



Louisiana

Vertebroplasty/Kyphoplasty

Policy # 00094

Original Effective Date: 11/21/2002

Current Effective Date: 09/11/2022

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; or

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

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- 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
 - 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.

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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 for all indications due to lack of conclusive evidence indicating a positive impact to overall health outcomes.

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).

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 (FDA)

Kyphoplasty

Kyphoplasty is a surgical procedure and, as such, is not subject to regulation by the U.S. FDA. Polymethyl methacrylate bone cement was available as a drug product before enactment of the FDA's device regulation and was at first considered what the FDA termed a "transitional device." It was transitioned to a class III device and then to a class II device, which required future 510(k)

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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 the 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 (Heraeus) have received 510(k) marketing clearance for the fixation of pathologic fractures of the vertebral body using vertebroplasty or kyphoplasty procedures.

Balloon kyphoplasty requires the use of an inflatable bone tamp. In July 1998, one such tamp, the KyphX®‡ inflatable bone tamp (Medtronic), was cleared for marketing by the FDA through the 510(k) process. Additional devices for balloon kyphoplasty are listed in Table 1.

There are several mechanical vertebral augmentation devices that have received marketing clearance by the FDA through the 510(k) process; these are listed in Table 1.

StabiliT®‡ Vertebral Augmentation System (Merit Medical) for radiofrequency vertebral augmentation was cleared for marketing in 2009.

FDA product code NDN.

Table 1. Kyphoplasty and Mechanical Vertebral Augmentation Devices Cleared by the U.S. Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Balloon Kyphoplasty				
TRACKER Plus Kyphoplasty System	GS Medical Co., Ltd	10/28/2021	K211797	Reduction of fractures and/or creation of a void
Joline Kyphoplasty System Allevo	Joline GmbH & Co.	5/27/2020	K192449	To repair vertebral compression fractures
TRACKER Kyphoplasty System	GS Medical Co., Ltd	12/4/2019	K192335	Reduction of fractures or creation of a void

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Stryker iVAS Elite Inflatable Vertebral Augmentation System (Stryker iVAS Elite Balloon Catheter)	Stryker Corporation	12/21/2018	K181752	To repair vertebral compression fractures
SpineKure Kyphoplasty System	Hanchang Co. Ltd.	5/29/2018	K172871	To repair vertebral compression fractures
Modified Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters	G-21 s.r.l.	8/23/2017	K172214	To repair vertebral compression fractures
13G InterV Kyphoplasty Catheter (Micro) and 11G InterV Kyphoplasty Catheter (Mini-Flex)	Pan Medical Ltd.	11/1/2016	K162453	To repair vertebral compression fractures
MEDINAUT Kyphoplasty System	Imedicom Co. Ltd.	7/29/2016	K153296	To repair vertebral compression fractures
AVAflex Vertebral Balloon System	Carefusion	11/24/2015	K151125	To repair vertebral compression fractures
Osseoflex SB Straight Balloon 10g/4ml Osseoflex SB Straight Balloon 10g/2ml	Osseon LLC	4/9/2015	K150607	To repair vertebral compression fractures
InterV Kyphoplasty Catheter (Balloon Length: 1015 and 20mm) InterV Kyphoplasty Catheter (Mini) (Balloon Length: 1015 and 20mm)	Pan Medical Ltd.	3/6/2015	K150322	To repair vertebral compression fractures

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GUARDIAN-SG Inflatable Bone Expander System	BM Korea Co. Ltd.	1/16/2015	K143006	To repair vertebral compression fractures
ZVPLASTY	Zavation LLC	9/12/2014	K141419	To repair vertebral compression fractures
Mechanical Vertebral Augmentation				
Kiva VCF Treatment System	Benvenue Medical Inc.	8/14/2014	K141141	To repair vertebral compression fractures
SpineJack Expansion Kit	Vexim SA	8/30/2018	K181262	To repair vertebral compression fractures
V-Strut Vertebral Implant	Hyprevention SAS	3/5/2020	K191709	Treatment of vertebral fractures in the thoracic and lumbar spine

Vertebroplasty and Sacroplasty

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

Polymethylmethacrylate bone cement was available as a drug product before enactment of the FDA's device regulation and was at first considered what the 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, polymethylmethacrylate 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 polymethylmethacrylate in vertebroplasty represented an off-label use of an FDA-regulated product before 2005. In 2005, polymethylmethacrylate bone cements such as Spine-Fix[®]‡ Biomimetic Bone Cement and Osteopal[®]‡ V were cleared for marketing by the FDA through the 510(k) process for the fixation of pathologic fractures of the vertebral body using vertebroplasty procedures.

The use of polymethylmethacrylate in sacroplasty is an off-label use of an FDA-regulated product (bone cements such as Spine-Fix[®]‡ Biomimetic Bone Cement [Teknimed] and Osteopal[®]‡ V

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[Heraeus]) because the 510(k) approval was for the fixation of pathologic fractures of the vertebral body using vertebroplasty procedures. Sacroplasty was not included. FDA product code: NDN.

In 2009, Cortoss[®] (Stryker) Bone Augmentation Material was cleared for marketing by the FDA through the 510(k) process. Cortoss[®] is a nonresorbable synthetic material that is a composite resin-based, bis-glycidyl dimethacrylate. The FDA classifies this product as a polymethylmethacrylate bone cement.

In 2010, the Parallax[®] Contour[®] Vertebral Augmentation Device (ArthroCare) was cleared for marketing by FDA through the 510(k) process. There have been several other augmentation and bone expander devices (eg, Balex[®] Bone Expander System, Arcadia[®] Ballon Catheter, Kyphon Element[®] Inflatable Bone Tamp) that were also cleared for marketing by FDA through the 510(k) process. These devices create a void in cancellous bone that can then be filled with bone cement. FDA product code: HXG.

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, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Supplemental Information

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.

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.

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3. AIM Specialty Health, AIM Musculoskeletal Program Guidelines for Spine Surgery, “Vertebroplasty/Kyphoplasty”, September 11, 2022. Last Reviewed 11/11/2021.

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- 11/21/2002 Managed Care Advisory Council approval
- 11/18/2003 Medical Policy Committee review
- 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.

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	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.
08/01/2019	Medical Policy Committee review
08/14/2019	Medical Policy Implementation Committee approval. No change to coverage.
08/06/2020	Medical Policy Committee review
08/12/2020	Medical Policy Implementation Committee approval. No change to coverage.
09/10/2020	Coding update
12/29/2020	Coding update
08/05/2021	Medical Policy Committee review
08/11/2021	Medical Policy Implementation Committee approval. No change to coverage.
08/04/2022	Medical Policy Committee review

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08/10/2022 Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 08/2023

Coding

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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	C1062
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, M80.0AXA-M80.0AXS,

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M80.8AXA-M80.8AXS, 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. Food and Drug Administration (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 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:

- 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

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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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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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