

Subject: Minimally Invasive Lumbar Decompression (Mild) for Treatment of Lumbar Spinal Stenosis		Original Effective Date: 12/10/19
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.¹

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL ^{2 18-20}

First-line treatment of lumbar spinal stenosis (LSS) includes conservative methods such as nonsteroidal anti-inflammatory medication, physical therapy, exercise, bedrest, and lumbar traction. If relief is not achieved, minimally invasive treatments may be pursued, including epidural steroid injections (ESIs). ESIs have a relatively short duration of effect (2 weeks to 6 months). Surgical treatment may be indicated in patients with

severe pain, constant neurological symptoms, failure of conservative methods, or in the setting of progressive neurological decline. Surgical intervention aims to decompress the neural structures at the level of stenosis and correct any instability. Traditional surgical options for LSS caused by hypertrophy of the ligamentum flavum include decompression alone or decompression with spinal fusion. Decompression may involve laminectomy, laminotomy, foraminectomy, or facetectomy in the affected vertebrae.

The most common surgery for chronic nonspecific low back pain with lumbar disc degenerative changes is spinal fusion, a procedure that fuses two or more vertebral bodies together. The goal is to restrict spinal motion and remove the degenerated disc (the presumed cause of pain) in order to relieve symptoms. A variety of fusion techniques are used. All involve the placement of a bone graft between the vertebrae. Fusion can be performed with or without supplemental hardware (instrumentation), such as pedicle rods, plates, screws, or cages that function as an internal splint while the bone graft heals. Fusion alters the normal mechanics of the spine and is associated with an increase in long-term degenerative changes in adjacent spine segments. The standard spinal fusion procedure for rigid spinal fixation involves the use of pedicle screws, rods, cages and plates. Spinal fusion is usually performed after decompression in cases where there is excessive facetectomy or if there is evidence of isthmic or degenerative spondylolisthesis, scoliosis, kyphosis, or synovial facet joint cysts. Fusion is also indicated in patients with prior fusion and adjacent-segment degeneration, recurrent stenosis, or a herniated disc after decompression.

The minimally invasive lumbar decompression (MILD) procedure (Vertos Medical Inc.) is a spine surgery technique that increases the dimensions of the spinal canal by removing or debulking the hypertrophied ligamentum flavum and small amounts of the lamina, achieving nerve or canal decompression. The procedure is performed under x-ray guidance (e.g., fluoroscopic, CT) with the assistance of contrast media to identify and monitor the compressed area via epidurogram. A small portal is used for the surgical instruments supplied in the MILD tool kit and is performed under local anesthesia with light sedation as a same-day surgery. The MILD procedure is proposed as a treatment for symptomatic lumbar spinal stenosis (LSS) unresponsive to conservative therapy.

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. A later approval for the Vertos Medical mild® Device Kit (Vertos Medical Inc.) was given by the FDA on February 4, 2010.

POSITION STATEMENT

The minimally invasive lumbar decompression (MILD) procedure (Vertos Medical Inc.) for spinal stenosis is considered experimental, investigational and/or unproven, due to insufficient clinical evidence of safety and efficacy in published peer-reviewed medical literature.

SUMMARY OF MEDICAL EVIDENCE³⁻¹⁷

Overall, there is low quality evidence in the peer-reviewed published medical literature to support the long-term safety and effectiveness of the MILD procedure for spinal fusion. The available studies are lower quality with short follow-up of two years so the long-term efficacy and safety of the procedure are not known. Limitations of

the individual studies included limited follow-up, lack of blinding, high attrition, absence of power analyses, and missing data for some outcomes and endpoints. Large well designed randomized controlled trials are needed to demonstrate the clinical utility of the procedure compared with established standard medical and surgical approaches. A summary of the most relevant studies are outlined below.

Staats et al., (2016, 2018) conducted a prospective, multicenter, randomized controlled clinical study that compared outcomes for 143 patients treated with MILD versus 131 treated with epidural steroid injections. Follow-up occurred at 6 months and at 1 year for the randomized phase and at 2 years for MILD subjects only. Oswestry Disability Index, Numeric Pain Rating Scale, and Zurich Claudication Questionnaire were used to evaluate function and pain. Safety was evaluated by assessing incidence of device-/procedure-related adverse events. At 6 months, all primary and secondary efficacy results provided statistically significant evidence that MILD is superior to the active control. At 2 years, Oswestry Disability Index improved by 22.7 points, Numeric Pain Rating Scale improved by 3.6 points, and Zurich Claudication Questionnaire symptom severity and physical function domains improved by 1.0 and 0.8 points, respectively. There were no serious device-/procedure-related adverse events, and 1.3% experienced a device-/procedure-related adverse event. MILD showed durability, and there was no evidence of spinal instability through 2-year follow-up. Reoperation and spinal fracture rates are lower, and safety is higher for MILD versus other lumbar spine interventions, including interspinous spacers, surgical decompression, and spinal fusion. Limitations include lack of patient blinding due to considerable differences in treatment protocols, and a potentially higher non-responder rate for both groups versus standard-of-care due to study restrictions on adjunctive pain therapies.

A randomized controlled trial (Benyamin et al., 2016) was performed to assess improvement of function and reduction in pain for Medicare beneficiaries following treatment with MILD in LSS patients with neurogenic claudication and verified ligamentum flavum hypertrophy and to compare to a control group receiving epidural steroid injections. 302 patients were enrolled, with 149 randomized to MILD and 153 to the active control. Outcomes were assessed using the Oswestry Disability Index (ODI), Numeric Pain Rating Scale (NPRS) and Zurich Claudication Questionnaire (ZCQ). At 1-year follow-up, ODI, NPRS, and all 3 ZCQ domains (Symptom Severity, Physical Function and Patient Satisfaction) demonstrated statistically significant superiority of MILD versus the active control. For primary efficacy, the 58.0% ODI responder rate in the MILD group was higher than the 27.1% responder rate in the epidural steroid group ($P < 0.001$). The primary safety endpoint was achieved, demonstrating that there is no difference in safety between MILD and ESIs ($P = 1.00$). Limitations of this study included a lack of patient blinding due to considerable differences in treatment protocols, and a potentially higher non-responder rate for both groups versus standard-of-care due to adjunctive pain therapy study restrictions. Study enrollment was not limited to patients that had never received ESI therapy and only one year follow-up is noted.

A Cochrane review (Zaina et al., 2016) evaluated the effectiveness of different types of surgery compared with different types of non-surgical interventions in adults with symptomatic LSS. Primary outcomes included

quality of life, disability, function and pain. Also, to consider complication rates and side effects, and to evaluate short-, intermediate- and long-term outcomes (six months, six months to two years, five years or longer). Randomised controlled trials (RCTs) comparing surgical versus non-operative treatments in participants with lumbar spinal stenosis confirmed by clinical and imaging findings were included. Low-quality evidence from the meta-analysis performed on two trials using the Oswestry Disability Index (pain-related disability) to compare direct decompression with or without fusion versus multi-modal non-operative care showed no significant differences at six months. Low-quality evidence from one small study revealed no difference in pain outcomes between decompression and usual conservative care (bracing and exercise) at three months. Low-quality evidence from one small study suggested no differences at six weeks in the Oswestry Disability Index for patients treated with minimally invasive mild decompression versus those treated with epidural steroid injections. The authors stated “We have very little confidence to conclude whether surgical treatment or a conservative approach is better for lumbar spinal stenosis, and we can provide no new recommendations to guide clinical practice. However, it should be noted that the rate of side effects ranged from 10% to 24% in surgical cases, and no side effects were reported for any conservative treatment. No clear benefits were observed with surgery versus non-surgical treatment. These findings suggest that clinicians should be very careful in informing patients about possible treatment options, especially given that conservative treatment options have resulted in no reported side effects. High-quality research is needed to compare surgical versus conservative care for individuals with lumbar spinal stenosis.”

A systematic review (Kreiner et al., 2014) evaluated the MILD procedure for the treatment of symptomatic LSS in adults with lower extremity claudication included 1 RCT, 7 prospective cohort studies, 4 retrospective cohort studies, and 1 case series. This review concluded that the low-quality body of evidence suggested statistically significant reductions in pain intensity and function. However, improvements did not meet some definitions of MCIDs. No substantial procedure-related complications were identified. Needs for future research included outcomes beyond 2 years, independently conducted studies, and patient selection criteria.

PROFESSIONAL SOCIETY GUIDELINES

The MIST Guidelines: The Lumbar Spinal Stenosis Consensus Group Guidelines for Minimally Invasive Spine Treatment (2019): The Lumbar Spinal Stenosis Group convened to evaluate the peer-reviewed literature as the basis for making minimally invasive spine treatment (MIST) recommendations. Eleven consensus points were clearly defined with evidence strength, recommendation grade, and consensus level using U.S. Preventive Services Task Force criteria. The Consensus Group also created a treatment algorithm. Literature searches yielded 9 studies (2 randomized controlled trial [RCTs]; 7 observational studies, 4 prospective and 3 retrospective) of minimally invasive spine treatments, and 1 RCT for spacers. The LSS treatment choice is dependent on the degree of stenosis; spinal or anatomic level; architecture of the stenosis; severity of the symptoms; failed, past, less invasive treatments; previous fusions or other open surgical approaches; and patient comorbidities. There is Level I evidence for percutaneous image-guided lumbar decompression as superior to lumbar epidural steroid injection, and 1 RCT supported spacer use in a non-inferiority study comparing 2 spacer products currently available. The guidelines state: “MISTs should be used in a judicious and algorithmic fashion to treat LSS, based on the evidence of efficacy and safety in the peer-reviewed literature. The MIST Consensus

Group recommend that these procedures be used in a multimodal fashion as part of an evidence-based decision algorithm.”

Centers for Medicare & Medicaid Services (CMS): A National Coverage Determination (NCD-150.13) for percutaneous image-guided lumbar decompression (PILD) for the treatment of symptomatic LSS unresponsive to conservative therapy was issued on December 7, 2016. PILD is only covered by CMS under the context of a clinical trial, as specified by the CMS NCD.

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
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 (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; 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
ICD-10	Description
	Any/All

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- Proposed National Coverage Determination (NCD) for Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis (CAG-00433R). October 6, 2016. Available at: <https://www.aans.org/pdf/Legislative/AANS-CNS%20Letter%20to%20CMS%20on%20PILD%20Procedure%20100616.pdf>.
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REVIEW/REVISION HISTORY

12/10/2019: New Policy

12/9/2020: Policy reviewed, no changes. There are no new clinical studies, procedure remains experimental/investigational and unproven.