## Medical Coverage Policy

**Effective Date .....06/15/2024**
**Next Review Date .....06/15/2025**
**Coverage Policy Number.....0040**

# Percutaneous Vertebroplasty, Kyphoplasty, and Sacroplasty

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Intervertebral Disc (IVD) Prostheses
Minimally Invasive Spine Surgery Procedures and Trigger Point Injections

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## 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. Sacroplasty, for the treatment of sacral insufficiency fracture, is also addressed.

## 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 symptoms, and ANY of the following criteria is met:**

- persistent, debilitating pain unresponsive to at least six weeks of conservative medical management with diagnosis of ONE of the following vertebral compression fracture types:
  - osteoporotic (based on predisposing factors which could include post-menopausal women, medical conditions that predispose to osteoporosis, fragility fractures)
  - osteolytic
  - osteonecrotic (i.e., Kummell disease)
  - steroid-induced
- 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 not medically necessary for any other indication.**

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

## Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing,

transportation and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

## General Background

Percutaneous vertebroplasty, percutaneous kyphoplasty, and sacroplasty are minimally invasive procedures involving the injection of bone cement into a fractured vertebrae (vertebral compression fracture [VCF]) and are proposed as an alternative to medical management with the purpose of alleviating pain, providing spine stability, and preventing further vertebral collapse.

Osteoporosis is currently the leading cause of vertebral compression fractures. The main causes of osteoporosis are aging, hormonal changes and genetic predisposition. Other predisposing factors include: menopause; autoimmune disorders (e.g., rheumatoid arthritis, lupus, multiple sclerosis, ankylosing spondylitis); hematologic disorders (e.g., leukemia, lymphoma, multiple myeloma, sickle cell disease, thalassemia); endocrine disorders (e.g., diabetes, hyperparathyroidism, hyperthyroidism, Cushing's syndrome, thyrotoxicosis); gastrointestinal disorders (e.g., celiac disease, inflammatory bowel disease); cancer (e.g., breast, prostate); neurological disorders (e.g., stroke, Parkinson's disease, multiple sclerosis, spinal cord injuries); mental illness (e.g., depression, eating disorders); surgical procedures (e.g., gastrectomy, gastrointestinal bypass, organ transplantation); AIDS/HIV; chronic obstructive pulmonary disease; chronic kidney disease; liver disease; poor diet; lack of weight bearing exercise; scoliosis; and medications (e.g., epilepsy drugs, steroids, diuretics).

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. In 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). Vertebral augmentation is not indicated in mild or moderate pain for osteoporotic compression fractures (Buchbinder, et al., 2018).

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

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

The Kiva® VCF Treatment System (Benvenue Medical) received FDA 510(k) marketing clearance in 2014 (K141141). It is indicated for use in the reduction and treatment of spinal fractures in the thoracic and/or lumbar spine from T6-LS. It is intended to be used in combination with the Benvenue Vertebral Augmentation Cement Kit.

The SpineJack Expansion Kit received FDA 510(k) marketing clearance in August 2018 (K181262). It indicated for use in the reduction of painful osteoporotic vertebral compression fractures. It is intended to be used in combination with Stryker Vertaplex and Vertaplex HV bone cements. The SpineJack is an implanted fracture reduction system, intended to reduce vertebral compression fractures. In 2022, the original 510(k) approval was expanded to added indications of traumatic vertebral compression fractures and compression fractures that result from malignant lesions (myeloma or osteolytic metastasis) under K223294**.** The SpineJack is available in three sizes to accommodate different vertebral body sizes (4.2mm, 5mm, and 5.8mm). After the SpineJack implant is inserted, it is expanded, and PMMA bone cement is injected at a low pressure to stabilize the restored vertebral body.

**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 histocytosis, (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) 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).

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 a., 2003).

RCTs evaluating vertebroplasty (Evans, et al., 2016; Yang, et al., 2016) demonstrated 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 more recent RCT did not lend support to vertebroplasty compared with sham. Firanescu 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.

Evidence in the form of meta-analyses is also available in the scientific literature and tends to support clinical efficacy. One 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. 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).

A systematic review and meta-analysis published by Zuo et al. (2018) lends additional support to percutaneous vertebral augmentation (vertebroplasty/kyphoplasty) for treatment of osteoporotic vertebral compression fractures. This group of authors concluded after reviewing 18 RCTS involving 1994 subjects that percutaneous kyphoplasty was considered a first option in relieving pain in the case of "acute/subacute" compression fractures for long term and "chronic" compression fractures for both short and long term. Percutaneous vertebroplasty had the most superiority in the case of the acute/subacute compression fractures for short term. Overall, the authors concluded percutaneous vertebral augmentation had better performance compared with conservative therapy for alleviating acute/subacute and chronic pain for both the short and long-term**.**

Lou et al. (2019) published their results of a meta-analysis of RCTs comparing vertebroplasty to non-operative treatment. A total of 13 RCTs involving 1624 subjects were included in the analysis. Five compared vertebroplasty with sham and eight compared vertebroplasty with conservative therapy. The primary outcomes were pain relief using VAS at one to two weeks, one to three months, and six to 12 months; the secondary outcome was the rate of occurrence of new vertebral fractures. For the blinded studies, statistical differences were found between vertebroplasty and sham injection subjects for the 3 primary outcomes in the subgroup of the Vertebroplasty for Acute Painful Osteoporotic Fractures (VAPOUR) trial. Although pain scores were similar between the vertebroplasty group and the sham injection group for the VAPOUR trial at each period, the effect size of vertebroplasty increased over time. For the open-label studies, vertebroplasty significantly reduced pain at all time points. The authors concluded vertebroplasty showed variable outcomes; it was beneficial to patients with acute compression fractures experiencing persistent and severe pain, but not for patients with older fractures or non-severe symptoms.

Láinez Ramos-Bossini et al. (2021) published results of a meta-analysis of RCTs assessing the efficacy of percutaneous vertebroplasty over conservative treatment and placebo in osteoporotic vertebral fractures. Fourteen RCTs (n=1367) were included in the analysis. The following variables were evaluated at short-term (one to four weeks), medium-term (one to six months) and long-term (six months or greater) time frames: pain relief, measured by the Visual Analogue Scale (VAS) or other quantitative scales (e.g., Numeric Rating Scale, NRS); improvement in functional disability measured by the Roland-Morris Disability Questionnaire (RMDQ) and the Oswestry Disability Index (ODI); improvement in quality of life assessed by the Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO). Percutaneous vertebroplasty results showed significant benefits in terms of pain, functional disability and quality of life over conservative treatment. However, compared to placebo, percutaneous vertebroplasty showed slight benefits in pain in the long-term, but other advantages were not so clear. The authors concluded that differences in the sham procedures or criteria regarding patient's selection/allocation seem to be the main causes of disparity in previous RCTs.

**Literature Review (Osteolytic Destruction):** Published studies evaluating vertebroplasty for treatment of osteolytic destruction (e.g., metastasis) consist mainly of retrospective case series (Chow, et al., 2004; Alvarez, et al., 2003; Fourney, et al., 2003; Deramond, et al., 1998). 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 with 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. The addition of a thermal source of energy to warm the PMMA bone cement prior to injection is considered integral to the base procedure. An additional mechanical device, the SpineJack, received FDA 510(k) clearance in 2018.

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):** Clinical trials in the peer reviewed medical literature 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 meta-analysis published by Wang et al. (2018) evaluated safety and efficacy of kyphoplasty versus percutaneous vertebroplasty for osteoporotic vertebral compression fractures. A total of 16 studies were included in their analysis. The results demonstrated kyphoplasty significantly decreased the kyphotic wedge angle, increased the postoperative vertebral body height, and decreased the risk of cement leakage in comparison to vertebroplasty although no statistical difference was noted was note din VAS score and ODI between the two groups.

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 ($p=0.15$). The kyphoplasty group had a greater improvement in the 10-point back pain score that was maintained at 24 months (-80 points, $p=0.009$). 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 (Garfin, et al., 2006; Ledlie and Renfro, 2006; Gaitanis, et al., 2005; Grohs, et al., 2005; Kasperk, et al., 2005; Lane, et al., 2004; Rhyne, et al., 2004; Ledlie and Renfro, 2003; Phillips, et al., 2003; Dudeney, et al., 2002; Lieberman, et al., 2001).

**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., 2014; Korovessis, et al., 2013), 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 anther 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 (SpineJack)**

In a prospective, randomized study, Vanni et al (2012) examined the outcomes of vertebral augmentation with SpineJack system compared to balloon kyphoplasty (BKP) for the treatment of patients with osteoporotic vertebral compression fractures (OVCFs) (type A1 fractures). From February 2010, a prospective randomized study was performed examining 300 patients who underwent PVAP due to OVF type A1 according to Magerl/AO spine classification. Patients enrolled in the study were divided in two homogenous groups with regards to age (65-85 years), sex, and general clinical findings. Group A included 150 patients who underwent PVAP using Spine Jack system; the second, group B (control group), included 150 patients treated by conventional balloon kyphoplasty. Patients underwent a clinical (visual analogue scale and Oswestry disability index) and radiographic follow-up, with post-operative standing plain radiogram of the spine at 1, 6, and 12 months. The radiographic parameters that were taken into account were: Post-operative anterior vertebral body height, pre-operative anterior vertebral body height, cephalic anterior vertebral body height, and caudal anterior vertebral body height. Compared to the Spine Jack group, the kyphoplasty group required a little longer operation time (an average of 40 min–group A vs. 45 min–group B, $P < 0.05$) and a greater amount of polymethylmethacrylate (4.0 mL–group A vs. 5.0 mL–group B, $P < 0.05$;). The post-operative increase in vertebral body height was

greater in the Spine Jack® group than in the kyphoplasty group (P < 0.05). PVAP are based on the cement injection into the vertebral body. Vertebroplasty does not allow the vertebral body height recovery. Balloon kyphoplasty allows a temporary height restoration. There was no statistical difference in VAS pain scores and in the ODI between the treatment groups at any stages from the pre-operative period, through the post-operative period, to the final follow-up. In group A, there were not leakage events, nor device loosening. In the group B, there were 20 clinically insignificant leakage events. In both groups, there were not iatrogenic vertebral endplates fractures or fractures. Spine Jack® has some new features compared to other systems: It is equipped with a mechanical and not a hydraulic opening control; this ensures a gradual and controlled vertebral fracture reduction. This study was limited by short term follow-up and study design. The authors concluded that the findings of this study showed significantly greater VB height restoration in the SpineJack group compared to the BKP group (85% of patients in the SpineJack group achieved more than 50% VB height restoration whereas only 58% of patients in the BKP group achieved similar VB height restoration).

Noriega, et al. (2019) conducted a pilot monocenter study in 30 patients with painful osteoporotic vertebral compression fractures and compared two vertebral augmentation procedures. The procedures compared were the SpineJack (SJ) and balloon kyphoplasty (BKP). Thirty patients were randomized to SJ (n = 15) or BKP (n = 15). Clinical endpoints were analgesic consumption, back pain intensity (visual analog scale (VAS)), the Oswestry Disability Index (ODI), and quality of life (EQ-VAS score). They were recorded preoperatively, at 5 days (except EQ-VAS), 1, 3, 6, 12, and 36 months post-surgery. Spine X-rays were taken 48 h prior to the procedure and 5 days, 6, 12, and 36 months after. Clinical improvements were observed with both procedures over the 3-year period without significant inter-group differences, but the final mean EQ-5D index score was significantly in favor of the SJ group (0.93 ± 0.11 vs 0.81 ± 0.09; p =0.007). Vertebral height restoration/kyphotic correction was still evident at 36 months with a greater mean correction of anterior (10 ± 13% vs 2 ± 8% for BKP, p = 0.007) and central height (10 ± 11% vs 3 ± 7% for BKP, p = 0.034) and a larger correction of the vertebral body angle (− 5.0° ± 5.1° vs 0.4° ± 3.4°; p = 0.003) for SJ group. Over a 3-year post-surgery follow-up, pain/disability/quality of life remained significantly improved with both balloon kyphoplasty and SpineJack® techniques, but the latter allowed better vertebral body height restoration/kyphosis correction. Due to small sample size, the authors warn their findings should be interpreted with caution and need to be proven during larger, multicenter studies with independent radiographic core lab assessments in order to minimize reader bias. The authors conclude both techniques displayed very good long-term clinical efficiency and safety in patients with osteoporotic VCFs. Over the 3-year follow-up, vertebral body height restoration/kyphosis correction was better with the SpineJack procedure.

Noriega, et al. (2019) completed a prospective, parallel group, controlled randomized study comparing an implantable titanium vertebral augmentation device (TIVAD – SpineJack) versus balloon kyphoplasty (BKP) in the reduction of vertebral compression fractures (SAKOS study). This study aimed to support a non-inferiority finding for the use of a titanium implantable vertebral augmentation device (TIVAD) compared to BKP. Patients were recruited in 13 hospitals across five countries and were assigned (1:1) to either TIVAD or BKP with electronic randomization. A total of 152 patients with OVCFs were initially randomized. Eleven patients were excluded (six met exclusion criteria, one with evidence of tumor, and four patients had T-score out of requested range). Anterior vertebral body height ratio, midline vertebral body height ratio, and Cobb angle were measured preoperatively and postoperatively by an independent imaging core lab. Adjacent and subsequent fractures and safety parameters were recorded throughout the study. Cement extravasation was evaluated on X-rays. Patients were considered eligible for inclusion if they met the following criteria: (1) male or female aged ≥50 years (2) had radiographic evidence of one or two painful VCFs from T7 to L4 due to osteoporosis, (3) fracture(s) aged <3 months, and (4) fracture(s) that showed a loss of height in the anterior, middle, or posterior third of the VB ≥15% but ≤40%. A DEXA was performed to check if the patients presented osteoporosis with a T-score

≤ -2.0. Patients were required to have undergone conservative therapy (bed rest, analgesic pain medication, and medications to address underlying osteoporosis such as bisphosphonates) for at least 6 weeks before enrollment. Patients who failed conservative medical therapy, defined as either having a VAS back pain score ≥50 mm at six weeks after initiation of fracture care or a VAS back pain score ≥70 mm at two weeks after initiation of fracture care, were considered eligible. Patients must also have had an Oswestry Disability Index (ODI) score ≥30%. Exclusion criteria consisted of: target VCF(s) due to underlying or suspected tumor, high-energy trauma, or osteonecrosis; segmental kyphosis of target vertebra of >30°; previous surgical treatment at the VCF index level(s); spinal canal compromise causing clinical manifestations of cord, neural foramen, or nerve root compression at the level(s) to be treated; any physical exam evidence of myelopathy or radiculopathy, pre-existing or clinically unstable neurologic deficit; pain based on clinical diagnosis of herniated nucleus pulposus or severe spinal stenosis (progressive weakness or paralysis); any radiographic evidence of pedicle fracture visible on pre-op CT scan, spondylolisthesis >Grade 1 at target VB(s); any underlying systemic bone disease other than osteoporosis; inability to ambulate without assistance before fracture(s);pain due to any other condition that required daily narcotic medication, disabling back pain due to causes other than acute fracture(s); medical contraindication to spinal surgery and/or general anesthesia, such as coagulopathy and/or regular intake of anticoagulants; and/or BMI >40. The primary composite endpoint was defined as: reduction in VCF fracture-related pain at 12 months from baseline and maintenance or functional improvement (ODI) at 12 months from baseline, and absence of device-related adverse event or surgical reintervention. If the primary composite endpoint was successful, a fourth component (absence of adjacent level fracture) was added for analysis. If the analysis of this additional composite endpoint was successful, then midline target height restoration at 6 and 12 months was assessed. Secondary clinical outcomes included back pain intensity, ODI score, EQ-5D index score (range 0=death to 1=full health) and EQ-VAS score (range 0−100). All patients were followed at screening at 5 days, 1 month, 6 months, and 12 months postoperatively. Among the 141 patients (78.7% female, mean age 73 ±9.5 years) who underwent surgery (TIVAD=68; BKP=73), 126 patients (89.4%) completed the 12-month follow-up period (TIVAD=61; BKP=65). The analysis of primary endpoint on the ITT population demonstrated noninferiority of the TIVAD to BKP. The analysis of the additional composite endpoint demonstrated the superiority of TIVAD over BKP ($p<0.0001$) at 6 months (88.1% vs. 60.9%) and at 12 months (79.7% vs. 59.3%). Midline VB height restoration was more improved for TIVAD than for BKP at 6 months (1.14±2.61 mm vs. 0.31±2.22 mm); $p=0.0246$) and 12 months after surgery (1.31±2.58 mm vs. 0.10±2.34 mm; $p=0.0035$). No statistically significant differences were shown between procedures for improvement in functional capacity and quality of life. Pain relief was significantly more marked in the TIVAD group compared to the BKP group at 1 month ($p=0.029$) and at 6 months ($p=0.021$) after surgery. No patient required surgical reintervention or retreatment at the treated level. No symptomatic cement leakage was reported. Adverse events were similar for both groups (41.2% in the TIVAD group and 45.2% in the BKP group). The incidence of adjacent fractures was significantly lower after the TIVAD procedure than after BKP (12.9% vs. 27.3%; $p=0.043$). Limitations in this study included a lack of patient blinding as well as certain study endpoints to support device clearance. VAS reduction of >20 mm or no change in ODI over 12 months may not be considered successful clinical outcomes, even though both endpoints demonstrated improvement throughout the duration of the study. Per the authors, "Study results demonstrated non-inferiority of the TIVAD to the predicate BKP with an excellent risk/benefit profile for results up to 12 months".

**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**
Chang et al (2021) stated that VP, KP, SpineJack (SJ), Radiofrequency kyphoplasty (RFK), Kiva system (Kiva), Sky kyphoplasty system (SK), and conservative treatment are widely used in the treatment of OVCFs; however, it is still unclear which approach is the best intervention. These researchers conducted a systematic review and meta-analysis of randomized controlled trials and cohort studies with an objective of examining the safety and effectiveness of VP, KP, SJ, RFK, Kiva, SK, and CT in the treatment of OVCFs. RCTs and cohort studies comparing VP, KP, SJ, RFK, Kiva, SK, or CT for the treatment of OVCFs were identified on the basis of data-bases including PubMed, the Cochrane Library, Web of Science, and Springer Link. A total of 56 studies with 6,974 patients and 7 interventions were included in this study. Studies were included on the basis of the following criteria: study design (RCTs or cohort studies with complete data); patients diagnosed with osteoporotic vertebral compression fractures; studies comparing the effectiveness for two or more interventions including VP, KP, SJ, RFK, Kiva, SK, and CT; conservative treatments including bed rest, back braces, various pharmacologic agents, and physical therapy. Excluded were: letters, abstracts, or meeting proceedings; duplicate studies; case reports; and animal studies. Outcomes included VAS scores, recovery of middle vertebral height, kyphotic angle, ODI scores, incidence of new fractures and bone cement leakage. Clinically, 44 studies including 4895 patients reported VAS as outcome. Compared with CT, the VAS in KP, VP, and SK decreased significantly, but there was no significant difference among the other groups. The cumulative probability of VAS to be the optimal intervention for OVCFs in KP, VP, RFK, Kiva, SJ, SK, and CT was 9.5%, 0.3%, 1.0%, 21.9%, 3.1%, 64.3%, and 0.0%, respectively. ODI was reported in 22 studies, which involved 2367 patients. When compared with KP, VP, Kiva, SJ, SK, and CT, the ODI of RFK was significantly lower. Furthermore, in comparison to the CT, the ODI in KP, VP, SJ, and RFK decreased significantly. RFK had the highest probability becoming the best intervention, followed by SJ, SK, VP, Kiva, and CT. Radiographically, 22 studies including 2607 patients reported kyphotic angle as outcome. The kyphosis angle in SJ group was significantly smaller than that in the KP, VP, RFK, SK, and CT groups, while there was no significant difference among the other groups. In addition, SJ had the highest probability of becoming the best intervention in the kyphotic angle, followed by Kiva, SK, KP, RFK, VP, and CT. Middle vertebral height was reported in 10 studies which involved 1385 patients. The KP, VP, Kiva, SJ, RFK, and SK groups had higher middle vertebral height than the CT group, but the Kiva, RFK, and SJ groups had lower middle vertebral height than the VP group. Moreover, the cumulative probability to be the optimal

intervention in KP, VP, RFK, Kiva, SJ, SK, and CT was 0.0%, 41.3%, 0.3%, 0.8%, 0.2%, 57.4%, and 0.0%, respectively. To summarize, the results demonstrated that SK was the best intervention in decreasing VAS scores and recovering middle vertebral height; RFK was the best intervention in improving ODI scores and decreasing incidence of new fractures; SJ was the best intervention to restore kyphosis angle; and Kiva was the best intervention to reduce incidence of bone cement leakage. Cluster analysis showed that SK was the preferable intervention based on the outcomes of VAS, ODI, middle vertebral height, and kyphotic angle, and RFK was the preferable treatment in decreasing the incidence of AEs. The authors acknowledges the limitations of this study which included: differences in indicators, data types, follow-up times, and variables in the included studies; all of which would lead to bias or extreme difficulty in combining data. The authors state these findings should be interpreted cautiously. The authors concluded that SK may be the most effective treatment in relieving pain, improving the QOL, and recovering vertebral body height and kyphotic angle, while RFK may be the safest intervention for OVCFs. However, considering the limitations of this study, more high-quality trials are needed in the future to confirm their current conclusions.

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. Sorensen et al. (2019) performed a systematic review evaluating the effectiveness and safety of vertebral augmentation for malignant vertebral compression fractures (VCFs). The studies reviewed included vertebroplasty or kyphoplasty as treatment of vertebral compression fractures in subjects with malignant spine disease. Two randomized controlled trials, 16 prospective studies, 44 retrospective studies, and 25 case series were included in the review with a total sample population of 3,426 subjects. A total of 2091 subjects were treated with vertebroplasty and 1335 were treated with kyphoplasty. Cement leakage occurred in 37.9% of vertebroplasty subjects and 13.6% of kyphoplasty subjects. Pain relief using VAS was recorded in 56 studies, with 18 using ODI score and 13 using Karnofsky Performance Score (KP). According to the authors review VAS pain score improved from 7.48 to 3.00 postoperative with vertebroplasty and from 7.05 to 2.96 with kyphoplasty. ODI improved from 74.68 to 17.74 with vertebroplasty, and from 66.02 to 34.73 with kyphoplasty at earliest follow-up (< 4 weeks postoperative). KPS improved from 66.99 to 80.28, with no regard to surgical procedure. With the exception of ODI the scores the improvements persisted with subsequent follow-up. Cement leakage was seen in 37.9% and 13.6% of patients treated with vertebroplasty and kyphoplasty, respectively. Symptomatic complications were rare (n=43). The authors concluded both procedures were safe and effective palliative procedures for painful vertebral compression fractures in subjects with malignant spine disease.

In 2018, Pourtaheri and colleagues published a systematic review and meta-analysis to assess the clinical outcomes with and without vertebral augmentation (VA) for osteoporotic vertebral compression fractures (VCFs) with versus without correlating signs and symptoms; and for acute (symptoms <3 month duration) and subacute VCFs (3 -6 month duration) versus chronic VCFs (>6 months). A total of 13 studies (n=1467 subjects) with minimum six month follow-up were

included in the review. Pain reduction was greater with vertebral augmentation compared with conservative management for fractures with correlating signs/symptoms (SVFs) and equivalent for fractures confirmed by radiograph alone(RVFs). Sub-analysis for acute/subacute SVFs and chronic SVFs showed that vertebral augmentation was superior to nonoperative care. No difference was observed in outcomes between vertebral augmentation and nonoperative care for chronic RVFs. The authors concluded that vertebral augmentation is superior to nonoperative care in reducing lower back pain for osteoporotic compression fractures with correlating signs and symptoms. Vertebral augmentation had no benefit over nonoperative care for chronic fractures that lacked clinical correlation (Pourtaheri, et al., 2018).

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 noted above. Similarly, randomized and quasi-randomized 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 randomized participants), eight with usual care (1136 randomized participants), seven with kyphoplasty (968 randomized participants) and one compared vertebroplasty with facet joint glucocorticoid injection (217 randomized 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, 2016b**).**

**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. At

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 comparitive trials. Measured clinical outcomes include relief of pain (e.g., VAS scores), change in analgesic use, ability to perfom ADLs, client 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 (Tian, et al., 2020; 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 (Tian, et al., 2020; 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 singnifcant 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 evaluting percutaneous sacroplasty for treatment of sacral insufficiency fractures (Hayes, 2014). Within the report Hayes noted althrough there were some new studies published (two prospective cohorts, two retrospecitve cohorts) the results would not change the conclusions in the exisitng Hayes report. In the intial 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.

Mahmood et al. (2019) published results of a systematic review evaluating sacroplasty as treatment of sacral insufficiency fractures. The authors reviewed 31 studies that met inclusion criteria; the studies consisted of eight prospective trials, 11 retrospective studies, and 12 case series; only one study included a control group. Sample populations ranged from 3 to 243 subjects. Sacroplasty was performed using different methods, the amount of PMMA injected varied, and a majority iof the studies included the VAS score as the primary outcome, eight studies did not use VAS. Of the studies that used VAS, all reported a mean reduction of VAS at follow-up (68-94% reduction). Follow-up ranged from one month to one year with the exception of one study that followed subjects for 10 years (Frey, et al., 2017 described above). Nine studies reported cement extravastion, although clinically insiginifcant. Two studies had patients with persistent pain that requried reoperation. In the authors opinion sacroplasty as a treatment of sacral insufficiency fratures is a safe and effective procedure, in terms of pain relief with early return to function.

The published evidence evaluating sacroplasty is conflicting and 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: Despite additional study, the strength of evidence was noted to be very low.
  - Function and quality of life: No evidence of efficacy for these outcomes.
- Sacroplasty: There is no new comparative evidence on sacroplasty and no evidence of efficacy.

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 committee stated 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. The Washington State Health Care Authority conducted literature reviews again in 2016 and 2020, but to date have not amended the 2010 published recommendations.

**Professional Societies/Organizations**
**American Academy of Orthopaedic Surgeons (AAOS):** 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 (McGuire, 2011). 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: Limited)"

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: Limited)"
- "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: Limited)"

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."

**American College of Radiology (ACR):** The American College of Radiology (ACR) Appropriateness Criteria for Management of Vertebral Compression Fractures was updated in 2022. The authors address management of both osteoporotic and pathologic vertebral compression fractures (VCFs). According to ACR, vertebroplasty is recommended for the treatment of patients with osteoporotic compression fracture(s) with spinal deformity, worsening symptoms, or pulmonary dysfunction. Asymptomatic osteoporotic VCFs do not require active management if not associated with focal mechanical pain and if there is no restriction of physical activity due to the fracture. 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, 2018).

**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):** A practice parameter 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 revised in 2022 (ACR-ASNR-SNIS-ASSR-SIR, 2022). The guideline stated that the major indication for vertebral augmentation is the treatment of one or more symptomatic osteoporotic vertebral body compression/ insufficiency macro or micro fracture(s) refractory to medical therapy or vertebral bodies weakened due to osteoporosis or neoplasia.

The guideline included the following indications for vertebral augmentation:

- Painful osteoporotic vertebral compression/ insufficiency macro or micro fracture(s) refractory to medical therapy (e.g., opioid intolerance, pain requiring reduction in ADLs)
- 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.
- Benign painful lesion of bone
- Rapidly progressive fracture, with or without pseudoarthrosis potentially leading to kyphosis
- Severe kyphosis resulting in decreased pulmonary function

**International Society for the Advancement of Spine Surgery (ISASS):** The International Society for the Advancement of Spine Surgery (ISASS) published an updated policy statement on vertebral augmentation procedures (Lamlice, et al., 2019). According to the policy statement clinical indications of coverage for patients who have all of the following criteria may be eligible for vertebral augmentation:

- Severe functional limitation due to pain or hospitalization due to a VCF
- History of VCFs: minimal or low-velocity fracture
- Physical examination consistent with VCFs: tenderness with palpation or percussion over the spinous process
- Fracture confirmed by advanced imaging (MRI, CT, bone scan)

Contraindications include the presence of blood-borne infection, infection at the surgical site, and/or osteomyelitis.

**North American Spine Society (NASS):** The North American Spine Society (NASS) published coverage recommendations in March 2023 regarding the use of vertebral augmentation (VA) for the treatment of painful vertebral body fractures due to osteoporosis or neoplasm. The authors stated, "Evidence supports VA for the treatment of painful vertebral body fractures in those with persistent moderate to severe pain, intolerance of analgesics, and physical limitations." This coverage recommendation does not address vertebral augmentation for traumatic fractures, primary vertebral body tumors, or pedicle screw augmentation in patients with poor bone quality. NASS recommends coverage for vertebral augmentation when the following criteria are met:

- Vertebral body fracture secondary to osteoporosis, avascular necrosis or neoplasm
- Moderate to severe fracture-related pain that is not responding to conservative treatment or pain
  that interferes with mobilizing the patient despite the use of analgesic medications
- Activities of daily living are impaired secondary to fracture-related pain
- Index fracture is acute/active as indicated by increased signal on STIR or fat suppressed T2 MRI images, bone scan, SPECT or comparative films within the last 8 weeks; or demonstrates nonunion in the form of a fracture cleft visible on CT

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.

**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.

## Medicare Coverage Determinations

| | Contractor | Determination Name/Number | Revision Effective Date |
|---|---|---|---|
| NCD | | No Determination found | |
| LCD | CGS Administrators, LLC | Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L38201) | 10/05/2023 |

| | Contractor | Determination Name/Number | Revision Effective Date |
|---|---|---|---|
| LCD | First Coast Service Options, Inc. | Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L34976) | 07/11/2021 |
| LCD | National Government Services, Inc. | Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L33569) | 12/01/2020 |
| LCD | Noridian Healthcare Solutions, LLC | Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L34106 & L34228) | 01/10/2021 |
| LCD | Novitas Solutions, Inc. | Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L35130) | 07/11/2021 |
| LCD | Palmetto GBA | Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L38737) | 07/20/2023 |
| LCD | Wisconsin Physicians Service Insurance Corporation | Percutaneous Vertebral Augmentation (PVA) for Osteoporotic Vertebral Compression Fracture (VCF) (L38213) | 09/01/2022 |

Note: Please review the current Medicare Policy for the most up-to-date information.
(NCD = National Coverage Determination; LCD = Local Coverage Determination)

## Coding Information

**Notes:**

1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
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 |

| CPT®* Codes | Description |
|---|---|
| | 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.**

| HCPCS Codes | Description |
|---|---|
| C1062 | Intravertebral body fracture augmentation with implant (e.g., metal, polymer) |
| C7507 | Percutaneous vertebral augmentations, first thoracic and any additional thoracic or lumbar vertebral bodies, including cavity creations (fracture reductions and bone biopsies included when performed) using mechanical device (eg, kyphoplasty), unilateral or bilateral cannulations, inclusive of all imaging guidance |
| C7508 | Percutaneous vertebral augmentations, first lumbar and any additional thoracic or lumbar vertebral bodies, including cavity creations (fracture reductions and bone biopsies included when performed) using mechanical device (eg, kyphoplasty), unilateral or bilateral cannulations, inclusive of all imaging guidance |

**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) |

| HCPCS Codes | Description |
|---|---|
| C7504†† | Percutaneous vertebroplasties (bone biopsies included when performed), first cervicothoracic and any additional cervicothoracic or lumbosacral vertebral bodies, unilateral or bilateral injection, inclusive of all imaging guidance |
| C7505†† | Percutaneous vertebroplasties (bone biopsies included when performed), first lumbosacral and any additional cervicothoracic or lumbosacral vertebral bodies, unilateral or bilateral injection, inclusive of all imaging guidance |

††**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 |



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## Revision Details

| Type of Revision | Summary of Changes | Date |
|---|---|---|
| Annual Review | • No clinical policy statement changes. | 06/15/2024 |