Image-Guided Minimally Invasive Lumbar Decompression for Spinal Stenosis

Policy Number: 7.01.126  Last Review: 5/2017

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for image-guided minimally invasive lumbar decompression. This is considered investigational.

When Policy Topic is covered
Not Applicable

When Policy Topic is not covered
Image-guided minimally invasive lumbar decompression is considered investigational.

Description of Procedure or Service

<table>
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<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<td>Individuals:</td>
<td>Interventions of interest are:</td>
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<td>Relevant outcomes include:</td>
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<td>With lumbar spinal stenosis</td>
<td>- Image-guided minimally invasive lumbar decompression</td>
<td>- Conservative therapy</td>
<td>- Symptoms</td>
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<td>- Open decompression</td>
<td>- Functional outcomes</td>
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Image-guided minimally invasive lumbar decompression (IG-MLD) describes a percutaneous procedure for decompression of the central spinal canal in patients with lumbar spinal stenosis (LSS) and hypertrophy of the ligamentum flavum. In this procedure, a specialized cannula and surgical tools (mild®) are used under fluoroscopic guidance for bone and tissue sculpting near the spinal canal. IG-MLD is proposed as an alternative to existing posterior decompression procedures.

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.

**Background**

In lumbar spinal stenosis (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, i.e., 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 over 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 ultra-minimally 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 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 post-operatively 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 multi-level 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.

**Regulatory Status**

The mild® tool kit (Vertos Medical) initially received 510(k) marketing clearance as the X-Sten MILD Tool Kit (X-Sten Corp.) from the U.S. Food and Drug Administration (FDA) in 2006, with intended use as a set of specialized surgical instruments to be used to perform percutaneous lumbar decompressive procedures for the treatment of various spinal conditions.

Vertos’ mild® instructions for use state that the devices are not intended for disc procedures but rather for tissue resection at the perilaminar 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 anatomical 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.

**Rationale**
This evidence review was created in 2010 and has been updated periodically using the MEDLINE database. The most recent literature review was performed through February 22, 2016. Following is a summary of key references to date.

**Conventional Posterior Decompressive Surgery**
Posterior decompression for lumbar spinal stenosis (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.(1,2) 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) that evaluated laminectomy for spinal stenosis (specifically with or without degenerative spondylolisthesis).3,4 All 4 studies found that initial decompressive surgery (laminectomy) was slightly to moderately superior to initial nonsurgical therapy (eg, average 8- to 18-point differences on the 36-Item Short-Form Health Survey [SF-36] and Oswestry Disability Index [ODI]). However, there was insufficient evidence to determine the optimal adjunctive surgical methods for laminectomy (ie, with or without fusion, 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.

The primary literature on image-guided minimally invasive lumbar decompression (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).(5) 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.(5) 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.(6) 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.(7) 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 studies, although the possibility of damage to dura and
nerve roots with this procedure was noted. Overall, the body of evidence addressing the IG-MLD procedure was of low quality.

The single randomized trial included in the systematic review was a small (N=38), double-blind study comparing mild® to ESIs.(8) 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.(9) 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.(10) 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.(11) 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.(12) 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.(7) 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 .(13) A 2010 publication by Deer and Kapural reported a chart review of 90 consecutive patients treated in the United States (14 physicians in 12 facilities) with mild® devices.(14) 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.(15)

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

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<td>NCT01129921a</td>
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<td>NCT01315145a</td>
<td>MiDAS III (Mild® Decompression Alternative to Open Surgery): Vertos Mild Patient Evaluation Study</td>
<td>138</td>
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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 image-guided minimally invasive lumbar decompression (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 lumbar spinal stenosis (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.

**SUPPLEMENTAL INFORMATION**

**Practice Guidelines and Position Statements**
The American Pain Society (APS) published clinical practice guidelines in 2009 on interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain.(2) As noted, the guidelines were based on a systematic review conducted at the Oregon Health Sciences University Evidence-based Practice Center.(1) APS provided a strong recommendation (high-quality evidence) that clinicians discuss risks and benefits of surgery as an option for patients with persistent and disabling radiculopathy due to spinal stenosis. This recommendation was based on evidence showing that decompressive laminectomy is associated with moderate benefits compared with nonsurgical therapy through 1 to 2 years for persistent and disabling leg pain due to spinal stenosis, with or without degenerative spondylolisthesis. There was insufficient evidence to determine if laminectomy with fusion was more effective than laminectomy without fusion. APS recommended that shared decision making regarding surgery include a specific discussion about average benefits, which appear to decrease over time in patients who undergo surgery. This recommendation was based on randomized trials of laminectomy. Evidence for more recent decompressive surgical procedures was not reviewed.

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
Effective for services performed on or after January 9, 2014, the Centers for Medicare and Medicaid Services (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.(16)

CMS determined that PILD would 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 meeting 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 contrast media to identify and monitor the compressed area via epidurogram.

References

Billing Coding/Physician Documentation Information
0275T Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous
resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar

**G0276** Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial

**ICD10 Codes**

**M43.15-M43.17** Spondylolisthesis lumbar region code range

**M48.05-M48.07** Spinal stenosis lumbar region code range

There is no specific CPT code for the mild® procedure. It is possible that the procedure may be coded using CPT code 63030 (laminotomy [hemilaminectomy], with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, including open and endoscopically-assisted approaches, 1 interspace, lumbar). This is not felt to be the correct code for the mild® procedure as the procedure is needle-based, and the anatomic structures are not directly or endoscopically visualized. Other CPT codes that might be used include 63056 and 63057 (transpedicular approach with decompression of spinal cord, equine and/or nerve root[s], [eg, herniated intervertebral disc], single segment; lumbar [including transfacet, or lateral extraforaminal approach] [eg, far lateral herniated intervertebral disc] first segment and each additional segment respectively).

The procedure utilizes an epidurogram so CPT code 72275 (epidurography, radiological supervision and interpretation) would probably also be reported.

**Additional Policy Key Words**

N/A

**Policy Implementation/Update Information**

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State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in
determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.