Molina Clinical Policy
Minimally Invasive Lumbar Decompression (MILD) for Treatment of Lumbar Spinal Stenosis: Policy No. 351

Last Approval: 12/14/2022
Next Review Due By: December 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. 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 (e.g., 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 MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

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. (FDA, 2010; American Association of Neurological Surgeons [AANS]; Levy et al., 2012; Lingreen et al., 2010; Mannion et al., 2012).

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. (FDA, 2010; AANS; Levy et al., 2012; Lingreen et al., 2010; Mannion et al., 2012).

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 LSS unresponsive to conservative therapy. (FDA, 2010; Levy et al., 2012; Lingreen et al., 2010; Mannion et al., 2012).

The MILD® Tool Kit initially received FDA 510(k) marketing clearance as the X-Sten MILD Tool Kit (X-Sten Corp.) in 2006. It was intended to be used as a set of specialized surgical instruments for percutaneous lumbar decompressive procedures for the treatment of various spinal conditions. Approval for the MILD® Device Kit by Vertos Medical, Inc. was given by the FDA in February 2010. (FDA, 2010).

COVERAGE POLICY

The Minimally Invasive Lumbar Decompression (MILD) procedure for spinal stenosis **is considered experimental, investigational, and unproven** due to insufficient clinical evidence of safety and efficacy in published peer-reviewed medical literature.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

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; long-term efficacy and safety of the procedure are unknown. 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.

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.

Benyamin et al. (2016) conducted a randomized controlled trial 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.

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 LSS 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 study reported little confidence on the efficacy of surgical treatment versus a conservative approach for LSS despite a low rate of side effects (10-24% in surgical cases). Additional research is needed.

Kreiner et al. (2014) evaluated the MILD procedure for the treatment of symptomatic LSS in adults with lower extremity claudication included one RCT, seven prospective cohort studies, four retrospective cohort studies, and one 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; future research is needed to include outcomes beyond two years, independently conducted studies, and patient selection criteria.

National and Specialty Organizations

The **Centers for Medicare and Medicaid Services (CMS)** (2016) published the *National Coverage Determination: Percutaneous Image-Guided Lumbar Decompression (PILD) (NCD 150.13)* for the treatment of symptomatic LSS unresponsive to conservative therapy. Per CMS, PILD is only covered by under the context of a clinical trial.

The **Lumbar Spinal Stenosis Consensus Group** published *Guidelines for Minimally Invasive Spine Treatment (MIST)* (2019). The Consensus Group convened to evaluate the peer-reviewed literature as the basis for MIST recommendations. Eleven consensus points were clearly defined with evidence strength, recommendation grade, and consensus level using United States Preventive Services Task Force (USPSTF) criteria. The Consensus Group also created a treatment algorithm. Literature searches yielded nine studies (two randomized controlled trial [RCTs]; seven observational studies, four prospective and three retrospective) of minimally invasive spine treatments, and one 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 one RCT supported spacer use in a non-inferiority study comparing two spacer products currently available. The guidelines states that this treatment should be used cautiously for MIST due to a lack of evidence in the medical literature.

The **American Association of Neurological Surgeons (AANS)** published the *Guideline Update for the Performance of Fusion Procedure for Degenerative Disease of the Lumbar Spine – Part 7: Lumbar Fusion for Intractable Low-Back Pain without Stenosis or Spondylolisthesis* (Eck, et al., 2014). The guidelines establish a treatment plan for patients with low-back pain without stenosis or spondylolisthesis. Medical literature does not support alternative treatments.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

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 (e.g., 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 (e.g., fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

12/14/2022	Policy reviewed, no changes to criteria.
12/8/2021	Policy reviewed, no changes to criteria; included AANS guidance; updated references; CPT code G0276 removed.
12/9/2020	Policy reviewed, no changes to criteria; no new clinical studies to support coverage.
12/10/2019	New policy.

REFERENCES

Government Agencies

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. National coverage determination (NCD) – percutaneous image-guided lumbar decompression for lumbar spinal stenosis (150.13). Available from CMS. Effective Date December 7, 2016. Accessed December 2, 2022.
2. Food and Drug Administration (FDA). Section 5: 510(k) summary – Vertos Medical Mild Device Kit (510[K] no. K093062). Available from FDA. Published February 4, 2010. Accessed December 2, 2022.

Other Evidence Based Reviews and Publications

1. AMR Peer Review. Policy reviewed on October 3, 2019 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the area of Orthopaedic Surgery.
2. Chou R. Subacute and chronic low back pain: Surgical treatment. Available from UpToDate. Updated November 2, 2022. Accessed December 2, 2022. Registration and login required.
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4. Levin K. Lumbar spinal stenosis: Treatment and prognosis. Available from UpToDate. Updated February 1, 2021. Accessed December 2, 2022. Registration and login required.

Peer Reviewed Publications

1. Benyamin RM, Staats PS, Investigators MiDAS Encore. MILD® is an effective treatment for lumbar spinal stenosis with neurogenic claudication: MiDAS ENCORE randomized controlled trial. Pain Physician. 2016;19(4):229-242. Available here.
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3. Levy RM, Deer TR. Systematic safety review and meta-analysis of procedural experience using percutaneous access to treat symptomatic lumbar spinal stenosis. Pain Med. 2012 Dec;13(12):1554-61. doi: 10.1111/j.1526-4637.2012.01504.x.
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Other Peer Reviewed and National Organization Publications (used in the development of this policy)

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3. Fukushi R, Yoshimoto M, Iesato N, Terashima Y, Takebayashi T, Yamashita T. Short-term results of microendoscopic muscle-preserving interlaminar decompression versus spinal process splitting laminectomy. J Neurol Surg A Cent Eur Neurosurg. 2018 Nov;79(6):511-517. doi: 10.1055/s-0037-1608871.
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