Sentara Health Plans

Commercial

Percutaneous Spinal Augmentation

Table of Content

Effective Date	5/2002
Next Review Date	7/15/2024
Coverage Policy	Surgical 231
Version	3

Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details *.

Purpose:

This policy addresses the medical necessity of 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:

- 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
- 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-ay, 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

Percutaneous Spinal Augmentation is considered **not medically necessary** for any use other than those indicated in clinical criteria, to include but not limited to:

- 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:

- 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:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

(2022, Aug 31). Retrieved Jul 07, 2023, from MCG: https://careweb.careguidelines.com/ed26/index.html

(2023). Retrieved Jul 11, 2023, from Hayes, Inc: https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522Vertebroplasty%2522,%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%2522:0,%2522size%2522:50%257D,%2522type%2522:%2522all%2522,%2522sources%2522:%2

(2023). Retrieved Jul 11, 2023, from Department of Medical Assistance Services: https://vamedicaid.dmas.virginia.gov/manuals/provider-manuals-library#gsc.tab=0&gsc.q=kyphoplasty&gsc.sort=

510(k) Premarket Notification - vertebroplasty. (2023, Jul 10). Retrieved Jul 11, 2023, from Food and Drug Administration: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm

Fitch, R. (2022, Nov 02). Minor pelvic fractures (pelvic fragility fractures) in the older adult. Retrieved Jul 10, 2023, from UpToDate: https://www.uptodate.com/contents/minor-pelvic-fractures-pelvic-fragility-fractures-in-the-older-adult?search=sacroplasty&source=search_result&selectedTitle=1~1&usage_type=default&display_rank=1#H2202713

LCD Percutaneous Vertebral Augmentation (PVA) for Vertebral Compression Fracture (VCF) (L38737). (2022, Aug 21). Retrieved Jul 10, 2023, from Centers for Medicare and Medicaid Services: https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=38737&ver=11&

North American Spine Society Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Osteoporotic Vertebral Compression Fractures in Adults. (2020, Sep 30). Retrieved Jul 11, 2023, from North American Spine Society: https://www.spine.org/Portals/0/assets/downloads/ResearchClinicalCare/Guidelines/OVCF-Question-List.pdf

Rosen, H., & Walega, D. (2022, Jun 09). Osteoporotic thoracolumbar vertebral compression fractures: Clinical manifestations and treatment. Retrieved Jul 10, 2023, from UpToDate: https://www.uptodate.com/contents/search?search=EXOSC3&sp=0&searchType=PLAIN_TEXT&source=USER_INPUT&searchControl=TOP_PULLDOWN&searchOffset=1&autoComplete=false&language=en&max=10&index=&autoCompleteTerm=

Sec. 888.3027 Polymethylmethacrylate (PMMA) bone cement. (2023, Jun 07). Retrieved Jul 11, 2023, from Code of Federal Regulations (National Archives): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=888.3027

Spine Surgery 2023-01-01. (2023, Jan 01). Retrieved Jul 10, 2023, from Carelon Medical Benefits Management: https://guidelines.carelonmedicalbenefitsmanagement.com/spine-surgery-2023-01-01/

Special Notes: *

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.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

Keywords:

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