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

Last Approval: 12/11/2024
Next Review Due By: December 2025

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

Lumbar Spinal Stenosis is the narrowing of the intraspinal canal, lateral recess, and/or neural foramen. This condition is generally caused by degenerative bone disease and is a common cause of disability in the older population. 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. 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 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) to relieve symptoms. Fusion alters the normal mechanics of the spine and is associated with an increase in long-term degenerative changes in adjacent spine segments.

The **Minimally Invasive Lumbar Decompression** (MILD) procedure 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.

Regulatory Status

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 under product code HRX as a set of specialized surgical instruments intended to be used to perform lumbar decompressive procedures for the treatment of various spinal conditions (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 one to 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 (Hayes 2024).

Randomized Controlled Trials

[1]Deer et al. (2022) conducted a prospective, multicenter, randomized controlled trial comparing the MILD® Procedure (minimally invasive lumbar decompression; Vertos Medical, Aliso Viejo, CA, USA) in combination with nonsurgical conventional medical management vs conventional medical management alone. One hundred and thirty-eight patients were included in the study and randomized in a 1:1 ratio to make up sixty-nine participants per each group. The conventional medical management control group received any conservative or low-risk interventional therapies that are standards of care as deemed appropriate per patient by the site investigator. The MILD + conventional medical management group received the MILD procedure as a first line therapy. The groups were analyzed at a one year follow up. Objective outcomes were measured with real-world assessments, including improvement in walking, incidence of subsequent lumbar spine interventions, and safety. The Walking Tolerance Test demonstrated that patients in the MILD + conventional medical management group achieved a statistically significant mean improvement of 258% in walking time to onset of severe symptoms compared with a 64% mean improvement for patients in the conventional medical management alone group. Subsequent lumbar spine surgical interventions were undergone in 26.1% of conventional medical management patients, compared with 5.8% of MILD procedure + conventional medical management participants. There were no device- or procedure-related adverse events reported in either study group. Subjective outcomes revealed the MILD + conventional medical management group experienced a 16.1-point composite Oswestry Disability Index mean improvement, compared with a 2.0-point mean improvement for patients in the conventional medical management alone group. Zurich Claudication Questionnaire patient satisfaction also indicated that MILD + conventional medical management participants were statistically significant in their satisfaction with the treatment than were conventional medical management participants.

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.

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Mekhail et al. (2021) conducted a single center retrospective longitudinal observational cohort study evaluating the 5-year outcomes of patients who underwent the MILD procedure between the years of 2010 – 2015. The primary outcome was measuring the incidence of patients who needed a subsequent open lumbar decompression surgery at

the same level as the MILD procedure intervention; and secondary outcomes was measuring pain via Numeric Rating Scale (NRS) and opioid utilization. A total of 75 patients underwent the MILD procedure, eight patients of those 75 were either lost to follow up, deceased, or no longer living in the United States; of the remaining participants 9 underwent an open surgical decompression after the MILD procedure. No major complications were reported in any of the MILD procedures performed. All participants reported a statistically significant ($p < 0.0001$ for each time point) reduction in NRS rating at the 3, 6, and 12 month follow ups post MILD. Eighteen of the 75 participants were being treated with opioids prior to the MILD procedure, after the MILD procedure there was a statistically significant change in opioid medications utilization between baseline and 3, 6, and 12-months after mild treatment ($p = 0.0048$, $p = 0.0015$, and $p = 0.0067$, respectively). The study demonstrated that the MILD procedure significantly reduced the need for open surgical lumbar decompression; however, the retrospective nature and small study population are limitations and emphasize the need for larger RCTs to validate the findings.

National and Specialty Organizations

The **American Society of Pain and Neuroscience (ASPN)** ([2]Deer 2022) published a consensus guideline on the best practices for minimally invasive lumbar spinal stenosis treatment. The consensus statement pertaining to percutaneous image guided lumbar decompression was as follows "Percutaneous image-guided lumbar decompression (PILD)] should be considered for the treatment of mild-to-moderate [lumbar spinal stenosis (LSS)] in the presence of [neurogenic claudication (NC)], with less than or equal to a grade 2 spondylolisthesis, and with a contribution of spinal narrowing with at least 2.5 mm of [ligamentum flavum hypertrophy (LFH)]. Grade A; Level of certainty high; Level of evidence 1-A". This statement was formulated via a systematic review of current 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.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
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

12/11/2024	Policy reviewed. No changes to coverage criteria.
12/13/2023	Policy reviewed, no changes to coverage criteria, updated references. IRO peer reviewed by a board-certified physician in Orthopedic Surgery in October 2023.
12/14/2022	Policy reviewed, no changes to coverage criteria, updated references.
12/08/2021	Policy reviewed, no changes to criteria; included AANS guidance; updated references; CPT code G0276 removed.
12/09/2020	Policy reviewed, no changes to criteria; no new clinical studies to support coverage.
12/10/2019	New policy.

REFERENCES

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). Accessed November 15, 2024. Effective Date December 7, 2016.

https://www.cms.gov.
2. [1]Deer TR, Costandi SJ, Washabaugh E, et al. The MOTION Study: A Randomized Controlled Trial with Objective Real-World Outcomes for Lumbar Spinal Stenosis Patients Treated with the mild® Procedure: One-Year Results. Pain Med. 2022 Apr 8;23(4):625-634. doi: 10.1093/pm/pnac028. PMID: 35167700; PMCID: PMC8992575.
3. [2]Deer TR, Grider JS, Pope JE, et al. Best Practices for Minimally Invasive Lumbar Spinal Stenosis Treatment 2.0 (MIST): Consensus Guidance from the American Society of Pain and Neuroscience (ASPN). J Pain Res. 2022 May 5; 15:1325-1354. doi: 10.2147/JPR.S355285. PMID: 35546905; PMCID: PMC9084394.
4. Eck JC, Sharan A, Ghogawala Z, et al. 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. J Neurosurg Spine. 2014 Jul;21(1):42-7. doi: 10.3171/2014.4. SPINE14270.
5. Hayes. Health technology assessment: Minimally Invasive Lumbar Decompression Device Kit (Vertos Medical Inc.) for Treatment of Lumbar Spinal Stenosis. Published March 26, 2019. Updated February 20, 2024. Accessed November 15, 2024. https://www.evidence.hayesinc.com
6. Mekhail N, Costandi S, Nageeb G, Ekladios C, Saied O. The durability of minimally invasive lumbar decompression procedure in patients with symptomatic lumbar spinal stenosis: Long-term follow-up. Pain Pract. 2021 Nov;21(8):826-835. doi: 10.1111/papr.13020. Epub 2021 May 13. PMID: 33942964; PMCID: PMC9291913.
7. Staats PS, Chafin TB, Golovac S, et al. Long-term safety and efficacy of minimally invasive lumbar decompression procedure for the treatment of lumbar spinal stenosis with neurogenic claudication: 2-year results of MiDAS ENCORE. Reg Anesth Pain Med. 2018;43(7):789-794. doi: 10.1097/AAP.0000000000000868.
8. Staats PS, Benyamin RM, MiDAS ENCORE Investigators. MiDAS ENCORE: Randomized controlled clinical trial report of 6-month results. Pain Physician. 2016;19(2):25-38.
9. United States Food and Drug Administration (FDA). Section 5: 510(k) summary – Vertos Medical Mild Device Kit (510[K] no. K093062). Product code HRX. Published February 4, 2010. Accessed November 15, 2024. https://www.fda.gov.