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</td>
<td>Image-guided minimally invasive spinal decompression is</td>
</tr>
<tr>
<td>decompression</td>
<td>considered investigational.</td>
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### Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<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>
</tr>
</tbody>
</table>

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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.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 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**

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>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a 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

<table>
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<th>Date</th>
<th>Comments</th>
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</thead>
<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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<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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<tr>
<td>09/30/13</td>
<td>Update Related Policies. Change title to 7.01.93.</td>
</tr>
<tr>
<td>01/21/14</td>
<td>Update Related Policies. Add 7.01.551.</td>
</tr>
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</table>
**Date** | **Comments**
---|---
06/17/15 | Annual Review. Policy updated with literature review through March 4, 2015; reference 15 added; policy statement unchanged.
11/13/15 | Removed related policy 6.01.46.

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**Scope**: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.
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  - Qualified sign language interpreters
  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
- Provides free language services to people whose primary language is not English, such as:
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  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.


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This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Oromo (Cushite):

Français (French):

Kreyòl ayisyen (Creole):
Avi si a gen enfòmasyon enpòtan laidann. Avi si a kapab genyen enfòmasyon enpòtan konpansyon a yon oswa konpansyon lai kouvèti asirans lan atravè Premera Blue Cross. Kapab genyen dat ki enpòtan nan avi si a. Ou ka gen pou pran kék aksyon avan seten dat limit pou ka bwa ki konbe kouvèti asirans sante w la oswa pou yo ka ede w avèk depans yo. Se dwa w pou resewa enfòmasyon sa a ak asisant sa nan lang ou pale a, san ou pa gen pou peyeye pou sa. Rate nan 800-722-1471 (TTY: 808-842-5357).

Deutsche (German):

Hmoob (Hmong):

Ilokano (Ilocano):
Daytoy a Pakdaar ket naglaon iti Napateg nga Improperson. Daytoy a pakdaar mabalini nga adda ket naglaon iti napatek nga improperson maipanggepp iti aplikasyonyo weno coverage babaen iti Premera Blue Cross. Daytoy ket mabalini dagiti importante a pelsa iti daytoy a pakdaar. Mabalini nga adda rumbeng nga aramindeny nga addang sakbay dagiti partikular a naituding nga aldaw tapno mapagtalinaedyo ti coverage ti salan-ayno weno tulong kadagiti gastos. Adda karbenganyo a mangala iti daytoy nga improperson ken tulong iti bukodyo a pagasaa nga awan ti bayadanyo. Tumawag ti numero nga 800-722-1471 (TTY: 808-842-5357).

Italiano (Italian):

中文 (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的申請或保費的重要訊息。本通知可能有重要的日期。您可能需要在截止日期之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母語得到本訊息和幫助。請撥電話 800-722-1471 (TTY: 808-842-5357)。
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この通知には重要な情報が含まれています。この通知には、Premera Blue Crossの申請または補償範囲に関する重要な情報が含まれています。この通知に記載されている情報が有効な日付をご確認ください。観光保険や有料サポートを維持するには、特定の期日にまでに行動を取らなければならない場合があります。このような情報に対するお問い合わせは、800-722-1471 (TTY: 800-842-5357)までお電話ください。

한국어 (Korean):
본 통지서에는 중요한 정보가 들어 있습니다. 즉 이 통지서는 귀하의 신청에 관하여 그리 Premera Blue Cross 를 통한 커버리지에 관한 정보를 포함하고 있을 수 있습니다. 귀하는 귀하의 건강 커버리지를 계속 유지하거나 이를 바꿀 기회를 위해서 일정한 마감일까지 조치를 취하여 할 필요가 있을 수 있습니다. 귀하는 이러한 정보와 도움을 귀하의 언어로 이용 부담없이 얻을 수 있는 권리가 있습니다. 800-722-1471 (TTY: 800-842-5357)로 전화하십시오.

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To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Polscy ministrowi lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utraty polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie prawo do bezpłatnej informacji we własnym języku. Zadzwoniono pod 800-722-1471 (TTY: 800-842-5357).

Português (Portuguese):
Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde e ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

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Русский (Russian):
Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

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Тагалог (Tagalog):
Ang Pagawa ni ito ay naglalaman ng mahalagang impormasyon. Ang pagawa ni ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Es posible que haya fechas claves en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

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ประกาศนี้อาจมีข้อมูลที่สําคัญเกี่ยวกับการการสมัครหรือขอบเขตประกันของคุณผ่าน Premera Blue Cross และมีข้อมูลที่สําคัญเกี่ยวกับการขอความช่วยเหลือผ่าน Premera Blue Cross ถ้าคุณมีข้อมูลที่สําคัญเกี่ยวกับการการสมัครหรือขอบเขตประกันของคุณผ่าน Premera Blue Cross โปรดติดต่อเราที่ 800-722-1471 (TTY: 800-842-5357).

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بنابراین، این اطلاعات مربوط به مزایده‌های اینترنتی است. این اطلاعات مربوط به مزایده‌های اینترنتی است و ممکن است برای راهنمایی و کمک به درخواست‌های شما مفید باشد. این اطلاعات به غیر از اطلاعات کمک به بهبود وضعیت بهینه شهروندی کشور، به طور فردی یا مالی بازسازی یا دریافت می‌شود. این راهنمایی اطلاعات به شماره 800-722-1471 (TTY: 800-842-5357) برقرار نمی‌شود.

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Tiếng Việt (Vietnamese):