INLAND EMPIRE HEALTH PLAN

IEHP UM Subcommittee Approved Authorization Guidelines
Percutaneous Vertebroplasty and Percutaneous Kyphoplasty

Policy:

Selection Criteria for Percutaneous Vertebroplasy and Kyphoplasty Procedure(s):

"*Percutaneous vertebroplasty* is the injection of a biomaterial, usually polymethylmethacrylate, into a thoracic or lumbar vertebral body under imaging guidance. The procedure is utilized for pain relief, stabilizing/strengthening weakened vertebral bodies. It does not restore the height or shape of the affected vertebra."

"*Kyphoplasty* is an optional variation of the vertebroplasty procedure. Kyphoplasty is a minimally invasive procedure used to treat fractures involving crushed or collapsed bone or for the creation of a void in cancellous bone. An inflatable bone tamp is inserted into a 1-2 cm incision at the fracture site, followed by creation of a narrow drill channel and insertion and inflation of an orthopedic balloon under low pressure to reduce the fracture creating a cavity. The balloon is removed and a bone void filler (e.g., methylmethacrylate) is inserted into the cavity creating an "internal cast" to stabilize the fracture."

Percutaneous vertebroplasty or kyphoplasty is considered medically necessary after failure of conservative medical therapy in patients when any of the following criteria is met:

A. Osteolytic vertebral metastasis or myeloma with severe back pain related to destruction of the vertebral body not involving the major part of the cortical bone, and chemotherapy and radiation therapy have failed to relieve symptoms; or

B. Vertebral hemangiomas with aggressive clinical signs (severe pain or nerve compression) and/or aggressive radiological signs, and radiation therapy has failed to relieve symptoms; or

C. Osteoporotic vertebral collapse with persistent debilitating pain, which has not responded to accepted standard medical therapy as documented in the patient medical record. Standard medical therapy may include initial bed rest with progressive activity, analgesics, physical therapy, bracing and exercises to correct postural deformity and increase muscle tone, salmon calcitonin, bisphosphonates and calcium supplementation; or

D. Painful vertebral eosinophilic granuloma with spinal instability; or

E. Traumatic or steroid-induced vertebral fracture presently at 50 percent of original height or greater with persistent debilitating pain and loss of mobility, which has not responded to standard medical therapy, including a minimal of a two week trial of NSAIDs/Opioids and physical therapy with modalities.

Investigational/Not Medically Necessary:

1. Kyphoplasty will not be considered reasonable and necessary for asymptomatic fractures, fractures healing by conservative means, kyphosis without fracture, and the treatment of secondary complications of kyphosis, such as reduced pulmonary function or gastrointestinal (GI) complications
2. Percutaneous vertebroplasty (PVP) and kyphoplasty (KP) are considered investigational / not medically necessary for all uses that do not meet the criteria as listed above. Clinical history, exam and imaging modalities (X-ray, MRI) should be used to exclude other causes of back pain and to identify the affected vertebrae.

Contraindications:

1. Patients with unacceptable operative risk.
2. Patients with evidence of spinal cord compression or compromise.

Background:

Percutaneous vertebroplasty (PV) and percutaneous kyphoplasty are interventional radiology procedures which involve the injection of bone cement into vertebral body compression fractures with the goal of relieving pain, improving mobility, and preventing further collapse of the bone. The procedure was initially proposed for the treatment of painful vertebral hemangiomas, myeloma, and metastatic lesions, and is now also being used in patients with osteoporotic compression fractures. This policy addresses percutaneous vertebroplasty and percutaneous kyphoplasty.

Severe, debilitating back pain is a common health concern that can lead to compromised mobility, decreased quality of life, morbidity, and loss of function and productivity. There are multiple causes for back pain including obesity, multiple myeloma, vertebral compression fractures, degenerative disc disease, spinal stenosis, spinal metastases, spondylolisthesis, vertebral hemangiomas and acute trauma. In patients with malignancy and osteoporosis, including steroid induced osteoporosis, vertebral compression fractures are a common complication caused by osteolytic destruction (Ross, 1997). Percutaneous vertebroplasty (PVP) is an interventional radiology procedure which involves inserting bone cement, into the fractured vertebrae (Yimin, 2013).

Additionally, a number of smaller prospective, uncontrolled studies and several retrospective studies (total of 564 patients) all reported that PV significantly reduced pain and improved mobility in the majority of patients, with few patients experiencing persistent mild pain (Amar,

2001; Kaufmann, 2001; Kim, 2002; McGraw, 2002; Vasconcelos, 2002; Brown, 2004). Results from the majority of these studies indicate PVP can produce significant pain relief, increase mobility, and improve quality of life in 70% to 80% of patients with osteolytic lesions from hemangiomas, metastases or myeloma, or osteoporotic compression fractures. In these studies, pain relief was apparent within 1 to 2 days after injection and persisted for at least several months and up to several years. Complications were relatively rare with a higher rate in patients with malignant processes, due primarily to leakage of cement from extensive lytic regions in the vertebral bodies and to the poor overall health status of these patients.

In regards to KP, one prospective, controlled trial of patients with osteoporotic vertebral fractures reported improvement in pain scores (P=0.008) in the KP group (40 patients) when compared to the control group (20 patients), as well as a reduction in back pain related physician visits in the KP group during the 12-month follow-up (P=0.006). In addition the KP group also had fewer new vertebral fractures after 12-months (P=0.0084) (Grafe, 2005). Another prospective, nonrandomized controlled study of patients with osteoporotic vertebral fractures found that within 3-6 months there was greater reported pain relief and return to daily activity in the KP group (40 patients) when compared to the control (20 patients treated with conventional medical management) (Kasperk, 2005).Furthermore, six prospective, uncontrolled studies (Lieberman 2001; Dudeney, 2002; Theodorou, 2002; Coumans, 2003; Phillips, 2003; Berlemann, 2004) and two retrospective studies (Ledlie, 2003; Rhyne, 2004) that evaluated KP (total of 342 patients) were identified in the literature. Patients included in the studies were generally those with vertebral compression fractures resulting from osteoporosis, although patients with other conditions were not excluded. These studies reported a degree of pain relief, improved mobility, and enhanced quality of life that was similar to that reported for patients in the PVP studies, with approximately 35% restoration of vertebral body height in the majority of patients. The largest of the prospective studies reported on 1-year clinical outcomes with a follow-up period up to 18 months. Both pain and disability scores improved significantly from preoperative to postoperative levels, and seven areas of the SF-36 inventory demonstrated significant improvement postoperatively. Early results suggest that KP can restore some vertebral height in patients with compression fractures. However, additional evidence is required from high quality studies before it can be concluded that KP can significantly reduce the severity of spinal curvature or the disability that accompanies this condition, or that partial restoration of vertebral body height translates into improved patient outcomes.

Since the first North American case series of PVP appeared in the literature (Deramond, 1998), there has been concern that the treatment of symptomatic vertebral fractures by either PVP or KP may cause subsequent vertebral fracture (Jensen, 2004; Kallmes, 2003; Grados, 2000). This concern was reinforced with biomechanical data from cadaver studies showing cement augmentation places additional stress on adjacent levels by creating reduced compliance in the treated vertebra. (Baroud, 2003; Bereleman, 2002). More recent retrospective studies (Uppin, 2003; Fribourg, 2004; Syed, 2005; Trout, 2006) suggest following either PVP or KP, patients are at increased risk for new adjacent level fractures. There is, however, difficulty demonstrating a casual relationship between either PVP or KP and subsequent spinal fracture as the natural

history of osteoporotic spine fractures is not well known. Anecdotal and small case series suggest there may be both temporal and spatial clustering of untreated vertebral fractures. The largest study of temporal clustering (Lindsay 2001) retrospectively looked at 2725 women in the placebo arms of four risedronate trials. The overall incidence of new vertebral fractures in the first year was 6.6%, but the presence of a vertebral fracture at baseline increased the risk of a new vertebral fracture five fold during the initial year of the study. Spatial clustering is defined as the known propensity for spontaneous osteoporotic spinal fractures to occur in a bi-modal distribution at mid thoracic (T7-T9) and thoracolumbar (T12-L1) regions. Since spinal fractures treated with either PVP or KP are more common in these regions to begin with and the adjacent vertebrae may be inherently at increased risk for fracture with or without treatment, a higher risk of adjacent rather than distant fracture might be a result of the natural history of clustered vertebral fracture and not cement augmentation. In the absence of an adequate control group of untreated spinal fractures in these studies (Uppin, 2003; Fribourg, 2004; Syed, 2005; Trout, 2006), it is difficult to establish a causal relationship between PVP or KP and subsequent spinal fracture.

Studies have associated PVP and KP with positive clinical outcomes, however it is unclear if the procedures are significantly more efficacious than conservative treatment options and more research on the topic is necessary. Currently, PVP and KP are considered medically necessary for the limited indications cited in this policy. However, patients who undergo either procedure should be informed of a significant risk of subsequent spinal fracture. Whether this risk is greater than the natural history of the treated condition as a result of the procedure is not known.

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