MEDICAL POLICY

POLICY TITLE	PERCUTANEOUS VERTEBROPLASTY AND SACROPLASTY
POLICY NUMBER	MP- 1.071

Original Issue Date (Created):	**8/9/2002**
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Effective Date:	**1/1/2019** **RETIRED** – See policy history*

I. POLICY

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, rest) for at least 6 weeks.

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 may be considered **medically necessary** for the treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

Percutaneous vertebroplasty is considered **investigational** for all other indications, including use in acute vertebral fractures due to osteoporosis or trauma. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

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. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

II. PRODUCT VARIATIONS

Top

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

III. DESCRIPTION/BACKGROUND

Top

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 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 the ability to ambulate and is not responsive to usual medical management. Also, a minority of patients will exhibit chronic pain following osteoporotic compression fracture that presents challenges for medical management.

Treatment

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.[1] Osteoporosis is the most common risk factor for SIF. Spontaneous fracture of the sacrum in patients with osteoporosis was described by Lourie (1982) and presents as lower back and buttock pain with or without referred pain in the legs.[2] Although common, SIFs can escape detection due to low provider suspicion and poor sensitivity on plain radiographs, slowing the application of appropriate intervention.

Treatment

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.[1,3]

Vertebral and Sacral Body Metastasis

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

Treatment

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 (e.g., polymethylmethacrylate [PMMA], bis-glycidal dimethacrylate [Cortoss][4]) 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 PMMA through a needle inserted into the fracture zone. While first described in 2000 as a treatment for symptomatic sacral metastatic lesions,[5,6] it is most often described as a minimally invasive alternative to conservative management[7-9] 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 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 PMMA or another injectate.[4]

REGULATORY STATUS
Vertebroplasty is a surgical procedure and, as such, is not subject to U.S. Food and Drug Administration (FDA) approval.

PMMA bone cement was available as a drug product before enactment of FDA's device regulation and was at first considered what FDA terms a "transitional device." It was transitioned to a class III device requiring premarketing applications. Several orthopedic companies have received approval of their bone cement products since 1976. In 1999, PMMA was reclassified from class III to class II, which requires future 510(k) submissions to meet "special controls" instead of "general controls" to assure safety and effectiveness. Thus, use of PMMA in vertebroplasty represented an off-label use of an FDA-regulated product before 2005. In 2005, PMMA bone cements such as Spine-Fix® Biomimetic Bone Cement and Osteopal® V were cleared for marketing by FDA through the 510(k) process for the fixation of pathologic fractures of the vertebral body using vertebroplasty procedures.

The use of PMMA in sacroplasty is an off-label use of an FDA-regulated product (bone cements such as Spine-Fix® Biomimetic Bone Cement [Teknimed] and Osteopal® V [Heraeus]) because

the 510(k) approval was for the fixation of pathologic fractures of the vertebral body using vertebroplasty procedures. Sacroplasty was not included. FDA product code: NDN.

In 2009, Cortoss® (Stryker) Bone Augmentation Material was cleared for marketing by FDA through the 510(k) process. Cortoss® is a nonresorbable synthetic material that is a composite resin-based, bis-glycidal dimethacrylate. FDA classifies this product as a PMMA bone cement.

In 2010, the Parallax® Contour® Vertebral Augmentation Device (ArthroCare) was cleared for marketing by FDA through the 510(k) process. The device creates a void in cancellous bone that can then be filled with bone cement. FDA product code: HXG.

IV. RATIONALE

Top

Summary of Evidence

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 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. Two meta-analysis studies which 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 patients screened who participated in the trial, the volume of polymethylmethacrylate 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 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 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 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 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.

V. DEFINITIONS

Top

HEMANGIOMA is a benign tumor of dilated blood vessels.

OSTEOLYTIC refers to osteolysis, which is the softening, and destruction of bone without osteoclastic activity. Osteolysis occurs within compact bone and results from a breakdown of the organic matrix and subsequent leaching out of the inorganic fracture.

OSTEOPOROSIS refers to the loss of bone mass that occurs throughout the skeleton, predisposing patients to fractures.

VERTEBRAE are any of the thirty-three (33) bony segments of the spinal column.

VI. BENEFIT VARIATIONS

Top

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

Top

Capital BlueCross medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

Top

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore not covered, percutaneous sacroplasty for all indications:

CPT Codes®								
0200T	0201T							

Covered when medically necessary:

CPT Codes®								
22510	22511	22512						

ICD-10-CM Diagnosis 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
M80.08.XA	Age-related osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture
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
M80.88XG	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

IX. REFERENCES

Top

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X. POLICY HISTORY

TOP

MP 1.071	**CAC 7/29/03**
	CAC 4/27/04
	CAC 10/26/04
	CAC 10/25/05
	CAC 9/26/06
	CAC 9/25/07
	CAC 5/27/08
	CAC 5/26/09
	CAC 5/25/10 Minor Revision. Added that use for acute vertebral fractures is investigational for both percutaneous vertebroplasty and kyphoplasty
	CAC 11/22/11 Minor Revision. Vertebroplasty and Kyphoplasty remain medically necessary with criteria. Deleted limitation of 2 levels per date of surgery. Added Sacroplasty as an investigational procedure to match BCBSA.
	CAC 10/30/12 Consensus. No change to policy statements. FEP variation changed to reference the FEP policy manual MP-6.01.38 Percutaneous Kyphoplasty and 6.01.25 Percutaneous Vertebroplasty and Sacroplasty. Codes reviewed 11/1/12
	CAC 11/26/13 Consensus review. References updated. Statement added to state that percutaneous mechanical vertebral augmentation using any other device, including but not limited to Kiva, is considered investigational**.**
	CAC 11/25/14 Medicare variation added to reference LCD L33652 Vertebroplasty, Vertebral Augmentation (Kyphoplasty) Percutaneous**.** Added vertebral body stenting as investigational. Other minor wording changes did not alter intent of policy statements. Coding Reviewed and ranged ICD 9 codes. - 11/07/2014

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	01/5/15- New 2015 codes added to the policy.
	CAC 1/26/16 Minor revision. Policy retitled "Percutaneous Vertebroplasty and Sacroplasty." BCBSA policy adopted for this review. Kyphoplasty criteria moved to new policy MP-1.148 Percutaneous Balloon Kyphoplasty and Mechanical Vertebral Augmentation. Background, rationale, and references revised. LCD numbers revised from L31686 to L35094 and L33652 to L35130 due to Novitas LCD updates. Coding reviewed/updated.
	Admin Update 1/1/17 Variation reformatting.
	CAC 5/23/17 Consensus review. Spinal lesions in 4th policy statement changed to "sacral lesions" to clarify the intent. No change to the policy statements. References reviewed. Coding reviewed.
	CAC 9/26/17 Minor revision. Added a new statement that 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. Background, rationale, and references updated. Coding reviewed.
	6/25/18 Consensus review. Policy statements unchanged. Description/Background, Rationale and Reference sections updated.
	9/25/18 Retired. Please refer to TurningPoint Healthcare for management of these services effective 1/1/2019.*

TOP