FEP 6.01.38 Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation

Effective Policy Date: July 1, 2019

Original Policy Date: December 2011

Related Policies:

None

Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation

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).

OBJECTIVE

The objective of this evidence review is to determine whether the use of balloon kyphoplasty, radiofrequency kyphoplasty, or mechanical vertebral augmentation improves the next health outcome for individuals who have osteoporotic vertebral compression fractures or osteolytic vertebral compression fractures.

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**POLICY STATEMENT**

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 (eg, analgesics, physical therapy, rest) for at least 6 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.

**POLICY GUIDELINES**

Based on currently available evidence, health outcomes for kyphoplasty, Kiva, and vertebroplasty appear to be equivalent.

**BENEFIT APPLICATION**

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Percutaneous kyphoplasty may be performed by interventional radiologists or orthopedic surgeons. Percutaneous kyphoplasty is a specialized procedure, and thus some patients may seek an out-of-network referral.

**FDA 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 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.

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.

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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</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>
<tr>
<td>MEDINAUT Kyphoplasty System</td>
<td>IMEDICOM Co. Ltd.</td>
<td>7/29/2016</td>
<td>K153296</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>OSTEOPAL plus</td>
<td>HERAEUS MEDICAL GMBH</td>
<td>4/22/2016</td>
<td>K153737</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>AVAflex Vertebral Balloon System</td>
<td>CAREFUSION</td>
<td>11/24/2015</td>
<td>K151125</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>Osseoflex SB Straight Balloon 10g/4ml Osseoflex SB Straight Balloon 10g/2ml</td>
<td>OSSEON LLC</td>
<td>4/9/2015</td>
<td>K150607</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>InterV Kyphoplasty Catheter (Balloon Length: 1015 and 20mm) InterV Kyphoplasty Catheter (Mini) (Balloon Length: 10,15 and 20mm)</td>
<td>PAN MEDICAL LTD</td>
<td>3/6/2015</td>
<td>K150322</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>GUARDIAN-SG Inflatable Bone Expander System</td>
<td>BM KOREA CO. LTD.</td>
<td>1/16/2015</td>
<td>K143006</td>
<td>To repair vertebral compression fractures</td>
</tr>
</tbody>
</table>

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RATIONALITY

Summary of Evidence

For individuals who have OVCF who receive balloon kyphoplasty, or mechanical vertebral augmentation (Kiva), the evidence includes RCTs and meta-analyses. The relevant outcomes include symptoms, functional outcomes, QOL, 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 VCF 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, QOL, 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 VCF who receive RFK, the evidence includes a systematic review and an RCT. The relevant outcomes include symptoms, functional outcomes, QOL, 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American College of Radiology et al

The American College of Radiology (2014) and 7 other surgical and radiologic specialty associations published a joint position statement on percutaneous vertebral augmentation.27 This document stated that percutaneous vertebral augmentation, using vertebroplasty or kyphoplasty and performed in a manner consistent with public standards, is a safe, efficacious, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures. The statement also indicated that these procedures be offered only when nonoperative medical therapy has not provided adequate pain relief, or pain is significantly altering the patient's quality of life.

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Society of Interventional Radiology

In a quality improvement guideline on percutaneous vertebroplasty from the Society of Interventional Radiology (2014) vertebral augmentation was recommended for compression fractures refractory to medical therapy. Failure of medical therapy includes the following situations:

1. Patients who are "rendered non-ambulatory as a result of pain from a weakened or fractured vertebral body, pain persisting at a level that prevents ambulation despite 24 hours of analgesic therapy";
2. Patients with "sufficient pain from a weakened or fractured vertebral body that physical therapy is intolerable, pain persisting at that level despite 24 hours of analgesic therapy"; or
3. Patients with "a weakened or fractured vertebral body, and unacceptable side effects such as excessive sedation, confusion, or constipation as a result of the analgesic therapy necessary to reduce pain to a tolerable level."

American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons (2010) approved clinical guidelines on the treatment of osteoporotic spinal compression fractures, which had a weak recommendation for offering kyphoplasty to patients who "present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact." The Academy indicated that future evidence could overturn existing evidence and that the quality of the current literature is poor. These recommendations were based on the literature reviewed through September 2009.

National Institute for Health and Care Excellence

The National Institute for Health and Care Excellence (2013) issued a guidance that recommended percutaneous vertebroplasty and percutaneous balloon kyphoplasty as treatment options for treating osteoporotic vertebral compression fractures in persons having severe, ongoing pain after a recent unhealed vertebral fracture, despite optimal pain management, and whose pain has been confirmed through physical exam and imaging at the level of the fracture. This guidance did not address balloon kyphoplasty with stenting, because the manufacturer of the stenting system (Synthes) stated there is limited evidence for vertebral body stenting given that the system had only recently become available.

The Institute (2008) issued guidance on the diagnosis and management of adults with metastatic spinal cord compression. It was last reviewed in 2014, and placed on the static list (no major ongoing studies identified, with the next review in 5 years). The guidance stated that vertebroplasty or kyphoplasty should be considered for patients who have vertebral metastases, and no evidence of spinal cord compression or spinal instability if they have mechanical pain resistant to conventional pain management and vertebral body collapse. Surgery should only be performed when all appropriate specialists agree. Despite a relatively small sample base, the Institute concluded the evidence suggests, in a select subset of patients, that early surgery may be more effective at maintaining mobility than radiotherapy.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.
REFERENCES


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.


POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2011</td>
<td>New policy</td>
<td>Policy updated with literature review through March 5, 2013; references 17, 30, 31 added and references reordered; statement added that all other percutaneous mechanical vertebral augmentation devices, including but not limited to Kiva, are considered investigational.</td>
</tr>
<tr>
<td>June 2014</td>
<td>Replace policy</td>
<td>Policy updated with literature review, references 31-32, 34-35, 37-39, 41 and 42 added; and others reordered. Vertebral body stenting added to investigational statement. Added policy statement that percutaneous balloon kyphoplasty for all other indication is considered investigational.</td>
</tr>
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</tr>
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<tbody>
<tr>
<td>June 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review; references 32-34 added; Kiva considered medically necessary</td>
</tr>
<tr>
<td>March 2017</td>
<td>Replace policy</td>
<td>Policy updated with literature review. Rationale revised; some references removed. The last investigational policy statement was revised to delete the wording, “including but not limited to vertebral body stenting”.</td>
</tr>
<tr>
<td>September 2017</td>
<td>Replace policy</td>
<td>Policy updated with literature review through June 22, 2017; references 20 and 24 added. Radiofrequency kyphoplasty added to title and investigational statement.</td>
</tr>
<tr>
<td>June 2018</td>
<td>Replace policy</td>
<td>Policy updated with literature review through February 22, 2018; references 19 and 25 added. Policy statements unchanged.</td>
</tr>
<tr>
<td>June 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through February 7, 2019; references 32-33 added. Policy statements unchanged.</td>
</tr>
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</table>

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