# Percutaneous Vertebroplasty and Kyphoplasty

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## Application

This Medical Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

| State | Policy/Guideline |
|---|---|
| Idaho | Percutaneous Vertebroplasty and Kyphoplasty (for Idaho Only) |
| Indiana | None |
| Kansas | Percutaneous Vertebroplasty and Kyphoplasty (for Kansas Only) |
| Kentucky | Percutaneous Vertebroplasty and Kyphoplasty (for Kentucky Only) |
| Nebraska | Percutaneous Vertebroplasty and Kyphoplasty (for Nebraska Only) |
| New Jersey | Percutaneous Vertebroplasty and Kyphoplasty (for New Jersey Only) |
| New Mexico | Percutaneous Vertebroplasty and Kyphoplasty (for New Mexico Only) |
| North Carolina | Percutaneous Vertebroplasty and Kyphoplasty (for North Carolina Only) |
| Ohio | Percutaneous Vertebroplasty and Kyphoplasty (for Ohio Only) |
| Pennsylvania | Percutaneous Vertebroplasty and Kyphoplasty (for Pennsylvania Only) |
| Tennessee | Percutaneous Vertebroplasty and Kyphoplasty (for Tennessee Only) |

## Coverage Rationale

**Percutaneous vertebroplasty and kyphoplasty are proven and medically necessary for treating pain causing Functional or Physical Impairment in cervical, thoracic, or lumbar vertebral bodies, within 4 months of pain onset, that has failed to respond to Optimal Medical Therapy for the following indications:**

- Osteoporotic vertebral compression fracture (VCF)
- Steroid-induced vertebral fracture
- Osteolytic metastatic disease involving a vertebral body
- Multiple myeloma involving a vertebral body
- Vertebral Hemangioma with aggressive features
- Unstable fractures due to Osteonecrosis (e.g., Kummel disease)

**and**

Computed tomography (CT) or magnetic resonance imaging (MRI) has ruled out other causes of spinal pain, including but not limited to:

- Foraminal stenosis
- Herniated intervertebral disk
- Other significant coexistent spinal or bony pain generators

**and**

The following are not present:

- Clinical evidence of spinal cord compression, as confirmed by CT or MRI; or
- Significant vertebral collapse or destruction (e.g., vertebra reduced to less than one-third of its original height), as confirmed by CT or MRI; or
- Healed VCF, as confirmed by CT or MRI; or
- Lesions of the sacrum or coccyx (refer to the Medical Policy titled Minimally Invasive Spine Surgery Procedures for additional information on percutaneous sacral augmentation); or
- Asymptomatic VCFs; or
- VCFs responding appropriately to conservative therapy

**Percutaneous vertebroplasty and kyphoplasty are unproven and not medically necessary for treating indications other than those listed above due to insufficient evidence of efficacy.**

## Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the federal, state, or contractual requirements, and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

## Definitions

**Functional or Physical Impairment**: A Functional or Physical or physiological Impairment causes deviation from the normal function of a tissue or organ. This results in a significantly limited, impaired, or delayed capacity to move, coordinate actions, or perform physical activities and is exhibited by difficulties in one or more of the following areas: physical and motor tasks, independent movement, and performance of basic life functions.

**Optimal Medical Therapy**: Treatments that are used as first line before moving to more invasive, risky, or complex procedures (Gibbons and Miller, 2017).

**Osteonecrosis**: Osteonecrosis (also referred to as avascular necrosis, aseptic necrosis, pseudarthrosis, or Kummel disease) is a disease caused by reduced blood flow to bones in the joints. With decreased blood flow, the bone may break down. Known causes of Osteonecrosis are steroid medications, alcohol use, injury, and increased pressure inside the bone. Risk factors are radiation treatment, chemotherapy, and kidney and other organ transplants. Nonsurgical treatments may relieve pain in the short term, but they do not cure the disease (National Institute of Arthritis and Musculoskeletal and Skin Diseases, 2014).

**Vertebral Hemangiomas**: Vertebral Hemangiomas are benign vascular tumors of the bony spine that are usually asymptomatic. A rare subset of them are characterized by extraosseous extension, bone expansion, disturbance of blood flow, and occasionally compression fractures and thereby referred to as aggressive hemangiomas. Aggressive Vertebral Hemangiomas most often occur between the T3 and T9 vertebral segments (Schrock, 2011).

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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



## Description of Services

Percutaneous vertebroplasty is a therapeutic, interventional, radiological procedure that involves injection of an acrylic polymer, such as polymethylmethacrylate, into a vertebral body fracture in an effort to relieve pain and provide stability. This procedure is used primarily for osteoporotic vertebral compression fractures or osteolytic vertebral lesions that are refractory to medical therapy. Medical management of vertebral body fractures can include analgesics, bed rest, and external bracing; however, despite these types of management, progressive kyphosis, prolonged pain, and disability still occur in some individuals. In these individuals, percutaneous vertebroplasty can be used to prevent further collapse of fractured vertebrae and to augment osteoporotic vertebral bodies at risk for fracture.

Kyphoplasty (KP) (also known as balloon-assisted vertebroplasty or vertebral augmentation) is a modification of vertebroplasty. The procedure involves guided insertion of an inflatable bone tamp into the partially collapsed vertebral body. Once in place, the balloon is expanded to the desired height and removed. An acrylic polymer is then injected into the space, where it hardens and binds to the vertebral body. KP is intended to relieve pain and improve function and quality of life by restoring vertebral height and integrity.

The primary difference in the case of KP is that the fracture itself is at least partially reduced by expanding the intrabody space by the use of inflatable bone tamps. Once the compression is reduced to an acceptable degree, the bone cement is then injected. In this way, some of the bony deformity and resulting kyphosis may be reduced, often significantly improving the individual's pain.

Painful vertebral compression fractures may cause a marked decline in physical activity and quality of life, leading to general physical deconditioning. This, in turn, may prompt further complications related to poor inspiratory effort (atelectasis and pneumonia) and venous stasis (deep venous thrombosis and pulmonary embolism). Successful management of painful vertebral compression fractures has the potential for improving quality of life, increasing the expectancy of an independent and/or productive life, and preventing superimposed medical complications (American College of Radiology, 2018).

## Clinical Evidence

There is a broad consensus based on the review of the clinical literature and professional organization that percutaneous vertebral augmentation with the use of vertebroplasty or kyphoplasty is a safe, efficacious, and durable procedure in selected individuals with symptomatic osteoporotic and neoplastic fractures. There is inadequate clinical evidence of safety and/or efficacy in published, peer-reviewed literature for the treatment of other indications.

## Osteoporotic Vertebral Compression Fractures

In a 2025 (revised from 2015) evidence analysis on the Kyphon™ Balloon Kyphoplasty Platform (Medtronic, Dublin, Ireland) for treating vertebral compression fractures (VCFs), ECRI concluded that this system is safe and improves pain, function, and quality of life better than conservative management and, similar to other VCF treatments, at short- and intermediate-term follow-up. Additional randomized controlled trials (RCTs) that compare Kyphon with other kyphoplasty systems and report on longer-term follow-up would be beneficial.

Zhan et al. (2024) conducted a retrospective, 10-year follow-up study to evaluate the long-term outcome of percutaneous kyphoplasty (PKP) for osteoporotic VCFs (OVCFs) and the factors influencing the long-term outcome of this procedure. A total of 91 patients underwent PKP for thoracolumbar OVCFs from June 2012 to December 2012. Pain visual analog scale (VAS) scores and the Oswestry Disability Index (ODI) were recorded prior to the operation and after the 10-year follow-up. Factors that may affect surgical outcome, such as gender, age, height, weight, hypertension, diabetes, cause of injury, fracture segment, length of hospitalization, history of previous spinal surgery, preoperative bone mineral density, preoperative VAS and ODI scores, length of surgery, bone cement dosage, postoperative standardized antiosteoporosis treatment, and other new vertebral fractures, were analyzed by multiple linear regression with VAS and ODI scores at the last follow-up. The correlation factors affecting the efficacy were analyzed. The preoperative and final follow-up pain VAS was 7.9 ±1.1 and 2.2 ±1.1. ODI scores were 30.4 ±4.2 and 10.7 ±2.6. The authors stated that the difference was statistically significant ($p < 0.05$). Most of the patients were female and aged 65 to 75 years who had low-energy injuries, with most of the fracture segments in the thoracolumbar region (T11-L2). At the final follow-up visit, 12 cases (13.19%) developed other new vertebral fractures, and 33 cases (36.26%) continued to adhere to antiosteoporosis treatment after discharge. Multiple linear regression analysis showed that there was a statistical difference between gender and VAS score at the last follow-up ($p < 0.05$) and between age, cause of injury, and postoperative standardized antiosteoporosis treatment and the ODI at the last follow-up ($p < 0.05$). There were no differences between the other factors and the final follow-up VAS and ODI scores ($p > 0.05$). The authors concluded that the long-term outcome after PKP is satisfactory. Age, gender, cause of injury, and standardized postoperative antiosteoporosis treatment may be factors that affected the long-term outcome. This study is limited by its retrospective observations, and not all patients were available for follow-up. General information about the patients was obtained from the medical records of the authors' hospital. Due to confounding factors, there may be inadequate records and possible selection bias by the researchers in the inclusion of case samples, among other effects. At the same time, the comparability of data may be affected by the different operating techniques and experience of the performers. Well-designed, adequately powered, prospective, controlled clinical trials of PKP for OVCFs are needed to further describe safety and clinical outcomes.

Daher et al. (2023) conducted a meta-analysis comparing vertebroplasty and kyphoplasty in the management of OVCFs. Two reviewers determined the eligibility of the studies independently. Eight studies were included in the meta-analysis. The clinical outcomes consisted of the complications (cement leakage and adjacent-level fractures), VAS scores, ODI, kyphotic wedge angle, and vertebral body height restoration. Kyphoplasty was shown to be superior to vertebroplasty in terms of reducing cement leakage and increasing postoperative vertebral body height. The comparison of the rest of the outcomes was statistically insignificant between both techniques. The authors concluded that although kyphoplasty could significantly increase postoperative vertebral body height and decrease the risk of cement leakage, the fact that it is more costly and has a longer operative time raises the question about the cost effectiveness of the procedure. This study has limitations, including the small number of studies and inconsistent inclusion and exclusion criteria.

Liu et al. (2023) conducted a systematic review and meta-analysis aimed to compare surgical methods for OVCF using a systematic review and network meta-analysis to understand effectiveness and outcomes, as current research provides limited overviews. The authors followed PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines, preregistering protocol with PROSPERO. English-published RCTs in adults with OVCFs that evaluated pain intensity or functionality using tools like the VAS or ODI were analyzed. Exclusions included non-RCTs, malignancy-related fractures, and certain interventions. Using the RoB 2 tool, bias and visualized results with Robvis were assessed. The primary outcome was pain intensity, with secondary outcomes that included disability, new fractures, and cement leakage. Results were synthesized using Stata/MP. Overall, 34 RCTs from 10 countries, totaling 4,384 individuals, were analyzed. Short-term VAS indicated kyphoplasty with facet joint injection (KIJ) as the top treatment at 87.7%, while unipedicular kyphoplasty (UKP) led to long term at 74.9%. The short-term ODI favored vertebroplasty with facet joint injection (VIJ) at 98.4%, with kyphoplasty leading long term at 66.0%. All surgical techniques were superior to conservative treatment. Vertebral augmentation devices reported the fewest new fractures, and curved vertebroplasty had the least cement leakage. SUCRA (surface under the cumulative ranking) analyses suggested UKP and VIJ as top choices for postoperative pain relief, with VIJ excelling in postoperative disability improvement. The authors concluded that their analysis evaluated 12 OVCF interventions, underscoring kyphoplasty with facet joint injection for short-term pain relief and VIJ and UKP for long-term efficacy. Notably, VIJ stands out in disability outcomes, emphasizing the need for comprehensive OVCF management. This study has a systematic review, and the meta-analysis has several limitations.

The underreporting of detailed characteristics of individuals and their respective protocols of treatment related to OVCF in the included studies altered the choices of treatment and could make this vary between studies. Moreover, information on fracture types, severity, and duration, which are pivotal for tailoring treatment modalities and predicting outcomes, was inconsistently documented. This lack of granularity limits the depth of the analysis and the generalizability of findings. Further research is needed to determine the clinical relevance of these findings.

Qiu et al. (2023) performed a systematic review and meta-analysis to investigate the effect of vertebral augmentation in the treatment of single-level OVCFs on new vertebral fractures. Eligible studies used vertebral augmentation as an intervention and conservative treatment as a control group. Studies explicitly reported whether new vertebral fractures occurred during follow-up. Data were extracted by multiple investigators. Data were pooled using random- or fixed-effects models depending on the degree of heterogeneity. Of the 682 articles screened, seven met the inclusion criteria and were included in the analysis, giving a total of 1,240 individuals. Meta-analysis showed that vertebral augmentation [odds ratio (OR), 2.10; 95% CI, 1.35-3.28; p = 0.001] increased the risk of new postoperative vertebral fractures compared with conservative treatment. Subgroup analyses showed that the risk was greater in the group with a follow-up time of greater than 1 year (OR, 2.57; 95% CI, 1.06-6.26; p = 0.001). Compared with conservative treatment, vertebral augmentation (OR, 2.17; 95% CI, 1.23-3.82; p = 0.007) increased the risk of postoperative adjacent vertebral fracture. The authors concluded that vertebral augmentation is associated with an increased risk of new vertebral fractures and adjacent vertebral fractures following single-level OVCFs. With longer follow-ups, new vertebral fractures may be more significant. Clinical surgeons should pay attention to long-term postoperative complications and choose treatment carefully. This systematic review has several limitations, including the low number of relevant studies. Data from RCTs and cohort studies were combined for analysis, and these may have resulted in distorted results. The Newcastle-Ottawa Scale has limitations in assessing the internal validity of the study. In addition, some of the included studies did not report baseline characteristics such as comorbidities, specific surgical procedures, cement distribution, and postoperative complications. The findings of this study need to be validated by well-designed studies. Further investigation is needed before the clinical usefulness of this procedure is proven.

Cheng et al. (2022) conducted a retrospective study aimed to analyze the risk factors of new VCF after percutaneous vertebroplasty (PVP) or PKP. From August 2019 to March 2021, the authors retrospectively analyzed patients who underwent PVP or PKP for OVCF at their institution. Age, gender, body mass index (BMI), smoking, drinking, hypertension, diabetes, fracture location, surgical method, Hounsfield unit (HU) value, preoperative degree of anterior vertebral compression, bisphosphonates, bone cement volume, bone cement leakage, and cement distribution were collected. The risk factors were obtained by univariate and multivariate analysis of the data. A total of 247 patients were included in the study. There were 23 (9.3%) with new VCF after PVP or PKP. Univariate analysis showed that age ($p < 0.001$), BMI ($p = 0.002$), fracture location ($p = 0.030$), and a low HU value ($p < 0.001$) were associated with new VCF after PVP or PKP. A low HU value was an independent risk factor for new VCF after PVP or PKP, obtained by multivariate regression analysis (OR, 0.963; 95% CI, 0.943-0.984; p = 0.001). The authors concluded that in this study, a low HU value was an independent risk factor of new VCF after PVP or PKP.

Joyce et al. (2022) conducted a retrospective study to evaluate surgical vs. nonsurgical treatment of 100 patients who were followed up for up to 6 years and diagnosed with severe OVCFs. Fractures were classified by percent collapse of vertebral body height as high-degree fractures (HDFs) (> 50%) or vertebra plana (> 70%). A total of 310 patients with VCF were reviewed, with 110 severe fractures identified in 100. The HDF group was composed of 47 patients, with a total of 50 fractures. The vertebra plana group was composed of 53 patients, with a total of 60 fractures. Surgical intervention was performed in 59, comprising entirely percutaneous vertebral cement augmentation procedures, including vertebroplasty, balloon kyphoplasty (BKP), or cement with expandable titanium implants. The remaining 41 underwent conservative treatment. All procedures were performed as an outpatient procedure under local anesthesia, with minimal sedation, and there were no procedural complications. The initial or preprocedural VAS score averaged 8.4 in all patients, with the surgical treatment group having the most marked drop in VAS, averaging 4 points. This efficacy was achieved to a greater degree in surgically treated vertebra plana fractures compared with HDFs. Nonsurgical patients persisted with the most pain in both the short- and long-term follow-up. This large series, with a follow-up of up to 6 years, demonstrated that the more severe fractures responded well to different percutaneous cement augmentation procedures, with reduction of pain without increased complications compared with conservatively treated patients.

An updated Hayes Health Technology Assessment reported on PKP for OVCFs. The report included 10 studies: six RCTs (eight publications), one quasi-RCT, and three database studies. The sample size was 59 to 1,038,956 individuals with VCFs due to osteoporosis, with a 6-month to 4-year follow-up. The authors concluded that there is moderate-quality evidence that kyphoplasty may be beneficial in some individuals with a VCF due to osteoporosis who have not responded to conservative treatment. There is consistent evidence that kyphoplasty and vertebroplasty provide similar improvements in pain, disability, and quality of life from baseline. There is limited evidence that kyphoplasty is favored over conservative treatment for pain relief. Large, fair-quality database analyses offer limited but consistent evidence of lower mortality risk

in individuals treated with kyphoplasty compared with those treated with vertebroplasty. In addition, limited evidence from these database studies suggest that vertebroplasty is associated with a higher risk for some postoperative complications (e.g., pulmonary embolism, deep vein thrombosis, pneumonia) (Hayes, 2017; updated 2021).

Otsuka et al. (2021) completed a single-center retrospective analysis to identify predictors of outcome after BKP in patients with OVCF. Between January 2001 and December 2019, 152 patients underwent BKP for painful OVCFs at the National Cerebral and Cardiovascular Center Hospital in Osaka, Japan. This study included 115 patients who were followed up for > 12 months, and their data were retrospectively analyzed. Regarding the degree of independent living 1 year after BKP, patients were divided into a good outcome group (composed of those who could independently go indoors) and a poor outcome group. The authors analyzed factors associated with outcome and subsequent OVCF. The mean age of patients was 77.9 years, 58.2% were female, 81% had a good outcome, and 19% had a poor outcome. A univariable analysis revealed significant differences in age, bone mineral density, preoperative vertebral body decompression rate, BMI, preoperative Japanese Orthopaedic Association score, preoperative modified Rankin Scale score, and subsequent OVCF. A multivariable logistic analysis showed that a low BMI (OR, 1.415; 95% CI, 1.06-1.87; p = 0.046) and subsequent OVCF (OR, 0.13; 95% CI, 0.02-0.69; p = 0.044) were independent risk factors. The incidence of subsequent OVCF was also lower among patients with a higher BMI (OR, 0.83; 95% CI, 0.72-0.95; p = 0.001). BMI and subsequent OVCF are the most influential predictors of independent living 1 year after BKP for OVCF.

A 2016 Hayes Health Technology Assessment, updated in 2021, reviewed the comparative effectiveness of PVP vs. sham, conservative treatment, or kyphoplasty for OVCFs. The evidence comprised 19 studies: 15 RCTs, one quasi-RCT, and three database studies. The sample sizes were 49 to 1,038,956 individuals with VCFs due to osteoporosis, with a follow-up of 6 months to 4 years. The authors reported that moderate-quality evidence found that in individuals with acute pain, pain relief was better with vertebroplasty vs. sham or conservative treatment in four of 10 studies and was similar to comparators (sham, facet block, or kyphoplasty) in six of 10 studies. In individuals with chronic pain, vertebroplasty was favored over conservative treatment in three of five studies, was equivocal relative to sham in one, and was similar to kyphoplasty in one of five studies. Findings were generally similar for disability and quality of life. The most reported adverse events across studies were the occurrence of additional VCFs following treatment and cement leakage. The 2021 annual review included two new key studies, with no change to the evidence or conclusion.

Li et al. (2021) performed a systematic review and meta-analysis comparing the safety and efficacy of vertebral augmentation with those of nonsurgical management (NSM) for the treatment of OVCFs. The study included 20 RCTs, which involved 2,566 individuals with painful OVCFs. There were no significant differences between PVP and the sham procedure VAS scores at most time points during the follow-up period. In a subgroup analysis based on fracture type and fracture location, significant differences in the VAS were found between PVP and conservative treatment and were not found between PVP and the sham procedure. In a subgroup analysis of duration of back pain, significant differences were found between PVP and conservative treatment in the VAS at 1 week, 3 months, and 1 year. The differences in the VAS were not significant between PVP and conservative treatment at 1 month and 6 months. The authors concluded that vertebral augmentation is safe and effective for the treatment of painful OVCFs, with good clinical outcomes compared with those in individuals undergoing conservative NSM. (Authors Berenson et al., 2011, Boonen et al., 2011, Blasco et al., 2012, Chen et al., 2014, Farrokhi et al., 2011, Firanescu et al., 2018, Kallmes et al., 2009, and Klazen et al., 2010, previously cited in this policy, are included in this systematic and meta-analysis review.)

Hinde et al. (2020) performed a systematic review and meta-analysis comparing mortality benefits in individuals with OVCFs who had undergone vertebral augmentation vs. those who received NSM. A total of 16 studies, including more than 2 million individuals with OVCF (vertebral augmentation = 382,070; NSM = 1,707,874), were included in the review. Only seven studies were included in the meta-analysis. Results showed hazard ratios (HRs) for mortality benefit for vertebral augmentation vs. NSM over a 2- and 5-year period as 0.78 (p < 0.001) and 0.79 (p = 0.05). The pooled HR for mortality comparing vertebral augmentation with conservative management was 0.78 (p = 0.003) at up to 10 years. BKP provided a mortality benefit over vertebral augmentation, with an HR of 0.77 vs. 8.87 (p < 0.001). The authors concluded that vertebral augmentation offers survival benefits when treating OVCFs and should be offered in carefully selected individuals as a best clinical practice. Individuals with OVCFs who underwent vertebral augmentation were 22% less likely to die at up to 10 years after treatment than those who received nonsurgical treatment.

Wei et al. (2020) performed a systematic review and meta-analysis to compare the clinical outcomes of PVP vs. those of PKP for the treatment of OVCFs with intravertebral cleft. The review included 688 individuals in nine studies: 378 individuals were treated with PVP, and 310 individuals were treated with PKP. The authors stated that the results indicated no significant differences between the two groups in the short- and long-term VAS, ODI, local kyphotic angle, or rate of vertebral height (p > 0.05). PKP was associated with significantly longer operation time, higher cost, and more injected cement volume. PKP had a lower risk of cement leakage. There was no significant difference in adjacent-level

fracture rates. The authors concluded that both PVP and PKP are safe and effective minimally invasive options for the treatment of OVCFs.

Beall et al. (2019) conducted a prospective, phase 4, open-label, multicenter, 12-month clinical study to investigate 12-month disability, quality of life, and safety outcomes, specifically in a Medicare-eligible population, representing characteristic individuals seen in routine clinical practice. A total of 354 participants with painful VCFs were enrolled at 24 U.S. sites, with 350 undergoing kyphoplasty. Four coprimary endpoints, including the numeric rating scale back pain, ODI, Short Form-36 Questionnaire Physical Component Summary (SF-36v2 PCS), and EuroQol-5-Domain (EQ-5D), were evaluated for statistical improvement 3 months after kyphoplasty. Data were collected at baseline, 7 days, and 1, 3, 6, and 12 months (www.ClinicalTrials.gov registration: NCT01871519). At the 3-month primary end point, the numeric rating scale improved from 8.7 to 2.7, and the ODI improved from 63.4 to 27.1; the SF-36 PCS was 24.2 at baseline, improving to 36.6, and the EQ-5D improved from 0.383 to 0.746 ($p < 0.001$ for each). Five device-/procedure-related adverse events, intraoperative asymptomatic balloon rupture, rib pain, and aspiration pneumonia, as well as a new VCF 25 days post procedure and myocardial infarction 105 days post procedure were reported, and each resolved with proper treatment. The authors concluded that this large, prospective clinical study demonstrates that kyphoplasty is a safe, effective, and durable procedure for treating individuals with painful VCF due to osteoporosis or cancer.

Cheng et al. (2019) conducted a retrospective cohort study to compare PVP and BKP for their effectiveness and safety in the treatment of newly onset OVCFs. Patients with a confirmed diagnosis of newly onset OVCF who were treated between January 2008 and December 2016 were retrospectively included in the study. Patients were divided into two groups according to the surgical treatment that they received. They were followed up for 12 months after surgery by outpatient visits and phone interviews. Changes in VAS and ODI scores, quantity of injected bone cement, cost of treatment, changes in the height of the vertebra, incidence of complications such as bone cement leakage, and adjacent-level vertebral fracture during follow-up and total were compared between the two groups. A total of 338 patients were included in the final analysis. Demographic characteristics were similar in the two groups. There were no differences between the two groups concerning VAS and ODI scores after the surgery and at the last follow-up ($p > 0.05$). However, the total cost of treatment, quantity of injected bone cement, incidence of adjacent-level fracture, restored vertebral height, and loss of vertebral body height at the last follow-up were higher in the BKP group than the vertebroplasty group ($p < 0.05$). Considering the similar key outcome parameters such as VAS and ODI scores and more cost of BKP, vertebroplasty can be prioritized over BKP in the treatment of individuals with newly onset OVCF.

Liu et al. (2019) performed an RCT to assess the effect of BKP on elderly participants with multiple osteoporotic vertebral fractures. The observation group was treated with BKP, and the control group was managed with conservative treatment. Image indices, pain degree, daily life disturbance, and occurrences of complications were compared between the two groups. Overall, 116 elderly participants with multiple osteoporotic vertebral fractures were divided randomly into observation (n = 58) and control groups (n = 58). The observation group showed a significantly higher trailing edge, leading edge, and midcourt line and larger upper thoracic kyphosis than the control group. Before the treatment, no statistically significant differences were observed between the two groups in terms of VAS score and daily life disturbance score. VAS score and daily life disturbance score in the two groups decreased sharply after the treatment. Moreover, VAS score and daily life disturbance score in the observation group were significantly lower than those in the control group. The observation group showed a lower occurrence rate of complications than the control group. The authors concluded that BKP can significantly improve the image indices in individuals with multiple osteoporotic vertebral fractures and relieve their pain degree and daily life disturbance. BKP exhibited a low occurrence rate of complications and high safety.

A pilot monocenter prospective study (Noriega et al., 2019) in 30 participants with painful OVCFs compared two vertebral augmentation procedures. Participants were randomized to SpineJack® (n = 15) or BKP (n = 15). The clinical end points were analgesic consumption, back pain intensity (VAS), the ODI, and quality of life (EQ-VAS score). They were recorded prior to the operation, at 5 days (except EQ-VAS), and 1, 3, 6, 12, and 36 months post surgery. Spine x-rays were taken 48 hours prior to the procedure and at 5 days and 6, 12, and 36 months after. Over a 3-year post surgery follow-up, pain/disability/quality of life remained significantly improved with both BKP and SpineJack techniques, but the latter allowed better vertebral body height restoration/kyphosis correction. Preliminary results showed that SpineJack resulted in a better restoration of vertebral heights and angles, which was maintained over 12 months.

Buchbinder et al. (2018) conducted a Cochrane review in order to update the clinical evidence on the benefits and harms of vertebroplasty for the treatment of osteoporotic vertebral fractures. RCTs in adults with painful osteoporotic vertebral fractures, comparing vertebroplasty with placebo (sham), usual care, or another intervention, were included. As it is least prone to bias, vertebroplasty compared with placebo was the primary comparison. Major outcomes were 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. Based on high- to moderate-quality evidence, the authors' updated review does not support a role for vertebroplasty for treating acute or subacute

osteoporotic vertebral fractures in routine practice. The authors found no demonstrable clinically important benefits compared with placebo (sham procedure), and subgroup analyses indicated that the results did not differ according to a duration of pain of ≤ 6 weeks vs. > 6 weeks. Sensitivity analyses confirmed that open trials comparing vertebroplasty with usual care are likely to have overestimated any benefit of vertebroplasty. Numerous serious adverse events have been observed following vertebroplasty. Due to the small number of events, they stated that they could not be certain about whether or not vertebroplasty results in a clinically important increased risk of new, symptomatic vertebral fractures and/or other serious adverse events. In the authors' opinion, individuals should be informed about both the high- to moderate-quality evidence that shows no important benefit of vertebroplasty and its potential for harm.

Pourtaheri et al. (2018) conducted a systematic review and meta-analysis to assess (1) the clinical outcomes with and without vertebral augmentation for OVCFs with vs. without correlating signs and symptoms and (2) acute (symptoms < 3-month duration) and subacute VCFs (3-6 month duration) vs. chronic VCFs (> 6 months). Thirteen studies, totaling 1,467 individuals with a minimum 6-month follow-up, were found. Pain reduction was greater with vertebral augmentation over conservative management for symptomatic VCFs and equivalent for radiographic-alone VCFs. A subanalysis for acute/subacute symptomatic VCFs and chronic symptomatic VCFs showed that vertebral augmentation was superior to nonoperative care. No difference was observed in outcomes between vertebral augmentation and nonoperative care for chronic radiographic-alone VCF. The authors concluded that vertebral augmentation is superior to nonoperative care in reducing lower back pain for OVCFs with correlating signs and symptoms. Vertebral augmentation had no benefit over nonoperative care for chronic VCFs that lacked clinical correlation. The authors also noted that lower back pain has many etiologies, and individuals should be clinically assessed before recommending vertebral augmentation.

Wang and colleagues (2018) completed a systematic review and meta-analysis, which included a total of 16 studies and was aimed at exploring the overall safety and efficacy of BKP vs. those of PVP for OVCF. The qualified studies included RCTs (n = 1), prospective or retrospective comparative studies, and cohort studies. The results indicated that kyphoplasty significantly decreased the kyphotic wedge angle [standardized mean difference (SMD), 0.98; 95% CI, 0.40-1.57], increased the postoperative vertebral body height (SMD, -1.27; 95% CI, -1.86 to -0.67), and decreased the risk of cement leakage (relative risk, 0.62; 95% CI, 0.47-0.80) compared with vertebroplasty. However, there was no statistical difference in VAS scores (weighted mean difference, 0.04; 95% CI, -0.28 to 0.36) and ODI scores (weighted mean difference, -1.30; 95% CI, -3.34 to 0.74) between the two groups. The authors concluded that kyphoplasty contributes especially to decreasing the mean difference of kyphotic wedge angle and risk of cement leakage and increasing the vertebral body height compared with vertebroplasty. However, radiographic differences did not significantly influence the clinical results (no significant difference was observed in VAS scores and ODI scores between the two groups); thus, kyphoplasty and PVP are equally effective in the clinical outcomes of OVCF. Furthermore, the authors indicated that more high-quality, multicenter RCTs, with a larger sample size and longer follow-up, are warranted to confirm the current findings. The findings are limited by inclusion of mostly observational studies.

A systematic review and network meta-analysis was conducted by Zuo et al. (2018). RCTs compared PVP, PKP, nerve block (NB), or conservative treatment for treating OVCFs. A total of 18 trials among 1,994 individuals were included. PKP was the first option in alleviating pain in the case of the acute/subacute OVCFs for the long term and chronic OVCFs for the short term and long term, while PVP had the most superiority in the case of the acute/subacute OVCFs for the short term. NB ranked higher probability than PKP and PVP on acute/subacute OVCFs in the short and long term, respectively. The authors concluded that the results suggest that percutaneous vertebral augmentation (PVP/PKP) had better performance than conservative treatment in alleviating acute/subacute and chronic OVCF pain for the short and long term and that NB may be used as an alternative or before percutaneous vertebral augmentation for pain relief. The findings are limited by the inherent indirectness of network meta-analyses. (Authors Evans et al., 2016, Farrokhi et al., 2011, Klazen et al., 2010, and Wang, 2016, previously cited in this policy, are included in this systematic review.)

## Osteolytic Metastatic Disease Involving a Vertebral Body

Zhan et al. (2024) conducted a retrospective cohort study to evaluate the clinical safety and efficacy of PVP combined with bone-filling mesh containers (BFMCs) for vertebral metastases with posterior wall defect. From January 2019 to December 2021, 43 patients with vertebral metastases and posterior wall defect who received BFMCs combined with PVP were included. VAS scores and ODI scores were evaluated before and 72 hours after the operation, respectively. Post operational x-ray and computed tomography scans were conducted to observe bone cement leakage, and complications were recorded. Follow-up computed tomography and magnetic resonance imaging were conducted to evaluate the condition of the operated vertebrae and the recurrence or progression of other bone metastases. A total of 43 patients, with 44 operated vertebrae, were included. All patients successfully completed the surgery. The average VAS score decreased from 7.35 ±0.78 to 1.63 ±0.93 ($p < 0.05$), and ODI score decreased from 80.06 ±8.91 to 32.5 ±4.87 ($p < 0.05$). Bone cement leakage was observed in 18 operated vertebrae, which were all asymptomatic. No intraspinal leakage, postoperative spinal nerve compression, pulmonary embolism, or other serious complications were recorded. A

total of 21 patients had a follow-up of more than 1 year, with no operated vertebral progression; 13 target vertebrae showed obvious sclerosis and necrosis, and no adjacent pathological fracture occurred. Of these patients, 16 had different degrees of bone metastasis of other sites other than the operated vertebrae. The authors concluded that for spinal metastases with posterior wall defect, PVP combined with BFMCs was highly safe and can effectively relieve pain for individuals. A 1-year follow-up showed a local antitumor effect.

Zhang et al. (2024) conducted a retrospective study aimed to analyze the effectiveness of microwave ablation combined with decompression and pedicle screw fixation in the palliative management of spinal metastases with pathological fractures. This retrospective study enrolled 82 patients with spinal metastases and pathological fractures, with 44 patients undergoing pedicle screw fixation along with laminectomy (fixation group), and the remaining 38 receiving microwave ablation in addition to the treatment provided to group fixation (MWA group). Before surgery, all patients underwent pain assessment using the VAS and evaluation of spinal cord injury using the Frankel classification. After surgery, the patients' prognoses were assessed using the Tomita score, modified Tokuhashi score system, and progression-free survival. Additionally, the authors compared operative time and blood loss between the two groups. Survival analysis used the Kaplan-Meier method with a log-rank test for group comparisons. Paired t tests and the Mann-Whitney U test were applied to metric and non-normally distributed data, respectively. Neurological function improvement across groups was evaluated using the $\chi 2$ test. All patients were followed up for a median duration of 18 and 20 months in the fixation and MWA groups, respectively, with follow-up periods ranging from 6 to 36 months. Reductions in postoperative VAS scores were observed in all patients compared with their preoperative scores. The MWA group exhibited reduced blood loss ($T = 2.74$; $p = 0.01$), lower VAS scores at the 1- and 3-month follow-ups ($T = 2.34$, $p = 0.02$; $T = 2.83$, $p = 0.006$), and longer progression-free survival than the fixation group ($p = 0.03$). Although the operation times in the MWA group were longer than those in the fixation group, this difference was not statistically significant ($T = 6.06$; $p = 0.12$). No statistically significant differences were found regarding improvements in spinal cord function between the two groups ($p = 0.77$). The authors concluded that when compared with decompression and pedicle screw fixation for treating spinal metastases with pathological fractures, microwave ablation combined with decompression and pedicle screw fixation showed better outcomes in terms of pain control, longer progression-free survival, and lower blood loss, without increasing operative time, which has favorable implications for clinical practice.

Shamhoot et al. (2022) performed a retrospective clinical case series study to evaluate the outcome of PVP of more than two multilevel osteoporotic and malignant fractures. This study was conducted in 30 patients. The VAS was used to evaluate the functional outcome. All patients were treated using PVP. They were followed up for 6 months post operation. The functional state of all patients improved after PVP. According to the VAS, the preoperative VAS score was (8.43 ±1.19). The immediate postoperative VAS was (3.07 ±1.20), and after 6 months it dropped to (1.13 ±0.67). There was noted improvement of pain ($p < 0.001$). Asymptomatic leakage in the disc space was reported in two patients. A single case of pulmonary embolism was seen in a patient who reported dyspnea. This patient was admitted to the intensive care unit and managed with proper medications, with satisfactory results. The authors concluded that multilevel PVP is proven to be a safe, cost-effective, and successful procedure that could reduce pain and improve individuals' mobility.

Wu et al. (2022) completed a retrospective study. From February 2017 to January 2020, a total of 31 patients, with 58 osteoblastic-related metastatic vertebral lesions, who underwent PKP were enrolled in this retrospective study. Among them, 12 were pure osteoblastic lesions, and 19 were mixed lesions. The clinical efficacy was assessed based on parameters, including the VAS, ODI, vertebral body height variation, and quality of life. Major and minor complications were systematically evaluated to assess the safety of the procedure. The average follow-up period was 22.5 ±11.1 months (range, 3-46 months). The procedure duration time ranged from 50 to 180 minutes (average, 96.8 ±36.9 minutes). The mean VAS scores decreased significantly from 6.1 ±1.8 prior to the operation to 2.7 ±1.5 at 3 days after PKP ($p < 0.001$) and remained largely immutable at 1 month (2.0 ±0.7; 31 patients; $p < 0.001$), 3 months (2.4 ±1.2; 30 patients; $p < 0.001$), and 1 year (3.0 ±1.0; 27 patients; $p < 0.001$). ODI scores and vertebral body height variation also changed after the procedure, with significant differences between preoperative scores and at each follow-up examination ($p < 0.001$). Mean quality-of-life scores were 90.8 ±12.9 prior to the operation and improved to 99.5 ±12.1 (27 patients; $p < 0.001$) at 1 year after PKP. The only minor encountered complication was bone cement leakage, which was seen in 6.5% (two of 31) of patients. None of the patients experienced major complications. The authors concluded that PKP is a safe and effective treatment strategy for osteoblastic-related metastatic vertebral lesions from a variety of tumor etiologies.

Astur and Aanzi conducted a systematic review (2019) of RCTs to assess the efficacy of kyphoplasty in controlling pain and improving quality of life in oncological individuals with metastatic spinal disease and pathological compression fractures of the spine. After a literature search through medical databases, two studies, with a combined total of 181 individuals, met the inclusion criteria. A meta-analysis was not possible due to data heterogeneity, and individual analysis of studies was performed. There was moderate evidence that individuals treated with BKP displayed better scores for pain (numeric rating scale), disability (Roland-Morris Disability Questionnaire), quality of life (SF-36 Health Survey), and functional status (Karnofsky Performance Status) than those undergoing conventional treatment. Individuals treated with

kyphoplasty also had better recovery of vertebral height. The authors concluded that although BKP could be considered as an early treatment option for individuals with symptomatic neoplastic spinal disease, further randomized clinical trials should be performed for improvement of the quality of evidence. (Authors Berenson et al., 2011, previously cited in this policy, are included in this systematic review.)

Sorensen et al. (2019) performed a systematic review evaluating the effectiveness and safety of vertebral augmentation for malignant VCFs. Studies on PVP or PKP for VCFs in individuals with malignant spinal lesions were reviewed. The review identified two RCTs, 16 prospective studies, 44 retrospective studies, and 25 case series for a sample size comprising 3,426 individuals. At the earliest follow-up, pain improved from 7.48 to 3.00 with PVP and from 7.05 to 2.96 with PKP. The ODI improved from 74.68 to 17.73 with PVP and from 66.02 to 34.73 with PKP. Karnofsky Performance Score (KPS) improved from 66.99 to 80.28. Cement leakage was seen in 37.9% and 13.6% of individuals treated with PVP and PKP, respectively. Symptomatic complications (n = 43) were rare. The authors concluded that the review showed clinically relevant improvements in pain, the ODI, and KPS in individuals with VCFs due to malignancy treated with either PVP or PKP. Cement leakage is common but rarely symptomatic. The authors concluded that PVP and PKP are safe and effective palliative procedures for painful VCFs in individuals with malignant spinal lesions. (Authors Anselmetti et al., 2012, Berenson et al., 2011, Farrokhi et al., 2012, and Sun et al., 2014, previously cited in this policy, are included in this systematic review.)

A systematic review was conducted by Sadeghi-Naini et al. (2018) to assess the effects of vertebroplasty and kyphoplasty compared with each other, usual care, or other treatments on pain, disability, and quality of life following metastatic spinal lesions (MSLs). Nine trials were included in the qualitative analysis. In total, there were 622 individuals enrolled in the trials, and of them, 432 were in the surgical treatment group (92 received kyphoplasty, 97 received vertebroplasty, 134 received vertebroplasty and chemotherapy, 68 received vertebroplasty and radiotherapy, and 41 received Kiva implant), and 190 were in the nonsurgical treatment group (83 received chemotherapy, 46 received radiotherapy, and 61 received other treatment). Using the Grading of Recommendations Assessment, Development, and Evaluation approach, pain (low-quality evidence) and functional scores (very low-quality evidence) improved more with vertebroplasty plus chemotherapy than with chemotherapy alone. Kyphoplasty seemed to lead to significantly greater improvement in pain, disability, and health-related quality of life than NSM. Vertebroplasty plus Iodine-125 seemed to lead to a significantly greater improvement in pain and disability than vertebroplasty alone. Vertebroplasty plus radiochemotherapy resulted in better pain relief and health-related quality of life post operation than routine radiochemotherapy. The authors concluded that there is low-quality evidence to prove that surgical treatment significantly decreases pain and improves functional score and health-related quality of life following MSL compared with NSM. Based on the analysis of currently published trial data, it is unclear whether vertebroplasty for MSL provides benefits over kyphoplasty.

Qi et al. (2016) conducted a meta-analysis to evaluate the function of PVP treatment in pain relief and life quality in individuals with spinal tumors. Overall, 26 studies, involving 1,351 individuals, met the selection criteria. Meta-analysis results among 10 case-control studies showed that the combined HR was -2.83 (95% CI, -2.92 to -2.73; $p < 0.0001$), indicating a 2.83-fold decrease in pain in the PVP group. In 12 single-arm studies, a significant decrease in pain after PVP treatment (HR , -4.79; 95% CI, -5.00 to -4.57; $p < 0.0001$) was also found in the PVP group. In addition, for KPS analysis, the combined HR was 16.31 (95% CI, 14.31-18.31; $p < 0.0001$), which indicated that PVP treatment was associated with a 16.31-fold increase in KPS. The combined HR was 0.58 (95% CI, 0.35-0.96; $p = 0.04$) for complication analysis. The authors concluded that PVP treatment of spinal tumors is significantly associated with better pain relief and life quality, which could improve the outcome in individuals with metastatic spinal tumor.

## Multiple Myeloma Involving a Vertebral Body

Reinas et al. (2021) conducted a retrospective study to evaluate minimally invasive spine surgery (MISS) techniques to treat patients presenting with spine fractures due to MM. A retrospective analysis included consecutive patients with histology-proven pathological fractures caused by MM treated with MISS between 2009 and 2018. Data from the clinical records on epidemiology, topography of spine lesions, surgical techniques, blood loss, operation time, complications, mean in-hospital time, and clinical evolution were collected. Overall, 21 patients were studied, including 13 who were male and eight who were female, with a mean age of 64 years (range, 43-83 years). The mean preoperative spinal instability neoplastic score was 9.8 ±6 (range, 5-16). All cases had a thoracolumbar location; 15 patients underwent kyphoplasty or vertebroplasty, and six were treated with other more complex procedures. All patients had a reduction of pain and/or analgesic load. Vertebral body height increased by a mean of 2.9 mm after vertebroplasty/kyphoplasty. The mean hospital stay was 1.3 days for kyphoplasty/vertebroplasty and 5.0 days for other MISS procedures. Three patients had complications. The heterogeneity of techniques used reflected the variety of spine involvement by MM. The authors concluded that kyphoplasty and vertebroplasty led to shorter hospital stays and less complications, being adequate for lesions without major instability. More complex MISS techniques offer an effective treatment, with a short delay for starting

MM adjuvant treatment. The retrospective nature of the study and lack of a control group submitted to non-MISS techniques limit the strength of the conclusions.

Nas et al. (2016) conducted a retrospective analysis to assess the effectiveness, benefits, and reliability of PVP in patients with vertebral involvement of MM. PVP procedures performed on 166 vertebrae of 41 patients with MM were retrospectively evaluated. Most patients were using level 3 (moderate to severe pain) analgesics. Magnetic resonance imaging was performed before the procedure to assess the vertebral involvement of MM. The following variables were evaluated: the affected vertebral levels, loss of vertebral body height, polymethylmethacrylate (PMMA) cement amount applied to the vertebral body during PVP, PMMA cement leakages, and pain before and after PVP, as assessed by a VAS. Median VAS scores in patients decreased from 9 one day before PVP, to 6 one day after the procedure, to 3 one week after the procedure, and eventually to 1 three months after the procedure ($p < 0.001$). During the PVP procedure, cement leakage was observed at 68 vertebral levels (41%). The median value of PMMA applied to the vertebral body was 6 mL. The authors concluded that being a minimally invasive and easily performed procedure with low complication rates, PVP should be preferred for serious back pain in individuals with MM.

In a systematic review, Health Quality Ontario (2016) evaluated the effectiveness and safety of percutaneous image-guided vertebral augmentation techniques, vertebroplasty, and kyphoplasty for palliation of cancer-related VCFs. Due to the heterogeneity of the clinical reports, the authors performed a narrative synthesis based on an analytical framework constructed for the type of cancer-related vertebral fractures and the diversity of the vertebral augmentation interventions. Overall, 111 clinical reports (4,235 individuals) were evaluated to determine the effectiveness of vertebroplasty (78 reports, 2,545 individuals) or kyphoplasty (33 reports, 1,690 individuals) in individuals with mixed primary spinal metastatic cancers, MM, or hemangiomas. Overall, the mean pain intensity scores, often reported within 48 hours of vertebral augmentation (kyphoplasty or vertebroplasty), were significantly reduced. Analgesic use, although variably reported, usually involved parallel decreases, particularly in opioids, and mean pain-related disability scores were also significantly improved. In an RCT comparing kyphoplasty with usual care, improvements in pain scores, pain-related disability, and health-related quality of life were significantly better in the kyphoplasty group than in the usual-care group. Bone cement leakage, mostly asymptomatic, was commonly reported after vertebroplasty and kyphoplasty. However, major adverse events were uncommon. The authors concluded that both vertebroplasty and kyphoplasty significantly and rapidly reduced pain intensity in individuals with cancer with VCFs. The procedures also significantly decreased the need for opioid pain medication and functional disabilities related to back and neck pain. Pain palliative improvements and low complication rates were consistent across the various cancer populations and vertebral fractures that were investigated.

In a retrospective observational study, Burton et al. (2011) evaluated outcomes in patients with cancer with painful VCFs treated with either PVP or kyphoplasty. A total of 407 patients with cancer had 1,156 fractures that had been treated with PVP or kyphoplasty; the majority of patients had pathological fractures due to MM or had osteoporotic fractures. The authors reported that surgery provided significant relief from pain and several related symptoms. Symptomatic, serious complications requiring open surgery occurred in two cases (< 0.01%). The authors concluded that the use of vertebroplasty or kyphoplasty in treating painful VCFs in individuals with cancer has good efficacy and an acceptably low complication rate. The findings are limited by the lack of a comparison group, without surgical intervention, and the observational design of the study.

## Vertebral Hemangioma With Aggressive Features

Nambiar et al. (2020) conducted a retrospective, multicenter cohort study to evaluate PVP for the treatment of symptomatic vertebral hemangioma. The study included 50 patients with painful vertebral hemangiomas who were treated with PVP by a single provider over a 14-year period (March 1999 to April 2013). There was a minimum 1-year follow-up. Two patients had recurrent symptoms and repeat vertebroplasty. The preintervention VAS score was 7.0, and the mean postintervention VAS at 1 year was 0.3. The mean reduction in VAS score was 6.8 points. All patients experienced pain relief following PVP, with 39 cases (74%) reporting complete pain relief. There were no cases of symptomatic cement leak and no cases of procedural morbidity or mortality. The authors concluded that PVP is a safe and effective treatment of symptomatic vertebral hemangioma, with a low risk of complication.

In a case series of surgical treatments for aggressive vertebral hemangiomas, Vasudeva et al. (2016) reported on five individuals who underwent surgery for the treatment of aggressive vertebral hemangiomas during the specified time period. Intraoperative vertebroplasty was used in three cases to augment the anterior column or to obliterate a residual tumor. The authors concluded that despite the variety of available treatment options, the optimal management strategy is unclear because aggressive vertebral hemangiomas are uncommon lesions, making it difficult to perform large trials. In their opinion, vertebroplasty provides hemostatic embolization and improves the load-bearing capacity of the anterior column; however, either kyphoplasty or vertebroplasty may also be used intraoperatively in conjunction with decompressive surgery.

Narayana et al. (2014) evaluated PVP in the treatment of painful vertebral hemangiomas refractory to medical management. In this case series, 14 participants (four thoracic and 10 lumbar vertebra) with painful vertebral hemangiomas presenting with severe back pain for more than 6 months not responding to medical therapy were treated by PVP. Cross-sectional imaging of the spine with magnetic resonance was done. The pain intensity numeric rating scale (PI-NRS-11) in these participants was in the range of 7 to 10 (severe pain). After vertebroplasty, eight participants were completely free of pain (PI-NRS score of 0), while six were significantly relieved (PI-NRS score of 1-3). No complications were observed. Two participants with associated radicular pain had good pain relief following PVP. No recurrence was found during 36 months of postoperative follow-up. The authors concluded that PVP is a safe and effective procedure in individuals with painful vertebral hemangiomas refractory to medical management. However, the findings are limited by the lack of a comparison group.

Hao and Hu (2012) conducted an observational study aimed to illustrate the validity of treatment with PVP in individuals with symptomatic vertebral hemangiomas. PVP in 26 individuals with symptomatic vertebral hemangiomas and its clinical effects were evaluated in 3 to 24 months of follow-up. Overall, 26 consecutive individuals were treated with PVP, including a total of 28 vertebral bodies. All individuals were followed up for 3 to 24 months, with an average of 8.6 months. The clinical effects were evaluated with the VAS and SF-36 at the preoperative, postoperative, and final follow-ups, comparing imaging before and post treatment. Overall, 26 individuals (28 vertebral bodies) were treated successfully, with a satisfying resolution of painful symptoms within 24 to 72 hours. Cement distribution was always diffuse and homogeneous. The authors found paravertebral cement leakage in three cases, without any onset of radicular symptoms related to epidural diffusion. Spinal canal and intervertebral foramen cement leakage was not noticed. No pulmonary embolism ever occurred, and no clinical and symptomatic complications were observed. Hemangioma was confirmed by pathology examination. VAS scores decreased from 7.5 ±1.5 prior to the operation to 1.6 ±0.6 post operation, with a final score of 0.7 ±0.5. There was a difference between post operation and prior to the operation and between final follow-up and prior to the operation ($p < 0.05$). At the postoperative and final follow-ups, the SF-36 scores in individuals were significantly higher than those prior to the operation in role physical, physical, bodily pain, general health, vitality, social functioning, role emotional, and mental health ($p < 0.05$). The authors concluded that PVP is an effective technique to treat symptomatic vertebral hemangioma, which is a valuable, minimally invasive, and quick method that allows a complete and lasting resolution of painful vertebral symptoms.

Boschi et al. (2012) studied, in this case series, treatment with vertebroplasty in individuals with painful vertebral hemangiomas to determine the treatment's validity for this usage. Individuals (n = 24) were treated with PVP: 16 thoracic and eight lumbar. The average age at the time of surgery was 48 years. All the individuals reported a pain syndrome resistant to continuing medication. Preprocedure imaging was conducted for confirmation. The mean follow-up was 5.8 years. In all the individuals, the authors observed a successful outcome, with a complete resolution of pain symptoms. Clinical and radiological follow-up showed stability of the treatment and absence of pain in all individuals. They concluded that percutaneous treatment with vertebroplasty for symptomatic vertebral hemangiomas is a valuable, less invasive, and quick method that allows a complete and enduring resolution of the painful vertebral symptoms, without findings of the vertebral body's fracture. However, the findings are limited by the lack of a comparison group.

## Unstable Fractures Due to Osteonecrosis (e.g., Kümmell Disease)

Li et al. (2022) conducted a retrospective study to compare the clinical and radiological outcomes of PKP and PVP in the treatment of stage III Kümmell disease without neurological deficit. This retrospective study involved 41 patients with stage III Kümmell disease without neurological deficit who underwent PKP or PVP from January 2018 to December 2019. Demographic data and clinical characteristics were comparable between these two groups before surgery. Operation time, volume of injected bone cement, intraoperative blood loss, and time of hospital stay were analyzed. VAS scoring and ODI scoring were assessed for each patient before and after the operation. Radiographic follow-up was assessed by the height of anterior, height of middle, Cobb angle, and vertebral wedge ratio. The preoperative and postoperative recovery values of these data were used for comparison. The two groups showed no difference in demographic features ($p > 0.05$). Operation time, intraoperative blood loss, and time of hospital stay revealed no sharp statistical distinctions either ($p > 0.05$), except PKP used more bone cement than PVP (7.4 ±1.7 mL vs. 4.7 ±1.4 mL; $p < 0.05$). Radiographic data, such as the height of anterior improvement ratio (35.1% ±10.2% vs. 16.2% ±9.4%), height of middle improvement ratio (41.8% ±11.3% vs. 22.4% ±9.0%), Cobb angle improvement (10.0° ±4.3° vs. 3.5° ±2.1°), and vertebral wedge ratio improvement ratio (30.0% ±10.6% vs. 12.7% ±12.0%) were all better in the PKP group than the PVP group ($p < 0.05$). There were no statistical differences in the improvement of the VAS and ODI 1 day after the surgery between these two groups ($p > 0.05$). However, at the final follow-up, the VAS and ODI in the PKP group were better than those with PVP ($p < 0.05$). Cement leakage, one of the most common complications, was less common in the PKP group than the PVP group (14.3% vs. 45.0%; $p < 0.05$). There was one case of adjacent vertebral fractures with both PKP and PVP (4.8% vs. 5.0%; $p > 0.05$), which showed no statistical difference, and there were no severe complications recorded. The authors concluded that for stage III Kümmell disease, both PKP and PVP can relieve pain effectively. Moreover, PKP can obtain

more satisfactory reduction effects and less cement leakage than PVP. The authors suggested that PKP is more suitable for stage III Kümmell disease without neurological deficit than PVP from a vertebral reduction point of view.

Liu et al. (2022) conducted a retrospective comparison study to evaluate the clinical and radiological outcomes of PKP vs. those of posterior fixation combined with vertebroplasty (PF + VP) for treating patients with stage III Kümmell disease without neurological deficits. From April 2016 to February 2020, a total of 88 patients with single-level, stage III Kümmell disease without neurological deficits, including 45 patients treated with PKP and 43 patients who underwent PF + VP, were retrospectively studied. The outcome parameters, including blood loss, operative time, kyphotic Cobb angle, height of vertebrae, the ODI, and VAS score, were compared between the PKP group and the PF + VP group. The mean follow-up time was 29.3 ±7.0 months, ranging from 24 to 48 months. The kyphotic angle and vertebral height in both groups were improved compared with those before surgery at 3 days, 3 months, and the final follow-up. The estimated blood loss, operative time, and length of stay were lower in the PKP group than in the PF + VP group ($p < 0.001$). The PF + VP group showed better results in kyphotic angle correction than the PKP group ($p = 0.024$). In the short-term follow-up (up to 3 months), the PKP group had lower VAS and ODI scores than the PF + VP group. In contrast, there were no differences between the two groups ($p > 0.05$) at the final follow-up. The average cost of PKP was lower than that of PF + VP. The authors concluded that the results of their study showed that both PKP and PF + VP were safe and effective for patients with stage III Kümmell disease without neurological deficits. Although PF + VP presents better performance in kyphotic angle correction, PKP was associated with less surgical trauma, quicker pain relief, and lower expense than PF + VP. Therefore, it can be considered an alternative option for individuals with advanced Kümmell disease.

Wang et al. (2022) performed a systematic review and meta-analysis to compare the efficacy of PVP, PKP, and BFMCs, which are three viable, minimally invasive techniques that have been used to treat Kümmell disease. This study summarized the pros and cons of the three techniques in the treatment of Kümmell disease through a network meta-analysis. All eligible, published clinical control studies comparing PVP, PKP, and BFMC for Kümmell disease up to December 2021 were collected by an online search of the Cochrane Library, PubMed, Embase, CNKI, the Wanfang Database, and the Chinese biomedical literature database. Data were extracted after screening, and Stata 16.0 software was used to perform the network meta-analysis. Four RCTs and 16 retrospective case-control studies, with a total of 1,114 individuals, were included. The network meta-analysis results showed no statistical difference between the three procedures in terms of improving individuals' clinical symptoms. PKP was most likely to be the most effective in correcting kyphosis, while BFMC was likely to be the most effective in managing the occurrence of cement leakage. No statistical differences were found in the incidence of new vertebral fractures in adjacent segments. The authors concluded that ranking analysis showed that BFMC has the highest likelihood of being the optimal procedure for the treatment of Kümmell disease, based on a combined assessment of effectiveness in improving individuals' symptoms and safety in the occurrence of adverse events. (Authors Chang et al., 2020, Dai et al., 2021, Wang et al., 2018, and Zhang et al., 2018, previously cited in this policy, are included in this systematic review.)

Zhang et al. (2022) performed a systematic review and meta-analysis to evaluate the clinical outcomes, imaging improvements, perioperative complications, and intraoperative resource consumption associated with PVP and PKP for the treatment of neurologically intact, osteoporotic Kümmell disease. Six databases were searched for all relevant studies based on the PRISMA guidelines. Two investigators independently conducted a quality assessment, extracted the data, and performed all statistical analyses. Results showed that eight studies, encompassing 438 individuals with neurologically intact, osteoporotic Kümmell disease, met the inclusion criteria. Compared with PVP, PKP was associated with greater improvement in the short- and long-term Cobb angle (SMD, -0.37, $p = 0.007$; SMD, -0.34, $p = 0.012$), short-term anterior vertebral height (SMD, 0.43; $p = 0.003$), and long-term middle vertebral height (SMD, 0.57; $p = 0.012$) and a lower cement leakage rate (SMD, 0.50; $p = 0.003$) but produced more consumption (cement injection volume, operative time, fluoroscopy times, intraoperative blood loss, and operation cost). However, there were no differences between the two procedures in the short- and long-term VAS and ODI scores, long-term anterior vertebral height, overall complications, or new vertebral fractures. The authors concluded that both procedures are equally effective for neurologically intact Kümmell disease in terms of the clinical outcomes, except for a lower cement leakage risk and better radiographic improvement for PKP but greater resource consumption. Based on the evidence available, good clinical judgment should be exercised in the selection of individuals for these procedures. (Authors Chang et al., 2020, and Zhang et al., 2015, previously cited in this policy, are included in this systematic review.)

Dai et al. (2021) performed a prospective study to compare the safety and efficacy of PVP vs. those of PKP as treatment for osteoporotic Kümmell disease. The study included 64 participants: 30 participants in the PVP group and 34 participants in the PKP group. Participants were followed up for 24 months. Statistical results were insignificant, with VAS and ODI scores showing comparative results ($p > 0.05$) among the PVP and PKP groups at all postoperative time points. The authors concluded that both PVP and PKP are safe and efficient procedures for eliminating pain and achieving kyphosis correction in the treatment of osteoporotic Kümmell disease. The volume of bone cement injection, intraoperative blood loss, occurrence of bone cement leakage, transient fever, and refracture between the two groups

showed no significant difference. The surgical time, operation cost, and fluoroscopy times in the PKP group were significantly higher than those in the PVP group. The postoperative VAS, ODI scores, height of the anterior edge of the injured vertebrae, and kyphosis deformity were significantly improved in both groups compared with prior to the operation. The improvement of vertebral height and kyphosis deformity in the PKP group was significantly better than that in the PVP group at every same time point during the follow-up periods, but VAS and ODI scores between the two groups showed no significant difference. The authors concluded that PVP and PKP can both significantly alleviate the pain in individuals with Kümmell disease and obtain good clinical efficacy and safety. By contrast, PKP can achieve better imaging height and kyphosis correction, while PVP has the advantages of shorter operation time, less radiation volume, and operation cost.

Zhang et al. (2021) performed a systematic review and meta-analysis to compare the clinical outcomes and efficacy of PVP with those of PKP for the treatment of neurologically intact, osteoporotic Kümmell disease. The study included eight nonrandomized observational studies and two prospective and five retrospective case-control studies. Overall, 438 individuals were included, with 195 individuals treated with PKP and 243 individuals treated with PVP. There were no statistically significant differences in the short-term and long-term VAS and ODI scores between the two groups. PKP provided better short-term and long-term kyphosis correction than PVP. There were no differences in most of the vertebral height measurements, except for greater restoration of short-term anterior vertebral height and long-term middle vertebral height for the PKP group. The authors concluded that both PVP and PKP are safe and effective treatment options for treatment of neurologically intact Kümmell disease, with comparable clinical outcomes, including improved functional status, quality of life, and pain relief.

Chang et al. (2020) performed a prospective study to compare clinical outcomes of PVP and PKP for Kümmell disease. The study included 56 participants: 28 participants received PVP, and 28 participants received PKP treatment. The VAS was used to evaluate the degree of low back pain, and the ODI was used to evaluate the severity of dysfunction. At 2 years post-surgery, VAS scores decreased from 8.0 ±77 to 2.5 ±0.70 in the PVP group and from 8.0 ±0.75 to 2.5 ±0.84 in the PKP group. ODI scores decreased from 84.5 ±5.94 to 29.9 ±7.11 in the PVP group and from 84.9 ±8.23 to 31.0 ±7.56 in the PKP group. The authors concluded that PVP and PKP are effective treatment options in Kümmell disease, as both treatments achieve similar results. Follow-up time, incidence of bone cement leakage, refracture rate of adjacent vertebra, and intraoperative amount of bone cement injection between the two groups did not show a statistical difference. Both groups significantly relieved participants' pain of the low back, recovered the height of vertebral body and kyphosis angle, and improved quality of life, but PVP was associated with less surgical time, blood loss, and radiation exposure than PKP.

Huang et al. (2018) conducted a retrospective study to compare the efficacy of PKP and bone cement augmented short segmental fixation (BCA + SSF) for treating Kümmell disease. Between June 2013 and December 2015, 60 patients were treated with PKP or BCA + SSF. All patients were followed up for 12 to 36 months. The authors retrospectively reviewed outcomes, including the ODI, VAS, and kyphotic Cobb angle. The VAS, ODI, and Cobb angle, measured post operation and at the final follow-up, were lower than those measured prior to the operation in both groups ($p < 0.05$). The VAS, ODI, and Cobb angle measured post operation demonstrated no significant differences compared with those measured at the final follow-up in the PKP group ($p > 0.05$). In the BCA + SSF group, the VAS and ODI at the final follow-up were lower than those measured post operation ($p < 0.05$), but no difference was found in the Cobb angle ($p > 0.05$). The PKP group had better VAS and ODI than the BCA + SSF group post operation ($p < 0.05$). No difference was found in the VAS and ODI at the final follow-up ($p > 0.05$) or the Cobb angle measured post operation and at the final follow-up ($p > 0.05$) between the two groups. Operative time, blood loss, and hospital stay in the PKP group were lower than those in the BCA + SSF group ($p < 0.05$). No difference was found in complications ($p > 0.05$). The authors concluded that PKP patients had better early clinical outcomes, shorter operation times and hospital admission times, and decreased blood loss but had similar complications, radiographic results, and long-term clinical outcomes to BCA + SSF patients.

## Clinical Practice Guidelines

### *American Academy of Orthopaedic Surgeons (AAOS)*

In its 2011 (updated 2023) guidance and evidence report on the treatment of symptomatic, osteoporotic spinal compression fractures, the AAOS recommends 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. This recommendation is based on strong evidence regarding level II studies that compared vertebroplasty with a sham procedure, in which there was no statistically significant difference between the two procedures in pain using the VAS and function using the Roland-Morris Disability scale (up to 1 month and 6 months, respectively).

In the same 2011 (updated 2023) guidance and evidence report, the AAOS considers kyphoplasty as 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. This is based on limited evidence regarding two level II studies that examined the use of kyphoplasty compared with conservative treatment. In the study of patients with subacute fractures,

clinically important benefits in pain were found at 1 week and 1 month, with possibly important effects at 3 and 6 months. There was no clinically important benefit in pain at 12 months. The study also found possibly clinically important benefits in physical function (at 1 and 3 months only) and the SF-36 Physical Component score (at 1, 3, and 6 months only). Clinically important improvement in quality of life was present at 1 month, and it was possibly clinically important at 3, 6, and 12 months (AAOS, 2010).

## *American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE)*

In a clinical practice guideline for the diagnosis and treatment of postmenopausal osteoporosis, the AACE and ACE (Camacho et al., 2016; updated 2020) do not recommend vertebroplasty and kyphoplasty as first-line treatment for vertebral fractures, given the unclear benefit on overall pain and potential increased risk of vertebral fractures in adjacent vertebrae (R44. Grade A, BEL 1; downgraded due to limitations of published studies).

## *American College of Radiology (ACR)*

The ACR appropriateness criteria for the management of VCFs note that conservative management (medical management with or without methods of immobility) is the initial first-line treatment for painful VCFs. The ACR defines failure of conservative therapy as pain refractory to oral medications (nonsteroidal anti-inflammatory drugs and/or narcotics) or a contraindication to such medications or a requirement for parenteral narcotics and hospital admission. The ACR observes that the ideal preprocedural imaging has not been identified. The following variants were noted:

Percutaneous vertebral augmentation is usually appropriate for the following:

- Symptomatic OVCF with bone marrow edema or intravertebral cleft
- New, symptomatic VCF with a history of prior vertebroplasty or surgery
- Benign VCF with worsening pain, deformity, or pulmonary dysfunction
- Pathological VCF with ongoing or increasing mechanical pain

Percutaneous vertebral augmentation is usually not appropriate for the following:

- Asymptomatic OVCF (2022)

## *North American Spine Society (NASS)*

In a 2024 clinical guideline on the diagnosis and treatment of adults with OVCFs, NASS states the following:

Grade A recommendation:

- Vertebral augmentation is recommended, as it provides rapid and sustained clinically and statistically significant improvement in pain and function in adults with acute OVCFs.

Grade B recommendations:

- The evidence suggests that kyphoplasty shows improved height restoration and kyphotic angle, but the degree of height restoration and kyphotic angle did not provide further improvement in pain relief or function in adults with OVCFs.
- The evidence suggests that vertebroplasty and kyphoplasty, regardless of height restoration or kyphotic angle improvement, are equivalent in providing pain relief and improved function in adults with OVCFs.
- In adults with OVCFs treated without augmentation or surgery, there is fair evidence to suggest that approximately one-third of patients will have persistent long-term (greater than 6 months) pain (VAS > 3).
- The evidence suggests that the new fracture rates are not different in adults with OVCFs treated with augmentation or surgery compared with medical treatment.
- Vertebral augmentation is suggested to improve the segmental alignment compared with medical treatment in adults with OVCFs.
- For adults with OVCFs containing vertebral cleft, it is suggested that vertebral augmentation can improve height and wedge angle, but this has no significant difference in pain relief.
- In adults with OVCFs, it is suggested that there is optimal timing for treatment with vertebral augmentation, and delayed treatment is associated with worse clinical outcomes (timing varies in the literature used to develop this clinical guideline; however, the general evidence shows that the sooner treatment is provided after a fracture, outcomes are better).

Grade I recommendations:

- There is insufficient evidence to make a recommendation for or against the impact of diabetes, smoking, nonsteroidal anti-inflammatory drugs, low Functional Independence Measure score, presentation of multiple fractures, or low segmental Cobb angle on the risk for refracture of the same or other vertebral level in adults with OVCFs.
- There is conflicting evidence to make a recommendation for or against vertebral augmentation compared with medical treatment in terms of new, adjacent-level, or distant fractures in adults with OVCFs.

### *American College of Radiology (ACR)/American Society of Neuroradiology (ASNR)/American Society of Spine Radiology (ASSR)/Society of Interventional Radiology (SIR)/Society of NeuroInterventional Surgery (SNIS)*

The ACR, ASNR, ASSR, SIR, and SNIS 2017 practice parameter (updated 2022) for the performance of vertebral augmentation states that the major indication for vertebral augmentation is the treatment of symptomatic osteoporotic vertebral body fracture(s) refractory to medical therapy or vertebral bodies weakened due to neoplasia. They comment that although most fractures heal within a few weeks or months, a minority of patients continue to experience pain that does not respond to conservative therapy. They note that there is no indication for the use of vertebral augmentation for prophylaxis against future fracture.

### *International Society for the Advancement of Spine Surgery (ISASS)*

The ISASS 2019 policy statement on vertebral augmentation states that vertebral augmentation procedures (vertebroplasty and kyphoplasty) are safe and effective procedures. The level 1 evidence is in favor of vertebral augmentation compared with conservative management. Failure to treat patients with painful VCFs has been associated with increased mortality and morbidity. The ISASS endorses the early treatment of painful VCFs with vertebral augmentation procedures (vertebroplasty and preferentially kyphoplasty) (Clerk-Lamalice et al., 2019).

### *National Institute for Health and Care Excellence (NICE)*

A NICE 2013 (reviewed and confirmed 2016) technology guidance appraisal on PVP and percutaneous BKP for treating OVCFs recommends PVP and percutaneous BKP without stenting as options for treating OVCFs 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

### *Society of Interventional Radiology (SIR), American Association of Neurological Surgeons (AANS), and Congress of Neurological Surgeons (CNS)/American College of Radiology (ACR)/American Society of Neuroradiology (ASNR)/American Society of Spine Radiology (ASSR)/Canadian Interventional Radiology Association (CIRA)/Society of NeuroInterventional Surgery (SNIS)*

The 2014 SIR, AANS, CNS, ACR, ASNR, ASSR, CIRA, and SNIS consensus statement on percutaneous vertebral augmentation (reaffirmed in 2017) states that percutaneous vertebral augmentation, with the use of vertebroplasty or 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. They further comment that these procedures are offered only when nonoperative medical therapy has not provided adequate pain relief or when pain is significantly altering the patient's quality of life.

Currently, there is no indication for the use of vertebral augmentation for prophylaxis against future fracture. The indications and contraindications for vertebral augmentation may change in the future as more research and information become available (Barr et al.).

### *Society of NeuroInterventional Surgery (SNIS)*

In a 2014 report, the Standards and Guidelines Committee of the Society of NeuroInterventional Surgery (Chandra et al.) on vertebral augmentation concluded that:

- Kyphoplasty in selected patients is superior to conservative medical therapy in reducing back pain and disability and improving Karnofsky Performance Status and quality of life in patients with cancer as well as disabling back pain from a vertebral fracture (AHA class IIA, level of evidence B).
- Vertebroplasty and kyphoplasty are reasonable therapeutic options in selected patients with cancer and severe back pain from a vertebral fracture that is refractory to conservative medical therapy (AHA class IIA, level of evidence B).
- Vertebroplasty and kyphoplasty are reasonable therapeutic options in selected patients with severe back pain from an osteoporotic vertebral fracture that is refractory to conservative medical therapy (AHA class IIA, level of evidence B).

# U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Percutaneous vertebroplasty and kyphoplasty are procedures and are not regulated by the FDA.

A number of bone cement products have been approved for marketing by the FDA as Class II devices. Refer to the following website for more information (use product codes NDN, LOD): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm. (Accessed October 2, 2025)

Polymethylmethacrylate (PMMA) bone cement is a device intended to be implanted that is made from methyl methacrylate, PMMA, esters of methacrylic acid, or copolymers containing PMMA and polystyrene. These bone cement products are intended for use in arthroplastic procedures of the hip, knee, and other joints for the fixation of polymer or metallic prosthetic implants to living bone.

The FDA has approved bone tamps for the creation of a void in cancellous bone in the spine (including use during a balloon kyphoplasty procedure with a PMMA-based bone cement that is cleared for use in kyphoplasty procedures). Bone tamps are categorized by the FDA as Class II devices. Refer to the following website for more information (use product codes HRX, HXG): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm. (Accessed October 2, 2025)

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# Policy History/Revision Information

| Date | Summary of Changes |
|---|---|
| 05/01/2026 | **Coverage Rationale**<br>• Revised list of examples of causes of spinal pain to be ruled out by computed tomography (CT) or magnetic resonance imaging (MRI); removed:<br>  ○ Facet arthropathy<br>  ○ Other spinal degenerative disease<br>**Medical Records Documentation Used for Reviews**<br>• Updated list of Medical Records Documentation Used for Reviews:<br>  ○ Added "condition requiring procedure"<br>  ○ Replaced:<br>  ▪ "Onset of the condition, *length,* and duration" with "onset of the condition, *including dates* and duration"<br>  ▪ "*Documentation of member's* symptoms, pain, location, and severity, including functional impairment that is interfering with activities of daily living *(meals, walking, getting dressed, driving)*" with "*signs and* symptoms, including pain, location, and severity, and functional impairment that interferes with activities of daily living"<br>  ▪ "*History and* comorbid medical condition(s)" with "comorbidities"<br>  ▪ "*No* evidence of spinal cord compression" with "*presence or absence of* evidence of spinal cord compression"<br>  ▪ "Treatments tried and failed" with "treatments tried, failed, *or contraindicated; include the dates, duration, and reason for discontinuation*"<br>  ▪ "*Complete report(s) of diagnostic* imaging *(MRI, CT Scan, X-rays, and/or* bone scan)" with "*results of all recent relevant* imaging, *including assessment of* bone density" |

| Date | Summary of Changes |
|---|---|
| | **Definitions**<br>• Updated definition of:<br>  ○ Functional or Physical Impairment<br>  ○ Optimal Medical Therapy<br>  ○ Osteonecrosis<br>  ○ Vertebral Hemangiomas<br>**Supporting Information**<br>• Updated *Clinical Evidence* and *References* sections to reflect the most current information<br>• Archived previous policy version CS330.E |

# Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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