

Corporate Medical Policy

Image-Guided Minimally Invasive Decompression (IG-MLD) for Spinal Stenosis

File Name: image-guided_minimally_invasive_decompression_for_spinal_stenosis
Origination: 9/2010
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Description of Procedure or Service

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

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 (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 one of the most common reasons for back surgery and the most common reason for lumbar spine surgery in adults older than 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 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 2009 systematic review of surgery for back pain, commissioned by the American Pain Society, was 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 (SPORT) that evaluated laminectomy for spinal stenosis (specifically with or without degenerative spondylolisthesis). All four studies found that initial decompressive surgery (laminectomy) was slightly to moderately superior to initial nonsurgical therapy (e.g., average 8- to 18-point differences on the 36-Item Short-Form Health Survey [SF-36] and Oswestry Disability Index [ODI]). However, there was

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insufficient evidence to determine the optimal adjunctive surgical methods for laminectomy (i.e., 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 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, 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 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 utilizes 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 (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 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.

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Regulatory Status

The mild® tool kit (Vertos Medical) initially received 510(k) marketing clearance as the X-Sten MILD Tool Kit (X-Sten Corp.) from the U.S. Food and Drug Administration (FDA) in 2006, with intended use as a set of specialized surgical instruments to be used to perform percutaneous lumbar decompressive procedures for the treatment of various spinal conditions.

Vertos's mild® instructions for use 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 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.

Related Policies

Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers)

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

Image-guided minimally invasive spinal decompression is considered investigational for all applications. BCBSNC does not provide coverage for investigational services or procedures.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Image-Guided Minimally Invasive Decompression for Spinal Stenosis is covered

Not applicable.

When Image-Guided Minimally Invasive Decompression for Spinal Stenosis is not covered

Image-guided minimally invasive spinal decompression is considered investigational. BCBSNC does not cover investigational services.

Policy Guidelines

For individuals who have lumbar spinal stenosis who receive image-guided minimally invasive lumbar decompression, the evidence includes a large, 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. Relevant outcomes are symptoms, functional outcomes, health status measures, and treatment-related morbidity. The largest RCT (MIDAS

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Encore) compared image-guided minimally invasive lumbar decompression 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 image-guided minimally invasive lumbar decompression 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 MOTION RCT compared MILD as first-line therapy in combination with nonsurgical CMM to CMM alone in 138 individuals with lumbar spinal stenosis. At one-year follow-up, patients in the MILD + 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. 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 to 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 the technology results in an improvement in the net health outcome.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 0274T, 0275T, G0276

The procedure utilizes an epidurogram, so code 72275 would probably also be reported.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.126, 3/11/2010

Medical Director 8/2010

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.126, 3/2011

Specialty Matched Consultant Advisory Panel – 5/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.126, 3/2012

Specialty Matched Consultant Advisory Panel – 5/2012

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.126, 3/2013

Specialty Matched Consultant Advisory Panel – 5/2013

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.126, 4/2014

Specialty Matched Consultant Advisory Panel – 5/2014

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.126, 4/23/2015

Specialty Matched Consultant Advisory Panel – 5/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.126, 4/14/2016

Specialty Matched Consultant Advisory Panel – 5/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.126, 4/13/2017

Specialty Matched Consultant Advisory Panel – 5/2017

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.126, 4/12/2018

Specialty Matched Consultant Advisory Panel – 5/2018

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.126, 4/8/2019

Specialty Matched Consultant Advisory Panel – 5/2019

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.126, 4/16/2020

Specialty Matched Consultant Advisory Panel – 5/2020

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.126, 4/8/2021

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Specialty Matched Consultant Advisory Panel – 5/2022

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

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>.

Specialty Matched Consultant Advisory Panel – 5/2023

Policy Implementation/Update Information

9/14/10 New policy written. Image-guided minimally invasive lumbar decompression is considered investigational. Medical Director review 8/12/2010. Notification given 9/14/2010. Policy effective date 12/21/2010. (btw)

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- 6/21/11 Specialty Matched Consultant Advisory Panel review 5/25/2011. No changes to policy. References added. Added new CPT code, "0275T" to Billing/Coding" section effective 7/1/2011. (btw)
- 5/29/12 Specialty Matched Consultant Advisory Panel review 5/16/2012. Policy Guidelines updated. No change to policy intent. Reference added. (btw)
- 7/1/13 Specialty Matched Consultant Advisory Panel review 5/15/2013. No changes to policy intent. Reference added. (btw)
- 6/10/14 Specialty Matched Consultant Advisory Panel review 5/27/2014. Reference added. No changes to policy intent. (btw)
- 7/1/15 Specialty Matched Consultant Advisory Panel review 5/26/2015. Reference added. (sk)
- 7/1/16 Reference added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/25/2016. (sk)
- 6/30/17 Reference added. Policy titled changed from Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis to Image-Guided Minimally Invasive Decompression (IG-MLD) for Spinal Stenosis. Description section extensively revised. Policy Guidelines updated. Codes 0274T and G0276 added to Billing/Coding section. Specialty Matched Consultant Advisory Panel review 5/31/2017. (sk)
- 6/29/18 Reference added. Specialty Matched Consultant Advisory Panel review 5/23/2018. (sk)
- 6/11/19 Reference added. Specialty Matched Consultant Advisory Panel review 5/15/2019. (sk)
- 6/9/20 Reference added. Specialty Matched Consultant Advisory Panel review 5/20/2020. (sk)
- 6/1/21 Reference added. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 5/19/2021. (sk)
- 6/14/22 Specialty Matched Consultant Advisory Panel review 5/18/2022. (sk)
- 6/30/23 Policy Guidelines updated. References added. Specialty Matched Consultant Advisory Panel review 5/17/2023. (sk)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.