Percutaneous Vertebroplasty and Kyphoplasty

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➲ Instructions for Use

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Related Policy

- Minimally Invasive Spine Surgery Procedures

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
- Facet arthropathy
- Herniated intervertebral disk
- Other spinal degenerative disease
- 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 Clinical Policy titled Minimally Invasive Spine Surgery Procedures for additional information on percutaneous sacral augmentation); or
- Asymptomatic vertebral compression fractures (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 member specific benefit plan document 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 protocol 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; performing basic life functions.

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, 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)

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

Vertebral Hemangiomas: Vertebral Hemangiomas are benign vascular tumors of the bony spine which are usually asymptomatic. A rare subset of them is characterized by extra-osseous 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 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 the member specific benefit plan document 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 radiologic procedure, which involves injection of an acrylic polymer, such as polymethylmethacrylate (PMMA) 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 kyphoplasty 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 clinical literature and professional organization that percutaneous vertebral augmentation with the use of vertebroplasty or kyphoplasty (KP) is a safe, efficacious, and durable procedure in selected patients with symptomatic osteoporotic and neoplastic fractures. There is inadequate clinical evidence of safety and/or efficacy in published, peer-reviewed literature for treatment of other indications.

Osteoporotic Vertebral Compression Fractures (VCFs)

Zhan et al. (2024) conducted a retrospective 10-year follow-up study to evaluate the long-term outcome of percutaneous kyphoplasty (PKP) for osteoporotic vertebral compression fractures (VCFs) and the factors influencing the long-term outcome of this procedure. A total of 91 patients underwent PKP for thoracolumbar osteoporotic VCFs from June 2012 to December 2012. Pain Visual Analogue Scores (VAS) and Oswestry Disability Index (ODI) were recorded preoperatively and after 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 (BMD), preoperative VAS and ODI scores, length of surgery, bone cement dosage, postoperative standardized anti-osteoporosis 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 the difference was statistically significant ($p < 0.05$). Most of the patients were females aged 65–75 years who suffered 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 anti-osteoporosis 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 anti-osteoporosis treatment and 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 anti-osteoporosis treatment may be factors affecting the long-term outcome. This study is limited by its retrospective observations. Only some of the original patients were followed 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, possible selection bias by the researchers in the inclusion of case samples, etc. 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 osteoporotic VCFs 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 osteoporotic vertebral compression fractures. Two reviewers determined the eligibility of the studies independently. Only 8 studies were included in the meta-analysis. The clinical outcomes consisted of the complications (cement leakage, adjacent level fractures), the visual analog scale scores, Oswestry disability index, 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 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, inclusion and exclusion criteria for patients were different, and all included studies were in English or French which could be a source of bias.

Liu et al. (2023) conducted a systematic review and meta-analysis aimed to compare surgical methods for osteoporotic vertebral compression fracture (OVCF) using systematic review and network meta-analysis to understand their effectiveness and outcomes, as current research provides limited overviews. The authors followed PRISMA (preferred reporting items for systematic reviews and meta-analyses) guidelines, pre-registering protocol with PROSPERO. English-published randomized controlled trials (RCTs) on adults with OVCFs that evaluated pain intensity or functionality using tools like visual analogue scale (VAS) or Oswestry Disability Index (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 including disability, new fractures, and cement leakage. Results were synthesized using Stata/MP. Thirty-four RCTs from 10 countries, totaling 4,384 patients, 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%. Short-term ODI favored vertebroplasty with facet joint injection (VIJ) at 98.4%, with kyphoplasty (KP) 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 evaluates 12 OVCF interventions, underscoring KIJ 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 systematic review, and meta-analysis has several limitations. The underreporting of detailed patient characteristics and their respective protocols of treatment related to OVCF in the included studies altered the choices of treatment and could make it 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 (VA) in the treatment of single-level osteoporotic vertebral compression fractures (OVCFs) on new vertebral fractures. Eligible studies had to use VA as an intervention and conservative treatment as a control group. Studies had to explicitly report 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, 7 met the inclusion criteria and were included in the analysis, giving a total of 1240 patients. Meta-analysis showed that VA (OR = 2.10, 95% CI: 1.35–3.28, p = .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 greater than 1 year (OR = 2.57, 95% CI: 1.06–6.26, p = .001). Compared with conservative treatment, VA (OR = 2.17, 95% CI: 1.23–3.82, p = .007) increased the risk of postoperative adjacent vertebral fracture. The authors concluded that VA 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. The low number of relevant studies. Data from randomized controlled trials 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 clinical usefulness of this procedure is proven.

Cheng et al. (2022) conducted a retrospective study aimed to analyze the risk factors of new vertebral compression fracture (VCF) after percutaneous vertebroplasty (PVP) or percutaneous kyphoplasty (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 (DAVC), 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 patients (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 versus non-surgical treatment of 100 patients followed for up to six years diagnosed with severe osteoporotic vertebral compression fractures (VCF). Fractures were classified by percent collapse of vertebral body height as "high-degree fractures" (HDF) (> 50%) or vertebra plana (VP) (> 70%). A total of 310 patients with VCF were reviewed, identifying 110 severe fractures in 100 patients. The HDF group was composed of 47 patients with a total of 50 fractures. The VP group was composed of 53 patients with a total of 60 fractures. Surgical intervention was performed in 59 patients, comprised entirely of percutaneous vertebral cement augmentation procedures, including vertebroplasty, balloon kyphoplasty, or cement with expandable titanium implants. The remaining 41 patients only underwent conservative treatment that is the basis of the comparison study. All procedures were performed as an outpatient under local anesthesia with minimal sedation and there were no procedural complications. The initial or pre-procedural visual analog scale (VAS) score averaged 8.4 in all patients, with surgical patients having the most marked drop in VAS, averaging four points. This efficacy was achieved to a greater degree in surgically treated VP fractures compared to HDF. Non-surgical patients persisted with the most pain in both short- and long-term follow-up. This large series, with follow-up up to six years, demonstrated that the more severe fractures respond well to different percutaneous cement augmentation procedures with reduction of pain without increased complications in a comparison to conservatively treated patients.

An updated Hayes Health Technology Assessment reported on percutaneous kyphoplasty (KP) for osteoporotic vertebral compression fractures. The report included 10 studies: 6 randomized controlled trials (RCTs) (8 publications), 1 quasi-RCT, and 3 database studies. The sample size was 59 to 1,038,956 patients with VCFs due to osteoporosis with a 6 month to 4 years follow-up. The authors concluded that there is moderate-quality evidence that KP may be beneficial to some patients with a VCF due to osteoporosis that have not responded to conservative treatment (CT). There is consistent evidence that KP and VP provide similar improvements in pain, disability, and QOL from baseline. There is limited evidence that KP is favored over CT for pain relief. Large fair-quality database analyses offer limited but consistent evidence of lower mortality risk in patients treated with KP compared with those treated with VP. In addition, limited evidence from these database studies suggested that VP is associated with a higher risk for some postoperative complications (e.g., pulmonary embolism, deep vein thrombosis, and pneumonia). (Hayes, 2017; updated 2021)

Otsuka et al. (2021) completed a single-center retrospective analysis to identify predictors of outcome after balloon kyphoplasty (BKP) in patients with osteoporotic vertebral compression fracture (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 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 patients who could independently go indoors) and a poor outcome group. The authors analyzed factors associated with outcome and subsequent OVCF. Mean age of patients was 77.9 years, 58.2% were female, 81% had a good outcome, and 19% had a poor outcome. Univariable analysis revealed significant differences in age, bone mineral density, preoperative vertebral body decompression rate, body mass index (BMI), pre-operative Japanese Orthopaedic Association score, pre-operative modified Rankin Scale score, and subsequent OVCF. Multivariable logistic analysis showed that low BMI (odds ratio 1.415, 95% confidence interval 1.06 - 1.87, $p = 0.046$) and subsequent OVCF (odds ratio 0.13, 95% confidence interval 0.02 - 0.69, $p = 0.044$) were independent risk factors. The incidence of subsequent OVCF was also lower among patients with higher BMI (odds ratio 0.83, 95% confidence interval 0.72 - 0.95, $p = 0.001$). Body mass index (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 comparative effectiveness of percutaneous vertebroplasty versus sham, conservative treatment, or kyphoplasty for osteoporotic vertebral compression fractures. The evidence comprised 19 studies: 15 RCTs, 1 quasi-RCT, and 3 database studies. The sample sizes were 49 to 1,038,956 patients with VCFs due to osteoporosis with a follow-up of 6 months to 4 years. The authors reported that moderate-quality evidence found that for patients with acute pain, pain relief was better for VP versus sham or CT in 4 of 10 studies, and was similar to comparators (sham, facet block, kyphoplasty) in 6 of 10 studies. For patients with chronic pain, VP was favored over CT in 3 of 5 studies, was equivocal relative to sham in 1 study, and was similar to kyphoplasty in 1 of 5

studies. Findings were generally similar for disability and QOL. 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, Cai & Cong (2021) performed a systematic review and meta-analysis comparing the safety and efficacy of vertebral augmentation (VA) with non-surgical management (NSM) for treatment of osteoporotic OVCFs. The study included 20 randomized controlled trials involving 2,566 patients with painful OVCFs. There were no significant differences between PVP and sham procedure VAS scores at most time points during follow-up period. In a subgroup analysis based on fracture type and fracture location, significant differences of VAS were found between PVP and CT and were not found between PVP and sham procedure. In a subgroup analysis of duration of back pain, significant differences were found between PVP and CT in VAS at 1 week, 3 months and 1 year. The differences of VAS were not significant between PVP and CT at 1 month and 6 months. The authors concluded that VA is safe and effective for treatment of painful OVCFs with good clinical outcomes compared to patients 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), which were 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 of individuals with osteoporotic vertebral compression fractures (OVCFs) who have undergone VA versus those who received non-surgical management (NSM). A total of 16 studies including more than 2 million patients with OVCF (VA = 382 070, NSM = 1 707 874) were included in the review. Only 7 studies were included in the meta-analysis. Results showed hazard ratios (HRs) for mortality benefit for VA versus NSM over a two- and five-year period as 0.78 ($p < .001$) and 0.79 ($p = .05$). Pooled hazard ratio for mortality comparing VA with conservative management was 0.78 ($p = .003$) at up to 10 years. Balloon kyphoplasty provided a mortality benefit over VA with a hazard ratio of 0.77 versus 8.87 ($p < .001$). The authors concluded that VA offers survival benefits when treating OVCFs and should be offered in carefully selected patients as a best clinical practice. Osteoporotic vertebral compression fractures 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 clinical outcomes of PVP versus PKP for treatment of osteoporotic vertebral compression fractures (OVCFs) with intravertebral cleft (IVC). The review included 688 patients in nine studies: 378 patients were treated with PVP and 310 patients with PKP. The authors stated the results indicated no significant differences between the two groups in the short-and long-term VAS, ODI, LKA, or VH% ($p > 0.05$). 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 treatment of OVCFs.

Beall et al. (2019) conducted a prospective, phase IV, 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 patients seen in routine clinical practice. A total of 354 patients with painful vertebral compression fractures (VCFs) were enrolled at 24 US sites with 350 undergoing kyphoplasty. Four coprimary endpoints-Numerical Rating Scale (NRS) back pain, Oswestry Disability Index (ODI), Short Form-36 Questionnaire Physical Component Summary (SF-36v2 PCS), 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 endpoint, NRS improved from 8.7 to 2.7 and ODI improved from 63.4 to 27.1; SF-36 PCS was 24.2 at baseline improving to 36.6, and EQ-5D improved from 0.383 to 0.746 ($p < .001$ for each). Five device-/procedure-related adverse events, intraoperative asymptomatic balloon rupture, rib pain, and aspiration pneumonia, and 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 this large, prospective, clinical study demonstrates that kyphoplasty is a safe, effective, and durable procedure for treating patients with painful VCF due to osteoporosis or cancer.

Cheng et al. (2019) conducted a retrospective cohort study to compare percutaneous vertebroplasty (VP) and balloon kyphoplasty (BKP) for their effectiveness and safety in the treatment of newly onset osteoporotic vertebral compression fractures (VCF). Patients with confirmed diagnosis of newly onset osteoporotic VCF and treated between January 2008 and December 2016 were retrospectively included in the study. Patients were divided into 2 groups according to the surgical treatment they have received. They were followed 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, adjacent level vertebral fracture during follow up and total were compared between the 2 groups. A total of 338 patients were included in the final analysis. Demographic characteristics were similar in 2 groups. There were no differences between the 2 groups concerning VAS and ODI scores after the surgery and at last follow up ($p > .05$). However, total cost of treatment, quantity of injected bone cement,

incidence of adjacent level fracture, restored vertebral height and the loss of vertebral body height at the last follow up were higher in the BKP group than the VP group ($p < .05$). Considering the similar key outcome parameters such as VAS and ODI scores and more cost of BKP, VP can be prioritized over BKP in the treatment of patients with newly onset osteoporotic VCF.

Liu et al. (2019) performed a randomized controlled trial to assess the effect of BKP on elderly patients 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. One hundred sixteen elderly patients with multiple osteoporotic vertebral fracture 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 compared with the control group. Before the treatment, no statistically significant differences were observed between the two groups in terms of visual analog scale (VAS) score and daily life disturbance score. The VAS score and the daily life disturbance score of the two groups decreased sharply after the treatment. Moreover, the VAS score and the daily life disturbance score of the observation group were significantly lower than those of the control group. The observation group showed lower occurrence rate of complications compared with the control group. The authors concluded that BKP can significantly improve the image indices of patients 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 patients with painful osteoporotic vertebral compression fractures compared two vertebral augmentation procedures. Patients were randomized to SpineJack® (SJ) (n = 15) or balloon kyphoplasty (BKP) (n = 15). Clinical endpoints were analgesic consumption, back pain intensity [visual analog scale (VAS)], the Oswestry Disability Index (ODI), and quality of life (EQ-VAS score). They were recorded preoperatively, at 5 days (except EQ-VAS), 1, 3-, 6-, 12-, and 36-months post-surgery. Spine X-rays were taken 48 hours prior to the procedure and 5 days, 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 SJ resulted in a better restoration of vertebral heights and angles, 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 treatment of osteoporotic vertebral fractures. Randomized and quasi- RCTs of 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 upon 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 duration of pain ≤ 6 weeks versus > 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, patients 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 (i) assess the clinical outcomes with and without vertebral augmentation (VA) for osteoporotic vertebral compression fractures (VCFs) with versus without correlating signs and symptoms; and (ii) acute (symptoms < 3-month duration) and subacute VCFs (3–6 month duration) versus chronic VCFs (> 6 months). Thirteen studies totaling 1467 patients with minimum 6-month follow-up were found. Pain reduction was greater with VA over conservative management for SVFs and equivalent for RVFs. Sub analysis for acute/subacute SVFs and chronic SVFs showed that VA was superior to nonoperative care. No difference was observed in outcomes between VA and nonoperative care for chronic RVF. The authors concluded that VA is superior to nonoperative care in reducing lower back pain for osteoporotic VCFs with correlating signs and symptoms. VA had no benefit over nonoperative care for chronic VCFs that lacked clinical correlation. The authors also note that lower back pain has many etiologies and patients should be clinically assessed before recommending VA.

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 versus PVP for osteoporotic vertebral compression fracture (OVCF). The qualified studies included randomized controlled trials (n = 1), prospective or retrospective comparative studies, and cohort studies. The results indicated that KP significantly decreased the kyphotic wedge angle (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 (RR, 0.62; 95% CI 0.47–0.80) in comparison with vertebroplasty. However, there was no statistical difference in visual analog scale (VAS) scores (WMD, 0.04; 95% CI − 0.28–0.36) and Oswestry Disability Index (ODI) scores (WMD, − 1.30; 95% CI − 3.34–0.74) between the two groups. The authors concluded that KP contributes especially to decreasing the mean difference of kyphotic wedge angle and risk of cement leakage and increasing the vertebral body height when compared with vertebroplasty. But 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, KP and PVP are equally effective in the clinical outcomes of OVCF. Furthermore, the authors indicated that more high-quality multi-center 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). Randomized controlled trials (RCTs) were compared percutaneous vertebroplasty (PVP), percutaneous kyphoplasty (PKP), nerve block (NB), or conservative treatment (CT) for treating osteoporotic vertebral compression fractures (OVCFs). A total of 18 trials among 1994 patients were included. PKP was first option in alleviating pain in the case of the acute/subacute OVCFs for long term, and chronic OVCFs for short term and long term, while PVP had the most superiority in the case of the acute/subacute OVCFs for short term. NB ranks higher probability than PKP and PVP on acute/subacute OVCFs in short and long-term, respectively. The authors concluded that the results suggest that PVA (PVP/PKP) had better performance than CT in alleviating acute/subacute and chronic OVCFs pain for short and long-term and that NB may be used as an alternative or before PVA, 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) which were previously cited in this policy are included in this systematic review.]

In a systematic review of pain, quality of life and safety outcomes of BKP compared to other surgical techniques and non-surgical management for vertebral compression fractures (VCF), a task force of the American Society of Bone and Mineral Research (ASBMR) evaluated ten unique trials (1,837 participants). BKP in comparison to non-surgical management, was associated with greater reductions in pain, back-related disability, and better quality of life that appeared to lessen over time but were less than minimally clinically important differences. Risk of new VCF at 3 and 12 months was not significantly different. Individuals with painful VCF experienced symptomatic improvement compared with baseline with all interventions. There were no significant differences between BKP and PVP in back pain, back disability, quality of life, risk of new VCF or any adverse events. Limitations of the studies included lack of a balloon kyphoplasty versus sham comparison, availability of only one randomized controlled trial of BKP versus non-surgical management, and lack of study blinding. The Task Force recommends well-conducted randomized trials comparing BKP with sham to help resolve remaining uncertainty about the relative benefits and harms of this procedure. (Rodriguez et al., 2017) [Author Boonen et al. (2011) which was previously cited in this policy is included in this systematic review.]

A meta-analysis of randomized controlled trials (RCTs) by Xie et al. (2017) aimed to evaluate the efficacy and safety in percutaneous vertebroplasty (PVP) and conservative treatment (CT) for osteoporotic vertebral compression fractures (OVCFs). Twelve RCTs with a total 1231 patients (623 in the PVP and 608 in the CT) were included. Patients were followed up for at least 2 weeks in all the studies. Statistical differences were found between pain relief and Quality of Life Questionnaires. No statistical differences were found between pain relief and the rate of adjacent vertebral fracture. PVP is associated with higher pain relief than CT in the early period. PVP did not increase the rate of adjacent vertebral fracture. The authors concluded that the results indicate that PVP is a safe and effective treatment for OVCFs. [Authors Blasco et al. (2012), Chen et al. (2014), Farrokhi et al. (2011), and Klazen et al. (2010), which were previously cited in this policy are included in this meta-analysis review.]

Zhao et al. (2017) performed a network meta-analysis to assess the efficacy and safety of vertebroplasty (VP), kyphoplasty (KP), and conservative treatment (CT) for the treatment of osteoporotic vertebral compression fractures (OVCFs). Sixteen RCTs with 2046 participants were included. Compared with CT, patients treated with VP had improved pain relief, daily function, and quality of life; however, no significant differences were found between VP and KP for these 3 outcomes. All treatment options were associated with comparable risk of new fractures. VP was the most effective treatment for pain relief, followed by KP and CT; conversely, KP was the most effective in improving daily function and quality of life and decreasing the incidence of new fractures, followed by VP and CT. The authors concluded that VP might be the best option when pain relief is the principle aim of therapy, but KP was associated with the lowest risk of new fractures and might offer better outcomes in terms of daily function and quality of life. The findings are limited by the inherent indirectness of network meta-analyses. [Authors Blasco et al. (2012), Boonen et al. (2011), Farrokhi et al. (2011), and Klazen et al. (2010), which were previously cited in this policy are included in this meta-analysis review.]

Mattie et al. (2016) compared the degree and duration of pain relief following percutaneous vertebroplasty (PVP) with that following conservative treatment and/or sham for osteoporotic compression fractures by means of meta-analysis of

randomized controlled trials. Based on their analysis, up to 1 year postoperatively, the effect of PVP exceeded the effect of conservative therapy with respect to pain relief in patients with osteoporotic compression fractures. The effect size was significant and close to the minimal clinically important difference. Those receiving PVP (531 out of 1,048 patients) had a significantly lower pain level compared with the control group at 1 to 2 weeks, 2 to 3 months, and 12 months. Based on their observations, the authors concluded that the effect of PVP exceeded the effect of conservative therapy up to 1 year postoperatively with respect to pain relief in patients with osteoporotic compression fractures. The effect size was significant and close to the minimal clinically important difference.

Yuan et al. (2016) conducted a meta-analysis to examine vertebroplasty or BKP for osteoporotic compression fractures compared to conservative treatment. The authors' review determined that overall vertebroplasty and KP reduce pain and improve function and quality of life as compared with conservative treatment. However, analysis by surgery type indicated that pain relief of kyphoplasty was similar to that of conservative management, but pain relief of vertebroplasty was greater than that of conservative management. Both procedures improved functional outcomes to a greater degree than conservative treatment, and that while KP improved quality of life to a greater degree than conservative treatment, there was no difference in quality-of-life improvement between vertebroplasty and conservative treatment. These results need to be interpreted with caution however, as only 2 studies examined KP and only 1 of these studies examined function and quality of life. [Authors Blasco et al. (2012), Chen et al. (2014), Boonen et al. (2011), Farrokhi et al. (2011), and Klazen et al. (2010) which were previously cited in this policy are included in this meta-analysis review.]

Wang et al. (2015) conducted a meta-analysis to assess the safety and efficacy of percutaneous kyphoplasty (PKP) compared to percutaneous vertebroplasty (PVP) in the treatment of single level osteoporotic vertebral compression fractures (OVCF). Studies with the following criteria were included: patients with VCFs due to osteoporosis; PKP comparing PVP; study design, RCT or prospective or retrospective comparative studies. Furthermore, the studies which reported at least one of the following outcomes: subjective pain perception, quality of life evaluation, incidence of new adjacent vertebral fracture, bone cement leakage, and post-operative kyphotic angle. Articles were excluded from the meta-analysis if they had a neoplastic etiology (i.e., metastasis or myeloma), infection, neural compression, traumatic fracture, neurological deficit, spinal stenosis, severe degenerative diseases of the spine, previous surgery at the involved vertebral body, and PKP or PVP with other invasive or semi-invasive intervention treatment. A systematic search of all articles published through May 2014 was performed by Medline, EMASE, OVID, and other databases. All the articles that compared PKP with PVP on single level OVCF were identified. The evidence quality levels of the selected articles were evaluated by Grade system. Data about the clinical outcomes and complications were extracted and analyzed. Eight studies, encompassing 845 patients, met the inclusion criteria. Overall, the results indicated that there were differences between the 2 groups in the short-term visual analog scale (VAS) scores, the long-term Oswestry Disability Index (ODI), short- and long-term kyphosis angle, the kyphosis angle improvement, the injected cement, and the cement leakage rates. However, there were no differences in the long-term VAS scores, the short-term ODI scores, the short- and long-term SF-36 scores, or the adjacent-level fracture rates. The authors concluded PKP and PVP are both safe and effective surgical procedures in treating OVCF. PKP has a similar long-term pain relief, function outcome (short-term ODI scores, short-and long-term SF-36 scores), and new adjacent VCFs in comparison to PVP. PKP is superior to PVP for the injected cement volume, the short-term pain relief, the improvement of short- and long-term kyphotic angle, and lower cement leakage rate. However, PKP has a longer operation time and higher material cost than PVP.

Tan et al. (2015) conducted a prospective study of percutaneous vertebroplasty (PVP) for chronic painful osteoporotic vertebral compression fracture. Sixty-two consecutive patients with chronic painful osteoporotic VCFs for ≥ 3 months underwent PVP on 92 vertebrae in 73 procedures three to five days after referral. All procedures were performed under local anesthesia. The outcomes were pain relief at one week, one month, three months, six months and one year, as measured by visual analogue scale, Oswestry Disability Index, Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO) and Roland Morris Disability Questionnaire scores. According to the authors, the PVP procedures were technically successful and well tolerated in all patients. Compared with baseline scores, improvement in visual analogue scale, Oswestry Disability Index, QUALEFFO and Roland Morris Disability Questionnaire scores was significantly greater after PVP at one week ($p < 0.001$), one month ($p < 0.001$), three months ($p < 0.001$), six months ($p < 0.001$) and one year ($p < 0.001$), and the number of patients using drugs for pain treatment was significantly reduced. Five new fractures were reported in five of 62 patients treated with PVP during follow-up. The authors concluded that PVP is effective in patients with chronic painful osteoporotic VCFs due to immediate pain relief that was sustained for one year and may be an important factor for reducing persistent pain. The findings are however limited by the lack of comparison group.

In a systematic review, Stevenson et al. (2014) evaluated the clinical effectiveness of percutaneous vertebroplasty (PVP) and balloon kyphoplasty (BKP) in reducing pain and disability in people with osteoporotic vertebral compression fractures (VCFs). Inclusion criteria were randomized controlled trials for VCFs treated with their PVP or BKP. Primary outcomes were health-related quality of life; back-specific functional status/mobility; pain/analgesic use; vertebral body height and

angular deformity; incidence of new vertebral fractures and progression of treated fracture. A total of nine RCTs were identified and included in the review of clinical effectiveness. This body of literature was of variable quality, with the two double-blind, OPLA-controlled trials being at the least risk of bias. The most significant methodological issue among the remaining trials was lack of blinding for both study participants and outcome assessors. According to the authors, broadly speaking, the literature suggests that both PVP and BKP provide substantially greater benefits than OPM in open-label trials. However, in double-blinded trials PVP was shown to have no more benefit than local anesthetic; no trials of BKP compared with local anesthesia have been conducted. The authors concluded that for people with painful osteoporotic VCFs refractory to analgesic treatment, PVP and BKP perform significantly better in unblinded trials than OPM in terms of improving quality of life and reducing pain and disability. However, there is as yet no convincing evidence that either procedure performs better than OPLA. They further commented that data on key parameters were uncertain and/or potentially confounded, making definitive conclusions difficult to make. [Authors Blasco et al. (2012), Farrokhi et al. (2011), and Boonen et al. (2011), which were 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 percutaneous vertebroplasty (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. The visual analog scale (VAS) scores and Oswestry disability index (ODI) scores were evaluated before and 72 hours after the operation, respectively. Post-operational X-ray and computed tomography (CT) scans were conducted to observe bone cement leakage, and complications were recorded. Follow-up CT and magnetic resonance imaging (MRI) 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 the 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, post-operative 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 for spinal metastases with posterior wall defect, PVP combined with BFMCs was highly safe and can effectively relieve pain for patients. 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 visual analogue scale (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 utilized 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 percutaneous vertebroplasty of more than two multi-level osteoporotic and malignant fractures. This study was conducted on 30 patients. Visual analogue scale (VAS) was used to evaluate the functional outcome. All patients were treated using percutaneous vertebroplasty. They were followed for 6 months postoperatively. The functional state of all patients improved after percutaneous vertebroplasty. According to the visual analogue scale (VAS), the preoperative VAS score was (8.43 ±1.19). Immediate postoperative VAS was (3.07 ±1.20) and after six 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 reported who complained of dyspnea. This patient was admitted to ICU and managed with proper medications with satisfactory results. The authors concluded that multilevel PV is proved to be a safe, cost effective and successful procedure that could reduce pain and improve patient's 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 visual analogue scale, Oswestry Disability Index, vertebral body height variation and quality of life. Major and minor complications were systematically evaluated to assess the safety of the procedure. Average follow-up period was 22.5 ±11.1 months (range, 3 to 46 months). The procedure duration time ranged from 50 to 180 minutes (average 96.8 ±36.9 minutes). Mean visual analogue scale scores decreased significantly from 6.1 ±1.8 pre-operatively 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; $p < 0.001$). Oswestry Disability Index scores and vertebral body height variation also changed after the procedure, with significant differences between pre-operative scores and at each follow-up examination ($p < 0.001$). Mean quality of life scores was 90.8 ±12.9 pre-operatively 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% (2 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 randomized controlled trials to assess the efficacy of kyphoplasty (KP) in controlling pain and improving quality of life in oncologic patients with metastatic spinal disease and pathologic compression fractures of the spine. After a literature search through medical databases, two studies with a combined total of 181 patients, met inclusion criteria. A meta-analysis was not possible due to data heterogenetic and individual analysis of studies was performed. There was moderate evidence that patients treated with balloon kyphoplasty (BKP) displayed better scores for pain (Numeric Rating Scale), disability (Roland-Morris Disability Questionnaire), quality of life (Short Form-36-Health Srey), and functional status (Karnofsky Performance Status) compared with those undergoing conventional treatment. Patients treated with KP also had better recovery of vertebral height. The authors concluded that although balloon kyphoplasty (KP) could be considered as an early treatment option for patients with symptomatic neoplastic spinal disease, further randomized clinical trials should be performed for improvement of the quality of evidence. [Authors Berenson et al. (2011) which was previously cited in this policy is included in this systematic review.]

Sorensen et al. (2019) performed a systematic review evaluating the effectiveness and safety of vertebral augmentation for malignant vertebral compression fractures (VCFs). Studies on percutaneous vertebroplasty (PVP) or percutaneous kyphoplasty (KP) for vertebral compression fractures (VCFs) in patients with malignant spinal lesions were reviewed. The review identified two randomized controlled trials, 16 prospective studies, 44 retrospective studies, and 25 case series for a patient sample size of 3,426. At the earliest follow-up, pain improved from 7.48 to 3.00 with PVP, and from 7.05 to 2.96 with KP. ODI improved from 74.68 to 17.73 with PVP, and from 66.02 to 34.73 with KP. KPS improved from 66.99 to 80.28. Cement leakage was seen in 37.9% and 13.6% of patients treated with PVP and KP, respectively. Symptomatic complications (n = 43) were rare. The authors concluded that the review showed clinically relevant improvements in pain, ODI, and KPS in patients with VCFs due to malignancy treated with either PVP or KP. Cement leakage is common, but rarely symptomatic. The authors conclude that PVP and KP are safe and effective palliative procedures for painful VCFs in patients with malignant spinal lesions. [Authors Anselmetti et al. (2012), Berenson et al. (2011), Farrokhi et al. (2012) and Sun et al. (2014) which were 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 (VP) and kyphoplasty (KP) compared with each other, usual care, or other treatments on pain, disability, and quality of life following metastatic spinal lesions (MSL). Nine trials were included in the qualitative analysis. In total, there were 622 patients enrolled in the trials and of them 432 were in the surgical treatment group (92 received KP, 97 received VP, 134 received VP and chemotherapy, 68 received VP 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 VP plus chemotherapy than with chemotherapy alone. KP seemed to lead to significantly greater improvement in pain, disability, and health-related quality of life (HRQoL) compared with nonsurgical management. VP plus Iodine-125 seemed to lead to significantly greater improvement in pain and disability in comparison with VP alone. VP plus radio chemotherapy resulted in better pain relief and HRQoL postoperatively in comparison with routine radio chemotherapy. The authors concluded that there was low-quality evidence to prove that surgical treatment significantly decreases pain and improves functional score and HRQoL following

MSL in comparison with nonsurgical management. Based on the analysis of currently published trial data, it is unclear whether VP for MSL provides benefits over KP.

Qi et al. (2016) conducted a meta-analysis to evaluate the function of percutaneous vertebroplasty (PVP) treatment to pain relief and life quality for patients with spinal tumors. Twenty-six studies involving 1351 patients met selection criteria. Meta-analysis results among 10 case-control studies showed that the combined hazard ratio was -2.83 [95% confidence interval (CI) -2.92, -2.73; p < .0001], indicating a 2.83-fold decrease of pain in PVP group. For 12 single-arm studies, a significantly decrease of pain after PVP treatment (HR = -4.79, 95% CI -5.00, -4.57, p < .0001) was also found in PVP group. In addition, for KPS analysis, the combined HR was 16.31 (95% CI 14.31, 18.31; p < .0001), which indicated that PVP treatment was associated with a 16.31-fold increase of KPS. The combined hazard ratio was 0.58 (95% CI 0.35, 0.96; p = .04) for complication analysis. The authors concluded that PVP treatment of spinal tumor is significantly associated with better pain relief and life quality, which could improve the outcome in metastatic spinal tumor patients.

Lim et al. (2009) conducted a retrospective study to evaluate follow-up results of percutaneous vertebroplasty (VP) in 185 pathologic fractures of 102 spinal tumor patients from 2001 to 2007. Retrospective analysis was done with medical records and radiological data. The change of visual analogue score (VAS), vertebral body (VB) height and kyphotic angle were measured preoperatively and on postoperative one day and at 3, 6, and 12 months. The patients were composed of metastatic spine tumors (81%) and multiple myeloma (19%). Involved spinal segments were between T6 and L5. Mean follow-up period was 12.2 months. VAS for back pain was 8.24 preoperatively, 3.59 (postoperative one day), 4.08 (three months) and 5.22 (one year). VB compression ratio changed from 21.33% preoperatively to 13.82% (postoperative one day), 14.36% (three month), and 16.04% (one year). Kyphotic angle changed from 15.35 degrees preoperatively to 12.03 degrees (postoperative one day), 13.64 degrees (three month), and 15.61 degrees (one year). The authors concluded that immediate pain relief was definite after VP in pathologic compression fracture of osteolytic spinal disease. Although VAS was slightly increased on one year follow-up, VP effect was maintained without change. These results indicate that VP could be a safe and effective procedure as a palliative treatment of the spinal tumor patients.

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 multiple myeloma (MM). Retrospective analysis of consecutive patients with histology-proven pathological fractures caused by MM treated with MISS between 2009 and 2018 were included. 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 was collected. Twenty-one patients were studied - 13 males and 8 females, with a mean age of 64 years (range 43-83). Mean preoperative spinal instability neoplastic score was 9.8 ±6 (range 5-16). All cases had a thoracolumbar location - 15 patients underwent kyphoplasty (KP) or vertebroplasty (VP) and 6 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 VP/KP. Mean hospital stay was 1.3 days for KP/VP 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 KP and VP led to shorter hospital stays and less complications, being adequate for lesions without major instability. More complex MISS techniques offer an effective treatment with short delay for starting MM adjuvant treatment. The retrospective nature of the study and the lack of 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 percutaneous vertebroplasty (PV) in patients with vertebral involvement of multiple myeloma. PV procedures performed on 166 vertebrae of 41 patients with multiple myeloma were retrospectively evaluated. Most patients were using level 3 (moderate to severe pain) analgesics. Magnetic resonance imaging was performed before the procedure to assess vertebral involvement of multiple myeloma. The following variables were evaluated: affected vertebral levels, loss of vertebral body height, polymethylmethacrylate (PMMA) cement amount applied to the vertebral body during PV, PMMA cement leakages, and pain before and after PV as assessed by a visual analogue scale (VAS). Median VAS scores of patients decreased from 9 one day before PV, 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 PV 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 being a minimally invasive and easily performed procedure with low complication rates, PV should be preferred for serious back pain of multiple myeloma patients.

In a systematic review, Health Quality Ontario (2016) evaluated the effectiveness and safety of percutaneous image-guided vertebral augmentation techniques, vertebroplasty and KP, for palliation of cancer-related vertebral compression fractures. Owing 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. One hundred and eleven clinical reports (4,235 patients) were evaluated to determine the

effectiveness of vertebroplasty (78 reports, 2,545 patients) or KP (33 reports, 1,690 patients) for patients with mixed primary spinal metastatic cancers, multiple myeloma, 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 a randomized controlled trial comparing KP 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 KP. Major adverse events, however, were uncommon. The authors concluded that both vertebroplasty and KP significantly and rapidly reduced pain intensity in cancer patients with vertebral compression fractures. 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 of cancer patients with painful vertebral compression fractures treated with either PVP or KP. A total of 407 cancer patients had 1,156 fractures that had been treated with PVP or KP; the majority of patients had pathological fractures due to multiple myeloma or osteoporotic fractures. The authors reported that surgery provided significant relief from pain and several related symptoms. 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 VP or KP in treating painful VCFs in cancer patients has good efficacy and an acceptably low complication rate. The findings are limited by lack of comparison group without surgical intervention and the observational design of the study.

Vertebral Hemangioma With Aggressive Features

Nambiar et al. (2020) conducted a retrospective multi-center cohort study to evaluate PVP for the treatment of symptomatic vertebral hemangioma. The study included 50 patients with painful vertebral hemangiomas and treated with PVP by a single provider over a 14-year period (March 1999 to April 2013). There was a minimum one-year follow-up. Two patients had recurrent symptoms and repeat vertebroplasty. Pre-intervention VAS score was 7.0 and mean post-intervention VAS at one 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 low risk of complication.

In a case series of surgical treatments for aggressive vertebral hemangiomas, Vasudeva et al. (2016) report on five patients who underwent surgery for treatment of aggressive vertebral hemangiomas during the specified time period. Intraoperative vertebroplasty was used in 3 cases to augment the anterior column or to obliterate residual tumor. The authors conclude 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 percutaneous vertebroplasty (PVP) in the treatment of painful vertebral hemangiomas refractory to medical management. In this case series, fourteen patients (four thoracic and ten 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) of these patients was in the range of 7-10 (Severe Pain). After vertebroplasty 8 patients were completely free of pain (PI NRS Score 0) while 6 were significantly relieved (PI-NRS Score 1-3). No complications were observed. Two patients 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 patients with painful vertebral hemangiomas refractory to medical management. The findings are however limited by lack of comparison group.

Hao and Hu (2012) conducted an observational study aimed to illustrate the validity of treatment with percutaneous vertebroplasty (PVP) in patients with symptomatic vertebral hemangiomas (VHs). PVP in 26 patients with symptomatic VHs and its clinical effects were evaluated in 3-24 months follow-up. Twenty-six consecutive patients were treated with PVP: a total of 28 vertebral bodies. All patients were followed-up for 3-24 months, average 8.6 months. The clinical effects were evaluated with the visual analog scale (VAS) and 36-item short-form (SF-36) at preoperative and postoperative and final follow-up, comparing imaging before and post-treatment. Twenty-six patients (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 3 cases without any onset of radicular symptoms

related to epidural diffusion. Spinal canal and intervertebral foramen cement leakage wasn't 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 preoperatively to 1.6 ±0.6 postoperatively, with a final score of 0.7 ±0.5. There was a difference between postoperative and preoperative, and between final follow-up and preoperative ($p < 0.05$). At the postoperative and final follow-up, the SF-36 scores of patients were significantly higher than the preoperative in Role Physical, Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role Emotional, and Mental Health ($p < 0.05$). The authors concluded 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 patients with painful vertebral hemangiomas to determine its validity for this usage. Patients (n = 24) were treated by percutaneous vertebroplasty: 16 thoracic, 8 lumbar. The average age at the time of surgery was 48 years. All the patients complained of a pain syndrome resistant to continuing medication. Pre-procedure imaging was conducted for confirmation. The mean follow-up was 5.8 years. In all the patients, the authors observed a successful outcome with a complete resolution of pain symptom. Clinical and radiological follow-up showed stability of the treatment and absence of pain in all patients. They concluded that percutaneous treatment with vertebroplasty for symptomatic vertebral hemangiomas is a valuable, less invasive, and a quick method that allows a complete and enduring resolution of the painful vertebral symptoms without findings of the vertebral body's fracture. The findings are however limited by the lack of comparison group.

Unstable Fractures due to Osteonecrosis (e.g., Kümmell's Disease)

Li et al. (2022) conducted a retrospective study to compare the clinical and radiological outcomes of percutaneous kyphoplasty (PKP) and percutaneous vertebroplasty (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. Visual analog scale (VAS) scoring, and Oswestry disability index (ODI) scoring were assessed for each patient before and after operation. Radiographic follow-up was assessed by the height of anterior (Ha), the height of middle (Hm), Cobb's angle, and Vertebral wedge ratio (VWR). 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 Ha improvement ratio (35.1 ±10.2% vs 16.2 ±9.4%), the Hm improvement ratio (41.8 ±11.3% vs 22.4 ±9.0%), the Cobb's angle improvement (10.0 ±4.3° vs 3.5 ±2.1°) and the VWR improvement ratio (30.0 ±10.6% vs 12.7 ±12.0%), were all better in PKP group than that in PVP group ($p < 0.05$). There were no statistical differences in the improvement of VAS and ODI 1-day after the surgery between these two groups ($p > 0.05$). However, at the final follow-up, VAS and ODI in PKP group were better than that in PVP ($p < 0.05$). Cement leakage, one of the most common complications, was less common in the PKP group than that in the PVP group (14.3% vs 45.0%, $p < 0.05$). And there was 1 case of adjacent vertebral fractures in 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 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 was more suitable for stage III Kümmell disease without neurological deficit compared to 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 percutaneous kyphoplasty (PKP) versus posterior fixation combined with vertebroplasty PF+VP for treating stage III Kümmell's disease (KD) patients without neurological deficits. From April 2016 to February 2020, a total of 88 patients with single-level stage III KD without neurological deficits, including 45 patients treated by PKP and 43 patients who underwent posterior fixation combined with vertebroplasty PF+VP, were retrospectively studied. The outcome parameters, including blood loss, operative time, kyphotic Cobb angle, height of vertebrae, Oswestry Disability Index (ODI), and visual analog scale (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 three 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 FP+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 the results of their study showed that both PKP and PF+VP were safe and effective for stage III KD patients 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 patients with advanced KD.

Wang et al. (2022) performed a systematic review and meta-analysis to compare the efficacy of percutaneous vertebroplasty (PVP), percutaneous kyphoplasty (PKP), and bone-filling mesh containers (BFC), three viable, minimally invasive techniques that have been used to treat Kümmell's disease (KD). This study summarized the pros and cons of the three techniques in the treatment of KD through network meta-analysis (NMA). All eligible published clinical control studies comparing PVP, PKP, and BFC for KD up to December 2021 were collected by online search of Cochrane Library, PubMed, Embase, CNKI, Wanfang Database, and Chinese biomedical literature database. Data were extracted after screening, and Stata 16.0 software was used to perform the network meta-analysis. Four randomized controlled trials (RCTs) and 16 retrospective case-control studies (CCTs) with a total of 1,114 patients were included. The NMA results showed no statistical difference between the 3 procedures in terms of improving patients' clinical symptoms. PKP was most likely to be the most effective in correcting kyphosis, while BFC 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 ranking analysis showed that BFC has the highest likelihood of being the optimal procedure for the treatment of KD, based on a combined assessment of effectiveness in improving patients' 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) who were previously cited in this policy are included in this systematic review.]

Zhang et al. (2022) performed a systematic review and meta-analysis to evaluate e the clinical outcomes, imaging improvements, perioperative complications and intraoperative resource consumption associated with percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) for the treatment of neurologically intact osteoporotic Kümmell’s disease (KD). 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: Eight studies encompassing 438 neurologically intact osteoporotic KD patients met the inclusion criteria. Compared to 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 2 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 KD 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 patients for these procedures. [Authors Change et al. (2020), and Zhang et al. (2015) who were 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 percutaneous vertebroplasty (PVP) versus percutaneous kyphoplasty (PKP) as treatment for osteoporotic Kümmell’s disease. The study included 64 patients: 30 patients in the PVP group and 34 patients in the PKP group. Patients were followed for 24 months. Statistical results were insignificant with visual analogue scale (VAS) and Oswestry disability index (ODI) scores showing comparative results ($p > 0.05$) among 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’s disease. The volume of bone cement injection, intraoperative blood loss, occurrence of bone cement leakage, transient fever, and re-fracture between two groups showed no significant difference. The surgical time, the operation cost and fluoroscopy times of the PKP group was significantly higher than that of the PVP group. The post-operative VAS, ODI scores, the height of the anterior edge of the injured vertebrae and kyphosis deformity were significantly improved in both groups compared with the pre-operation. The improvement of vertebral height and kyphosis deformity in PKP group was significantly better than that in the PVP group at every same time point during the follow-up periods, but the 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 of patients with KD 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 clinical outcomes and efficacy of PVP with those of PKP for treatment of neurologically intact osteoporotic Kümmell’s disease. The study included eight nonrandomized observational studies; 2 prospective and 5 retrospective case-control studies. Four hundred and thirty-eight patients were included with 195 patients treated with PKP and 243 patients 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 did 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's 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 percutaneous vertebroplasty (PVP) and percutaneous kyphoplasty (PKP) for Kümmell's disease. The study included 56 patients: 28 patients received PVP, and 28 patients received PKP treatment. Visual analogue scale (VAS) was used to evaluate degree of low back pain and the ODI to evaluate the severity of dysfunction. At two 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's 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 was not statistical difference. Both groups significantly relieved patients' pain of low back, recovered the height of vertebral body and kyphosis angle and improved their quality of life, but PVP was associated with less surgical time, blood loss, and radiation exposure than those of PKP.

Huang et al. (2018) conducted a retrospective study to compare the efficacy of percutaneous kyphoplasty (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 12–36 months. The authors retrospectively reviewed outcomes, including Oswestry Disability Index (ODI), visual analogue scale (VAS), and kyphotic Cobb angle. VAS, ODI, and Cobb angle, measured postoperatively and at the final follow-up, were lower than those measured preoperatively in both groups ($p < 0.05$). VAS, ODI, and Cobb angle measured postoperatively demonstrated no significant differences when compared with those measured at the final follow-up in the PKP group ($p > 0.05$). In the BCA+SSF group, VAS and ODI at the final follow-up were lower than those measured postoperatively ($p < 0.05$), 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, postoperatively ($p < 0.05$). No difference was found in VAS and ODI at the final follow-up ($p > 0.05$) or the Cobb angle measured postoperatively and at the final follow-up ($p > 0.05$) between the 2 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 compared with BCA+SSF patients.

Clinical Practice Guidelines

American Academy of Orthopaedic Surgeons (AAOS)

In its 2010 (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 compare vertebroplasty to 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 one month and six months respectively).

In the same 2010 (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 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 to 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 of vertebral fractures given the unclear benefit on overall pain and the 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 vertebral compression fractures notes that conservative management (medical management with or without methods of immobility) is the initial first-line treatment of painful vertebral compression fractures. The ACR defines failure of conservative therapy as pain refractory to oral medications (NSAIDs 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 osteoporotic VCF with bone marrow edema or intravertebral cleft
- New symptomatic VCF with 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, osteoporotic VCF (2022)

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 (updated 2022) practice parameter 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 suffer 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 when compared to conservative management. Failure to treat patients with painful VCFs has been associated with an increased mortality and morbidity. 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 percutaneous vertebroplasty and percutaneous balloon kyphoplasty for treating osteoporotic vertebral compression fractures recommends percutaneous vertebroplasty, and percutaneous balloon kyphoplasty without stenting, as options for treating osteoporotic vertebral compression fractures only in people who:

- Have severe ongoing pain after a recent, unhealed vertebral fracture despite optimal pain management; and
- In whom the pain has been confirmed to be at the level of the fracture by physical examination and imaging.

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

The 2014 SIR, AANS, CNS, ACR, ASNR, ASSR, CIRA and the 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 non-operative medical therapy has not provided adequate pain relief or 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, disability and improving Karnofsky performance status and quality of life for patients with cancer and 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 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 August 19, 2024)

Polymethylmethacrylate (PMMA) bone cement is a device intended to be implanted that is made from methyl methacrylate, polymethylmethacrylate, esters of methacrylic acid, or copolymers containing polymethylmethacrylate 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 August 19, 2024)

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The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2024T0581M]

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Policy History/Revision Information

Date	Summary of Changes
02/01/2025	**Supporting Information** • Updated *Clinical Evidence and FDA* sections to reflect the most current information • Archived previous policy version PAIN 023.13

Instructions for Use

This Clinical Policy provides assistance in interpreting UnitedHealthcare Oxford standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare Oxford reserves the right to modify its Policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice.

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