Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation

(60138)

**Medical Benefit**

**Effective Date:** 10/01/18  
**Next Review Date:** 07/20

**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

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**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.

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### Populations

- **Individuals:**
  - With osteoporotic vertebral compression fractures

### Interventions

- **Interventions of interest are:**
  - Balloon kyphoplasty or mechanical vertebral augmentation (Kiva)

### Comparators

- **Comparators of interest are:**
  - Conservative care

### Outcomes

- **Relevant outcomes include:**
  - Symptoms
  - Functional outcomes
  - Quality of life
  - Hospitalizations
  - Treatment-related morbidity

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### Populations

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  - With osteolytic vertebral compression fractures

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### Populations

- **Individuals:**
  - With osteoporotic or osteolytic vertebral compression fractures

### Interventions

- **Interventions of interest are:**
  - Radiofrequency kyphoplasty

### Comparators

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### Outcomes

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  - Symptoms
  - Functional outcomes
  - Quality of life
  - Hospitalizations
  - Treatment-related morbidity

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**DESCRIPTION**

Percutaneous balloon kyphoplasty, radiofrequency kyphoplasty (RFK), 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).

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**SUMMARY OF EVIDENCE**

For individuals who have osteoporotic vertebral compression fractures who receive balloon kyphoplasty, or me-
Mechanical vertebral augmentation (Kiva), the evidence includes randomized controlled trials (RCTs) and meta-analyses. The 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. The 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.

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.

For individuals who have osteoporotic or osteolytic vertebral compression fractures who receive RFK, the evidence includes a systematic review and a 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 RFK and balloon kyphoplasty. The systematic review suggested that RFK 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 RFK 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. 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). 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 the FDA 510(k) marketing clearance include the AVAmx® 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.

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

Table 1 lists examples of FDA-cleared devices for kyphoplasty and vertebral augmentation.

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

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stryker iVAS Elite Inflatable Vertebral Augmentation System (Stryker iVAS Elite Balloon Catheter)</td>
<td>Stryker Corporation</td>
<td>12/21/2018</td>
<td>K181752</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>SpineJack Expansion Kit</td>
<td>Vexim SA</td>
<td>8/30/2018</td>
<td>K181262</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>SpineKure Kyphoplasty System</td>
<td>Hanchang Co. Ltd.</td>
<td>5/29/2018</td>
<td>K172871</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>KYPHON HV-R Bone Cement</td>
<td>Medtronic Sofamor Danek USA Inc.</td>
<td>5/18/2018</td>
<td>K180700</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>Modified Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters</td>
<td>G-21 s.r.l.</td>
<td>8/23/2017</td>
<td>K172214</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>13G InterV Kyphoplasty Catheter (Micro) and 11G InterV Kyphoplasty Catheter (Mini-Flex)</td>
<td>Pan Medical Ltd.</td>
<td>11/1/2016</td>
<td>K162453</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>Kyphon HV-R Bone Cement</td>
<td>MEDTRONIC INC</td>
<td>8/24/2016</td>
<td>K160983</td>
<td>To repair vertebral compression fractures</td>
</tr>
</tbody>
</table>
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.

REFERENCES

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

3. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Percutaneous vertebroplasty or kyphoplasty for vertebral fractures caused by osteoporosis or malignancy. TEC Assessments. 2008;Volume 23:Tab 5.


