PERCUTANEOUS VERTEBROPLASTY AND KYPHOPLASTY

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INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, 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.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines 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.

CONDITIONS OF COVERAGE

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<th>Applicable Lines of Business/ Products</th>
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| Precertification with Medical Director Review Required | Yes  
| Applicable Site(s) of Service            | All                                                      |
| Special Considerations                   | 1^Precertification is encouraged (but not required) for out-of-network services covered under the general benefits package when provided in a physician's office. If precertification is not obtained, Oxford may review for medical necessity after the service is rendered.  
|                                           | 2^Precertification with review by a Medical Director review or their designee is required. |

^1Precertification is encouraged (but not required) for out-of-network services covered under the general benefits package when provided in a physician's office. If precertification is not obtained, Oxford may review for medical necessity after the service is rendered.

^2Precertification with review by a Medical Director review or their designee is required.
BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Percutaneous vertebroplasty and kyphoplasty are proven and medically necessary for treating severe debilitating pain in cervical, thoracic or lumbar vertebral bodies within 4 months of pain onset that has failed to respond to optimal medical therapy (e.g., acetaminophen, non-steroidal anti-inflammatory drugs [NSAIDS], narcotic analgesics, braces, physical therapy, etc.) 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 (see the policy titled Surgical Treatment for Spine Pain 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 inadequate clinical evidence of safety and/or efficacy in published, peer-reviewed literature.

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.

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<th>CPT Code</th>
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<td>22510</td>
<td>Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic</td>
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Percutaneous vertebroplasty and Kyphoplasty

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)
Percutaneous Vertebroplasty

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.

Klazen 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

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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≤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. (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.

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
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-blind 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.

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 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.

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 PV 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 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**

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 terms 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 (<0.1%). 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 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.

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).
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Percutaneous Vertebroplasty and Kyphoplasty examined the use of kyphoplasty compared to conservative treatment. Symptoms and 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

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 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

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 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.

Society of NeuroInterventional Surgery (SNS)
The SNS Standards and Guidelines Committee report on vertebral augmentation (Chandra, 2014) has the following recommendations:

- 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).
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.

American Society of Bone and Mineral Research (ASBMR)
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), the 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 authors noted that the clinical importance of the greater improvements with balloon kyphoplasty versus non-surgical management is uncertain, may be due to placebo effect, and may not counterbalance short-term adverse event risks. Outcomes appeared similar between balloon kyphoplasty and other surgical interventions. The ASMBR 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)

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/pmn.cfm. (Accessed June 6, 2017)

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/pmn.cfm. (Accessed June 6, 2017)

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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. [2017T0581B]


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POLICY HISTORY/REVISION INFORMATION

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