Medical Policy

Image-Guided Minimally Invasive Decompression for Spinal Stenosis

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- Policy: Commercial
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Policy Number: 240
BCBSA Reference Number: 7.01.126
NCD/LCD: National Coverage Determination (NCD) for percutaneous image-guided lumbar decompression for lumbar spinal stenosis (150.13)

Related Policies
Interspinous and Interlaminar Stabilization/Distraction Devices (Spacers), #584

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Image-guided minimally invasive spinal decompression is considered INVESTIGATIONAL.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Medical necessity criteria and coding guidance can be found through the link below.

National Coverage Determination (NCD) for percutaneous image-guided lumbar decompression for lumbar spinal stenosis (150.13)

Prior Authorization Information

Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required for outpatient services.

Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
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<th>Outpatient</th>
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<tr>
<td>Commercial Managed Care (HMO and POS)</td>
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<td>Medicare HMO BlueSM</td>
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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 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 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.

Treatment

Conventional Posterior Decompression Surgery
For patients with cervical or thoracic 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; they 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).3,4 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 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 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, supraspinous and interspinous ligaments, a major portion of the lamina, or the muscular attachments. Muscular dissection and retraction are required to achieve adequate surgical visualization.

MEDL, 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 MEDL, an endoscopic curette, rongeur, and drill are used for the laminotomy, facetectomy, and foramotomy. 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**

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.

For individuals who have lumbar spinal stenosis or cervical or thoracic spinal stenosis who receive IGMLD, the evidence 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 is comparing IG-MLD to epidural steroid injections (control) in patients with ligamentum flavum hypertrophy and who have failed conservative therapy. Early results have suggested reductions in pain and improvements in function scores in the IG-MLD group versus the control group. The trial is unblinded and there is 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 or to determine the efficacy of IG-MLD compared to 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.

Policy History

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<td>6/2017</td>
<td>BCBSA National medical policy review. Policy statement clarified from “lumbar” to “spinal” to include cervical/thoracic decompression, “Lumbar” removed from title. 6/1/2017</td>
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<td>1/2017</td>
<td>Coverage clarified for Medicare Advantage members based on National Coverage Determination (NCD) for percutaneous image-guided lumbar decompression for lumbar spinal stenosis (150.13). 1/1/2017</td>
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<td>5/2016</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References


