PERCUTANEOUS VERTEBROPLASTY AND SACROPLASTY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

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 individuals 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 and as a technique to limit blood loss related to surgery. Injection of PMMA is also being investigated for the treatment of sacral insufficiency fractures.

Vesselplasty using Vessel-X®, (MAXXSPINE) and a similar procedure from A-Spine, are variations of vertebroplasty that are reported to eliminate leakage of bone cement by containing the filler in an inflatable vessel. FDA clearance of these devices has not been identified.
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.

**Criteria:**

### Vertebroplasty:

- Percutaneous vertebroplasty is considered **medically necessary** for an individual with continual incapacitating pain who the treatment of symptomatic osteoporotic vertebral fractures that have failed a trial of greater than 4 weeks of conservative care 1 with documentation of **ANY** of the following:
  1. Osteoporotic vertebral fracture(s)
  2. Trauma-related vertebral compression fracture(s)
  3. Steroid-induced vertebral compression fracture(s)

- Percutaneous vertebroplasty is considered **medically necessary** for an individual with osteolytic vertebral body fracture with documentation of **ALL** of the following:
  1. Individual has continual incapacitating pain
  2. No evidence of vertebral body destruction
  3. Vertebral body fracture is related to multiple myeloma or metastatic malignancies
  4. Chemotherapy and radiation therapy have failed to relieve the pain
  5. No involvement of the major part of the cortical bone

- Percutaneous vertebroplasty is considered **medically necessary** for vertebral hemangioma with documentation of **ALL** of the following:
  1. Procedure is intended to limit the extent of surgical resection
  2. Procedure is intended as an adjunct to decrease associated surgical blood loss
PERCUTANEOUS VERTEBROPLASTY AND SACROPLASTY (cont.)

Criteria: (cont.)

Vertebroplasty: (cont.)

- Percutaneous vertebroplasty for all other indications not previously listed or if above criteria not met is considered experimental or investigational based upon:

  1. Insufficient evidence to support improvement of the net health outcome, and
  2. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

These indications include, but are not limited to:

- Acute vertebral fractures due to osteoporosis or trauma

Vesselplasty:

- Vesselplasty is considered experimental or investigational based upon:

  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

Sacroplasty:

- Percutaneous sacroplasty for all indications is considered experimental or investigational based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

1 A trial of conservative care includes, but is not limited to, bedrest, immobilization/bracing devices, non-narcotic analgesic medications, narcotic analgesic medications and physical therapy. A trial of conservative care may be contraindicated.
PERCUTANEOUS VERTEBROPLASTY AND SACROPLASTY (cont.)

Resources:

Resources prior to 05/28/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.


3. InterQual ® Care Planning, Procedures. Vertebroplasty or Kyphoplasty.