Medical Policy

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Title: Image-Guided Minimally Invasive Lumbar Decompression (IG-MLD) for Spinal Stenosis

Professional
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DESCRIPTION

Image-guided minimally invasive lumbar decompression (IG-MLD) describes a novel percutaneous procedure for decompression of the central spinal canal in patients with lumbar spinal stenosis (LSS). In this procedure, a specialized cannula and surgical tools (mild®) 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 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 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 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 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, 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 flavuum and the medial aspect of the facet joint. In contrast to 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 (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, facetectomy, and foraminotomy. The working channel may be repositioned from a single incision for multilevel and bilateral dissections.

Regulatory Status

The mild® tool kit (Vertos Medical) initially received 510(k) marketing clearance as the X-Sten 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.

POLICY

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

RATIONALE

The most recent literature update was performed through January 31, 2013. Following is a summary of key references to date.

Posterior Decompressive Surgery

Laminectomy

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. (1, 2) Four higher-quality randomized trials were reviewed that compared surgery to nonsurgical therapy for spinal stenosis, including 2 studies from the multicenter Spine Patient Outcomes Research Trial (SPORT) evaluating laminectomy for spinal stenosis (specifically with or without degenerative spondylolisthesis). (3, 4) Baseline pain scores averaged 31 to 32 on the Short Form

(SF)-36 bodily pain score or 7 on a 0 to 10 pain scale. Two trials permitted enrollment of patients with greater than 12 weeks of symptoms; however, symptoms were present for more than 6 months in the majority of patients in all trials. All 4 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]). Although differences were decreased at longer follow-up, interpretation of results was complicated by the large proportion of patients in the nonsurgical therapy group who crossed over to surgery before the final follow-up. Dural tears were the most common complication of laminectomy, occurring in 7% to 11% of patients. There was insufficient evidence to determine the optimal adjunctive surgical methods for laminectomy (i.e., with or without fusion, and instrumented vs. non-instrumented fusion) in patients with or without degenerative spondylolisthesis.

Laminotomy versus Laminectomy

A 2005 study randomized 120 patients with lumbar stenosis to bilateral laminotomy, unilateral laminotomy, or laminectomy. (5) Patients were refractory to at least 3 months of conservative therapy, with neurogenic claudication or radiculopathy, imaging evidence of degenerative lumbar stenosis, and absence of herniation or instability. Three patients were excluded due to discectomies during surgery; follow-up of at least 1 year was obtained in 110 patients (94% of the cohort of 117 and 97% of surviving patients). The average visual analog score (VAS) for overall pain at baseline was 7.5, improving to 2.3 for bilateral laminotomy, 3.6 for unilateral laminotomy, and 4 for laminectomy. Neurogenic claudication improved in 92% of patients with bilateral laminotomy, compared with 74% treated with unilateral laminotomy and 68% of patients who had laminectomy. Similar improvements were obtained for the SF-36 (postoperative bodily pain scores of 61, 47, 45), Roland-Morris scale (8, 8.5, and 11 postoperatively), and patient satisfaction scores (97%, 74%, and 74% satisfied – all respectively). The perioperative morbidity rate was lower with bilateral laminotomy (5%) than unilateral laminotomy (17.5%) or laminectomy (22.5%), due primarily to the incidence of dural tears with the 3 procedures. Blinding of patients to the procedure to which they were randomized was not described; the potential for bias is unknown.

A 2008 quasi-randomized study from Asia compared laminoforaminotomy with laminectomy in 152 consecutive patients. (6) Inclusion criteria required that each patient have 1) neurogenic claudication as defined by leg pain limiting standing, ambulation, or both; 2) a history of exercise intolerance; 3) magnetic resonance imaging (MRI), myelogram, or computed tomography (CT) confirmation of compressive central stenosis (central sagittal diameter less than 10 mm) with or without lateral recess stenosis (lateral recess diameter less than 3 mm); and 4) failure of conservative therapy after an adequate trial (not defined). Patients were excluded from the study if they had 1) previous surgery at the same level; 2) isthmic spondylolisthesis; 3) congenital spinal stenosis less than 8 mm caused by short pedicles; 4) dynamic instability; 5) cauda equina syndrome; 6) worker's compensation claim or other litigation; 7) dying of other disease or otherwise lost to follow-up. At an average 40 months after surgery, the ODI and VAS for back and leg pain and were low (e.g., less than 1 on VAS) for both groups, and significantly lower for laminotomy. The proportion of patients with good to excellent results (absent or occasional mild back and leg pain and the ability to ambulate more than 1 mile or 20 minutes) was 89% for patients treated with laminotomy and 63% for patients treated with laminectomy. Seven percent of patients treated with laminectomy had poor results at the final interview (range: 27–58 months), compared with none in the laminotomy group. The study is limited by the lack of information about the number of patients lost to follow-up and the lack of blinding.

Microendoscopic Decompressive Laminotomy (MEDL)
No comparative trials with MEDL were identified. In 2009, Castro-Menendez et al. reported 4-year outcomes (from a prospectively maintained institutional database) of 50 patients with lumbar spinal stenosis (LSS) who were treated by single-level microendoscopic decompression. Twenty of the patients received microendoscopic discectomy at the same time, which may be considered a part of the endoscopic procedure that can be performed when needed. (7) Inclusion criteria for the study were 1) low back pain and/or radicular pain (70%); 2) neurogenic claudication (58%); 3) personal history of exercise intolerance; 4) radiologic/neuroimaging evidence of degenerative lumbar stenosis; 5) clinical-radiologic concordance; 6) failure of conservative management after at least 6 months of therapy. Excluded from the study were patients with 1) nonclinical-nonradiologic correlation; 2) congenital stenosis; 3) previous lumbar spinal surgery; 4) higher than grade I degenerative spondylolisthesis; 5) spondylolisthesis with spondylolysis; 6) preoperative instability; 7) more than 1 level clinically affected; 8) associated degenerative scoliosis of more than 20 degrees; and 9) the presence of an associated pathology such as acute inflammation, tumor, or cauda equina syndrome. The mean postoperative hospital stay was 3.2 days. The ODI decreased by 30 (65.2 preoperatively), leg pain VAS by 6.02 (8.3 preoperatively), and lumbar pain VAS by 0.84 (5.3 preoperatively) at an average 4-year follow-up (range: 24–72 months). Of the 29 patients (58%) with neurogenic claudication, 21 (72%) reported improvement in the ability to walk (more than 1 mile) at the end of the study. Dural tears occurred in 5 patients (10%), all in the first 25 interventions. One patient (2%) had epidural hematoma causing cauda equina syndrome. Although the study may be relatively representative of outcomes during the learning curve for this highly selected population, the report is limited by the restricted selection criteria, retrospective review, and lack of blinding.

Conclusions. For patients with lumbar spinal stenosis, surgical laminectomy has established benefits in reducing pain and improving quality of life. Less invasive surgical procedures have been developed, such as open laminotomy and microendoscopic laminotomy. Limited evidence on the comparative efficacy of these procedures suggests that less invasive procedures may achieve a roughly similar benefit with less adverse effects. Further randomized controlled trials (RCTs) are needed to determine the comparative efficacy of different surgical approaches to lumbar spinal stenosis with greater certainty.

Image-Guided Percutaneous Minimally Invasive Lumbar Decompression (IG-MLD)

Literature on IG-MLD consists of one small controlled trial and several prospective and retrospective case series. In 2012, Brown reported a small (n=38) randomized double-blind trial of mild® compared to epidural steroid injections. (8) 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 LSS, fixed spondylolisthesis greater than grade 1, disk protrusion or osteophyte formation, or excessive facet hypertrophy were excluded from the study. In order to maintain blinding, patients receiving steroid injection also received skin anesthesia with a small incision, followed by trocar placement under fluoroscopy. The primary efficacy endpoint was pain measured by VAS at 6 weeks' post-treatment. Results showed that 76.2% of mild® treated patients had a 2-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 non-significant improvement from 40.5 to 34.8. There was no significant difference between groups on the Zurich Claudication Questionnaire (ZCQ, 2.2 for mild® vs. 2.8 for steroid) at 6 weeks. After the 6-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 6 to 12 weeks (6.3 at baseline, 3.8 at 6 weeks, and 3.4 at 12 weeks). There were no major procedure-related or device-related complications. In 2010, Chopko and Caraway reported 6-week follow-up of an ongoing multi-center study (NCT00956631) of IG-MLD at 14 centers. (9) Included were patients with symptomatic LSS that was caused primarily by dorsal element hypertrophy with a hypertrophic ligamentum flavum greater than 2.5 mm and central canal sectional area equal to or less than 100 square mm and had failed conservative therapy. Of 78 patients treated, 6-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, post-operative infection, hemodynamic instability, or post-operative spinal structural instability) were reported. The average VAS pain score improved from 7.3 at baseline to 3.7 at the 6-week follow-up. Scores on the ODI improved from 47.4 to 29.5, a 38% improvement. Scores on the Zurich Claudication Questionnaire 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.

Chopko also reported a prospective study of IG-MLD in 14 patients who were considered at high risk for complications from open spine surgery and general anesthesia. (10) 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 3 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 to 72 weeks). Scores on the ODI were 50% at baseline and 43.9% at follow-up; this change was not statistically significant. Two post-operative 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. One-year follow-up from an industry-sponsored multicenter study (NCT00956631) of 58 patients who were treated with mild® devices was reported in 2012. (11) All patients had failed conservative medical management, with 75.9% of patients treated with conservative therapy for more than 6 months. Twenty-nine patients (50%) were discharged from the surgical facility on the same day as the procedure, and none of the patients stayed longer than 24 hours. There were no reports of major intraoperative or postoperative procedure-related adverse events. The primary outcome of patient success was defined as a 2-point improvement in VAS pain, but the percentage of patients who achieved success was not reported. VAS for pain improved from a mean of 7.4 at baseline to 4.5 at 1-year follow-up. 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).

Several case series on IG-MLD were reported in 2012. Deer et al. reported a prospective study of mild® in 46 consecutive patients with neurogenic claudication related to lumbar spinal stenosis that was caused primarily by ligamentum flavum hypertrophy. (12) Complete follow-up to 1 year was available for 35 patients (76%). VAS improved from 6.9 at baseline to 4.0 at 1 year, the ODI improved from a mean of 49.4 to 32.0, and the ZCQ improved for all ZCQ domains. An independent prospective study by Mekhail et al. evaluated outcomes in 40 patients following IG-MLD. (13) At 1-year follow-up, VAS had improved by 7.1 to 3.6, standing time increased from 8 to 56 minutes, and walking distance increased by 246 feet to 3,956 feet. Pain Disability Index (PDI) and Roland-Morris Disability Questionnaire (RMQ) were also significantly improved.

Wilkinson and Fourney reported a prospective trial of 10 subjects with intermittent claudication because of lumbar spinal stenosis due primarily to hypertrophy of the ligamentum flavum. (14) Pain and disability were reduced in the 26-week follow-up period after mild®, but there was no evidence of significant decompression of the spinal canal observed with imaging. Recurrent claudication requiring laminectomy developed in 6 patients (60%) during an 18-month observation period.

A 2010 publication describes a chart review of 90 consecutive patients treated in the U.S. (14 physicians in 12 facilities) with mild® devices under fluoroscopic guidance. (15) No efficacy data were reported. No major adverse events (dural puncture or tear, blood transfusion, nerve injury, epidural bleeding, or hematoma) were found in the chart review. The authors state that prospective, randomized studies have been initiated to evaluate the efficacy of this new procedure. The safety review was updated in 2012 with a total of 373 patients treated with IG-MLD. (16) Another retrospective review from 2010 reported outcomes from a consecutive series of 42 patients who underwent IG-MLD by interventional pain specialists. (17) All patients met MRI criteria (spinal stenosis and ligamentum flavum hypertrophy) for IG-MLD and had undergone previous conservative treatment to include lumbar epidural steroid injections, opioid and non-opioid medication and physical therapy. Most of the patients were considered non-surgical candidates in consultation with or referral from a spine surgeon (no further details were provided). All patients had bilateral IG-MLD with the majority (n=26) at 2 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 equal to or greater than 3. Thirty patients (71%) reported an improvement in function following IG-MLD. No major adverse events were identified.

Conclusions. There is one small randomized trial with short-term follow-up that reports improved outcomes from mild® compared to 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 to 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 lumbar spinal stenosis 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.

Ongoing clinical trials. A search of online site ClinicalTrials.gov in January 2013 found a number of trials on IG-MLD. Three studies are Phase IV open label with mild® (NCT00956631, NCT01076244, NCT01082159), and 3 are randomized controlled trials (NCT01315145, NCT00995371, NCT01129921). NCT01315145 and NCT00995371 compare mild® with epidural corticosteroid injection. NCT01129921 is a sham-controlled trial that was completed in 2012 but has not yet been published. NCT01315145 has completed recruiting with an enrollment of 138 patients and estimated completion in June 2013. . NCT00995371 has completed enrollment of an estimated 40 patients with expected completion (26-week follow-up) in 2013.

Summary

Posterior decompression for lumbar spinal stenosis has been evolving toward increasingly minimally invasive procedures in an attempt to minimize post-operative 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 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 studies 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

The American Pain Society (APS) published clinical practice guidelines in 2009 on interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain. (2) The guidelines were based on a systematic review commissioned by the APS and conducted at the Oregon Health Sciences University Evidence-Based Practice Center. (1) 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 to nonsurgical therapy through 1 to 2 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. The 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.

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

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), with or without the use of an endoscope, single or multiple levels, unilateral or bilateral; lumbar

- Effective July 1, 2011, there is a CPT category III code that is applicable to this procedure: 0275T.
- Prior to April 2011, there was no specific CPT code for the mild® procedure and the procedure might have been 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 was 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 have been 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 procedure utilizes an epidurogram, so CPT code 72275 (epidurography, radiological supervision and interpretation) would probably also be reported.

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

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