Protocol

Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation

(60138)

(Formerly Percutaneous Balloon Kyphoplasty and Mechanical Vertebral Augmentation)

Medical Benefit		**Effective Date**: 10/01/18	**Next Review Date**: 07/19
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	

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.

Populations	Interventions	Comparators	Outcomes
Individuals: • With osteoporotic vertebral compression fractures	Interventions of interest are: • Balloon kyphoplasty or mechanical vertebral augmentation (Kiva)	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 (Kiva)	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 with Kiva are interventional techniques involving the fluoroscopically guided injection of polymethylmethacrylate 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 fractures who receive balloon kyphoplasty, or mechanical vertebral augmentation (Kiva), the evidence includes randomized controlled trials (RCTs) and meta-analyses. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. A meta-analysis and moderately sized unblinded 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. Two randomized trials that compared mechanical vertebral augmentation (Kiva) 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 fractures who receive balloon kyphoplasty or mechanical vertebral augmentation (Kiva), 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 fractures 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 the effects of the technology on health outcomes.

POLICY

Balloon kyphoplasty or mechanical vertebral augmentation using Kiva® may be considered **medically necessary** for the treatment of symptomatic 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 or mechanical vertebral augmentation using Kiva® 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 using Kiva® 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

Kyphoplasty (also called vertebral augmentation) is considered **medically necessary** for the following indications:

1. Recent* osteoporotic or osteopenic compression fracture of the lumbar or thoracic vertebrae with persistent debilitating pain that has not responded to accepted standard medical treatment and/or
2. Osteolytic vertebral collapse secondary to multiple myeloma or osteolytic metastatic disease causing persisting or progressive pain.

*A "recent" compression fracture is defined as one which demonstrates uptake on a bone scan or exhibits increased intensity on fluid-sensitive MRI sequences.

Percutaneous kyphoplasty is considered **not medically necessary** as a prophylactic procedure for osteoporosis of the spine or kyphosis without fracture. It also should not be used for chronic back pain of long-standing duration, even if associated with old compression fractures, unless pain is localized to a specific chronic fracture and medical therapy has failed.

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.

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.

Kyphoplasty

Balloon kyphoplasty is a variant of vertebroplasty and uses a specialized bone tamp with an inflatable balloon to expand a collapsed vertebral body as close as possible to its natural height before injection of polymethylmethacrylate (PMMA). Radiofrequency kyphoplasty (also known as radiofrequency targeted vertebral augmentation)

is a modification of balloon kyphoplasty. In this procedure, a small diameter articulating osteotome creates paths across the vertebra. An ultra-high viscosity cement is injected into the fractured vertebral body, and radiofrequency is used to achieve the desired consistency of the cement. The ultra-high viscosity cement is designed to restore height and alignment to the fractured vertebra, along with stabilizing the fracture.

It has been proposed that kyphoplasty may provide an analgesic effect through mechanical stabilization of a fractured or otherwise weakened vertebral body. However, other possible mechanisms of effect have been postulated, one of which is thermal damage to intraosseous nerve fibers, given that PMMA undergoes a heat-releasing (exothermic) reaction during its hardening process.

Vertebral Augmentation

Kiva is another mechanical vertebral augmentation technique that uses an implant for structural support of the vertebral body to provide a reservoir for bone cement. The Kiva VCF Treatment System consists of a shaped memory coil and an implant, which is filled with bone cement. The coil is inserted into the vertebral body over a removable guidewire. The coil reconfigures itself into a stack of loops within the vertebral body and can be customized by changing the number of loops of the coil. The implant, made from PEEK-OPTIMA, a biocompatible polymer, is deployed over the coil. The coil is then retracted, and PMMA is injected through the lumen of the implant. The PMMA cement flows through small slots in the center of the implant, which fixes the implant to the vertebral body and contains the PMMA in a cylindrical column. The proposed advantage of the Kiva system is a reduction in cement leakage.

Outcome Measures

For treatment of osteoporosis and malignancy with percutaneous kyphoplasty, the primary beneficial outcomes of interest are relief of pain and improvement in the ability to function. Kyphoplasty may also restore lost vertebral body height and reduce kyphotic deformity. Potential health outcomes related to kyphotic deformity include pulmonary or gastrointestinal compression and associated symptoms, and vertebral compression fractures may be associated with lower health-related quality of life.

REGULATORY STATUS

Kyphoplasty is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration (FDA). 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. Other devices with FDA 510(k) marketing clearance include the AVAmax® Vertebral Balloon system (CareFusion), NeuroTherm Parallax® Balloon Inflatable Bone Tamp (NeuroTherm), Stryker iVAS® Balloon catheter, and Synthes Synflate™ Vertebral Balloon System (Synthes [West Chester, PA]). StabiliT® Vertebral Augmentation System (Merit Medical) for radiofrequency vertebral augmentation was cleared for marketing in 2009. FDA product code NDN.

In 2014, the Kiva® VCF Treatment System (Benvenue Medical) was cleared for marketing by the FDA through the 510(k) process. FDA product code NDN.

PMMA bone cement was available as a drug product before enactment of FDA's device regulation and was at first considered what 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 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 SpineFix® Biomimetic Bone Cement, KYPHON® HV-R® Bone Cement, and Osteopal® V (Heraeus) have received issued

510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. FDA product code: NDN.

RELATED PROTOCOL

Percutaneous Vertebroplasty and Sacroplasty

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

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

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32. National Government Services, Inc. (Primary Geographic Jurisdiction - Illinois, New York - Entire State, Connecticut, Massachusetts, Maine, New Hampshire, Rhode Island, Vermont, Wisconsin, Minnesota) Local Coverage Determination Vertebroplasty and Vertebral Augmentation (Percutaneous) (L33569) (Original ICD-9 LCD ID L26439) Revision Effective Date For services performed on or after 10/01/2015.