



Louisiana

Image-Guided Minimally Invasive Decompression for Spinal Stenosis

Policy # 00278

Original Effective Date: 11/16/2010

Current Effective Date: 03/12/2018

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Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers image-guided minimally invasive spinal decompression to be **investigational**.*

Background/Overview

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 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. 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). 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

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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, 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.

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 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

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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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

In 2006, the mild tool kit (Vertos Medical) was cleared for marketing by the U.S. FDA through the 510(k) process as the X-Sten MILD Tool Kit (X-Sten Corp.) 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.

FDA product code: HRX.

Centers for Medicare and Medicaid Services (CMS)

Effective for services performed on or after January 9, 2014, the Centers for Medicare and Medicaid Services (CMS) has determined that percutaneous image-guided lumbar decompression (PILD) for LSS is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act.

CMS determined that PILD would be covered by Medicare when provided in a clinical study under section 1862(a)(1)(E) through coverage with evidence development for beneficiaries with LSS who are enrolled in an approved clinical study meeting criteria in the decision memo.

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

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Rationale/Source

IMAGE-GUIDED MINIMALLY INVASIVE LUMBAR DECOMPRESSION

The present evidence review addresses posterior decompression of LSS with percutaneous treatment performed under fluoroscopic guidance. The primary literature on image-guided minimally invasive lumbar decompression (IG-MLD) includes 1 large randomized controlled trial (RCT; N=302) that is ongoing, 1 small RCT (N=38), and a number of prospective and retrospective cohort studies and case series.

Randomized Controlled Trials

The protocol for the MiDAS ENCORE (Evidence-based Neurogenic Claudication Outcomes Research) trial (NCT02093520) was approved by the Centers for Medicare and Medicaid Services under coverage with evidence development. This nonblinded study, conducted at 26 interventional pain management centers in the United States, randomized 302 patients in a 1:1 ratio to IG-MLD or epidural steroid injections (ESIs). This trial included Medicare beneficiaries 65 years of older who had neurogenic claudication symptoms for at least 3 months and had failed standard therapies, including physical therapy, home exercise programs, and oral analgesics.

Selection criteria required radiologic evidence of LSS with ligamentum flavum greater than 2.5 mm confirmed by preoperative magnetic resonance imaging or computed tomography. Patients had a number of spinal stenosis cofactors in addition to ligamentum flavum hypertrophy, including bulging disc (91%), foraminal narrowing (88%), facet hypertrophy (84%), facet arthropathy (82%), and degenerative disc disease (71%), that could not be addressed by the IG-MLD technique.

Baseline scores were similar in the 2 groups (see Table 1). However, more patients in the ESI group withdrew prior to trial treatment (22 patients vs 6 patients) due to dissatisfaction with randomization results and decisions to have surgery or other nonstudy therapy. This unequal dropout rate raises the possibility of bias due to nonblinding of patients and assessors and patient expectations. Patients who withdrew from the trial after treatment but before the 1-year follow-up (22 IG-MLD, 32 ESI) were considered treatment failures.

Six-month and 1-year results were published in 2016 (see Table 1). Patients in the ESI group were allowed up to 4 ESI treatments and received a mean of 2 injections over 1 year. The primary end point—the proportion of responders achieving the minimally important difference (MID) of at least a 10-point improvement on the ODI score—was significantly higher in the IG-MLD group than in the ESI group at both 6 months and 1 year. Secondary efficacy end points were the proportion of responders achieving the MID on the numeric rating scale for pain and the Zurich Claudication Questionnaire (ZCQ). Adverse events were low (1.3% for both groups). Responder rates in patients with spinal comorbidities were reported to be similar to overall responder rates. However, it may be difficult to separate out the effect of comorbidities, because over 80% of patients had 1 or more spinal stenosis comorbidities.

Table 1. MiDAS ENCORE Results

Measures	Baseline Score	Percent Responders at 6 Months	Percent Responders at 1 Year
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Measures	Baseline Score	Percent Responders at 6 Months	Percent Responders at 1 Year
ODI (100-point scale)		≥10-point improvement	
IG-MLD	53.0	62.2% ^a	58.0% ^a
ESI	51.7	35.7%	27.1%
NRS (out of 10)		≥2-point improvement	
IG-MLD	7.7	55.9% ^a	57.3%
ESI	7.8	33.3%	27.1%
ZCQ subdomains	2.8-3.8		
Symptom severity		≥0.5-point improvement	
IG-MLD	3.8	52.8% ^a	51.7% ^b
ESI	3.8	28.7%	31.8%
Physical function			
IG-MLD	2.9	52.4% ^a	44.1% ^a
ESI	2.8	14.0%	17.8%
Patient satisfaction			
IG-MLD		64.8% ^a	61.5% ^a
ESI		30.2%	33.3%

ESI: epidural steroid injection; IG-MLD: image-guided minimally invasive lumbar decompression; NRS: numeric rating scale; ODI: Oswestry Disability Index; ZCQ: Zurich Claudication Questionnaire.

^a p<0.001.

^b p<0.01.

Systematic Reviews

Prior to publication of MiDAS ENCORE trial results, the International Spine Intervention Society published a systematic review of the IG-MLD literature. Included were 1 RCT with 38 patients and 12 cohort studies or series. Pain measurements, using a visual analog score (VAS) or the ZCQ, showed a weighted mean improvement of 41% in the short term (4-6 weeks), 46% at 3 months, 42% at 6 months, and 49% at 1 year. However, mean VAS scores exceeded 3 at all times posttreatment. Ten studies assessed function, 9 using the ODI or 1 using the Roland-Morris Disability Questionnaire. ODI scores improved by a weighted mean of 16.5 at 6 weeks, 16.2 at 12 weeks, 15.4 at 6 months, and 14.0 at 1 year, a weighted cumulative decline to 33 from 47 at baseline. One study (2013), reporting 2-year outcomes, was of questionable validity, and data were not included. Mean final ODI scores exceeded 30 for most studies, which would not be considered in the normal range. No direct procedure-related complications were identified in the selected studies, although the possibility of damage to dura and nerve roots with this procedure was noted. Overall, the body of evidence addressing the IG-MLD procedure was of low quality.

Case Series

One potential indication for IG-MLD is patients with symptomatic LSS primarily caused by a hypertrophic ligamentum flavum who are considered poor candidates for traditional decompressive surgery.

In 2011, Chopko reported on IG-MLD in 14 patients considered at high risk for complications from open spine surgery and general anesthesia. Comorbidities included obesity, diabetes, hypertension, chronic

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obstructive pulmonary disease, chemotherapy, and coronary artery disease. Postoperatively, 9 (64%) of the 14 patients reported improvement in VAS pain scores of at least 3 points. ODI scores did not change significantly. A 2010 retrospective review reported outcomes from a consecutive series of 42 patients who underwent IG-MLD by an interventional pain specialist. Most patients had not been considered surgical candidates by a spine surgeon. VAS pain scores averaged 9.6 at baseline and 5.8 at 30 days postprocedure, with 34 (80%) of patients reporting changes in VAS score of 3 or more points. Thirty (71%) patients reported improvements in function following IG-MLD. No major adverse events were identified.

IMAGE-GUIDED MINIMALLY INVASIVE CERVICAL OR THORACIC DECOMPRESSION

No evidence assessing use of image-guided minimally invasive cervical or thoracic decompression for treatment of patients with cervical or thoracic spinal stenosis was found.

SUMMARY OF EVIDENCE

For individuals who have lumbar spinal stenosis or cervical or thoracic spinal stenosis who receive IG-MLD, 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.

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Policy History

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11/04/2010 Medical Policy Committee review

11/16/2010 Medical Policy Implementation Committee approval. New policy.

11/03/2011 Medical Policy Committee review.

11/16/2011 Medical Policy Implementation Committee.

12/06/2011 Posted as Archived policy.

03/05/2012 Re-posted as active policy.

11/01/2012 Medical Policy Committee review.

11/28/2012 Medical Policy Implementation Committee. No change to coverage.

11/07/2013 Medical Policy Committee review.

11/20/2013 Medical Policy Implementation Committee. No change to coverage.

11/06/2014 Medical Policy Committee review.

11/21/2014 Medical Policy Implementation Committee. No change to coverage.

08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.

10/29/2015 Medical Policy Committee review.

11/16/2015 Medical Policy Implementation Committee. No change to coverage.

11/03/2016 Medical Policy Committee review.

11/16/2016 Medical Policy Implementation Committee. No change to coverage.

11/02/2017 Medical Policy Committee review.

11/15/2017 Medical Policy Implementation Committee. Policy statement changed from "lumbar" to "spinal" to include cervical/thoracic decompression. "Lumbar" removed from title.

Next Scheduled Review Date: 11/2018

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Code Type	Code
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HCPCS	G0276
ICD-10 Diagnosis	All related diagnoses

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- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
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