

Percutaneous Spinal Augmentation, Surgical 231

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<u>Effective Date</u>	5/2002
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<u>Coverage Policy</u>	Surgical 231
<u>Version</u>	4

All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member’s condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

Purpose:

This policy addresses Percutaneous Spinal Augmentation surgery.

Description & Definitions:

Percutaneous vertebral augmentation procedures include vertebroplasty, balloon kyphoplasty, and mechanical kyphoplasty. Vertebroplasty uses imaged-guided injection(s) of cement. Balloon kyphoplasty inflates a balloon inside the compressed vertebral body prior to cement injection. Mechanical kyphoplasty uses a device to expand the collapsed vertebral body. Percutaneous sacroplasty injects bone cement or similar material through the skin and into the sacrum to form a permanent bond.

Criteria:

Percutaneous spinal augmentation in the cervical, thoracic and lumbar vertebrae (and not sacrum and coccyx) may be considered medically necessary for **1 or more of the** following:

- Vertebroplasty or balloon kyphoplasty or mechanical vertebral augmentation with **ALL** of the following:
 - Individual with severe, debilitating pain due to vertebral compression fractures from **1 or more** of the following conditions:
 - Symptomatic osteoporotic vertebral fractures for **1 or more of the following**:
 - Present for at least 6 weeks and have failed to respond to conservative treatment (e.g. include initial bed rest with progressive activity, analgesics, physical therapy, bracing, graded exercises to improve muscle tone and correct postural deformity, medications such as calcitonin, bisphosphonates and calcium supplementation)

- Present for less than 6 weeks but interfering with ambulation and requiring hospitalization for pain control
 - Osteolytic lesions of the spine due to multiple myeloma, plasmacytoma or metastatic malignancies refractory to chemotherapy and/or radiation therapy
 - Aggressive hemangiomas causing severe pain or nerve compression and refractory to radiation therapy
 - Vertebral eosinophilic granuloma causing spinal instability
 - Unstable, osteonecrotic (i.e., Kummell disease) vertebral compression fractures
 - Steroid-induced vertebral compression fracture
 - Primary malignant cancers of bone
 - Imaging (x-ray, CT scan, MRI) shows **all of the following**:
 - The fracture is recent (less than 4 months old)
 - The affected vertebra is at least 1/3 of its original height
 - The affected vertebra is not already healed
 - Rules out other causes of back pain (e.g. herniated intervertebral disk, degenerative disc disease, facet arthropathy, foraminal stenosis, spinal cord compression)
 - Not more than 3 levels performed at once.
- Sacroplasty for **all of the following**:
 - Osteoporotic sacral fracture(s)
 - Treatment of acute (< 6 weeks) or subacute (6 to 12 weeks) sacral fractures confirmed by recent (within 30 days) advanced imaging (bone marrow edema on MRI or bone-scan/SPECT/CT uptake) that has not responded to conservative treatment, which may have included NSAIDs, opioid medications, physical therapy, and/or rest

Percutaneous Spinal Augmentation is **NOT COVERED for ANY** of the following:

- Allergy to bone cement or opacification agents
- Current back pain not primarily due to identified acute or subacute VCF(s)
- Fracture retropulsion/canal compromise
- Greater than 3 vertebral fractures per procedure
- Individual with existing uncorrected coagulopathy or anticoagulation therapy
- Individual with known allergy to any materials used in procedure, such as contrast media or bone cement
- Kyphoplasty for individual when vertebral body fracture is associated with widened pedicles or retropulsion of bone as in a burst fracture
- Kyphoplasty for individual with fracture caused by high-velocity injury or other causes of disabling back pain not due to acute fracture
- Neural impingement
- Neurologic deficit
- Osteomyelitis, discitis, active systemic infection, or surgical site infection
- Pain that has shown progressive improvement with non-invasive measures
- Pregnancy
- Retropulsed bone fragments resulting in spinal canal compromise and myopathy;
- Spinal canal compromise secondary to tumor resulting in myelopathy
- Spinal instability
- Vesselplasty

Coding:

Medically necessary with criteria:

Coding	Description
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)
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed

Considered Not Medically Necessary:

Coding	Description
	None

U.S. Food and Drug Administration (FDA) - approved only products only.

Document History:

Revised Dates:

- 2024: July- Added not more than 3 levels performed at once to criteria
- 2023: July
- 2022: July
- 2020: August
- 2016: April
- 2015: February, May, September
- 2014: January, June, August, November
- 2013: May, June

- 2012: February, May
- 2011: May, June, November
- 2010: May
- 2009: May
- 2008: May
- 2006: October
- 2004: September
- 2002: August

Reviewed Dates:

- 2023: July
- 2021: September
- 2019: April
- 2018: November
- 2017: December
- 2016: May
- 2014: May
- 2010: April
- 2007: December
- 2005: February, October
- 2004: July
- 2003: July

Effective Date:

- May 2002

References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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Cement, bone, vertebroplasty. (2024, Jun 10). Retrieved Jun 14, 2024, from U.S. Food and Drug Administration: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnm.cfm?ID=K240084>

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Sec. 888.3027 Polymethylmethacrylate (PMMA) bone cement. (2023, Dec 22). Retrieved Jun 14, 2024, from Code of Federal Regulations: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=888.3027>

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Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

Keywords:

Percutaneous Spinal Augmentation, SHP Surgical 231, Percutaneous vertebroplasty, balloon kyphoplasty, compression fractures, osteoporotic vertebral fractures, Osteolytic lesions, Percutaneous sacroplasty