



Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Percutaneous Balloon Kyphoplasty and Mechanical Vertebral Augmentation

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Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for percutaneous kyphoplasty when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Percutaneous kyphoplasty may be considered **medically necessary** for the treatment of symptomatic osteoporotic vertebral fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy, and rest) for at least 6 weeks.

Percutaneous kyphoplasty may be considered **medically necessary** for the treatment of severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

When Policy Topic is not covered

Percutaneous kyphoplasty 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 not limited to Kiva and vertebral body stenting, is considered **investigational**.

Description of Procedure or Service

Percutaneous balloon kyphoplasty and mechanical vertebral augmentation with Kiva® are interventional techniques involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) into a cavity created in the vertebral body with a balloon or mechanical device. These techniques have been investigated as an option to provide mechanical support and symptomatic relief in patients with osteoporotic vertebral compression fracture, or in those with osteolytic lesions of the spine, i.e., multiple myeloma or metastatic malignancies.

Balloon kyphoplasty is a variant of vertebroplasty and uses a specialized bone tamp with an inflatable balloon to expand a collapsed vertebral body as close as possible to its natural height before injection of the PMMA. Radiofrequency kyphoplasty is a modification of balloon kyphoplasty. In this procedure, an ultra-high viscosity cement is injected into the fractured vertebral body, and radiofrequency is used to achieve the desired consistency of the cement. The ultrahigh viscosity cement is designed to restore height and alignment to the fractured vertebra, along with stabilizing the fracture.

It has been proposed that kyphoplasty may provide an analgesic effect through mechanical stabilization of a fractured or otherwise weakened vertebral body. However, other possible mechanisms of effect have been postulated, one of which is thermal damage to intraosseous nerve fibers given that PMMA undergoes a heat-releasing (exothermic) reaction during its hardening process.

Kiva® is another mechanical vertebral augmentation technique that uses an implant for structural support of the vertebral body and to provide a reservoir for bone cement. The implant is made from

PEEK-OPTIMA®, a biocompatible polymer, and is inserted into the vertebral body over a guide wire. The implant can be customized by changing the coil stack height, with a maximum height of 12 mm. PMMA is injected through the lumen of the implant, which fixes the implant to the vertebral body and contains the PMMA in a cylindrical column. The proposed advantage of the Kiva system is a reduction in cement leakage.

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

Osteoporotic Vertebral Compression Fracture

Osteoporotic compression fractures are a common problem, and it is estimated that up to one half of women and approximately one quarter of men will have a vertebral fracture at some point in their lives. However, only about one third of vertebral fractures actually reach clinical diagnosis, and most symptomatic fractures will heal within a few weeks or 1 month. However, a minority of patients will exhibit chronic pain following osteoporotic compression fracture that presents challenges for medical management. Chronic symptoms do not tend to respond to the management strategies for acute pain such as bed rest, immobilization/bracing device, and analgesic medication, sometimes including narcotic analgesics. The source of chronic pain after vertebral compression fracture may not be from the vertebra itself but may be predominantly related to strain on muscles and ligaments secondary to kyphosis. This type of pain frequently is not improved with analgesics and may be better addressed through exercise.

Vertebral Body Metastasis

Metastatic malignant disease involving the spine generally involves the vertebral bodies, with pain being the most frequent complaint. While radiation and chemotherapy are frequently effective in reducing tumor burden and associated symptoms, pain relief may be delayed days to weeks, depending on tumor response. Further, these approaches rely on bone remodeling to regain vertebral body strength, which may necessitate supportive bracing to minimize the risk of vertebral body collapse during healing.

Vertebral Hemangiomas

Vertebral hemangiomas are relatively common lesions noted in up to 12% of the population based on autopsy series; however, only rarely do these lesions display aggressive features and produce neurologic compromise and/or pain. Treatment of aggressive vertebral hemangiomas has evolved from radiation therapy to surgical approaches using anterior spinal surgery for resection and decompression. There is the potential for large blood loss during surgical resection, and vascular embolization techniques have been used as adjuncts to treatment to reduce blood loss. Percutaneous cementoplasty has been proposed as a way to treat and stabilize some hemangioma to limit the extent of surgical resection and as an adjunct to reduce associated blood loss from the surgery.

Regulatory Status

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

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

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

PMMA bone cement was available as a drug product before enactment of FDA's device regulation and was at first considered what the FDA terms a "transitional device." It was transitioned to a class III device requiring premarketing applications. Several orthopedic companies have received approval of their bone cement products since 1976. In October 1999, PMMA was reclassified from class III to class II, which requires future 510(k) submissions to meet "special controls" instead of "general controls" to assure safety and effectiveness.

Thus, use of PMMA in kyphoplasty represented an off-label use of an FDA-regulated product before July 2004. In July 2004, KyphX® HV-RTM bone cement was given 510(k) marketing clearance by FDA for the treatment of pathologic fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a balloon kyphoplasty procedure. Subsequently, other products such as Spine-Fix® Biomimetic Bone Cement and Osteopal® V have been issued 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

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

Rationale

This policy was originally based on a 2000 TEC Assessment,⁽²⁾ updated with TEC Assessments in 2004,⁽³⁾ 2005,⁽⁴⁾ 2008,⁽⁵⁾ 2009,⁽⁶⁾ and 2010,⁽⁷⁾ and since then with periodic searches of the MEDLINE database. The most recent literature review was performed through March 27, 2014

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 result in restoration of lost vertebral body height with associated reduction in kyphotic deformity. Potential health outcomes related to kyphotic deformity include pulmonary or gastrointestinal compression and associated symptoms, and vertebral compression fractures may be associated with lower health-related quality of life. Ex vivo cadaver studies reporting bone strength as a surrogate outcome measure have been reported but are not included in this evaluation of health outcomes.

Pain and functional ability are subjective outcomes and, thus, may be susceptible to placebo effects. Furthermore, the natural history of pain and disability associated with these conditions may be variable. Therefore, controlled comparison studies would be valuable to demonstrate the clinical effectiveness of kyphoplasty over and above any associated nonspecific or placebo effects and to demonstrate the effect of treatment compared with an alternative such as continued medical management.

In all clinical situations, adverse effects related to complications from kyphoplasty are the primary harms to be considered. Principal safety concerns relate to the incidence and consequences of leakage of the injected polymethylmethacrylate (PMMA).

Originally the available data were observational. Evidence from observational studies were generally consistent in showing significant decreases in pain from an initial preoperative level of 7 to 9 on a visual analog scale ([VAS] or similar score proportionate to the highest possible score) to 2 to 4, typically within 1 day of receiving the procedure. Such pain relief appeared to be lasting in the 4 studies that reported long-term outcomes, although most of the studies had large losses to follow-up.⁽⁸⁻¹¹⁾

In terms of other outcomes, results generally showed improvement after kyphoplasty. For example, Coumans et al⁽⁸⁾ reported statistically significant improvements in several subscores of the Short Form-36 (SF-36), including physical function, mental health, pain, vitality, and social function. Crandall et al⁽¹⁰⁾ showed decreases in the amount of medication use over time, and Ledlie et al⁽¹²⁾ showed that the proportion of patients fully ambulatory increased after the procedure. Two nonrandomized

studies that compared kyphoplasty with conservative management for treatment of osteoporotic fractures showed that patients receiving kyphoplasty had greater improvements in pain and function.(13,14)

In terms of adverse outcomes, the most common adverse outcome reported in these studies was leakage of the cement outside of the vertebral body, occurring between 6% and 38% in 6 studies that reported its occurrence. The early literature review also identified a publication on treatment of pathologic compression fractures in which kyphoplasty and spinal radiosurgery were combined.(15) The 2008 TEC Assessment found that although many case series had been published, there was a lack of rigorous comparative trials of kyphoplasty.(5) Because case series studies are subject to many sources of bias and are generally not reliable evidence of efficacy, it was concluded that the evidence for kyphoplasty did not meet TEC criteria.

Beginning in 2009, data from randomized controlled trials (RCTs) began appearing in the literature. This policy is now focused on RCT data.

Balloon Kyphoplasty

Osteoporotic Compression Fractures

In 2009, Wardlaw et al reported on the findings of the FREE trial, an industry-sponsored multisite RCT in which 300 adult participants with 1 to 3 painful osteoporotic vertebral fractures of less than 3 months' duration were assigned to undergo kyphoplasty or conservative care.(16) Twenty-four month results of this study were reported by Boonen et al in 2011 and by Van Meirhaeghe et al in 2013.(17,18) This study was designed to examine efficacy and safety of kyphoplasty for the treatment of acute vertebral compression fractures. There was no blinding in this trial. Participants were recruited from 21 sites in 8 countries. Participants needed to have back pain of no more than 3 months' duration and the presence of at least 1 but no more than 3 acute vertebral fractures. Participants were evaluated at baseline, then at 1, 3, 6, 12, and 24 months after the procedure. The primary outcome was the difference in change from baseline to 1 month in the SF-36 Physical Component Summary (PCS) between the kyphoplasty and control groups.

A total of 138 participants who underwent kyphoplasty and 128 control patients completed 1 month of follow-up. Scores for the primary outcome, 1-month change in SF-36 PCS score, were significantly higher for those in the kyphoplasty group. The difference between the 2 groups was 5.2 points (95% confidence interval, 2.9 to 7.4; $p < 0.001$). Data were available from 232 patients (77%) at 24 months. 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 months. 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) score 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%). While not a study outcome, the authors also noted that patients who received kyphoplasty had approximately 60 fewer days of restricted activity during the year than controls. Other differences between the groups were no longer apparent at 12 months; possibly due to natural healing of fractures. At 24 months, there was no significant difference between groups in the number of patients with new radiographic vertebral fractures (47.5% for kyphoplasty, 44.1% for control). Two device-related serious adverse events (a spondylitis and an anterior cement migration) were reported.

Berenson et al reported the results of an international multicenter RCT in 2011.(19) 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 vertebral compression fractures (VCF). (These appear to be due to osteoporosis, rather than from a metastatic lesion.) 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. The authors report scores in the kyphoplasty and nonsurgical groups of 17.6 and 18.2 at baseline, respectively, and 9.10 and 18.0 at 1-month follow-up ($p < 0.001$ for the between-group difference in scores).

In 2011, Edidin et al reported mortality risk in Medicare patients who had vertebral compression fractures and had been treated with vertebroplasty, kyphoplasty, or nonoperatively.(20) This study was industry-funded. Using the U.S. Medicare data set, they identified 858,978 patients who had vertebral compression fractures 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 was used to evaluate the joint effect of multiple covariates, which included gender, 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 operated cohort (vertebroplasty or kyphoplasty) were found to have a higher adjusted survival rate (60.8%) than patients in the nonoperated 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 relationship cannot be determined from this study.

Section Summary

Two moderate-sized unblinded RCTs report short-term benefits for kyphoplasty on pain and other outcomes in patients with painful osteoporotic fractures. Similar results are seen in numerous case series that report large short-term improvements in pain following kyphoplasty. There are no sham-controlled RCTs that have been completed for this technique.

The major limitation of these RCTs was the lack of a sham procedure. Nonspecific or placebo effects can be quite large for an invasive procedure such as kyphoplasty in which there is not blinding.(21,22) Due to the possible sham effect observed in the recent trials of vertebroplasty, the validity of results from non-sham-controlled trials are questionable. The placebo effect may be on the order of 6 to 7 mm on a 100-mm scale, for invasive procedures,(21-24) and even larger effects (10%) were observed in the sham-controlled vertebroplasty trials.(25,26) The analyses were appropriate; however, it would have been preferable to have the number of participants reporting a clinically meaningful change as the primary outcome. In cases of chronic pain, mean differences in continuous measures may not be reflective of the percent of patients who have a meaningful clinical response.

Due to the concerns about the validity of the available RCTs, it is difficult to come to conclusions regarding the efficacy of kyphoplasty. Despite most case series showing consistent improvements in pain after the procedure, and the same conclusion being reached in the 2 RCTs, it is not possible to conclude that these improvements are a true treatment effect, or a nonspecific, placebo effect.(27)

Vertebral Body Metastasis

In the early literature reviews, 3 case series were reviewed evaluating a total of 52 patients.(28-30) 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 Hemangiomas

For symptomatic vertebral body hemangioma with aggressive features, no studies reported pre- and postprocedure pain evaluations. Therefore, the findings of all studies that reported more than a single case (6 studies, totaling 64 patients) were evaluated. The studies using percutaneous cementoplasty as an adjunct to surgical treatment suggest that the use of percutaneous cementoplasty to treat the vertebral body component of the vascular lesion may contribute to avoiding the substantial blood loss that has been historically described with primary surgical resection (curettage). However, the additional use of other procedures in these studies may make it difficult to attribute the lower blood loss to this procedure. These studies do not provide controlled comparisons of the morbidity of treating hemangiomas with percutaneous cementoplasty as an adjunct to surgery and the morbidity of surgical treatment without cementoplasty.

Adverse Events

Yi et al assessed the occurrence of new vertebral compression fractures after treatment with cement augmenting procedures (vertebroplasty or kyphoplasty) versus conservative treatment in an RCT with 290 patients (363 affected vertebrae).(31) Surgically treated patients were discharged the next day. Patients treated conservatively (pain medication, bedrest, a body brace, physiotherapy) had a mean length of stay of 13.7 days. Return to usual activity occurred at 1 week for 87.6% of operatively 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), 10.7% of patients had experienced 42 new symptomatic vertebral compression fractures. There was no significant difference in the incidence of new vertebral fractures between the operative (18 total, 9 adjacent 9 nonadjacent) and conservative (24 total, 5 adjacent, 16 nonadjacent, 3 same level) groups, but the mean time to a new fracture was significantly shorter in the operative compared with nonoperative group (9.7 vs 22.4 months).

Cement leakage, although reduced in kyphoplasty relative to vertebroplasty, remains a concern. There continue to be case reports of right ventricle perforation, cardiac tamponade, and embolism of cement into pulmonary vessels.

Mechanical Vertebral Augmentation with Kiva® versus Balloon Kyphoplasty

Kiva® System as Vertebral Augmentation Treatment (KAST) is an industry-sponsored multicenter phase 3 randomized IDE trial (NCT01123512). Vertebral augmentation with the Kiva® VCF System® was compared with balloon kyphoplasty in 300 patients with 1 or 2 osteoporotic vertebral compression fractures. The study was completed in May 2013. Preliminary results of this study were presented at the Society for Interventional Radiology Annual Scientific Meeting in March 2014, reporting noninferiority of KIVA® compared with kyphoplasty.(32) However, this study has not yet been published in a peer-reviewed journal.

In 2013, Korovessis reported a randomized trial comparing mechanical vertebral augmentation with the Kiva® device versus balloon kyphoplasty in 180 patients with osteoporotic vertebral body fractures.(33) The groups showed similar improvements in VAS for back pain, SF-36, and Oswestry Disability Index (ODI). For example, there was a greater than 5.5 point improvement in VAS in 54% of patients in the Kiva® group and 43% of patients in the balloon kyphoplasty group. Radiologic measures of vertebral height were similar in the 2 groups. Kiva® reduced the Gardner kyphotic angle, while residual kyphosis of more than 5 degrees was more frequently observed in the balloon kyphoplasty group. Patients and outcome assessors were reported to be unaware of the group assignment, although it is not clear if the Kiva® device was apparent in the radiographs. Cement leakage into the canal occurred in 2 patients treated with balloon kyphoplasty, necessitating decompression, compared with none following the Kiva procedure.

Another 2013 study was a retrospective matched pair comparison of Kiva® versus balloon kyphoplasty in 52 patients with VCFs.(34) Data were collected for the Kiva® group between 2010 and 2011, and the

data for the balloon kyphoplasty group were collected between 2004 and 2009. The 2 groups were matched for the vertebral body treated, age, and approximate caudal acantha. Back pain (numeric rating scale [NRS] for kyphoplasty and VAS for Kiva®) and motility (ODI) were assessed preoperatively and at 6 months postoperatively. The mean operation time was 12.7 minutes per vertebra for Kiva® and 46.5 minutes for balloon kyphoplasty. There was no significant difference in the incidence of cement extravasation between the Kiva® (23.1%) and kyphoplasty (30.7%) groups. At 6-month follow-up, pain scores were significantly better in the Kiva® group (10.8 NRS vs 24.6 VAS). The improvement in ODI was similar in the 2 groups (43.9 for Kiva®, vs 47.4 for kyphoplasty). There were significantly fewer adjacent and nonadjacent fractures in the Kiva® group (1 and 2) compared with the kyphoplasty group (9 and 5, both respectively). The mean postoperative height was 21.65 mm in the Kiva® group compared with 25.09 mm in the balloon kyphoplasty group. It is not clear whether the difference in postoperative vertebral wall height for the 2 procedures is operator dependent, or whether this is a contributing factor in the occurrence of adjacent and nonadjacent fractures.

Section Summary

Evidence to date includes a preliminary report of a large industry-sponsored multicenter IDE trial, a large independent randomized trial, and a retrospective matched pair comparison. The IDE trial has not yet been published in a peer-reviewed journal. The matched pair comparison reported favorable outcomes for Kiva®, although this study is limited by the retrospective nature of the study and the nonconcurrent controls.

Vertebral Body Stenting versus Balloon Kyphoplasty

An RCT by Werner et al, performed independent of industry support, found no advantage of VBS over balloon kyphoplasty.⁽³⁵⁾ Sixty-five patients were included who had 1 or more fresh osteoporotic vertebral compression fractures and marked pain. A total of 100 VCFs were randomized to either 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 1 of the 50 vertebral levels (balloon rupture) in the kyphoplasty group.

Ongoing and Unpublished Clinical Trials

NCT01847898 is an industry-sponsored multicenter RCT that will compare vertebral body stenting vs kyphoplasty. The study is being conducted in Europe with approximately 100 patients enrolled. The study is ongoing, but no longer recruiting participants. Study completion is expected in September 2015.

Clinical Input Received Through 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.

In response to requests, input was received from 6 physician specialty societies (1 unsolicited) and 2 academic medical centers while this policy was under review in 2008. All reviewers disagreed with the proposed policy, referring to a body of evidence from uncontrolled studies that support use of kyphoplasty.

Summary

After consideration of the available evidence and uniform clinical input, it was concluded that although the scientific evidence does not permit conclusions about the impact on health outcomes and that comparative studies with long-term outcomes are lacking; numerous case series, including large prospective reports, consistently showed that vertebroplasty or kyphoplasty may alleviate pain and improve function in patients with vertebral fractures who fail to respond to conservative treatment (at least 6 weeks) with analgesics, physical therapy, and rest. More recent randomized trials that compare kyphoplasty with medical management have also reported benefit, so have not changed these conclusions. Given the absence of alternative treatment options and the morbidity associated with extended bed rest, kyphoplasty may be considered a reasonable treatment option in patients with vertebral fractures who fail to improve after 6 weeks of conservative therapy and therefore may be considered medically necessary both for this patient population, as well as for patients who have severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies.

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

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

Practice Guidelines and Position Statements

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

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

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

1. Patients who are rendered nonambulatory as a result of pain from a weakened or fractured vertebral body, pain persisting at a level that prevents ambulation despite 24 hours of analgesic therapy;

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

In 2013, ACR updated their appropriateness criteria on the management of compression fractures. The criteria for management of these fractures state that most vertebral compression fractures are resolved within 4 to 6 weeks with the more conservative first-line treatment including the use of nonsteroidal anti-inflammatory drugs and possibly narcotic medications. However, due to expanded use of percutaneous vertebroplasty and balloon-assisted vertebroplasty by the medical community, rapidity of clinical response, and relatively low procedural risk, threshold for performing these procedures has declined. There has also been an increased number of studies describing successful results using vertebral augmentation for painful malignant fractures and symptomatic myelomatous vertebral replacement. The criteria indicate that vertebroplasty should be reserved for patients who either have failed or cannot tolerate traditional conservative treatment. Failure can be defined as pain refractory to oral medications (NSAIDs and/or narcotic) over 6 to 12 weeks. However, failure can also be defined as contraindications to such medications or a requirement for parenteral narcotics and hospital admission.(39)

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

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

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

References

1. U.S. Food and Drug Administration. FDA Public Health web notification. 2009. Available online at: http://google2.fda.gov/search?as_sitesearch=www.fda.gov/medicaldevices/safety/alertsandnotices&q=Bone+Cement&spell=1&proxystylesheet=FDAgov&output=xml_no_dtd&site=FDAgov-PubHealthNotifications-Devices&client=FDAgov&ie=UTF-8&access=p&ulang=en&ip=10.100.50.81,69.25.144.254&sort=date:D:L:d1&entqr=3&entqrm=0&oe=UTF-8&ud=1
2. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Percutaneous Vertebroplasty. TEC Assessments 2000; Volume 15, Tab 21.

3. 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.
4. 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.
5. 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.
6. 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.
7. 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.
8. Coumans JV, Reinhardt MK, Lieberman IH. Kyphoplasty for vertebral compression fractures: 1-year clinical outcomes from a prospective study. *J Neurosurg* 2003; 99(1 Suppl):44-50.
9. Berlemann U, Franz T, Orlor R et al. Kyphoplasty for treatment of osteoporotic vertebral fractures: a prospective non-randomized study. *Eur Spine J* 2004; 13(6):496-501.
10. Crandall D, Slaughter D, Hankins PJ et al. Acute versus chronic vertebral compression fractures treated with kyphoplasty: early results. *Spine J* 2004; 4(4):418-24.
11. Gaitanis IN, Hadjipavlou AG, Katonis PG et al. Balloon kyphoplasty for the treatment of pathological vertebral compressive fractures. *Eur Spine J* 2005; 14(3):250-60.
12. 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.
13. Kasperk C, Hillmeier J, Noldge G et al. Treatment of painful vertebral fractures by kyphoplasty in patients with primary osteoporosis: a prospective nonrandomized controlled study. *J Bone Miner Res* 2005; 20(4):604-12.
14. 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).
15. Gerszten PC, Germanwala A, Burton SA et al. Combination kyphoplasty and spinal radiosurgery: a new treatment paradigm for pathological fractures. *J Neurosurg Spine* 2005; 3(4):296-301.
16. 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* 2009; 373(9668):1016-24.
17. 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* 2011; 26(7):1627-37.
18. Van Meirhaeghe J, Bastian L, Boonen S et al. A Randomized Trial of Balloon Kyphoplasty and Non-Surgical Management for Treating Acute Vertebral Compression Fractures: Vertebral Body Kyphosis Correction and Surgical Parameters. *Spine (Phila Pa 1976)* 2013.
19. 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* 2011; 12(3):225-35.
20. 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* 2011; 26(7):1617-26.
21. Jarvik JG, Deyo RA. Cementing the evidence: time for a randomized trial of vertebroplasty. *AJNR Am J Neuroradiol* 2000; 21(8):1373-4.
22. Moerman DE, Jonas WB. Deconstructing the placebo effect and finding the meaning response. *Ann Intern Med* 2002; 136(6):471-6.
23. Hrobjartsson A, Gotzsche PC. Is the placebo powerless? An analysis of clinical trials comparing placebo with no treatment. *N Engl J Med* 2001; 344(21):1594-602.

24. Vase L, Riley JL, 3rd, Price DD. A comparison of placebo effects in clinical analgesic trials versus studies of placebo analgesia. *Pain* 2002; 99(3):443-52.
25. Buchbinder R, Osborne RH, Ebeling PR et al. A randomized trial of vertebroplasty for painful osteoporotic vertebral fractures. *N Engl J Med* 2009; 361(6):557-68.
26. Kallmes DF, Comstock BA, Heagerty PJ et al. A randomized trial of vertebroplasty for osteoporotic spinal fractures. *N Engl J Med* 2009; 361(6):569-79.
27. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Special Report: measuring and reporting pain outcomes in randomized controlled trials TEC Assessments 2006; Volume 21, Tab 11
28. Dudeney S, Lieberman IH, Reinhardt MK et al. Kyphoplasty in the treatment of osteolytic vertebral compression fractures as a result of multiple myeloma. *J Clin Oncol* 2002; 20(9):2382-7.
29. Fourney DR, Schomer DF, Nader R et al. Percutaneous vertebroplasty and kyphoplasty for painful vertebral body fractures in cancer patients. *J Neurosurg* 2003; 98(1 Suppl):21-30.
30. Lane JM, Hong R, Koob J et al. Kyphoplasty enhances function and structural alignment in multiple myeloma. *Clin Orthop Relat Res* 2004; (426):49-53.
31. 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* 2014; 134(1):21-30.
32. 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.
33. 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)* 2013; 38(4):292-9.
34. 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):E505-12.
35. Werner CM, Osterhoff G, Schlickeiser J et al. Vertebral body stenting versus kyphoplasty for the treatment of osteoporotic vertebral compression fractures: a randomized trial. *J Bone Joint Surg Am* 2013; 95(7):577-84.
36. Jensen ME, McGraw JK, Cardella JF et al. 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. *J Vasc Interv Radiol* 2007; 18(3):325-30.
37. 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* 2014; 25(2):171-81.
38. Baerlocher MO, Saad WE, Dariushnia S et al. Quality improvement guidelines for percutaneous vertebroplasty. *J Vasc Interv Radiol* 2014; 25(2):165-70.
39. American College of Radiology (ACR). ACR Appropriateness criteria, management of vertebral compression fractures. 2013. Available online at: <http://www.acr.org/~media/ACR/Documents/AppCriteria/Interventional/ManagementVertebralCompressionFractures.pdf>
40. American Academy of Orthopaedic Surgeons (AAOS). Clinical practice guideline, Treatment of osteoporotic spinal compression fractures. 2010. Available online at: <http://www.aaos.org/Research/guidelines/SCFguideline.asp>
41. National Institute for Health and Clinical Excellence (NICE). TA 279 Percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures. 2013. Available online at: <http://publications.nice.org.uk/percutaneous-vertebroplasty-and-percutaneous-balloon-kyphoplasty-for-treating-osteoporotic-vertebral-ta279>
42. National Institute for Health and Clinical Excellence (NICE). CG 75 Metastatic Spinal Cord Compression, Diagnosis and management of adults 2008. Available online at: <http://publications.nice.org.uk/metastatic-spinal-cord-compression-cg75>

Billing Coding/Physician Documentation Information

22523	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device, one vertebral body, unilateral or bilateral cannulation (eg, kyphoplasty); thoracic
22524	Lumbar
22525	Each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure)
72291	Radiological supervision and interpretation, percutaneous vertebroplasty or vertebral augmentation including cavity creation, per vertebral body; under fluoroscopic guidance
72292	Radiological supervision and interpretation, percutaneous vertebroplasty or vertebral augmentation including cavity creation, per vertebral body; under CT guidance

Additional Policy Key Words

N/A

Policy Implementation/Update Information

6/1/04	New indication added to the Percutaneous Vertebroplasty medical policy. Considered investigational.
2/1/05	No policy statement changes.
2/1/06	Policy changed to address only percutaneous kyphoplasty. Previously was combined with the percutaneous vertebroplasty policy. Remains investigational. Added new CPT codes for kyphoplasty.
8/1/06	No policy statement changes.
2/1/07	No policy statement changes.
8/1/07	No policy statement changes.
2/1/08	No policy statement changes.
8/1/08	No policy statement changes.
10/7/08	Policy statement revised to indicate may be medically necessary if conservative treatment has failed.
11/1/09	No policy statement changes.
11/1/10	Policy statement revised to indicate use in acute vertebral fractures as investigational.
11/1/11	No policy statement changes.
11/1/12	No policy statement changes.
11/1/13	Added to policy: Percutaneous mechanical vertebral augmentation using any other device, including but not limited to Kiva, is considered investigational.
9/1/14	Vertebral body stenting added to investigational statement.

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