BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 05/28/13
LAST REVIEW DATE: 08/19/14
LAST CRITERIA REVISION DATE: 05/27/14
ARCHIVE DATE:

PERCUTANEOUS BALLOON KYPHOPLASTY AND MECHANICAL VERTEBRAL AUGMENTATION

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Percutaneous balloon kyphoplasty and mechanical vertebral augmentation with KIVA® are interventional techniques involving the fluoroscopically guided injection of polymethylmethacrylate (PMMA) into a cavity created in the vertebral body with a balloon or mechanical device.

PERCUTANEOUS BALLOON KYPHOPLASTY AND MECHANICAL VERTEBRAL AUGMENTATION (cont.)

Description: (cont.)

Percutaneous Balloon Kyphoplasty:
Balloon kyphoplasty is a variant of vertebroplasty and uses a specialized bone tamp with an inflatable balloon to expand a collapsed vertebral body as close as possible to its natural height before injection of the PMMA. Radiofrequency kyphoplasty is a modification of balloon kyphoplasty for vertebral fractures. In this procedure, an ultrahigh viscosity cement is injected into the fractured vertebral body and radiofrequency is used to achieve the desired consistency of the cement. The ultrahigh viscosity cement is designed to restore height and alignment to the fractured vertebra along with stabilizing the fracture. Balloon kyphoplasty has been investigated as an option to provide mechanical support and symptomatic relief in individuals with osteoporotic vertebral compression fracture or in those with osteolytic lesions of the spine, i.e., multiple myeloma or metastatic malignancies. Another variant of kyphoplasty is vertebral body stenting, which utilizes an expandable scaffold instead of a balloon to restore vertebral height. The proposed advantages of vertebral body stenting are to reduce the risk of cement leakage by formation of a cavity for cement application and to prevent the loss of correction that is seen following removal of the balloon used for balloon kyphoplasty.

Mechanical Vertebral Augmentation:
The KIVA® VCF Treatment System is another mechanical vertebral augmentation technique that uses an implant for structural support of the vertebral body and to provide a reservoir for bone cement. The implant is inserted into the vertebral body over a guide wire and can be customized by changing the coil stack height, with a maximum height of 12 mm. PMMA is injected through the lumen of the implant, which fixes the implant to the vertebral body and contains the PMMA in a cylindrical column. KIVA has been investigated as a technique to reduce cement leakage.

Optiplasty:
A variant of kyphoplasty, also referred to as “biologic vertebral reconstruction”, where a drill is used to create a cavity in the vertebral body and a porous mesh sack (OptiMesh™) is inserted into the cavity and then filled with bone graft material. OptiMesh does not provide structural support and is contraindicated for individuals with instability (e.g., resected or collapsed vertebral bodies or fracture of the anterior column). Optiplasty has been investigated as a technique to restore vertebral body integrity.

PERCUTANEOUS BALLOON KYPHOPLASTY AND MECHANICAL VERTEBRAL AUGMENTATION (cont.)

Criteria:

Percutaneous Balloon Kyphoplasty:

- Percutaneous balloon kyphoplasty is considered ***medically necessary*** for an individual with continual incapacitating pain who has failed a trial of greater than 4 weeks of conservative care [1] with documentation of **ANY** of the following:

  1. Osteoporotic vertebral fracture(s)
  2. Trauma-related vertebral compression fracture(s)
  3. Steroid-induced vertebral compression fracture(s)

- Percutaneous balloon kyphoplasty is considered ***medically necessary*** for an individual with osteolytic vertebral body fracture with documentation of **ALL** of the following:

  1. Individual has continual incapacitating pain
  2. No evidence of vertebral body destruction
  3. Vertebral body fracture is related to multiple myeloma or metastatic malignancies
  4. Chemotherapy and radiation therapy have failed to relieve the pain
  5. No involvement of the major part of the cortical bone

- Percutaneous balloon kyphoplasty for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:

  1. Insufficient evidence to support improvement of the net health outcome, and
  2. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

  These indications include, *but are not limited to:*

  - Acute vertebral fractures due to osteoporosis or trauma
  - Kienbock's disease

PERCUTANEOUS BALLOON KYPHOPLASTY AND MECHANICAL VERTEBRAL AUGMENTATION (cont.)

Criteria: (cont.)

Percutaneous Mechanical Vertebral Augmentation:

- Percutaneous mechanical vertebral augmentation using any other device, *including but not limited to*, vertebral body stenting, is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

  These devices include, *but are not limited to*:

  - KIVA® VCF Treatment System

Optiplasty:

- Optiplasty for all indications is considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

[1] A trial of conservative care includes, *but is not limited to,* bedrest, immobilization/bracing devices, non-narcotic analgesic medications, narcotic analgesic medications and physical therapy. A trial of conservative care may be contraindicated.

PERCUTANEOUS BALLOON KYPHOPLASTY AND MECHANICAL VERTEBRAL AUGMENTATION (cont.)

Resources:

Resources prior to 05/28/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 6.01.38 BCBS Association Medical Policy Reference Manual. Percutaneous Balloon Kyphoplasty and Mechanical Vertebral Augmentation. Re-issue date 07/10/2014, issue date 12/18/2002.

2. American Association of Neurological Surgeons, Khoo LT, Cosar M. The Results of Minimal Invasive Optimesh Graft Technique for Stand-Alone Lumbar Interbody Fusion in Spondylolisthesis. 03/15/2006.

3. American Association of Neurological Surgeons, Stechison II MT. Biologic Vertebral Augmentation in Thoracic and Lumbar Fractures. 04/24/2006.

4. Chen W, Wang J, Pan J, Zhang Q, Shao X, Zhang Y. Primary results of Kienbock's disease treated using balloon kyphoplasty system. *Arch Orthop Trauma Surg.* May 2012;132(5):677-683.

5. External Consultant Review. Orthopedic Surgery. 06/10/2008 2008.

6. InterQual® Care Planning, Procedures Adult. Vertebroplasty or Kyphoplasty.

FDA 510K Summary for OptiMesh 500E:

- FDA-approved indication: For use as a cement restrictor in orthopedic surgeries such as those involving the femoral canal or tibial plateau in hip stem and total knee replacement. This device is not intended for use in spinal applications. The safety and effectiveness of this device when implanted in the spine have not been established.