MASSACHUSETTS

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Medical Policy

Percutaneous Vertebroplasty and Sacroplasty

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Policy Number: 484

BCBSA Reference Number: 6.01.25
NCD/LCD: Local Coverage Determination (LCD): Vertebroplasty and Vertebral Augmentation (Percutaneous) (L33569)

Related Policies

- Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation, #485
- Diagnosis and Treatment of Sacroiliac Joint Pain, #320

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Percutaneous vertebroplasty may be considered **MEDICALLY NECESSARY** for the treatment of:

- Symptomatic osteoporotic vertebral fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy and rest) for at least 6 weeks, or
- Severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

And when:[1]

- There is a high degree of certainty through targeted, documented physical exam and ancillary studies (e.g., x-ray, MRI, CT, fluoroscopy, bone scan), that the pain is being caused by a non-healing fracture, AND
- The procedure is not being performed on a prophylactic basis, either for osteoporosis of the spine or chronic back pain, even if associated with old, healed compression fracture(s).

Percutaneous vertebroplasty may be considered **MEDICALLY NECESSARY** for the treatment of symptomatic osteoporotic vertebral fractures that are less than 6 weeks in duration that have led to hospitalization or persist at a level that prevents ambulation.

Percutaneous vertebroplasty is considered **INVESTIGATIONAL** for all other indications, including use in acute vertebral fractures due to osteoporosis or trauma.

Percutaneous sacroplasty is considered **INVESTIGATIONAL** for all indications, including use in sacral insufficiency fractures due to osteoporosis and sacral lesions due to metastatic malignancies or multiple myeloma.

Medicare HMO Blue[SM] and Medicare PPO Blue[SM] Members

Medical necessity criteria and coding guidance for **Medicare Advantage members living in Massachusetts** can be found through the link(s) below.

Local Coverage Determinations (LCDs) for National Government Services, Inc.

Local Coverage Determination (LCD): Vertebroplasty and Vertebral Augmentation (Percutaneous) (L33569)

Note: To review the specific LCD, please remember to click "accept" on the CMS licensing agreement at the bottom of the CMS webpage.

For medical necessity criteria and coding guidance for **Medicare Advantage members living outside of Massachusetts**, please see the Centers for Medicare and Medicaid Services website at https://www.cms.gov for information regarding your specific jurisdiction.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **required**.
Commercial PPO and Indemnity	Prior authorization is **not required**.
Medicare HMO Blue[SM]	Prior authorization is **required**.
Medicare PPO Blue[SM]	Prior authorization is **not required**.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The above medical necessity criteria MUST be met for the following codes to be covered for Commercial Members: Managed Care (HMO and POS), PPO and Indemnity:

CPT Codes

CPT codes:	Code 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)

ICD-10 Procedure Codes

ICD-10-PCS procedure codes:	Code Description
0PU33JZ	Supplement Cervical Vertebra with Synthetic Substitute, Percutaneous Approach
0PS33ZZ	Reposition Cervical Vertebra, Percutaneous Approach
0PS43ZZ	Reposition Thoracic Vertebra, Percutaneous Approach
0PU34JZ	Supplement Cervical Vertebra with Synthetic Substitute, Percutaneous Endoscopic Approach
0PU43JZ	Supplement Thoracic Vertebra with Synthetic Substitute, Percutaneous Approach
0PU44JZ	Supplement Thoracic Vertebra with Synthetic Substitute, Percutaneous Endoscopic Approach
0QS03ZZ	Reposition Lumbar Vertebra, Percutaneous Approach
0QS13ZZ	Reposition Sacrum, Percutaneous Approach
0QSS3ZZ	Reposition Coccyx, Percutaneous Approach
0QU03JZ	Supplement Lumbar Vertebra with Synthetic Substitute, Percutaneous Approach
0QU04JZ	Supplement Lumbar Vertebra with Synthetic Substitute, Percutaneous Endoscopic Approach
0QU13JZ	Supplement Sacrum with Synthetic Substitute, Percutaneous Approach
0QU14JZ	Supplement Sacrum with Synthetic Substitute, Percutaneous Endoscopic Approach
0QUS3JZ	Supplement Coccyx with Synthetic Substitute, Percutaneous Approach

The following ICD Diagnosis Codes are considered medically necessary when submitted with the CPT and/or ICD Procedure codes above if medical necessity criteria are met:

ICD-10 Diagnosis Codes

ICD-10-CM Diagnosis codes:	Code Description
C41.2	Malignant neoplasm of vertebral column
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C90.00	Multiple myeloma not having achieved remission
C90.01	Multiple myeloma in remission
C90.02	Multiple myeloma in relapse
D18.09	Hemangioma of other sites
D47.Z9	Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
G89.3	Neoplasm related pain (acute) (chronic)
M48.50xA	Collapsed vertebra, not elsewhere classified, site unspecified, initial encounter for fracture
M48.50xD	Collapsed vertebra, not elsewhere classified, site unspecified, subsequent encounter for fracture with routine healing
M48.50xG	Collapsed vertebra, not elsewhere classified, site unspecified, subsequent encounter for fracture with delayed healing
M48.50xS	Collapsed vertebra, not elsewhere classified, site unspecified, sequela of fracture
M48.51xA	Collapsed vertebra, not elsewhere classified, occipito-atlanto-axial region, initial encounter for fracture

M48.51xD	Collapsed vertebra, not elsewhere classified, occipito-atlanto-axial region, subsequent encounter for fracture with routine healing
M48.51xG	Collapsed vertebra, not elsewhere classified, occipito-atlanto-axial region, subsequent encounter for fracture with delayed healing
M48.51xS	Collapsed vertebra, not elsewhere classified, occipito-atlanto-axial region, sequela of fracture
M48.52xA	Collapsed vertebra, not elsewhere classified, cervical region, initial encounter for fracture
M48.52xD	Collapsed vertebra, not elsewhere classified, cervical region, subsequent encounter for fracture with routine healing
M48.52xG	Collapsed vertebra, not elsewhere classified, cervical region, subsequent encounter for fracture with delayed healing
M48.52xS	Collapsed vertebra, not elsewhere classified, cervical region, sequela of fracture
M48.53xA	Collapsed vertebra, not elsewhere classified, cervicothoracic region, initial encounter for fracture
M48.53xD	Collapsed vertebra, not elsewhere classified, cervicothoracic region, subsequent encounter for fracture with routine healing
M48.53xG	Collapsed vertebra, not elsewhere classified, cervicothoracic region, subsequent encounter for fracture with delayed healing
M48.53xS	Collapsed vertebra, not elsewhere classified, cervicothoracic region, sequela of fracture
M48.54xA	Collapsed vertebra, not elsewhere classified, thoracic region, initial encounter for fracture
M48.54xD	Collapsed vertebra, not elsewhere classified, thoracic region, subsequent encounter for fracture with routine healing
M48.54xG	Collapsed vertebra, not elsewhere classified, thoracic region, subsequent encounter for fracture with delayed healing
M48.54xS	Collapsed vertebra, not elsewhere classified, thoracic region, sequela of fracture
M48.55xA	Collapsed vertebra, not elsewhere classified, thoracolumbar region, initial encounter for fracture
M48.55xD	Collapsed vertebra, not elsewhere classified, thoracolumbar region, subsequent encounter for fracture with routine healing
M48.55xG	Collapsed vertebra, not elsewhere classified, thoracolumbar region, subsequent encounter for fracture with delayed healing
M48.55xS	Collapsed vertebra, not elsewhere classified, thoracolumbar region, sequela of fracture
M48.56xA	Collapsed vertebra, not elsewhere classified, lumbar region, initial encounter for fracture
M48.56xD	Collapsed vertebra, not elsewhere classified, lumbar region, subsequent encounter for fracture with routine healing
M48.56xG	Collapsed vertebra, not elsewhere classified, lumbar region, subsequent encounter for fracture with delayed healing
M48.56xS	Collapsed vertebra, not elsewhere classified, lumbar region, sequela of fracture
M48.57xA	Collapsed vertebra, not elsewhere classified, lumbosacral region, initial encounter for fracture
M48.57xD	Collapsed vertebra, not elsewhere classified, lumbosacral region, subsequent encounter for fracture with routine healing
M48.57xG	Collapsed vertebra, not elsewhere classified, lumbosacral region, subsequent encounter for fracture with delayed healing
M48.57xS	Collapsed vertebra, not elsewhere classified, lumbosacral region, sequela of fracture
M48.58xA	Collapsed vertebra, not elsewhere classified, sacral and sacrococcygeal region, initial encounter for fracture
M48.58xD	Collapsed vertebra, not elsewhere classified, sacral and sacrococcygeal region, subsequent encounter for fracture with routine healing

M48.58xG	Collapsed vertebra, not elsewhere classified, sacral and sacrococcygeal region, subsequent encounter for fracture with delayed healing
M48.58xS	Collapsed vertebra, not elsewhere classified, sacral and sacrococcygeal region, sequela of fracture
M80.08xA	Age-related osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M80.08xD	Age-related osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with routine healing
M80.08xG	Age-related osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with delayed healing
M80.08xK	Age-related osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with nonunion
M80.08xP	Age-related osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with malunion
M80.08xS	Age-related osteoporosis with current pathological fracture, vertebra(e), sequela
M80.88xA	Other osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
M80.88xD	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with routine healing
M80.88xG	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with delayed healing
M80.88xK	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with nonunion
M80.88xP	Other osteoporosis with current pathological fracture, vertebra(e), subsequent encounter for fracture with malunion
M80.88xS	Other osteoporosis with current pathological fracture, vertebra(e), sequela
M84.48xA	Pathological fracture, other site, initial encounter for fracture
M84.48xD	Pathological fracture, other site, subsequent encounter for fracture with routine healing
M84.48xG	Pathological fracture, other site, subsequent encounter for fracture with delayed healing
M84.48xK	Pathological fracture, other site, subsequent encounter for fracture with nonunion
M84.48xP	Pathological fracture, other site, subsequent encounter for fracture with malunion
M84.48xS	Pathological fracture, other site, sequela
M84.58xA	Pathological fracture in neoplastic disease, other specified site, initial encounter for fracture
M84.58xD	Pathological fracture in neoplastic disease, other specified site, subsequent encounter for fracture with routine healing
M84.58xG	Pathological fracture in neoplastic disease, other specified site, subsequent encounter for fracture with delayed healing
M84.58xK	Pathological fracture in neoplastic disease, other specified site, subsequent encounter for fracture with nonunion
M84.58xP	Pathological fracture in neoplastic disease, other specified site, subsequent encounter for fracture with malunion
M84.58xS	Pathological fracture in neoplastic disease, other specified site, sequela
M84.68xA	Pathological fracture in other disease, other site, initial encounter for fracture
M84.68xD	Pathological fracture in other disease, other site, subsequent encounter for fracture with routine healing
M84.68xG	Pathological fracture in other disease, other site, subsequent encounter for fracture with delayed healing
M84.68xK	Pathological fracture in other disease, other site, subsequent encounter for fracture with nonunion
M84.68xP	Pathological fracture in other disease, other site, subsequent encounter for fracture with malunion

M84.68xS	Pathological fracture in other disease, other site, sequela

The following CPT codes are considered investigational for <u>Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:</u>

CPT Codes

CPT codes:	Code Description
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device, when used, 2 or more needles

Description

OSTEOPOROTIC FRACTURE

Vertebral Compression Fracture

Osteoporotic compression fractures are common. It is estimated that up to one-half of women and approximately one-quarter of men will have a vertebral fracture at some point in their lives. However, only about one-third of vertebral fractures actually reach clinical diagnosis, and most symptomatic fractures will heal within a few weeks or 1 month. Nonetheless, some individuals with acute fractures will have severe pain and decreased function that interferes with ability to ambulate and is not responsive to usual medical management. In addition, a minority of patients will exhibit chronic pain following osteoporotic compression fracture that presents challenges for medical management. Chronic symptoms do not tend to respond to the management strategies for acute pain such as bedrest, immobilization or bracing device, and analgesic medication, sometimes including narcotic analgesics. The source of chronic pain after vertebral compression fracture may not be from the vertebra itself but may be predominantly related to strain on muscles and ligaments secondary to kyphosis. This type of pain frequently does not improve with analgesics and may be better addressed through exercise. Improvements in pain and ability to function are the principal outcomes of interest for treatment of osteoporotic fractures.

Sacral Insufficiency Fractures

Sacral insufficiency fractures (SIFs) are the consequence of stress on weakened bone and often cause low back pain in the elderly population. Osteoporosis is the most common risk factor for SIF. Spontaneous fracture of the sacrum in patients with osteoporosis was described by Lourie in 1982 and presents as lower back and buttock pain with or without referred pain in the legs. Although common, SIFs can escape detection due to low provider suspicion and poor sensitivity on plain radiographs, slowing the application of appropriate intervention. Similar interventions are used for sacral and vertebral fractures and include bedrest, bracing, and analgesics. Initial clinical improvements may occur quickly; however, resolution of all symptoms may not occur for 9 to 12 months.

Vertebral and Sacral Body Metastasis

Metastatic malignant disease of the spine generally involves the vertebrae/sacrum, with pain being the most frequent complaint. While radiation and chemotherapy are frequently effective in reducing tumor burden and associated symptoms, pain relief may be delayed days to weeks, depending on tumor response. Further, these approaches rely on bone remodeling to regain strength in the vertebrae/sacrum, which may necessitate supportive bracing to minimize the risk of vertebral/sacral collapse during healing. Improvements in pain and function are the primary outcomes of interest for treatment of bone malignancy with percutaneous vertebroplasty or sacroplasty.

Treatment

Percutaneous Vertebroplasty

It has been proposed that vertebroplasty may provide an analgesic effect through mechanical stabilization of a fractured or otherwise weakened vertebral body. However, other mechanisms of effect have been postulated, including thermal damage to intraosseous nerve fibers.

Percutaneous Sacroplasty

Sacroplasty evolved from the treatment of insufficiency fractures in the thoracic and lumbar vertebrae with vertebroplasty. The procedure, essentially identical to vertebroplasty, entails guided injection of polymethylmethacrylate (PMMA) through a needle inserted into the fracture zone. While first described in 2000 as a treatment for symptomatic sacral metastatic lesions, it is most often described as a minimally invasive alternative to conservative management for SIFs.

Pain and function are subjective outcomes and, thus, may be susceptible to placebo effects. Furthermore, the natural history of pain and disability associated with these conditions may vary. Therefore, controlled comparison studies would be valuable to demonstrate the clinical effectiveness of vertebroplasty and sacroplasty over and above any associated nonspecific or placebo effects and to demonstrate the effect of treatment compared with alternatives such as continued medical management.

In all clinical situations, adverse effects related to complications from vertebroplasty and sacroplasty are the primary harms to be considered. Principal safety concerns relate to the incidence and consequences of leakage of the injected PMMA. Use of a bis-glycidal dimethacrylate (Bis-GMA) composite material (Cortoss) for vertebroplasty has also been reported.

Summary

For individuals who have symptomatic osteoporotic vertebral fractures of between 6 weeks and 1 year old who receive vertebroplasty, the evidence includes 2 randomized sham-controlled trials, nonblinded randomized controlled trials (RCTs) comparing vertebroplasty with conservative management, and systematic reviews of these RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, hospitalizations, medication use, and treatment-related morbidity. Despite the completion of numerous RCTs, including 2 with sham controls, the efficacy of vertebroplasty for painful osteoporotic compression fractures remains uncertain. A 2016 meta-analysis, which included the 2 sham-controlled trials, found that vertebroplasty showed no significant benefit above sham for painful osteoporotic fractures, although alternative interpretations are possible. These studies have some methodologic issues, including the choice of sham procedure and the potential effect of the sham procedure having a therapeutic effect by reducing pain. Questions have also been raised about the low percentage of patients screened who participated in the trial, the volume of PMMA injected, and the inclusion of patients with chronic pain. Overall, conclusions about the effect of vertebroplasty remain unclear. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals with symptomatic osteoporotic vertebral fractures less than 6 weeks old who receive vertebroplasty, the evidence includes a randomized sham-controlled trial and other nonblinded RCTs comparing vertebroplasty with conservative management. Relevant outcomes are symptoms, functional outcomes, quality of life, hospitalizations, medication use, and treatment-related morbidity. For acute fractures, conservative therapy consisting of rest, analgesics, and physical therapy is an option, and symptoms will resolve in a large percentage of patients with conservative treatment only. However, a sham-controlled randomized trial in patients who had severe pain of less than 6 weeks in duration found a significant benefit of vertebroplasty for the treatment of osteoporotic vertebral fracture at the thoracolumbar junction. Other RCTs without sham controls have reported that vertebroplasty is associated with significant improvements in pain and reductions in the duration of bedrest. Given the high morbidity associated with extended bedrest in older adults, this procedure is considered to have a significant health benefit. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals with sacral insufficiency fractures who receive sacroplasty, the evidence includes a prospective cohort study and a case series. Relevant outcomes are symptoms, functional outcomes, quality of life, hospitalizations, medication use, and treatment-related morbidity. No RCTs have been reported. The available evidence includes a prospective cohort study and a retrospective series with 243 patients. These studies have reported rapid and sustained decreases in pain following percutaneous sacroplasty. Additional literature has mostly reported immediate improvements following the procedure. However, due to the small size of the evidence base, the harms associated with sacroplasty have not been adequately studied. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History

Date	Action
5/2018	New references added from BCBSA National medical policy. Summary clarified.
10/2017	BCBSA National medical policy review. New medically necessary indications described. Effective 10/1/2017.
9/2016	BCBSA National medical policy review. "Spinal lesions" in 3rd policy statement changed to "sacral lesions" to clarify the intent. References added.
1/2016	Clarified coding information.
6/2015	New references added from BCBSA National medical policy.
1/2015	Clarified coding information.
7/2014	New references added from BCBSA National medical policy.
6/2014	Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015.
2/2014	Local Coverage Determination (LCD) for Percutaneous Vertebroplasty/Percutaneous Augmentation (L11417) retired and replaced by LCD L26439 Vertebroplasty and Vertebral Augmentation (Percutaneous). Effective October 25, 2013.
6/2013	New references from BCBSA National medical policy.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
1/2012	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
12/1/2011	BCBSA National medical policy review. Changes to policy statements.
1/2011	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
7/2010	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
6/2010	BCBSA National medical policy review. Changes to policy statements.
1/2010	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
7/2009	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
6/1/2009	New policy, effective 6/1/2009, describing covered and non-covered indications.
11/2008	BCBSA National medical policy review. No changes to policy statements.
7/2008	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and Rheumatology. No changes to policy statements.
1/2008	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.
1/2007	Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

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Endnotes

[1] Based on expert opinion