

**EFFECTIVE DATE:** 10|01|2015

**POLICY LAST UPDATED:** 05|07|2020

## OVERVIEW

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.

## MEDICAL CRITERIA

Not applicable

## PRIOR AUTHORIZATION

Not applicable

## POLICY STATEMENT

### BlueCHiP for Medicare

Percutaneous image-guided lumbar decompression (PILD) for lumbar spinal stenosis is covered only as part of a Center for Medicare and Medicaid (CMS) approved clinical trial. Refer to the Related Policy section.

**Note:** Blue Cross & Blue Shield of Rhode Island (BCBSRI) must follow Centers for Medicare and Medicaid Services (CMS) guidelines, such as national coverage determinations or local coverage determinations for all BlueCHiP for Medicare policies. Therefore, BlueCHiP for Medicare policies may differ from Commercial products. In some instances, benefits for BlueCHiP for Medicare may be greater than what is allowed by the CMS.

### Commercial Products

Image-guided minimally invasive spinal decompression (cervical, thoracic, and lumbar) is considered not medically necessary, as the evidence is insufficient to determine the effects of the technology on health outcomes.

## COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate section of the Benefit Booklet, Evidence of Coverage or Subscriber Agreement for services not medically necessary.

## 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 symptoms of lumbar spinal stenosis (LSS) are back pain with neurogenic claudication (ie, pain, numbness, 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 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 Decompressive Surgery***

For patients with LSS, surgical laminectomy has established benefits in reducing pain and improving quality of life. For patients with cervical or thoracic 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 by an evidence-based center. 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). 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 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, 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, 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.

### **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 through the 510(k) process 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 device is 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.

For individuals who have lumbar spinal stenosis, or cervical or thoracic spinal stenosis who receive IG-MLD, the evidence includes a large, ongoing 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 with ESIs (control) in patients who had ligamentum flavum hypertrophy and who failed conservative therapy. Early results have suggested reductions in pain and improvements in function scores in the IG-MLD group vs 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 with open decompression. Trials with relevant control groups could provide greater certainty on the risks and benefits of this procedure. The evidence is insufficient to determine the effects of the technology on health outcomes. Therefore, this service is considered not medically necessary for Commercial products.

### **BlueCHiP for Medicare**

Effective for services performed on or after January 09, 2014, the Centers for Medicare & Medicaid Services (CMS) has determined that percutaneous image guided lumbar decompression (PILD) will be covered by Medicare when provided in a clinical study through Coverage with Evidence Development (CED) for beneficiaries with lumbar spinal stenosis who are enrolled in an approved clinical study that meets the CMS criteria.

## **CODING**

### **BlueCHiP for Medicare**

The following codes may be allowed for BlueCHiP for Medicare members as part of a CMS approved clinical study:

**0275T** 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; lumbar

**G0276** Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial

**Note:** If you are treating a BlueCHiP for Medicare member as part of a CMS approved study, please follow the procedures for correct billing and coding of services found in the policy for Clinical Trials BlueCHiP for Medicare.

Claims for services rendered as part of a CMS approved clinical study must be billed with an appropriate modifier:

**Modifier Q0** – Investigational clinical service provided in a clinical research study that is in an approved research study (Medicare claims filed without the Q0 modifier will deny as not medically necessary)

**Modifier Q1** – Routine clinical service provided in a clinical research study that is in an approved clinical research study

The following code is not medically necessary:

**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 (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic

### **Commercial Products**

The following codes are not medically necessary:

**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 (eg, fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; cervical or thoracic

**0275T** 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; lumbar

**G0276** Blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control, performed in an approved coverage with evidence development (CED) clinical trial

## **RELATED POLICIES**

Clinical Trials BlueCHiP for Medicare

BlueCHiP for Medicare National and Local Coverage Determinations

New Technology

## **PUBLISHED**

Provider Update, July 2020

Provider Update, August 2019  
Provider Update, June 2018  
Provider Update, July 2017  
Provider Update, June 2016  
Provider Update, August 2015

## REFERENCES

1. Chou R, Baisden J, Carragee EJ, et al. Surgery for low back pain: a review of the evidence for an American Pain Society Clinical Practice Guideline. *Spine*. May 1 2009; 34(10):1094-1109. PMID 19363455
2. Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. *Spine*. May 1 2009;34(10):1066-1077. PMID 19363457
3. Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical versus nonsurgical treatment for lumbar degenerative spondylolisthesis. *N Engl J Med*. May 31 2007; 356(22):2257-2270. PMID 17538085
4. Weinstein JN, Tosteson TD, Lurie JD, et al. Surgical versus nonsurgical therapy for lumbar spinal stenosis. *N Engl J Med*. Feb 21 2008; 358(8):794-810. PMID 18287602
5. Kreiner DS, Macvicar J, Duszynski B, et al. The mild(R) Procedure: A Systematic Review of the Current Literature. *Pain Med*. Feb 2014; 15(2):196-205. PMID 24308292
6. Chopko BW. Long-term results of percutaneous lumbar decompression for LSS: two-year outcomes. *Clin J Pain*. Nov 2013;29(11):939-943. PMID 23446067
7. Brown LL. A double-blind, randomized, prospective study of epidural steroid injection vs. the mild(R) procedure in patients with symptomatic lumbar spinal stenosis. *Pain Pract*. Jun 2012; 12(5):333-341. PMID 22272730
8. Chopko B, Caraway DL. MiDAS I (mild Decompression Alternative to Open Surgery): a preliminary report of a prospective, multi-center clinical study. *Pain Physician*. Jul-Aug 2010; 13(4):369-378. PMID 20648206
9. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis (150.13). 2016; <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=358>. Accessed March 10, 2020.
11. Lingreen R, Grider JS. Retrospective review of patient self-reported improvement and post-procedure findings for mild (minimally invasive lumbar decompression). *Pain Physician*. Nov-Dec 2010;13(6):555-560. PMID 21102968
12. Staats PS, Benyamin RM. MiDAS ENCORE: randomized controlled clinical trial report of 6-month results. *Pain Physician*. Feb 2016;19(2):25-38. PMID 26815247
13. Deer TR, Grider JS, Pope JE et al. The MIST Guidelines: The Lumbar Spinal Stenosis Consensus Group Guidelines for Minimally Invasive Spine Treatment. *Pain Pract*. 2019 Mar;19(3). PMID 30369003
14. North American Spine Society (NASS). Evidence-Based Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis. 2011; <https://www.spine.org/Portals/0/Assets/Downloads/ResearchClinicalCare/Guidelines/LumbarStenosis.pdf>. Accessed March 10, 2020.

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