***DRAFT***

BlueCross BlueShield of Alabama

**Name of Policy:**

# Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty and Mechanical Vertebral Augmentation

Policy #: 648 Latest Review Date: April 2018
Category: Radiology/Surgical Policy Grade: B

## Background/Definitions:

*As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.*

*The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:*

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

*Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:*

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

## Description of Procedure or Service:

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 Fractures**

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.

Treatment

Chronic symptoms do not tend to respond to the management strategies for acute pain such as bedrest, immobilization or bracing device, and analgesic medication, sometimes including narcotic analgesics. The source of chronic pain after vertebral compression fracture may not be from the vertebra itself but may be predominantly related to strain on muscles and ligaments secondary to kyphosis. This type of pain frequently 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.

Treatment

While radiotherapy and chemotherapy are frequently effective in reducing tumor burden and associated symptoms, pain relief may be delayed days to weeks, depending on tumor response. Further, these approaches rely on bone remodeling to regain vertebral body strength, which may necessitate supportive bracing to minimize the risk of vertebral body collapse during healing.

*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 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.

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.

*Vertebral Augmentation*
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.

Note: Vertebroplasty and sacroplasty are addressed separately in medical policy, #004-*Percutaneous Vertebroplasty and Sacroplasty.*

## Policy:

**Effective for dates of service on or after May 1, 2018:**

**Percutaneous balloon kyphoplasty or mechanical vertebral augmentation using Kiva meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage for the treatment of the following conditions:

- 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.
- Severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.
- Vertebral hemangiomas with severe pain or nerve compression.

**Percutaneous balloon kyphoplasty and mechanical vertebral augmentation using Kiva** for any other indication not listed above **do not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational.**

**Percutaneous mechanical vertebral augmentation using any other device does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational.**

**Percutaneous radiofrequency kyphoplasty does not meet** Blue Cross and Blue Shield of Alabama's criteria for coverage and is considered **investigational**.

**Vertebral body stenting does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational.**

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**Effective for dates of service November 3, 2013 through April 30, 2018:**
**Percutaneous balloon kyphoplasty meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage 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.**

**Percutaneous balloon kyphoplasty meets** Blue Cross and Blue Shield of Alabama's medical criteria for the **treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.**

**Percutaneous balloon kyphoplasty meets** Blue Cross and Blue Shield of Alabama's medical criteria for the treatment of **vertebral hemangiomas with severe pain or nerve compression.**

**Percutaneous balloon kyphoplasty and percutaneous vertebroplasty do not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational for all other indications, including use in acute vertebral fractures due to osteoporosis or trauma.**

**Percutaneous mechanical vertebral augmentation using any other device, including but limited to Kiva, and vertebral body stenting does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

## Key Points:

This policy has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through February 22, 2018. This review has been informed by a 2000 TEC Assessment, updated with TEC Assessments in 2004, 2005, 2008, 2009, and 2010.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function- including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

The natural history of pain and disability associated with these conditions vary. In addition, pain and functional ability are subjective outcomes, susceptible to placebo effects. Nonspecific or placebo effects can be quite large for an invasive procedure such as kyphoplasty for which there is no blinding. The placebo effect may be on the order of 6 to 7 mm on a 100-mm scale, for invasive procedures, and even larger effects (10%) have been observed in the sham-controlled vertebroplasty trials. Therefore, sham-controlled comparison studies are important to demonstrate the clinical effectiveness of kyphoplasty over and above any associated nonspecific or placebo effects.

Adverse effects related to kyphoplasty are the primary harms to be considered. Principal safety concerns relate to the incidence and consequences of leakage of the injected polymethylmethacrylate (PMMA).

### Osteoporotic Vertebral Compression Fractures

Balloon Kyphoplasty vs Conservative Care

In 2009, Wardlaw et al reported on the FREE trial, a nonblinded industry-sponsored, multisite RCT in which 300 adults with 1 to 3 painful osteoporotic VCFs of less than 3 months in duration were assigned to kyphoplasty or conservative care. Twenty-four-month results were reported by Boonen et al and by Van Meirhaeghe et al. Scores for the primary outcome, 1-month change in 36-Item Short-Form Health Survey (SF-36) Physical Component Summary (PCS) score, were

significantly higher for those in the kyphoplasty group. The difference between groups was 5.2 points (95% confidence interval, 2.9 to 7.4 points; p<0.001). Kyphoplasty was associated with greater improvements in SF-36 PCS scores at 6-month follow-up (3.39 points), but not at 12- or 24-month follow-ups. Greater improvement in back pain was observed over 24 months for kyphoplasty (-1.49 points) and remained statistically significant at 24 months. Participants in the kyphoplasty group also reported greater improvements in quality of life and Roland-Morris Disability Questionnaire (RMDQ) scores at short-term follow-up. At 12 months, fewer kyphoplasty patients (26.4% vs 42.1%) had received physical therapy or walking aids, back braces, wheelchairs, miscellaneous aids, or other therapy. Fewer kyphoplasty patients used opioid medications through 6 months (29.8% vs 42.9%) and fewer pain medications through 12 months (51.7% vs. 68.3%). Other differences between groups were no longer apparent at 12 months, possibly due to natural healing of fractures.

Berenson et al reported on the results of an international multicenter RCT in 2011. They enrolled 134 patients with cancer who were at least 21 years of age. Participants had at least 1 and not more than 3 painful VCFs. The primary outcome was change in functional status from baseline at 1 month as measured by the RMDQ. Treatment allocation was not blinded, and the primary outcome at 1 month was analyzed using all participants with data both at baseline and at 1 month. Participants needed to have a pain score of at least 4 on a 0-to-10 scale. Crossover to the balloon kyphoplasty arm was allowed after 1 month. Reviewers reported scores for the kyphoplasty and nonsurgical groups of 17.6 and 18.2 at baseline, respectively, and 9.10 and 18.0 at 1-month follow-ups (between-group difference in scores, p<0.001).

In 2011, Edidin et al reported on mortality risk in Medicare patients who had VCFs and had been treated with vertebroplasty, kyphoplasty, or nonoperatively. This study was industry-funded. Using the U.S. Medicare dataset, the authors identified 858,978 patients who had VCFs between 2005 and 2008. The data set included 119,253 kyphoplasty patients and 63,693 vertebroplasty patients. Survival was calculated from the index diagnosis date until death or the end of follow-up (up to 4 years). Cox regression analysis was used to evaluate the joint effect of multiple covariates, which included sex, age, race/ethnicity, patient health status, type of diagnosed fracture, site of service, physician specialty, socioeconomic status, year of diagnosis, and census region. After adjusting for covariates, patients in the surgical cohorts (vertebroplasty or kyphoplasty) had a higher adjusted survival rate (60.8%) than patients in the nonsurgical cohort (50.0%) and were 37% less likely to die. The adjusted survival rates for vertebroplasty or kyphoplasty were 57.3% and 62.8%, respectively, a 23% lower relative risk for kyphoplasty. As noted by the authors, a causal relation could not be determined from this study.

Balloon Kyphoplasty vs Vertebroplasty

In 2015, Chang et al reported on a meta-analysis of prospective studies that compared vertebroplasty with kyphoplasty. Included were 6 RCTs and 14 prospective comparative studies (total N=1429 patients). Outcomes were compared for the short (≤1 week after surgery) and long (>6 months) terms. The time to perform vertebroplasty was significantly shorter than kyphoplasty. There was no significant difference between groups in visual analog scale (VAS) pain scores or Oswestry Disability Index (ODI) scores at either short- or long-term follow-up. There was no significant difference between treatments in adjacent-level fractures. Cobb angle at long-term follow-up was improved in the kyphoplasty group compared with vertebroplasty.

Kyphoplasty had a significantly lower number of procedures with cement extravasion, although the percentage of cases with cement leakage is high for both procedures. For example, a 2014 RCT by Dohm et al (KAVIAR study) reported overall cement extravasion in 157 (73.4%) of 214 levels treated with kyphoplasty compared with 164 (81.6%) of 201 levels treated with vertebroplasty (p=0.047).19 Intravascular cement extravasion occurred in 59 (27.6%) of 214 levels treated with kyphoplasty compared with 76 (37.8%) of 201 levels treated with vertebroplasty. The clinical significance of a 10% difference in cement extravasion is uncertain; the occurrences of device-related cement embolism were similar, with 1 (0.5%) case in each group. Kyphosis correction was better in the kyphoplasty group by 1.42°(p=0.036). Pain and function improvements were similar for both procedures.

In a Bayesian network meta-analysis (NMA), Zhao et al (2017) examined the efficacy and safety of vertebroplasty, kyphoplasty, and CT for the treatment of OVCFs. Sixteen RCTs were identified (total N=2046 participants; vertebroplasty, 816; kyphoplasty, 478; CT = 752). Eleven of the RCTs compared vertebroplasty with CT; 2 RCTs compared kyphoplasty with CT; and 3 RCTs compared kyphoplasty with vertebroplasty. Each trial assessed at least one of the following: VAS, the RMDQ, the European Quality of Life-5 Dimensions (EQ-5D), and the observance of any new fractures. Network meta-analysis demonstrated that kyphoplasty was superior to conservative therapy as assessed by VAS (mean difference [MD], 0.94; 95% CI, -0.40 to 2.39), EQ-5D (MD -0.10; 95% CI, -0.17 to -0.01), and RMDQ (MD=5.72; 95% CI, 1.05 to 10.60). Insufficient data were present to complete pairwise comparison of kyphoplasty with CT for some metrics. No significant differences were found between vertebroplasty and kyphoplasty for pain relief, daily function, and quality of life. Kyphoplasty was associated with the lowest risk of new fractures, while vertebroplasty was the most effective treatment for pain relief. This review was limited by significant heterogeneity across measured outcomes and length of follow-up in studies; the presence of performing and reporting bias in studies was also a concern.

Mechanical Vertebral Augmentation with Kiva vs Balloon Kyphoplasty

Vertebral augmentation with the Kiva VCF System was compared with balloon kyphoplasty in a 2015 pivotal noninferiority RCT. This industry-sponsored, multicenter open-label (KAST) trial was conducted in 300 patients with 1 or 2 osteoporotic VCFs. Included were patients with VAS scores for back pain of at least 70 mm (/100 mm) after 2 to 6 weeks of conservative care or VAS scores of at least 50 mm after 6 weeks of conservative care, and ODI scores of at least 30%. The primary composite end point at 12 months was a reduction in fracture pain by at least 15 mm on the VAS, maintenance or improvement in function on the ODI, and absence of device-related serious adverse events. The primary end point was met by 94.5% of patients treated with Kiva and 97.6% of patients treated with kyphoplasty (Bayesian posterior probability of 99.92% for noninferiority, using as-treated analysis). In the 285 treated patients, Kiva resulted in a mean improvement of 70.8 points in VAS scores, compared with a 71.8-point improvement for kyphoplasty. There was a 38.1-point improvement in ODI score for the Kiva group compared with a 42.2-point improvement for the kyphoplasty group. There were no device-related serious adverse events. The total volume of cement was 50% less with Kiva and there was less cement extravasation (16.9%) compared with kyphoplasty (25.8%).

In 2013, Korovessis reported on a randomized trial comparing mechanical vertebral augmentation with the Kiva device with balloon kyphoplasty in 180 patients with osteoporotic VCFs. The groups showed similar improvements in VAS scores for back pain, SF-36 scores, and ODI scores. For example, there was a more than 5.5-point improvement in VAS scores in 54% of patients in the Kiva group and in 43% of patients in the balloon kyphoplasty group. Radiologic measures of vertebral height were similar in both groups. Kiva reduced the Gardner kyphotic angle, while residual kyphosis of more than 5°was more frequently observed in the balloon kyphoplasty group. Patients and outcome assessors were reported to be unaware of group assignments, although it is not clear if the Kiva device was visible on radiographs. Cement leakage into the canal only occurred in 2 patients treated with balloon kyphoplasty, necessitating decompression, compared with none following the Kiva procedure.

Section Summary: Osteoporotic Vertebral Compression Fractures
Two moderately sized unblinded RCTs have reported short-term benefits of kyphoplasty for pain and other outcomes in patients with painful osteoporotic fractures compared with conservative care. Other relevant studies, including additional RCTs and meta-analysis studies, found similar outcomes for kyphoplasty and vertebroplasty.

For mechanical vertebral augmentation with Kiva, evidence includes a large industry-sponsored, multicenter investigational device exemption trial and a large independent randomized trial. These randomized comparative trials showed outcomes similar to kyphoplasty.

**Osteolytic Vertebral Compression Fractures**
In 2016, Health Quality Ontario produced a technology assessment on vertebral augmentation for cancer-related VCFs. The assessment identified 33 reports with 1690 patients who were treated with kyphoplasty for spinal metastatic cancers, multiple myeloma, or hemangiomas. For cancer-related VCFs there were 5 case series (110 patients) on multiple myeloma and 6 reports (2 RCTs, 4 case series; 308 patients) on mixed cancers with spinal metastases. Vertebral augmentation resulted in reductions in pain intensity scores, opioid or other analgesic use, and disability scores. One RCT (N=129) compared kyphoplasty with nonsurgical management for cancer-related VCFs, reporting that pain scores, pain-related disability, and health-related quality of life were significantly improved in the kyphoplasty group than in the usual care group. The second RCT compared the Kiva device with kyphoplasty in 47 patients with cancer-related compression fractures, finding no significant differences between groups for improvements in VAS pain and ODI scores.

**Radiofrequency Kyphoplasty vs Balloon Kyphoplasty**
In 2016, Petersen et al reported on an RCT with 80 patients that compared radiofrequency kyphoplasty (RFK) with balloon kyphoplasty. Patients had been admitted to the hospital for severe back pain and met criteria for surgery after failed conservative treatment. All had osteoporotic compression fractures. Prior to treatment, VAS pain scores on movement were similar in both groups (8.4 in the balloon kyphoplasty group vs 8.0 in the RFK group). Postoperatively, VAS scores improved by 4.6 after balloon kyphoplasty and 4.4 after RFK (p=NS). Pain at 12 months also did not differ significantly between both groups, with 58% of patients in the balloon kyphoplasty group and 66% of patients in the RFK group reporting no to mild pain on movement (p=NS). There was a trend for greater restoration of the kyphosis angle.

Feng et al (2017) performed a meta-analysis comparing radiofrequency kyphoplasty with BK in patients with VCFs. Six studies (total N=833 patients) evaluating VCFs were identified. The main outcomes were pain relief (VAS), functionality improvement (ODI), operation time, reduction of deformity (i.e., the restoration of vertebral height and kyphosis angle), and incidence of cement leakage. VAS scores improved for both groups after the respective procedure; however, VAS score dropped 3.96 points more in the radiofrequency kyphoplasty group (95% CI, 1.67 to 6.24; p=0.001), with improvement persisting until the 12-month mark. While functionality improvement was initially improved more after radiofrequency kyphoplasty than BK (p=0.04), the difference between the 2 groups was not significant after a year (p=0.6). No significant difference in cement leakage between groups was observed. This review was limited by the small number of studies included as well as the presence of significant bias within these studies.

Adverse Events

Yi et al assessed the occurrence of new VCFs after treatment with cement augmenting procedures (vertebroplasty or kyphoplasty) vs conservative treatment in an RCT with 290 patients (363 affected vertebrae). Surgically treated patients were discharged the next day. Patients treated conservatively (pain medication, bedrest, a body brace, physical therapy) had a mean length of stay of 13.7 days. Return to usual activity occurred at 1 week for 87.6% of surgically treated patients and at 2 months for 59.2% of conservatively treated patients. All patients were evaluated with radiographs and magnetic resonance imaging at 6 months and then at yearly intervals until the last follow-up session. At a mean follow-up of 49.4 months (range, 36-80 months), 10.7% of patients had experienced 42 new symptomatic VCFs. There was no significant difference in the incidence of new vertebral fractures between the operative (n=18; 9 adjacent, 9 nonadjacent) and conservative (n=24; 5 adjacent, 16 nonadjacent, 3 same level) groups, but the mean time to a new fracture was significantly shorter in the surgical group (9.7 months) compared with the nonoperative group (22.4 months).

Section Summary: Radiofrequency Kyphoplasty vs Balloon Kyphoplasty

For RFK, the evidence includes a meta-analysis study and a RCT. While the RCT showed similar results compared with balloon kyphoplasty, an improvement in immediate pain relief after RCT was noted in the meta-analysis. Further high quality studies are needed to determine with greater certainty whether RFK has outcomes similar to balloon kyphoplasty.

The major limitation of all these RCTs was the lack of a sham procedure. Due to the possible sham effect observed in the recent trials of vertebroplasty, the validity of results from non-sham-controlled trials is questionable. Therefore, it is not possible to conclude that these improvements are a true treatment effect. Cement leakage, although slightly reduced in kyphoplasty relative to vertebroplasty, remains a concern.

**Vertebral Body Metastasis**

In the early literature reviews, 3 case series were reviewed evaluating a total of 52 patients. Outcome measures varied among these 3 studies, but all showed improvements either in VAS pain score, several aspects of physical functioning as measured by SF-36, or improvement in a disability score. There are no RCTs of kyphoplasty for vertebral body metastasis. Because the results of the comparative studies of vertebroplasty suggest possible placebo or natural history

effects, case series are insufficient to make conclusions about the effect of kyphoplasty on health outcomes.

**Vertebral Body Stenting**

Vertebral Body Stenting vs Balloon Kyphoplasty

An RCT by Werner et al, performed independent of industry support, found no advantage of vertebral body stenting over balloon kyphoplasty. Sixty-five patients were included who had one or more fresh osteoporotic VCFs and marked pain. A total of 100 VCFs were randomized to either vertebral body stenting (VBS) or balloon kyphoplasty, with the condition that if there were multiple levels in a single patient, the same procedure was used for all levels. There was no significant difference between the procedures in radiation time, or in the mean reduction of kyphosis (4.7 degrees after VBS and 4.5˚ after kyphoplasty). There was also no significant difference between the 2 intervention arms in cement leakage (20% balloon kyphoplasty and 30% VBS). Intraoperative pressure was higher and material-related complications were greater (9 of the 50 levels, including failure of the cannulas, incomplete or no opening of the stent, and balloon rupture) in the VBS group compared with one of the 50 vertebral levels (balloon rupture) in the kyphoplasty group.

**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. A meta-analysis and 2 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.

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.

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 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. 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 for patients who have 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 the effects of the technology on health outcomes.

Early evidence suggests that vertebral body stenting may have worse outcomes compared with balloon kyphoplasty and is considered investigational.

## Key Words:

Percutaneous kyphoplasty, polymethylmethacrylate, PMMA, vertebral fracture, vertebral compression fracture, skyphoplasty, SKy bone expander, mechanical vertebral augmentation, Kiva®, VCF Treatment System, KyphX , StabiliT®, AVA*max*® Vertebral Balloon system, NeuroTherm Parallax® Balloon Inflatable Bone Tamp (NeuroTherm), Stryker iVAS® Balloon catheter, Synthes Synflate™ Vertebral Balloon System (Synthes), radiofrequency kyphoplasty, vertebral body stenting.

## Approved by Governing Bodies:

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 (Medtronic), 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 [West Chester, PA]). StabiliT® Vertebral Augmentation System (Merit Medical) for radiofrequency vertebral augmentation was cleared for marketing in 2009.

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

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 (Heraeus) have received issued 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

## Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply.
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

## Current Coding:

CPT Codes:

| | |
|---|---|
| **22513** | Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic **(Effective 01/01/15)** |
| **22514** | Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar **(Effective 01/01/15)** |
| **22515** | Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (e.g., kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure) **(Effective 01/01/15)** |
| **64999** | Unlisted procedure, nervous system |

## References:


1. American Academy of Orthopaedic Surgeons (AAOS). Clinical practice guideline, Treatment of osteoporotic spinal compression fractures. 2010; www.aaos.org/research/guidelines/SCFguideline.pdf.

2. ACR–ASNR–ASSR–SIR–SNIS Practice guideline for the performance of vertebral augmentation 2012. www.acr.org/~/media/ACR/Documents/PGTS/guidelines/Vertebral_Augmentation.pdf.
3. Baerlocher MO, Saad WE, Dariushnia S, et al. Quality improvement guidelines for percutaneous vertebroplasty. J Vasc Interv Radiol. Feb 2014; 25(2):165-170.
4. Barr JD, Jensen ME, Hirsch JA, et al. Position statement on percutaneous vertebral augmentation: a consensus statement developed by the Society of Interventional Radiology (SIR), American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), American College of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spine Radiology (ASSR), Canadian Interventional Radiology Association (CIRA), and the Society of NeuroInterventional Surgery (SNIS). J Vasc Interv Radiol. Feb 2014; 25(2):171-181.
5. Berenson J, Pflugmacher R, Jarzem P, et al. Balloon kyphoplasty versus non-surgical fracture management for treatment of painful vertebral body compression fractures in patients with cancer: a multicentre, randomised controlled trial. Lancet Oncol. Mar 2011; 12(3):225-235.
6. Betts A. Sacral vertebral augmentation; confirmation of fluoroscopic landmarks by open dissection. Pain Physician 2008;11(1):57-65.
7. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Percutaneous vertebroplasty or kyphoplasty for vertebral fractures caused by osteoporosis or malignancy. TEC Assessments. 2008;Volume 23:Tab 5.
8. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Percutaneous kyphoplasty for vertebral fractures caused by osteoporosis or malignancy. TEC Assessments. 2005;Volume 20:Tab 7.
9. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Percutaneous kyphoplasty for vertebral fractures caused by osteoporosis and malignancy. TEC Assessments. 2004;Volume 19:Tab 12.
10. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Percutaneous Vertebroplasty. TEC Assessments. 2000;Volume 15:Tab 21.
11. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Percutaneous vertebroplasty or kyphoplasty for vertebral fractures caused by osteoporosis. TEC Assessments. 2009;Volume 24:Tab 7.
12. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Percutaneous vertebroplasty or kyphoplasty for vertebral fractures caused by osteoporosis. TEC Assessments. 2010;Volume 25:Tab 9.
13. Boonen S, Van Meirhaeghe J, Bastian L, et al. Balloon kyphoplasty for the treatment of acute vertebral compression fractures: 2-year results from a randomized trial. J Bone Miner Res. Jul 2011; 26(7):1627-1637.
14. Buchbinder R, Osborne RH, Ebeling PR, et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. N Engl J Med. Aug 6 2009; 361(6):557-568.
15. Chang X, Lv YF, Chen B, et al. Vertebroplasty versus kyphoplasty in osteoporotic vertebral compression fracture: a meta-analysis of prospective comparative studies. Int Orthop. Mar 2015; 39(3):491-500.
16. Dohm M, Black CM, Dacre A, et al. A randomized trial comparing balloon kyphoplasty and vertebroplasty for vertebral compression fractures due to osteoporosis. AJNR Am J Neuroradiol. Dec 2014; 35(12):2227-2236.

17. Edidin AA, Ong KL, Lau E, et al. Mortality risk for operated and nonoperated vertebral fracture patients in the medicare population. J Bone Miner Res. Jul 2011;26(7):1617-1626.
18. Edidin AA, Ong KL, Lau E, et al. Mobidity and mortality after vertebral fractures: comparison of vertebral augmentation and nonoperative management in the Medicare population. Spine (Phila Pa 1976). Aug 01 2015;40(15):1228-1241.
19. Feng L, Shen JM, Feng C, et al. Comparison of radiofrequency kyphoplasty (RFK) and balloon kyphoplasty (BKP) in the treatment of vertebral compression fracturs: A meta-analysis. Medicine (Baltimore). Jun 2017; 96(25):e7150.
20. Foo L.S., Yeo W., Fook S., et al. Results, experience and technical points learnt with use of the Sky Bone Expander kyphoplasty system for osteoporotic vertebral compression fractures: a prospective study of 40 patients with a minimum of 12 months of follow-up. Eur Spine J 2007; 6:944-1950.
21. Fournery DR, et al. Percutaneous vertebroplasty and kyphoplasty for painful vertebral body fractures in cancer patients. J of Neurosurg. Jan 2003: 98 (1 Suppl): 21-30.
22. Gaitanis IN, Hadjipavlou AG, Katonis PG et al. Balloon kyphoplasty for the treatment of pathological vertebral compressive fractures. Eur Spine J 2005; 14(3):250-260.
23. Garfin S.R., Yuan H.A., and Reiley M.A. Kyphoplasty and vertebroplasty for the treatment of painful osteoporotic compression fractures, Spine: 26(14); 1511-1515.
24. Health Quality Ontario. Vertebral augmentation involving vertebroplasty or kyphoplasty for cancer-related vertebral compression fractures: a systematic review. Ont Health Technol Assess Ser. 2016; 16(11):1-202.
25. Hrobjartsson A, Gotzsche PC. Is the placebo powerless? An analysis of clinical trials comparing placebo with no treatment. N Engl J Med. May 24 2001; 344(21):1594-1602.
26. Jarvik JG, Deyo RA. Cementing the evidence: time for a randomized trial of vertebroplasty. AJNR Am J Neuroradiol. Sep 2000; 21(8):1373-1374.
27. Jensen ME, McGraw JK, Cardella JF, Hirsch JA. Standards of practice. Position statement on percutaneous vertebral augmentation: a consensus statement developed by the American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, American Association of neurological Surgeons/congress of Neurological Surgeons, and American society of Spine Radiology. JVasc Interv Radiol 2008; 18(3):325-330.
28. Kallmes DF, Comstock BA, Heagerty PJ, et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. N Engl J Med. Aug 6 2009; 361(6):569-579.
29. Komp M RS, Godolias G. Minimally invasive therapy for functional unstable osteoporotic vertebral fracture by means of kyphoplasty: a prospective comparative study of 18 surgically and 17 conservatively treatment patients. J Miner Stoffwechs 2004; 11 (suppl 1):13-15 (in German; translated).
30. Korovessis P, Vardakastanis K, Repantis T et al. Balloon Kyphoplasty Versus KIVA Vertebral Augmentation-Comparison of 2 Techniques for Osteoporotic Vertebral Body Fractures: A Prospective Randomized Study. Spine (Phila Pa 1976). Feb 15 2013; 38(4):292-299.
31. Lane JM, Hong R, Koob J et al. Kyphoplasty enhances function and structural alignment in multiple myeloma. Clin Orthop Relat Res. Sep 2004; (426):49-53.
32. Ledlie JT, Renfro M. Balloon kyphoplasty: one-year outcomes in vertebral body height restoration, chronic pain, and activity levels. J Neurosurg 2003; 98(1 Suppl):36-42.

33. Lieberman IH, Dudeney S, Reinhard MK, and Bell G. Initial outcome of efficacy of "kyphoplasty" in the treatment of painful osteoporotic vertebral compression fractures, Spine: 26(14); 1631-1638.
34. Moerman DE, Jonas WB. Deconstructing the placebo effect and finding the meaning response. Ann Intern Med. Mar 19 2002; 136(6):471-476.
35. National Institute for Health and Care Excellence (NICE). Metastatic spinal cord compression in adults: risk assessment, diagnosis and management [CG75]. 2014; https://www.nice.org.uk/guidance/cg75/chapter/1-Guidance.
36. National Institute for Health and Care Excellence (NICE). Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures [TA279]. 2013; https://www.nice.org.uk/guidance/ta279.
37. Otten LA, Bornemnn R, Jansen TR et al. Comparison of balloon kyphoplasty with the new Kiva(R) VCF system for the treatment of vertebral compression fractures. Pain Physician 2013; 16(5):E505-512.
38. Peh WCG, Munk PL, Rashid F, Gilula LA. Percutaneous vertebral augmentation: vertebroplasty, skyphoplasty and skyphoplasty. Radiol Clin N Am 2008; 46(3):611-635 vii.
39. Petersen A, Hartwig E, Koch EM, et al. Clinical comparison of postoperative results of balloon kyphoplasty (BKP) versus radiofrequency-targeted vertebral augmentation (RF-TVA): a prospective clinical study. Eur J Orthop Surg Traumatol. Jan 2016; 26(1):67-75.
40. Schofer MD, Efe T, Timmesfeld N et al. Comparison of kyphoplasty and vertebroplasty in the treatment of fresh vertebral compression fractures. Arch Orthop Trauma Surg 2009; 129(10):1391-1399.
41. Tong S.C., Eskey C.J., Pomerantz S.R., et al. "SKyphoplasty": a single institution's initial experience. J Vasc Interv Radiol 2006; 17(6):1025-1030.
42. Tutton SM, Pflugmacher R, Davidian M et al. KAST study: the Kiva® system as a vertebral augmentation treatment - a safety and effectiveness trial. J Vasc Interv Radiol 2014; 25(3):S111.
43. Tutton SM, Pflugmacher R, Davidian M, et al. KAST Study: The Kiva System as a vertebral augmentation treatment-a safety and effectiveness trial: a randomized, noninferiority trial comparing the Kiva System with balloon kyphoplasty in treatment of osteoporotic vertebral compression fractures. Spine (Phila Pa 1976). Jun 15 2015; 40(12):865-875.
44. Van Meirhaeghe J, Bastian L, Boonen S, et al. A randomized trial of balloon kyphoplasty and nonsurgical management for treating acute vertebral compression fractures: vertebral body kyphosis correction and surgical parameters. Spine (Phila Pa 1976). May 20 2013; 38(12):971-983.
45. Vase L, Riley JL, 3rd, Price DD. A comparison of placebo effects in clinical analgesic trials versus studies of placebo analgesia. Pain. Oct 2002; 99(3):443-452.
46. Wang LJ, Yang HL, Shi YX et al. Pulmonary cement embolism associated with percutaneous vertebroplasty or kyphoplasty: a systematic review. Orthop Surg. Aug 2012; 4(3):182-189.
47. Wardlaw D, Cummings SR, Van Meirhaeghe J, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. Lancet. Mar 21 2009; 373(9668):1016-1024.

48. Watts, N.B., Harris, S.T., and Genant, H.K. Treatment of painful osteoporotic vertebral fractures with percutaneous vertebroplasty or kyphoplasty. Osteoporosis International, 2001, Vol. 12, pp. 429-437.
49. Yi X, Lu H, Tian F, et al. Recompression in new levels after percutaneous vertebroplasty and kyphoplasty compared with conservative treatment. Arch Orthop Trauma Surg. Jan 2014; 134(1):21-30.
50. Zhao S, Xu CY, Zhu AR, et al. Comparison of the efficacy and safety of 3 treatments for patients with osteoportoic vertebral compression fractures: A network meta-analysis. Medicine (Baltimore). Jun 2017; 96(26):e7328.

## Policy History:

Medical Policy Panel, April 2018
Medical Policy Group, April 2018 **(7)**: New Policy. Kyphoplasty and mechanical vertebral augmentation material removed from MP#004 to create separate policy; refer to MP# 004 for policy history details. Policy statement updated to include percutaneous radiofrequency kyphoplasty as investigational. Removed policy statement related to Kiva. Description and Key Points updated with current literature. Updated Key Words and Approved by Governing Bodies.
Medical Policy Administration Committee, May 2018
Available for comment May 1 through June 14, 2018