Kyphoplasty and Vertebroplasty

I. Description
Percutaneous balloon kyphoplasty and mechanical vertebral augmentation with Kiva are procedures used to treat individuals with one or more vertebral body compression fractures. Performed by interventional radiologists or orthopedic surgeons under fluoroscopic guidance, a small cannula is introduced and balloon catheters are inserted and inflated to create a space within the vertebra. The balloon catheters are removed and the space is filled with a bone cement mixture, usually polymethylmethacrylate (PMMA). The goal is to restore height to the bone, thus reducing deformity of the spine and to immediately stabilize the fracture. The procedure is usually performed on both sides of the vertebral body through the pedicles.

Vertebroplasty is an interventional radiology procedure using fluoroscopic guidance, in which polymethylmethacrylate (PMMA) is injected into a weakened vertebral body. The procedure is used for relief of pain caused by vertebral compression fractures or osteolytic lesions of the spine due to multiple myeloma or metastatic malignancy. Vertebroplasty may also be used for vertebral hemangioma causing severe pain or nerve compression.

II. Criteria/Guidelines
A. Percutaneous kyphoplasty or mechanical vertebral augmentation with Kiva are covered (subject to Limitations and Administrative Guidelines) when the following criteria are met:

1. The patient has acute vertebral compression fractures secondary to osteoporosis, has experienced severe back pain for at least four weeks and has failed an adequate trial of conservative therapy that includes, but is not limited to:
   a. Initial bed rest with progressive activity
   b. Back bracing
   c. Analgesics; or
2. The patient has osteolytic vertebral lesions (i.e., metastases or myeloma) with severe back pain related to a destruction of the vertebral body; and
3. Other causes of pain such as herniated intervertebral disc have been ruled out.
4. The severity of pain causes significant immobility and impairment of activities of daily living and/or requires maximal pain management.
5. The affected vertebra has not been extensively damaged and is at least one-third of its original height.
6. All patients with osteoporosis receiving kyphoplasty must be treated medically for osteoporosis to prevent additional fractures.

B. Vertebroplasty will be covered (subject to Limitations and Administrative Guidelines) when the following criteria are met:
   1. The patient has osteolytic vertebral lesions (i.e., metastases or myeloma) with severe back pain related to a destruction of the vertebral body; or
   2. The patient has vertebral hemangiomas with aggressive clinical signs including severe pain; or
   3. The patient has painful vertebral eosinophilic granuloma; and all of the following:
      4. Other causes of pain such as herniated intervertebral disc have been ruled out.
      5. The severity of pain causes significant immobility and impairment of activities of daily living and/or requires maximal pain management.
      6. The affected vertebra has not been extensively damaged and is at least one-third of its original height.

III. Limitations
   A. Vertebroplasty is not covered for osteoporotic compression fracture because randomized controlled trials have not demonstrated that it improves health outcomes (results were no better than the sham control group).
   B. Kyphoplasty will not be covered for more than three vertebral bodies in a single operative session.
   C. Peer-reviewed literature for kyphoplasty/Kiva/vertebroplasty has not been shown to be medically effective for indications other than those listed in this policy.
   D. Kyphoplasty is contraindicated for compression fractures that are more than one year old.
   E. Kyphoplasty is not to be performed as prophylaxis for either osteoporosis of the spine or chronic back pain if associated with old, healed compression fracture(s).
   F. Because of safety concerns, kyphoplasty/Kiva/vertebroplasty is contraindicated for patients with the following conditions:
      1. Uncorrected coagulation disorders;
      2. Underlying infection (e.g., osteomyelitis of the involved vertebra);
      3. Severe cardiopulmonary disease;
      4. Neurological symptoms related to spinal compression;
      5. Allergy to any component required for the procedure.
      6. Consideration must be given to the extent of the disease, the spinal level involved and previous treatments attempted before considering kyphoplasty/Kiva/vertebroplasty as an option.
      7. In situations when a patient's condition makes the procedure unsafe, or if there will be limited or no significant improvement in activities of daily living, kyphoplasty/Kiva/vertebroplasty will not be eligible for payment.

IV. Administrative Guidelines
   A. Precertification is required. To precertify, please complete HMSA's Precertification Request and mail or fax the form as indicated.
   B. The following must be submitted:
      1. Documentation showing a high degree of certainty through targeted physical exam and ancillary studies such as x-ray, bone scan, MRI that the pain is caused by a non-healing fracture.
      a. Documentation of imaging reports (i.e., x-rays, CT, MRI studies).
      b. Documentation of bone scan or MRI, if indicated (i.e., if the age of the fracture(s) is indeterminate).
2. An ancillary study confirms that the pain is not caused by the presence of a spinal or disc fragment.
3. The vertebral body height is not less than one-third of its original height.

C. In order for procedures to be covered in an office setting, the following conditions must be met:
   1. The office must be equipped with imaging equipment that meets State licensing requirements.
   2. The provider must be board certified and have completed an accredited residency or fellowship in orthopedic surgery, neurosurgery, radiology, anesthesia or pain management.
   3. The provider must have privileges to perform the procedure at an accredited surgery center or hospital in the State in which they are licensed.
   4. The provider must be ACLS certified and have office capability for advanced resuscitation (e.g. intubation, IV's, crash cart).
   5. The provider must be willing to provide documentation of all of the above and allow HMSA to visit/inspect the facility to verify compliance if requested.

D. CPT code 20225 for a bone biopsy is considered incidental to the kyphoplasty/Kiva/vertebroplasty procedure and is not payable separately.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>22510</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic</td>
</tr>
<tr>
<td>22511</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral</td>
</tr>
<tr>
<td>25212</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body (list separately in addition to code for primary procedure)</td>
</tr>
<tr>
<td>22513</td>
<td>Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic</td>
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<tr>
<td>22514</td>
<td>Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar</td>
</tr>
<tr>
<td>22515</td>
<td>Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body (list separately in addition to code for primary procedure)</td>
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<tr>
<td>ICD-10 Procedure Codes</td>
<td>Description</td>
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<tr>
<td>0PU33JZ</td>
<td>Supplement Cervical Vertebra With Synthetic Substitute, Percutaneous Approach</td>
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<tr>
<td>0PU34JZ</td>
<td>Supplement Cervical Vertebra With Synthetic Substitute, Percutaneous Endoscopic Approach</td>
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<td>Supplement Thoracic Vertebra With Synthetic Substitute, Percutaneous Approach</td>
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<td>0PU44JZ</td>
<td>Supplement Thoracic Vertebra With Synthetic Substitute, Percutaneous Endoscopic Approach</td>
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<td>0QU03JZ</td>
<td>Supplement Lumbar Vertebra With Synthetic Substitute, Percutaneous Approach</td>
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<td>Supplement Lumbar Vertebra With Synthetic Substitute, Percutaneous Endoscopic Approach</td>
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<td>Supplement Sacrum With Synthetic Substitute, Percutaneous Approach</td>
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<tr>
<td>0PS33ZZ</td>
<td>Reposition Cervical Vertebra, Percutaneous Approach</td>
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<tr>
<td>0PS43ZZ</td>
<td>Reposition Thoracic Vertebra, Percutaneous Approach</td>
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<td>Reposition Coccyx, Percutaneous Approach</td>
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<td>Supplement Sacrum With Synthetic Substitute, Percutaneous Approach</td>
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V. **Important Reminder**

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VI. **References**

11. Tutton SM, Pflugmacher R, Davidian M, et al. KAST Study: The Kiva(R) System as a Vertebral Augmentation Treatment - A Safety and Effectiveness Trial: A Randomized, Non-inferiority Trial


https://asmbs.org/resources/peri-operative-management-of-obstructive-sleep-apnea