Vertebroplasty/Kyphoplasty

Policy #  00094
Original Effective Date: 11/21/2002
Current Effective Date: 11/08/2020

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

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Page 1 of 12
Vertebroplasty/Kyphoplasty

Policy # 00094
Original Effective Date: 11/21/2002
Current Effective Date: 11/08/2020

- 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.

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Page 2 of 12
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)
Vertebroplasty/Kyphoplasty

Policy # 00094
Original Effective Date: 11/21/2002
Current Effective Date: 11/08/2020

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 (Medronic), 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

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balloon Kyphoplasty</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TRACKER Kyphoplasty System</td>
<td>GS Medical Co., Ltd</td>
<td>12/4/2019</td>
<td>K192335</td>
<td>Reduction of fractures or creation of a void</td>
</tr>
<tr>
<td>Stryker iVAS Elite Inflatable Vertebral Augmentation System (Stryker iVAS Elite Balloon Catheter)</td>
<td>Stryker Corporation</td>
<td>12/21/2018</td>
<td>K181752</td>
<td>To repair vertebral compression fractures</td>
</tr>
</tbody>
</table>
Vertebroplasty/Kyphoplasty

Policy #  00094
Original Effective Date:  11/21/2002
Current Effective Date:  11/08/2020

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Date</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SpineKure Kyphoplasty System</td>
<td>Hanchang Co. Ltd.</td>
<td>5/29/2018</td>
<td>K172871</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>Modified Winch Kyphoplasty (15 and 20 mm) 11 Gauge Balloon Catheters</td>
<td>G-21 s.r.l.</td>
<td>8/23/2017</td>
<td>K172214</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>13G InterV Kyphoplasty Catheter (Micro) and 11G InterV Kyphoplasty Catheter (Mini-Flex)</td>
<td>Pan Medical Ltd.</td>
<td>11/1/2016</td>
<td>K162453</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>MEDINAUT Kyphoplasty System</td>
<td>Imedicom Co. Ltd.</td>
<td>7/29/2016</td>
<td>K153296</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>AVAflex Vertebral Balloon System</td>
<td>Carefusion</td>
<td>11/24/2015</td>
<td>K151125</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>Osseoflex SB Straight Balloon 10g/4ml Osseoflex SB Straight Balloon 10g/2ml</td>
<td>Osseon LLC</td>
<td>4/9/2015</td>
<td>K150607</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>InterV Kyphoplasty Catheter (Balloon Length: 1015 and 20mm)  InterV Kyphoplasty Catheter (Mini) (Balloon Length: 10 15 and 20mm)</td>
<td>Pan Medical Ltd.</td>
<td>3/6/2015</td>
<td>K150322</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>GUARDIAN-SG Inflatable Bone Expander System</td>
<td>BM Korea Co. Ltd.</td>
<td>1/16/2015</td>
<td>K143006</td>
<td>To repair vertebral compression fractures</td>
</tr>
</tbody>
</table>
Vertebroplasty/Kyphoplasty

Policy # 00094
Original Effective Date: 11/21/2002
Current Effective Date: 11/08/2020

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Manufacturer</th>
<th>Date</th>
<th>FDA Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ZVPLASTY</td>
<td>Zavation LLC</td>
<td>9/12/2014</td>
<td>K141419</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>Mechanical Vertebral Augmentation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kiva VCF Treatment System</td>
<td>Benvenue Medical Inc.</td>
<td>8/14/2014</td>
<td>K141141</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>SpineJack Expansion Kit</td>
<td>Vexim SA</td>
<td>8/30/2018</td>
<td>K181262</td>
<td>To repair vertebral compression fractures</td>
</tr>
<tr>
<td>V-Strut Vertebral Implant</td>
<td>Hypevention SAS</td>
<td>3/5/2020</td>
<td>K191709</td>
<td>Treatment of vertebral fractures in the thoracic and lumbar spine</td>
</tr>
</tbody>
</table>

**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 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.

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Vertebroplasty/Kyphoplasty

Policy # 00094
Original Effective Date: 11/21/2002
Current Effective Date: 11/08/2020

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-glycidal 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.

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.

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
Vertebroplasty/Kyphoplasty

Policy # 00094
Original Effective Date: 11/21/2002
Current Effective Date: 11/08/2020


Policy History
Original Effective Date: 11/21/2002
Current Effective Date: 11/08/2020
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
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.

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.

Page 8 of 12
Vertebroplasty/Kyphoplasty

Policy #  00094
Original Effective Date:  11/21/2002
Current Effective Date:  11/08/2020

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
08/09/2018  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

Next Scheduled Review Date:  08/2021

©2020 Blue Cross and Blue Shield of Louisiana

Blue Cross and Blue Shield of Louisiana is an independent licensee of the Blue Cross and Blue Shield Association and incorporated as Louisiana Health Service & Indemnity Company.

No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from Blue Cross and Blue Shield of Louisiana.
Vertebroplasty/Kyphoplasty

Policy # 00094
Original Effective Date: 11/21/2002
Current Effective Date: 11/08/2020

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 2019 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.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>0200T, 0201T, 22510, 22511, 22512, 22513, 22514, 22515</td>
</tr>
<tr>
<td>HCPCS</td>
<td>Added code eff 1/1/2021: C1062</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>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 Added codes eff 10/1/2020: M80.0AXA-M80.0AXS, M80.8AXA-M80.8AXS</td>
</tr>
</tbody>
</table>
Vertebroplasty/Kyphoplasty

Policy # 00094
Original Effective Date: 11/21/2002
Current Effective Date: 11/08/2020

*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 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:

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.
Vertebroplasty/Kyphoplasty

Policy #  00094
Original Effective Date:  11/21/2002
Current Effective Date:  11/08/2020

‡ Indicated trademarks are the registered trademarks of their respective owners.

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.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.