Percutaneous Vertebroplasty, Kyphoplasty and Sacroplasty

DESCRIPTION

Percutaneous vertebral augmentation (e.g. vertebroplasty, kyphoplasty, sacroplasty) encompasses a variety of minimally invasive procedures for treating vertebral compression fractures (VCF). Clinical symptoms associated with VCFs include: back pain, limited spinal mobility, height loss, and/or deformity and disability. Compression fractures are diagnosed using a combination of medical history and physical examination and may be confirmed using imaging techniques. On x-ray a wedge-shaped vertebra may be visible or there may be loss of height of the vertebra. The weakened bone compresses, or collapses in on itself; a fracture may occur while one is bending, twisting, or a fall from standing height or less. Only about one-third of vertebral compression fractures reach clinical diagnosis, with most symptomatic fractures healing within a few weeks. Medical management, including nonsteroidal anti-inflammatory drugs, oral analgesics, bracing and physical therapy remains the first-line therapy for individuals with a vertebral compression fracture. If medical management is unsuccessful or unfeasible surgical management can include:

Vertebroplasty - performed by percutaneous injection of radiopaque bone cement, usually polymethylmethacrylate (PMMA) (e.g., Spine-Fix® Biomimetic Bone Cement, Osteopal® V) into a painful osteoporotic or neoplastic compression fracture. Percutaneous vertebroplasty has also been used as to treat osteolytic vertebral metastasis or myeloma, and as an adjunct to surgery for aggressive vertebral body hemangiomas, as a technique to limit blood loss related to surgery. The technique has been used in all levels of the vertebrae (i.e., cervical, thoracic, and lumbar).

Kyphoplasty - a variant of vertebroplasty and has traditionally been done by inflation of a balloon (e.g., Kyphoon®) in the fractured vertebral body to restore vertebral height before the balloon is removed and cement injected. Newer techniques also known as mechanical vertebral augmentation include implantation of a continuous loop-like spinal device (i.e., Kiva® VCF Treatment System) through which the cement is injected with the device remaining in place.

Radiofrequency targeted vertebral augmentation - a modified technique being investigated to treat vertebral compression fractures where a motorized cement delivery system in vertebroplasty or kyphoplasty allows for radiofrequency warming of high viscosity cement during delivery. The high viscosity cement is designed to restore height and alignment to the fractured vertebra, along with stabilizing the fracture. However, thermal damage to intraosseous nerve fibers is a concern.

Sacroplasty - is being investigated as a technique to provide stabilization to the sacral area. Percutaneous sacroplasty involves the injection of PMMA into sacral insufficiency fractures (SIFs) for stabilization. It has been proposed that this procedure may provide an analgesic effect through mechanical stabilization of a fractured or otherwise weakened vertebral body.

These procedures require fluoroscopic or ultrasound guidance. With any type of vertebral augmentation, there is risk of the bone cement migrating out of place (called extravasation). In some cases this has led to transient radicular pain, neurologic symptoms, pulmonary embolism, deep vein thrombosis, and/or pneumonia. Evidence also suggests there may be an increased rate of subsequent fractures in adjacent vertebrae.

POLICY

The proposal is to add words in red text and to delete words or statements with a strikethrough:
Percutaneous vertebroplasty or kyphoplasty for the treatment of pain associated with symptomatic osteoporotic compression fractures, osteolytic vertebral lesions related to metastasis or myeloma, or vertebral hemangioma is considered medically necessary if the medical appropriateness criteria are met. (See Medical Appropriateness below.)

Percutaneous vertebroplasty or kyphoplasty, either balloon or mechanical vertebral augmentation (i.e., KIVA® VCS Treatment System), for the treatment of pain associated with symptomatic osteoporotic compression fractures, osteolytic vertebral lesions related to metastasis or myeloma, or vertebral hemangioma is considered medically necessary if the medical appropriateness criteria are met. (See Medical Appropriateness below.)

Percutaneous mechanical vertebral augmentation using any device other than Kiva® VCS Treatment System is considered investigational.

Percutaneous vertebroplasty or kyphoplasty (using any device) for the treatment of pain associated with all other conditions/diseases is considered investigational, including but not limited to:
- Traumatic vertebral fractures
- Vertebral eosinophilic granuloma

Percutaneous radiofrequency targeted vertebroplasty or kyphoplasty for all indications is considered investigational.

Percutaneous sacroplasty for all indications is considered investigational.

MEDICAL APPROPRIATENESS

Percutaneous vertebroplasty or kyphoplasty is considered medically appropriate if ANY ONE of the following are met:

- Percutaneous vertebroplasty for ANY ONE of the following:
  - Osteoporotic vertebral compression fracture with ALL ANY of the following:
    - Symptoms for less than 6 weeks that are so severe they prevent ambulation
    - Symptoms for 6 weeks or longer that have not responded to standard medical therapy (e.g., initial bed rest with progressive activity, bisphosphonates, physical therapy, bracing, analgesics)
    - A period of more than six weeks that is documented in the medical records
  - Osteolytic vertebral lesions related to metastasis or myeloma with ALL of the following:
    - Severe back pain related to destruction of the vertebral body not involving the major part of the cortical bone
    - Chemotherapy and radiation therapy have failed to relieve symptoms
  - Vertebral hemangiomas with ALL of the following:
    - Aggressive clinical signs (e.g., severe pain or nerve compression) and/or aggressive radiological signs
    - Radiation therapy has failed to relieve symptoms

- Percutaneous kyphoplasty, either balloon or mechanical vertebral augmentation (i.e., KIVA® VCS Treatment System) for ANY ONE of the following:
• Osteoporotic vertebral compression fracture that has not responded to 6 weeks of standard medical therapy (e.g., initial bed rest with progressive activity, bisphosphonates, physical therapy, bracing, analgesics)
• Osteolytic vertebral lesions related to metastasis or myeloma with severe back pain related to destruction of the vertebral body not involving the major part of the cortical bone
• Vertebral hemangiomas with ALL of the following:
  • Aggressive clinical signs (e.g., severe pain or nerve compression) and/or aggressive radiological signs
  • Radiation therapy has failed to relieve symptoms

IMPORTANT REMINDERS

• Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g. statement.

• We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits, or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the Medical Policy and a health plan, the express terms of the health plan will govern.

ADDITIONAL INFORMATION

There is a lack of randomized controlled trials on percutaneous sacroplasty for sacral insufficiency. The small numbers of treated individuals in cohort studies and retrospective reviews leave uncertainty regarding the impact of sacroplasty on health outcomes. Devices for kyphoplasty, other than the Kiva® VCS Treatment System, have few or no high quality clinical studies to demonstrate safety and/or effectiveness.

SOURCES


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**EFFECTIVE DATE**

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