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MEDICAL POLICY – 7.01.126

Image-Guided Minimally Invasive Decompression for Spinal Stenosis

BCBSA Ref. Policy:	7.01.126
Effective Date:	July 1, 2024
Last Revised:	June 10, 2024
Replaces:	N/A

RELATED MEDICAL POLICIES:

7.01.107	Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)
7.01.551	Lumbar Spine Decompression Surgery: Discectomy, Foraminotomy, Laminotomy, Laminectomy

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POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Spinal stenosis is the narrowing of the spinal canal. This narrowing 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, resulting in pain, numbness, or weakness. When surgery is needed to remove the material pressing on the nerves — which is known as decompression surgery — the usual method is an open procedure. A newer method of decompression surgery is being 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. More studies are needed comparing the results of this surgery to standard decompression surgery.

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

Service	Investigational
Image-guided minimally invasive spinal decompression (e.g., mild device kit)	**Image-guided minimally invasive spinal decompression is considered investigational.**

Coding

Code	Description
CPT	
0274T	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 (e.g., fluoroscopic, CT), 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 (e.g., fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar

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 individuals 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 its nerve roots. The goal of surgical treatment is to "decompress" the spinal cord and/or nerve roots.

The most common symptom of lumbar spinal stenosis (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 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 over 65 years of age.

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 Decompression Surgery

For individuals with LSS, surgical laminectomy has established benefits in reducing pain and improving quality of life.

For individuals 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 an evidence-based center.[1,2] 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 (SPORT) that evaluated laminectomy for spinal stenosis (specifically with or without degenerative spondylolisthesis).[3,4] All four studies found that initial decompressive surgery (laminectomy) was slightly to moderately superior to initial nonsurgical therapy (e.g., average 8-point 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 (i.e., with or without fusion, instrumented vs noninstrumented fusion) in individuals with or without degenerative spondylolisthesis. SPORT 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 individuals. Posterior decompressive surgical procedures include decompressive laminectomy, hemilaminotomy and laminotomy, and microendoscopic decompressive laminotomy.

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 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. 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 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 (e.g., 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 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

For individuals who have LSS who receive IG-MLD, the evidence includes a large, ongoing randomized controlled trial (RCT; n=302), a second RCT (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. The relevant outcomes are symptoms, functional outcomes, health status measures, and treatment-related morbidity. The largest RCT (MiDAS Evidence-based Neurogenic Claudication Outcomes Research [ENCORE]) compared IG-MLD with epidural steroid injections (control) in individuals who have ligamentum flavum hypertrophy and who failed conservative therapy. Results suggested reductions in pain and improvements in function scores in the IG-MLD 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 IG-MLD as first-line therapy in combination with nonsurgical CMM to CMM alone in 138 individuals with lumbar spinal stenosis. At one-year follow-up, individuals in the IG-MLD + CMM group experienced a 16.1-point composite 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. The 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 or to determine the efficacy of IG-MLD compared with placebo, open decompression, or conservative treatment. Well-designed and conducted trials with relevant control groups could provide greater certainty regarding 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 IG-MLD, no evidence was identified. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this policy are listed in **Table 1**.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03072927[a]	MILD Percutaneous Image-Guided Lumbar Decompression: A Medicare Claims Study	4000	Dec 2026
NCT04594980	An Open-Label Randomized Controlled Study of the Efficacy of Surgical Treatment in Patients With Single Level Lumbar Spinal Stenosis Using Minimally Invasive Decompression and Fusion and Traditional Open	96	Feb 2025

NCT: national clinical trial

[a] Denotes industry-sponsored or cosponsored trial

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

Lumbar Spinal Stenosis Consensus Group

In 2018, the Lumbar Spinal Stenosis Consensus Group, composed of a panel of nationally recognized spine experts, convened to evaluate the available literature and develop guidelines for minimally invasive spine treatment (MIST Guidelines).[13] Based on a systematic review of the available literature on percutaneous image-guided lumbar decompression, the consensus committee determined there is sufficient support to warrant Level I evidence (Grade A, Level I, Consensus strong). Grade A evidence is defined as "extremely recommendable (good evidence that the measure is effective and that benefits outweigh the harms)."

North American Spine Society

In 2011, the North American Spine Society revised clinical practice guidelines on the diagnosis and treatment of degenerative LSS.[14] Treatment recommendations included:

- Interlaminar epidural steroid injection for short-term (six weeks to six months) symptom relief in patients with neurogenic claudication or radiculopathy; however, there is conflicting evidence regarding long-term efficacy. (Grade of Recommendation: B)
- A multiple injection regimen of radiographically-guided transforaminal epidural steroid injection or caudal injection for medium-term relief of pain. (Grade of Recommendation: C)
- Decompressive surgery to improve outcomes in patients with moderate to severe symptoms of LSS. (Grade of Recommendation: B)

No specific recommendations on percutaneous image-guided lumbar decompression were provided.

Medicare National Coverage

The Centers for Medicare & Medicaid Services determined that percutaneous image-guided lumbar decompression would be covered by Medicare when provided in a clinical study, through coverage with evidence development for beneficiaries with LSS enrolled in an approved clinical study meeting criteria in the decision memo (NCD 150.13).[15].

According to the national coverage decision, percutaneous image-guided lumbar decompression is a posterior decompression of the lumbar spine performed under indirect image guidance without any direct visualization of the surgical area. This procedure is 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 (e.g., fluoroscopic, computed tomography) with contrast media to identify and monitor the compressed area via epidurogram.

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 US Food and Drug Administration (FDA) through the 510(k) process for the treatment of various spinal conditions. This set of specialized surgical instruments is 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. The device is not intended for use near the lateral neural elements and remains dorsal to the dura using image guidance and anatomic landmarks.

FDA product code: HRX.

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 (Phila Pa 1976). May 01 2009; 34(10): 1094-109. 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 (Phila Pa 1976). May 01 2009; 34(10): 1066-77. 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): 2257-70. 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. 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
6. Benyamin RM, Staats PS, MiDAS Encore I. MILD® 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
7. 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
8. 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
9. 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
10. Kreiner DS, MacVicar J, Duszynski B, et al. The mild® procedure: a systematic review of the current literature. Pain Med. Feb 2014; 15(2): 196-205. PMID 24308292
11. Brown LL. A double-blind, randomized, prospective study of epidural steroid injection vs. the mild® procedure in patients with symptomatic lumbar spinal stenosis. Pain Pract. Jun 2012; 12(5): 333-41. PMID 22272730
12. 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
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. Mar 2019; 19(3): 250-274. 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 May 14, 2024.
15. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis (2020) **https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=358&ncdver=2**. Accessed May 14, 2024.

History

Date	Comments
05/10/11	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.
05/22/12	Replace policy. Policy updated with literature review through January 2012; reference 10 added; updated related policies cross reference. Policy statement unchanged.
09/26/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
05/28/13	Replace policy. Policy updated with literature review through January 31, 2013; references 8, 12-14 and 16 added; policy statement unchanged.
07/25/13	Update Related Policies. Change title to 7.01.107.
09/30/13	Update Related Policies. Change title to 7.01.93.
01/21/14	Update Related Policies. Add 7.01.551.
06/09/14	Annual Review. Policy updated with literature review through February 28, 2014. References 5-6 added; others renumbered/removed. Policy statement unchanged. ICD-10 codes removed.
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.
07/01/16	Annual Review, approved June 14, 2016. Policy updated with literature review through February 22, 2016; rationale section revised. Reference 5 added. Policy statement unchanged.
07/01/17	Annual Review, approved June 6, 2017. Policy moved into new format. Policy updated with literature review through February 23, 2017; reference 6 added. Policy statement changed from "lumbar" to "spinal" to include cervical/thoracic decompression. "Lumbar" removed from title.
01/01/18	Coding update, removed CPT code 0275T as it was terminated 1/1/17.
07/01/18	Annual Review, approved June 22, 2018. Policy updated with literature review through February 2018; no references added. Policy statement unchanged.
07/01/19	Annual Review, approved June 20, 2019. Policy updated with literature review through February 2019; no references added. Policy statement unchanged.
07/01/20	Annual Review, approved June 4, 2020. Policy updated with literature review through January 2020; references added. Policy statement unchanged. Removed CPT code 64999.

Date	Comments
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through March 7, 2021; no references added. Policy statement unchanged. Related Policies updated; removed policy 7.01.93 as it has been archived.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through March 4, 2022; no references added. Policy statement unchanged.
07/01/23	Annual Review, approved June 12, 2023. Policy updated with literature review through March 6, 2023; reference added. Policy statements unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
07/01/24	Annual Review, approved June 10, 2024. Policy updated with literature review through March 11, 2024; reference added. Policy statement unchanged.

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.