



Medical Coverage Policy

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Percutaneous Vertebroplasty, Kyphoplasty, and Sacroplasty

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Coverage Policy

Percutaneous vertebroplasty or percutaneous kyphoplasty is considered medically necessary when imaging (e.g., x-ray, MRI, bone scan) demonstrates recent (i.e., < 3 months) vertebral compression fracture (e.g., progressive collapse on x-ray, edema on MRI) that correlates with the patient's clinical signs and symptom, and ANY of the following criteria is met:

- osteoporotic, osteolytic, osteonecrotic (i.e., Kummell disease), or steroid-induced vertebral compression fracture with persistent, debilitating pain unresponsive to at least six weeks of conservative medical management
- severe back pain secondary to destruction of vertebral body due to osteolytic vertebral metastasis or multiple myeloma
- painful and/or aggressive hemangioma or eosinophilic granuloma of the spine

Percutaneous vertebroplasty or kyphoplasty is considered experimental, investigational, or unproven for any other indication.

Percutaneous sacroplasty is considered experimental, investigational, or unproven for ALL indications.

Overview

This Coverage Policy addresses percutaneous vertebroplasty and percutaneous kyphoplasty as treatment for osteoporotic vertebral compression fractures, vertebral fractures resulting from osteolytic destruction secondary to malignancy and treatment of aggressive vertebral body hemangioma and eosinophilic granuloma. In addition, sacroplasty for treatment of sacral insufficiency fracture is addressed.

General Background

Percutaneous vertebroplasty, percutaneous kyphoplasty, and sacroplasty are minimally invasive procedures that have been proposed as treatment of vertebral compression fractures (VCF) as an alternative to medical management to alleviate pain, provide spine stability, and prevent further vertebral collapse.

Conservative medical management of osteoporotic vertebral fractures may include analgesics, activity modification, bracing, physical therapy, and medications including calcitonin, strontium ranelate, or ibadronate may be provided in an attempt to prevent future fractures. For patients with osteolytic destruction secondary to malignancy, these procedures have been proposed as alternatives to medical management, localized radiation therapy, and traditional surgical stabilization. Most current guidelines recommend four to six weeks of medical therapy before pursuing surgical intervention in neurologically intact VCFs (Anderson, 2017).

Vertebroplasty and kyphoplasty are contraindicated in burst fractures, which result from extreme force applied straight down on the vertebrae, and involve compression of both the anterior and middle columns. Burst fractures can be unstable if the posterior column has sustained injury, and may result in spinal cord injury. Additional contraindications include pedicle fractures, spinal canal or neural foramen compromise, cortical disruption, infection, myelopathy, coagulopathy, allergy to device or material, radiculopathy symptoms, pregnancy, high energy trauma, severe cardiopulmonary deficiencies, active osteomyelitis of the target vertebra, asymptomatic vertebral body compression fracture of patient improving with medical therapy, and use as prophylaxis in osteoporotic patients.

U.S. Food and Drug Administration (FDA)

Several bone cements received 510(k) approval in 2004–2005 for use in vertebroplasty and/or kyphoplasty, including KyphX® HV-R™ Bone Cement (Medtronic, Minneapolis, Minn.); Symphony™ VR Radiopaque Bone Cement (Advanced Biomaterial Systems, Inc. Chatham, NJ); and Parrallax® Acrylic Resin with TRACERS® (ArthroCare Corp., Sunnyvale, CA. Numerous additional manufacturers subsequently received 510(k) FDA approval for bone cement for use in vertebroplasty and kyphoplasty.

According to information available from the FDA, contraindications for use of PMMA products vary according to the specific product labeling. In general, contraindications include nonpathological acute traumatic vertebral fractures, prophylactic use in metastatic or osteoporotic patients with no evidence of acute fracture, compromise of vertebral body/walls of the pedicles, compromise or instability of vertebral fractures due to posterior involvement, vertebral body collapse to less than 1/3 (33%) original height, vertebral plan (collapse of >90%), active or incompletely treated infection, coagulation disorders, and sensitivity to any of the components.

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

StabiliT® Vertebral Augmentation System (DFINE, Merit Medical Systems, Inc.) received FDA 510(k) marketing clearance 2009 as radiofrequency targeted vertebral augmentation (RF-TVA) for treatment for vertebral compression fractures. According to the FDA approval The StabiliT ERX Bone Cement is a two-component PMMA bone cement with a powder component and a liquid component and may be used for either a vertebroplasty or kyphoplasty procedure. The StabiliT Vertebral Augmentation System is a motorized, microprocessor controlled bone cement delivery system intended for percutaneous delivery of bone cement in vertebroplasty or kyphoplasty procedures that allows for warming of the cement during cement delivery. According to the manufacturer, the StabiliT system contains an integrated low power bipolar radiofrequency (RF) warming source that warms the bone cement.

Percutaneous Vertebroplasty

Percutaneous vertebroplasty (PV) is an interventional radiological procedure consisting of injection of an acrylic polymer into a partially collapsed vertebral body with a goal of relieving pain and providing stability. The procedure is usually performed using local anesthesia and light to moderate sedation.

Percutaneous vertebroplasty was first reported in France in 1987 as a treatment for complicated vertebral body hemangioma. Vertebroplasty is primarily used for treatment of osteoporotic fractures but has also been investigated for treatment of vertebral metastasis, vertebral involvement of multiple myeloma, and, less frequently, aggressive vertebral hemangiomas, Langerhans cell histiocytosis, (i.e., eosinophilic granuloma), and vertebral lymphoma. The mechanism of pain relief attributed to vertebroplasty is not well understood. It has been proposed that pain relief is achieved through stabilization of a weakened vertebral body or by thermal damage to intraosseous nerve fibers.

Hayes reported within a Technology Directory Report (Hayes, 2016a, reviewed 2018) limited evidence suggests PV is associated with higher risk of postoperative complications, such as pulmonary embolism, deep vein thrombosis, and pneumonia, although relevance of the differences in risk of complications is uncertain.

Literature Review (Vertebral Compression Fracture): In 2009 two randomized, blinded sham controlled trials found no short term benefit of vertebroplasty when compared with sham (Buchbinder et al., 2009; Kallmes et al., 2009, discussed below). These studies included subacute fractures that were up to 12 months old and bone edema on MRI was not a consistent inclusion criteria (Savage, et al., 2014). In theory, it is possible these negative results indicate that injection of local anesthetic during the sham procedure had a treatment effect. Alternately, it is also possible that the positive results seen in nonblinded studies comparing PV with conventional treatment (rather than a sham procedure) were due to patient and assessor expectations. Placebo effects such as these may be greater with an invasive procedure (Hayes, 2015).

Buchbinder et al. (2009) conducted a multicenter, randomized double-blind sham controlled trial to determine the short-term efficacy and safety of vertebroplasty for alleviating pain and improving physical functioning in patients with osteoporotic vertebral fractures (n=78). Patients with one or two painful osteoporotic vertebral fractures of less than 12 months duration, confirmed as unhealed by magnetic resonance imaging (MRI), were randomly assigned to vertebroplasty (n=38) or a sham procedure (n=40). Outcomes were evaluated at one week and at one, three, and six months. The primary outcome was overall pain at three months. In the vertebroplasty group, the left pedicle of the fracture site was identified, the skin overlying the pedicle was infiltrated with a 25-gauge needle, and the periosteum of the posterior lamina was infiltrated with a 23-gauge needle. An incision was made in the skin, and a 13-gauge needle was placed posterolaterally relative to the eye of the pedicle. Gentle tapping guided the needle through the pedicle into the anterior two thirds of the fractured vertebral body. PMMA was then injected into the vertebral body. Patients in the sham intervention group underwent the same procedure up until the insertion of the 13-gauge needle. To simulate vertebroplasty, the vertebral body was gently tapped, and PMMA was prepared so that the smell permeated the room. Of the 78 enrolled patients, 35 of 38 in the vertebroplasty group and 36 of 40 in the placebo group completed the six month follow-up. Vertebroplasty did not result in a significant advantage in any measured outcome at any time point. There was a significant reduction in overall pain in both groups at each assessment. Similar improvements were seen in both groups for pain at night and at rest, physical functioning, quality of life, and perceived improvement. The authors concluded that no significant benefit of vertebroplasty over a sham procedure was demonstrated after six months of follow-up, and that these findings call into question the use of vertebroplasty in such patients.

Kallmes et al. (2009) conducted a multicenter randomized, double-blind controlled trial to evaluate the efficacy of vertebroplasty in the treatment of painful osteoporotic compression fractures (n=131). Patients were randomized to receive vertebroplasty with PMMA (n=68) or a simulated procedure without PMMA (n=63). For all patients, the skin and subcutaneous tissues overlying the pedicle of the target vertebra or vertebrae were infiltrated with lidocaine, and the periosteum of the pedicle was infiltrated with bupivacaine. Patients were then randomly assigned to receive vertebroplasty or the control intervention. In the vertebroplasty group, needles were passed into the central aspect of the target vertebra or vertebrae, and PMMA was infused. During the control intervention, verbal and physical cues (e.g., pressure on the patient's back) were given, and the methacrylate monomer was opened to simulate the odor of PMMA, but the needle was not placed and PMMA was not infused. The primary outcomes were scores on the modified Rolan-Morris Disability Questionnaire (RDQ) (on a scale of 0–23, with higher scores indicating greater disability), and patients' rating of average pain intensity during the preceding 24 hours at one month (on a scale of 0–10, with higher scores indicating more severe pain). At one month, there was no significant difference between the two groups in the RDQ score (p=0.49) or the pain rating

($0=0.19$). Both groups had immediate improvement in disability and pain scores after the intervention. Although the groups did not differ significantly on any secondary outcome measure at one month, there was a trend toward a higher rate of clinically meaningful improvement in pain in the vertebroplasty group ($p=0.06$).

Since 2009, additional evidence evaluating PV in the form of randomized controlled trials (RCTs), prospective comparative trials, case series, systematic reviews and meta-analysis (Farrokhi, et al., 2011; Staples, et al., 2011; Klazen, et al., 2010; Winking, et al., 2004; Diamond, et al., 2003; McGraw, et al., 2002) have been published. In general, the results of these trials suggest PV is safe and effective in a well-defined subset of individuals with vertebral compression fractures. Improvement in visual analog score (VAS), Oswestry Disability Index (ODI) score, and greater pain relief overall have been reported in comparison to conventional medical care (Farrokhi, et al., 2011; Klazen, et al., 2010; Diamond, et al., 2003). In 2013 Anderson and colleagues published the results of a meta-analysis that showed vertebroplasty resulted in significantly greater pain relief, functional recovery, and improvement in quality of life scores when compared with nonsurgical treatment or sham (Anderson, et al., 2013).

More recently, RCTs evaluating vertebroplasty (Evans, et al., 2016; Yang, et al., 2016) have continued to demonstrate pain relief and improved quality of life following vertebroplasty in a subset of individuals with acute osteoporotic vertebral compression fractures at one year post-treatment. Evans et al. (2016) compared vertebroplasty ($n=59$) to kyphoplasty ($n=56$) in a RCT using the primary outcomes of pain and disability assessed at three days, one month, six months, and one year following treatment. Both groups experienced reduction in pain, pain frequency, and functional limitations due to pain. The authors concluded that both PV and kyphoplasty are equally effective for reducing pain and disability and improving both physical and mental health; significant clinically meaningful outcomes were seen as early as three days post procedure in both groups. Yang et al. (2016) published the results of a prospective RCT designed to determine whether percutaneous vertebroplasty for aged subjects over 70 years of age offered extra benefit in comparison to conservative care (e.g., bedrest, use of a brace with ambulation, pain medications, and physical therapy). The results of this trial demonstrated that at every time point from post-op day one to one year post surgery pain relief and quality of life were significantly improved in the vertebroplasty group.

A meta-analysis published in 2017 (Xie, et al., 2017) evaluated PV in comparison to conservative treatment for osteoporotic compression fractures and concluded PV is safe and effective. A total of 13 publications were included, 12 of which were RCTs. Cochrane risk of bias was used to assess the quality of evidence. The authors reported statistical differences between pain relief (one week, one month and six months) and QUALEFFO quality of life scores in favor of PV. No statistical differences were found between pain relief at three months, or when using quality of life measurement tools RDQ, ED-5Q, or for the rate of adjacent vertebral fracture.

A more recent RCT however did not lend support to vertebroplasty compared with sham. Firanesco et al. (2018) published the results of a randomized, double blind, sham controlled trial to assess whether vertebroplasty resulted in more pain relief than sham treatment. A total of 180 subjects with acute osteoporotic compression fracture and bone edema on MRI, were randomized to undergo vertebroplasty ($n=91$) or sham treatment ($n=89$). The primary outcome measure was mean reduction in VAS score at one day, one week, and one, three, six, and twelve months post-surgery; secondary outcomes included quality of life and physical functioning at the same time intervals. Clinically significant pain relief was defined as a decrease in VAS of 1.5 points from baseline. The median time from onset of symptoms to treatment was 43 days in the vertebroplasty group versus 36 days in the sham group. Compared with baseline, the mean reduction in VAS score in both groups during 12 months was clinically and statistically significant at all measurement points. Results for quality of life and physical functioning were statistically significant compared to baseline. There was no statistically significant difference between groups at any follow-up points. In the author's opinion, vertebroplasty did not result in statistically significant greater pain relief compared with sham during 12 months follow-up post procedure. Factors that might have contributed to clinical improvement included effect of local anesthesia, expectations of pain relief (placebo effect), natural healing of the fracture and regression to the mean. The authors further noted if vertebroplasty is performed too early treatment will be for fractures that may heal naturally, and if performed too late treatment may not be effective as the fracture may be healed and no longer responsive.

Literature Review (Osteolytic Destruction): Published studies evaluating vertebroplasty for treatment of osteolytic destruction (e.g., metastasis) consist mainly of retrospective case series (Deramond, et al, 1998; Alvarez, et al., 2003; Fourney, et al., 2003; Chow, et al., 2004). Cement leakage was reported in each of these studies, although most patients had no associated symptoms. These studies demonstrate significant short-term

pain relief as measured by VAS. It is difficult to draw conclusions from these studies, however, because of the study designs and small number of included patients.

Percutaneous Kyphoplasty

Percutaneous kyphoplasty involves the expansion of the vertebra with a balloon or mechanical device prior to the injection of bone cement. Balloon kyphoplasty, also referred to as balloon-assisted vertebroplasty, or percutaneous vertebral augmentation, was introduced in 2001 as a variation of percutaneous vertebroplasty. A specialized bone tamp with an inflatable balloon is inserted to expand the vertebra, creating a cavity to be filled with bone cement. Acrylic bone cement is injected into the vertebral body using a large-bore needle using CT or fluoroscopic guidance. The bone cement may be mixed with contrast material to enhance imaging. An alternative procedure involves the use of a mechanical device. The Kiva[®] Vertebral Compression System received 510(k) clearance from the FDA January 2014. Kiva[®] is a unipedicular, PEEK-OPTIMA implant approved for vertebral augmentation. The device is indicated for treatment of painful vertebral compression fractures in the thoracic and/or lumbar spine from T6-L5. The Kiva[®] System (Benvenue Medical) is designed to provide structural support of the vertebral body during vertebral augmentation. During the procedure, the implant is inserted percutaneously over a removable guidewire in a continuous loop inserted into the vertebral body through a small diameter, single incision. Once the device is in place, injection of PMMA cement is performed through the lumen of the implant. Radiofrequency kyphoplasty, (also referred to as radiofrequency targeted vertebral augmentation) is a non-balloon kyphoplasty procedure that employs the use of heat to control the viscosity of the PMMA cement prior to injection. A small cannula is inserted into the vertebra creating a pathway for the cement. In theory, the high viscosity cement is designed to restore height and alignment to the fractured vertebra along with stabilizing the fracture. However, the addition of a thermal source of energy to warm the PMMA bone cement prior to injection is considered integral the base procedure.

Complications of percutaneous kyphoplasty procedures are similar to those seen with vertebroplasty and are relatively rare. Complication rates are highest in patients with malignancy, due to cement leakage from lytic regions in the vertebral bodies. Reported complications are also higher in this population due to poor overall health.

Literature Review (Balloon Kyphoplasty): Recent clinical trials continue to support improved clinical outcomes following kyphoplasty. Liu et al. (2019) published the results of a RCT (n=116) comparing balloon kyphoplasty (n=58) with conservative treatment. (n=58). The authors compared image indices, degree of pain, daily life disturbance and complications between the observation group and control group. Following treatment both groups' experienced improved VAS scores and daily life disturbance scores, however the observation group demonstrated significantly lower scores. The kyphoplasty group also had lower complications compared with the control group; and significant improvements in imaging indices.

A randomized unblinded controlled trial was conducted by Berenson et al. (2011) to assess the efficacy and safety of kyphoplasty in patients with cancer and vertebral compression fractures (n=134). Patients with cancer and one to three painful VCFs were randomized to kyphoplasty (n=70) or non-surgical management (n=64). Non-surgical treatment was not standardized; each study center was asked to provide care consistent with local practice. The primary endpoint was back-specific functional status as measured by the Roland-Morris disability questionnaire (RDQ) score at one month. At one month, 65 patients in the kyphoplasty group and 52 in the control group had data available. The mean RDQ score in the kyphoplasty group changed from 17.6 at baseline to 9.1 at one month ($p<0.0001$). The mean control group score changed from 18.2 to 18.0 ($p=0.83$). The kyphoplasty treatment effect for RDQ was -8.4 points at one month ($p<0.0001$). At one month, patients were able to cross over to the kyphoplasty group from the control group, preventing long-term analysis of the randomized population.

Wardlaw et al. (2009) conducted a multisite randomized controlled trial to assess the efficacy and safety of balloon kyphoplasty in the treatment of painful vertebral fractures (n=300). Fractures were a mean of 5.6 weeks old at randomization in the kyphoplasty group and 6.4 weeks old in the control group. Inclusion criteria consisted of one to three vertebral fractures. At least one fracture was required to have edema assessed by MRI and at least one fracture had to show at least 15% loss of height. Patients were randomized to kyphoplasty treatment (n=149) or to non-surgical care (n=151). The primary outcome was the difference in change from baseline to one month in the short-form (SF)-36 physical component summary score (scale 1–100). One month follow-up was completed by 138 of 149 kyphoplasty patients and 128 of 151 control patients. Mean SF-36 scores improved by 7.2 points at one month in the kyphoplasty group, and by 2.0 points in the non-surgical group ($p<0.0001$). At 12

months, the difference between kyphoplasty and control had diminished. The authors suggested that improvement in the non-surgical group during the 12 month follow-up was likely due to fracture healing.

Boonen et al. (2011) published two-year results of the Wardlaw study (above). Quality of life, function, disability, and pain were assessed over 24 months. Most outcome measures for kyphoplasty compared to medical treatment were improved when averaged over the 24 month period, but were not significantly different at 24 months. There was no significant difference in physical symptoms between groups, as assessed by the 100-point PCS component of the SF-36 at 24 months ($p=.15$). The kyphoplasty group had a greater improvement in the 10-point back pain score that was maintained at 24 months (-80 points, $p=.009$). There was no significant difference between groups in the number of subsequent adjacent fractures; approximately 50% of patients in the study had subsequent vertebral fractures that were brought to clinical attention because of renewed pain. Two serious adverse events occurred more than a year following kyphoplasty; a re-collapse of a treated vertebra with anterior migration of the cement, and a case of spondylitis.

Additional case series and comparative trials evaluating kyphoplasty in the treatment of vertebral fractures reported improvement in pain and functional scores at short-term follow-up ranging from one week to 24 months (Lieberman et al., 2001; Dudeney, et al., 2002; Ledlie and Renfro, 2003; Phillips et al., 2003; Rhyne et al., 2004; Lane, et al., 2004; Kasperk, et al., 2005; Grohs, et al., 2005; Gaitanis, et al., 2005; Ledlie and Renfro, 2006; Garfin, et al., 2006).

Literature Review (Kiva® Vertebral Compression Fracture Treatment System (Kiva VCS): Evidence in the peer-reviewed scientific literature evaluating Kiva® VCS includes a multicenter randomized controlled trial (Tutton, et al., 2015 [Kiva Safety and Effectiveness Trial]), prospective randomized controlled trials (Korovessis, et al., 2013; Korovessis, et al., 2014), a comparative trial (Otten, et al., 2013) and other case series, case reports and pilot studies. According to the manufacturer, one proposed advantage of the Kiva system is a reduction in cement leakage. While leakage of cement did occur within the published trials comparing Kiva to balloon kyphoplasty, results of these studies tend to support less leakage with Kiva implant (Korovessis, et al., 2013; Otten, et al., 2013).

One randomized controlled trial supported noninferiority of Kiva when compared to balloon kyphoplasty. Tutton et al. (2015) reported the results of a randomized controlled multicenter trial comparing Kiva to balloon kyphoplasty ($n=300$). Subjects were randomized to receive either Kiva ($n=153$) or balloon kyphoplasty ($n=147$) as treatment of painful osteoporotic vertebral compression fracture. The primary endpoint was reduction in fracture pain by at least 15mm VAS, maintenance or improvement in function using ODI, and absence of device related serious adverse events at 12 months follow-up. The authors reported 94.5% of Kiva subjects and 97.6% of balloon kyphoplasty subjects were successful at 12 months. VAS scores improved significantly over baseline in both groups at 12 months (70.8, 71.8, respectively) as well as ODI scores (38.1, 42.2, respectively). Extravasation of bone cement observed at the time of the procedure was significantly lower for the Kiva group compared with the balloon kyphoplasty group. In the author's opinion, measured outcomes supported noninferiority for safety and effectiveness of Kiva. Limitations noted by the authors included potential bias due to blinding methods, insufficient power to demonstrate superiority, and limited statistical power for secondary endpoints.

The results of another trial published by Korovessis and associates (2013) compared sagittal vertebral height and wedge deformity restoration leakage, as well as functional outcomes of Kiva versus balloon kyphoplasty for treatment of osteoporotic fractures. The kyphoplasty group consisted of 86 subjects with 122 fractures, and the Kiva group consisted of 82 subjects with 133 fractures. There were no statistically significant differences in the preoperative baseline characteristics of the two groups. Post-operative follow-up evaluations averaged 14 months for all subjects. At follow-up, the authors reported both kyphoplasty and Kiva restored osteoporotic vertebral body height. Kiva restored the body wedge deformity safely, and in a larger amount. Additionally, Kiva showed significantly lower leakage rate per vertebra than balloon kyphoplasty. Short-form 36 scores, ODI and back pain scores improved significantly in both groups.

More recently, Korovessis et al. (2014) reported the results of short-term prospective randomized controlled study comparing the Kiva implant to kyphoplasty for the treatment of osteolytic metastasis to the spine. The kyphoplasty group consisted of 24 subjects with 43 osteolytic vertebral bodies and the Kiva group consisted of 23 subjects with 41 osteolytic vertebral bodies. There were no survivors after 3 months; however, the authors reported that both kyphoplasty and Kiva provided equally significant pain relief in patients with cancer with osteolytic metastasis. In addition, it was noted there was no cement leakage reported in the Kiva group.

Literature Review (Radiofrequency Targeted Vertebral Augmentation [RF-TVA]): Evidence in the peer-reviewed scientific literature evaluating RF-TVA is limited, consisting mainly of few randomized controlled trials (Peterson, et al., 2016; Riesner, et al., 2016) few retrospective observational studies with short to medium term follow-up (Bornemann, et al., 2017) and a meta-analysis (Feng, et al., 2017). Subjects in one RCT (Peterson, et al., 2016) included a total of 80 patients with osteoporotic fractures of vertebral bodies assigned to undergo either a balloon-kyphoplasty procedure (n = 44) or RF-TVA (n = 36). Follow-up extended to one year post surgery. The published outcomes showed similar reduction of VAS scores between radiofrequency kyphoplasty and balloon kyphoplasty subjects, without significant difference (p=0.05) and restoration of kyphosis angle.

Riesner et al. (2016) evaluated cement leakage and associated clinical complications (i.e., pulmonary, vascular, neurological) as part of radiofrequency kyphoplasty compared with cement leakage from balloon kyphoplasty in a prospective RCT (n=100, 79 balloon kyphoplasty, 83 had RF kyphoplasty). The authors concluded there was no significant difference between the two methods (63.9% versus 60.8%, respectively) and clinically relevant differences were not found.

Feng et al. (2017) published the results of their meta-analysis which included a total of six studies (2 RCTS, 1 prospective cohort, and 3 retrospective cohorts) involving 833 subjects. Five studies were from Germany and one study was from the United States. Radiofrequency kyphoplasty appeared to be more effective and safer than balloon kyphoplasty with lower cement leakage and better pain relief until 12 months post-procedure. Additionally operation time was shorter in the RF group (P=.01), increase in vertebral height was greater in the RF group (P=.01), there was no difference in cement leakage (P=.06). In the author's opinion, confirmation of these results in a larger number of patients is needed to firmly establish whether radiofrequency kyphoplasty has outcomes comparable to balloon kyphoplasty.

Systematic Reviews: Vertebroplasty, Kyphoplasty

Outcomes of vertebroplasty have been compared to kyphoplasty in early published systematic reviews and meta-analyses (Eck, et al., 2008; Gill, et al., 2007; Hulme, et al., 2006; Taylor, et al., 2006). The conclusions of these publications are mixed and much of the evidence included in the reviews is purported to be methodologically flawed with small sample populations, short-term outcomes and lack of blinding. Some comparisons demonstrate both percutaneous vertebroplasty and kyphoplasty result in reduction of pain using VAS scores and improved ODI scores, although Gill et al. (2007) reported the difference from preoperative scores were not significant. Although fractures were reported during both procedures, risk of new fracture was higher with vertebroplasty compared with kyphoplasty (Eck, et al., 2008; Taylor, et al., 2006). Cement leakage was reportedly lower for kyphoplasty in some of the reviews (Eck, et al., 2008; Bouza, et al., 2006; Hulme, et al., 2006).

More recent systematic reviews and meta-analyses have been published, some with an overlap of studies. Zhang et al. (2017) published results of their meta-analysis of comparative studies to evaluate the incidence of new vertebral fracture following PV and kyphoplasty compared with conservative treatment. The review included 12 studies (five RCTs, seven prospective controlled trials) involving 1328 subjects, 768 who underwent an operative procedure using PMMA and 560 who received non-operative care. Both procedures had a more favorable effect on pain relief compared with non-operative care. The authors reported no significant difference was found between PV or kyphoplasty for total new fractures or fractures adjacent to the treated one when compared with conservative care. In the authors' opinion, new fracture is not due to the augmentation but rather subsequent fractures may be due to the bone quality (e.g., osteoporosis). Limitations of the meta-analysis reported by the authors included one trial that did not report new fracture occurrence and possible reporting bias.

In 2016 Yuan et al. published the results of a meta-analysis evaluating vertebroplasty and balloon kyphoplasty versus conservative treatment for osteoporotic vertebral compression fracture. Ten RCTs were included in the review, 8 vertebroplasty and 2 kyphoplasty, with 626 and 628 subjects in each treatment group respectively. Vertebroplasty was associated with greater pain relief and significant improvement in daily function compared to conservative management. A subgroup analysis demonstrated there was beneficial effect on quality of life for kyphoplasty but not for vertebroplasty. Pain relief associated with kyphoplasty was similar to that of conservative care but subjects who underwent vertebroplasty had greater pain compared to conservative care. Limitations of the analysis noted by the authors included lack of blinding within studies, significant heterogeneity, small sample populations and variation of technique and outcomes measured. Compared with conservative care the authors concluded vertebroplasty and kyphoplasty procedures for osteolytic vertebral compression fractures reduced pain, improved function and quality of life. Results should be interpreted with caution as only two studies examined kyphoplasty.

In 2015, Buchbinder et al. published results of a Cochrane systematic review to analyze the evidence regarding the benefits and harms of vertebroplasty for the treatment of osteoporotic vertebral fractures. A total of 11 RCTs and one quasi-RCT were included in the review. Overall, the trials were considered moderate quality evidence. Two trials compared vertebroplasty with placebo (n=209 randomized subjects), six compared vertebroplasty with usual care (n=566 randomized subjects) and four compared vertebroplasty with kyphoplasty (n=545 randomized subjects). Based on their review the authors determined the evidence does not support a role for vertebroplasty for treating osteoporotic vertebral fractures in routine practice and there were no clinically important benefits when compared with sham. Sensitivity analysis confirmed that open trials comparing vertebroplasty with usual care are likely to have overestimated any benefit of vertebroplasty. In addition, although adverse events were observed following vertebroplasty, based on the research the authors reported it was challenging to determine if vertebroplasty resulted in a clinically important increased risk for new, symptomatic vertebral fractures and/or other serious events (Buchbinder, et al, 2015). Buchbinder et al. (2018) published an update to the review. Similarly, randomised and quasi-randomised controlled trials (RCTs) of adults with painful osteoporotic vertebral fractures, comparing vertebroplasty with placebo (sham), usual care, or another intervention were included. Observed outcomes included mean overall pain, disability, disease-specific and overall health-related quality of life, patient-reported treatment success, new symptomatic vertebral fractures and number of other serious adverse events. A total of 21 trials were reviewed, the authors noted five compared vertebroplasty with placebo (541 randomised participants), eight with usual care (1136 randomised participants), seven with kyphoplasty (968 randomised participants) and one compared vertebroplasty with facet joint glucocorticoid injection (217 randomised participants). There was no change to authors original conclusion; high-quality evidence illustrates vertebroplasty does not provide more clinically important benefits compared with placebo.

Percutaneous Sacroplasty

Percutaneous sacroplasty, a variation of vertebroplasty, is an evolving technique that has been proposed for the treatment of sacral insufficiency fractures. The treatment goal of sacroplasty is to restore stability and integrity of the sacral spine, relieve pain and restore mobility. Sacral insufficiency fractures have traditionally been treated with conservative measures, including bed rest, analgesics, orthoses/corsets and physical therapy. In some cases pain persists, and is refractory to these measures. These patients are predominately elderly, and hardware implantation may not be possible in weakened bone. Percutaneous sacroplasty is a minimally invasive procedure, in which PMMA is injected through a needle inserted into the sacrum at the fracture site under fluoroscopic guidance.

Sacral kyphoplasty is similar to standard sacroplasty although sacral kyphoplasty involves advancement of a balloon or osteotome through the cannulated needle to enlarge the space created by the fracture or to create a new channel to optimize cement delivery and, ultimately, bone stability. In addition, a more recent modification of these procedures involves the application of radiofrequency (RF) energy to the PMMA cement immediately before cement delivery. The RF energy accelerates cement polymerization, rendering the cement considerably more viscous than conventionally prepared PMMA. Patients typically receive local anesthesia and conscious sedation or general anesthesia (Hayes, 2016).

Literature Review (Sacroplasty): Frey, et al., 2007 published the results of case series evaluating the safety and efficacy of sacroplasty in 37 patients with sacral insufficiency fractures. VAS scores were monitored periodically for one year, and analgesic usage and patient satisfaction were assessed at the final follow-up. The mean VAS score was 7.7 at baseline, 3.2 within 30 minutes, 2.1 at two weeks, 1.7 at four weeks, 1.3 at 12 weeks, 1.0 at 24 weeks, and 0.7 at 52 weeks post-procedure. At baseline, 20 patients were using narcotic analgesics compared to 12 patients at last follow-up. The procedure was terminated in one patient who developed radicular pain prior to the injection of PMMA that persisted following the procedure (Frey, et al, 2007). In a second trial published by Frey and colleagues (2008) the authors evaluated outcomes and complication rates in 52 patients with incapacitating lumbar and/or gluteal pain, with failure of or intolerance to conservative measures. The mean VAS was 8.1 at baseline, 3.6 thirty minutes following the procedure, 2.5 at two weeks, 2.1 at four weeks, 1.7 at 12 weeks, 1.4 at 24 weeks, and 0.8 at 52 weeks. Improvement was statistically significant (Frey, et al., 2008). The authors noted in both studies that the natural history of osteoporotic sacral insufficiency fractures is gradual improvement starting within one to two weeks of treatment initiation, but considered it unlikely that regression toward the mean accounted for the rapid pain reduction seen in this study. The authors also acknowledged in both studies that, because of the lack of a control group, a placebo effect could not be excluded.

In 2009 Bayley and colleagues performed a review of the literature to identify various techniques used for surgical treatment of sacral insufficiency fractures and to evaluate their outcomes. The techniques described included sacroplasty with or without augmented iliosacral screws. No level I, II, or III evidence was available, and only five articles provided follow-up of one year or more. A total of 108 patients were included in the analysis. The authors concluded that results of cement augmentation techniques such as sacroplasty are promising, with immediate pain relief and maintenance of benefit in the medium-to long-term, but questions remain. The optimal technique and long term outcomes of this procedure need further analysis. The authors stated that future prospective clinical studies with an independent observer to analyze the long-term success rate and complications of this procedure are warranted (Bayley et al., 2009).

Several additional studies have been published evaluating sacroplasty although evidence is limited primarily to case reports, prospective and retrospective case series, published reviews, with few comparative trials. Measured clinical outcomes include relief of pain (e.g., VAS scores), change in analgesic use, ability to perform ADLs, patient satisfaction, and complications. On average, follow-up periods range from two weeks to 12 months with few authors measuring outcomes beyond that. Although not robust, the evidence lends some support to reduction of VAS scores (Frey, et al., 2017; Choi, et al., 2017; Heo, et al., 2017; Eichler, et al., 2014; Gupta, et al., 2014; Kortman, et al., 2013; Pereira, et al., 2013), decreased usage of analgesic medications (Frey, et al., 2017; Dougherty, et al., 2014; Gupta, et al., 2014; Pereira, et al., 2013; Kamel, et al., 2009), and improvement in ambulation in the short-term (Gupta, et al., 2014; Talmadge, et al., 2014; Kortman, et al., 2013).

Frey et al. (2017) reported the results of a prospective observational cohort of subjects treated for sacral insufficiency fractures using either sacroplasty (n=210) or non-surgical management (n=34). The non-surgical group consisted of subjects who did not meet inclusion criteria for sacroplasty. Follow-up occurred at various intervals from pretreatment to two years post treatment; the experimental group was also contacted at 10 years post treatment; the control group was not. Both groups had statistically significant decreases in VAS scores from pre-treatment to two year follow-up (p<0.001). The experimental group had more significant decreases from follow-up to follow-up extending out to one year, the control group had significant decrease in mean VAS only at the pre-treatment to two week follow-up. Additionally, the authors reported decreased use of opioid and non-opioid medications from preoperatively to postoperatively in the experimental group, which was sustained at the 10-year follow-up. Limitations of the study include small sample populations and lack of outcomes at 10 year followup for the control group.

Hayes published an updated review to a Technology Brief evaluating percutaneous sacroplasty for treatment of sacral insufficiency fractures (Hayes, 2016b). Within the report Hayes noted although there were some new studies published (two prospective cohorts, two retrospective cohorts) the results would not change the conclusions in the existing Hayes report. In the initial report Hayes concluded the overall body of evidence is poor and additional research is needed to establish the value and role of sacroplasty for treatment of sacral insufficiency fractures.

The published evidence evaluating sacroplasty is insufficient to support improved clinical outcomes. A majority of the studies lack control groups, large sample populations, and measurement of long-term outcomes, therefore no conclusions can be made regarding the safety and efficacy of sacroplasty.

Technology Assessments

Washington State Health Care Authority Health Technology Assessment: A Washington State Health Technology Assessment, Vertebroplasty, Kyphoplasty and Sacroplasty, was initially published in November, 2010, based on a structured, systematic search of the peer reviewed literature. In summarizing the purpose of the review, the authors noted that these procedures are less invasive than other spinal surgical procedures, but more invasive than conservative medical therapy, and although non-randomized studies have reported improvements in pain and functioning, significant questions remain about the safety, efficacy, effectiveness, and cost-effectiveness of these procedures. The original assessment provided the following conclusions:

Efficacy

- Vertebroplasty
 - Pain relief: Uncertain whether vertebroplasty is effective for pain relief.
 - Function and quality of life: Uncertain whether vertebroplasty improves patient functioning and quality of life..
- Kyphoplasty

- Pain relief: Uncertain whether kyphoplasty is effective for pain relief.
- Function and quality of life: Uncertain whether kyphoplasty improves patient functioning and quality of life.
- Vertebroplasty compared with kyphoplasty
 - Pain relief: A single poor-quality RCT found equal improvement in back pain scores over six months. The strength of evidence was noted to be very low.
 - Function and quality of life: No evidence of efficacy for these outcomes.
- Sacroplasty: No evidence of efficacy since the only available evidence consists of case series.

Effectiveness

- Vertebroplasty
 - Pain relief: Uncertain whether vertebroplasty is more effective than conservative medical treatment in reducing pain. Four nonrandomized studies with follow-up of up to a year found that vertebroplasty was more effective than conservative medical treatment up to approximately six months. Pain levels were comparable at one year in both groups. The strength of evidence was noted to be very low.
 - Function and quality of life: A similar pattern was seen in improvements in these four studies in functioning and quality of life, with superior effectiveness in the first 3-6 months followed by equivalent levels of functioning at one year. The strength of evidence was noted to be very low.
- Kyphoplasty:
 - Pain relief: In two non-randomized studies, kyphoplasty reduced pain more than conservative medical treatment for periods up to three years.
 - Function and quality of life: In these two studies, kyphoplasty improved a limited set of functional outcomes more than conservative medical treatment.
- Vertebroplasty compared with kyphoplasty
 - Pain relief: In 8 of 10 non-randomized studies, vertebroplasty and kyphoplasty led to comparable pain reduction up to 2 years.
 - Function and quality of life: In 4 of 5 non-randomized studies, vertebroplasty and kyphoplasty patients demonstrated comparable improvements in ODI up to 2 years.
- Sacroplasty: Unable to draw conclusions due to very limited data.

Regarding safety, the authors stated that, while it appears that the rate of serious complications with associated symptoms are low for vertebroplasty and kyphoplasty, studies with long-term follow up for greater than five years are few, and comparative studies, especially randomized controlled trials, may have too few patients to detect more rare but serious outcomes.

An updated literature review of vertebroplasty, kyphoplasty and sacroplasty was conducted to determine if the evidence published since the prior report would change the original decision (WSHTA, 2016). According to the authors assessing data for the update, with the exception of safety and efficacy of percutaneous vertebroplasty compared with sham surgery, updates to the original 2010 conclusions were not necessary. Within the data assessment the authors acknowledged a change in the evidence supported by one randomized controlled trial (Clark, et al, 2016), which demonstrated an associated reduction in pain and disability at all time frames to six months in favor of percutaneous vertebroplasty, however there was no change to the evidence longer term (> six months to 24 months).

Professional Societies/Organizations

Although it has not been updated, the American Academy of Orthopaedic Surgeons (AAOS) published a clinical practice guideline and evidence report on the treatment of symptomatic osteoporotic spinal compression fractures in 2010 (AAOS, 2010). The guideline was based on a systematic review of studies published in English in peer reviewed journals in or after 1966. Additional study requirements included the following: enrollment of ten or more patients per group; results presented quantitatively; enrolled patients 18 years of age or older; not an in vitro, biomechanical or cadaver study; results for patients with osteogenesis imperfecta or solid metastatic tumors of the spine excluded or reported separately; and at least 50% patient follow-up (in studies with > 50% but < 80% follow-up, the study quality was downgraded). Results reported as post-hoc subgroup analyses were excluded. The guideline includes the following recommendations regarding vertebroplasty and kyphoplasty:

- We recommend against vertebroplasty for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact. (Strength of recommendation: strong)
- Kyphoplasty is an option for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact. (Strength of recommendation: weak)

Additional AAOS recommendations regarding treatment of osteoporotic compression fractures include:

- We suggest patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms suggesting an acute injury (0-5 days after identifiable event or onset of symptoms) and who are neurologically intact be treated with calcitonin for 4 weeks. (Strength of recommendation: moderate)
- Ibandronate and strontium ranelate are options to prevent additional symptomatic fractures in patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms. (Strength of recommendation: weak)
- It is an option to treat patients who present with an osteoporotic spinal compression fracture at L3 or L4 on imaging with correlating clinical signs and symptoms suggesting an acute injury and who are neurologically intact with an L2 nerve root block. (Strength of recommendation: weak)

The authors were unable to recommend for or against the following treatments (Strength of each recommendation: inconclusive):

- Bed rest, complementary and alternative medicine, or opioids/analgesics for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.
- Treatment with a brace for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.)
- A supervised or unsupervised exercise program for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.
- Electrical stimulation for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact.

A practice guideline for the performance of vertebral augmentation (including vertebroplasty and kyphoplasty) developed in collaboration by the American College of Radiology (ACR), American Society of Neuroradiology (ASNR), Society of Neurointerventional Surgery (SNIS), American Society of Spine Radiology (ASSR), and the Society of Interventional Radiology (SIR), was amended in 2014 (ACR-ASNR-ASSR-SIR-SNIR, 2014). The guideline states that the major indication for vertebroplasty is the treatment of symptomatic osteoporotic vertebral body compression fracture(s) refractory to medical therapy or vertebral bodies weakened due to neoplasia. Failure of medical therapy is defined as follows:

- For a patient rendered nonambulatory due to pain from weakened or fractured vertebral body, pain persisting at a level that prevents ambulation despite 24 hours of analgesic therapy.
- For a patient with sufficient pain from weakened or fractured vertebral body that physical therapy is intolerable, pain persisting at that level despite 24 hours of analgesic therapy.
- For any patient with weakened or fractured vertebral body, unacceptable side effects such as excessive sedation, confusion, or constipation due to the analgesic therapy necessary to reduce pain to a tolerable level.

The guideline includes the following indications for vertebral augmentation:

- Painful osteoporotic vertebral compression fracture(s) refractory to medical therapy
- Vertebral bodies weakened by neoplasm
- Symptomatic vertebral body microfracture (as documented by magnetic resonance imaging [MRI] or nuclear imaging, and/or lytic lesion seen on CT) without obvious loss of vertebral body height.

The American College of Radiology (ACR) Appropriateness Criteria for Management of Vertebral Compression Fractures was updated in 2014, and again in 2017. According to ACR vertebroplasty is recommended for the treatment of symptomatic osteoporotic vertebral body fracture(s) refractory to medical therapy or vertebral bodies weakened because of neoplasia. Currently, there is a lack of conclusive evidence to support the use of prophylactic vertebral augmentation to prevent future osteoporotic fracture. The ACR suggests “magnetic resonance imaging (MRI) evaluation should be considered prior to any planned vertebral augmentation in patients with a history of malignancy or atypical clinical features. MRI, especially using a short tau inversion recovery (STIR), prior to vertebroplasty may differentiate synchronous fractures and is useful for differentiating recent from chronic fractures. Recent fractures exhibit edema, which can be detected by STIR MRI for up to 3 months after the fracture occurs. Minimally deforming fractures that are overlooked by conventional radiographs but detected on MRI may be a cause of clinical failure” (ACR, 2014).

A 2007 position statement on percutaneous vertebral augmentation developed by the American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, American Association of Neurological Surgeons/Congress of Neurological Surgeons, and the American Society of Spine Radiology, states that percutaneous vertebral augmentation with vertebroplasty and kyphoplasty is a safe, efficacious, and durable procedure in appropriate patients with symptomatic osteoporotic and neoplastic fractures when performed in a manner in accordance with published standards. These procedures are offered only when traditional medical therapy has not provided pain relief or pain is substantially altering the patient’s lifestyle (Jensen, et al, 2007).

Sacroplasty is not addressed in published specialty society statements or guidelines.

Although professional guidelines address VP and KP, they do not recommend any specific tools, products, or bone cement for the procedure.

Centers for Medicare & Medicaid Services (CMS)

- National Coverage Determinations (NCDs): No NCDs found.
- Local Coverage Determinations (LCDs): Multiple LCDs found, similar in scope to this Coverage Policy. Refer to the LCD table of contents link in the reference section.

Use Outside of the US

Vertebral Body Stenting: One method of treatment under investigation as an alternative to 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 body stenting (VBS™; Synthes, Switzerland) is only available in Europe at this time.

National Institute for Health and Care Excellence (NICE) (United Kingdom): NICE technology appraisal guidance issued in April 2013 states that percutaneous vertebroplasty, and percutaneous balloon kyphoplasty without stenting, are recommended as options for treating osteoporotic vertebral compression fractures only in people who have severe ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management and in whom the pain has been confirmed to be at the level of the fracture by physical examination and imaging (NICE, 2013).

An additional recommendation made as part of the clinical guideline on metastatic spinal cord compression published in November 2008 states that vertebroplasty or kyphoplasty should be considered in patients who have vertebral metastases and no evidence of metastatic spinal cord compression or spinal instability, if they have either mechanical pain resistant to analgesia, or vertebral body collapse. Vertebroplasty or kyphoplasty for spinal metastases should only be performed after agreement between appropriate specialists, including an oncologist, interventional radiologist, and spinal surgeon, and in facilities where there is good access to spinal surgery (NICE, 2008).

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.

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Medical Coverage Policy: 0040

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Percutaneous Kyphoplasty

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
22513	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, 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 (eg, 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 (eg, 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)
22899†	Unlisted procedure, spine

†Note: Considered medically necessary when used to report percutaneous cervical kyphoplasty

Percutaneous Vertebroplasty

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
22510	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic
22511††	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral
22512	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body (List separately in addition to code for primary procedure)

††Note: Considered Experimental/Investigational/Unproven when used to report percutaneous sacroplasty.

Percutaneous Sacroplasty

Considered Experimental/Investigational/Unproven:

CPT®* Codes	Description
0200T	Percutaneous sacral augmentation (sacroplasty), unilateral injection(s), including the use of a balloon or mechanical device, when used, 1 or more needles, includes imaging guidance and bone biopsy, when performed
0201T	Percutaneous sacral augmentation (sacroplasty), bilateral injections, including the use of a balloon or mechanical device when used, 2 or more needles, includes imaging guidance and bone biopsy, when performed

***Current Procedural Terminology (CPT®) ©2018 American Medical Association: Chicago, IL.**

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