BLUE CROSS OF NORTHEASTERN PA "BCNEPA" MEDICAL POLICY BULLETIN	**MANUAL:** MEDICAL POLICY
	REFERENCE NO.: MPO-490-0145
EFFECTIVE DATE September 1, 2014	**SUBJECT:** Percutaneous Kyphoplasty, Vertebroplasty and Sacroplasty

Blue Cross of Northeastern Pennsylvania ("BCNEPA") Medical Policy

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical policy and claims payment policy are applied. Policies are provided for informational purposes only and are developed to assist in administering plan benefits and do not constitute medical advice. Treating providers are solely responsible for medical advice and treatment. Policies are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and information are constantly changing and BCNEPA may review and revise its medical policies periodically. Also, due to the rapid pace of changing technology and the advent of new medical procedures, BCNEPA may not have a policy to address every procedure. In those cases, BCNEPA may review other sources of information including, but not limited to, current medical literature and other medical resources, such as Technology Evaluation Center Assessments (TEC) published by the Blue Cross Blue Shield Association. BCNEPA may also consult with health care providers possessing particular expertise in the services at issue.

DESCRIPTION:

Percutaneous balloon kyphoplasty and mechanical vertebral augmentation with KIVA® are interventional radiology techniques involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) through a needle inserted into a weakened vertebral body. These techniques have 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 (PVP) is an interventional radiology 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. The technique has been used in all levels of the vertebrae, i.e., cervical, thoracic, and lumbar.

Sacroplasty is a minimally invasive procedure employed as an alternative to conservative management 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. Osteoporosis is the most common risk factor for SIF. The procedure entails guided injection of polymethylmethacrylate (PMMA) through a needle inserted into the fracture zone.

BENEFIT POLICY STATEMENT:

BCNEPA makes decisions on coverage based on Policy Bulletins, benefit plan documents, and the member's medical history and condition. Benefits may vary based on product line, group or contract, therefore, Member benefits must be verified. In the event of a conflict between the Member's benefit plan document and topics addressed in Medical Policy Bulletins (i.e., specific contract exclusions), the Member's benefit plan document always supersedes the information in the Medical Policy Bulletins. BCNEPA determines medical necessity only if the benefit exists and no contract exclusions are applicable.

Benefits are determined by the terms of the Member's specific benefit plan document [i.e., the Fully Insured policy, the Administrative Services Only (ASO) agreement applicable to the Self-Funded Plan Participant, or the Individual Policy] that is in effect at the time services are rendered.

BACKGROUND:

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 the PMMA. Radiofrequency kyphoplasty is a modification of balloon kyphoplasty. In this procedure, an ultrahigh viscosity cement is injected into the fractured vertebral body, and radiofrequency is used to achieve the desired consistency of the cement. The ultrahigh viscosity cement is designed to restore height and alignment to the fractured vertebra, along with stabilizing the fracture.

It has been proposed that 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, one of which is thermal damage to intraosseous nerve fibers given that PMMA undergoes a heat-releasing (exothermic) reaction during its hardening process.

Kiva® is another mechanical vertebral augmentation technique that uses an implant for structural support of the vertebral body and to provide a reservoir for bone cement. The Kiva® VCF system consists of a flexible polymer implant which is filled with bone cement. The implant is made from PEEK-OPTIMA®, a biocompatible polymer, and is inserted into the vertebral body over a removable spiral shaped guide wire. The implant can be customized by changing the number of loops of the coil, with a maximum height of 12 mm. PMMA is injected through the lumen of the implant, which fixes the implant to the vertebral body and contains the PMMA in a cylindrical column. The proposed advantage of the Kiva system is a reduction in cement leakage.

Another variant of kyphoplasty is vertebral body stenting, which utilizes an expandable scaffold instead of a balloon to restore vertebral height. The proposed advantages of vertebral body stenting are to reduce the risk of cement leakage by formation of a cavity for cement application and to prevent the loss of correction that is seen following removal of the balloon used for balloon kyphoplasty.

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.

Vertebral Body Metastasis
Metastatic malignant disease involving the spine generally involves the vertebral bodies, 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 vertebral body strength, which may necessitate supportive bracing to minimize the risk of vertebral body 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 cementoplasty 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.

MEDICAL POLICY STATEMENT:

Percutaneous Balloon Kyphoplasty and Mechanical Vertebral Augmentation

BCNEPA will provide coverage for percutaneous kyphoplasty when medically necessary.

1. Percutaneous balloon kyphoplasty 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 six (6) weeks.

2. Percutaneous balloon kyphoplasty 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.

3. Percutaneous balloon kyphoplasty is considered investigational for all other indications, including use in acute vertebral fractures due to osteoporosis or trauma.

4. Percutaneous mechanical vertebral augmentation using any other device, including but not limited to Kiva® VCF Treatment System and vertebral body stenting is considered investigational.

Percutaneous Vertebroplasty

BCNEPA will provide coverage for percutaneous vertebroplasty when medically necessary.

1. 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 six (6) weeks.

2. 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.

a. Use in acute vertebral fractures due to osteoporosis or trauma.

b. All other indications not identified above as medically necessary.

Percutaneous Sacroplasty

BCNEPA will not provide coverage for percutaneous sacroplasty as it 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.

GUIDELINES:

Kyphoplasty is a surgical procedure and, as such, is not subject to U.S. Food and Drug Administration (FDA) approval. Balloon kyphoplasty requires the use of an inflatable bone tamp. One such tamp, the KyphX® inflatable bone tamp, received 510(k) marketing clearance from FDA in July 1998. Other devices with FDA 510(k) marketing clearance include AVAmax® Vertebral Balloon system (Carefusion), NeuroTherm Parallax® Balloon Inflatable Bone Tamp (NeuroTherm, Inc.), Stryker iVAS® Balloon catheter, and Synthes Synflate™ Vertebral Balloon System, Synthes (USA) LLC (FDA product code NDN).

The Kiva® VCF Treatment System (Benvenue Medical) received FDA 510(k) marketing clearance in January 2014 (FDA product code NDN).

Vertebral body stenting (VBS™, Synthes, Switzerland) is available in Europe at this time.

PMMA bone cement was available as a drug product before enactment of 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.

Thus, use of PMMA in kyphoplasty represented an off-label use of an FDA-regulated product before July 2004. In July 2004, KyphX® HV-RTM bone cement was given 510(k) marketing clearance by 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 and Osteopal ® V have been issued 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

FDA also issued a "Public Health Web Notification: Complications related to the use of bone cement in vertebroplasty and kyphoplasty procedures." (1) This notification is intended to inform the public about reports on safety and to encourage hospitals and other user facilities to report adverse events related to bone cement malfunctions either directly to manufacturers or to MedWatch, FDA's voluntary reporting program.

RATIONALE:

After consideration of the available evidence and 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, consistently showed that vertebroplasty or kyphoplasty may alleviate pain and improve function in patients with vertebral fractures who fail to respond to conservative treatment (at least 6 weeks) with analgesics, physical therapy, and rest. More recent randomized trials that compare kyphoplasty with medical management have also reported benefit, so have not changed these conclusions. Given the absence of alternative treatment options and the morbidity associated with

extended bed rest, kyphoplasty may be considered a reasonable treatment option 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, as well as for patients who have severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

There is insufficient evidence to permit conclusions on the use of kyphoplasty for an acute (<6 weeks) vertebral fracture. The scientific evidence does not permit conclusions about the impact on net health outcome; sham-controlled comparative studies are needed. There are no additional data to alter these conclusions.

There is a single published randomized trial on mechanical vertebral augmentation using the Kiva VCF System. Results from the pivotal FDA-regulated investigational device exemption trial have been reported as an abstract from a scientific meeting. In both trials, the Kiva system is compared with kyphoplasty. It is considered investigational pending publication and review of the IDE trial. Early evidence suggests that vertebral body stenting may have worse outcomes compared with balloon kyphoplasty and is considered investigational.

Practice Guidelines and Position Statements

In 2012, a joint practice guideline on the performance of vertebral augmentation was published by the American College of Radiology (ACR), the American Society of Neuroradiology (ASN), the American Society of Spine Radiology (ASSR), the Society of Interventional Radiology (SIR), and the Society of Neurointerventional Surgery (SNIS). This guideline addresses vertebral augmentation in general and refers to all percutaneous techniques used to achieve internal vertebral body stabilization, including vertebroplasty, balloon kyphoplasty, radiofrequency ablation and coblation, mechanical void creation, and injection of bone graft material or bone substitutes. The ACR, ASN, ASSR, SIR, and SNIS consider vertebral augmentation to be an established and safe procedure, and provide guidelines for appropriate patient selection, qualifications and responsibilities of personnel, specifications of the procedure, equipment quality control, and quality improvement and documentation. (36)

These societies (ACR, ASN, ASSR, SIR, and SNIS) published a joint position statement on percutaneous vertebral augmentation in 2014. (37) This document states that percutaneous vertebral augmentation, using vertebroplasty or kyphoplasty and performed in a manner in accordance with public standards, is a safe, efficacious, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures.. The document also states that these procedures are offered only when nonoperative medical therapy has not provided adequate pain relief or pain is significantly altering the patient's quality of life.

In a 2014 quality improvement guideline from SIR, failure of medical therapy includes the following situations (38):

1. Patients who are rendered nonambulatory as a result of pain from a weakened or fractured vertebral body, pain persisting at a level that prevents ambulation despite 24 hours of analgesic therapy;
2. Patients with sufficient pain from a weakened or fractured vertebral body that physical therapy is intolerable, pain persisting at that level despite 24 hours of analgesic therapy; or
3. Patient with a weakened or fractured vertebral body, and unacceptable side effects such as excessive sedation, confusion, or constipation as a result of the analgesic therapy necessary to reduce pain to a tolerable level.

In 2013, ACR updated their appropriateness criteria on the management of compression fractures. The criteria for management of these fractures state that most verterbral compression fractures are resolved within 4 to 6 weeks with the more conservative first-line treatment including the use of nonsteroidal anti-inflammatory drugs and possibly narcotic medications. However, due to expanded use of percutaneous

vertebroplasty and balloon-assisted verterbroplasty by the medical community, rapidity of clinical response, and relatively low procedural risk, threshold for performing these procedures has declined. There has also been an increased number of studies describing successful results using vertebral augmentation for painful malignant fractures and symptomatic myelomatous verterbral replacement. The criteria indicate that vertebroplasty should be reserved for patients who either have failed or cannot tolerate traditional conservative treatment. Failure can be defined as pain refractory to oral medications (NSAIDs and/or narcotic) over 6 to 12 weeks. However, failure can also be defined as contraindications to such medications or a requirement for parenteral narcotics and hospital admission. (39)

In 2010 the American Academy of Orthopaedic Surgeons Board of Directors approved a new clinical practice guideline on the treatment of osteoporotic spinal compression fractures, which had a weak recommendation for offering the option of kyphoplasty for patients who "present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact." In coming out with a weak recommendation, the committee expressed that future evidence could overturn the existing evidence and that the quality of the current literature is poor. As a note, these recommendations were based on a literature review through September 2009. (40)

The United Kingdom's National Institutue for Health and Clinical Excellence (NICE) issued a 2013 technology appraisal guidance TA279, which stated that percutaneous vertebroplasty and percutaneous balloon kyphoplasty are recommended as treatment options for treating osteoporotic VCFs in persons having severe, ongoing pain after a recent unhealed vertebral fracture, despite optimal pain management, and whose pain has been confirmed through physical exam and imaging to be at the level of the fracture. This appraisal does not address balloon kyphoplasty with stenting, because the manufacturer of the stenting system (Synthes) states there is limited evidence for vertebral body stenting as it has only recently become available. (41)

In 2008, NICE issued CG75 on the diagnosis and management of adults with metastatic spinal cord compression. The guideline states that vertebroplasty or kyphoplasty should be considered for the patients who have vertebral metastases, and no evidence of spinal cord compression or spinal instability, if they have mechanical pain resistant to conventional pain management and verterbral body collapse. Surgery should only be performed when all appropriate specialists, including the oncologist, interventional radiologist, and spinal surgeon agree. At present, there are relatively few patients in England receiving surgery; however, there is evidence to suggest that in a selected subset of patients, early surgery may be more effective at maintaining mobility than radiotherapy. (42)

DEFINITIONS:

N/A

CODING:

- **The identification of a code in this section does not denote coverage or separate reimbursement.**
- Covered procedure codes are dependent upon meeting criteria of the policy and appropriate diagnosis code.
- The following list of codes may not be all-inclusive, and are subject to change at any time.
- Benefits are determined by the terms of the Member's specific benefit plan document [i.e., the Fully Insured policy, the Administrative Services Only (ASO) agreement applicable to the Self-Funded Plan Participant, or the Individual Policy] that is in effect at the time services are rendered.

PROCEDURE CODES

0200T	22520	22522	22524	72291	S2360
0201T	22521	22523	22525	72292	S2361