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

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>• With osteoporotic vertebral compression fractures</td>
<td>• Balloon kyphoplasty or mechanical vertebral augmentation</td>
<td>• Conservative care</td>
<td>• Symptoms</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Functional outcomes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Quality of life</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Hospitalizations</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>• With osteolytic vertebral compression fractures</td>
<td>• Balloon kyphoplasty or mechanical vertebral augmentation</td>
<td>• Conservative care</td>
<td>• Symptoms</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Functional outcomes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Quality of life</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Hospitalizations</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Treatment-related morbidity</td>
</tr>
<tr>
<td>Individuals:</td>
<td>Interventions of interest are:</td>
<td>Comparators of interest are:</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>• With osteoporotic or osteolytic vertebral compression fractures</td>
<td>• Radiofrequency kyphoplasty</td>
<td>• Conservative care</td>
<td>• Symptoms</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Functional outcomes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Quality of life</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Hospitalizations</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>• Treatment-related morbidity</td>
</tr>
</tbody>
</table>

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 fractures.
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, the evidence includes an Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness review, randomized controlled trials (RCTs), and meta-analyses. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. The AHRQ review concluded that vertebroplasty was probably more effective at reducing pain and improving function in patients >65 years of age, but benefits were small. Kyphoplasty was found to be probably more effective than usual care for pain and function in older patients with vertebral compression fracture at up to 1 month and may be more effective at >1 month to ≥1 year but has not been compared against sham therapy. A meta-analysis and moderately sized unblinded RCT have compared kyphoplasty with conservative care and found short-term benefits in pain and other outcomes. One systematic review of RCTs found no significant difference in subsequent fracture between vertebroplasty and conservative treatment, and another systematic review of prospective and retrospective studies reported improved mortality with either vertebroplasty or balloon kyphoplasty compared with conservative treatment. 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 that the technology results in an improvement in the net health outcome.

For individuals who have osteolytic vertebral compression fracture who receive balloon kyphoplasty or mechanical vertebral augmentation, the evidence includes RCTs, case series, and systematic reviews 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 that the technology results in an improvement in the net health outcome.

For individuals who have osteoporotic or osteolytic vertebral compression fracture 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 that the technology results in an improvement in the net health outcome.
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)
Protocol  

Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation

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 1 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 bed rest, 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 the 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

<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>Balloon Kyphoplasty</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TRACKER Plus Kyphoplasty System</td>
<td>GS Medical Co., Ltd</td>
<td>10/28/2021</td>
<td>K211797</td>
<td>Reduction of fractures and/or creation of a void</td>
</tr>
<tr>
<td>Joline Kyphoplasty System Allevo</td>
<td>Joline GmbH &amp; Co.</td>
<td>5/27/2020</td>
<td></td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>TRACKER Kyphoplasty System</td>
<td>GS Medical Co., Ltd</td>
<td>12/4/2019</td>
<td>K192335</td>
<td>Reduction of fractures or creation of a void</td>
</tr>
<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>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>
</tbody>
</table>
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.


32. 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 12/01/2020.