IEHP UM Subcommittee Approved Authorization Guidelines
Percutaneous Vertebroplasty and Percutaneous Kyphoplasty

Policy:

Selection Criteria for Kyphoplasty Procedure(s):
Percutaneous vertebroplasty or kyphoplasty is considered medically necessary after failure of standard 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 with persistent debilitating pain, which has not responded to standard medical therapy.

Investigational/Not Medically Necessary:
Percutaneous vertebroplasty or kyphoplasty is considered investigational/not medically necessary for all uses that do not meet the criteria identified as medically necessary listed above.

Contraindications:
Patients with unacceptable operative risk.

Rationale:
Evidence regarding efficacy of PV comes from a number of prospective, uncontrolled trials, case series reports, and several retrospective studies. Two large case series (total of 421 patients) indicated percutaneous vertebroplasty (PV) was highly effective in significantly reducing pain...
and increasing mobility in over 70% of patients with vertebral body lesions, with minimal complications (Deramond, 1998; Gangi, 1999). 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 PV 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.

Percutaneous balloon kyphoplasty is a modification of vertebroplasty and involves inflation of a balloon within the collapsed vertebral body prior to stabilization with bone cement. Evidence regarding efficacy comes from a number of prospective, uncontrolled studies and two retrospective studies. 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 kyphoplasty (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 vertebroplasty 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 kyphoplasty 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 kyphoplasty 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.

**Literature/Supportive Documentation:**

Since the first North American case series of vertebroplasty appeared in the literature (Deramond, 1998), there has been concern that the treatment of symptomatic vertebral fractures by either percutaneous vertebroplasty or kyphoplasty 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 vertebroplasty or kyphoplasty, patients are at increased risk for new adjacent level fractures.
There is, however, difficulty demonstrating a casual relationship between either vertebroplasty or kyphoplasty 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 vertebroplasty or kyphoplasty 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 vertebroplasty or kyphoplasty and subsequent spinal fracture. The results suggest following either vertebroplasty or kyphoplasty, patients are at risk of new onset adjacent fractures and when these adjacent fractures occur, they occur sooner than non-adjacent level fractures. Randomized, prospective studies comparing vertebroplasty or kyphoplasty patients and untreated controls are necessary to determine if there is a causal relationship between these procedures and subsequent spinal fracture.

Since studies have repeatedly associated vertebroplasty and kyphoplasty with positive clinical outcomes, percutaneous vertebroplasty and percutaneous kyphoplasty 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.

**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.
Bibliography:


Disclaimer

IEHP Clinical Authorization Guidelines (CAG) are developed to assist in administering plan benefits, they do not constitute a description of plan benefits. The Clinical Authorization Guidelines (CAG) express IEHP's determination of whether certain services or supplies are medically necessary, experimental and investigational, or cosmetic. IEHP has reached these conclusions based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). IEHP makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in the Clinical Authorization Guidelines (CAG). IEHP expressly and solely reserves the right to revise the Clinical Authorization Guidelines (CAG), as clinical information changes.