MEDICAL POLICY – 7.01.126

Image-Guided Minimally Invasive Decompression for Spinal Stenosis

BCBSA Ref. Policy: 7.01.126

Effective Date: July 1, 2020
Last Revised: June 4, 2020
Replaces: N/A

Related Medical Policies:
7.01.18 Automated Percutaneous and Percutaneous 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

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Spinal stenosis is the narrowing of the spinal canal. This narrowing can be caused by bone spurs, thickening of nearby ligaments, or a bulging disc. As the spinal canal gets narrower, more pressure is put on the nerves, resulting in pain, numbness, or weakness. When surgery is needed to remove the material pressing on the nerves — which is known as decompression surgery — the usual method is an open procedure. A newer method of decompression surgery is being studied. A small opening is made in the back and special instruments are inserted. Instead of seeing the surgical area directly, the surgeon views the area using a certain type of imaging. Image-guided minimally invasive decompression surgery is considered unproven. More studies are needed comparing the results of this surgery to standard decompression surgery.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
### Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Service</th>
<th>Investigational</th>
</tr>
</thead>
<tbody>
<tr>
<td>Image-guided minimally invasive spinal decompression (eg, mild® device kit)</td>
<td>Image-guided minimally invasive spinal decompression is considered investigational.</td>
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### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT 0274T</td>
<td>Percutaneous laminotomy/laminectomy (interlaminar 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), single or multiple levels, unilateral or bilateral; cervical or thoracic</td>
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</tr>
</tbody>
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### Related Information

N/A

### Evidence Review
Description

Image-guided minimally invasive lumbar decompression (IG-MLD) describes a percutaneous procedure for decompression of the central spinal canal in patients with spinal stenosis 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.

Background

Spinal Stenosis

In spinal stenosis, the space around the spinal cord narrows, compressing the spinal cord and its nerve roots. The goal of surgical treatment is to “decompress” the spinal cord and/or nerve roots.

The most common symptom of lumbar spinal stenosis (LSS) is back pain with neurogenic claudication (ie, pain, numbness, or weakness) in the legs that worsens with standing or walking and is alleviated with sitting or leaning forward. Compression of neural elements generally occurs from a combination of degenerative changes including ligamentum flavum hypertrophy, bulging of the intervertebral disc, and facet thickening with arthropathy. Spinal stenosis is often linked to age-related changes in disc height and arthritis of the facet joints. LSS is among 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 most common symptoms of cervical/thoracic spinal stenosis are neck pain and radiculopathy of the shoulder and arm. The most common cause of cervical radiculopathy is degenerative changes, including disc herniation.

Treatment

Conventional Posterior Decompression Surgery

For patients with LSS, surgical laminectomy has established benefits in reducing pain and improving quality of life.
For patients with cervical or thoracic spinal stenosis, surgical treatment includes discectomy or foraminal decompression.

A systematic review by Chou et al (2009) assessed surgery for back pain; it was commissioned by the American Pain Society and conducted an evidence-based center.\(^1,2\) Four higher quality randomized trials were reviewed; they compared surgery with nonsurgical therapy for spinal stenosis, including two studies from the multicenter Spine Patient Outcomes Research Trial 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-point to 18-point differences on the 36-Item Short-Form Health Survey and Oswestry Disability Index). 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. Spine Patient Outcomes Research Trial continues to be referenced as the highest quality evidence published on decompressive surgery.

Less invasive surgical procedures include open laminotomy and microendoscopic laminotomy. In general, the literature comparing surgical procedures is limited. The literature has suggested that less invasive surgical decompression may reduce perioperative morbidity without impairing long-term outcomes when performed in appropriately selected patients. Posterior decompressive surgical procedures include decompressive laminectomy, hemilaminotomy and laminotomy, and microendoscopic decompressive laminotomy.

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. Unlike 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, similar to laminotomy, uses endoscopic visualization. The position of the tubular working channel is confirmed by fluoroscopic guidance, and serial dilators are used to dilate the musculature and expand the fascia. For microendoscopic decompressive laminotomy, 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.

**Image-Guided Minimally Invasive Lumbar Decompression**

Posterior decompression for LSS has been evolving toward increasingly minimally invasive procedures in an attempt to reduce postoperative morbidity and spinal instability. 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.

Percutaneous image-guided minimally invasive lumbar decompression 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 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 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 for use near the lateral neural elements and are contraindicated for disc procedures.

**Summary of Evidence**

For individuals with lumbar spinal stenosis or cervical or thoracic spinal stenosis who receive IG-MLD, the evidence includes a large, ongoing randomized controlled trial (RCT; N=302), a systematic review of a small RCT (N=38), and a number of prospective and retrospective cohort studies and case series. The relevant outcomes are symptoms, functional outcomes, health status measures, and treatment-related morbidity. The largest RCT compared IG-MLD to epidural steroid injections (control) in patients who have ligamentum flavum hypertrophy and who failed conservative therapy. Early results suggest improvement in pain and function scores in the IG-MLD group versus the control group. The trial was unblinded and there is evidence of
differing expectations and follow-up in the two groups, suggesting a high risk of bias. The available evidence is insufficient to determine the efficacy of mild® compared with 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

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>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>NCT03072927</td>
<td>MILD® Percutaneous Image-Guided Lumbar Decompression: A Medicare Claims Study</td>
<td>4000</td>
<td>Dec 2020</td>
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<tr>
<td>NCT03610737</td>
<td>A Multi-center, Randomized Controlled Study of the VertosMILD Procedure With Conventional Medical Management Versus Conventional Medical Management Alone in the Treatment of Lumbar Spinal Stenosis (MOTION)</td>
<td>150</td>
<td>Feb 2022</td>
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<tr>
<td><strong>Unpublished</strong></td>
<td></td>
<td></td>
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<tr>
<td>NCT01129921</td>
<td>Comparative Study of Sham Versus Mild® (Minimally Invasive Lumbar Decompression) Procedure in Patients Diagnosed With Symptomatic Moderate to Severe Lumbar Central Canal Stenosis</td>
<td>40</td>
<td>Oct 2011</td>
</tr>
</tbody>
</table>

NCT: national clinical trial

* Denotes industry-sponsored or cosponsored trial
Practice Guidelines and Position Statements

North American Spine Society

In 2011, the North American Spine Society revised clinical practice guidelines on the diagnosis and treatment of degenerative lumbar spinal stenosis.\textsuperscript{13} Treatment recommendations included:

- Interlaminar epidural steroid injection for short-term (two weeks to six months) symptom relief in patients with neurogenic claudication or radiculopathy; however, there is conflicting evidence regarding long-term efficacy. (Grade of Recommendation: B)

- A multiple injection regimen of radiographically-guided transforaminal epidural steroid injection or caudal injection for medium-term relief of pain. (Grade of Recommendation: C)

- Decompressive surgery to improve outcomes in patients with moderate to severe symptoms of lumbar spinal stenosis. (Grade of Recommendation: B)

No specific recommendations on percutaneous image-guide lumbar decompression were provided.

Lumbar Spinal Stenosis Consensus Group MIST Guidelines

In 2018, the Lumbar Spinal Stenosis Consensus Group, composed of a panel of nationally recognized spine experts, convened to evaluate the available literature and develop guidelines for minimally invasive spine treatment.\textsuperscript{14} Based on a systematic review of the available literature on percutaneous image-guided lumbar decompression, the consensus committee determined there is sufficient support to warrant Level I evidence (Grade A, Level I, Consensus strong). Grade A evidence is defined as "extremely recommendable (good evidence that the measure is effective and that benefits outweigh the harms."

Medicare National Coverage

Effective for services performed on or after January 9, 2014, the Centers for Medicare & Medicaid Services (CMS) has determined that percutaneous image-guided lumbar decompression for lumbar spinal stenosis is not reasonable and necessary.\textsuperscript{15}

The Centers for Medicare & Medicaid Services determined that percutaneous image-guided lumbar decompression would be covered by Medicare when provided in a clinical study,
through coverage with evidence development for beneficiaries with lumbar spinal stenosis enrolled in an approved clinical study that meets the criteria in the decision memo.

According to the national coverage decision, percutaneous image-guided lumbar decompression is a posterior decompression of the lumbar spine performed under indirect image guidance without any direct visualization of the surgical area. This procedure is proposed as a treatment for symptomatic lumbar spinal stenosis 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.

**Regulatory Status**

In 2006, the X-Sten MILD Tool Kit, now the mild® device kit (X-Sten Corp. renamed Vertos Medical), was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for the treatment of various spinal conditions. This set of specialized surgical instruments is 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. The device is not intended for use near the lateral neural elements and remains dorsal to the dura using image guidance and anatomic landmarks.

Food and Drug Administration product code: HRX.

**References**


**History**

<table>
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<th>Date</th>
<th>Comments</th>
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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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<tr>
<td>05/22/12</td>
<td>Replace policy. Policy updated with literature review through January 2012; reference 10 added; updated related policies cross reference. Policy statement unchanged.</td>
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<tr>
<td>09/26/12</td>
<td>Update Coding Section – ICD-10 codes are now effective 10/01/2014.</td>
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<tr>
<td>05/28/13</td>
<td>Replace policy. Policy updated with literature review through January 31, 2013; references 8, 12-14 and 16 added; policy statement unchanged.</td>
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<td>09/30/13</td>
<td>Update Related Policies. Change title to 7.01.93.</td>
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<tr>
<td>01/21/14</td>
<td>Update Related Policies. Add 7.01.551.</td>
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<tr>
<td>06/17/15</td>
<td>Annual Review. Policy updated with literature review through March 4, 2015; reference 15 added; policy statement unchanged.</td>
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<tr>
<td>11/13/15</td>
<td>Removed related policy 6.01.46.</td>
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<tr>
<td>01/01/18</td>
<td>Coding update, removed CPT code 0275T as it was terminated 1/1/17.</td>
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<tr>
<td>07/01/19</td>
<td>Annual Review, approved June 20, 2019. Policy updated with literature review through February 2019; no references added. Policy statement unchanged.</td>
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Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)

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