Name of Policy: Image-Guided Minimally Invasive Lumbar Decompression for Spinal Stenosis

Policy #: 419
Category: Surgery

Latest Review Date: March 2014
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:**

Image-guided minimally invasive lumbar decompression (IG-MLD) describes a novel percutaneous procedure for decompression of the central spinal canal with lumbar spinal stenosis (LSS). In this procedure, a specialized cannula and surgical tools are used under fluoroscopic guidance for bone and tissue sculpting near the spinal canal.

In lumbar spinal stenosis (LSS), the space around the spinal cord narrows, compressing the spinal cord and the nerve roots. The most common symptom of LSS is 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 goal of surgical treatment is to “decompress” the spinal cord and/or nerve roots. Although treatment of disc herniation may be required as a component of lumbar decompression, the present policy addresses posterior decompression of central LSS with a percutaneous treatment that is performed under fluoroscopic guidance.

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, 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.

Alternative posterior decompressive surgical procedures include:

- **Decompressive laminectomy**, the classic treatment for LSS, which unroofs the spinal canal by extensive resection of posterior spinal elements, including the lamina, spinoous 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.

**Policy:**
Image-guided minimally invasive lumbar 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 members' 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 28, 2014. Following is a summary of key references to date.

**Conventional Posterior Decompressive Surgery**
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.
Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD)

Primary literature on image-guided minimally invasive lumbar decompression (IG-MLD) consists of one small controlled trial and a number of prospective and retrospective cohort studies and case series. Members of the Standards Division of 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 (described next) 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 remained greater than three at all times after treatment. Ten studies assessed function using the ODI or Roland-Morris Disability Questionnaire. With a baseline ODI score of 47.0, the ODI 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. One study 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 meet one author’s definition of a minimally acceptable outcome. No direct procedure-related complications were identified in the included 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.

The single randomized trial included in the systematic review was a small (n=38) double-blind study of mild® compared with epidural steroid injections. The study included patients with painful lower limb neurogenic claudication and hypertrophic ligamentum flavum as a contributing factor. Patients with a history of recent spinal fractures, disabling back or leg pain from causes other than lumbar spinal stenosis (LSS), fixed spondylolisthesis greater than Grade I, disc protrusion or osteophyte formation, or excessive facet hypertrophy were excluded from the study. To maintain blinding, patients receiving steroid injection also received skin anesthesia with a small incision, followed by trocar placement under fluoroscopy. The primary efficacy end point was pain measured by VAS at 6 weeks after treatment. Results showed that 76.2% of mild®-treated patients had a two-point or greater improvement in pain scores, compared with 35.3% of steroid-treated patients. The ODI improved significantly from 38.8 to 27.4 after mild®, while the steroid-treated patients showed a nonsignificant improvement from 40.5 to 34.8. There was no significant difference between groups on ZCQ (2.2 for mild® vs 2.8 for steroid) at six weeks. After the six-week assessment, patients were unblinded and allowed to cross over to the other treatment. Fourteen (82%) of the steroid-treated patients crossed over to mild®. Follow-up at 12 weeks in patients treated with mild® showed no significant change in mean VAS from six to 12 weeks (6.3 at baseline, 3.8 at six weeks, 3.4 at 12 weeks). There were no major procedure-related or device-related complications. The study was continued with crossover allowed for the epidural steroid group until 26-week results. The study was completed in 2013. The 26-week results have been posted on the online site – available at www.clinicaltrials.gov (NCT00995371).

MiDAS I (NCT00956631) is an industry-sponsored multicenter study of IG-MLD at 14 centers. In 2010, Chopko and Caraway reported six-week results of this study. Included were patients with symptomatic LSS that was primarily caused by dorsal element hypertrophy with a hypertrophic ligamentum flavum greater than 2.5 mm and central canal sectional area of 100 square mm or less and had failed conservative therapy. Of 78 patients treated, six-week follow-
up was available for 75 (96%). Thirty-nine of the patients (52%) were discharged from the hospital on the same day, and 36 patients (48%) stayed for one night. No major device or procedure-related complications (e.g., dural tears, nerve root injury, postoperative infection, hemodynamic instability, or postoperative spinal structural instability) were reported. The average VAS pain score improved from 7.3 at baseline to 3.7 at the six-week follow-up. Scores on the ODI improved from 47.4 to 29.5, a 38% improvement. Scores on the ZCQ improved 26.8% on the symptom severity subscale and 17.5% for physical function. Scores on all subscales of the SF-12 health survey were improved. At one-year follow-up, VAS for pain from 58 patients was 4.5. The ODI improved from 48.6 to 36.7, and there was significant improvement on all domains of the ZCQ and the SF-12 physical component score (from 27.4 to 33.5). Functional and self-reported outcomes were also reported for 40 of the 78 patients at one year. In 2013, Chopko reported two-year outcomes with 45 patients from this trial. Validity of the longer-term results is uncertain due to the high loss to follow-up.

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. The average VAS score improved from 7.6 to 3.6 (53% improvement) at a mean follow-up of 23.5 weeks (range, 4-72 weeks). Scores on the ODI were 50% at baseline and 43.9% at follow-up; this change was not statistically significant. Two postoperative complications (calf deep venous thrombosis and pulmonary embolism) related to the procedure were observed in a single patient. One patient subsequently received open lumbar decompressive laminectomy due to continued decline in function.

Several other reports on IG-MLD have been published by Deer et al. A 2012 report by Deer et al describes a prospective study of mild® in 46 consecutive patients with neurogenic claudication related to LSS that was primarily caused by ligamentum flavum hypertrophy (NCT01076244). Complete follow-up to one year was available for 35 patients (76%). VAS improved from 6.9 at baseline to 4.0 at one year, ODI improved from a mean of 49.4 to 32.0, and the ZCQ improved for all ZCQ domains. A 2010 publication by Deer and Kapural describes a chart review of 90 consecutive patients treated in the U.S. (14 physicians in 12 facilities) with mild® devices under fluoroscopic guidance. No major adverse events (dural puncture or tear, blood transfusion, nerve injury, epidural bleeding, hematoma) were found in the chart review. The safety review was updated in 2012 by Levy and Deer with a total of 373 patients treated with IG-MLD.

Another retrospective review from 2010 reported outcomes from a consecutive series of 42 patients who underwent IG-MLD by interventional pain specialists. All patients met magnetic resonance imaging criteria (spinal stenosis and ligamentum flavum hypertrophy) for IG-MLD and had undergone previous conservative treatment to include lumbar epidural steroid injections, opioid and nonopioid medication and physical therapy. Most of the patients were considered nonsurgical candidates in consultation with or referral from a spine surgeon (no further details were provided). All patients had bilateral IG-MLD with most (n=26) at two levels. 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 three or more. Thirty patients (71%) reported an improvement in function following IG-MLD. No major adverse events were identified.
Summary
There is one small randomized trial with short-term follow-up that reports improved outcomes from mild® compared with epidural steroid injections. Evidence from prospective case series in patients who have failed conservative management reports that pain is reduced and functional status is improved following treatment with mild®.

This evidence is insufficient to determine the efficacy of mild® compared with placebo and is also insufficient to determine the comparative efficacy of IG-MLD in relation to alternative surgical approaches. Because of the variable natural history of back pain and the subjective nature of the outcomes of pain and functional status, randomized controlled trials are necessary to determine which surgical approach to LSS achieves the best outcomes. Further trials with larger numbers of subjects, longer follow-up, and relevant control groups are needed to determine the effect on health outcomes with greater certainty.

Posterior decompression for lumbar spinal stenosis has been evolving toward increasingly minimally invasive procedures in an attempt to minimize postoperative morbidity and spinal instability. In general, the literature comparing surgical procedures is limited. The evidence available suggests that less invasive surgical decompression may reduce perioperative morbidity without impairing long-term outcomes when performed in appropriately selected patients.

In contrast to conventional surgical decompression, the mild® procedure is a percutaneous decompressive procedure 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 it be required. One small controlled trial with short-term follow-up and small case series of patients treated with image-guided minimally invasive lumbar decompression (IG-MLD) report improvements in pain and functioning, but controlled trials are lacking, and the efficacy of this procedure compared to alternatives cannot be determined at this time. Due to the unknown impact on health outcomes, randomized controlled trials in appropriate patients are needed to compare this novel procedure with the established alternatives. Therefore, this procedure is considered investigational.

Practice Guidelines and Position Statements
APS published clinical practice guidelines in 2009 on interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain. The guidelines were based on a systematic review commissioned by APS and conducted at the Oregon Health Sciences University Evidence-Based Practice Center. APS provided a strong recommendation (high-quality evidence) that clinicians discuss risks and benefits of surgery as an option for patients with persistent and disabling radiculopathy due to spinal stenosis. This recommendation was based on evidence showing that decompressive laminectomy is associated with moderate benefits compared with nonsurgical therapy through one to two years for persistent and disabling leg pain due to spinal stenosis, either with or without degenerative spondylolisthesis. There was insufficient evidence to determine if laminectomy with fusion was more effective than laminectomy without fusion. APS recommended that shared decision making regarding surgery include a specific discussion about average benefits, which appear to decrease over time in
patients who undergo surgery. It should be noted that this recommendation was based on randomized trials of laminectomy. Evidence for more recent decompressive surgical procedures was not reviewed.

**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’ mild®

**Approved by Governing Bodies:**
The mild® tool kit (Vertos Medical) initially received 510(k) marketing clearance as the X-Ten 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’ 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: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity
Pre-certification requirements: Not applicable

**Current Coding:**
CPT Codes:

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<th>Code</th>
<th>Description</th>
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<td>0275T</td>
<td>Percutaneous laminotomy/laminectomy (intralaminar approach) for decompression of neural elements, (with or without ligamentous resection, disectomy, 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</td>
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The procedure utilizes an epidurogram so CPT code 72275 (epidurography, radiological supervision and interpretation) would probably also be reported.

**Previous Coding**

*Effective for dates of service prior to July 1, 2011:*

There is no specific CPT code for the mild® procedure. It is possible that the procedure may be coded using CPT code 63030 (laminotomy [hemilaminectomy], with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, including open and endoscopically-assisted approaches, 1 interspace, lumbar). This is not felt to be the correct code for the mild® procedure as the procedure is needle-based, and the anatomic structures are not directly or endoscopically visualized. Other CPT codes that might be used include 63056 and 63057 (transpedicular approach with decompression of spinal cord, equine and/or nerve root[s], [e.g., herniated intervertebral disc], single segment; lumbar [including transfacet, or lateral extraforaminal approach] [e.g., far lateral herniated intervertebral disc] first segment and each additional segment respectively).

The more correct CPT code to use for this procedure is code 64999 (unlisted procedure, nervous system).

**References:**


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 Panel April 2014
Medical Policy Group April 2014 (4): Updated Key Points, Key Words and References. No change to the policy at this time.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.