

Protocol

Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation

(60138)

Medical Benefit		Effective Date: 10/01/20	Next Review Date: 07/21
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	

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 (Kiva), the evidence includes randomized control trials and meta-analyses. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. A meta-analysis and moderately sized unblinded randomized control trial (RCT) have compared kyphoplasty with conservative care and found short-term benefits in pain and other outcomes. 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 the effects of the technology on health outcomes.

For individuals who have osteolytic vertebral compression fracture who receive balloon kyphoplasty or mechanical vertebral augmentation, the evidence includes RCTs, case series, and a systematic review 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 the effects of the technology on health outcomes.

For individuals who have osteoporotic or osteolytic vertebral compression fracture who receive radiofrequency kyphoplasty, the evidence includes a systematic review and an RCT. The 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 the effects of the technology on health outcomes.

ADDITIONAL INFORMATION

After consideration of clinical input, we concluded that, although the scientific evidence does not permit conclusions about the impact on health outcomes and that comparative studies with long-term outcomes are lacking, numerous case series, including large prospective reports, have consistently shown that vertebroplasty and percutaneous balloon kyphoplasty may alleviate pain and improve function in patients with osteoporotic vertebral fractures that have failed to respond to conservative treatment (at least six weeks) with analgesics, physical therapy, and rest. More recent randomized trials, which have compared percutaneous balloon kyphoplasty with medical management, have also reported benefit. Given the absence of alternative treatment options and the morbidity associated with extended bedrest, percutaneous balloon kyphoplasty and mechanical vertebral augmentation may be considered reasonable treatment options in patients with vertebral fractures who fail to improve after six weeks of conservative therapy and, therefore, may be considered medically necessary both for this patient population and populations with severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

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 one 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 bedrest, 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 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 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
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)	Pan Medical Ltd.	11/1/2016	K162453	To repair vertebral compression

Device	Manufacturer	Date Cleared	510(k) No.	Indication
and 11G InterV Kyphoplasty Catheter (Mini-Flex)				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.

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33. 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 12/01/2019.