Vertebroplasty, Kyphoplasty, and Sacroplasty Percutaneous

Percutaneous Vertebroplasty
Percutaneous vertebroplasty (PVP) is an interventional radiology technique involving the fluoroscopically guided injection of polymethylmethacrylate 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 fractures, or in those with osteolytic lesions of the spine, e.g., 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.

Percutaneous Kyphoplasty
Percutaneous balloon kyphoplasty, radiofrequency kyphoplasty, and mechanical vertebral augmentation are interventional techniques involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) into a cavity created in the vertebral body with a balloon or mechanical device. These techniques have been investigated as options 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.

It has been proposed that percutaneous vertebroplasty and kyphoplasty 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 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 procedure employed as an alternative to conservative management for sacral insufficiency fractures (SIFs). SIFs are the consequence of 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.

Spineoplasty
Spineoplasty is a new minimally invasive procedure similar to vertebroplasty currently being researched. The procedure includes a graft consisting of mesh filled with bone chips instead of the traditional cement used to fix a fracture. The OptiMesh® 1500E is a Polyethylene Terephthalate (PET) mesh pouch designed to contain impacted granular bone chips and allows it to be deployed to the area needing repair. This mesh graft is used most commonly for traumatic fracture repair and interbody fusion. This graft has not received FDA approval for this use.
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**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 one month. 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 or physical therapy. Conventional vertebroplasty surgical intervention may be required in severe cases not responsive to conservative measures. 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 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.

**Vertebral/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.

**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 neurological 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.

**Regulatory Status**
Vertebroplasty and kyphoplasty are surgical procedures and, as such, are not subject to U.S. Food and Drug Administration (FDA) approval.

The Kiva® VCF Treatment System (Benvenue Medical) received FDA 510(k) marketing clearance in January 2014 (FDA product code NDN). The SpineJack Expansion Kit (Vexim SA) received FDA
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510(k) marketing clearance in August 2018, The V-Strut Vertebral Implant (Hyprevention SAS) received FDA 510(k) marketing clearance in March 2020.

PMMA bone cement was available as a drug product prior to enactment of the FDA’s device regulation and was at first considered what the 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 October 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. The use of PMMA in kyphoplasty represented an off-label use of an FDA-regulated product prior to July 2004. In July 2004, KyphX® HV-RTM bone cement was given 510K marketing clearance by the FDA for the treatment of pathologic fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a balloon kyphoplasty procedure. Subsequently, other products such as Spine-Fix® Biomimetic Bone Cement, KYPHON® HV-R® Bone Cement, and Osteopal® V (Heraeus) have received 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. 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.

Balloon kyphoplasty requires the use of an inflatable bone tamp. One such tamp, the KyphX® inflatable bone tamp, received 510(k) marketing clearance from the FDA in July 1998. Other devices with FDA 510(k) marketing clearance include Joline Kyphoplasty System Allevo (Joline GmbH & Co.), AVAflex® Vertebral Balloon system (Carefusion), TRACKER Kyphoplasty System (GS Medical Co., LTD), Stryker iVAS® Elite Balloon catheter, and SpineKure Kyphoplasty System (Hanchang Co., LTD).

The use of PMMA in sacroplasty represents an off-label use of an FDA-regulated product (bone cements such as Spine-Fix® Biomimetic Bone Cement and Osteopal® V) as the 510(k) marketing clearance was for the fixation of pathological fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Sacroplasty was not included.

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.

ArthroCare received FDA clearance for the Parallax® Contour® Vertebral Augmentation Device in 2010. The device creates a void in cancellous bone that can then be filled with bone cement.

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

BCBSNC will provide coverage for percutaneous vertebroplasty or balloon kyphoplasty or mechanical vertebral augmentation using an FDA cleared device when it is determined to be medically necessary and when the medical criteria and guidelines shown below are met.

Percutaneous sacroplasty and spineoplasty are considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application
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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Vertebroplasty and Kyphoplasty are covered

Percutaneous vertebroplasty or balloon kyphoplasty or mechanical vertebral augmentation using an FDA cleared device may be considered medically necessary for patients when the following criteria are met:

- 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.
- 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.
- For the treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

When Vertebroplasty, Kyphoplasty, and Sacroplasty are not covered

Vertebal augmentation, such as balloon kyphoplasty, is not appropriate when the vertebral body fracture is associated with widened pedicles or retropulsion of bone as in a burst fracture. For vertebroplasty and kyphoplasty, neurological deficit or radiculopathy and systemic or local infections are contraindications. Any existing uncorrected coagulopathy or anticoagulation therapy is an absolute contraindication, as is known allergy to any materials used in the procedure, such as the contrast media or bone cement. Balloon kyphoplasty is considered not medically necessary for treatment of burst fractures. Vertebroplasty and balloon kyphoplasty are considered not medically necessary when there are contraindications to their use.

Percutaneous vertebroplasty and balloon kyphoplasty and mechanical vertebral augmentation using an FDA cleared device are considered investigational for all indications that do not meet the medical necessity criteria listed above, including use in acute vertebral fractures due to osteoporosis or trauma.

Radiofrequency kyphoplasty is considered investigational.

Mechanical vertebral augmentation using any other device is considered investigational.

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

Spineoplasty is considered investigational for all indications.

Policy Guidelines

For individuals who have osteoporotic vertebral compression fracture who receive balloon kyphoplasty or mechanical vertebral augmentation (Kiva), the evidence includes randomized controlled trials (RCTs) and meta-analyses. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. A meta-analysis and moderately sized unblinded RCT compared kyphoplasty to conservative care and found short-term benefits in pain and other outcomes. One systematic review of RCTs found no significant difference in subsequent fracture between vertebroplasty and conservative treatment, and another systematic review of prospective and retrospective studies reported improved mortality with either vertebroplasty or balloon kyphoplasty compared with conservative treatment. Other RCTs, summarized in a meta-analysis, reported similar outcomes for kyphoplasty and vertebroplasty. Three randomized trials that compared mechanical vertebral augmentation (Kiva or Spine-Jack) to kyphoplasty reported similar outcomes for both procedures. A major limitation of all
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these RCTs is the lack of a sham procedure. Due to the possible sham effect observed in the recent trials of vertebroplasty, the validity of the results from non-sham-controlled trials is unclear. Therefore, it is not possible to conclude that these improvements are a true treatment effect. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have osteolytic vertebral compression fracture who receive balloon kyphoplasty or mechanical vertebral augmentation, the evidence includes RCTs, case series, and a systematic review of these studies. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. Two RCTs have compared balloon kyphoplasty with conservative management, and another has compared Kiva with balloon kyphoplasty. Results of these trials, along with case series, would suggest a reduction in pain, disability, and analgesic use in patients with cancer-related compression fractures. However, because the results of the comparative studies of vertebroplasty have suggested possible placebo or natural history effects, the evidence these studies provide is insufficient to warrant conclusions about the effect of kyphoplasty on health outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

After consideration of uniform clinical input, it was concluded that although the scientific evidence does not permit conclusions about the impact on health outcomes and that comparative studies with long-term outcomes are lacking, numerous case series, including large prospective reports, have consistently shown that vertebroplasty or percutaneous balloon kyphoplasty may alleviate pain and improve function in patients with osteoporotic vertebral fractures who fail to respond to conservative treatment (at least 6 weeks) with analgesics, physical therapy, and rest. More recent randomized trials that have compared percutaneous balloon kyphoplasty with medical management have also reported benefit. Given the absence of alternative treatment options and the morbidity associated with extended bedrest, percutaneous balloon kyphoplasty and mechanical vertebral augmentation may be considered reasonable treatment options in patients with vertebral fractures who fail to improve after 6 weeks of conservative therapy and therefore may be considered medically necessary both for this patient population and populations with severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

For individuals who have osteoporotic or osteolytic vertebral compression fractures who receive radiofrequency kyphoplasty, the evidence includes a systematic review and an RCT. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. The only RCT (N=80) identified showed similar results between radiofrequency kyphoplasty and balloon kyphoplasty. The systematic review suggested that radiofrequency kyphoplasty is superior to balloon kyphoplasty in pain relief, but the review itself was limited by the inclusion of a small number of studies as well as possible bias. Corroboration of these results in a larger number of patients would be needed to determine with greater certainty whether radiofrequency kyphoplasty provides outcomes similar to balloon kyphoplasty. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have symptomatic osteoporotic vertebral fractures between 6 weeks and 1 year old who receive vertebroplasty, the evidence includes two randomized sham-controlled trials, nonblinded 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 two with sham controls, the efficacy of vertebroplasty for painful osteoporotic compression fractures remains uncertain. Two meta-analysis studies, which included the two sham-controlled trials have demonstrated mixed results. The two studies had 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. Other meta-analyses had numerous limitations due to the heterogeneity of included studies or not specifying the timeframe for osteoporotic vertebral compression
Vertebroplasty, Kyphoplasty, and Sacroplasty Percutaneous 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 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 two 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 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 that the technology results in an improvement in the net health outcome.

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. Clinical input obtained in 2008 provided 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). It is also clinically reasonable to consider the evidence supporting the clinical benefit of vertebroplasty in osteoporotic vertebral fracture to support its use in osteolytic lesions of the spine (e.g., multiple myeloma, metastatic malignancies).

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina website at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 22510, 22511, 22512, 22513, 22514, 22515, 0200T, 0201T, C1062

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.
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**Scientific Background and Reference Sources**

- Specialty Matched Consultant Advisory Panel, 8/01
- BCBSA Medical Policy Reference Manual, 12/18/02; 6.01.25
- BCBSA Medical Policy Reference Manual, 12/18/02; 6.01.38
- Specialty Matched Consultant Advisory Panel, 7/03
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Senior Medical Director - 12/2008


Medical Director - 8/2010


Medical Director – 8/2012


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Policy Implementation/Update Information

1/01 Original policy issued.
4/01 76012, 76013 added to coding section.
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7/01 Changed name of policy from Percutaneous Vertebroplasty to Vertebroplasty, Percutaneous.

9/01 Specialty Matched Consultant Advisory Panel, 8/01. Policy renamed to include Kyphoplasty. Revised sections to include Kyphoplasty as investigational.


8/12/04 Codes S2362 and S2363 added to Billing/Coding section.

8/26/04 Reference added.

7/21/05 Specialty Matched Consultant Advisory Panel review 6/24/2005. Created bullet # 3 under "When not covered" section to indicate that "very severe cardiopulmonary disease" as a separate contraindication. Added CPT 76012 and 76013 to "Billing/Coding" section as they are specific to this policy. Added policy number to "Key Words" section. References added.

1/05/06 Added CPT codes 22523, 22524 and 22525 to Billing/Coding section.

2/16/06 Added additional information on the findings from a recent Mayo Clinic study regarding vertebral fractures in relation to vertebroplasty to "Policy Guidelines" section. References added.

1/12/09 Reviewed with Senior Medical Director 12/10/08. Reworded the "When Covered" section and added "osteoporotic vertebral compression fracture" to #1. Added definition of "Persistent debilitating pain". Added #2 under "When covered" section to indicate "2. For treatment of severe pain in patients with osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies". Updated "Policy Guidelines" section and added the following comment; "Therefore, preventive treatment, including a combination of vitamin D and calcium supplementation, calcitonin, and bisphosphonates is important for all patients in whom it is not otherwise contraindicated." References added.


6/22/10 Policy Number(s) removed (amw)

9/28/10 Policy reviewed by Medical Director 8/26/2010. Added Sacroplasty to policy name. Added information pertaining to Percutaneous Sacroplasty to “Description” section. Added under “Policy” section; “Percutaneous Sacroplasty is considered investigational for all applications. BCBSNC does not procedures.” Added comment to the “When Not Covered” section to indicate; “Percutaneous sacroplasty is considered investigational for all indications.” CPT 0200T and 0201T added to the “Billing/Coding” section. “Policy Guidelines” updated. References added. (btw)
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10/26/10 Removed “Sacroplasty” from the title of the “When Covered” section. (btw)

7/1/11 Specialty Matched Consultant Advisory Panel review 5/25/2011. Revised “Description” section. Added “including use in sacral insufficiency fractures due to osteoporosis and spinal lesions due to metastatic malignancies or multiple myeloma.” to the “When Not Covered” statement regarding, “Percutaneous Sacroplasty is considered investigational for all indications”. Updated “Policy Guidelines” section. References added. (btw)

5/29/12 Specialty Matched Consultant Advisory Panel review 5/16/2012. Revised Description section. No change to policy intent. References added. (btw)

9/18/12 Information regarding spineoplasty added to Description section. Policy Statement updated to indicate that spineoplasty is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures. The graft used in spineoplasty has not received FDA approval. Medical Director review 8/28/2012. (btw)

7/1/13 Description and Policy Guidelines updated. Added the following statement to the When Not Covered section; “Percutaneous mechanical vertebral augmentation using any other device, including but not limited to Kiva®, is considered investigational.” Specialty Matched Consultant Advisory Panel review 5/15/2013. References added. Notification given 7/1/2013. Policy effective 9/10/2013. (btw)

6/10/14 Specialty Matched Consultant Advisory Panel review 5/27/2014. Updated Description section to include information regarding Parallax® Contour® Vertebral Augmentation and Vessel-X®, (MAXXSPINE) and vertebral body stenting. Updated Policy Guidelines section. No change to policy intent. Reference added. (btw)

8/26/14 References added. Vertebral body stenting added to investigational statement. (sk)

12/30/14 Codes 22520, 22521, 22522, 22523, 22524, 22525, 72291, and 72292 deleted from Billing/Coding Section. Codes 22510, 22511, 22512, 22513, 22514, and 22515 added to Billing/Coding section for effective date 1/1/2015. (sk)

7/1/15 References added. Specialty Matched Consultant Advisory Panel review 5/27/2015. Kiva® may be considered medically necessary. (sk)

12/30/15 Codes S2360 and S2361 removed from Billing/Coding section. (sk)

7/1/16 Specialty Matched Consultant Advisory Panel review 5/25/2016. (sk)

3/31/17 Reference added. Information on vertebral body stenting removed from policy. Policy Guidelines updated. Clarifying statements on kyphoplasty and vertebroplasty added to When Not Covered section. (sk)


7/28/17 Reference added. Policy Guidelines updated. Added the following to the When Covered section: vertebroplasty may be 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. (sk)
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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.