Image-Guided Minimally Invasive Decompression for Spinal Stenosis

**Introduction**

Spinal stenosis is the narrowing of the spinal canal. It 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. The result is pain, numbness, or weakness. When surgery is needed to remove the material pressing on the nerves, the usual method is an open procedure. This is known as a decompression surgery. A newer method of decompression surgery has been 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 (investigational). More studies are needed comparing the results of this surgery to standard decompression.

**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>
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<tbody>
<tr>
<td>Image-guided minimally invasive spinal decompression</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</td>
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<tr>
<td>0275T</td>
<td>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 (e.g., fluoroscopic, [computed tomography] CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar (code terminated 1/1/17, replaced with 64999)</td>
</tr>
<tr>
<td>64999</td>
<td>Unlisted procedure, nervous system</td>
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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 the nerve roots. The goal of surgical treatment is to “decompress” the spinal cord and/or nerve roots.

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. 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.

Treatment

Conventional Posterior Decompression Surgery

For patients with cervical or thoracic spinal stenosis, surgical treatment includes discectomy or foraminal decompression. For patients with LSS, surgical laminectomy has established benefits in reducing pain and improving quality of life. 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.\textsuperscript{1,2} Four higher quality randomized trials were
reviewed. These studies 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). 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.

Less invasive surgical procedures have been developed, such as 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**, 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 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 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.

**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 decomposition 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**

The evidence for IG-MLD in individuals who have lumbar spinal stenosis or cervical or thoracic spinal stenosis includes a large, ongoing randomized controlled trial (RCT; N=302), 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. 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. 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.

**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>NCT03072927</td>
<td>MILD® Percutaneous Image-Guided Lumbar Decompression: A Medicare Claims Study</td>
<td>4000</td>
<td>Feb 2021</td>
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</tbody>
</table>

NCT: national clinical trial.

 Denotes industry-sponsored or cosponsored trial

**Practice Guidelines and Position Statements**

No guidelines or statements were identified.

**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.¹²

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 (eg, fluoroscopic, computed tomography) with the assistance of contrast media to identify and monitor the compressed area via epiduragram.

**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 was 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.

**References**


### History

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<tr>
<th>Date</th>
<th>Comments</th>
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<tbody>
<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>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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<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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<td>Date</td>
<td>Comments</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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<td>11/13/15</td>
<td>Removed related policy 6.01.46.</td>
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Premera Blue Cross.

Polskie (Polish):

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