

Medical Coverage Policy | Image-Guided Minimally Invasive Spinal Decompression for Spinal Stenosis



EFFECTIVE DATE: 11|01|2025

POLICY LAST REVIEWED: 08|20|2025

OVERVIEW

Image-guided minimally invasive decompression (IG-MILD) 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-MILD is proposed as an alternative to existing posterior decompression procedures.

Note: This policy only addresses HCPCS Code G0276 for Medicare Advantage Plans and Commercial Products.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

A 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 is covered only as part of a Center for Medicare and Medicaid (CMS) approved clinical trial.

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 Medicare Advantage Plan policies. Therefore, Medicare Advantage Plan policies may differ from Commercial products. In some instances, benefits for Medicare Advantage Plans may be greater than what is allowed by the CMS.

Commercial Products

A blinded procedure for lumbar stenosis, percutaneous image-guided lumbar decompression (PILD) or placebo-control is considered not medically necessary, as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

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.

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 Spinal Decompression

Posterior decompression for spinal stenosis 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 spinal decompression using a specially designed tool kit (mild®) has been proposed as an ultra-minimally invasive treatment of central lumbar spinal stenosis. 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.

Commercial Products

For individuals who have lumbar spinal stenosis who receive IG-MILD, the evidence includes a large, randomized control trial (RCT) (n=302), a second RTC (N = 138) comparing MILD to non-surgical conventional medical management (CMM), a systematic review that included a 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 compared IG-MILD with epidural steroid injections (control) in patients who had ligamentum flavum hypertrophy and who failed conservative therapy. Results suggested reductions in pain and improvements in function scores in the IG-MILD 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 MOTION RCT compared MILD as first-line therapy in combination with nonsurgical CMM to CMM alone in 138 individuals with lumbar spinal stenosis. At 1-year follow-up, patients in the MILD + CMM group experienced a 16.1-point composite Oswestry Disability Index (ODI) mean improvement (the primary outcome), compared with a 2.0-point mean improvement for participants in the CMM-alone arm (p<.001). A major limitation of this trial was the wide variation in CMM interventions received by individuals in both the intervention and control groups; for example, 38.7% of individuals in the CMM alone group received no interventional therapy. Lack of blinding and follow-up for only 12 months were additional limitations. The available evidence is insufficient to determine the efficacy of MILD compared with placebo, open decompression, or conservative treatment. Well-designed and conducted trials with relevant control groups could provide greater certainty on the risks and benefits of this procedure. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cervical or thoracic spinal stenosis who receive image-guided minimally invasive spinal decompression, no evidence was identified. The evidence is insufficient to determine that technology results in an improvement in the net health outcome.

Medicare Advantage Plans

Effective for services performed on or after January 09, 2014, the Centers for Medicare & Medicaid Services (CMS) has determined that a 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 will be covered by Medicare for beneficiaries with lumbar spinal stenosis enrolled in an approved clinical study meeting criteria in the decision memo.

CODING

Medicare Advantage Plans

The following HCPCS code may be covered for Medicare Advantage Plan members as part of a CMS approved clinical study:

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 Medicare Advantage Plan 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 Medicare Advantage Plans.

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

Commercial Products

The following service is not medically for Commercial Products:

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 Medicare Advantage Plans

PUBLISHED

Provider Update, August/September 2025

Provider Update, August 2024

Provider Update, July 2023

Provider Update, September/December 2022

Provider Update, July 2021

REFERENCES

1. Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) 150.13, Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis
2. 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 (Phila Pa 1976)*. May 01 2009; 34(10): 1094-109. PMID 19363455
3. 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 (Phila Pa 1976)*. May 01 2009; 34(10): 1066-77. PMID 19363457
4. 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): 2257-70. PMID 17538085
5. 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
6. Staats PS, Benyamin RM, McDonnell F, et al. MiDAS ENCORE: Randomized Controlled Clinical Trial Report of 6-Month Results. *Pain Physician*. Feb 2016; 19(2): 25-38. PMID 26815247
7. Benyamin RM, Staats PS, MiDAS Encore I. MILD(R) Is an Effective Treatment for Lumbar Spinal Stenosis with Neurogenic Claudication: MiDAS ENCORE Randomized Controlled Trial. *Pain Physician*. May 2016; 19(4): 229-42. PMID 27228511
8. Staats PS, Chafin TB, Golovac S, et al. Long-Term Safety and Efficacy of Minimally Invasive Lumbar Decompression Procedure for the Treatment of Lumbar Spinal Stenosis With Neurogenic Claudication: 2-Year Results of MiDAS ENCORE. *Reg Anesth Pain Med*. Oct 2018; 43(7): 789-794. PMID 30199512

9. Deer TR, Costandi SJ, Washabaugh E, et al. The MOTION Study: A Randomized Controlled Trial with Objective Real-World Outcomes for Lumbar Spinal Stenosis Patients Treated with the mild® Procedure: One-Year Results. *Pain Med.* Apr 08 2022; 23(4): 625-634. PMID 35167700
10. Deer TR, Chafin TB, Costandi SJ, et al. The MOTION study: Two-year results of a real-world randomized controlled trial of the mild® procedure for treatment of lumbar spinal stenosis. *Pain Pract.* Jan 2024; 24(1): 109-119. PMID 37661347
11. 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
12. Brown LL. A double-blind, randomized, prospective study of epidural steroid injection vs. the mild(R) procedure inpatients with symptomatic lumbar spinal stenosis. *Pain Pract.* Jun 2012; 12(5): 333-41. PMID 22272730
13. Chopko BW. Long-term results of percutaneous lumbar decompression for LSS: two-year outcomes. *Clin J Pain.* Nov 2013; 29(11): 939-43. PMID 23446067
14. 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.* Mar 2019; 19(3): 250-274. PMID 30369003
15. 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 12, 2025.

CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

