

## Medical Policy Manual

**Topic:** Image-Guided Minimally Invasive Spinal Decompression (IG-MSD) for Spinal Stenosis      **Date of Origin:** August 2010

**Section:** Surgery

**Last Reviewed Date:** January 2014

**Policy No:** 176

**Effective Date:** April 1, 2014

### **IMPORTANT REMINDER**

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 spinal decompression (IG-MSD) describes a novel percutaneous procedure for decompression of the spinal canal in patients with spinal stenosis using image-guided navigation systems for the purpose of improving orientation to the unexposed anatomy. Common imaging techniques include fluoroscopy, computer-tomography and X-ray. In this procedure, a specialized cannula and surgical tools are used under image-guidance for bone and tissue sculpting near the spinal canal.

### **Background**

In spinal stenosis, the space around the spinal cord narrows, compressing the spinal cord and the nerve roots. Lumbar spinal stenosis is the most common, the most frequent symptom of which 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 with symptom onset beginning at 40-50 years and older. The goal of surgical treatment is to “decompress” the spinal cord and/or nerve roots. Although treatment of disc herniation or surgical fusion of vertebrae may be required as a component of decompression, the present policy addresses decompression of spinal stenosis with a percutaneous treatment that is performed under image-guidance.

Most image-guided minimally invasive spinal decompression procedures are performed on the lumbar spine. Percutaneous image-guided minimally invasive lumbar decompression (IG-MLD) using a specially designed tool kit has been proposed as an ultra-minimally invasive treatment of central spinal stenosis. In percutaneous IG-MLD, the epidural space is filled with contrast medium under image-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 image-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 decompressive surgical procedures include:

- Decompressive laminectomy, the classic treatment for spinal stenosis, which unroofs the spinal canal by extensive resection of posterior or anterior 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. In cases of lumbar decompression, 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. In thoracic decompression cases, neurological complications rates in up to 14.5% of cases, have been reported.<sup>[1]</sup> 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 of the lumbar spine. 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.

The Totalis™ Direct Decompression System received 510(k) market clearance from the FDA in November 2012, with the intended use as an interspinous access platform to perform percutaneous lumbar decompressive procedures for a variety of conditions. The Totalis™ system uses a small cannula, or tube, which is placed

through a small incision where a specialized instrument is inserted in order to remove bone or tissue. X-ray images are used to help guide the Totalis instrument during the procedure.

There are no FDA approved guidance tool kits for image-guided cervical or thoracic spinal decompression.

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 cervical, thoracic or lumbar decompression is considered **investigational**.

## **SCIENTIFIC EVIDENCE**

Evaluating the safety and effectiveness of image-guided minimally invasive spinal decompression (IG-MSD) requires randomized comparisons with conventional techniques for decompression of spinal stenosis. These comparisons are necessary to determine whether the benefits of IG-MSD outweigh any risks and whether they offer advantages over the conventional surgical techniques described above with respect to symptom control, durability of treatment effects, adverse effects, and the need for further surgical treatment.

The primary outcomes for treatment of spinal stenosis are pain reduction and improvement in functional levels. Both of these outcomes can be influenced by variables other than the spinal surgery under investigation such as nonspecific effects, placebo response, the natural history of the disease, and/or regression to the mean.

Therefore, they need to be evaluated in well-designed randomized, controlled trials that include large study populations and long-term follow-up.

- Random treatment assignment to either a control group (standard surgical treatment) or an experimental group (new therapy) promotes equal distribution of patient characteristics across study groups and helps control for the variables noted above that could distort or bias treatment outcomes.
- Large study populations are needed to rule out the element of chance as an explanation of study outcomes and to identify any subgroups with different treatment responses than the overall population.
- Long-term follow-up is needed to determine the durability of any treatment effects and the rates of long-term adverse events and reoperation rates, a common concern for spinal surgery.

## **Literature Appraisal**

### *Systematic Reviews*

One systematic review of percutaneous lumbar decompression for symptomatic lumbar spinal stenosis (LSS) was published in 2012.<sup>[2]</sup> The review found no reports of major device- or procedure-related adverse events or deaths in 373 patients. One-year efficacy data was reported to show statistically significant improvement in pain and mobility. However, this review precludes conclusions because it included all IRB-approved study patients as well as a retrospective safety survey, apparently without regard to the design quality of each study. A 2009 systematic review was commissioned by the American Pain Society (APS) and conducted at the Oregon Health Sciences University Evidence-Based Practice Center.<sup>[3]</sup> The review included randomized controlled trials and systematic reviews of surgery for various causes of low back pain including symptomatic spinal stenosis. However, studies were limited to laminectomy; evidence related to more recent decompressive surgical procedures was not reviewed.

### *Randomized Clinical Trials (RCTs)*

In 2012, Brown reported a small (n=38), short-term randomized double-blind trial comparing mild® with epidural steroid injections for symptomatic LSS.<sup>[4]</sup> The study included patients with painful lower limb neurogenic claudication and hypertrophic ligamentum flavum as a contributing factor. Patients with a history of recent spinal fractures, disabling back or leg pain from causes other than LSS, fixed spondylolisthesis greater than grade 1, disk protrusion or osteophyte formation, or excessive facet hypertrophy were excluded from the study. In order 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 post-treatment. Results showed that 76.2% of mild® treated patients had a 2-point or greater improvement in pain scores, compared with 35.3% of steroid-treated patients. The ODI improved significantly from 38.8 to 27.4 after mild®, while the steroid-treated patients showed a non-significant improvement from 40.5 to 34.8. There was no significant difference between groups on the Zurich Claudication Questionnaire (ZCQ, 2.2 for mild® vs. 2.8 for steroid) at 6 weeks. After the 6-week assessment, patients were unblinded and allowed to cross over to the other treatment. Fourteen (82%) of the steroid-treated patients crossed over to mild®. 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, and 3.4 at 12 weeks). There were no major procedure-related or device-related complications. Data from large, long-term RCTs are needed to validate these outcomes. In addition, there is controversy about the efficacy of epidural steroid injections for LSS.

### *Nonrandomized Clinical Trials*

The remainder of the published literature on IG-MSD is limited to several small nonrandomized prospective studies<sup>[5-14]</sup> (n range = 3-78), image-guided feasibility studies<sup>[15-19]</sup> for a variety of conditions, and two retrospective chart reviews<sup>[20,21]</sup> (n = 42 and 90). While these studies suggest that IG-MSD may result in short-term improvements, it is not possible to determine the durability of any treatment effects due to the short-term follow-up and small sample sizes. Other methodological limitations that make these studies unreliable include the lack of randomized comparison of IG-MSD with standard surgical treatments. In addition, the small study populations limit the ability to rule out the role of chance as an explanation of study findings. Therefore, this evidence is insufficient to determine whether IG-MSD offers any advantages over standard surgical procedures.

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

While a number of US clinical practice guidelines were found for interventional and minimally invasive spinal decompression procedures for treatment of spinal stenosis, none addressed image-guided spinal decompression. This includes the following published practice guidelines:

- American Academy of Orthopaedic Surgeons (AAOS)<sup>[22]</sup>
- American Pain Society (APS)<sup>[23]</sup>
- American Society of Anesthesiologists/American Society of Regional Anesthesia and Pain Medicine<sup>[24]</sup>
- American Society of Interventional Pain Physicians<sup>[25]</sup>
- North American Spine Society (NASS)<sup>[26]</sup>

### **Summary**

The current evidence on image-guided minimally invasive spinal decompression (IG-MSD) for symptomatic spinal stenosis is limited to a single small randomized trial and a number of small, short-term, nonrandomized trials. Due to significant methodological limitations, these types of studies do not permit conclusions about the safety and effectiveness of this procedure compared with conventional surgical spinal decompression techniques. In addition, the lack of long-term data does not permit conclusions about the durability of any beneficial effects. Therefore, IG-MSD is considered investigational.

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27. BlueCross BlueShield Association Medical Policy Reference Manual "Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis." Policy No. 7.01.126

## CROSS REFERENCES

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

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

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

[Automated Percutaneous and Endoscopic Discectomy](#), Surgery, Policy No. 145

[Interspinous and Interlaminar Stabilization/Distraktion Devices \(Spacers\)](#), Surgery, Policy No. 155

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

[Interspinous Fixation \(Fusion\) Devices](#), Surgery, Policy No. 172

[Lumbar Spinal Fusion](#), Surgery, Policy No. 187

CODES	NUMBER	DESCRIPTION
CPT	0274T	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; cervical or thoracic
	0275T	; lumbar
HCPCS	None	