Percutaneous kyphoplasty for vertebral fractures caused by osteoporosis and malignancy

BlueCross BlueShield Association

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Citation

Authors’ objectives
This Assessment evaluates the available evidence to determine whether kyphoplasty is demonstrated to be an effective treatment. This procedure uses a specialized bone tamp with an inflatable balloon to expand a collapsed vertebral body as close as possible to its natural height before introducing the mechanical fixation by injecting bone cement into the expanded cavity. The primary uses reported in the literature include: 1) osteoporotic vertebral compression fracture and 2) vertebral fractures caused by osteolytic destruction secondary to malignancy. Beneficial effects would include relief of associated symptoms (e.g., pain) as well as improvement in ability to function (e.g., mobility and activities of daily living). Adverse effects would include complications associated with kyphoplasty.

Authors’ conclusions
1. The technology must have final approval from the appropriate governmental regulatory bodies.

Kyphoplasty is a surgical procedure and, as such, is not subject to U.S. Food and Drug Administration (FDA) approval. Kyphon, Inc., has received 510(k) marketing clearance for a bone cement product to be used in vertebroplasty and kyphoplasty. Kyphoplasty also requires the use of an inflatable bone tamp. One such tamp, the KyphX inflatable bone tamp, received 510(k) marketing clearance from the FDA in July 1998. Other bone cements and bone-void-filling products used represent an off-label use of such products.

2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.

The available evidence is not sufficient to permit conclusions of the effect of kyphoplasty on health outcomes. The published evidence describing the outcomes of kyphoplasty consists mostly of uncontrolled studies. These uncontrolled studies were mostly retrospective and enrolled heterogeneous patient populations. Such studies cannot eliminate placebo and natural history effects as explanations for the apparent effectiveness of kyphoplasty. Two studies of vertebroplasty (PVP), a closely related procedure, raise concern about such effects. In a nonrandomized study, patients undergoing PVP had immediate pain relief from the procedure. However, at 6 weeks of follow-up and at 612 months follow-up, there was no difference between the group undergoing PVP and another group of patients that had not undergone PVP. In another pilot study reported only in abstract form, patients did not respond to PVP, but did respond to a sham procedure. These studies raise concern that nonspecific placebo effects may be important in determining results following either procedure.

The published literature on outcomes of kyphoplasty consists of case series studies. For the indication of osteoporosis, 7 case studies meeting selection criteria were reviewed that evaluated outcomes of 353 patients. Results were generally consistent in showing significant decreases in pain from an initial preoperative level of 7 to 9 on a visual analog scale (VAS) and decreasing to 2 to 4 within 1 day of the procedure. For the indication of osteolytic destruction due to metastasis, 3 studies were reviewed evaluating a total of 52 patients. Outcome measures varied between these 3 studies, but all showed improvements either in VAS pain score, several aspects of physical functioning as measured by SF-36,
or improvement in a disability score. Because of the results of the comparative studies of vertebroplasty suggest possible placebo or natural history effects, case series studies are insufficient to make conclusions about the effect of kyphoplasty on health outcomes. Rigorous, controlled studies would help determine the efficacy of kyphoplasty.

3. The technology must improve the net health outcome; and

4. The technology must be as beneficial as any established alternatives.

The available evidence does not permit conclusions regarding the effect of percutaneous kyphoplasty on health outcomes or compared with alternatives.

5. The improvement must be attainable outside the investigational settings.

It has not yet been demonstrated whether percutaneous kyphoplasty improves health outcomes in the investigational setting. Therefore, it cannot be demonstrated whether improvement is attainable outside the investigational settings.

For the above reasons, percutaneous kyphoplasty for vertebral fractures from osteoporosis or malignancy does not meet the TEC criteria.

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**Address for correspondence**
BlueCross BlueShield Association, Technology Evaluation Center, 225 North Michigan Ave, Chicago, Illinois, USA.
Tel: 888 832 4321 Email: tec@bcbsa.com

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