

## Medical Coverage Policy | Percutaneous Vertebroplasty and Scaroplasty



**EFFECTIVE DATE:** 02|01|2011

**POLICY LAST UPDATED:** 07|02|2013

### OVERVIEW

Percutaneous vertebroplasty is an interventional technique involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) through a needle inserted into a weakened vertebral body. The technique has been investigated as an option to provide mechanical support and symptomatic relief in patients with osteoporotic vertebral compression fracture or in those with osteolytic lesions of the spine, i.e., multiple myeloma or metastatic malignancies. Percutaneous vertebroplasty has also been investigated as an adjunct to surgery for aggressive vertebral body hemangiomas, as a technique to limit blood loss related to surgery.

### PRIOR AUTHORIZATION

Prior Authorization is not required.

### POLICY STATEMENT

#### **BlueCHiP for Medicare:**

Percutaneous Vertebroplasty and Percutaneous Augmentation may be considered medically necessary when used for the indications listed in the background.

Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from CMS (Centers for Medicare and Medicaid Services), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services as Medicare offers.

#### **Commercial:**

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 and for the treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies. All other indications are considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

#### **BlueCHiP for Medicare and Commercial:**

Percutaneous sacroplasty is considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

### MEDICAL CRITERIA

None.

## **BACKGROUND**

### **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 possible mechanisms of effect have been postulated, including thermal damage to intraosseous nerve fibers, since PMMA undergoes a heat-releasing (exothermic) reaction during its hardening process.

### **Percutaneous Sacroplasty**

Sacroplasty evolved from the treatment of insufficiency fractures in the thoracic and lumbar vertebrae with vertebroplasty. The procedure, essentially identical, entails guided injection of PMMA through a needle inserted into the fracture zone. While first described in 2001 as a treatment for symptomatic sacral metastatic lesions, (1, 2) it is most often described as a minimally invasive procedure employed as an alternative to conservative management (3-5) for sacral insufficiency fractures (SIFs). SIFs are the consequence of excessive stress on weakened bone and are often the cause of low back pain among the elderly population. Osteoporosis is the most common risk factor for SIF.

### **Osteoporotic Vertebral Compression Fracture**

Osteoporotic compression fractures are a common problem, and 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. However, 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 bed rest, immobilization/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 is not improved with analgesics and may be better addressed through exercise.

### **Sacral Insufficiency Fractures**

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. (6, 7) 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 including bed rest, bracing, and analgesics. Initial clinical improvements may occur quickly; however, the resolution of all symptoms may not occur for 9 to 12 months. (6, 8)

### **Vertebral/Sacral Body Metastasis**

Metastatic malignant disease involving 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.

### **Vertebral Hemangiomas**

Vertebral hemangiomas are relatively common lesions noted in up to 12% of the population based on autopsy series; however, only rarely do these lesions display aggressive features and produce neurologic compromise and/or pain. Treatment of aggressive vertebral hemangiomas has evolved from radiation therapy to surgical approaches using anterior spinal surgery for resection and decompression. There is the potential for large blood loss during surgical resection, and vascular embolization techniques have been used as adjuncts to treatment to reduce blood loss. Percutaneous vertebroplasty has been proposed as a way to treat and stabilize some hemangioma to limit the extent of surgical resection and as an adjunct to reduce associated blood loss from the surgery.

Vertebroplasty has been investigated as an intervention to provide mechanical support and symptomatic relief in patients with osteoporotic vertebral compression fracture or in those with osteolytic lesions of the spine, i.e., multiple myeloma or metastatic malignancies. The results of clinical vetting in 2008 indicated uniform support for the use of vertebroplasty in painful osteoporotic fractures. After consideration of the available evidence and clinical input, it was concluded that the consistent results of numerous case series, including large prospective reports, together with the results of clinical vetting, were sufficient to determine that vertebroplasty was a reasonable treatment option in patients with vertebral fractures who fail to respond to conservative treatment (at least 6 weeks with analgesics, physical therapy, and rest). Given the absence of alternative treatment options and the morbidity associated with extended bed rest, vertebroplasty may be considered medically necessary in patients with vertebral fractures who fail to improve after 6 weeks of conservative therapy.

There is insufficient evidence to permit conclusions on the use of vertebroplasty for acute fractures. 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. Therefore, the use of vertebroplasty for acute osteoporotic fractures is considered not medically necessary as there is no proven efficacy.

Sacroplasty is under development. Varying techniques, patient indications, and small numbers of treated patients leaves uncertainty regarding the impact of sacroplasty on health outcomes and does not permit conclusion on its use for sacral insufficiency fractures or other indications. Therefore, sacroplasty is considered not medically necessary as there is no proven efficacy.

#### **BlueCHiP for Medicare:**

BlueCHiP for Medicare covers Percutaneous Vertebroplasty and Percutaneous Augmentation for the following indications:

Percutaneous Vertebroplasty and Percutaneous Augmentation are considered reasonable and necessary, when ALL of the following conditions are met:

- 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
- An ancillary study indicates non-healing osteoporotic or pathologic 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), and
- The risks of open surgical vertebroplasty are greater than the risks associated with the percutaneous approach, and
- Who have one of the following conditions:
  - Osteoporotic vertebral collapse with persistent debilitating pain which has not responded to accepted standard medical treatment (physical therapy, bed rest, bracing, and analgesics) for at least six weeks
  - Osteoporotic vertebral collapse requiring hospitalization due to incapacitating pain
  - Osteoporotic vertebral collapse which has not required hospitalization, but has required narcotics for at least 2 weeks due to incapacitating pain
  - Osteolytic vertebral metastasis or myeloma with severe back pain related to the destruction of a vertebral body that does not involve the major part of the cortical bone
  - Vertebral hemangioma with aggressive clinical signs

Limitations of coverage:

Percutaneous Vertebroplasty and Percutaneous Augmentation are not considered reasonable and necessary when ANY of the following exists:

- 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 not being caused by a non-healing fracture
- An ancillary study does not indicate a non-healing osteoporotic or pathologic fracture
- The procedure is 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)
- The risks of open surgical vertebroplasty are less than the risks associated with the percutaneous approach
- An uncorrected coagulation disorder exists
- Neurological symptoms, related to compression, exist, or
- When the patient does not have one of the following conditions:
  - Osteoporotic vertebral collapse with persistent debilitating pain which has not responded to accepted standard medical treatment (physical therapy, bed rest, bracing, and analgesics) for at least six weeks
  - Osteoporotic vertebral collapse requiring hospitalization due to incapacitating pain
  - Osteoporotic vertebral collapse which has not required hospitalization, but has required narcotics for at least 2 weeks due to incapacitating pain
  - Osteolytic vertebral metastasis or myeloma with severe back pain related to the destruction of a vertebral body that does not involve the major part of the cortical bone
  - Vertebral hemangioma with aggressive clinical signs

**Note:**

- No more than 2 vertebral levels at a time should be treated via percutaneous or the augmentation approach.
- The decision for treatment should be multi-disciplinary, taking into consideration the local and general extent of the disease, the spinal level involved, the severity of pain experienced by the patient as well as his or her neurologic condition, previous treatments and their outcomes, and the general state of health and life expectancy.

## COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate evidence of coverage or subscriber agreement for applicable radiology or surgery benefits

## CODING

### BlueCHiP for Medicare and Commercial

The following codes are considered **medically necessary**:

<b>22520</b>	<b>22521</b>	<b>22522</b>	<b>72291</b>	<b>72291</b>
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The following codes are **not medically necessary**:

S2360	S2361	0200T	0201T
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## RELATED POLICIES

None.

## PUBLISHED

Provider Update	Mar 2014
Provider Update	Jul 2012
Provider Update	Sep 2011
Provider Update	Nov 2010

## REFERENCES

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