

PERCUTANEOUS VERTEBROPLASTY AND KYPHOPLASTY

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[Instructions for Use](#) ⓘ

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Related Policies

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- [Epidural Steroid and Facet Injections for Spinal Pain](#)
- [Epiduroscopy, Epidural Lysis of Adhesions and Functional Anesthetic Discography](#)
- [Surgical Treatment for Spine Pain](#)
- [Total Artificial Disc Replacement for the Spine](#)

CONDITIONS OF COVERAGE

Applicable Lines of Business/Products	This policy applies to Oxford Commercial plan membership.
Benefit Type	General Benefit Package
Referral Required (Does not apply to non-gatekeeper products)	No
Authorization Required (Precertification always required for inpatient admission)	Yes ^{1,2}
Precertification with Medical Director Review Required	Yes ^{1,2}
Applicable Site(s) of Service (If site of service is not listed, Medical Director review is required)	All
Special Considerations	<p>¹Participating Providers in the Office Setting: Precertification is required for services performed in the office of a participating provider. Non-Participating/ Out-of-Network Providers in the Office setting: Precertification is not required, but is encouraged for out-of-network services performed in the office. If precertification is not obtained, Oxford will review for out-of-network benefits and medical necessity after the service is rendered.</p> <p>²Precertification with review by a Medical Director review or their designee is required.</p>

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); or
 - Steroid-induced vertebral fracture; or
 - Osteolytic metastatic disease involving a vertebral body; or
 - Multiple myeloma involving a vertebral body; or
 - Vertebral hemangioma with aggressive features; or

- o 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:
 - o Foraminal stenosis; or
 - o Facet arthropathy; or
 - o Herniated intervertebral disk; or
 - o Other spinal degenerative disease; or
 - o Other significant coexistent spinal or bony pain generators;

and

- The following are not present:
 - o Clinical evidence of spinal cord compression as confirmed by CT or MRI; or
 - o 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
 - o Healed VCF as confirmed by CT or MRI; or
 - o Lesions of the sacrum or coccyx (see the policy titled [Surgical Treatment for Spine Pain](#) for additional information on percutaneous sacral augmentation); or
 - o Asymptomatic vertebral compression fractures (VCFs); or
 - o 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.

DEFINITIONS

Functional or Physical Impairment: A Physical or Functional 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.

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 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 includes analgesics, bed rest, and external bracing; however, despite these types of management, progressive kyphosis, prolonged pain, and disability still occur in some patients. In these patients, 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 patient'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, 2013)

Vertebral hemangiomas are benign vascular tumors of the bony spine which are usually asymptomatic. A rare subset of them are 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)

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)

CLINICAL EVIDENCE

Percutaneous Vertebroplasty

In the VERTOS IV study, soFiranescu et al. (2018) conducted a randomized, double blind, sham controlled clinical trial to assess whether percutaneous vertebroplasty results in more pain relief than a sham procedure in patients with acute osteoporotic compression fractures of the vertebral body. Participants requiring treatment for acute osteoporotic vertebral compression fractures were randomized to either vertebroplasty (n=91) or a sham procedure (n=89). Main outcome measure was mean reduction in visual analogue scale (VAS) scores at one day, one week, and one, three, six, and 12 months. Clinically significant pain relief was defined as a decrease of 1.5 points in VAS scores from baseline. Secondary outcome measures were the differences between groups for changes in the quality of life for osteoporosis and Roland-Morris disability questionnaire scores during 12 months' follow-up. The mean difference in VAS scores between groups was 0.20 (95% confidence interval -0.53 to 0.94) at baseline, -0.43 (-1.17 to 0.31) at one day, -0.11 (-0.85 to 0.63) at one week, 0.41 (-0.33 to 1.15) at one month, 0.21 (-0.54 to 0.96) at three months, 0.39 (-0.37 to 1.15) at six months, and 0.45 (-0.37 to 1.24) at 12 months. Percutaneous vertebroplasty did not result in statistically significantly greater pain relief than a sham procedure during 12 months' follow-up among patients with acute osteoporotic vertebral compression fractures.

Wang et al. (2016) compared the clinical and radiological outcomes of patients undergoing percutaneous vertebroplasty (PVP) versus those undergoing facet blocking (FB) for severe pain due to osteoporotic vertebral compression fractures (OVCFs). 206 patients who had OVCFs on spine radiography and intractable back pain for ≤ 8 weeks were randomly assigned to the PVP group (100 patients) or the FB group (106 patients). Significantly lower

VAS, ODI, Roland Morris disability (RMD) scores for patients in the PVP group compared to those in the FB group were observed at follow-up of 1 day and 1 week ($p < 0.05$). However, differences in the VAS, ODI, RMD and SPC/MCS (SF-36) scores between the two groups at follow-ups of more than 1 month were statistically insignificant ($p > 0.05$). Difference in numbers of new fractures in the two groups at the follow-up of 12 months was also statistically insignificant. The authors concluded that PVP produced better pain relief than FB in the short term (≤ 1 week). However, the difference in pain-relief between these two techniques was insignificant in the long term (follow-up between 1 month and 12 months).

Farrokhi et al. (2011) conducted a randomized controlled trial that compared the efficacy of percutaneous vertebroplasty (PV) versus optimal medical therapy (OMT) in controlling pain and improving the quality of life (QOL) in patients with vertebral compression fractures. Efficacy was measured as the incidence of new vertebral fractures after PV, restoration of vertebral body height (VBH), and correction of deformity. Forty patients underwent PV and 42 received OMT. Primary outcomes were control of pain and improvement in QOL before treatment, and these were measured at 1 week and at 2, 6, 12, 24, and 36 months after the beginning of the treatment. Radiological evaluation to measure VBH and sagittal index was performed before and after treatment in both groups and after 36 months of follow-up. The authors found a statistically significant improvement in pain in the PV group compared with the OMT group at 1 week (difference -3.1, 95% CI -3.72 to -2.28; $p < 0.001$). The QOL improved significantly in the PV group (difference -14, 95% CI -15 to -12.82; $p < 0.028$). One week after PV, the average VBH restoration was 8 mm and the correction of deformity was 8°. The incidence of new fractures in the OMT group (13.3%) was higher than in the PV group (2.2%; $p < 0.01$). The authors observed that the PV group had statistically significant improvements in visual analog scale and QOL scores maintained over 24 months, improved VBH maintained over 36 months, and fewer adjacent-level fractures compared with the OMT group.

Klazien et al. (2010) conducted an open-label prospective randomized trial (VERTOS II) from the radiology departments of six hospitals in the Netherlands and Belgium. Patients were aged 50 years or older, had vertebral compression fractures on spine radiograph (minimum 15% height loss; level of fracture at Th5 or lower; bone edema on MRI), with back pain for 6 weeks or less, and a visual analogue scale (VAS) score of 5 or more. Patients ($n=202$) were randomly allocated to percutaneous vertebroplasty (101) or conservative treatment (101) by computer-generated randomization codes with a block size of six. Masking was not possible for participants, physicians, and outcome assessors. The primary outcome was pain relief at 1 month and 1 year as measured by VAS score. Vertebroplasty resulted in greater pain relief than did conservative treatment; difference in mean VAS score between baseline and 1 month was -5.2 (95% CI -5.88 to -4.72) after vertebroplasty and -2.7 (-3.22 to -1.98) after conservative treatment, and between baseline and 1 year was -5.7 (-6.22 to -4.98) after vertebroplasty and -3.7 (-4.35 to -3.05) after conservative treatment. The difference between groups in reduction of mean VAS score from baseline was 2.6 (95% CI 1.74-3.37, $p < 0.0001$) at 1 month and 2.0 (1.13-2.80, $p < 0.0001$) at 1 year. No serious complications or adverse events were reported. The authors concluded that in a subgroup of patients with acute osteoporotic vertebral compression fractures and persistent pain, percutaneous vertebroplasty is effective and safe as pain relief was immediate, is sustained for at least a year, and is significantly greater than that achieved with conservative treatment.

Kallmes et al. (2010) conducted a multicenter, randomized control trial for patients ($n= 131$) with 1-3 painful, osteoporotic vertebral compression fractures who were assigned to vertebroplasty or to a simulated vertebroplasty without cement. The primary outcomes were modified Roland-Morris Disability Questionnaire (RDQ) scores (range, 0-23) and patient ratings of average pain intensity in the preceding 24 hours (0-10 numerical rating scale) at one month. Patients were allowed to cross over after one month. The baseline characteristics were similar in the two groups. At one month, the vertebroplasty and control groups did not differ significantly on either the RDQ (treatment difference: 0.7; 95% CI: -1.3, 2.8; $P = 0.49$) or the pain rating (treatment difference: 0.7; 95% CI: -0.3, 1.7; $P = 0.19$). Both groups showed immediate improvement in disability and pain after the intervention. Although the groups did not differ significantly on any secondary outcome at one month, there was a trend toward a higher rate of clinically meaningful improvement in pain (30% decrease from baseline) in the vertebroplasty group (64% versus 48%, $P = 0.06$). At three months, there was a higher crossover rate in the control group (43% versus 12%, $P < 0.001$). There was one serious adverse event in each group. The authors concluded that improvement in osteoporotic compression fracture pain and pain-related disability was similar in patients treated with vertebroplasty and patients treated with simulated vertebroplasty without cement.

Rousing et al. (2010) reported the twelve-month outcomes from their previously described randomized trial to compare percutaneous vertebroplasty to conservative treatment in 50 patients. Pain score before and after the operation in the PVP group was 7.9 and 2.0, respectively. There was no difference between the groups concerning pain at the 3- and 12-months follow-up. Supplementary assessment of back pain 1 month after discharge from hospital showed a significant lower VAS score in the PVP group over the conservative group. In the study period, 2 adjacent fractures in the PVP group and no adjacent fractures in the conservative group were registered. The authors concluded that PVP is a good treatment for some patients with acute/subacute painful osteoporotic vertebral fractures,

and commented that the majority of fractures will heal after 8-12 weeks of conservative management with subsequent decline in pain.

In a multicenter, randomized, double-blind, placebo-controlled trial, Buchbinder et al. (2009) evaluated the short-term efficacy and safety of vertebroplasty for alleviating pain and improving physical functioning in persons with painful osteoporotic vertebral fractures. Participants with one or two painful osteoporotic vertebral fractures that were of less than 12 months' duration and unhealed, as confirmed by magnetic resonance imaging, were randomly assigned to undergo vertebroplasty or a sham procedure. Participants (n=78) were stratified according to treatment center, sex, and duration of symptoms (<6 weeks or ≥6 weeks). Outcomes were assessed at 1 week and at 1, 3, and 6 months. The primary outcome was overall pain (on a scale of 0 to 10, with 10 being the maximum imaginable pain) at 3 months. Of the total 78 participants, 71 (35 of 38 in the vertebroplasty group and 36 of 40 in the placebo group) completed the 6-month follow-up (91%). The authors found no beneficial effect of vertebroplasty over a sham procedure at 1 week or at 1, 3, or 6 months. Overall scores on measures of pain improved modestly in both groups over time, as did scores for pain at rest and during the night, physical functioning, and quality of life, but there were no significant between-group differences.

Rousing et al. (2009) compared percutaneous vertebroplasty to conservative treatment of patients with osteoporotic vertebral fractures in a randomized clinical study with respect to pain, physical and mental outcome. Fifty patients (41 females) were included from January 2001 until January 2008. Patients with acute (<2 weeks) and subacute (between 2 and 8 weeks) osteoporotic fractures were included and randomized to either PVP or conservative treatment. Pain was assessed with a visual analogue scale (VAS) and physical and mental outcome were assessed by validated questionnaires and tests. Tests, questionnaires, and plain radiographs were performed at the inclusion and after 3 months. Reduction in pain from initial visit to 3-month follow-up was comparable in the 2 groups (P = 0.33) from approximate visual analogue scale 8.0 to visual analogue scale 2.0, intragroup difference was significant (P = 0.00). Reduction in pain in the PVP group was immediate 12 to 24 hours after the procedure (P = 0.00). There was no significant difference in the other parameters when comparing the results at inclusion and after 3 months within both groups and between the groups after 3 months with a few exceptions. They observed 2 adjacent fractures in the PVP group and none in the conservative group. The authors concluded that the majority of patients with acute or subacute painful osteoporotic compression fractures in the spine will recover after a few months of conservative treatment. The risk of adjacent fractures needs further research.

Blasco et al. (2012) conducted a prospective, controlled, randomized single-center trial to compare the effects of percutaneous vertebroplasty (VP) versus conservative treatment on the quality of life and pain in patients with painful osteoporotic vertebral fractures, new fractures and secondary adverse effects were also analyzed during a 12-month follow-up period. Patients (n=125) were randomly assigned to receive conservative treatment or VP. The primary end point was to compare the evolution of the quality of life (Quality of Life Questionnaire of the European Foundation for Osteoporosis [Qualeffo-41] and pain [Visual Analogue Scale (VAS)]) during a 12 month follow-up. Secondary outcomes included comparison of analgesic consumption, clinical complications, and radiological vertebral fractures at the same time points. The authors reported that both arms showed significant improvement in VAS scores at all-time points, with greater improvement (p=0.035) in the VP group at the 2-month follow-up. In addition, significant improvement in Qualeffo total score was seen in the VP group throughout the study, whereas this was not seen in the conservative treatment arm until the 6-month follow-up. VP treatment was associated with a significantly increased incidence of vertebral fractures [odds ratio (OR)], 2.78; 95% confidence interval [CI], 1.02-7.62, p=0.0462). The authors observed that VP and conservative treatment are both associated with significant improvement in pain and quality of life in patients with painful osteoporotic vertebral fractures over a 1-year follow-up period. They concluded that VP achieved faster pain relief with significant improvement in the pain score at the 2-month follow-up but was associated with a higher incidence in vertebral fractures.

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.

Anselmetti et al. (2012) prospectively evaluated the safety and efficacy of percutaneous vertebroplasty (PV) in the treatment of vertebral compression fractures (VCFs) resulting from multiple myeloma (MM). PV was performed in 106 consecutive MM patients who had back pain due to VCFs, the treatment of which had failed conservative therapies. Follow-up (28.2 ± 12.1 months) was evaluated at 7 and 15 days as well as at 1, 3, 6, 12, 18, and every 6 months after PV. Visual analog scale (VAS) pain score, opioid use, external brace support, and Oswestry Disability Index (ODI) score were recorded. The median pretreatment VAS score of 9 (range 4-10) significantly ($P < 0.001$) decreased to 1 (range 0-9) after PV. Median pre-ODI values of 82% (range 36-89%) significantly improved to 7% (range 0-82%) ($P < 0.001$). Differences in pretreatment and posttreatment use of analgesic drug were statistically significant ($P < 0.001$). The majority of patients (70 of 81; 86%) did not use an external brace after PV ($P < 0.001$). The authors concluded that PV is a safe, effective, and long-lasting procedure for the treatment of vertebral compression pain resulting from MM.

Boschi et al. (2012) studied 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. Preprocedure 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.

Narayana et al. (2014) evaluated percutaneous vertebroplasty (PVP) in the treatment of painful vertebral hemangiomas refractory to medical management. 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 followup. The authors concluded that PVP is a safe and effective procedure in patients with painful vertebral hemangiomas refractory to medical management.

In a prospective randomized study, Chen et al. (2014) compared the efficacy of percutaneous vertebroplasty (PV) and conservative treatment (CT) for pain relief and functional outcome in patients with chronic compression fractures and persistent pain. Ninety-six patients with chronic compression fractures confirmed by MRI and persistent severe pain for 3 months or longer were prospectively randomly assigned to undergo PVP ($n=46$, Group A) or CT ($n=50$, Group B). The primary outcome was pain relief and functional outcome at 1 week, 1 month, 3 months, 6 months and 1 year. A total of 89 patients (46 in Group A and 43 in Group B) completed the 1 year follow-up assessment. Pain relief and functional outcomes were significantly better in Group A than in Group B, as determined by visual analogue scale scores, Oswestry Disability Index scores, and Roland Morris Disability scores at 1 week, 1 month, 3 months, 6 months and 1 year (all $p < 0.001$). The final clinical follow-up assessment indicated complete pain relief in 39 Group A patients and 15 Group B patients ($p < 0.001$). PVP for patients with chronic compression fractures and persistent severe pain was associated with better pain relief and improved functional outcomes at 1 year compared to CT.

In a prospective cohort study, Farrokhi et al. (2012) evaluated the efficacy of percutaneous vertebroplasty (PVP) in pain-relief in patients with spinal fractures due to metastatic spinal tumors. Patients ($n=25$) consisted of 11 males and 14 females with mean age of 53.5 (range 37 to 70 years). Severe pain was the main presenting symptom in these patients that had decreased their quality of life. The authors reported that the original pain was improved. VAS scores of the patients were compared before and after the procedure and meaningful P-value of 0.00 was obtained 24 hours and 2 months after PVP ($P \leq 0.05$) that was considered statistically significant. Mean VAS pain degree of these patients was 8.23 before PVP that was decreased to 2.12 and 1 in 24 hours and 2 months afterwards. The authors concluded that PVP is a safe, effective and minimally invasive surgical technique with decreased overall surgical complications which is successful at improving pain and contributes to spinal stabilization.

In the VERTOS study, Voormolen et al. (2007) prospectively assessed the short-term clinical outcome of patients with subacute or chronic painful osteoporotic vertebral compression fractures (VCF) treated with percutaneous vertebroplasty (PV) compared with optimal pain medication (OPM). Patients ($n=34$) were randomized into 2 groups: treatment by PV or OPM. After 2 weeks, patients from the OPM arm could change therapy to PV. Patients were evaluated 1 day and 2 weeks after treatment. A visual analog score (VAS) for pain and analgesic use were assessed before, and 1 day and 2 weeks after start of treatment. Quality of Life Questionnaire of the European Foundation for Osteoporosis (QUALEFFO) and Roland-Morris Disability (RMD) questionnaire scores were assessed before and 2 weeks after start of treatment. Follow-up scores in patients requesting PV treatment after 2 weeks OPM treatment were compared with scores during their OPM period. Eighteen patients treated with PV compared with 16 patients treated

with OPM had significantly better VAS and used less analgesics 1 day after treatment. Two weeks after treatment, the mean VAS was less but not significantly different in patients treated with OPM, whereas these patients used significantly less analgesics and had better QUALEFFO and RMD scores. Scores in the PV arm were influenced by occurrence of new VCF in 2 patients. After 2 weeks OPM, 14 patients requested PV treatment. All scores, 1 day and 2 weeks after PV, were significantly better compared with scores during conservative treatment. The authors concluded that pain relief and improvement of mobility, function, and stature after PV is immediate and significantly better in the short term compared with OPM treatment. The study is limited by small sample size.

In a systematic review, Health Quality Ontario (2016) evaluated the effectiveness and safety of percutaneous image-guided vertebral augmentation techniques, vertebroplasty and kyphoplasty, for palliation of cancer-related 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. 111 clinical reports (4,235 patients) were evaluated to determine the effectiveness of vertebroplasty (78 reports, 2,545 patients) or kyphoplasty (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 kyphoplasty with usual care, improvements in pain scores, pain-related disability, and health-related quality of life were significantly better in the kyphoplasty group than in the usual care group. Bone cement leakage, mostly asymptomatic, was commonly reported after vertebroplasty and kyphoplasty. Major adverse events, however, were uncommon. The authors concluded that both vertebroplasty and kyphoplasty 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.

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.

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.

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.

Buchbinder et al. (2015) reviewed available evidence regarding the benefits and harms of vertebroplasty for treatment of osteoporotic vertebral fractures. Inclusion criteria were randomized and quasi-randomized controlled trials including adults with painful osteoporotic vertebral fractures of any duration and comparing vertebroplasty with placebo (sham), usual care, or any other intervention. Vertebroplasty compared with placebo was the primary comparison, the authors noting it was least prone to bias. 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. Eleven RCTs and one quasi-RCT conducted in various countries were included. Based upon moderate quality evidence, the authors concluded that there does not appear to be a role for vertebroplasty in the treatment of osteoporotic vertebral fractures in routine practice. They found no demonstrable clinically important benefits compared with a sham procedure and subgroup analyses indicated that results did not differ according to duration of pain ≤ 6 weeks versus > 6 weeks.

Park et al. (2018) assess vertebral height restoration, re-collapse and change of back pain in osteoporotic vertebral compression fracture (OVCF) patients with or without intra-vertebral cleft (IVC) through a retrospective review. The records of 108 patients with IVC (group I) and 233 patients without IVC (group II) were included. The heights of the anterior, middle, and posterior columns, as well as the wedge angle (WA) of the fractured vertebral body were measured. The overall incidence of IVC in OVCF patients who underwent vertebroplasty was 20.8% (127/611 patients). Group I showed significantly higher CR over the entire follow-up period, with the exception of CR for the anterior column at final follow-up, and CR for the posterior column throughout the follow-up. The mean restoration rates at the anterior and middle column immediately after vertebroplasty were also significantly larger in group I. Re-collapse rate in all columns was similar for groups I and II. The mean wedge angle was significantly larger in group I over the entire follow-up period. The groups did not differ in terms of NRS score at final follow-up. The authors concluded that vertebroplasty restores vertebral body heights and WA more effectively in OVCF patients with IVC, and provides satisfactory radiographic and clinical outcomes regardless of the presence of IVC.

Park et al. (2017) conducted a retrospective review to evaluate the radiographic and clinical outcomes of percutaneous vertebroplasty (PVP) in patients with Kümmell's disease (N=18). The mean VAS score significantly decreased after PVP and the decrease was maintained through to the final follow-up ($p < 0.05$). However, the regional and global kyphotic angle, LL, and TLJ angle were not improved. Cement leakage was observed in 5 cases (26.3%); however, there were no cases of cement leakage into the spinal canal. No neurological deterioration was observed, even among patients with cement leakage. Adjacent level fractures were detected in 3 cases (15.8%). In the authors' opinion, PVP can be considered as an effective treatment option for pain relief and maintenance of sagittal balance in patients with Kümmell's disease.

Sun et al. (2014) conducted a retrospective analysis to evaluate the safety and efficacy of percutaneous vertebroplasty (PVP) in patients with painful spinal metastasis and encroachment of epidural space. Patients (n=43) with spinal metastasis underwent PVP, for a total of 69 affected levels. All patients had at least 1 level associated with epidural encroachment related to metastasis. Among these patients, 14 had signs of spinal cord or cauda equina compression. Pain intensity was scored on a visual-analog scale (VAS). The analgesic efficacy was defined as at least 50% improvement in pain score as compared with the pre-procedure baseline and post-procedure. Clinical improvement of neurological compressive symptoms was defined as a decrease in ASIA impairment scale from baseline of 1 point or more. The authors reported that analgesic efficacy was achieved in 89.7% of survival patients at 1 month, 87.5% at 3 months, 86.9% at 6 months, and 84.6% at 1 year. No deterioration of spinal cord or cauda equina compression symptoms was observed after a PVP in any patients. The different grade of epidural encroachment of the lesions was not correlated with filling volume or extraosseous leakage ($P > 0.05$). The treated levels with epidural encroachment showed a statistically significant relationship to spinal-canal leakage ($P > 0.05$). The authors concluded that PVP can be performed safely and effectively in patients with painful spinal metastasis and epidural encroachment.

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. 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 anaesthetic; no trials of BKP compared with local anaesthesia 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.

In a meta-analysis of randomized controlled trials, Liu et al. (2013) compared the amount of pain reduction measured using the visual analog scale (VAS) when osteoporotic vertebral compression fractures are treated with percutaneous vertebroplasty (PVP) or conservatively. They also assessed the clinical utility of PVP. Five randomized controlled trials met the analysis criteria; conservative treatments used as comparators in these trials were different. There was no difference in pain relief in the PVP group at 2 weeks and one month when compared with the conservatively managed group. Pool results from the 5 studies showed that pain relief in the PVP group was greater than that of the conservative group at 3 months, 6 months, and 12 months. However, after subgroup analysis, pain scores were similar between the PVP group and the sham injection group from 2 weeks to 6 months. Compared with non-operative therapy, PVP reduced pain at all times studied. The authors concluded that PVP has some value for relieving pain; however, the possibility of a placebo effect should be considered. They recommend more large scale, double blinded, controlled trials in order to quantify the pain relief afforded by PVP more precisely.

Yuan et al. (2016) conducted a meta-analysis to examine vertebroplasty or balloon kyphoplasty for osteoporotic compression fractures compared to conservative treatment. The authors' review determined that overall vertebroplasty and kyphoplasty 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 kyphoplasty 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 kyphoplasty and only 1 of these studies examined function and quality of life.

Shi et al. (2012) performed a meta-analysis to determine whether, when compared to non-operative management or sham procedures, percutaneous vertebroplasty (PVP) provided greater improvement in pain and pain-related disability for patients with vertebral compression fractures. Using a random effects model, the authors calculated the weighted mean differences to evaluate the pain reduction at different times as the primary outcome. Pain-related disability was assessed by a quality of life (QOL) measure. Improvement of QOL and recurrence of vertebral fractures were the secondary outcomes. We used subgroup analysis to reinvestigate pain relief and function improvement of PVP based on two different controls: nonoperative therapy and sham injection. The total number of patients was 886. Based on the outcome of their review, pain scoring was similar between the PVP group and the sham injection group at 1 to 29 days and 90 days. However, compared with nonoperative therapy, PVP reduced pain at all times studied. QOL in the PVP group was improved or tended to be improved compared with QOL for both control groups. The risk of new fractures was similar between the PVP groups and both control groups. They noted that different control groups may have accounted for the different conclusions in the literature regarding the ability of PVP to relieve pain and restore function recovery. Compared with nonoperative treatment PVP relieved pain better and improved QOL. PVP did not increase the risk of new fractures.

In a retrospective analysis, Lim et al. (2009) evaluated outcomes of percutaneous vertebroplasty (PV) in 102 patients (185 vertebral bodies) with metastatic spine tumors (81%) and multiple myeloma (19%). Indications for VP were; 1) pathologic compression fractures of bone metastasis or hematological malignancies on imaging, 2) back pain without neurological deficit, and 3) intractable pain unresponsive to conservative treatment (consisting of analgesic medication, bed rest, and in some cases external brace therapy). The median age was 55 years (range 22-82 years). 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° preoperatively to 12.03° (postoperative one day), 13.64° (three month), and 15.61° (one year). The authors observed that immediate pain relief was definite after VP in pathologic compression fracture of osteolytic spinal disease and although VAS was slightly increased on one year follow-up, VP effect was maintained without significant change. They concluded that these results indicate that VP could be a safe and effective procedure as a palliative treatment of the spinal tumor patients.

In an analysis of the National Inpatient Sample (NIS) database to determine trends in kyphoplasty and vertebroplasty, Laratta et al. (2018) reported that vertebroplasty has been associated with retropulsion of cement into the spinal canal in up to 67% of cases. The NIS was developed for the Healthcare Cost and Utilization Project (HCUP) and constitutes the largest all-payer inpatient database in the United States. The database represents a 20% sample of discharges from U.S. hospitals (excluding rehabilitation and long-term acute care hospitals), which is weighted to provide national estimates. Further prospective randomized trials are necessary to more rigorously evaluate the long-term outcomes and cost-effectiveness of kyphoplasty versus vertebroplasty from a national healthcare perspective.

Semaan et al. (2017) conducted a comparative review to evaluate the clinical outcome and subsequent sequelae of cement extravasation after percutaneous kyphoplasty (n=223) and vertebroplasty (N=188) and found that the most common site of cement extravasation was in paravertebral soft tissues for vertebroplasty (n = 33, 40.7%) and for kyphoplasty (n = 30, 30%). In the subgroup where cement leaked into the intradiscal space, adjacent vertebral body fractures occurred in 3/26 vertebrae (11.5%) in the vertebroplasty group and in 2/18 vertebrae (11.1%) in the kyphoplasty group. Both groups showed a statistically significant decrease in both VAS (P < 0.001) and ODI scores (rs concluded that although kyphoplasty has an advantage in terms of cement extravasation, this factor did not reflect on subsequent sequelae or final clinical outcomes.

In a review of surgical treatments for aggressive vertebral hemangiomas, Vasudeva et al. (2016) report 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.

Kyphoplasty

In the KAST trial, Beall et al. (2018) assessed the effect of 2 different augmentation procedures (balloon kyphoplasty and implant-based approach) on unplanned readmission rates due to significant adverse effects. Forty (27.8%) patients with implants had 69 SAEs associated with readmission compared to 44 (31.2%) patients with BK having 103 events. The risk for all SAEs leading to readmission was 34.4% lower with the implant than for BK (95% confidence interval = 11.1%, 51.7%; P < 0.01). Multivariate analysis showed that the risk of SAEs associated with readmission was decreased in subjects treated with the implant compared to BK, and increased in patients with prior histories of vertebral compression fractures (VCFs) or significant osteoporosis. The augmentation approaches compared in this study have similar pain relief and quality of life effects; the implant showed a lower risk of readmissions. The authors noted that the sample size is underpowered, although the results remain significant.

Boonen et al. (2011) compared the efficacy and safety of balloon kyphoplasty to nonsurgical therapy over 24 months in patients with acute painful fractures. Adults with one to three vertebral fractures were randomized within 3 months from onset of pain to undergo kyphoplasty (n = 149) or nonsurgical therapy (n = 151). Quality of life, function, disability, and pain were assessed over 24 months. The authors reported that kyphoplasty was associated with greater improvements in Short-Form 36 (SF-36) Physical Component Summary (PCS) scores when averaged across the 24-month follow-up period compared with nonsurgical therapy [overall treatment effect 3.24 points, 95% confidence interval (CI) 1.47-5.01, p = .0004]; the treatment difference remained statistically significant at 6 months (3.39 points, 95% CI 1.13-5.64, p = .003) but not at 12 months (1.70 points, 95% CI -0.59 to 3.98, p = .15) or 24 months (1.68 points, 95% CI -0.63 to 3.99, p = .15). Greater improvement in back pain was observed over 24 months for kyphoplasty (overall treatment effect -1.49 points, 95% CI -1.88 to -1.10, p < .0001); the difference between groups remained statistically significant at 24 months (-0.80 points, 95% CI -1.39 to -0.20, p = .009). There was no statistically significant difference between groups in the number of patients (47.5% for kyphoplasty, 44.1% for control) with new radiographic vertebral fractures; fewer fractures occurred (~18%) within the second year. The authors commented that compared with nonsurgical management, kyphoplasty rapidly reduced pain and improved function, disability, and quality of life without increasing the risk of additional vertebral fractures. They concluded that the differences from nonsurgical management are statistically significant when averaged across 24 months; most outcomes are not statistically different at 24 months, but the reduction in back pain remains statistically significant at all-time points.

In a multicenter, randomized controlled trial [Cancer Patient Fracture Evaluation (CAFÉ) study], Berenson et al. (2011) evaluated the efficacy and safety of balloon kyphoplasty compared with non-surgical management for patients with cancer who have painful vertebral compression fractures. Patients (n=134) aged 21 and over with cancer and painful vertebral compression fractures were randomly assigned by a computer-generated minimization randomization algorithm to kyphoplasty (n=70) or non-surgical management (n=64). Investigators and patients were not masked to treatment allocation. The primary endpoint was back-specific functional status measured by the Roland-Morris disability questionnaire (RDQ) score at 1 month. Outcomes at 1 month were analyzed by modified intention to treat, including all patients with data available at baseline and at 1 month follow-up. Patients in the non-surgical management group (control) were allowed to crossover to receive kyphoplasty after 1 month. The mean RDQ score in the kyphoplasty group changed from 17.6 at baseline to 9.1 at 1 month (mean change -8.3 points, 95% CI -6.4 to -10.2; p<0.0001). The mean score in the control group changed from 18.2 to 18.0 (mean change 0.1 points; 95% CI -0.8 to 1.0; p=0.83). At 1 month, the kyphoplasty treatment effect for RDQ was -8.4 points (95% CI -7.6 to -9.2; p<0.0001). The authors concluded that for painful VCFs in patients with cancer, kyphoplasty is an effective and safe treatment that rapidly reduces pain and improves function.

In a randomized controlled trial (FREE trial) at 21 sites and eight countries, Wardlaw et al. (2009) assessed the efficacy and safety of balloon kyphoplasty. Adults with one to three acute vertebral fractures were eligible for enrolment. Patients (n= 300) were assigned by a computer-generated sequence to receive kyphoplasty treatment (n=149) or non-surgical care (n=151). The primary outcome was the difference in change from baseline to 1 month in the short-form (SF)-36 physical component summary (PCS) score (scale 0-100) between the kyphoplasty and control groups. Quality of life and other efficacy measurements and safety were assessed up to 12 months. 138 participants in the kyphoplasty group and 128 controls completed follow-up at 1 month. By use of repeated measures mixed effects modelling, all 300 randomized participants were included in the analysis. Mean SF-36 PCS score improved by 7.2 points (95% CI 5.7-8.8), from 26.0 at baseline to 33.4 at 1 month, in the kyphoplasty group, and by 2.0 points (0.4-3.6), from 25.5 to 27.4, in the non-surgical group (difference between groups 5.2 points, 2.9-7.4; $p < 0.0001$). The frequency of adverse events did not differ between groups. There were two serious adverse events related to kyphoplasty (hematoma and urinary tract infection); other serious adverse events (such as myocardial infarction and pulmonary embolism) did not occur perioperatively and were not related to procedure. The authors conclude that balloon kyphoplasty is an effective and safe procedure for patients with acute vertebral fractures and will help to inform decisions regarding its use as an early treatment option. The FREE study was limited by the inclusion of less than 80% of randomized patients in its final analysis, and an imbalance in drop-outs by treatment arm.

In a retrospective analysis Zhang et al. (2015) evaluated a total of 73 patients who underwent percutaneous vertebroplasty (n=38) or kyphoplasty (n=35) for the management of Kummel disease. Visual analogue score (VAS) was used to evaluate pain. The anterior vertebral height was measured. The operative time, the incidence of cement leakage and the costs were recorded. In both the percutaneous vertebroplasty and kyphoplasty group, the VAS and anterior vertebral height significantly improved at 1-day postoperatively ($P < 0.05$), and the improvement sustained at the final followup ($P > 0.05$). Between the PVP and PKP groups, there were no significant differences in VAS and the anterior vertebral height at 1-day postoperatively and at the final followup ($P > 0.05$). The operating time and expense in the PKP group were higher than the PVP group ($P < 0.001$). Cement leakages in the PKP group were fewer than PVP group ($P < 0.05$). The authors concluded that PVP is a faster, less expensive option that still provides a comparable pain relief and restoration of vertebral height to PKP for the treatment of Kummel disease. PKP has a significant advantage over PVP in term of the fewer cement leakages.

In a retrospective analysis, Burton et al. (2011) evaluated outcomes of cancer patients with painful vertebral compression fractures treated with either percutaneous vertebroplasty or kyphoplasty. A total of 407 cancer patients had 1,156 fractures that had been treated with percutaneous vertebroplasty or kyphoplasty; 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 National Institute for Health and Care Excellence (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.

Deibert et al. (2016) conducted a longitudinal cohort investigation of the development of symptomatic adjacent level compression fractures following balloon-assisted kyphoplasty (BAK). Seventy-seven of 726 patients (10.6%) underwent a second BAK procedure on average 350 days following the initial procedure (range 21 to 2,691 days). Third and fourth procedures were less common, treated in 11 and 3 patients, respectively. Forty-eight of 77 patients (62%) suffered a fracture at a level immediately adjacent to the index level at mean time of 256 days. Remote level fractures were treated at a mean time of 489 days, but no statistical difference was noted. There was no statistically significant difference between tobacco use, BMI, and chronic steroid use between patients suffering from remote and adjacent level VCFs. Specific risk factors for remote versus adjacent level fractures could not be determined. This was not a population based study and the true incidence of subsequent fractures after BAK might be underestimated by this analysis.

In a randomized clinical trial of 115 subjects, Evans et al. (2016) found kyphoplasty and vertebroplasty equally effective in substantially reducing pain and disability in patients with vertebral body compression fractures.

Zhang et al. (2018) conducted a meta-analysis to evaluate whether percutaneous vertebroplasty or balloon kyphoplasty for osteoporotic vertebral compression fractures increase the incidence of new vertebral fractures. Twelve studies and 1,328 patients were included; 768 underwent a surgical procedure, and 560 received non-operative treatments. For new-level vertebral fractures, the meta-analysis found no significant difference between the 2

methods, including total new fractures ($P = 0.55$) and adjacent fractures ($P = 0.5$). For pre-existing vertebral fractures, there was no significant difference between the 2 groups (operative and non-operative groups) ($P = 0.24$). Additionally, there was no significant difference in bone mineral density, both in the lumbar ($P = 0.13$) and femoral neck regions ($P = 0.37$), between the 2 interventions. The analysis did not reveal evidence of an increased risk of fracture of vertebral bodies, especially those adjacent to the treated vertebrae, following augmentation with either method compared with conservative treatment.

In a review of pain, quality of life and safety outcomes of balloon kyphoplasty 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). Balloon kyphoplasty 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 balloon kyphoplasty and percutaneous vertebroplasty 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 balloon kyphoplasty versus non-surgical management, and lack of study blinding. The Task Force recommends well-conducted randomized trials comparing balloon kyphoplasty with sham to help resolve remaining uncertainty about the relative benefits and harms of this procedure. (Rodriguez et al., 2017)

Chandra et al. (2014) conducted a systematic review on vertebral augmentation and 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); and 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)

Gu et al. (2016) performed a systematic review and meta-analysis of studies comparing the outcomes of vertebroplasty and kyphoplasty in the treatment of vertebral compression fractures, which included prospective non-randomized, retrospective, comparative and randomized studies. No significant difference was found between vertebroplasty and kyphoplasty in short- and long-term pain and disability outcomes. Further studies are needed to better determine if any particular subgroups of patients would benefit more from vertebroplasty or kyphoplasty in the treatment of vertebral body compression fractures.

Professional Societies

American Association of Clinical Endocrinologists (AACE)/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) 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. (Grade B, BEL 1; downgraded due to limitations of published studies)

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), Society of NeuroInterventional Surgery (SNIS)

The 2014 SIR, AANS, CNS, ACR, ASNR, ASSR, CIRA and the SNIS consensus statement on percutaneous vertebral augmentation 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, 2014)

American College of Radiology (ACR)

The ACR appropriateness criteria for the management of vertebral compression fractures (2013) 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 ACR also comments that most patients with osteoporotic vertebral compression fractures have spontaneous resolution of pain, even without medication. Vertebral augmentation has been reserved for patients who have failed conservative therapy.

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 2014 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.

American Academy of Orthopaedic Surgeons (AAOS)

In its 2010 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 two Level I 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 guidance and evidence report, the AAOS considers kyphoplasty as an option for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact. This is based on limited evidence regarding two Level II studies that examined the use of kyphoplasty compared 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.

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

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. See the following website for more information (use product codes NDN, LOD): <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnm.cfm>. (Accessed July 10, 2018)

Polymethylmethacrylate (PMMA) bone cement is a device intended to be implanted that is made from methylmethacrylate, 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. See the following website for more information (use product codes HRX, HXG): <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnm.cfm>. (Accessed July 10, 2018)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
01/01/2019	<ul style="list-style-type: none"> • Reorganized policy template: <ul style="list-style-type: none"> ○ Simplified and relocated <i>Instructions for Use</i> ○ Removed <i>Benefit Considerations</i> section • Updated and reformatted coverage rationale: <ul style="list-style-type: none"> ○ Simplified content ○ Replaced reference to “severe debilitating pain” with “pain causing <i>Functional or Physical Impairment</i>” • Added definition of “Functional or Physical Impairment” • Archived previous policy version PAIN 023.3 T2

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.

The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Oxford Clinical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.