Percutaneous Vertebroplasty, Kyphoplasty and Sacroplasty

Policy Number: 2013M0026A       Effective Date: January 1, 2014

Table of Contents:

<table>
<thead>
<tr>
<th>POLICY DESCRIPTION</th>
<th>Page: 2</th>
<th>Cross Reference Policy:</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVERAGE RATIONALE/CLINICAL CONSIDERATIONS</td>
<td>2</td>
<td>Spinal Cord Stimulator, 2012M0002A</td>
</tr>
<tr>
<td>BACKGROUND</td>
<td>3</td>
<td>Epidural Steroid Injections For Low Back Pain And Sciatica, 2012M0014A</td>
</tr>
<tr>
<td>REGULATORY STATUS</td>
<td>4</td>
<td>Interspinous Spacers In The Lumbar Spine, 2013M0017A</td>
</tr>
<tr>
<td>CLINICAL EVIDENCE</td>
<td>5</td>
<td>Radiofrequency Ablation For Chronic Spinal Pain, 2013M0019A</td>
</tr>
<tr>
<td>APPLICABLE CODES</td>
<td>6</td>
<td>Artificial Intervertebral Disc Replacement, 2012M0005A</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>POLICY HISTORY/REVISION INFORMATION</td>
<td>15</td>
<td></td>
</tr>
</tbody>
</table>

INSTRUCTIONS:

“Medical Policy assists in administering UCare benefits when making coverage determinations for members under our health benefit plans. When deciding coverage, all reviewers must first identify enrollee eligibility, federal and state legislation or regulatory guidance regarding benefit mandates, and the member specific Evidence of Coverage (EOC) document must be referenced prior to using the medical policies. In the event of a conflict, the enrollee’s specific benefit document and federal and state legislation and regulatory guidance supersede this Medical Policy. In the absence of benefit mandates or regulatory guidance that govern the service, procedure or treatment, or when the member’s EOC document is silent or not specific, medical policies help to clarify which healthcare services may or may not be covered. This Medical Policy is provided for informational purposes and does not constitute medical advice. In addition to medical policies, UCare also uses tools developed by third parties, such as the InterQual Guidelines®, to assist us in administering health benefits. The InterQual Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. Other Policies and Coverage Determination Guidelines may also apply. UCare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary and to provide benefits otherwise excluded by medical policies when necessitated by operational considerations.”
POLICY DESCRIPTION:

This policy provides information on the use of percutaneous vertebral augmentation procedure (formerly known as Kyphoplasty), percutaneous vertebroplasty, and percutaneous sacroplasty. These are surgeries that are used for the treatment of compression fractures of the spine with the goal of relieving pain, improving mobility, and preventing further collapse of the bone by stabilizing the broken bone with a substance that works like cement. These surgeries are not done very often, because most fractures heal on their own. Fractures can happen because of osteoporosis, tumors, or other conditions.

Vertebral Augmentation (kyphoplasty): This is a two step process and involves expansion of the partially collapsed vertebrae with an inflatable bone tamp/balloon, followed by injection of an acrylic polymer cement which hardens. The balloon restores height in the vertebrae body and provides stability by creating a more normal state.

Percutaneous Vertebroplasty (PV): This procedure involves injection of bone cement into fracture and is intended to reinforce the vertebrae, relieve pain, improve mobility, and prevent further deterioration of the bone.

Percutaneous Sacroplasty: This procedure is a variation of vertebroplasty technique involving injection of acrylic polymer cement into painful osteoporotic sacral insufficiency fractures.

COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

Percutaneous vertebroplasty or kyphoplasty of the cervical, lumbar or thoracic region is considered MEDICALLY NECESSARY for the following indications:

- Osteoporotic or osteolytic compression fractures of the thoracic or lumbar vertebrae resulting in persistent debilitating pain which has not responded to accepted standard medical treatment as documented in the medical records.
- Osteolytic metastasis with severe back pain related to a destruction of the vertebral body;
- Multiple myeloma with severe back pain related to a destruction of the vertebral body;
- Painful and/or aggressive vertebral hemangiomas (or eosinophilic granulomas of the spine);
- Painful vertebral fracture associated with osteonecrosis (Kummell Disease); and
- Reinforcement, or stabilization, of vertebral body prior to surgery.
- Steroid-induced fractures

Note: Standard medical therapy may include initial bed rest with progressive activity, analgesics, physical therapy, bracing and exercises to correct postural deformity and increase muscle tone, and use of pharmacologic agents such as bisphosphonates, estrogens, selective estrogen receptor modulators, and calcitonin.

Percutaneous vertebroplasty or kyphoplasty of the cervical, lumbar or thoracic region is considered EXPERIMENTAL AND INVESTIGATIONAL for all uses that do not meet the criteria identified as medically necessary listed above.

Percutaneous sacroplasty in the treatment of sacral insufficiency fractures is considered EXPERIMENTAL AND INVESTIGATIONAL for all indications. There is a lack of peer reviewed literature demonstrating the effects of sacroplasty on health outcomes. The evidence to date is limited to individual case reports and
Clinical Considerations:
Limitations and Contraindications and Relative Contraindications:
Percutaneous Vertebroplasty/vertebral augmentation including cavity creation are contraindicated for the following:
- Uncorrected coagulation disorders (due to the large diameter of the needles used for injection).
- Presence of infection (local or systemic)
- Known allergy to any of the materials used in either of the procedures

The following is a list of relative contraindications:
- Extensive vertebral destruction;
- Significant vertebral collapse in which the vertebra is less than 1/3 of its original height;
- Neurologic symptoms related to spinal cord and nerve root compression;
- Cervical Vertebroplasty (However, in rare instances, these are performed by physicians who are highly killed in this procedure).

Neither percutaneous vertebroplasty, nor percutaneous kyphoplasty, are to be considered prophylactic procedures for osteoporosis of the spine. They 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. The decision for treatment should be multidisciplinary and consider such factors as the extent of disease, the underlying etiology, the severity of the pain, the nature of any neurologic dysfunction, the outcome of any previous non-invasive treatment attempts, and the general state of the patient’s health.

BACKGROUND:
Percutaneous Vertebroplasty (PV): PV is a therapeutic interventional procedure involving the radiologically guided injection of an acrylic polymer bone cement into an osteolytic or osteoporotic vertebral body compression fracture. The technique has been used in all levels of the vertebrae, i.e., cervical, thoracic, lumbar and sacral (sacroplasty). The procedure is usually performed under local anesthesia combined with sedation and may be performed on an outpatient basis or may require a short hospital stay. Procedural complications are relatively rare and most that do occur are related to leakage of the cement. The goal of PV is relieving pain, improving mobility, and preventing further collapse of the bone. The technique has been performed in individuals with osteolytic metastases, frequently those associated with multiple myeloma, and also as a therapy for vertebral collapse related to osteoporosis, or as a treatment of a painful vertebral hemangioma. Spinal compression fractures are a common problem with osteoporosis and occur in more than 25% of women over the age of 50. These fractures may cause persistent pain, deformation, and the potential loss of sensation, mobility and continence.

Percutaneous Kyphoplasty (PK): PK combines vertebroplasty with a preliminary step to attempt to restore vertebral height using an inflatable bone tamp. A small incision is made in the skin creating a path to the fractured vertebra, after which an inflatable bone tamp is placed in the channel. When inflated, under x-ray
image guidance, the bone tamp compacts the surrounding bone and pushes the collapsed bone back up toward its normal position. A cavity is created which, after balloon removal, can be filled with liquid bone cement creating a permanent, internal cast. The risk of cement leakage is theoretically reduced because inflation of the balloon creates a void within the vertebral body into which cement can be injected under relatively low pressure.

The mechanism of action of vertebroplasty or kyphoplasty is unknown; necrosis of tumor or destruction of nerve endings in adjacent healthy tissue may be caused by mechanical, vascular, chemical and or thermal changes due to heat produced during cement hardening. Mechanical stabilization of bone is another possible treatment effect.

**Percutaneous Sacroplasty (PS):** PS is a variation of the vertebroplasty technique that involves the use of CT or fluoroscopic guidance to inject polymethylmethacrylate cement into the sacral fracture(s). This procedure is being investigated as an alternative treatment in those with sacral insufficiency fractures (SIF) related to osteoporosis. Sacral insufficiency fractures as a result of osteoporosis may produce pain in the low back, hip, buttock or groin.

Before a patient is selected for percutaneous vertebroplasty, kyphoplasty or sacroplasty, radiography, computed tomography (CT) and/or magnetic resonance imaging (MRI) are performed to assess the extent of vertebral collapse, the location and extent of the lytic process, the visibility and degree of involvement of the pedicles, the presence of cortical destruction or fracture, and the presence of epidural or foraminal stenosis caused by tumor extension or bone fragment retropulsion. In addition, the pain must be reproducible with manual palpation over the posterior aspect of the compressed vertebrae.

**REGULATORY STATUS:**

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):** The FDA had issued a guidance document entitled “Class II Special Controls Guidance Document: Polymethylmethacrylate (PMMA) Bone Cement” as the special control for these devices (CDRH, 2002). In some instances, the FDA recommends clinical studies to support a new material or change to an existing formulation, depending on how significantly different the material or formulation is from those of devices that have cleared for the same intended use. Therefore, the FDA issued another guidance entitled “Clinical Trial Considerations: Vertebral Augmentation Devices to Treat Spinal Insufficiency Fractures” to provide information related to clinical studies that FDA may recommend to support the premarket notification submissions, 510(k), for these devices (CDRH, 2004a).

The FDA classifies the orthopedic devices and the bone cement delivery systems as Class I devices (21 CFR 888.1100; 21 CFR 888.4200) and the bone cements that are used in vertebral augmentation as Class II devices (21 CFR 888.3027), with classification codes of NDN, LOD, KIH, MBB, or HRX. The FDA has cleared for market numerous bone cements, cement injectors, inflatable bone tamps, and balloons that are being used in Kyphoplasty (KP) to treat pain associated with vertebral compression fractures (VCFs) due to osteoporosis, cancer, or benign lesions (CDRH, 2011a; CDRH, 2011b; CDRH, 2011c; CDRH, 2012a).

Examples of FDA 510(k)-cleared devices include:
- Kyphx™ Inflatable Bone Tamp (Kyphon Inc.; K010246) on September 30, 2005;
- Inflatable Bone Tamp (Cardinal Health; K090211) on July 1, 2009; and
• Avamax Vertebral Balloon (CareFusion; K093463) on February 26, 2010.
• The Symphony™ VR Radiopaque bone cement (Advanced Biomaterial Systems Inc.; K042168), cleared on January 14, 2005, and Parallax® Acrylic Resin Cartridge with TRACERS (ArthroCare; K053180) on January 25, 2006, for fixation of pathological VCFs using the vertebroplasty (VP) or kyphoplasty (KP) procedures (CDRH, 2005b; CDRH, 2006).
• Parallax® Contour® Vertebral Augmentation Device (ArthroCare Corp.; K100479), cleared on September 21, 2010, is used to disrupt cancellous bone and create a void in the vertebral body and fill the void with Parallax Acrylic Resin (bone cement) during KP or vertebral augmentation procedures (CDRH, 2010b). The Stryker® iVAS balloon catheter (Stryker; K113154), cleared on January 24, 2012, is a bone tamp with an inflatable component (balloon) at the distal end. The balloon is inflated to create a void within the vertebral body. The Stryker® iVAS Inflatable Vertebral Augmentation System (system) is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. The system is to be used with cleared spinal PMMA bone cements and Cortoss® (Orthovita Inc.) Bone Augmentation Material indicated for use during percutaneous vertebral augmentation procedures (CDRH, 2012b).

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS): CMS does not specifically have a Medicare National Coverage Determination (NCD) for percutaneous vertebral augmentation, percutaneous vertebroplasty, or percutaneous sacroplasty. National Government Services (NGS) has a Medicare Local Coverage Determination (LCD) L26439 for Vertebroplasty and Vertebral Augmentation. Available at http://apps.ngsmedicare.com/lcd/LCD_L26439.htm

3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):

Minnesota DHS does not have a policy statement regarding percutaneous vertebroplasty, kyphoplasty or sacroplasty in its Provider Manual or other specific provider references.

CLINICAL EVIDENCE:

SUMMARY:
There is insufficient evidence to support the use of percutaneous kyphoplasty (KP) for conditions that do not meet the medically necessity criteria identified in this medical policy. The results from the only randomized controlled trial in this population were mixed, and the interpretation of the results was hampered by several serious design limitations. Three nonrandomized studies suggested that, compared with conventional treatment, KP reduces pain from compression fractures, but evidence of long-term benefits was not observed consistently. None of the studies included a sham control procedure. This is important in light of the negative results from sham-controlled studies on vertebroplasty that raise the possibility that the bone cement injection is not key to the beneficial effects observed in studies comparing vertebroplasty with conventional treatment. Only one study evaluated KP for patients with cancer and painful vertebral fractures and reported positive findings.

There is a lack of peer reviewed literature demonstrating the health outcomes effects of percutaneous sacroplasty in the treatment of sacral insufficiency fractures. The evidence to date is limited to individual case reports and small case series. No randomized controlled trials regarding its safety and efficacy or
improved patient outcomes have been published in the scientific peer-reviewed literature.

**APPLICABLE CODES:**

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

<table>
<thead>
<tr>
<th>HCPSC Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2360</td>
<td>Percutaneous vertebroplasty, one vertebral body, unilateral or bilateral injection; cervical</td>
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<tr>
<td>S2361</td>
<td>Each additional cervical vertebral body (list separately in addition to code for primary procedure)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>IDC-9 Codes</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>170.2</td>
<td>Malignant neoplasm of vertebral column, excluding sacrum and coccyx</td>
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<tr>
<td>198.5</td>
<td>Secondary malignant neoplasm of bone and bone marrow</td>
</tr>
<tr>
<td>203.00</td>
<td>Multiple myeloma without mention of remission</td>
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<tr>
<td>203.01</td>
<td>Multiple myeloma in remission</td>
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<tr>
<td>228.09</td>
<td>Hemangioma of other specified sites</td>
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<tr>
<td>238.9</td>
<td>Neoplasm of uncertain behavior of plasma cells</td>
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<tr>
<td>733.x*</td>
<td>Osteoporosis</td>
</tr>
<tr>
<td>733.13</td>
<td>Pathologic fracture of the vertebrae</td>
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</table>

* The x represents a range of codes; it is dependent on the specific diagnosis

<table>
<thead>
<tr>
<th>ICD-10 Codes</th>
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</tr>
</thead>
<tbody>
<tr>
<td>C41.2</td>
<td>Malignant neoplasm of vertebral column</td>
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<td>C79.5 – C79.52</td>
<td>Secondary malignant neoplasm of bone and bone marrow</td>
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<td>D16.6</td>
<td>Benign neoplasm of vertebral column</td>
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<tr>
<td>M48.50xA – M48.58xS</td>
<td>Collapsed vertebra, not elsewhere classified</td>
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<td>M80.08XA – M80.08XS</td>
<td>Osteoporosis with pathological fracture</td>
</tr>
<tr>
<td>C90.0</td>
<td>Multiple myeloma</td>
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<td>C90.01</td>
<td>Multiple myeloma in remission</td>
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<td>S12.000A – S12.691S</td>
<td>Fracture of cervical vertebra</td>
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<td>S12.9xxA – S12.9xxS</td>
<td>Fracture of neck, unspecified</td>
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<tr>
<td>S22.000A – S22.089S</td>
<td>Fracture of thoracic vertebra</td>
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<tr>
<td>S32.000A – S32.059S</td>
<td>Fracture of lumbar vertebra</td>
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* The x represents a range of codes; it is dependent on the specific diagnosis

<table>
<thead>
<tr>
<th>CPT® Codes</th>
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<tbody>
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<td>0200T</td>
<td>Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, one or more needles (investigational)</td>
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<td>0201T</td>
<td>Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, two or more needles (investigational)</td>
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<td>CPT</td>
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<tr>
<td>22520</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection; thoracic</td>
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<td>22521</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection; lumbar</td>
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<td>22522</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), one vertebral body, unilateral or bilateral injection; each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)</td>
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<td>22523</td>
<td>Percutaneous vertebral augmentation, including cavity creation (fraction reduction and bone biopsy included when performed) using mechanical device, 1 vertebral body, unilateral or bilateral cannulation (e.g., kyphoplasty); thoracic</td>
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<td>22524</td>
<td>Percutaneous vertebral augmentation, including cavity creation (fraction reduction and bone biopsy included when performed) using mechanical device, one vertebral body, unilateral or bilateral cannulation (e.g., kyphoplasty); lumbar</td>
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<td>22525</td>
<td>Percutaneous vertebral augmentation, including cavity creation (fraction reduction and bone biopsy included when performed) using mechanical device, one vertebral body, unilateral or bilateral cannulation (e.g., kyphoplasty); each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)</td>
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<td>72291</td>
<td>Radiological supervision and interpretation, percutaneous vertebroplasty, vertebral augmentation, or sacral augmentation (sacroplasty), including cavity creation, per vertebral body or sacrum; under fluoroscopic guidance</td>
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<tr>
<td>72292</td>
<td>Radiological supervision and interpretation, percutaneous vertebroplasty, vertebral augmentation, or sacral augmentation (sacroplasty), including cavity creation, per vertebral body or sacrum; under CT guidance</td>
</tr>
</tbody>
</table>

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REFERENCES:

8. AO Foundation. AO Classification of Fractures. Modified February 13, 2012. Available at:


<table>
<thead>
<tr>
<th>Page 9 of 15</th>
<th></th>
<th></th>
</tr>
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120. Saliou G, Rutgers DR, Kocheida EM, et al. Balloon-related complications and technical failures in kyphoplasty for...


**POLICY HISTORY:**

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