BlueCross BlueShield of Alabama

Name of Policy:

Image-Guided Minimally Invasive Decompression for Spinal Stenosis

Policy #: 419
Category: Surgery

Latest Review Date: May 2018
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

Spinal Stenosis

Image-guided minimally invasive lumbar decompression (IG-MLD) describes a percutaneous procedure for decompression of the central spinal canal 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.

In spinal stenosis, the space around the spinal cord narrows, compressing the spinal cord and the 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 with sitting or leaning forward. Compression of neural elements generally occurs from a combination of degenerative change 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 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 Decompressive 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 (APS), was conducted by the Oregon Health Sciences University Evidence-Based Practice Center. Four higher-quality randomized trials were reviewed that compared surgery with nonsurgical therapy for spinal stenosis, including two studies from the multicenter Spine Patient Outcomes Research Trial (SPORT) evaluating laminectomy for spinal stenosis (specifically with or without degenerative spondylolisthesis). All four trials found that initial decompressive surgery (laminectomy) was slightly to moderately superior to initial nonsurgical therapy (e.g., average 8- to 18-point difference on the SF-36 and Oswestry Disability Index [ODI]). There was insufficient evidence to determine the optimal adjunctive surgical methods for laminectomy (i.e., with or without fusion, and instrumented versus non-instrumented fusion) in patients with or without degenerative spondylolisthesis. The SPORT trials continue to be referenced as the highest quality evidence that has been 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 procedures 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 (MEDL).

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 muscles 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, laminectomy 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 (METRx™ lumbar endoscopic system, Medtronic) are used to dilate the musculature and expand the fascia. For MEDL, an endoscopic curette, rongeur, and drill are used for the laminotomy, fasciectomy, 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 IG-MLD 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 that is clamped in place with a back plate, single use tools (portal cannula, surgical guide, bone rongeur, tissue sculptor, and 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 additional

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 to be used near the lateral neural elements and are contraindicated for disc procedures.

Policy:

Image-guided minimally invasive spinal decompression does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational.**

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

This policy was created in 2010 and updated periodically using the MEDLINE database. The most recent literature review was performed through February 8, 2018. Following is a summary of key references to date.

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

Selection criteria required radiologic evidence of lumbar spinal stenosis (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 study treatment (22 vs 6), due primarily to a decision to have surgery or other non-study therapy (n=8) or dissatisfaction with randomization results (n=6). This unequal dropout rate raises the possibility of bias due to patient expectations and non-blinding of patients and assessors. Patients who withdrew from the study after treatment but before the 6-month follow-up (10 IG-MLD, 20 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 10 on the ODI, was significantly higher in the IG-MLD group than the ESI group at both 6 months and 1 year. Secondary efficacy end points were the proportion of responders for 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
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)		≥-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	2837%	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 the publication of the MiDAS ENCORE trial, the International Spine Intervention Society (ISIS) published a systematic review of the IG-MLD literature in 2014. Included in the review were one randomized controlled trial with 38 patients and 12 cohort studies/series. Pain measurements using a visual analog score (VAS) or Zurich Claudication Questionnaire (ZCQ) showed a weighted mean improvement of 41% in the short-term (four to six weeks), 46% at three months, 42% at six months, and 49% at one year. However, mean VAS scores exceeded three at all times after treatment. 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 six weeks, 16.2 at 12 weeks, 15.4 at six months, and 14.0 at one year, a weighted cumulative decline to 33 from 47 at baseline.. One study (2013) that reported two-year outcomes was considered to be of questionable validity, and the data were not accepted. The mean final ODI was greater than 30 in the most of the 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 while performing 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 also reported on IG-MLD in 14 patients who were considered at high risk for complications from open spine surgery and general anesthesia. Comorbidities included obesity, diabetes mellitus, hypertension, chronic obstructive pulmonary disease, chemotherapy, and coronary artery disease. Nine of the 14 patients (64%) reported an improvement in VAS pain

scores of three points or more. ODI scores did not change significantly. A 2010 publication reported outcomes from a consecutive series of 42 patients who underwent IG-MLD by an interventional pain specialist. Most of the patients were considered non-surgical candidates by a spine surgeon. VAS pain scores averaged 9.6 at baseline and 5.8 at 30 days after the procedure, with 80% of patients reporting a change in VAS of 3 or more. Thirty (71%) patients reported an improvement 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 the use of image-guided minimally invasive lumbar 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 central lumbar spinal stenosis who receive IG-MLD, the evidence includes a large, ongoing randomized controlled trial (RCT; N=302) and 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 compares IG-MLD with epidural steroid injections in patients who have ligamentum flavum hypertrophy and have failed conservative therapy. Early results suggest an improvement in pain and function in the IG-MLD group in comparison with the control group. The trial was unblinded and there was 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 with placebo and is also insufficient to determine the efficacy of IG-MLD in comparison to open decompression. Trials with relevant control groups would allow greater certainty regarding 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

Key Words:

Image-guided minimally invasive lumbar decompression, mild®, image-guided percutaneous minimally invasive lumbar decompression, IG-MILD, lumbar spinal stenosis, LSS, posterior lumbar decompression, microendoscopic decompressive laminotomy, MEDL, X-Sten MILD Vertos's mild®

Approved by Governing Bodies:

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 for use 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. These devices are not intended for use near the lateral neural elements and remain 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.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP: Special benefits may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT Codes:

0274T	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 (e.g., fluoroscopic, CT), with or without the use of an endoscope, 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 (e.g., fluoroscopic, CT), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar

HCPC Codes:

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. **(Effective 01/01/15)**

The procedure utilizes an epidurogram so CPT code 72275 (epidurography, radiological supervision and interpretation) would probably also be reported.

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Policy History:

Medical Policy Group, March 2010 **(1)**

Medical Policy Administration Committee, April 2010
Available for comment April 7-May 21, 2010
Medical Policy Group, March 2011 **(1):** Updated Coding, Key Points and References
Medical Policy Administration Committee, April 2011
Available for comment April 4 – May 18, 2011
Medical Policy Group, March 2012 **(1):** Update to Key Points and References related to MPP update; no change to policy statement
Medical Policy Group, June 2013 **(4):** Update to Key Points and References related to IG-MLD. No policy change.
Medical Policy Group, January 2014 **(4):** References related to IG-MLD. No policy change.
Medical Policy Panel April 2014
Medical Policy Group April 2014 **(4):** Updated Key Points, Key Words and References. No change to the policy at this time.
Medical Policy Group, February 2015: 2015 Annual Coding Update. Added HCPC codes section to include G0276.
Medical Policy Panel, April 2015.
Medical Policy Group, April 2015 (**2**): 2015 Updates to Description, Key Points, and References; no change to policy statement.
Medical Policy Panel, April 2016.
Medical Policy Group, April 2016 **(7):** 2016 Updates to Key Points and References; no change in policy statement.
Medical Policy Group, December 2016: 2017 Annual Coding Update. Updated verbiage for revised cpt code 0275T.
Medical Policy Panel, April 2017
Medical Policy Group, April 2017 **(7)**: Updates to Description, Key Points, Coding and References. Added CPT code 0274T (has always been investigational) to Current Coding and removed Previous Coding section as it pertained to changes made in 2011. Policy statement updated to state "spinal" decompression rather than lumbar decompression.
Medical Policy Panel, April 2018
Medical Policy Group, May 2018 **(7)**: Updates to Description and Key Points. No change to Policy Statement.
