This Protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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</thead>
</table>
| Individuals:  
- With lumbar spinal stenosis | Interventions of interest are:  
- Image-guided minimally invasive lumbar decompression | Comparators of interest are:  
- Conservative therapy  
- Open decompression | Relevant outcomes include:  
- Symptoms  
- Functional outcomes  
- Health status measures  
- Treatment-related morbidity |

Description

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. IG-MLD is proposed as an alternative to existing posterior decompression procedures.

Summary of Evidence

The evidence for image-guided minimally invasive lumbar decompression (IG-MLD) in individuals who have central lumbar spinal stenosis includes a large, ongoing randomized controlled trial (RCT; N=302) and a systematic review of one 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 lumbar spinal stenosis (LSS). In addition, the trial was not blinded and there was evidence of differing expectations and follow-up in the two groups, resulting in a high risk of bias. Studies completed but unpublished, one comparing IG-MLD to sham and another larger trial comparing IG-MLD to 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 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 compared to open decompression. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy

Image-guided minimally invasive lumbar decompression is considered investigational.

Medicare Advantage

For Medicare Advantage percutaneous image-guided lumbar decompression may have potential for coverage when provided through Coverage with Evidence Development (CED) for members with lumbar spinal stenosis who meet the criteria of and are enrolled in an approved clinical study.

Background

In lumbar spinal stenosis (LSS), the space around the spinal cord narrows, compressing the spinal cord and its 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 by 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 over the age of 65. 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 roughly similar benefits with fewer adverse effects. The present evidence review addresses posterior decompression of central LSS with a percutaneous treatment performed under fluoroscopic guidance.

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 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 musculature 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 resultant instability. Laminectomy may also be used for extensive multilevel 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, supraspinous 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), similar to laminotomy, 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 treatment of various spinal conditions. This set of specialized surgical instruments is used to perform percutaneous lumbar decompressive procedures.

Vertos’s 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 anatomic 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.

**Related Protocols**

- Cochlear Implant
- Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced...
procedures. Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.
