Medical Policy

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Title: Image-Guided Minimally Invasive Decompression for Spinal Stenosis

Professional
Original Effective Date: September 30, 2010
Revision Date(s): April 22, 2011; August 12, 2011; July 17, 2012; July 12, 2013; November 10, 2015, October 12, 2016; July 10, 2017; May 23, 2018
Current Effective Date: July 10, 2017

Institutional
Original Effective Date: May 23, 2011
Revision Date(s): May 23, 2011; August 12, 2011; July 17, 2012; July 12, 2013; November 10, 2015; October 12, 2016; July 10, 2017; May 23, 2018
Current Effective Date: July 10, 2017

Populations	Interventions	Comparators	Outcomes
Individuals: • With lumbar spinal stenosis	Interventions of interest are: • Image-guided minimally invasive lumbar decompression	Comparators of interest are: • Conservative therapy • Open decompression	Relevant outcomes include: • Symptoms • Functional outcomes • Health status measures • Treatment-related morbidity
Individuals: • With cervical or thoracic spinal stenosis	Interventions of interest are: • Image-guided minimally invasive cervical or thoracic decompression	Comparators of interest are: • Conservative therapy • Open decompression	Relevant outcomes include: • Symptoms • Functional outcomes • Health status measures • Treatment-related morbidity

DESCRIPTION

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.

Objective

The objective of this evidence review is to determine whether image-guided minimally invasive lumbar decompression improves the net health outcomes in patients with spinal stenosis.

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 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 systematic review by Chou et al (2009) assessed surgery for back pain; it was commissioned by the American Pain Society and conducted by and evidence-based 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 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 and Oswestry Disability Index). 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. Spine Patient Outcomes Research Trial 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, 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 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 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.

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' 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 anatomical landmarks.

Food and Drug Administration product code: HRX.

POLICY

Image-guided minimally invasive spinal decompression is considered **experimental / investigational.**

RATIONALE

This evidence review has been updated with searches of the MEDLINE database. The most recent literature update was performed through February 5, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Image-Guided Minimally Invasive Lumbar Decompression

This evidence review addresses posterior decompression of lumbar spinal stenosis (LSS) with percutaneous treatment performed under fluoroscopic guidance. The primary literature on image-guided minimally invasive lumbar decompression (IG-MLD) includes a large RCT (N=302) that is ongoing, a 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 & 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).[5] 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 both 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 would suggest 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).[5,6] 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 of at least a 10-point improvement on the Oswestry Disability Index (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 minimally important difference on the numeric rating scale for pain and the Zurich Claudication Questionnaire. 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, %
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.[7] Included were an RCT with 38 patients[8]

and 12 cohort studies or series. Pain measurements, using a visual analog score (VAS) or the Zurich Claudication Questionnaire, 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, nine using the ODI or one 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. The study by Chopko (2013), reporting 2-year outcomes, was of questionable validity, and data were not included.[9] 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.

Chopko (2011) also reported on IG-MLD in 14 patients considered at high risk for complications from open spine surgery and general anesthesia.[10] Comorbidities included obesity, diabetes, hypertension, chronic 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 retrospective review by Lingreen and Grider (2010) reported on outcomes of a consecutive series of 42 patients who underwent IG-MLD by an interventional pain specialist.[11] 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.

Section Summary: Image-Guided Minimally Invasive Lumbar Decompression

The evidence on the use of IG-MLD to treat LSS or cervical/thoracic spinal stenosis consists of a large, ongoing RCT (N=302), a systematic review of a small RCT (N=38), and a number of prospective and retrospective cohort studies and case series. The largest RCT compared IG-MLD with epidural steroid injections (control) in patients with ligamentum flavum hypertrophy and who failed conservative therapy. Early results have suggested reductions in pain and improvements in function scores in the IG-MLD group vs the control group. The trial was unblinded and there is evidence of differing expectations and follow-up in both groups, suggesting a high risk of bias. The available evidence is insufficient to determine the efficacy of mild® compared with placebo or to determine the efficacy of IG-MLD compared with open decompression. Trials with relevant control groups could provide greater certainty on the risks and benefits of this procedure.

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.

Section Summary: Image-Guided Minimally Invasive Cervical or Thoracic Decompression

There is no evidence to inform conclusions about use of image-guided minimally invasive cervical or thoracic decompression to treat cervical or thoracic spinal stenosis.

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 RCT (N=302), a systematic review of 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-MLD with epidural steroid injections (control) in patients who had ligamentum flavum hypertrophy and who failed conservative therapy. Early results have suggested reductions in pain and improvements in function scores in the IG-MLD group vs the control group. The trial was unblinded and there is evidence of differing expectations and follow-up in the 2 groups, suggesting a high risk of bias. The available evidence is insufficient to determine the efficacy of mild® compared with placebo or to determine the efficacy of IG-MLD compared with 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.

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 2.

Table 2. 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 2020

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

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 (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; cervical or thoracic
0275T	Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy) any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar
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

- There are CPT category III codes applicable to this procedure: 0274T, 0275T.
- The procedure uses an epidurogram, so CPT code 72275 (epidurography, radiological supervision and interpretation) would probably also be reported.
- Effective January 1, 2015 there is a HCPCS "G" code specific to percutaneous image-guided lumbar decompression: G0276.

DIAGNOSIS

Experimental / Investigational for all diagnoses related to this policy.

REVISIONS	
04-22-2010	Policy added to the bcbsks.com web site.
08-12-2011	Added consultant review to references section.
07-17-2012	Rationale section updated
	In Coding section: ▪ Removed CPT code: 64999
	Referenced updated
07-12-2013	Rationale section updated
	References updated
11-10-2015	Description section updated
	Rational section updated
	In Coding section: ▪ Added HCPCS Code: G0276 ▪ Updated Coding notations.
	References updated
10-12-2016	Description section updated
	Rationale section updated
	In Coding section:

REVISIONS	
	▪ Coding notations updated
	References updated
07-10-2017	Policy published 06-09-2017. Policy effective 07-10-2017.
	Title updated to "Image-Guided Minimally Invasive Decompression for Spinal Stenosis" from "Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis"
	Description section updated
	In Policy section: Added "spinal" and removed "lumbar" to read "Image-guided minimally invasive spinal decompression is considered experimental / investigational."
	Rational section updated
	In Coding section: ▪ Added CPT code: 0274T ▪ Coding notations updated
	References updated
05-23-2018	Description section updated
	Rational section updated
	References updated

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Other References

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