Percutaneous balloon kyphoplasty and Kiva® may be considered medically necessary for the treatment of any of the following indications:

- Symptomatic osteoporotic vertebral compression fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy, rest) for at least 6 weeks
- Severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies
- Vertebral eosinophilic granuloma with spinal instability
- Vertebral hemangiomas with both of the following:
  - Aggressive signs (e.g., myelopathy, radiculopathy, bone fracture, collapse or destruction)
  - Radiation therapy has failed to relieve symptoms

Percutaneous balloon kyphoplasty and Kiva® are considered investigational for all other indications, including use in acute vertebral fractures due to osteoporosis or trauma.

Percutaneous radiofrequency kyphoplasty or percutaneous mechanical vertebral augmentation using any other device is considered investigational.

Policy Guidelines

Based on currently available evidence, health outcomes for kyphoplasty, Kiva®, and vertebroplasty appear to be equivalent, therefore, the “least costly alternative” provision of the medically necessary definition may apply. In accordance with Blue Shield of California’s medical necessity criteria, if there are two or more medically necessary services that may be provided for an illness, injury or medical condition, Blue Shield of California will provide benefits based on the most cost-effective service. Treatment with mechanical vertebral augmentation with kyphoplasty or Kiva® is likely to produce equivalent outcomes compared with vertebroplasty but may be more costly. In these cases, when it is determined that a strategy using kyphoplasty or Kiva® is more costly than one using vertebroplasty, then kyphoplasty or Kiva® may be considered not medically necessary.

Coding

There are CPT codes that combine the kyphoplasty procedure with all of the necessary imaging guidance:

- **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
- **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
- **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)
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).

### Related Policies

- Percutaneous Vertebroplasty and Sacroplasty

### Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates [e.g., Federal Employee Program (FEP)] prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

### 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 the FDA through the 510(k) process. Other devices with the FDA 510(k) marketing clearance include the AVAmax® 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 the FDA through the 510(k) process. FDA product code NDN.

PMMA bone cement was available as a drug product before enactment of the FDA’s device regulation and was at first considered what the 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 the 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.
Rationale

Background
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 bed rest, 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.

Literature Review
This review has been informed by a 2000 Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment,1 updated with TEC Assessments in 2004,2 2005,3 2008,4 2009,5 and 2010.6

Assessment of efficacy for therapeutic intervention involves a determination of whether the intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as non-comparability of treatment groups, placebo effect, and variable natural history of the condition.

For treatment of osteoporosis and malignancy with percutaneous kyphoplasty, the primary beneficial outcomes of interest are relief of pain and improvement in ability to function. Kyphoplasty may also restore lost vertebral body height and reduce kyphotic deformity. Potential health outcomes related to kyphotic deformity include pulmonary or gastrointestinal compression and associated symptoms, and vertebral compression fractures (VCFs) may be associated with lower health-related quality of life.

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.7,8 The placebo effect may be on the order of 6 to 7 mm on a 100-mm scale, for invasive procedures,7,10 and even larger effects (10%) have been observed in the sham-controlled vertebroplasty trials.11,12 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**

The evidence on the treatment of VCFs includes 2 multicenter RCTs that compared kyphoplasty with conservative care, a comparative analysis of mortality risk from the Medicare dataset, a meta-analysis of trials that compared kyphoplasty with vertebroplasty, and 2 RCTs that compared mechanical vertebral augmentation with balloon kyphoplasty.

**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.13 Twenty-four-month results were reported by Boonen et al (2011) and by Van Meirhaeghe et al (2013).14,15 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). 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 1.4° (p=0.036). Pain and function improvements were similar for both procedures.

**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 (0-100 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 endpoint 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 RCTs, summarized in a meta-analysis, found similar outcomes for kyphoplasty and vertebroplasty.

For mechanical vertebral augmentation with Kiva, evidence to date 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.
6.01.38 Percutaneous Balloon Kyphoplasty, Radiofrequency Kyphoplasty, and Mechanical Vertebral Augmentation

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Adverse Events
Yi et al (2014) 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, bed rest, 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, a randomized comparative trial with 80 patients was identified that showed similar results compared with balloon kyphoplasty. Corroboration of these results in a larger number of patients is 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.

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.

Supplemental Information
Clinical Input from Physician Specialty Societies and Academic Medical Centers
While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2014 Input
In response to requests from Blue Cross Blue Shield Association, input was received from 2 physician specialty societies and 3 academic medical centers in 2014. Focused input was sought on the treatment of acute vertebral fractures when severe pain has led to hospitalization or persists at a level that prevents ambulation, and on the treatment of traumatic fractures that have remained symptomatic after 6 weeks of conservative treatment. Clinical input on these issues was mixed.

2008 Input
In response to requests from Blue Cross Blue Shield Association, input was received from 6 physician specialty societies (1 unsolicited) and 2 academic medical centers in 2008. All reviewers disagreed with the proposed policy, referring to a body of evidence from uncontrolled studies that supported use of kyphoplasty.

Practice Guidelines and Position Statements
American College of Radiology et al
The American College of Radiology (ACR) and 7 other surgical and radiologic specialty associations published a joint position statement on percutaneous vertebral augmentation in 2014. This document stated that percutaneous vertebral augmentation, using vertebroplasty or kyphoplasty and performed in a manner consistent with public standards, is a safe, efficacious, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures. The statement also indicated that these procedures be offered only when nonoperative medical therapy has not provided adequate pain relief or pain is significantly altering the patient’s quality of life.

Society of Interventional Radiology
In a 2014 quality improvement guideline on percutaneous vertebroplasty from the Society of Interventional Radiology, vertebral augmentation was recommended for compression fractures refractory to medical therapy. Failure of medical therapy includes the following situations:
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”;
3. Patients 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.”
American Academy of Orthopaedic Surgeons
In 2010, the American Academy of Orthopaedic Surgeons approved clinical guidelines on the treatment of osteoporotic spinal compression fractures, which had a weak recommendation for offering kyphoplasty to patients who “present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.”

The Academy indicated that future evidence could overturn existing evidence and that the quality of the current literature is poor. These recommendations were based on literature reviewed through September 2009.

National Institute for Health and Care Excellence
The National Institute for Health and Care Excellence issued a 2013 guidance that recommended percutaneous vertebroplasty and percutaneous balloon kyphoplasty as treatment options for treating osteoporotic vertebral compression fractures 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 at the level of the fracture.

This guidance did not address balloon kyphoplasty with stenting, because the manufacturer of the stenting system (Synthes) stated there is limited evidence for vertebral body stenting given that the system had only recently become available.

In 2008, the Institute issued guidance on the diagnosis and management of adults with metastatic spinal cord compression. It was last reviewed in 2014, and placed on the static list (no major ongoing studies identified, with the next review in 5 years). The guidance stated that vertebroplasty or kyphoplasty should be considered for 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 vertebral body collapse. Surgery should only be performed when all appropriate specialists agree. Despite a relatively small sample base, the Institute concluded the evidence suggests, in a select subset of patients, that early surgery may be more effective at maintaining mobility than radiotherapy.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

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<tr>
<th>NCT No.</th>
<th>Trial Name</th>
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<th>Completion Date</th>
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<td>A Prospective, Multicenter, Randomized, Comparative Clinical Study to Compare the Safety and Effectiveness of Two Vertebral Compression Fracture (VCF) Reduction Techniques: the SpineJack® and the KyphX Xpander® Inflatable Bone Tamp</td>
<td>152</td>
<td>Mar 2018</td>
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</table>

NCT: National Clinical Trial.

a Denotes industry-sponsored or cosponsored trial.

References

4. 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.

Documentation for Clinical Review

Please provide the following documentation (if/when requested):

- History and physical and/or consultation notes including:
  - Reason for procedure
  - Description of prior treatment and response (including time frame of treatment)
  - Imaging report(s)

Post Service

- Procedure report
## Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

**MN/IE**

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

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<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<td>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</td>
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<tr>
<td></td>
<td>22514</td>
<td>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</td>
</tr>
<tr>
<td></td>
<td>22515</td>
<td>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)</td>
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<td>0PU34JZ</td>
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<td>0QU14JZ</td>
<td>Supplement Sacrum with Synthetic Substitute, Percutaneous Endoscopic Approach</td>
</tr>
<tr>
<td><strong>ICD-10 Diagnosis</strong></td>
<td>All Diagnoses</td>
<td></td>
</tr>
</tbody>
</table>
Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/14/2001</td>
<td>New Policy Adoption Policy for Vertebroplasty</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>10/24/2001</td>
<td>New Policy Adoption Policy for Kyphoplasty</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>11/05/2002</td>
<td>Policy Revision Addition of FDA notification to description</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>10/01/2005</td>
<td>Policy Name Change Policy review, title modifications</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>12/01/2006</td>
<td>BCBSA Medical Policy adoption MPC adopted BCBSA MPP review for Percutaneous Vertebroplasty 4:2006 &amp; Percutaneous Kyphoplasty</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>10/15/2007</td>
<td>Policy Revision Policy changed based on expert input and evidence review. Approved under certain conditions (see policy for details).</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>06/19/2009</td>
<td>Policy Revision</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>03/30/2012</td>
<td>Policy Name Change Combination of two BCBSA medical policies: Percutaneous Vertebroplasty and Sacroplasty (6.01.25) and Percutaneous Kyphoplasty (6.01.38)</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>07/06/2012</td>
<td>Policy title change from Percutaneous Kyphoplasty and Vertebroplasty with position change</td>
<td>Medical Policy Committee</td>
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<tr>
<td>07/13/2012</td>
<td>Coding Update</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>12/15/2014</td>
<td>Policy title change from Percutaneous Kyphoplasty, Vertebroplasty and Sacroplasty Policy revision with position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>04/08/2015</td>
<td>Coding update</td>
<td>Administrative Review</td>
</tr>
<tr>
<td>08/31/2015</td>
<td>Policy revision with position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>01/01/2017</td>
<td>Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
<tr>
<td>10/01/2017</td>
<td>Policy title change from Percutaneous Balloon Kyphoplasty and Mechanical Vertebral Augmentation Policy revision without position change</td>
<td>Medical Policy Committee</td>
</tr>
</tbody>
</table>

Definitions of Decision Determinations

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.
Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.