

Medical Affairs Policy & Procedure

Service: Percutaneous Vertebroplasty and Kyphoplasty
(Balloon Assisted Vertebroplasty, Percutaneous Vertebroplasty)

Revised	
Reviewed	02/21/03, 02/24/06, 05/18/07, 11/21/08, 12/28/09, 07/27/10, 1/20/12
Developed	
Policy Committee Approval	01/20/12

Description:

Vertebroplasty is a minimally invasive procedure where bone cement is placed into a diseased vertebral body using imaging guidance. It is expected that the procedure will stabilize the vertebral body and reduce painful symptoms. Kyphoplasty is a related procedure where a balloon is inserted into a vertebral body and inflated to restore the height of the body. Bone cement is then placed into the area created when the balloon was inflated.

Indications of Coverage:

Vertebroplasty is considered medically necessary when the affected vertebra has not been excessively damaged and one of the following conditions is described:

- A. Vertebral fracture and/or collapse with persistent debilitating pain that has not responded to a six-week trial of more conservative therapies (restricted activities, physical therapy, bracing, medication); the requirement of a six-week trial of conservative therapy may be waived if the pain symptoms are severe enough to require hospitalization
- B. Malignant involvement of the vertebral bodies with pain directly related to the affected vertebral body when radiation therapy has failed to relieve the symptoms
- C. Vertebral hemangiomas with aggressive clinical signs (severe pain and/or severe radiologic signs) when radiation therapy has failed to relieve the symptoms
- D. Unstable fracture due to osteoporosis (Kummell's disease)
- E. Reinforcement or stabilization of a vertebral body is required prior to surgery
- F. Vertebroplasty for fracture types or conditions other than those listed above requires physician review

- G. Kyphoplasty is considered medically necessary for the treatment of acute vertebral fracture when a minimum of 25% of the original height of the vertebral body is maintained and the procedure is performed on an outpatient basis

Limitations of Coverage:

- A. Review contract and endorsements for exclusions and prior authorization or benefit requirements.
- B. If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.
- C. If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.
- D. Vertebroplasty and/or kyphoplasty is considered not medically necessary if any of the following are documented:
- 1) Unresolved coagulation disorder
 - 2) Infection
 - 3) Fracture greater than one year old
 - 4) Fragments (for example, bone or disc) or tumor in the spinal canal

Documentation Required:

- Office notes
- Procedure report
- Imaging (CT, MRI, x-ray) reports

Rationale:

Pain relief as a result of percutaneous vertebroplasty is hypothesized to be related to immobilization of the fracture site, increase support at the fracture site, or due to the destruction of sensory nerve fibers as a result of the introduction of bone cement. Although the evidence of the effectiveness of vertebroplasty and kyphoplasty is minimal, it has become accepted practice in certain limited situations. Most of the literature is from uncontrolled clinical trials and does not include long-term follow up. Complications, such as leakage of bone cement into the surrounding tissues, have been reported in many studies. For kyphoplasty, as with vertebroplasty, much of the available literature is from nonrandomized studies that included small numbers of individuals without assessment of long-term effectiveness. The Institute for Clinical Systems Improvement recommended that both vertebroplasty and kyphoplasty be performed only in the context of controlled clinical trials. Several other reports have recommended controlled clinical trials.

The results from two recent studies were recently published, which found no significant benefit from vertebroplasty. The authors of the one study (Buchbinder) found no benefit from vertebroplasty when compared with a sham procedure in individuals with vertebral fractures who were evaluated at one week, one month, three months, and six months after treatment. The authors of the second study (Kallmes) concluded that improvements in pain and pain-related disability in individuals with vertebral fractures were similar to the improvements in a control group.

Both of the above trials have been criticized for selecting for participants who did not have fresh osteoporotic fractures, and for measuring endpoints of pain far beyond the expected benefit of vertebroplasty or kyphoplasty. In September 2010 the VERTOS II study was published in the Lancet. In this prospective randomized controlled study vertebroplasty for acute fractures (less than 6 weeks) was found to be significantly superior to conservative treatment regarding pain reduction after 1 month and 1 year. Since the study did not include a placebo arm (sham surgery) it was held to be not as convincing as the studies published in the NEJM. Currently VERTOS IV is recruiting. In this study 180 patients with acute vertebral compression fractures will be prospectively randomized to receive either percutaneous vertebroplasty or a sham intervention. Randomization started January 2011 with an expected completion of enrollment by January 2013. There is a one-year follow-up, with the possibility of an extended follow-up at two years.

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Approved by the Medical Director