Protocol

Percutaneous Balloon Kyphoplasty and Mechanical Vertebral Augmentation

(60138)

Medical Benefit		**Effective Date**: 10/01/14	**Next Review Date**: 07/15
Preauthorization	No	**Review Dates**: 04/07, 05/08, 01/09, 01/10, 09/10, 07/11, 07/12, 07/13, 07/14	

The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. ***Preauthorization is not required.*** *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.*

Description

Percutaneous balloon kyphoplasty and mechanical vertebral augmentation with Kiva® are interventional techniques involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) into a cavity created in the vertebral body with a balloon or mechanical device. These techniques have been investigated as an option to provide mechanical support and symptomatic relief in patients with osteoporotic vertebral compression fracture, or in those with osteolytic lesions of the spine, i.e., multiple myeloma or metastatic malignancies.

Background

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 the PMMA. Radiofrequency kyphoplasty is a modification of balloon kyphoplasty. In this procedure, 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.

Kiva® is another mechanical vertebral augmentation technique that uses an implant for structural support of the vertebral body and to provide a reservoir for bone cement. The Kiva® VCF system consists of a flexible polymer implant which is filled with bone cement. The implant is made from PEEK-OPTIMA®, a biocompatible polymer, and is inserted into the vertebral body over a removable spiral shaped guide wire. The implant can be customized by changing the number of loops of the coil, with a maximum height of 12 mm. PMMA is injected through the lumen 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.

Another variant of kyphoplasty is vertebral body stenting, which utilizes an expandable scaffold instead of a balloon to restore vertebral height. The proposed advantages of vertebral body stenting are to reduce the risk of cement leakage by formation of a cavity for cement application and to prevent the loss of correction that is seen following removal of the balloon used for balloon kyphoplasty.

Osteoporotic Vertebral Compression Fracture

Osteoporotic compression fractures are a common problem, and it is estimated that up to one-half of women and approximately one quarter of men will have a vertebral fracture at some point in their lives. However, only about one-third of vertebral fractures actually reach clinical diagnosis, and most symptomatic fractures will heal within a few weeks or one month. However, a minority of patients will exhibit chronic pain following osteoporotic compression fracture that presents challenges for medical management. Chronic symptoms do not tend to respond to the management strategies for acute pain such as bedrest, immobilization/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.

Vertebral Body Metastasis

Metastatic malignant disease involving the spine generally involves the vertebral bodies, with pain being the most frequent complaint. While radiation 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.

Vertebral Hemangiomas

Vertebral hemangiomas are relatively common lesions noted in up to 12% of the population based on autopsy series; however, only rarely do these lesions display aggressive features and produce neurologic compromise and/or pain. Treatment of aggressive vertebral hemangiomas has evolved from radiation therapy to surgical approaches using anterior spinal surgery for resection and decompression. There is the potential for large blood loss during surgical resection, and vascular embolization techniques have been used as adjuncts to treatment to reduce blood loss. Percutaneous cementoplasty has been proposed as a way to treat and stabilize some hemangioma to limit the extent of surgical resection and as an adjunct to reduce associated blood loss from the surgery.

Regulatory Status

Kyphoplasty is a surgical procedure and, as such, is not subject to U.S. Food and Drug Administration (FDA) approval. Balloon kyphoplasty requires the use of an inflatable bone tamp. One such tamp, the KyphX® inflatable bone tamp, received 510(k) marketing clearance from FDA in July 1998. Other devices with FDA 510(k) marketing clearance include AVAmax® Vertebral Balloon system (Carefusion), NeuroTherm Parallax® Balloon Inflatable Bone Tamp (NeuroTherm Inc.), Stryker iVAS® Balloon catheter, and Synthes Synflate™ Vertebral Balloon System, Synthes (USA) LLC (FDA product code NDN).

The Kiva® VCF Treatment System (Benvenue Medical) received FDA 510(k) marketing clearance in January 2014 (FDA product code NDN).

Vertebral body stenting (VBS™; Synthes, Switzerland) is available in Europe at this time.

PMMA bone cement was available as a drug product before enactment of FDA's device regulation and was at first considered what the FDA terms a "transitional device." It was transitioned to a class III device requiring premarketing applications. Several orthopedic companies have received approval of their bone cement products since 1976. In October 1999, PMMA was reclassified from class III to class II, which requires future 510(k) submissions to meet "special controls" instead of "general controls" to assure safety and effectiveness.

Thus, use of PMMA in kyphoplasty represented an off-label use of an FDA-regulated product before July 2004. In July 2004, KyphX® HV-RTM bone cement was given 510(k) marketing clearance by FDA 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 and Osteopal® V have been issued 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

FDA also issued a "Public Health Web Notification: Complications related to the use of bone cement in vertebroplasty and kyphoplasty procedures." (1) This notification is intended to inform the public about reports on safety and to encourage hospitals and other user facilities to report adverse events related to bone cement malfunctions either directly to manufacturers or to MedWatch, FDA's voluntary reporting program.

Related Protocol

Percutaneous Vertebroplasty and Sacroplasty

Policy (Formerly Corporate Medical Guideline)

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

Percutaneous 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.

Percutaneous balloon kyphoplasty are considered **investigational** for all other indications, including use in acute vertebral fractures due to osteoporosis or trauma.

Percutaneous mechanical vertebral augmentation using any other device, including but not limited to Kiva and vertebral body stenting, is considered **investigational**.

Medicare Advantage

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

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

Percutaneous kyphoplasty is **not considered 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.

Members enrolled in ongoing investigational device exemption (IDE) trials for mechanical vertebral augmentation, such as with Kiva®, may need consideration by Medicare Advantage for the routine services associated with the trial.

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.**

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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