Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis

Policy # 00278
Original Effective Date: 11/16/2010
Current Effective Date: 11/16/2016

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.

Services Are Considered Investigational

Based on review of available data, the Company considers image-guided minimally invasive lumbar decompression (IG-MLD) to be investigational.*

Background/Overview

Image-guided minimally invasive lumbar decompression describes a novel percutaneous procedure for decompression of the central spinal canal in patients with lumbar spinal stenosis (LSS). In this procedure, a specialized cannula and surgical tools (mild®)‡ are used under fluoroscopic guidance for bone and tissue sculpting near the spinal canal.

In LSS, the space around the spinal cord narrows, compressing the spinal cord and the nerve roots. The most common symptom of LSS is back pain with neurogenic claudication, ie, pain, numbness, or weakness in the legs that worsens with standing or walking and is alleviated with sitting or leaning forward. Compression of neural elements generally occurs from a combination of degenerative changes including ligamentum flavum hypertrophy, bulging of the intervertebral disc, and facet thickening with arthropathy. Spinal stenosis is often linked to age-related changes in disc height and arthritis of the facet joints. LSS is one of the most common reasons for back surgery and the most common reason for lumbar spine surgery in adults older than 65 years of age. The goal of surgical treatment is to “decompress” the spinal cord and/or nerve roots.

For patients with LSS, surgical laminectomy has established benefits in reducing pain and improving quality of life. Less invasive surgical procedures have been developed, such as open laminotomy and microendoscopic laminotomy. Limited evidence on the comparative efficacy of these procedures suggests that less invasive procedures may achieve a roughly similar benefit with less adverse effects. The present policy addresses posterior decompression of central LSS with a percutaneous treatment that is performed under fluoroscopic guidance.

Percutaneous IG-MLD using a specially designed tool kit (mild) has been proposed as an ultraminimally invasive treatment of central LSS. In this procedure, the epidural space is filled with contrast medium under fluoroscopic guidance. Using a 6-gauge cannula that is clamped in place with a back plate, single-use tools (portal cannula, surgical guide, bone rongeur, tissue sculpter, trocar) are used to resect thickened ligamentum flavum and small pieces of lamina. The tissue and bone sculpting is conducted entirely under fluoroscopic guidance, with additional contrast media added throughout the procedure to aid visualization of the decompression. The process is repeated on the opposite side for bilateral decompression of the central

* Please note: The information provided is for general knowledge and should not be used as a substitute for professional medical advice. Always consult with a healthcare provider for diagnosis and treatment of any health condition.

** See additional notes and disclosures regarding specific conditions and treatments.
Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis

Policy # 00278
Original Effective Date: 11/16/2010
Current Effective Date: 11/16/2016

canal. The devices are not intended to be used near the lateral neural elements and are contraindicated for disc procedures.

Alternative posterior decompressive surgical procedures include:

- Decompressive laminectomy, the classic treatment for LSS, which unroofs the spinal canal by extensive resection of posterior spinal elements, including the lamina, spinous processes, portions of the facet joints, ligamentum flavum, and the interspinous ligaments. Wide muscular dissection and retraction is needed to achieve adequate surgical visualization. The extensive resection and injury to the posterior spine and supporting muscles can lead to instability with significant morbidity, both postoperatively and longer term. Spinal fusion, performed at the same time as laminectomy or after symptoms have developed, may be required to reduce the resultant instability. Laminectomy may be used for extensive multilevel decompression.

- Hemilaminotomy and laminotomy, sometimes termed laminoforaminotomy, are less invasive than laminectomy. These procedures focus on the interlaminar space, where most of the pathologic changes are concentrated, minimizing resection of the stabilizing posterior spine. A laminotomy typically removes the inferior aspect of the cranial lamina, superior aspect of the subjacent lamina, ligamentum flavum, and the medial aspect of the facet joint. In contrast to laminectomy, laminotomy does not disrupt the facet joints, supra- and interspinous ligaments, a major portion of the lamina, or the muscular attachments. Muscular dissection and retraction are required to achieve adequate surgical visualization.

- Microendoscopic decompressive laminotomy (MEDL) is similar to laminotomy but utilizes endoscopic visualization. The position of the tubular working channel is confirmed by fluoroscopic guidance, and serial dilators (METRx™ lumbar endoscopic system, Medtronic) are used to dilate the musculature and expand the fascia. For MEDL, an endoscopic curette, rongeur, and drill are used for the laminotomy, facetectomy, and foraminotomy. The working channel may be repositioned from a single incision for multilevel and bilateral dissections.

**FDA or Other Governmental Regulatory Approval**

U.S. Food and Drug Administration (FDA)

In 2006, the mild™ tool kit (Vertos Medical) was initially cleared for marketing by the U.S. FDA through the 510(k) process as the X-Sten MILD Tool Kit (X-Sten Corp.) for treatment of various spinal conditions. This set of specialized surgical instruments is used to perform percutaneous lumbar decompressive procedures.

Vertos’s mild instructions state that the devices are not intended for disc procedures but rather for tissue resection at the perlaminal space, within the interlaminar space, and at the ventral aspect of the lamina. These devices are not intended for use near the lateral neural elements and remain dorsal to the dura using image guidance and anatomic landmarks.

Note: The abbreviation MILD has also been used for microscopic muscle-preserving interlaminar decompression, which involves a small skin incision at the interspinous level and partial drilling of the spinous process, with decompression performed under microscopic visualization.

FDA product code: HRX.
Centers for Medicare and Medicaid Services (CMS)
Effective for services performed on or after January 09, 2014, the CMS has determined that percutaneous image guided lumbar decompression (PILD) for LSS is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act.

CMS has determined that PILD will be covered by Medicare when provided in a clinical study under section 1862(a)(1)(E) through coverage with evidence development for beneficiaries with LSS who are enrolled in an approved clinical study that meets the criteria in the decision memo.

According to the national coverage decision, PILD is a posterior decompression of the lumbar spine performed under indirect image guidance without any direct visualization of the surgical area. This is a procedure proposed as a treatment for symptomatic LSS unresponsive to conservative therapy. This procedure is generally described as a noninvasive procedure using specially designed instruments to percutaneously remove a portion of the lamina and debulk the ligamentum flavum. The procedure is performed under x-ray guidance (eg, fluoroscopic, computed tomography) with the assistance of contrast media to identify and monitor the compressed area via epiduragram.

Rationale/Source
Conventional Posterior Decompressive Surgery
Posterior decompression for LSS has been evolving toward increasingly minimally invasive procedures in an attempt to minimize postoperative morbidity and spinal instability. In general, the literature comparing surgical procedures is limited. The evidence available suggests that less invasive surgical decompression may reduce perioperative morbidity without impairing long-term outcomes when performed in appropriately selected patients.

A 2009 systematic review of surgery for back pain, commissioned by the American Pain Society, was conducted by the Oregon Health Sciences University Evidence-based Practice Center. Four higher-quality randomized trials were reviewed that compared surgery with nonsurgical therapy for spinal stenosis, including 2 studies from the multicenter Spine Patient Outcomes Research Trial (SPORT) evaluating laminectomy for spinal stenosis (specifically with or without degenerative spondylolisthesis). All 4 four trials found that initial decompressive surgery (laminectomy) was slightly to moderately superior to initial nonsurgical therapy (eg, average 8- to 18-point difference on the 36-Item Short-Form Health Survey [SF-36] and Oswestry Disability Index [ODI]). There was insufficient evidence to determine the optimal adjunctive surgical methods for laminectomy (ie, with or without fusion, and instrumented vs noninstrumented fusion) in patients with or without degenerative spondylolisthesis. SPORT continues to be referenced as the highest quality evidence published on decompressive surgery.

Image-Guided Minimally Invasive Lumbar Decompression
Unlike conventional surgical decompression, the percutaneous mild decompressive procedure is performed solely under fluoroscopic guidance (eg, without endoscopic or microscopic visualization of the work area). This procedure is indicated for central stenosis only, without the capability of addressing nerve root compression or disc herniation, should either be required.
Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis

Policy #  00278
Original Effective Date:  11/16/2010
Current Effective Date:  11/16/2016

The primary literature on IG-MLD includes 1 large randomized controlled trial (RCT; N=302) that is ongoing, 1 small RCT (N=38), and a number of prospective and retrospective cohort studies and case series.

Randomized Controlled Trials and Systematic Reviews

The protocol for the MiDAS ENCORE (Evidence-based Neurogenic Claudication Outcomes Research) trial (NCT02093520) was approved by the Centers for Medicare and Medicaid Services under coverage with evidence development. This nonblinded study, conducted at 26 interventional pain management centers in the United States, randomized 302 patients in a 1:1 ratio to IG-MLD or epidural steroid injections (ESIs). This trial included Medicare beneficiaries 65 years of older who had neurogenic claudication symptoms for at least 3 months and had failed standard therapies, including: physical therapy, home exercise programs, and oral analgesics. Selection criteria required radiologic evidence of LSS with ligamentum flavum greater than 2.5 mm confirmed by preoperative magnetic resonance imaging or computed tomography. Comorbidities know to affect spinal stenosis were allowed if they were not considered severe by the treating physician. More patients in the ESI group withdrew prior to study treatment (22 vs 6), due primarily to decisions to have surgery or other nonstudy therapy (n=8) or to dissatisfaction with randomization results (n=6). This unequal dropout rate raises the possibility of bias due to patient expectations and nonblinding of patients and assessors.

At baseline, the IG-MILD group scored 53.0 on the 100-point ODI, 7.7 out of 10 points on a numeric rating scale for pain (NRS-P), and 2.9 to 3.8 on the subscales of the Zurich Claudication Questionnaire (ZCQ). Baseline scores in the control group were similar (51.7, 7.8, and 2.8 to 3.8, respectively). Six-month results were published in 2016. Patients in the ESI group received a mean of 1.7 injections over the first 6 months of the study. Patients who withdrew from the study after treatment but before the 6-month follow-up (10 IG-MLD, 20 ESI) were considered treatment failures. The primary end point—the proportion of responders achieving the minimally important difference (MID) of 10 on the ODI—was significantly higher in the IG-MLD group (62.2%) than the ESI group (35.7%; p<0.001). Secondary efficacy end points were the proportion of responders achieving the MID on the NRS-P (2 of 10 points) and the ZCQ (0.5 change). For the NRS-P score, 55.9% of IG-MLD patients were responders compared with 33.3% of controls. Mean improvement in NRS-P scores were 2.9 for the IG-MLD group and 0.9 for the controls. The percentage of responders on the ZCQ was greater for the IG-MLD group than for the ESI group in all subscales. Adverse events were low (1.3% for both groups), with no serious device or procedure-related adverse events in either group. One-year follow-up is ongoing.

Prior to publication of the MiDAS ENCORE trial, the International Spine Intervention Society published a systematic review of the IG-MLD literature. Included in the review were 1 RCT (described next) and 12 cohort studies/series. Pain measurements, using a visual analog score (VAS) or the ZCQ, showed a weighted mean improvement of 41% in the short term (4-6 weeks), 46% at 3 months, 42% at 6 months, and 49% at 1 year. However, mean VAS scores exceeded 3 at all times posttreatment. Ten studies assessed function, 9 using the ODI or 1 using the Roland-Morris Disability Questionnaire. ODI scores improved by a weighted mean of 16.5 at 6 weeks, 16.2 at 12 weeks, 15.4 at 6 months, and 14.0 at 1 year, a weighted cumulative decline to 33 from 47 at baseline. One study, reporting 2-year outcomes was of questionable validity, and data were not included. Mean final ODI scores exceeded 30 for most studies, which would not be considered in the normal range. No direct procedure-related complications were identified in the included
Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis

Policy #  00278
Original Effective Date:  11/16/2010
Current Effective Date:  11/16/2016

The single randomized trial included in the systematic review was a small (N=38), double-blind study comparing mild to ESIs. To maintain blinding, patients receiving steroid injection also received skin anesthesia with a small incision, followed by trocar placement under fluoroscopy. The primary efficacy end point was pain measured by VAS at 6 weeks after treatment. Results showed that 76.2% of mild-treated patients improved more than 2 points on pain scores, compared with 35.3% of steroid-treated patients. ODI scores improved significantly (decreasing from 38.8 to 27.4; \( p<0.05 \)) after mild, but not after ESI (decreasing from 40.5 to 34.8; \( p=0.05 \)). There was no significant difference between groups on ZCQ scores (2.2 for mild vs 2.8 for ESI) at 6 weeks. After the 6-week assessment, patients were unblinded and allowed to cross over to the other treatment. Follow-up at 12 weeks in patients treated with mild showed no significant change in mean VAS score from 6 to 12 weeks (6.3 at baseline, 3.8 at 6 weeks, 3.4 at 12 weeks). There were no major procedure-related or device-related complications. The study was continued with crossover allowed for the epidural steroid group until 26-week results. The study was completed in 2013. The 26-week results have been posted on ClinicalTrials.gov (NCT00995371).

Case Series
One potential indication for IG-MLD is patients with symptomatic LSS primarily caused by a hypertrophic ligamentum flavum who are considered to be poor candidates for traditional decompressive surgery.

In 2011, Chopko reported on IG-MLD in 14 patients considered at high risk for complications from open spine surgery and general anesthesia. Comorbidities included obesity, diabetes, hypertension, chronic obstructive pulmonary disease, chemotherapy, and coronary artery disease. Postoperatively, 9 (64%) of the 14 patients reported improvement in VAS pain scores of at least 3 points. ODI scores did not change significantly. A 2010 retrospective review reported outcomes from a consecutive series of 42 patients who underwent IG-MLD by an interventional pain specialist. Most of these patients had not been considered surgical candidates by a spine surgeon. VAS pain scores averaged 9.6 at baseline and 5.8 at 30 days postprocedure, with 34 (80%) of patients reporting changes in VAS score of 3 or more points. Thirty (71%) patients reported an improvement in function following IG-MLD. No major adverse events were identified.

Other case series include MiDAS I, which was an industry-sponsored, 14-center study of IG-MLD with 78 patients who had failed conservative therapy. At the 6-week follow-up, average VAS pain scores improved from 7.3 (baseline) to 3.7, ODI scores improved by 18%, and ZCQ scores improved by 26.8% on the symptom severity and by 17.5% for physical function subscales. At 1-year follow-up, data from 58 patients was available. Mean VAS for pain score was 4.5, ODI score improved from 48.6 to 36.7, and there was significant improvement on all ZCQ subscales and the SF-12 Physical Component Summary scores. In 2013, Chopko reported 2-year outcomes with 45 patients from this trial. The validity of the longer term results is uncertain due to the high loss to follow-up.

Several other studies of IG-MLD have been published by Deer and colleagues. In 2012, Deer et al described a prospective study of mild in 46 consecutive patients with neurogenic claudication related to LSS caused primarily by ligamentum flavum hypertrophy. A 2010 publication by Deer and Kapural reported a
Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis

Policy # 00278
Original Effective Date: 11/16/2010
Current Effective Date: 11/16/2016

A chart review of 90 consecutive patients treated in the United States (14 physicians in 12 facilities) with mild devices. No major adverse events (dural puncture or tear, blood transfusion, nerve injury, epidural bleeding, hematoma) were found in the review. The safety review was updated in 2012 by Levy and Deer with a total of 373 patients treated with IG-MLD.

Ongoing and Unpublished Clinical Trials
Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unpublished</td>
<td>Comparative Study of Sham Versus Mild Procedure in Patients Diagnosed With Symptomatic Lumbar Central Canal Stenosis</td>
<td>40</td>
<td>Oct 2011a</td>
</tr>
<tr>
<td>NCT01129921a</td>
<td>MIDAS III (Mild Decompression Alternative to Open Surgery): Vertos Mild Patient Evaluation Study</td>
<td>138</td>
<td>May 2014o</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

b Results are posted on www.ClinicalTrials.gov. The study limitations include technical problems with measurement leading to unreliable or uninterpretable data.

Summary of Evidence

The evidence for IG-MLD in individuals who have central lumbar spinal stenosis includes a large, ongoing randomized controlled trial (RCT; N=302) and a systematic review of 1 small RCT (N=38) and a number of prospective and retrospective cohort studies and case series. Relevant outcomes are symptoms, functional outcomes, health status measures, and treatment-related morbidity. The largest RCT compares IG-MLD to epidural steroid injections (control) in patients who have ligamentum flavum hypertrophy and have failed conservative therapy. Early results suggest improvement in pain and function scores in the IG-MLD group versus the control group. However, the control therapy is problematic, because epidural steroid injection has not been shown to be effective for treating LSS (see evidence review on epidural steroid injections for back pain). In addition, the trial was not blinded and there was evidence of differing expectations and follow-up in the 2 groups, resulting in a high risk of bias. Studies completed but unpublished, one comparing IG-MLD to sham and another larger trial comparing IG-MLD to open surgery, also raise concerns about the efficacy of this procedure. The available evidence is insufficient to determine the efficacy of mild compared to placebo or to determine the efficacy of IG-MLD compared to open decompression. Trials with relevant control groups could provide greater certainty regarding the risks and benefits of this procedure compared to open decompression. The evidence is insufficient to determine the effects of the technology on health outcomes.

References

Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis

Policy # 00278
Original Effective Date: 11/16/2010
Current Effective Date: 11/16/2016


Policy History
Original Effective Date: 11/16/2010
Current Effective Date: 11/16/2016

11/04/2010 Medical Policy Committee review
11/03/2011 Medical Policy Committee review.
12/06/2011 Posted as Archived policy.
03/05/2012 Re-posted as active policy.
11/01/2012 Medical Policy Committee review.
11/28/2012 Medical Policy Implementation Committee. No change to coverage.
11/07/2013 Medical Policy Committee review.
11/20/2013 Medical Policy Implementation Committee. No change to coverage.
11/06/2014 Medical Policy Committee review.
11/21/2014 Medical Policy Implementation Committee. No change to coverage.
08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015 Medical Policy Committee review.

©2016 Blue Cross and Blue Shield of Louisiana
An independent licensee of the Blue Cross and Blue Shield Association

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.
Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis

Policy # 00278
Original Effective Date: 11/16/2010
Current Effective Date: 11/16/2016

11/16/2015 Medical Policy Implementation Committee. No change to coverage.
11/03/2016 Medical Policy Committee review.
11/16/2016 Medical Policy Implementation Committee. No change to coverage.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes and CPT code update
Next Scheduled Review Date: 11/2017

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 2015 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 direct 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>0275T</td>
</tr>
<tr>
<td></td>
<td>New code eff 1/1/17: 62380</td>
</tr>
<tr>
<td>HCPCS</td>
<td>G0276</td>
</tr>
<tr>
<td>ICD-10 Diagnosis</td>
<td>All related diagnoses</td>
</tr>
</tbody>
</table>

*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.
Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis

Policy # 00278
Original Effective Date: 11/16/2010
Current Effective Date: 11/16/2016

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

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.