder. The injection is performed by introducing a needle (usually 10–15 gauge, depending on the spinal level) through a transpedicular or paravertebral approach into the vertebral body. Either fluoroscopic or computed tomographic (CT) guidance is used to guide needle placement.

Vertebral Augmentation (Percutaneous Kyphoplasty)

Policy Number: PA-086
 Last Review Date: 05/09/2019
 Effective Date: 07/01/2019

Percutaneous Vertebral Augmentation (also known as balloon-assisted percutaneous vertebroplasty, kyphoplasty or PVA) is similar to percutaneous vertebroplasty in that stabilization of the collapsed vertebra is accomplished by the injection of methylmethacrylate cement into the body of the vertebra. The primary difference in the case of percutaneous vertebral augmentation is that the fracture itself is at least partially reduced by expanding the intrabody space by the use of inflatable bone tamps or other device that displaces, removes or compacts bone to create a space, void or cavity. Once the compression is reduced to an acceptable degree, the bone cement is then injected. In this way, some of the bony deformity and resulting kyphosis may be reduced, often significantly improving the patient's pain.

The Centers for Medicare and Medicaid Services (CMS) has provided a table distinguishing the different nomenclature within the scientific community:

Association/ Organization	Vertebral Augmentation Injection Only	Vertebral Augmentation Injection and Mechanical Devices
ACR	Vertebroplasty, acrylic vertebroplasty	Balloon Kyphoplasty, balloon-assisted vertebroplasty
AMA CPT	Percutaneous vertebroplasty	Percutaneous vertebroplasty augmentation including cavity creation using mechanical devices, kyphoplasty
FDA	Vertebroplasty	Kyphoplasty
LCD	Vertebroplasty	Kyphoplasty

Codes:

CPT Codes	
Code	Description
22510	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic
22511	Lumbosacral
22512	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, 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic

Vertebral Augmentation (Percutaneous Kyphoplasty)

Policy Number: PA-086
 Last Review Date: 05/09/2019
 Effective Date: 07/01/2019

22514	Lumbar
22515	Each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)

References

1. American Academy of Orthopaedic Surgeons: The treatment of symptomatic osteoporotic spinal compression fractures- Guideline and Evidence Report. Adopted: September 24, 2010. AAOS Clinical Practice Guideline Unit. V1.0 092510. <http://www.aaos.org/Research/guidelines/SCFguideline.pdf>
2. American College of Radiology, American Society of Neuroradiology, American Society of Spine Radiology, Society of Interventional Radiology, and Society of NeuroInterventional Surgery: ACR-ASNR-ASSR-SIR-SNIS Practice Parameter for the Performance of Vertebral Augmentation. Amended 2017 – Resolution 16 - <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/vertebraaug.pdf?la=en>
3. Barr JD, Jensen ME, Hirsch JA, et al. [Society of Interventional Radiology; American Association of Neurological Surgeons; Congress of Neurological Surgeons; American College of Radiology; American Society of Neuroradiology; American Society of Spine Radiology; Canadian Interventional Radiology Association; Society of Neurointerventional Surgery]. 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):171-181. doi: 10.1016/j.jvir.2013.10.001. Epub 2013 Dec 8. <http://www.sciencedirect.com/science/article/pii/S1051044313014875#>
4. BlueCross BlueShield Association, Technology Evaluation Center (TEC). Percutaneous Vertebroplasty or Kyphoplasty for Vertebral Fractures Caused by Osteoporosis: Executive Summary. September 2008; Vol 25, No. 9. <https://pdfs.semanticscholar.org/14c9/54757d9fa54500a9834c05a5b20fdb1aa62.pdf>
5. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) No. L35130 – Vertebroplasty, Vertebral Augmentation (Kyphoplasty) Percutaneous. Revision Effective Date: 05/04/2017. <https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35130&ver=42&Date=&DocID=L35130&bc=iAAAABAAAA&&>

Vertebral Augmentation (Percutaneous Kyphoplasty)

Policy Number: PA-086
Last Review Date: 05/09/2019
Effective Date: 07/01/2019

6. Centers for Medicare and Medicaid Services (CMS). Draft Technology Assessment: Percutaneous Kyphoplasty for Vertebral Fractures Caused by Osteoporosis and Malignancy. 2005. <http://www.cms.gov/medicare-coverage-database/details/technology-assessments-details.aspx?TAId=25&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7CCAL%7CNCD%7CMEDCAC%7CTA%7CMCD&ArticleType=Ed%7CKey%7CSAD%7CFAQ&PolicyType=Both&s=All&CntrctrType=1&Keyword=health&KeywordLookUp=Title&KeywordSearchType=Exact&ICD=525.65&CptHcpcsCode=22222&DateTag=C&bc=AAAAABAAAA&>
7. Centers for Medicare and Medicaid Services (CMS), MLN Matters Number MM3632. Original Effective Date: January 1, 2005. Last updated May 9, 2013. Update of the Hospital Outpatient Prospective Payment System (OPPS): Summary of Payment Policy Changes. <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM3632.pdf>
8. Hayes. Medical Technology Directory. Percutaneous Kyphoplasty. March 9, 2016. Annual Report April 04, 2019.
9. Karliner L. Balloon Kyphoplasty as a Treatment for Vertebral Compression Fractures. California Technology Assessment Forum. Published: 06/17/2009. http://icer-review.org/wp-content/uploads/2016/01/1025_file_Kyphoplasty_W2.pdf
Mcguire Jr. RA. Treating spinal compression fractures. New guideline recommends against use of vertebroplasty. American Academy of Orthopedic Surgeons. AAOS Now. October 2010. http://www6.aaos.org/news/PDFopen/PDFopen.cfm?page_url=http://www.aaos.org/news/aaosnow/oct10/cover1.asp
10. Medtronic Inc. Kyphon Balloon Kyphoplasty. Last Updated: April 2019. Last Accessed: April 21, 2019. ©2019, Medtronic, Inc. <http://www.medtronic.com/for-healthcare-professionals/products-therapies/spinal/balloon-kyphoplasty/kyphon-balloon-kyphoplasty/index.htm>
11. National Institute for Health and Clinical Excellence (NICE). Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures. NICE Technology Appraisal Guidance No. 279. Issued: April 2013. <https://www.nice.org.uk/guidance/ta279/resources/guidance-percutaneous-vertebroplasty-and-percutaneous-balloon-kyphoplasty-for-treating-osteoporotic-vertebral-compression-fractures-pdf>
12. National Institute for Health and Clinical Excellence (NICE). Balloon kyphoplasty for vertebral compression fractures. Interventional Procedure Guidance (IPG) No. 166. Issued: April 2006. <https://www.nice.org.uk/guidance/ipg166/chapter/2-The-procedure>

Vertebral Augmentation (Percutaneous Kyphoplasty)

Policy Number: PA-086
Last Review Date: 05/09/2019
Effective Date: 07/01/2019

13. U.S. Department of Health & Humans Services (HHS). Agency for Healthcare Research and Quality (AHRQ). National Guideline Clearinghouse (NGC): ACR Appropriate Criteria ® radiologic management of vertebral compression fractures. NGC #10149. Summary Updated:2018.
<https://acsearch.acr.org/docs/70545/Narrative/>
14. U.S. Department of Health & Humans Services (HHS). Agency for Healthcare Research and Quality (AHRQ). National Guideline Clearinghouse (NGC): Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures. NGC# 9800. Summary Completed: June 17, 2013. Updated 2014. <https://www.ncbi.nlm.nih.gov/pubmed/24650687>
Washington State Health Care Authority, Health Technology Assessment. Vertebroplasty, Kyphoplasty and Sacroplasty. Final Report Published: November 4, 2010. Updated December 9, 2016.
<https://www.hca.wa.gov/assets/Vertebroplasty-Kyphoplasty-Sacroplasty-Signals-for-Update-20170202.pdf>

Disclaimer:

Evolent Health medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of Evolent Health and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

Evolent Health reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

These policies are the proprietary information of Evolent Health. Any sale, copying, or dissemination of said policies is prohibited.