Protocol

Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation

(60138)

Medical Benefit		**Effective Date**: 10/01/20	**Next Review Date**: 07/23
Preauthorization	No	**Review Dates**: 04/07, 05/08, 01/09, 01/10, 09/10, 07/11, 07/12, 07/13, 07/14, 07/15, 07/16, 07/17, 07/18, 07/19, 07/20, 07/21, 07/22	

Preauthorization is not required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

RELATED PROTOCOL

Percutaneous Vertebroplasty and Sacroplasty

Populations	Interventions	Comparators	Outcomes
Individuals: • With osteoporotic vertebral compression fractures	Interventions of interest are: • Balloon kyphoplasty or mechanical vertebral augmentation	Comparators of interest are: • Conservative care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Hospitalizations • Treatment-related morbidity
Individuals: • With osteolytic vertebral compression fractures	Interventions of interest are: • Balloon kyphoplasty or mechanical vertebral augmentation	Comparators of interest are: • Conservative care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Hospitalizations • Treatment-related morbidity
Individuals: • With osteoporotic or osteolytic vertebral compression fractures	Interventions of interest are: • Radiofrequency kyphoplasty	Comparators of interest are: • Conservative care	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Hospitalizations • Treatment-related morbidity

DESCRIPTION

Percutaneous balloon kyphoplasty, radiofrequency kyphoplasty, and mechanical vertebral augmentation are interventional techniques involving the fluoroscopically guided injection of polymethyl methacrylate into a cavity created in the vertebral body with a balloon or mechanical device. These techniques have been investigated as options to provide mechanical support and symptomatic relief in patients with osteoporotic vertebral

compression fracture or those with osteolytic lesions of the spine (i.e., multiple myeloma, metastatic malignancies).

SUMMARY OF EVIDENCE

For individuals who have osteoporotic vertebral compression fracture who receive balloon kyphoplasty, or mechanical vertebral augmentation, the evidence includes an Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness review, randomized controlled trials (RCTs), and meta-analyses. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. The AHRQ review concluded that vertebroplasty was probably more effective at reducing pain and improving function in patients >65 years of age, but benefits were small. Kyphopasty was found to be probably more effective than usual care for pain and function in older patients with vertebral compression fracture at up to 1 month and may be more effective at >1 month to ≥1 year but has not been compared against sham therapy. A meta-analysis and moderately sized unblinded RCT have compared kyphoplasty with conservative care and found short-term benefits in pain and other outcomes. One systematic review of RCTs found no significant difference in subsequent fracture between vertebroplasty and conservative treatment, and another systematic review of prospective and retrospective studies reported improved mortality with either vertebroplasty or balloon kyphoplasty compared with conservative treatment. Other RCTs, summarized in a meta-analysis, have reported similar outcomes for kyphoplasty and vertebroplasty. Three randomized trials that compared mechanical vertebral augmentation (Kiva or SpineJack) with kyphoplasty have reported similar outcomes for both procedures. A major limitation of all these RCTs is the lack of a sham procedure. Due to the possible sham effect observed in the recent trials of vertebroplasty, the validity of the results from non-sham-controlled trials is unclear. Therefore, whether these improvements represent a true treatment effect is uncertain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have osteolytic vertebral compression fracture who receive balloon kyphoplasty or mechanical vertebral augmentation, the evidence includes RCTs, case series, and systematic reviews of these studies. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. Two RCTs have compared balloon kyphoplasty with conservative management, and another has compared Kiva with balloon kyphoplasty. Results of these trials, along with case series, would suggest a reduction in pain, disability, and analgesic use in patients with cancer-related compression fractures. However, because the results of the comparative studies of vertebroplasty have suggested possible placebo or natural history effects, the evidence these studies provide is insufficient to warrant conclusions about the effect of kyphoplasty on health outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have osteoporotic or osteolytic vertebral compression fracture who receive radiofrequency kyphoplasty, the evidence includes a systematic review and an RCT. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. The only RCT (N=80) identified showed similar results between radiofrequency kyphoplasty and balloon kyphoplasty. The systematic review suggested that radiofrequency kyphoplasty is superior to balloon kyphoplasty in pain relief, but the review itself was limited by the inclusion of a small number of studies as well as possible bias. Corroboration of these results in a larger number of patients would be needed to determine with greater certainty whether radiofrequency kyphoplasty provides outcomes similar to balloon kyphoplasty. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

POLICY

Balloon kyphoplasty may be considered **medically necessary** for the treatment of symptomatic thoracolumbar osteoporotic vertebral compression fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy; rest) for at least six weeks.

Mechanical vertebral augmentation with an FDA cleared device may be considered **medically necessary** for the treatment of symptomatic thoracolumbar osteoporotic vertebral compression fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy; rest) for at least six weeks.

Balloon kyphoplasty may be considered **medically necessary** for the treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

Mechanical vertebral augmentation with an FDA cleared device may be considered **medically necessary** for the treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

Balloon kyphoplasty or mechanical vertebral augmentation with an FDA cleared device are considered **investigational** for all other indications, including use in acute vertebral fractures due to osteoporosis or trauma.

Radiofrequency kyphoplasty is considered **investigational**.

Mechanical vertebral augmentation using any other device is considered **investigational**.

MEDICARE ADVANTAGE

The following only addresses Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF). See above for other indications.

PVA [kyphoplasty (PKP)] is considered **medically necessary** with BOTH the following:

1. Inclusion criteria (ALL are required):
    a. Acute* (less than six weeks) osteoporotic Vertebral Compression Fracture (VCF) (T5 – L5) by recent (within 30 days) advanced imaging (bone marrow edema on MRI or bone-scan/SPECT/CT uptake)
    b. Symptomatic (ONE):
        i. Hospitalized with severe pain (Numeric Rating Scale (NRS) or Visual Analog Scale (VAS) pain score ≥8)
        ii. Non-hospitalized with moderate to severe pain (NRS or VAS ≥5) despite optimal non-surgical management** (ONE):
            1. Worsening pain
            2. Stable to improved pain (but NRS or VAS still ≥5) (with two or more of the following)**:**
                A. Progression of vertebral body height loss
                B. More than 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 (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 (Can have NONE of the following):
   a. Absolute contraindication
      i. Current back pain is not primarily due to the identified acute VCF(s).
      ii. Osteomyelitis, discitis or active systemic infection
      iii. Pregnancy
      iv. Greater than three vertebral fractures
   b. Relative contraindication
      i. Allergy to bone cement or opacification agents
      ii. Coagulopathy
      iii. Spinal instability
      iv. Myelopathy from the fracture
      v. Neurologic deficit
      vi. Neural impingement
      vii. Fracture retropulsion/canal compromise

*at least an acute component (e.g., acute on chronic)

**consider including pedicle periosteal infiltration

BACKGROUND

OSTEOPOROTIC VERTEBRAL COMPRESSION FRACTURE

Osteoporotic compression fractures are common. It is estimated that up to 50% of women and 25% of men will have a vertebral fracture at some point in their lives. However, only about one-third of vertebral fractures reach clinical diagnosis, and most symptomatic fractures will heal within a few weeks or 1 month. A minority of patients will exhibit chronic pain following osteoporotic compression fracture that presents challenges for medical management.

Treatment

Chronic symptoms do not tend to respond to the management strategies for acute pain such as bed rest, immobilization or bracing device, and analgesic medication, sometimes including narcotic analgesics. The source of chronic pain after vertebral compression fracture may not be from the vertebra itself but may be predominantly related to the strain on muscles and ligaments secondary to kyphosis. This type of pain frequently is not improved with analgesics and may be better addressed through exercise. Conventional vertebroplasty surgical intervention may be required in severe cases not responsive to conservative measures.

OSTEOLYTIC VERTEBRAL BODY FRACTURES

Vertebral body fractures can also be pathologic, due to osteolytic lesions, most commonly from metastatic tumors. Metastatic malignant disease involving the spine generally involves the vertebral bodies, with pain being the most frequent complaint.

Treatment

While radiotherapy and chemotherapy are frequently effective in reducing tumor burden and associated symptoms, pain relief may be delayed days to weeks, depending on tumor response. Further, these approaches rely on bone remodeling to regain vertebral body strength, which may necessitate supportive bracing to minimize the risk of vertebral body collapse during healing.

REGULATORY STATUS

Kyphoplasty is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration (FDA). Polymethyl methacrylate bone cement was available as a drug product before enactment of the FDA's device regulation and was at first considered what the FDA termed a "transitional device." It was transitioned to a class III device and then to a class II device, which required future 510(k) submissions to meet "special controls" instead of "general controls" to assure safety and effectiveness. In July 2004, KyphX® HV-RTM bone cement was cleared for marketing by the FDA through the 510(k) process for the treatment of pathologic fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a balloon kyphoplasty procedure. Subsequently, other products such as Spine-Fix® Biomimetic Bone Cement, KYPHON® HV-R® Bone Cement, and Osteopal® V (Heraeus) have received 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

Balloon kyphoplasty requires the use of an inflatable bone tamp. In July 1998, one such tamp, the KyphX® inflatable bone tamp (Medtronic), was cleared for marketing by the FDA through the 510(k) process. Additional devices for balloon kyphoplasty are listed in Table 1.

There are several mechanical vertebral augmentation devices that have received marketing clearance by the FDA through the 510(k) process; these are listed in Table 1.

StabiliT® Vertebral Augmentation System (Merit Medical) for radiofrequency vertebral augmentation was cleared for marketing in 2009.

FDA product code NDN.

Table 1. Kyphoplasty and Mechanical Vertebral Augmentation Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Balloon Kyphoplasty				
TRACKER Plus Kyphoplasty System	GS Medical Co., Ltd	10/28/2021	K211797	Reduction of fractures and/or creation of a void
Joline Kyphoplasty System Allevo	Joline GmbH & Co.	5/27/2020		To repair vertebral compression fractures
TRACKER Kyphoplasty System	GS Medical Co., Ltd	12/4/2019	K192335	Reduction of fractures or creation of a void
Stryker iVAS Elite Inflatable Vertebral Augmentation System (Stryker iVAS Elite Balloon Catheter)	Stryker Corporation	12/21/2018	K181752	To repair vertebral compression fractures
SpineKure Kyphoplasty System	Hanchang Co. Ltd.	5/29/2018	K172871	To repair vertebral compression fractures

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Modified Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters	G-21 s.r.l.	8/23/2017	K172214	To repair vertebral compression fractures
13G InterV Kyphoplasty Catheter (Micro) and 11G InterV Kyphoplasty Catheter (Mini-Flex)	Pan Medical Ltd.	11/1/2016	K162453	To repair vertebral compression fractures
MEDINAUT Kyphoplasty System	Imedicom Co. Ltd.	7/29/2016	K153296	To repair vertebral compression fractures
AVAflex Vertebral Balloon System	Carefusion	11/24/2015	K151125	To repair vertebral compression fractures
Osseoflex SB Straight Balloon 10g/4ml Osseoflex SB Straight Balloon 10g/2ml	Osseon LLC	4/9/2015	K150607	To repair vertebral compression fractures
InterV Kyphoplasty Catheter (Balloon Length: 1015 and 20mm) InterV Kyphoplasty Catheter (Mini) (Balloon Length: 10 15 and 20mm)	Pan Medical Ltd.	3/6/2015	K150322	To repair vertebral compression fractures
GUARDIAN-SG Inflatable Bone Expander System	BM Korea Co. Ltd.	1/16/2015	K143006	To repair vertebral compression fractures
ZVPLASTY	Zavation LLC	9/12/2014	K141419	To repair vertebral compression fractures
Mechanical Vertebral Augmentation				
Kiva VCF Treatment System	Benvenue Medical Inc.	8/14/2014	K141141	To repair vertebral compression fractures
SpineJack Expansion Kit	Vexim SA	8/30/2018	K181262	To repair vertebral compression fractures
V-Strut Vertebral Implant	Hyprevention SAS	3/5/2020	K191709	Treatment of vertebral fractures in the thoracic and lumbar spine

---

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Jarvik JG, Deyo RA. Cementing the evidence: time for a randomized trial of vertebroplasty. AJNR Am J Neuroradiol. Sep 2000;21(8):1373-4. PMID 11003266
2. Moerman DE, Jonas WB. Deconstructing the placebo effect and finding the meaning response. Ann Intern Med. Mar 19 2002;136(6):471-6. PMID 11900500
3. Hrobjartsson A, Gotzsche PC. Is the placebo powerless? An analysis of clinical trials comparing placebo with no treatment. N Engl J Med. May 24 2001;344(21):1594-602. PMID 11372012

4. Vase L, Riley JL, Price DD. A comparison of placebo effects in clinical analgesic trials versus studies of placebo analgesia. Pain. Oct 2002;99(3):443-452. PMID 12406519
5. Buchbinder R, Osborne RH, Ebeling PR, et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. N Engl J Med. Aug 06 2009;361(6):557-68. PMID 19657121
6. Kallmes DF, Comstock BA, Heagerty PJ, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. N Engl J Med. Aug 06 2009;361(6):569-79. PMID 19657122
7. Chou R, Fu R, Dana T, et al. Interventional treatments for acute and chronic pain: systematic review [Internet]. AHRQ Comparative Effectiveness Reviews. Rockville (MD): Agency for Healthcare Research and Quality; 2021 Sep. Report No.: 21-EHC030
8. Zhao S, Xu CY, Zhu AR, et al. Comparison of the efficacy and safety of 3 treatments for patients with osteoporotic vertebral compression fractures: A network meta-analysis. Medicine (Baltimore). Jun 2017;96(26): e7328. PMID 28658144
9. Hinde K, Maingard J, Hirsch JA, et al. Mortality Outcomes of Vertebral Augmentation (Vertebroplasty and/or Balloon Kyphoplasty) for Osteoporotic Vertebral Compression Fractures: A Systematic Review and Meta-Analysis. Radiology. Apr 2020;295(1):96-103. PMID 32068503
10. Sun HB, Jing XS, Tang H, et al. Clinical and radiological subsequent fractures after vertebral augmentation for treating osteoporotic vertebral compression fractures: a meta-analysis. Eur Spine J. Oct 2020;29(10):2576-2590. PMID 32776263
11. Halvachizadeh S, Stalder AL, Bellut D, et al. Systematic Review and Meta-Analysis of 3 Treatment Arms for Vertebral Compression Fractures: A Comparison of Improvement in Pain, Adjacent-Level Fractures, and Quality of Life Between Vertebroplasty, Kyphoplasty, and Nonoperative Management. JBJS Rev. Oct 25 2021;9(10). PMID 34695056
12. 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):1617-26. PMID 21308780
13. Ong KL, Beall DP, Frohbergh M, et al. Were VCF patients at higher risk of mortality following the 2009 publication of the vertebroplasty "sham" trials?. Osteoporos Int. Feb 2018;29(2):375-383. PMID 29063215
14. 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):1016-24. PMID 19246088
15. 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):1627-37. PMID 21337428
16. Van Meirhaeghe J, Bastian L, Boonen S, et al. A randomized trial of balloon kyphoplasty and nonsurgical management for treating acute vertebral compression fractures: vertebral body kyphosis correction and surgical parameters. Spine (Phila Pa 1976). May 20 2013;38(12):971-83. PMID 23446769
17. Tutton SM, Pflugmacher R, Davidian M, et al. KAST Study: The Kiva System As a Vertebral Augmentation Treatment-A Safety and Effectiveness Trial: A Randomized, Noninferiority Trial Comparing the Kiva System With Balloon Kyphoplasty in Treatment of Osteoporotic Vertebral Compression Fractures. Spine (Phila Pa 1976). Jun 15 2015;40(12):865-75. PMID 25822543
18. 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):292-9. PMID 23407406
19. Noriega D, Marcia S, Theumann N, et al. A prospective, international, randomized, noninferiority study comparing an implantable titanium vertebral augmentation device versus balloon kyphoplasty in the reduction of vertebral compression fractures (SAKOS study). Spine J. Nov 2019;19(11):1782-1795. PMID 31325625
20. Pron G, Holubowich C, Kaulback K. Vertebral Augmentation Involving Vertebroplasty or Kyphoplasty for Cancer-Related Vertebral Compression Fractures: A Systematic Review. Ont Health Technol Assess Ser. 2016; 16(11):1-202. PMID 27298655

21. Mattie R, Brar N, Tram JT, et al. Vertebral Augmentation of Cancer-Related Spinal Compression Fractures: A Systematic Review and Meta-Analysis. Spine (Phila Pa 1976). Dec 15 2021;46(24):1729-1737. PMID 33958537
22. 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):225-35. PMID 21333599
23. Korovessis P, Vardakastanis K, Vitsas V, et al. Is Kiva implant advantageous to balloon kyphoplasty in treating osteolytic metastasis to the spine? Comparison of 2 percutaneous minimal invasive spine techniques: a prospective randomized controlled short-term study. Spine (Phila Pa 1976). Feb 15 2014;39(4):E231-9. PMID 24253785
24. Feng L, Shen JM, Feng C, et al. Comparison of radiofrequency kyphoplasty (RFK) and balloon kyphoplasty (BKP) in the treatment of vertebral compression fractures: A meta-analysis. Medicine (Baltimore). Jun 2017; 96(25):e7150. PMID 28640091
25. Petersen A, Hartwig E, Koch EM, et al. Clinical comparison of postoperative results of balloon kyphoplasty (BKP) versus radiofrequency-targeted vertebral augmentation (RF-TVA): a prospective clinical study. Eur J Orthop Surg Traumatol. Jan 2016;26(1):67-75. PMID 26482590
26. 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
27. Baerlocher MO, Saad WE, Dariushnia S, et al. Quality improvement guidelines for percutaneous vertebroplasty. J Vasc Interv Radiol. Feb 2014;25(2):165-70. PMID 24238815
28. ACR-ASNR-ASSR-SIR-SNIS Practice Parameter for the Performance of Vertebral Augmentation. Available at https://www.acr.org/-/media/ACR/Files/Practice-Parameters/VerebralAug.pdf. Accessed February 16, 2022.
29. American Academy of Orthopaedic Surgeons (AAOS). The treatment of symptomatic osteoporotic spinal compression fractures: Summary of Recommendations. 2010; https://www.mainegeneral.org/app/files/public/921/aaossummary.pdf. Accessed February 16, 2022.
30. National Institute for Health and Care Excellence (NICE). Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures [TA279]. 2013; https://www.nice.org.uk/guidance/ta279. Accessed February 16, 2022.
31. National Institute for Health and Care Excellence (NICE). Metastatic spinal cord compression in adults: risk assessment, diagnosis and management [CG75]. 2008; https://www.nice.org.uk/guidance/cg75/chapter/1-Guidance. Accessed February 16, 2022.
32. National Government Services, Inc. (Primary Geographic Jurisdiction 06 & K - Illinois, Minnesota, Wisconsin, Connecticut, New York - Entire State, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont) Local Coverage Determination (LCD): Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L33569), Revision Effective Date For services performed on or after 12/01/2020.