Medica Coverage Policy

Policy Name:	**Percutaneous Vertebroplasty, Kyphoplasty, and Sacroplasty - Mayo Medical Plan Only**
Effective Date:	**8/15/2022**

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment.

NOTE: THIS POLICY APPLIES TO MAYO MEDICAL PLAN (MMP) MEMBERS.

NOTE: For all other medica members, Medica is using clinical criteria developed by Carelon, a utilization management (UM) program third-party vendor, to assist in administering these services.

Coverage Policy

Note: This policy is no longer scheduled for routine review of the scientific literature.

Percutaneous vertebroplasty and kyphoplasty are **COVERED** for patients with medically refractory pain due to osteolytic or osteoporotic lesions of the vertebrae.

Percutaneous vertebroplasty and kyphoplasty are investigative and therefore **NOT COVERED** for all other indications. There is insufficient reliable evidence in the form of high-quality peer-reviewed medical literature to establish the safety and efficacy or effects on health care outcomes.

Percutaneous sacroplasty is investigative and unproven and therefore **NOT COVERED**. There is insufficient reliable evidence in the form of high-quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes.

Description

Percutaneous vertebroplasty (PVP) is a surgical procedure that involves injection of bone cement into a vertebra to stabilize compression. PVP has been proposed for the treatment of (1) osteoporotic vertebral compression fractures, (2) vertebral osteolytic destruction secondary to malignancy, and (3) vertebral body hemangiomas.

Sacroplasty, a variation of vertebroplasty, is proposed for treatment of sacral insufficiency fractures related to osteoporosis and for sacral neoplastic lesions. Both the left and right halves of the sacrum are normally injected with the bone cement.

Kyphoplasty is intended to reduce and stabilize vertebral compression fractures primarily associated with osteoporosis. Kyphoplasty involves inserting one or two bone tamp balloon devices into the fractured vertebra, followed by balloon inflation intended to restore uniform vertebral height and compact the deteriorated bone. The balloon is then removed and the resulting cavity is filled with bone cement.

These procedures are typically performed by a neurological surgeon or an interventional radiologist either under general anesthesia, local anesthesia, or conscious sedation. The procedures can be performed in either an outpatient or an inpatient facility. Needle placement is most often aided by radiographic x-ray and/or computed tomography (CT) guidance. Following needle placement, the physician injects rapidly-polymerizing bone cement, such as polymethylmethacrylate (PMMA), into the affected vertebra. During vertebroplasty or kyphoplasty, several vertebrae may be injected during a single session. Opacification agents and antibiotics are often added to the bone cement prior to administration. The intent is to strengthen and stabilize the vertebrae, with accompanying partial or complete pain resolution and increased patient mobility.

FDA Approval

Percutaneous vertebroplasty, kyphoplasty, and sacroplasty are procedures, and therefore not regulated by the FDA approval process. Bone cements, dispensing devices, and balloon tamps are regulated under the FDA 510(k) approval process.

Examples of FDA-approved bone cements approved for use in vertebroplasty include:
1. Cobalt™ MV with Gentamicin Bone Cement [aka Cobalt™ GMV] (Biomet Manufacturing Corp)
2. Stabili ERx bone cement (DFine Inc)
3. Kyphon® Xpede™ bone cement (Medtronic).

Examples of FDA-approved bone cements approved for vertebroplasty or kyphoplasty include:
1. Symphony™ VR Radiopaque bone cement (Advanced Biomaterial Systems Inc.)
2. Parallax® Acrylic
3. Resin Cartridge with TRACERS (ArthroCare)

Examples of FDA approved bone cement dispensers include:
1. ARCUATE™ Vertebral Augmentation System (Medtronic Sofamor Danek USA, Inc.)
2. Stabili vertebral augmentation system (DFine Inc.)

Examples of 510(k) FDA-approved balloon tamps used in kyphoplasty procedures include:
1. Parallax® Contour® Vertebral Augmentation Device (ArthroCare Corp.)
2. Stryker® iVAS Inflatable Vertebral Augmentation System (Stryker)

Use of bone cement for sacroplasty is considered an off-label use.

In 2004, the FDA released an updated Public Health Web Notification warning about serious complications related to the use of bone cement and bone-void fillers in treating compression fractures of the spine. They advised that serious complications have been associated with leakage of bone cement and stated that bone void fillers have only been cleared for use in non–load-bearing applications, not treatment of vertebral compression fractures.

Prior Authorization

Prior authorization is not required. However, services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial may result if criteria are not met. (split)

Coding Considerations

Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes

- **0200T** - Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device (if utilized), 1 or more needles
- **0201T** - Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device (if utilized), 2 or more needles

- **22510** - Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic
- **22511** - Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral
- **22512** - 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)
- **22513** - Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic
- **22514** - Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar
- **22515** - Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, 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)

Original Effective Date:	8/1/2003
Re-Review Date(s):	11/27/2007 9/28/2010 8/27/2013 10/19/2016 2/21/2018 – Administrative update; code updates 2/20/2020 – Administrative update; format 6/15/2022 – Clinical Review Reserve 5/01/2024 – Administrative update; policy applies to Mayo Medical Plan members only