



Minimally Invasive Lumbar Decompression (mild[®]) Device Kit

Spine, Pain, and Joint (SPJ)
Utilization Management Policy

Approval Date: 02/02/2026

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Policy Statement

Minimally invasive lumbar decompression using the mild® Device Kit is considered unproven and not medically necessary. There is insufficient high-quality evidence to determine the efficacy of this approach for the treatment of lumbar spinal stenosis.

For Medicare beneficiaries, refer first to any relevant local coverage determinations (LCDs) and then to the [Medicare Benefit Policy Manual](#), section 16.20, for services considered not reasonable and necessary.

Scope

All in and out of network programs where utilization review determinations are rendered. This policy also serves as a resource for peer-to-peer interactions in describing the position of Optum on the reporting of the minimally invasive lumbar decompression procedure using the mild® Device Kit.

Background Information

Chronic low back pain (cLBP) is a major source of morbidity and healthcare expenditure in the United States, with lumbar spinal stenosis (LSS) representing a common degenerative cause. LSS, which impacts over 200,000 Americans and is most common in adults aged 50-60, results from narrowing of the spinal canal or foraminal spaces due to factors such as disc protrusion, facet degeneration, spondylolisthesis, osteophyte formation, or—most commonly—hypertrophic ligamentum flavum. This narrowing can compress neural structures and lead to pain, limited mobility, and neurogenic claudication, characterized by activity-related leg or gluteal symptoms relieved by sitting or flexion. Initial treatment typically includes physical therapy, exercise, and analgesic medications, though these approaches may offer limited long-term relief for some individuals. Interventional options such as epidural steroid injections can provide short-term benefit but may be less effective in patients with neurogenic claudication, leading some to pursue more invasive surgical decompression, which carries higher complication risks. Minimally invasive lumbar decompression (MILD) has emerged as an alternative aimed at enlarging the spinal canal and alleviating nerve compression. (Orhurhu et al., 2025).

The minimally invasive lumbar decompression procedure using the mild® device kit is an FDA-cleared minimally invasive treatment option that addresses a major root cause of lumbar spinal stenosis (LSS). The procedure treats LSS in lumbar levels L5-S1 by removing excess, thickened ligament tissue to restore space in the spinal canal and reduce the pressure on the spinal nerves. (U.S. Food and Drug Administration, 2024; Vertos Medical, Inc., 2024).

Clinical Evidence

The systematic review of 15 randomized and prospective trials by Orhurhu et al. (2025) found that MILD consistently produced statistically significant reductions in pain across all included studies, with 64.3% of trials achieving clinically significant pain improvement (≥ 3 -point decrease on 0–10 scales) and the remaining studies still showing statistically significant reductions, though three fell just short of the 3-point threshold at 2.9 points. Functional outcomes showed similarly strong results, with 84.6% of studies demonstrating clinically significant Oswestry Disability Index improvements, and all but one reporting statistically significant gains in mobility and disability reduction. Safety findings were favorable, with most studies reporting no major adverse events, although the authors noted adverse-event data were inconsistent and likely underreported. Major limitations included the lack of double-blind randomized controlled trials, variable definitions of clinical significance, heterogeneous outcome reporting, and overlapping study populations that prevented meta-analysis. The authors concluded that MILD is a safe, effective, and statistically validated minimally invasive treatment for lumbar spinal stenosis, with benefits lasting up to two years. Further research including larger blinded RCTs, standardized adverse-event and

outcome reporting, and long-term evaluations of restenosis risk and population-specific effectiveness is needed.

A systematic review and meta-analysis conducted by Zhang et al. (2025) evaluated 12 clinical trials involving 500 patients to determine the effectiveness and safety of the Minimally Invasive Lumbar Decompression (MILD) procedure for lumbar spinal stenosis caused by ligamentum flavum (LF) hypertrophy. Across studies, MILD produced significant and sustained improvements in pain (Visual Analog Scale (VAS) reduction of ~3 points) and function (Oswestry Disability Index (ODI) reduction of 12–15 points) at all follow-up intervals, including beyond one year, with low reported complication rates (8.2% overall, mostly minor soreness). Results showed consistent clinical improvement for patients with stenosis from LF hypertrophy. However, the evidence is limited by non-standardized conservative treatment protocols, variation in study inclusion/exclusion criteria, and reliance on subjective outcome tools (VAS, ODI) prone to bias. Additionally, some included studies were retrospective, and clinical heterogeneity may influence results. Overall, the review concludes that MILD is an effective, durable, and safe decompression option, particularly for patients with stenosis due primarily to ligamentum flavum hypertrophy, though larger, standardized, prospective trials are needed to strengthen these findings.

A Health Technology Assessment completed by Hayes (2025) reports that percutaneous image-guided lumbar decompression (PILD) using the Vertos minimally invasive lumbar decompression (mild®) device kit offers statistically and clinically significant short- to intermediate-term improvements in pain, disability, physical function, and symptom severity for adults with lumbar spinal stenosis due to ligamentum flavum hypertrophy. Patients had mean improvements in pain of 25–49% and disability of 17.7–55%, sustained up to two years, and with low complication rates and no treatment-related mortality. Comparative findings indicate the procedure outperforms epidural steroid injections (ESI) and conventional medical management (CMM) on most clinical outcomes, though PILD shows higher surgical reintervention rates than outpatient laminectomy and mixed results compared with interspinous spacer devices (ISDs). However, the evidence base is limited by overall low study quality, with most studies being retrospective, nonrandomized, small in sample size, unblinded, short in follow-up, and often industry-funded. Outcome reporting is inconsistent, and generalizability is limited due to underrepresentation of younger and diverse populations. The report concludes that while PILD via mild® is likely safe and beneficial in the short to intermediate term, its long-term durability and comparative effectiveness remain uncertain, and definitive patient-selection criteria are not yet established. Future research needs include well-powered, blinded randomized controlled trials, studies with long-term outcomes, standardized reporting, independent funding, cost-effectiveness analyses, and development of validated patient-selection criteria to clarify which patients are most likely to benefit. (Hayes, 2025).

The MOTION Study (NCT03610737) is a Level-1, prospective, multicenter randomized controlled trial evaluating the mild® (minimally invasive lumbar decompression) procedure combined with conventional medical management (CMM) versus CMM alone for patients with lumbar spinal stenosis and neurogenic claudication due to hypertrophic ligamentum flavum. At 1-year follow-up (n=69 per group), the mild+CMM group demonstrated significantly superior improvements across all primary and secondary outcomes, including a 258% increase in walking tolerance versus 64% with CMM alone, greater reductions in disability (Oswestry Disability Index), pain (Numerical Pain Rating Scale), and symptom severity (Zurich Claudication Questionnaire), and far fewer subsequent lumbar interventions (5.8% vs 26.1%). No device- or procedure-related adverse events occurred, reaffirming the mild procedure's strong safety profile. Study limitations include the non-blinded design, broad variability in CMM regimens determined by investigators, and capped walking-test duration, which may underestimate maximal functional gains. The findings support mild+CMM as a safe, effective, and durable first-line therapy for this patient population. (Deer et al., 2022).

A retrospective cohort study by Mekhail et al. (2021) followed 75 patients (mean age 74.4 ± 9 years) with lumbar spinal stenosis who underwent the minimally invasive lumbar decompression (MILD) procedure to evaluate its durability over five years. Only 12% of patients required subsequent open decompression, reflecting a low annual surgery rate of 2.4%. The procedure produced significant reductions in pain at 3, 6, and 12 months, along with meaningful decreases in opioid use, and postoperative issues were limited to minor complications such as soreness and ecchymosis. Study limitations included its retrospective

design, missing follow-up data for some patients, potential unmeasured confounders, and restricted reporting of pain and opioid outcomes to the first 12 months due to follow-up attrition. Overall, these findings suggest that the mild® procedure offers durable symptom relief and allows most older adults to avoid open lumbar decompression while maintaining clinically significant improvement for at least five years.

The ECRI Evidence Analysis finds that the mild® Device Kit—a minimally invasive lumbar decompression mild® tool for treating lumbar spinal stenosis—consistently improves pain and physical function up to one year, supported by two systematic reviews, one randomized controlled trial, and two retrospective comparative studies. Evidence suggests mild® may be as effective as laminectomy but with fewer complications, and superior to epidural steroid injections in both pain and functional outcomes; however, these conclusions are limited by generally low-quality evidence, high risk of bias, small sample sizes, lack of blinding, and few long-term (>5-year) data. Safety findings indicate very low rates of device- or procedure-related complications, with only one MAUDE injury report (epidural hematoma) in the prior year, and no major complications in reviewed studies. Overall, mild® appears safe and beneficial in the short term, but higher-quality randomized trials and long-term follow-up are needed to confirm its comparative effectiveness and define its role in the treatment pathway. (ECRI, 2021).

Coding Information

Note: The Current Procedural Terminology (CPT) codes (2026) listed in this policy may not be all inclusive and are for reference purposes only. The listing of a service code in this policy does not imply that the service described by the code is a covered or non-covered health service. Coverage is determined by the member's benefit document.

Code	Description
62330	Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (i.e., CT or fluoroscopy), bilateral; one interspace, lumbar
62331	Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (i.e., CT or fluoroscopy), bilateral; additional interspace(s), lumbar (List separately in addition to code for primary procedure)

CPT® is a registered trademark of the American Medical Association

References

American Medical Association. (2025). CPT 2026 Professional Edition. American Medical Association Press.

Centers for Medicare and Medicaid Services. (2025, June 18). Medicare benefit policy manual chapter 16: General exclusions from coverage. Rev. 13272. Retrieved January 8, 2026, from: <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c16.pdf#page=3&zoom=100,117,816>

Deer, T. R., Costandi, S. J., Washabaugh, E., et al. (2022). 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 medicine (Malden, Mass.)*, 23(4), 625–634. <https://doi.org/10.1093/pm/pnac028>

ECRI Institute (2021, June 21). Evidence Analysis: mild Device Kit (Vertos Medical, Inc.) for treating lumbar spinal stenosis. Retrieved January 8, 2026, from <https://members.ecri.org/evidenceanalysis/mild-device-kit-vertos-medical-inc-for-treating-lumbar-spinal-stenosis>

Hayes, Inc. (2025, May 13). Health Technology Assessment: Percutaneous image-guided lumbar decompression via mild Procedure (Vertos Medical Inc.) for lumbar spinal stenosis. Retrieved January 8, 2026, from <https://evidence.hayesinc.com/report/htb.minimally1986>

Mekhail, N., Costandi, S., Nageeb, G., et al. (2021). The Durability of Minimally Invasive Lumbar Decompression Procedure in Patients with Symptomatic Lumbar Spinal Stenosis: Long-term Follow-up. *Pain Practice: The Official Journal of World Institute of Pain*, 21(8), 826–835. <https://doi.org/10.1111/papr.13020>

Orhurhu, V., Brancolini, S., Zheng, D., et al. (2025). Minimally Invasive Lumbar Decompression (MILD) in Patients with Lumbar Spinal Stenosis: A Systematic Review of Randomized and Prospective Trials. *Journal of Pain Research*, 18, 3527–3540. <https://doi.org/10.2147/JPR.S521038>

U.S. Food and Drug Administration (2024, May 6). Vertos Medical mild Device Kit Modification Premarket Notification. Section 5: 510(k) Summary. Retrieved January 8, 2026, from <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K233800>

Vertos Medical, Inc. (2024). Healthcare Professionals. Retrieved January 21, 2026, from <https://www.vertosmed.com/healthcare-professionals/>

Zhang, X. Y., Zhao, J. L., Wang, Y. J., et al. (2025). The Efficacy of the Minimally Invasive Lumbar Decompression (MILD®) Procedure: A PRISMA-compliant Systemic Review and Meta-analysis. *Pain Physician*, 28(2), 71–81.

Review and Approval History

Date	Description
02/02/2026	Approved by Optum UM Quality Oversight Committee (QOC).
02/10/2026	Optum Clinical Guideline Advisory Committee advised of new policy.
