

Kyphoplasty and Vertebroplasty

Policy Number:

MM.06.007

Line(s) of Business:

HMO; PPO; QUEST Integration

Section:

Surgery

Place(s) of Service:

Inpatient; Outpatient; Office

Original Effective Date:

01/11/2005

Current Effective Date:

09/01/2018

I. Description

Percutaneous balloon kyphoplasty and mechanical vertebral augmentation with Kiva are procedures used to treat individuals with one or more vertebral body compression fractures. Performed by interventional radiologists or orthopedic surgeons under fluoroscopic guidance, a small cannula is introduced and balloon catheters are inserted and inflated to create a space within the vertebra. The balloon catheters are removed and the space is filled with a bone cement mixture, usually polymethylmethacrylate (PMMA). The goal is to restore height to the bone, thus reducing deformity of the spine and to immediately stabilize the fracture. The procedure is usually performed on both sides of the vertebral body through the pedicles.

Vertebroplasty is an interventional radiology procedure using fluoroscopic guidance, in which PMMA is injected into a weakened vertebral body. The procedure is used for relief of pain caused by vertebral compression fractures or osteolytic lesions of the spine due to multiple myeloma or metastatic malignancy. Vertebroplasty may also be used for vertebral hemangioma causing severe pain or nerve compression.

II. Criteria/Guidelines

Percutaneous kyphoplasty, mechanical vertebral augmentation with Kiva, or vertebroplasty are covered (subject to Limitations and Administrative Guidelines) when the following criteria are met:

- A. The patient has acute vertebral compression fractures secondary to osteoporosis, has experienced severe back pain for at least six weeks and has failed an adequate trial of conservative therapy that includes, but is not limited to:
 - a. Initial bed rest with progressive activity
 - b. Physical therapy and/or
 - c. Analgesics
- B. The patient has osteolytic vertebral lesions related to multiple myeloma or metastatic malignancies.

III. Limitations/Exclusions

- A. Kyphoplasty will not be covered for more than three vertebral bodies in a single operative session.
- B. Peer-reviewed literature for kyphoplasty/vertebroplasty has not been shown to be medically effective for indications other than those listed in this policy.
- C. Kyphoplasty is contraindicated for compression fractures that are more than one year old.

- D. Kyphoplasty is not to be performed as prophylaxis for either osteoporosis of the spine or chronic back pain if associated with old, healed compression fracture(s).
- E. Because of safety concerns, kyphoplasty/vertebroplasty is contraindicated for patients with the following conditions:
1. Uncorrected coagulation disorders;
 2. Underlying infection (e.g., osteomyelitis of the involved vertebra);
 3. Severe cardiopulmonary disease;
 4. Neurological symptoms related to spinal compression;
 5. Allergy to any component required for the procedure.
 6. Consideration must be given to the extent of the disease, the spinal level involved and previous treatments attempted before considering kyphoplasty/Kiva/vertebroplasty as an option.
 7. In situations when a patient's condition makes the procedure unsafe, or if there will be limited or no significant improvement in activities of daily living, kyphoplasty/vertebroplasty will not be eligible for payment.

IV. Administrative Guidelines

- A. Precertification is not required for kyphoplasty, mechanical vertebral augmentation with Kiva, or vertebroplasty. HMSA reserves the right to perform retrospective reviews using the above criteria to validate if services rendered met payment determination criteria.
- B. CPT code 20225 for a bone biopsy is considered incidental to the kyphoplasty/Kiva/vertebroplasty procedure and is not payable separately.

CPT Codes	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
25212	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 (e.g., 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 (e.g., 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 (e.g., 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)
--	---

ICD-10 Codes	Description
0PU33JZ	Supplement Cervical Vertebra with Synthetic Substitute, Percutaneous Approach
0PU34JZ	Supplement Cervical Vertebra with Synthetic Substitute, Percutaneous Endoscopic Approach
0PU43JZ	Supplement Thoracic Vertebra with Synthetic Substitute, Percutaneous Approach
0PU44JZ	Supplement Thoracic Vertebra with Synthetic Substitute, Percutaneous Endoscopic Approach
0QU03JZ	Supplement Lumbar Vertebra with Synthetic Substitute, Percutaneous Approach
0QU04JZ	Supplement Lumbar Vertebra with Synthetic Substitute, Percutaneous Endoscopic Approach
0QU13JZ	Supplement Sacrum with Synthetic Substitute, Percutaneous Approach
0QU14JZ	Supplement Sacrum with Synthetic Substitute, Percutaneous Endoscopic Approach
0PS33ZZ	Reposition Cervical Vertebra, Percutaneous Approach
0PS43ZZ	Reposition Thoracic Vertebra, Percutaneous Approach
0PU33JZ	Supplement Cervical Vertebra with Synthetic Substitute, Percutaneous Approach
0PU43JZ	Supplement Thoracic Vertebra with Synthetic Substitute, Percutaneous Approach
0QS03ZZ	Reposition Lumbar Vertebra, Percutaneous Approach
0QS13ZZ	Reposition Sacrum, Percutaneous Approach
0QSS3ZZ	Reposition Coccyx, Percutaneous Approach
0QU03JZ	Supplement Lumbar Vertebra with Synthetic Substitute, Percutaneous Approach
0QU13JZ	Supplement Sacrum with Synthetic Substitute, Percutaneous Approach
0QUS3JZ	Supplement Coccyx with Synthetic Substitute, Percutaneous Approach

V. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii's Patients' Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA's determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VI. References

1. 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.* Jul 2011;26(7):1627-1637. PMID 21337428
2. Van Meirhaeghe J, Bastian L, Boonen S, et al. A Randomized Trial of Balloon Kyphoplasty and Non-Surgical Management for Treating Acute Vertebral Compression Fractures: Vertebral Body Kyphosis Correction and Surgical Parameters. *Spine (Phila Pa 1976).* Mar 5 2013. PMID 23446769
3. Berenson J, Pflugmacher R, Jarzem P, et al. Balloon kyphoplasty versus non-surgical fracture management for treatment of painful vertebral body compression fractures in patients with cancer: a multicentre, randomised controlled trial. *Lancet Oncol.* Mar 2011;12(3):225-235. PMID 21333599
4. Edidin AA, Ong KL, Lau E, et al. Mortality risk for operated and nonoperated vertebral fracture patients in the medicare population. *J Bone Miner Res.* Jul 2011;26(7):1617-1626. PMID 21308780
5. Moerman DE, Jonas WB. Deconstructing the placebo effect and finding the meaning response. *Ann Intern Med.* Mar 19 2002;136(6):471-476. PMID 11900500
6. Buchbinder R, Osborne RH, Ebeling PR, et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. *N Engl J Med.* Aug 6 2009;361(6):557-568. PMID 19657121
7. Kallmes DF, Comstock BA, Heagerty PJ, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. *N Engl J Med.* Aug 6 2009;361(6):569-579. PMID 19657122
8. Yi X, Lu H, Tian F, et al. Recompression in new levels after percutaneous vertebroplasty and kyphoplasty compared with conservative treatment. *Arch Orthop Trauma Surg.* Jan 2014;134(1):21-30. PMID 24287674
9. Chang X, Lv YF, Chen B, et al. Vertebroplasty versus kyphoplasty in osteoporotic vertebral compression fracture: a meta-analysis of prospective comparative studies. *Int Orthop.* Mar 2015;39(3):491-500. PMID 25260399
10. Dohm M, Black CM, Dacre A, et al. A randomized trial comparing balloon kyphoplasty and vertebroplasty for vertebral compression fractures due to osteoporosis. *AJNR Am J Neuroradiol.* Dec 2014;35(12):2227-2236. PMID 25300981

11. Tutton SM, Pflugmacher R, Davidian M, et al. KAST Study: The Kiva(R) System as a Vertebral Augmentation Treatment - A Safety and Effectiveness Trial: A Randomized, Non-inferiority Trial Kyphoplasty and Vertebroplasty 6
Comparing the Kiva(R) System to Balloon Kyphoplasty in Treatment of Osteoporotic Vertebral Compression Fractures. *Spine (Phila Pa 1976)*. Mar 27 2015. PMID 25822543
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)*. Feb 15 2013;38(4):292-299. PMID 23407406
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*. Sep-Oct 2013;16(5):E505-512. PMID 24077200
14. Werner CM, Osterhoff G, Schlickeiser J, et al. Vertebral body stenting versus kyphoplasty for the treatment of osteoporotic vertebral compression fractures: a randomized trial. *J Bone Joint Surg Am*. Apr 3 2013;95(7):577-584. PMID 23553291
15. Jensen ME, McGraw JK, Cardella JF, et al. Position statement on percutaneous vertebral augmentation: a consensus statement developed by the American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, American Association of Neurological Surgeons/Congress of Neurological Surgeons, and American Society of Spine Radiology. *J Vasc Interv Radiol*. Mar 2007;18(3):325-330. PMID 17377175
16. 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*. Feb 2014;25(2):171-181. PMID 24325929
17. Baerlocher MO, Saad WE, Dariushnia S, et al. Quality improvement guidelines for percutaneous vertebroplasty. *J Vasc Interv Radiol*. Feb 2014;25(2):165-170. PMID 24238815
18. 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*. Mar 21 2009;373(9668):1016-1024. PMID 19246088
19. 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*. Jul 2011;26(7):1627-1637. PMID 21337428
20. Van Meirhaeghe J, Bastian L, Boonen S, et al. A Randomized Trial of Balloon Kyphoplasty and Non-Surgical Management for Treating Acute Vertebral Compression Fractures: Vertebral Body Kyphosis Correction and Surgical Parameters. *Spine (Phila Pa 1976)*. Mar 5 2013. PMID 23446769
21. Berenson J, Pflugmacher R, Jarzem P, et al. Balloon kyphoplasty versus non-surgical fracture management for treatment of painful vertebral body compression fractures in patients with cancer: a multicentre, randomised controlled trial. *Lancet Oncol*. Mar 2011;12(3):225-235. PMID 21333599
22. Edidin AA, Ong KL, Lau E, et al. Mortality risk for operated and nonoperated vertebral fracture patients in the medicare population. *J Bone Miner Res*. Jul 2011;26(7):1617-1626. PMID 21308780
23. Buchbinder R, Osborne RH, Ebeling PR, et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. *N Engl J Med*. Aug 6 2009;361(6):557-568. PMID 19657121
24. Kallmes DF, Comstock BA, Heagerty PJ, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. *N Engl J Med*. Aug 6 2009;361(6):569-579. PMID 19657122

25. Yi X, Lu H, Tian F, et al. Recompression in new levels after percutaneous vertebroplasty and kyphoplasty compared with conservative treatment. *Arch Orthop Trauma Surg*. Jan 2014;134(1):21-30. PMID 24287674
26. Chang X, Lv YF, Chen B, et al. Vertebroplasty versus kyphoplasty in osteoporotic vertebral compression fracture: a meta-analysis of prospective comparative studies. *Int Orthop*. Mar 2015;39(3):491-500. PMID 25260399
27. Dohm M, Black CM, Dacre A, et al. A randomized trial comparing balloon kyphoplasty and vertebroplasty for vertebral compression fractures due to osteoporosis. *AJNR Am J Neuroradiol*. Dec 2014;35(12):2227-2236. PMID 25300981
28. Tutton SM, Pflugmacher R, Davidian M, et al. KAST Study: The Kiva(R) System as a Vertebral Augmentation Treatment - A Safety and Effectiveness Trial: A Randomized, Non-inferiority Trial Comparing the Kiva(R) System to Balloon Kyphoplasty in Treatment of Osteoporotic Vertebral Compression Fractures. *Spine (Phila Pa 1976)*. Mar 27 2015. PMID 25822543
29. 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)*. Feb 15 2013;38(4):292-299. PMID 23407406
30. 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*. Sep-Oct 2013;16(5):E505-512. PMID 24077200
31. Werner CM, Osterhoff G, Schlickeiser J, et al. Vertebral body stenting versus kyphoplasty for the treatment of osteoporotic vertebral compression fractures: a randomized trial. *J Bone Joint Surg Am*. Apr 3 2013;95(7):577- 584. PMID 23553291
32. Jensen ME, McGraw JK, Cardella JF, et al. Position statement on percutaneous vertebral augmentation: a consensus statement developed by the American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, American Association of Neurological Surgeons/Congress of Neurological Surgeons, and American Society of Spine Radiology. *J Vasc Interv Radiol*. Mar 2007;18(3):325-330. PMID 17377175
33. 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*. Feb 2014;25(2):171-181. PMID 24325929
34. Baerlocher MO, Saad WE, Dariushnia S, et al. Quality improvement guidelines for percutaneous vertebroplasty. *J Vasc Interv Radiol*. Feb 2014;25(2):165-170. PMID 24238815
35. American Society for Metabolic and Bariatric Surgery. Peri-Operative Management of Obstructive Sleep Apnea. May 2012.
<https://asmbs.org/resources/peri-operative-management-of-obstructive-sleep-apnea>
36. Medical Policy Reference Manual. Blue Cross Blue Shield Association. Percutaneous Vertebroplasty and Sacroplasty, Policy #6.01.38; August 2017
37. Medical Policy Reference Manual. Blue Cross Blue Shield Association. Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation, Policy #6.01.25; May 2017