

## **Medical Policy Manual**

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

**Date of Origin:** August 2010

**Section:** Surgery

**Approved Date:** February 23, 2012

**Policy No:** 176

**Effective Date:** May 1, 2012

### **IMPORTANT REMINDER**

Regence Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

### **DESCRIPTION**

Image-guided minimally invasive lumbar decompression (IG-MLD) describes a novel percutaneous procedure for decompression of the central spinal canal in patients with lumbar spinal stenosis. In this procedure, a specialized cannula and surgical tools 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 over 65 years of age. The goal of surgical treatment is to “decompress” the spinal cord and/or nerve roots. Although treatment of disc herniation may be required as a component of lumbar decompression, 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 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.

## POLICY/CRITERIA

Image-guided minimally invasive lumbar decompression is considered **investigational**.

## SCIENTIFIC EVIDENCE<sup>[1]</sup>

### Posterior Decompressive Surgery

#### *Laminectomy*

A 2009 systematic review of surgery for back pain, commissioned by the American Pain Society (APS), was conducted by the Oregon Health Sciences University Evidence-Based Practice Center.<sup>[2,3]</sup> Four higher-quality randomized trials were reviewed that compared surgery to 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).<sup>[4,5]</sup> Baseline pain scores averaged 31 to 32 on the SF-36 bodily pain score or 7 on a 0 to 10 pain scale. Two trials permitted enrollment of patients with greater than 12 weeks of symptoms; however, symptoms were present for more than 6 months in the majority of patients in all trials. All 4 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 SF-36 and Oswestry Disability Index). Although differences were decreased at longer follow-up, interpretation of results was complicated by the large proportion of patients in the nonsurgical therapy group who crossed over to surgery before the final follow-up. Dural tears were the most common complication of laminectomy, occurring in 7% to 11% of patients. 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.

#### *Laminotomy versus Laminectomy*

A 2005 study randomized 120 patients with lumbar stenosis to bilateral laminotomy, unilateral laminotomy or laminectomy.<sup>[6]</sup> Patients were refractory to at least 3 months of conservative therapy, with neurogenic claudication or radiculopathy, imaging evidence of degenerative lumbar stenosis, and absence of herniation or instability. Three patients were excluded due to discectomies during surgery; follow-up of at least 1 year was obtained in 110 patients (94% of the cohort of 117 and 97% of surviving patients). The average visual analog score (VAS) for overall pain at baseline was 7.5, improving to 2.3 for bilateral laminotomy, 3.6 for unilateral laminotomy, and 4 for laminectomy. Neurogenic claudication improved in 92% of patients with bilateral laminotomy, compared with 74% treated with unilateral laminotomy and 68% of patients who had laminectomy. Similar improvements were obtained for the SF-36 (postoperative bodily pain scores of 61, 47, 45, respectively), Roland-Morris scale (8, 8.5, and 11 postoperatively), and patient satisfaction scores (97%, 74%, and 74% satisfied). The perioperative morbidity rate was lower with bilateral laminotomy (5%) than unilateral laminotomy (17.5%) or laminectomy (22.5%), due primarily to the incidence of dural tears with the 3 procedures. Blinding of patients to the procedure to which they were randomized was not described; the potential for bias is unknown.

A 2008 quasi-randomized study from Asia compared laminoforaminotomy with laminectomy in 152 consecutive patients.<sup>[7]</sup> Inclusion criteria required that each patient have 1) neurogenic claudication as defined by leg pain limiting standing, ambulation, or both; 2) a history of exercise intolerance; 3) magnetic resonance imaging (MRI), myelogram, or computed tomography (CT) confirmation of compressive central stenosis (central sagittal diameter less than 10 mm) with or without lateral recess stenosis (lateral recess diameter less than 3 mm); and 4) failure of conservative therapy after an adequate trial (not defined). Patients were excluded from the study if they had 1) previous surgery at the same level; 2) isthmic spondylolisthesis; 3) congenital spinal stenosis less than 8 mm caused by short pedicles; 4) dynamic instability; 5) cauda equina syndrome; 6) worker's compensation claim or other litigation; 7) dying of other disease or otherwise lost to follow-up. At an average 40 months after surgery, the Oswestry Disability Index and VAS for back and leg pain and were low (e.g., less than 1 on VAS) for both groups, and significantly lower for laminotomy. The proportion of patients with good to excellent results (absent or occasional mild back and leg pain and the ability to ambulate more

than 1 mile or 20 minutes) was 89% for patients treated with laminotomy and 63% for patients treated with laminectomy. Seven percent of patients treated with laminectomy had poor results at the final interview (range: 27–58 months), compared with none in the laminotomy group. The study is limited by the lack of information about the number of patients lost to follow-up and the lack of blinding.

#### *Microendoscopic Decompressive Laminotomy (MEDL)*

No comparative trials with MEDL were identified. In 2009, Castro-Menendez et al. reported 4-year outcomes (from a prospectively maintained institutional database) of 50 patients with LSS who were treated by single level microendoscopic decompression. Twenty of the patients received microendoscopic discectomy at the same time, which may be considered a part of the endoscopic procedure that can be performed when needed.<sup>[8]</sup> Inclusion criteria for the study were 1) low back pain and/or radicular pain (70%); 2) neurogenic claudication (58%); 3) personal history of exercise intolerance; 4) radiologic/neuroimaging evidence of degenerative lumbar stenosis; 5) clinical-radiologic concordance; 6) failure of conservative management after at least 6 months of therapy. Excluded from the study were patients with 1) nonclinical-nonradiologic correlation; 2) congenital stenosis; 3) previous lumbar spinal surgery; 4) higher than grade I degenerative spondylolisthesis; 5) spondylolisthesis with spondylolysis; 6) preoperative instability; 7) more than 1 level clinically affected; 8) associated degenerative scoliosis of more than 20 degrees; and 9) the presence of an associated pathology such as acute inflammation, tumor, or cauda equina syndrome. The mean postoperative hospital stay was 3.2 days. The Oswestry Disability Index decreased by 30 (65.2 preoperatively), leg pain VAS by 6.02 (8.3 preoperatively) and lumbar pain VAS by 0.84 (5.3 preoperatively) at an average 4-year follow-up (range: 24–72 months). Of the 29 patients (58%) with neurogenic claudication, 21 (72%) reported improvement in the ability to walk (more than 1 mile) at the end of the study. Dural tears occurred in 5 patients (10%), all in the first 25 interventions. One patient (2%) had epidural hematoma causing cauda equina syndrome. Although the study may be relatively representative of outcomes during the learning curve for this highly selected population, the report is limited by the restricted selection criteria, retrospective review, and lack of blinding.

#### **Image-Guided Percutaneous Minimally Invasive Lumbar Decompression (IG-MLD)**

There are currently no published randomized controlled trials for IG-MLD. The largest nonrandomized trial was a case series in which 58 patients underwent 170 unilateral or bilateral percutaneous decompression at one or two lumbar levels using mild® tools.<sup>[9]</sup> At 1-year follow-up, significant improvements were reported for pain reduction and physical functionality. No procedure-related complications were reported. Basu also reported statistically significant improvement in pain reduction and function level for 27 consecutive patients 6 months following the mild® procedure.<sup>[10]</sup>

Chopko and Caraway published 6-week follow-up of an ongoing multi-center study of IG-MLD at 14 centers.<sup>[11]</sup> Included were patients with symptomatic LSS that was caused primarily by dorsal element hypertrophy with a hypertrophic ligamentum flavum greater than 2.5 mm and central canal sectional area equal to or less than 100 square mm and had failed conservative therapy. Of 78 patients treated, 6-week follow-up was available for 75 (96%). Thirty nine of the patients (52%) were discharged from the hospital on the same day, and 36 patients (48%) stayed for one night. No major device or procedure-related complications (e.g. dural tears, nerve root injury, post-operative infection, hemodynamic instability, or post-operative spinal structural instability) were reported. The average VAS pain score improved from 7.3 at baseline to 3.7 at the 6-week follow-up. Scores on the ODI improved from 47.4 to 29.5, a 38% improvement. Scores on the Zurich Claudication Questionnaire improved 26.8% on the symptom severity subscale and 17.5% for physical function. Scores on all subscales of the Short-Form 12 (SF-12) health survey were improved.

Chopko also reported a prospective study of IG-MLD in 14 patients who were considered at high risk for complications from open spine surgery and general anesthesia.<sup>[12]</sup> 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. The average VAS

score improved from 7.6 to 3.6 (53% improvement) at a mean follow-up of 23.5 weeks (range: 4 to 72 weeks). Scores on the ODI were 50% at baseline and 43.9% at follow-up; this change was not statistically significant. Two post-operative complications (calf deep venous thrombosis and pulmonary embolism) related to the procedure were observed in a single patient. One patient subsequently received open lumbar decompressive laminectomy due to continued decline in function.

A 2010 publication described a chart review of 90 consecutive patients treated in the U.S. (14 physicians in 12 facilities) with mild® devices under fluoroscopic guidance.<sup>[13]</sup> No efficacy data were reported. No major adverse events (dural puncture or tear, blood transfusion, nerve injury, epidural bleeding, or hematoma) were found in the chart review. The authors stated that prospective, randomized studies have been initiated to evaluate the efficacy of this new procedure.

Another retrospective review from 2010 reported outcomes from a consecutive series of 42 patients who underwent IG-MLD by interventional pain specialists.<sup>[14]</sup> All patients met MRI criteria (spinal stenosis and ligamentum flavum hypertrophy) for IG-MLD and had undergone previous conservative treatment to include lumbar epidural steroid injections, opioid and non-opioid medication and physical therapy. Most of the patients were considered non-surgical candidates in consultation with or referral from a spine surgeon (no further details were provided). All patients had bilateral IG-MLD with the majority (n=26) at 2 levels. 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 of equal to or greater than 3. Thirty patients (71%) reported an improvement in function following IG-MLD. No major adverse events were identified.

## **Clinical Practice Guidelines and Position Statements**

While a number of US clinical practice guidelines were found for interventional and minimally invasive lumbar decompression procedures for treatment of spinal stenosis, none addressed IG-MLD. The American Pain Society published clinical practice guidelines in 2009 on interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain.<sup>[3]</sup> The guidelines were based on a systematic review commissioned by the APS and conducted at the Oregon Health Sciences University Evidence-Based Practice Center.<sup>[2]</sup> The 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 to 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. The 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.

## **Summary**

Posterior decompression for lumbar spinal stenosis has been evolving towards increasingly minimally invasive procedures in an attempt to minimize post-operative 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. In contrast to surgical decompression, the mild® procedure is a percutaneous decompressive procedure performed solely under fluoroscopic guidance (e.g., 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 it be required. Due to the unknown impact of these limitations on health outcomes, randomized, controlled studies in appropriate patients are needed to compare this novel procedure with the established alternatives. Although studies have been initiated,

no evidence is available at this time to evaluate the efficacy of image-guided percutaneous lumbar decompression; therefore, this technique is considered investigational.

## REFERENCES

1. BlueCross BlueShield Association Medical Policy Reference Manual "Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis." Policy No. 7.01.126
2. Chou, R, Baisden, J, Carragee, EJ, Resnick, DK, Shaffer, WO, Loeser, JD. Surgery for low back pain: a review of the evidence for an American Pain Society Clinical Practice Guideline. *Spine (Phila Pa 1976)*. 2009 May 1;34(10):1094-109. PMID: 19363455
3. Chou, R, Loeser, JD, Owens, DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. *Spine (Phila Pa 1976)*. 2009 May 1;34(10):1066-77. PMID: 19363457
4. Weinstein, JN, Lurie, JD, Tosteson, TD, et al. Surgical versus nonsurgical treatment for lumbar degenerative spondylolisthesis. *N Engl J Med*. 2007 May 31;356(22):2257-70. PMID: 17538085
5. Weinstein, JN, Tosteson, TD, Lurie, JD, et al. Surgical versus nonsurgical therapy for lumbar spinal stenosis. *N Engl J Med*. 2008 Feb 21;358(8):794-810. PMID: 18287602
6. Thome, C, Zevgaridis, D, Leheta, O, et al. Outcome after less-invasive decompression of lumbar spinal stenosis: a randomized comparison of unilateral laminotomy, bilateral laminotomy, and laminectomy. *J Neurosurg Spine*. 2005 Aug;3(2):129-41. PMID: 16370302
7. Fu, YS, Zeng, BF, Xu, JG. Long-term outcomes of two different decompressive techniques for lumbar spinal stenosis. *Spine (Phila Pa 1976)*. 2008 Mar 1;33(5):514-8. PMID: 18317196
8. Castro-Menendez, M, Bravo-Ricoy, JA, Casal-Moro, R, Hernandez-Blanco, M, Jorge-Barreiro, FJ. Midterm outcome after microendoscopic decompressive laminotomy for lumbar spinal stenosis: 4-year prospective study. *Neurosurgery*. 2009 Jul;65(1):100-10; discussion 10; quiz A12. PMID: 19574831
9. Mekhail N, Vallejo R, Coleman MH, et al. Long-Term Results of Percutaneous Lumbar Decompression mild(®) for Spinal Stenosis. *Pain Pract*. 2011 Jun 16. doi: 10.1111/j.1533-2500.2011.00481.x. [Epub ahead of print] PMID 21676166
10. Basu S. Mild Procedure: Single-site Prospective IRB Study. *Clin J Pain*. 2012 Mar;28(3):254-8. PMID 21926907
11. Chopko B, Caraway DL. MiDAS I (mild Decompression Alternative to Open Surgery): A preliminary report of a prospective, multi-center clinical study. *Pain Physician* 2010; 13(4):369-78. PMID 20648206
12. Chopko BW. A novel method for treatment of lumbar spinal stenosis in high-risk surgical candidates: pilot study experience with percutaneous remodeling of ligamentum flavum and lamina. *J Neurosurg Spine* 2011; 14(1):46-50. PMID 21142460
13. Deer, TR, Kapural, L. New image-guided ultra-minimally invasive lumbar decompression method: the mild procedure. *Pain Physician*. 2010 Jan;13(1):35-41. PMID: 20119461
14. Lingreen R, Grider JS. Retrospective review of patient self-reported improvement and post-procedure findings for mild(R) (minimally invasive lumbar decompression). *Pain Physician* 2010; 13(6):555-60. PMID 21102968

## CROSS REFERENCES

[Percutaneous Intradiscal Electrothermal Annuloplasty \(IDET\) and Percutaneous Intradiscal Radiofrequency Thermocoagulation](#), Regence Medical Policy Manual, Surgery, Policy No. 118

[Artificial Intervertebral Disc Surgery](#), Regence Medical Policy Manual, Surgery, Policy No. 127

[Decompression of Intervertebral Discs Using Laser \(Laser Discectomy\) or Radiofrequency Energy \(Disc Nucleoplasty™\)](#), Regence Medical Policy Manual, Surgery, Policy No. 131

[Lumbar Dynamic Stabilization](#), Regence Medical Policy Manual, Surgery, Policy No. 143

[Automated Percutaneous Discectomy](#), Regence Medical Policy Manual, Surgery, Policy No. 145

[Interspinous Distraction Devices \(Spacers\)](#), Regence Medical Policy Manual, Surgery, Policy No. 155

[Total Facet Arthroplasty](#), Regence Medical Policy Manual, Surgery, Policy No. 171

<b>CODES</b>	<b>NUMBER</b>	<b>DESCRIPTION</b>
CPT	0275T	Percutaneous laminotomy/laminectomy (intradiscal 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, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar
HCPCS	None	