MASSACHUSETTS

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Medical Policy

# Percutaneous Vertebroplasty and Sacroplasty

## Table of Contents



## Policy Number: 484

BCBSA Reference Number: 6.01.25 (For Plan internal use only)

## 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 multiple myeloma or metastatic malignancies.

## 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** | Prior authorization is **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 CPT codes are considered investigational for Commercial Members: Managed Care (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:**

## 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

**Treatment of Vertebral Compression Fracture**

Chronic symptoms do not tend to respond to the management strategies for acute pain such as bed rest, 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 or physical therapy. Improvements in pain and ability to function are the principal outcomes of interest for treatment of osteoporotic fractures.

**Treatment of Sacral Insufficiency Fractures**

Similar interventions are used for sacral and vertebral fractures and include bed rest, bracing, and analgesics. Initial clinical improvements may occur quickly; however, resolution of all symptoms may not occur for 9 to 12 months.[1,2,]

**Vertebral and Sacral Body Metastasis**

Metastatic malignant disease of the spine generally involves the vertebrae/sacrum, with pain being the most frequent complaint.

**Treatment of Vertebral and Sacral Body Metastasis**

While radiotherapy 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.

**Surgical Treatment Options**

**Percutaneous Vertebroplasty**

Vertebroplasty is a surgical procedure that involves the injection of synthetic cement (eg, polymethylmethacrylate, bis-glycidal dimethacrylate [Cortoss][3,]) into a fractured vertebra. It has been suggested 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 through a needle inserted into the fracture zone. Although first described in 2000

as a treatment for symptomatic sacral metastatic lesions,[4,5] it is most often described as a minimally invasive alternative to conservative management[6,7,8] for sacral insufficiency fractures.

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 events 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 polymethyl methacrylate or another injectate.

## Summary

Percutaneous vertebroplasty is an interventional technique involving the fluoroscopically guided injection of polymethyl methacrylate into a weakened vertebral body. The technique has been investigated to provide mechanical support and symptomatic relief in individuals with osteoporotic vertebral compression fractures or those with osteolytic lesions of the spine (eg, multiple myeloma, metastatic malignancies); as a treatment for sacral insufficiency fractures; and as a technique to limit blood loss related to surgery.

**Summary of Evidence**

For individuals who have symptomatic osteoporotic vertebral fractures 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 several meta-analyses. Relevant outcomes are symptoms, functional outcomes, quality of life, hospitalizations, medication use, and treatment-related morbidity. Despite the completion of multiple RCTs, including 2 with sham controls, the efficacy of vertebroplasty for painful osteoporotic compression fractures remains uncertain. Two meta-analysis studies that included the 2 sham-controlled trials have demonstrated mixed results. The 2 studies had methodologic issues, including the choice of sham procedure and the potential of the sham procedure to have a therapeutic effect by reducing pain. Questions have also been raised about the low percentage of individuals screened who participated in the trial, the volume of polymethylmethacrylate injected, and the inclusion of individuals with chronic pain. Other meta-analyses had numerous limitations due to the heterogeneity of included studies or not specifying the timeframe for osteoporotic vertebral compression fractures. Overall, conclusions about the effect of vertebroplasty remain unclear. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with symptomatic osteoporotic vertebral fractures less than 6 weeks old who receive vertebroplasty, the evidence includes a randomized sham-controlled trial and 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 individuals with conservative treatment only. However, a sham-controlled randomized trial in individuals who had severe pain of fewer 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 bed rest. Given the high morbidity associated with extended bed rest in older adults, this procedure is considered to have a significant health benefit. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals with sacral insufficiency fractures who receive sacroplasty, the evidence includes 2 prospective cohort studies 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 of 243 individuals. 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 that the technology results in an improvement in the net health outcome.

**Additional Information**
Vertebroplasty has been investigated as an intervention to provide mechanical support and symptomatic relief in individuals with an osteoporotic vertebral compression fracture and in those with osteolytic lesions of the spine (ie, multiple myeloma, metastatic malignancies). Clinical input obtained in 2008 provided uniform support for the use of vertebroplasty in painful osteoporotic fractures. Reconsideration of the available evidence and evaluation of the input led to a conclusion that, consistent results of numerous case series, including large prospective reports, the evidence was sufficient to determine that vertebroplasty is a reasonable treatment option in individuals with vertebral fractures who have failed to respond to conservative treatment (at least 6 weeks with analgesics, physical therapy, and rest). It is also clinically reasonable to consider the evidence supporting the clinical benefit of vertebroplasty in the osteoporotic vertebral fracture to support its use in osteolytic lesions of the spine (eg, multiple myeloma, metastatic malignancies).

## Policy History

| Date | Action |
|---|---|
| 6/2022 | Annual policy review. Description, summary, and references updated. Policy statements unchanged. |
| 6/2022 | Prior authorization information clarified for PPO plans. Effective 6/1/2022. |
| 6/2021 | Annual policy review. Investigational policy statement edited for clarity. Policy statements otherwise unchanged. |
| 1/2021 | Medicare information removed. See MP #132 Medicare Advantage Management for local coverage determination and national coverage determination reference. |
| 6/2020 | Annual policy review. Description, summary and references updated. Policy statements unchanged. |
| 5/2019 | Annual policy review. Description, summary and references updated. Policy statements unchanged. |
| 5/2018 | Annual policy review. New references added. Summary clarified. |
| 10/2017 | Annual policy review. New medically necessary indications described. Effective 10/1/2017. |
| 9/2016 | Annual 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 | Annual policy review. New references added. |
| 1/2015 | Clarified coding information. |
| 7/2014 | Annual policy review. New references added. |
| 6/2014 | Updated Coding section with ICD10 procedure and diagnosis codes. Effective 10/2015. |
| 6/2013 | Annual policy review. New references added. |
| 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 | Annual 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 | Annual policy review. Changes to policy statements. |
| 1/2010 | Reviewed - Medical Policy Group - Neurology and Neurosurgery. No changes to policy statements. |

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|---|---|
| 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 | Annual 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