MEDICAL POLICY

POLICY TITLE	PERCUTANEOUS BALLOON KYPHOPLASTY, RADIOFREQUENCY KYPHOPLASTY, AND MECHANICAL VERTEBRAL AUGMENTATION (FORMALLY KNOWN AS PERCUTANEOUS BALLOON KYPHOPLASTY AND MECHANICAL VERTEBRAL AUGMENTATION)
POLICY NUMBER	MP-1.148

Original Issue Date (Created):	**7/1/2016**
Most Recent Review Date (Revised):	**10/30/2018**
Effective Date:	**1/1/2019** **RETIRED** – See policy history*

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I. POLICY

Percutaneous balloon kyphoplasty and Kiva 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 balloon kyphoplasty and Kiva 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 balloon kyphoplasty and Kiva are 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 radiofrequency kyphoplasty or percutaneous mechanical vertebral augmentation using any other device, is considered **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

II. PRODUCT VARIATIONS

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

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FEP PPO - Refer to FEP Medical Policy Manual MP-6.01.38, Percutaneous Balloon Kyphoplasty and Mechanical Vertebral Augmentation. The FEP Medical Policy manual can be found at: www.fepblue.org.

III. DESCRIPTION/BACKGROUND

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Percutaneous balloon kyphoplasty, radiofrequency kyphoplasty, and mechanical vertebral augmentation with Kiva are interventional techniques involving the fluoroscopically guided injection of polymethylmethacrylate 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, metastatic malignancies).

OSTEOPOROTIC VERTEBRAL COMPRESSION FRACTURE

Osteoporotic compression fractures are common. It is estimated that up to 50% of women and 25% 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. 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 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 is not improved with analgesics and may be better addressed through exercise.

OSTEOLYTIC VERTEBRAL BODY FRACTURES

Vertebral body fractures can also be pathologic, due to osteolytic lesions, most commonly from metastatic tumors. Metastatic malignant disease involving the spine generally involves the vertebral bodies, with pain being the most frequent complaint. 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 vertebral body strength, which may necessitate supportive bracing to minimize the risk of vertebral body collapse during healing.

TREATMENT

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 polymethylmethacrylate (PMMA). 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.

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 to provide a reservoir for bone cement. The Kiva VCF 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 guidewire. 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 PMMA is injected through the lumen of the implant. The PMMA cement flows through small slots in the center 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.

REGULATORY STATUS

Kyphoplasty is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration (FDA). Balloon kyphoplasty requires the use of an inflatable bone tamp. In July 1998, one such tamp, the KyphX® inflatable bone tamp, was cleared for marketing by FDA through the 510(k) process. Other devices with FDA 510(k) marketing clearance include the AVA*max*® Vertebral Balloon system (CareFusion), NeuroTherm Parallax® Balloon Inflatable Bone Tamp (NeuroTherm), Stryker iVAS® Balloon catheter, and Synthes Synflate™ Vertebral Balloon System (Synthes). StabiliT® Vertebral Augmentation System (DFINE) for radiofrequency vertebral augmentation was cleared for marketing in 2009. FDA product code NDN.

In 2014, the Kiva® VCF Treatment System (Benvenue Medical) was cleared for marketing by FDA through the 510(k) process. FDA product code NDN.

PMMA bone cement was available as a drug product before enactment of FDA's device regulation and was at first considered what FDA termed a "transitional device." It was transitioned to a class III device and then to a class II device, which required future 510(k) submissions to meet "special controls" instead of "general controls" to assure safety and effectiveness. In July 2004, KyphX® HV-RTM bone cement was cleared for marketing by FDA through the 510(k) process 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 have received issued 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. FDA product code: NDN.

IV. RATIONALE

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Summary of Evidence

For individuals who have osteoporotic vertebral compression fractures who receive balloon kyphoplasty, or mechanical vertebral augmentation (Kiva), the evidence includes randomized controlled trials (RCTs) and meta-analyses of RCTs. Relevant outcomes include symptoms, functional outcomes, quality of life, hospitalizations, and treatment-related morbidity. Two moderately sized unblinded RCTs have compared kyphoplasty with conservative care and found short-term benefits in pain and other outcomes. Other RCTs, summarized in a meta-analysis, have reported similar outcomes for kyphoplasty and vertebroplasty. Two randomized trials that compared mechanical vertebral augmentation (Kiva) with kyphoplasty have 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, whether these improvements represent a true treatment effect is uncertain. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have osteolytic vertebral compression fractures who receive balloon kyphoplasty or mechanical vertebral augmentation (Kiva), 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. One RCT has 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 the effects of the technology on health outcomes.

For individuals who have osteoporotic or osteolytic vertebral compression fractures who receive radiofrequency kyphoplasty, the evidence includes 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. Corroboration of these results in a larger number of patients is needed to

determine with greater certainty whether radiofrequency kyphoplasty has outcomes similar to balloon kyphoplasty. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS

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N/A

VI. BENEFIT VARIATIONS

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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

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Capital BlueCross's 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

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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.

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Covered when medically necessary:

CPT Codes®								
22513	22514	22515						

ICD-10-CM Diagnosis Codes	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
D18.09	Hemangioma of other sites
D47.Z9	Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
M48.50XG	Collapsed vertebra, not elsewhere classified, site unspecified, subsequent encounter for fracture with delayed healing
M48.50XS	Collapsed vertebra, not elsewhere classified, site unspecified, sequela of fracture
M48.51XG	Collapsed vertebra, not elsewhere classified, occipito-atlanto-axial region, subsequent encounter for fracture with delayed healing
M48.51XS	Collapsed vertebra, not elsewhere classified, occipito-atlanto-axial region, sequela of fracture
M48.52XG	Collapsed vertebra, not elsewhere classified, cervical region, subsequent encounter for fracture with delayed healing
M48.52XS	Collapsed vertebra, not elsewhere classified, cervical region, sequela of fracture
M48.53XG	Collapsed vertebra, not elsewhere classified, cervicothoracic region, subsequent encounter for fracture with delayed healing
M48.53XS	Collapsed vertebra, not elsewhere classified, cervicothoracic region, sequela of fracture
M48.54XG	Collapsed vertebra, not elsewhere classified, thoracic region, subsequent encounter for fracture with delayed healing
M48.54XS	Collapsed vertebra, not elsewhere classified, thoracic region, sequela of fracture
M48.55XG	Collapsed vertebra, not elsewhere classified, thoracolumbar region, subsequent encounter for fracture with delayed healing
M48.55XS	Collapsed vertebra, not elsewhere classified, thoracolumbar region, sequela of fracture
M48.56XG	Collapsed vertebra, not elsewhere classified, lumbar region, subsequent encounter for fracture with delayed healing
M48.56XS	Collapsed vertebra, not elsewhere classified, lumbar region, sequela of fracture

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M48.57XG	Collapsed vertebra, not elsewhere classified, lumbosacral region, subsequent encounter for fracture with delayed healing
M48.57XS	Collapsed vertebra, not elsewhere classified, lumbosacral region, sequela of fracture
M48.58XG	Collapsed vertebra, not elsewhere classified, sacral and sacrococcygeal region, subsequent encounter for fracture with delayed healing
M48.58XS	Collapsed vertebra, not elsewhere classified, sacral and sacrococcygeal region, sequela of 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
M80.88XG	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
M84.48XG	Pathological fracture, other site, subsequent encounter for fracture with delayed healing
M84.48XK	Pathological fracture, other site, subsequent encounter for fracture with nonunion
M84.48XP	Pathological fracture, other site, subsequent encounter for fracture with malunion
M84.48XS	Pathological fracture, other site, sequela
M84.58XG	Pathological fracture in neoplastic disease, other specified site, subsequent encounter for fracture with delayed healing
M84.58XK	Pathological fracture in neoplastic disease, other specified site, subsequent encounter for fracture with nonunion
M84.58XP	Pathological fracture in neoplastic disease, other specified site, subsequent encounter for fracture with malunion
M84.58XS	Pathological fracture in neoplastic disease, other specified site, sequela
M84.68XG	Pathological fracture in other disease, other site, subsequent encounter for fracture with delayed healing
M84.68XK	Pathological fracture in other disease, other site, subsequent encounter for fracture with nonunion
M84.68XP	Pathological fracture in other disease, other site, subsequent encounter for fracture with malunion
M84.68XS	Pathological fracture in other disease, other site, sequela

IX. REFERENCES

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X. POLICY HISTORY

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MP 1.148	**CAC 1/26/16** New policy. BCBSA adopted. Criteria for kyphoplasty previously were addressed in MP-1.071 Percutaneous Vertebroplasty, Kyphoplasty, and Sacroplasty. For this review, Kiva was added as medically necessary. Percutaneous mechanical vertebral augmentation using any other device, including but not limited to Kiva and vertebral body stenting was previously considered investigational. FEP and Medicare variations added. Policy coded.
	1/1/17 Admin Update Variation reformatting

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	CAC 5/23/17 Consensus review. The last investigational statement was revised to delete the wording "including but not limited to vertebral body stenting". No other changes to the policy statements. Background, rationale and references updated. Coding reviewed.
	1/1/18 Admin Update: Medicare variations removed from Commercial Policies.
	2/09/18 Minor revision. Radiofrequency kyphoplasty added to the title and investigational statement. Description/Background, Rationale and Reference sections updated. Coding reviewed and ICD10 codes updated.
	9/27/18 Retirement. Please refer to TurningPoint Healthcare for management of these services effective 1/1/2019.*

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