Corporate Medical Policy

Vertebroplasty, Kyphoplasty, and Sacroplasty Percutaneous

File Name: vertebroplasty_kyphoplasty_and_sacroplasty_percutaneous
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Description of Procedure or Service

Percutaneous vertebroplasty, percutaneous balloon kyphoplasty, radiofrequency kyphoplasty, and mechanical vertebral augmentation are interventional techniques involving the fluoroscopically guided injection of polymethyl methacrylate into a weakened vertebral body or a cavity created in the vertebral body with a balloon or mechanical device. The techniques have been investigated to provide mechanical support and symptomatic relief in individuals with osteoporotic vertebral compression fractures or those with osteolytic lesions of the spine (e.g., multiple myeloma, metastatic malignancies); as a treatment for sacral insufficiency fractures; and as a technique to limit blood loss related to surgery.

Osteoporotic Vertebral Compression Fracture
Vertebral compression fractures are the most common complication of osteoporosis, with 700,000 cases reported every year in the United States. The condition is more frequently seen in women than men, with an annual incidence of 10.7 per 1000 women and 5.7 per 1000 men. Furthermore, the prevalence of these fractures increases with age and has been estimated to affect approximately 25% of postmenopausal women and 40% of women ≥80 years of age. Symptoms of vertebral compression fracture are nonspecific, and more than two-thirds of fractures are detected incidentally when individuals undergo imaging for other reasons. Most symptomatic fractures will heal within six to eight weeks, but a minority of individuals will exhibit chronic pain and disability following osteoporotic compression fracture that present 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 individuals 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 to limit the extent of surgical resection and as an adjunct to reduce associated blood loss from the surgery.

Surgical Treatment Options

Percutaneous Vertebroplasty
Vertebroplasty is a surgical procedure that involves the injection of synthetic cement (e.g., polymethylmethacrylate, bis-glycidal dimethacrylate) 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 Kyphoplasty
Balloon kyphoplasty is a variant of vertebroplasty and uses a specialized bone tamp with an inflatable balloon to expand a collapsed vertebral body as close as possible to its natural height before injection of polymethyl methacrylate. Radiofrequency kyphoplasty (also known as radiofrequency targeted vertebral augmentation) is a modification of balloon kyphoplasty. In this procedure, a small diameter articulating osteotome creates paths across the vertebra. An ultra-high viscosity cement is injected into the fractured vertebral body, and radiofrequency is used to achieve the desired consistency of the cement. The ultra-high viscosity cement is designed to restore height and alignment to the fractured vertebra, along with stabilizing the fracture.

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.

Mechanical Vertebral Augmentation
Kiva is a mechanical vertebral augmentation technique that uses an implant for structural support of the vertebral body to provide a reservoir for bone cement. The Kiva vertebral compression fractures treatment system consists of a shaped memory coil and an implant, which is filled with bone cement. The coil is inserted into the vertebral body over a removable guide wire. The coil reconfigures itself into a stack of loops within the vertebral body and can be customized by changing the number of loops of the coil. The implant, made from PEEK-OPTIMA™, a biocompatible polymer, is deployed over the coil. The coil is then retracted, and polymethyl methacrylate is injected through the lumen of the implant. The polymethyl methacrylate cement flows through small slots in the center of the implant, which fixes the implant

to the vertebral body and contains the polymethyl methacrylate in a cylindrical column. The proposed advantage of the Kiva system is a reduction in cement leakage.

SpineJack is a mechanical vertebral augmentation technique that utilizes bipedicular 4.2 mm to 5.0 mm self-expanding jacks to restore vertebral height. Placement of the titanium devices are verified in antero-posterior and lateral view prior to expansion. Once the devices are expanded, a proprietary bone cement is injected. The proposed benefit is greater control over expansion and greater restoration of vertebral height compared to balloon kyphoplasty. The procedure requires good bone quality.

Spineoplasty

Spineoplasty is a 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.

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 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, KYPHON™ VuE™ 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 (Medtronic), received 510(k) marketing clearance from the FDA in July 1998. Additional devices for balloon kyphoplasty, cleared by the FDA, include:

- ZVPLASTY by Zavation LLC
- GUARDIAN-SG Inflatable Bone Expander System by BM Koreo Co., Ltd.
- InterV Kyphoplasty Catheter (Balloon Length: 1015 and 20mm) InterV Kyphoplasty Catheter (Mini) (Balloon Length: 10 15 and 20mm) and 13G InterV Kyphoplasty Catheter (Micro) and 11G InterV Kyphoplasty Catheter (Mini-Flex) by Pan Medical Ltd.
- Osseoflex SB Straight Balloon 10g/4ml Osseoflex SB Straight Balloon 10g/2ml byOsseon LLC

- AVAflex Vertebral Balloon System by Carefusion
- MEDINAUT Kyphoplasty System by Imedicom Co., Ltd.
- Modified Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters by G-21 s.r.l.
- SpineKure Kyphoplasty System bu Hanchang Co., Ltd.
- Stryker iVAS Elite Inflatable Vertebral Augmentation System (Stryker iVAS Elite Balloon Catheter) by Stryker Corporation
- TRACKER and TRACKER Plus Kyphoplasty Systems by GS Medical Co., Ltd
- Joline Kyphoplasty System Allevo by Joline GmbH & Co.
- Renova Spine Baloon Catheter by Biopsybell S.R.L.
- Balloon Inflation System by Ningbo Biotechnology 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, bisglycidal 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. There have been several other augmentation and bone expander devices (eg, Balex® Bone Expander System, Arcadia® Ballon Catheter, Kyphon Element® Inflatable Bone Tamp) that were also cleared for marketing by FDA through the 510(k) process. These devices create a void in cancellous bone that can then be filled with bone cement.

StabiliT® Vertebral Augmentation System (Merit Medical) for radiofrequency vertebral augmentation was cleared for marketing in 2009.

Related Policies
Diagnosis and Treatment of Sacroiliac Joint Pain

******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, 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

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.

Vertebroplasty, Kyphoplasty, and Sacroplasty Percutaneous

When Vertebroplasty and Kyphoplasty are covered

Percutaneous vertebroplasty, balloon kyphoplasty, or mechanical vertebral augmentation using an FDA cleared device may be considered **medically necessary** for individuals 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

Vertebral 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, 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 sacral 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, the evidence includes an Agency for Healthcare Research and Quality (AHRQ) comparative effectiveness review, randomized controlled trials (RCTs) and meta-analyses. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. The AHRQ review concluded that vertebroplasty was probably more effective at reducing pain and improving function in patients >65 years of age, but benefits were small. Kyphoplasty was found to be probably more effective than usual care for pain and function in older patients with vertebral compression fracture at up to one month and may be more effective at >1 month to ≥1 year but has not been compared against sham therapy. 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 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 systematic reviews 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 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 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. One network meta-analysis found that relative to conservative treatment, vertebroplasty provided short-term and long-term improvements to pain relief and disability scores. 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 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 three 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 prospective cohort studies and a retrospective series of 243 patients 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 web site 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, C7504, C7505, C7507, C7508*

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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Medical Director review- 5/2024

Policy Implementation/Update Information

1/01 Original policy issued.

4/01 76012, 76013 added to coding section.

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.

9/01 Specialty Matched Consultant Advisory Panel, 7/15/2003. Benefits Application section revised. Policy reformatted to allow for indications, contraindications, and guidelines for coverage of percutaneous vertebroplasty and kyphoplasty. Added HCPCS Level II codes S2360 and S2361 and CPT code 22899 to Billing/Coding section and deleted CPT codes 76012 & 76013.

9/03 Specialty Matched Consultant Advisory Panel, 7/15/2003. Benefits Application section revised. Policy reformatted to allow for indications, contraindications, and guidelines for coverage of percutaneous vertebroplasty and kyphoplasty. Added HCPCS Level II codes S2360 and S2361 and CPT code 22899 to Billing/Coding section and deleted CPT codes 76012 & 76013.

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, micalcin, and bisphosphonates is important for all patients in whom it is not otherwise contraindicated." References added.

7/6/09 Specialty Matched Consultant Advisory Panel Review 5/28/09. "Description" section revised. Combined policy statements into one statement, no change to intent. References added. (btw)

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)

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)

6/30/17 Specialty Matched Consultant Advisory Panel review 5/31/2017. (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)

6/29/18 References added. Policy Guidelines updated. Radiofrequency kyphoplasty added to investigational statement. Specialty Matched Consultant Advisory Panel review 5/23/2018. (sk)

6/11/19 References added. Specialty Matched Consultant Advisory Panel review 5/15/2019. (sk)

12/31/20 References added. Description section updated. Regulatory Status updated. The tradename "Kiva" was removed from policy statements. Specialty Matched Consultant Advisory Panel review 5/20/2020. Code C1062 added to Billing/Coding section for effective date 1/1/2021. (sk)

6/15/21 References added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/19/2021. (sk)

6/14/22 References added. Specialty Matched Consultant Advisory Panel review 5/18/2022. (sk)

12/30/22 Added new codes C7504, C7505, C7507, and C7508 to Billing/Coding section. (sk)

6/30/23 Description section updated. Policy Guidelines updated. References added. Specialty Matched Consultant Advisory Panel review 5/17/2023. (sk)

6/12/24 Description section updated. Regulatory Status updated with additional devices and reformatted for clarity. Added related policy. Updated Policy Guidelines. No change to policy intent. Specialty Matched Consultant Advisory Panel review 5/2024. Medical Director review 5/2024. (ldh)