Image-Guided Minimally Invasive Lumbar Decompression for Spinal Stenosis

Number: 7.01.126  
Effective Date: July 1, 2016  
Revision Date(s): 06/14/16; 06/17/15; 06/09/15; 06/09/14; 05/13/13; 05/08/12  
Replaces: N/A

Policy

Image-guided minimally invasive lumbar decompression (IG-MLD) is considered investigational.

Related Policies

7.01.18 Automated Percutaneous and Endoscopic Discectomy
7.01.93 Decompression of the Intervertebral Disc Using Laser Energy (Laser Discectomy) or Radiofrequency Coblation (Nucleoplasty)
7.01.107 Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)
7.01.551 Lumbar Spine Decompression Surgery: Discectomy, Foraminotomy, Laminotomy, Laminectomy

Policy Guidelines

Coding

<table>
<thead>
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<th>CPT</th>
<th>Description</th>
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<tr>
<td>0275T</td>
<td>Percutaneous laminotomy/laminectomy (intralaminal approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method under indirect image guidance (e.g., fluoroscopic, [computed tomography] CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar</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.

**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 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 image-guided minimally invasive lumbar decompression (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 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 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 uses 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**

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

Vertos’ mild® instructions 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.

FDA product code: HRX.

### Scope

Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

### Benefit Application

N/A

### Rationale

<table>
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<tr>
<th>Populations</th>
<th>Interventions of interest are:</th>
<th>Comparators of interest are:</th>
<th>Relevant outcomes include:</th>
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<tbody>
<tr>
<td>Individuals:</td>
<td>• Image-guided minimally invasive lumbar decompression</td>
<td>• Conservative therapy • Open decompression</td>
<td>• Symptoms • Functional outcomes • Health status measures • Treatment-related morbidity</td>
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This evidence review was created in 2010 and updated periodically using the MEDLINE database. The most recent literature review was performed through February, 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) evaluating laminectomy for spinal stenosis (specifically with or without degenerative spondylolisthesis). (3,4) All four trials found that initial decompressive surgery (laminectomy) was slightly to moderately superior to initial nonsurgical therapy (e.g., average 8- to 18-point difference 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 (i.e., with or without fusion, and instrumented vs. non-instrumented 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) consists of 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) study (NCT02093520) was approved by the Centers for Medicare and Medicaid Services under coverage with evidence development. This nonblinded study was conducted at 26 interventional pain management centers in the United States and randomized 302 patients in a 1:1 ratio to IG-MLD or epidural steroid injections (ESIs). This study included Medicare beneficiaries 65 years of older who had neurogenic claudication symptoms for at least 3 months and had failed physical therapy, home exercise programs, and oral analgesics. The study also required radiologic evidence of lumbar spinal stenosis (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 providing they were not considered to be severe by the treating physician. More patients in the ESI group withdrew prior to study treatment (22 vs 6), due primarily to a decision to have surgery or other nonstudy therapy (n=8) or 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-MLD group scored 53.0 on the 100-point ODI, 7.7 out of 10 points on the 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, at 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 than the ESI group (62.2% vs 35.7%, p<0.001). Secondary efficacy end points were the proportion of responders for 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 score was 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 in the ESI group in all subdomains. Adverse events were low (1.3% for both groups), and there were no serious device or procedure-related adverse events in either group. One-year follow-up is ongoing.

Prior to the publication of the MiDAS ENCORE trial, members of the Standards Division of the International Spine Intervention Society published a systematic review of the IG-MLD literature in 2014. (6) Included in the review were 1 randomized controlled trial (described next) and 12 cohort studies/series. Pain measurements using a visual analog score (VAS) or Zurich Claudication Questionnaire (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 remained greater than 3 at all times after treatment. Ten studies assessed function using the ODI or Roland-
Morris Disability Questionnaire. With a baseline ODI score of 47.0, the ODI 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. One study that reported 2-year outcomes was considered to be of questionable validity, and the data were not accepted. (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 epidural steroid injections (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 endpoint 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 (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 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 are posted online at www.ClinicalTrials.gov (NCT00995371).

Case Series
One potential indication is for patients who have 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 who were considered at high risk for complications from open spine surgery and general anesthesia. (9) Comorbidities included obesity, diabetes mellitus, hypertension, chronic obstructive pulmonary disease, chemotherapy, and coronary artery disease. Nine of the 14 patients (64%) reported an improvement in VAS pain scores of 3 points or more. ODI scores did not change significantly. A 2010 publication reported outcomes from a consecutive series of 42 patients who underwent IG-MLD by an interventional pain specialist. (10) Most patients were considered nonsurgical candidates by a spine surgeon. VAS pain scores averaged 9.6 at baseline and 5.8 at 30 days after the procedure, with 80% of patients reporting a change in VAS score of 3 or more. Thirty (71%) patients reported an improvement in function following IG-MLD. No major adverse events were identified.

Other series include MiDAS I (NCT00956631) that 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 the average VAS pain score improved by 18% and ZCQ scores improved 26.8% on the symptom severity subscale and 17.5% for physical function. At 1-year follow-up, data from 58 patients was available. (12) VAS for pain score was 4.5, ODI score improved from 48.6 to 36.7, and there was significant improvement on all domains of the ZCQ and the SF-12 Physical Component Summary score. In 2013, Chopko reported 2-year outcomes with 45 patients from this trial. (7) Validity of the longer-term results is uncertain due to the high loss to follow-up.

Several other reports on IG-MLD have been published by Deer et al. The 2012 report by Deer et al. describes a prospective study of mild® in 46 consecutive patients with neurogenic claudication related to LSS that was primarily caused by ligamentum flavum hypertrophy (NCT01076244). (13) A 2010 publication by Deer and Kapural describes 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 chart 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 policy are listed in Table 1.

Table 1. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
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<th>Completion</th>
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[See Table 1 for details]
Summary of Evidence
The evidence for IG-MLD in individuals who have lumbar spinal stenosis includes a large, ongoing randomized controlled trial (RCT; N=302), 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 that were completed but not published, one comparing IG-MLD with sham and another larger trial that compared IG-MLD with 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 and is also insufficient to determine the efficacy of IG-MLD compared to open decompression. Trials with relevant control groups would allow greater certainty regarding the risks and benefits of this procedure compared with open decompression. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

The American Pain Society (APS)
The APS published clinical practice guidelines in 2009 on interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain. (2) The guidelines were based on a systematic review commissioned by APS and 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, either 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. It should be noted that 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 09, 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 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 (e.g., fluoroscopic, computed tomography) with the assistance of contrast media to identify and monitor the compressed area via epiduragram.

References

Reviewed by orthopedic surgeon specializing in spine surgery (April 2011).


Appendix

N/A

History

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<tr>
<td>05/10/11</td>
<td>Add to Surgery Section - New medical policy. This policy was created by BCBSA in 3/2010; it was not adopted because there was no specific code. A new specific CPT code, 0275T, will become effective 7/11; ICD-10 codes have been incorporated into the policy.</td>
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<td>09/26/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
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<td>05/28/13</td>
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<td>01/21/14</td>
<td>Update Related Policies. Add 7.01.551.</td>
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<td>06/14/16</td>
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Washington, D.C. 20201

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