



Louisiana

Vertebroplasty/Kyphoplasty

Policy # 00094

Original Effective Date: 11/21/2002

Current Effective Date: 11/05/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider percutaneous vertebroplasty or kyphoplasty of the cervical, lumbar, or thoracic region for treatment of the following conditions to be **eligible for coverage**:

Patient Selection Criteria

Coverage eligibility for percutaneous vertebroplasty or kyphoplasty of the cervical, lumbar, or thoracic region will be considered for any of the following conditions:

- Osteolytic vertebral metastasis, myeloma, or plasmacytoma with severe back pain related to destruction of the vertebral body not involving the major part of the cortical bone, where chemotherapy or radiation therapy have failed to relieve symptoms; or
- Vertebral hemangiomas with severe pain or nerve compression, or aggressive radiologic signs, when radiation therapy has failed to relieve symptoms; or
- Eosinophilic granuloma with pain and spinal instability.

Based on review of available data, the Company may consider vertebral compression fracture due to osteoporosis or osteopenia to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility for percutaneous vertebroplasty or kyphoplasty of the cervical, lumbar, or thoracic region will be considered when all of the following criteria are met:

- Recent onset of back pain localized to the fracture site which has not responded to at least six (6) weeks of conservative medical management***; and
- Tenderness to palpation directly over the fracture site; and
- Advanced imaging studies confirming a non-traumatic, acute compression fracture; and
- Recent imaging studies (Magnetic Resonance Imaging [MRI] or Computerized Tomography [CT]) which eliminate disc herniation or other causes of spine pain; and
- Absence of imaging findings which would confer unacceptable risk to the spinal cord or related structures, including all of the following:
 - Spinal stenosis of greater than 20% due to retropulsed fragments; and
 - Vertebral body collapse to less than one third (33%) original height; and

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- Vertebral plana (collapse greater than 90%); and
- Anatomical damage of the vertebra that prevents safe access of the needle to the vertebral body; and
- Burst fracture with retropulsed fragments demonstrated by imaging.

*****Note:**

Percutaneous vertebroplasty may be considered medically necessary for the treatment of symptomatic vertebral compression fractures due to osteoporosis or osteopenia that are less than 6 weeks in duration that have led to hospitalization or persist at a level that prevents ambulation.

Conservative management should include, but is not limited to, 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.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Some of the established medical contraindications to vertebroplasty/ kyphoplasty include the following:

- Severe cardiopulmonary disease; or
- Coagulation disorders; or
- Known allergy to any of the materials used in either procedure; or
- Active or incompletely treated infection.

Based on review of available data, the Company considers indications other than those addressed in the criteria section including but not limited to any of the following to be **investigational**.*

- Prophylaxis in patients deemed to be at risk but with no evidence of acute vertebral fracture; or
- Non-pathologic, acute, traumatic fractures of the vertebra; or
- Compression fractures shown by the medical record to be more than one year old; or
- Asymptomatic vertebral compression fracture; or
- Percutaneous sacroplasty.

Background/Overview

Vertebral augmentation procedures have been developed as a treatment option for debilitating pain due to bony destruction of the vertebral body. These are interventional techniques in which bone cement is injected via percutaneous insertion of a needle into the vertebral body under image guidance. The most commonly utilized material is polymethylmethacrylate (PMMA).

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Vertebroplasty involves direct injection of material into the bone to stabilize an area of collapse, while kyphoplasty utilizes inflatable bone tamps to create a cavity, thus reducing the fracture and creating a space into which material is then injected.

The objective in both procedures is to alleviate pain and strengthen bone. Their efficacy has been well established for treatment of pain related to malignant lytic bone lesions. The evidence regarding their use in treating pain due to osteoporotic fractures and other bone pathology is less compelling.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration

Kyphoplasty

Kyphoplasty is a surgical procedure and, as such, is not subject to regulation by the U.S. FDA. Balloon kyphoplasty requires the use of an inflatable bone tamp. In July 1998, 1 such tamp, the KyphX^{®†} inflatable bone tamp, was cleared for marketing by FDA through the 510(k) process. Other devices with FDA 510(k) marketing clearance include the AVAmax^{®†} Vertebral Balloon system (CareFusion), NeuroTherm Parallax^{®†} Balloon Inflatable Bone Tamp (NeuroTherm), Stryker iVAS^{®†} Balloon catheter, and Synthes Synflate^{™‡} Vertebral Balloon System (Synthes). FDA product code NDN.

In 2014, the Kiva^{®†} VCF Treatment System (Benvenue Medical) was cleared for marketing by FDA through the 510(k) process. FDA product code NDN.

PMMA bone cement was available as a drug product before enactment of FDA's device regulation and was at first considered what FDA terms a "transitional device." It was transitioned to a class III device and then to a class II device, which required future 510(k) submissions to meet "special controls" instead of "general controls" to assure safety and effectiveness. In July 2004, KyphX HV-RTM bone cement was cleared for marketing by FDA through the 510(k) process for the treatment of pathologic fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a balloon kyphoplasty procedure. Subsequently, other products such as Spine-Fix^{®†} Biomimetic Bone Cement, KYPHON^{®†} HV-R^{®†} Bone Cement, and Osteopal^{®†} V have received issued 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. FDA product code: NDN.

Vertebroplasty and Sacroplasty

Vertebroplasty is a surgical procedure and, as such, is not subject to U.S. FDA approval.

PMMA bone cement was available as a drug product before enactment of FDA's device regulation and was at first considered what FDA terms a "transitional device." It was transitioned to a class III device requiring premarketing applications. Several orthopedic companies have received approval of their bone cement products since 1976. In 1999, PMMA was reclassified from class III to class II, which requires future 510(k) submissions to meet "special controls" instead of "general controls" to assure safety and effectiveness. Thus, use of PMMA in vertebroplasty represented an off-label use of an FDA-regulated product before

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2005. In 2005, PMMA bone cements such as Spine-Fix Biomimetic Bone Cement and Osteopal V were cleared for marketing by FDA through the 510(k) process for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

The use of PMMA in sacroplasty is an off-label use of an FDA-regulated product (bone cements such as Spine-Fix Biomimetic Bone Cement and Osteopal V), because the 510(k) approval was for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures. Sacroplasty was not included. FDA product code: NDN.

In May 2009, Cortoss^{®†} Bone Augmentation Material was cleared for marketing by FDA through the 510(k) process. Cortoss is a nonresorbable synthetic material that is a composite resin-based, bis-glycidyl dimethacrylate. FDA classifies this product as a PMMA bone cement.

In February 2010, the Parallax^{®†} Contour^{®†} Vertebral Augmentation Device (ArthroCare) was cleared for marketing by FDA through the 510(k) process. The device creates a void in cancellous bone that can then be filled with bone cement. FDA product code: HXG.

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

References

1. McGuire R. AAOS Clinical Practice Guideline: the Treatment of Symptomatic Osteoporotic Spinal Compression Fractures. The Journal of the American Academy of Orthopaedic Surgeons. 2011;19(3):183-4.
2. Washington State Health Care Authority, Vertebroplasty, Kyphoplast and Sacroplasty Health Technology Assessment, (2010) Olympia WA, 126 pgs.
3. Blue Cross and Blue Shield Association, Medical Policy Reference Manual, "Percutaneous Vertebroplasty and Sacroplasty", 6.01.25, 5:2017.
4. AIM Specialty Health, AIM Musculoskeletal Program Guidelines for Spine Surgery, "Vertebroplasty/Kyphoplasty", November 1, 2017. Last Reviewed June 13, 2017.

Policy History

Original Effective Date: 11/21/2002

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11/21/2002 Managed Care Advisory Council approval

11/18/2003 Medical Policy Committee review

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01/26/2004	Managed Care Advisory Council approval
01/04/2005	Medical Director review
01/18/2005	Medical Policy Committee review. Format revision. Policy statement added to clarify that all other uses are considered investigational. Coverage eligibility unchanged.
01/31/2005	Managed Care Advisory Council approval
01/04/2006	Medical Director review
01/17/2006	Medical Policy Committee review. Format revision.
02/23/2006	Quality Care Advisory Council approval
02/07/2007	Medical Director review
02/21/2007	Medical Policy Committee approval. Coverage eligibility for percutaneous kyphoplasty changed to investigational. Coverage statement for percutaneous vertebroplasty remains unchanged.
08/06/2008	Medical Director review
08/20/2008	Medical Policy Committee approval. Added coverage for kyphoplasty.
08/06/2009	Medical Policy Committee approval.
08/26/2009	Medical Policy Implementation Committee approval. No change to coverage eligibility.
12/01/2010	Medical Policy Committee review
12/15/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/01/2011	Coding revision
12/08/2011	Medical Policy Committee review
12/21/2011	Medical Policy Implementation Committee approval. Policy updated with literature search; sacroplasty added to the document. Title changed to include sacroplasty. References updated. Policy statement added to state that sacroplasty considered investigational.
12/06/2012	Medical Policy Committee review
12/19/2012	Medical Policy Implementation Committee approval. No change to coverage.
12/12/2013	Medical Policy Committee review
12/18/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/05/2014	Medical Policy Committee review
06/18/2014	Medical Policy Implementation Committee approval. Added new investigational statement regarding Kiva and vertebral body stenting.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed
09/03/2015	Medical Policy Committee review
09/23/2015	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2016	Coding update
05/05/2016	Medical Policy Committee review
05/18/2016	Medical Policy Implementation Committee approval. Added mechanical vertebral augmentation (with Kiva) to coverage statement and title, removed from INV statement.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
08/03/2017	Medical Policy Committee review
08/23/2017	Medical Policy Implementation Committee approval. Coverage changed to match AIM guidelines.
08/09/2018	Medical Policy Committee review
08/15/2018	Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 08/2019

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Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT)[®]†, copyright 2017 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0200T, 0201T, 22510, 22511, 22512, 22513, 22514, 22515
HCPCS	No codes
ICD-10 Diagnosis	C41.2 C79.51-C79.52 C90.00-C90.02 D18.09 D47.Z9 M48.50XA-M48.58XA M80.08XA M80.88XA M84.48XA-M84.68XA

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. FDA and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 - 3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

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- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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