CLINICAL MEDICAL POLICY	
Policy Name:	Minimally Invasive Lumbar Decompression (MILD)
Policy Number:	MP-103-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	07/01/2025; 09/01/2024; 02/01/2023; 01/21/2022; 02/13/2021; 02/17/2020
Effective Date:	08/01/2025; 10/01/2024; 03/01/2023; 02/21/2022; 03/15/2021; 03/16/2020
Next Annual Review:	05/2026
Revision Date:	05/21/2025; 12/20/2023; 12/21/2022; 12/15/2021; 12/16/2020
Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
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Policy History

Date	Activity
08/01/2025	Provider Effective date
06/13/2025	PARP Approval
05/21/2025	QI/UM Committee review
05/21/2025	Annual Review: No change to E/I status. Updated 'Summary of Literature' and 'Reference Sources' sections.
10/01/2024	Provider Effective date
01/29/2024	PARP Approval
12/20/2023	QI/UM Committee review
12/20/2023	Annual Review: No changes to E/I stance. Updated 'Summary of Literature' and 'Reference Sources' sections.
03/01/2023	Provider Effective date
01/10/2023	PARP Approval
12/21/2022	QI/UM Committee review
12/21/2022	Annual Review: No changes to clinical stance. Updated 'Summary of Literature' and 'Reference Sources' sections.
08/20/2019	Initial policy developed

Disclaimer

Highmark Wholecare℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare℠ does not provide coverage under the medical-surgical benefits of the Company's Medicaid products for the minimally invasive lumbar decompression (MILD) procedure.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Prior Authorization Review Panel (PARP) - A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Lumbar Spinal Stenosis (LSS) - A common degenerative disease where the dural sac and nerve roots are compressed by a combination of degenerative features including bulging of the intervertebral discs, hypertrophy of the facet joints, and thickening of the ligamentum flavum. The space within the spinal canal narrows, leading to asymptomatic compression of the nerves and ultimately symptomatic neurogenic claudication.

Minimally Invasive Lumbar Decompression (MILD) - A minimally invasive, image-guided, posterior spinal procedure, also referred to as percutaneous image-guided lumbar decompression (PLID), that increases the dimensions of the spinal canal by achieving nerve decompression via debulking the hypertrophied ligamentum flavum or small amounts of the lamina.

Open Decompressive Laminectomy - A surgical procedure that removes the entire vertebral bone called the lamina, which is the roof of the spinal canal.

Open Decompressive Laminotomy - A surgical procedure that removes a small portion of the lamina and ligaments, usually on one side. Using this method, the natural support of the lamina is left in place, decreasing the chance of spinal instability.

Interspinous Spacer Implantation - An implantation of a minimally invasive implant that sits between two interspinous processes in the lower spine. The spacer increases height between the processes, relieving the symptoms of spinal stenosis.

Mild® Medical Device and Tool Kit - A sterile, single-use system of surgical instruments manufactured by Vertos Medical Inc. The device offers an outpatient, minimally invasive, fluoroscopically guided treatment for lumbar spinal stenosis (LSS).

Procedures

1. Minimally invasive lumbar/spinal decompression (MILD), and devices such as the *mild®* Device Kit, are considered experimental and investigational and therefore, are not medically necessary.

2. Post-payment Audit Statement
   The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

3. Place of Service
   The proper place of service for the MILD procedure is outpatient.

Governing Bodies Approval

The Vertos Medical *mild®* Device Kit was approved by the Food and Drug Administration Act (FDA) in December 2006 through the 510k process as a set of specialized surgical instruments intended to be used to perform lumbar decompressive procedures for the treatment of various spinal conditions.

CMS
The Centers for Medicare and Medicaid Services (CMS) has published the following guidance:

- National Coverage Determination (NCD) Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis (150.13)

The Pennsylvania Department of Human Services Technology Assessment Group (TAG) workgroup meets quarterly to discuss issues revolving around new technologies and technologies or services that were previously considered to be a program exception. During this meeting, decisions are made as to whether or not certain technologies will be covered and how they will be covered. TAG's decisions are as follow:

- Option #1: Approved - Will be added to the Fee Schedule
- Option #2: Approved as Medically Effective - Will require Program Exception
- Option #3: Approved with (or denied due to) Limited/Minimal Evidence of Effectiveness - Will require Program Exception
- Option #4: Denied - Experimental/Investigational

As of November 2021, the TAG workgroup assigned laminotomy/laminectomy (interlaminar approach) for decompression of neural elements an Option # 4, specifically for CPT code 0275T.

Summary of Literature

Spinal stenosis affects more than 200,000 adults in the United States and is a source of substantial pain and disability. There are several types of spinal stenosis, with the type depending on the location of the condition. Lumbar spinal stenosis (LSS) is a narrowing that occurs in the lumbar, i.e., lower back, area, and it is the most common form of spinal stenosis. In most cases, LSS is caused by arthritis and most commonly affects adults over the age of 40 years old. LSS has several symptoms, including back pain, burning pain in the legs or buttocks, numbness and/or tingling, weakness in legs, bowel or bladder dysfunction, and loss of coordination. (Mayo Clinic, 2019).

Stenosis does not always present with typical complaints on examination because the same symptoms may occur in a wide variety of disorders (Boden, 1996). LSS must be correctly diagnosed with an algorithm of confirmed diagnostic imaging studies, a thorough history, and a physical exam. Nonoperative conservative management is indicated if there is not a thorough definitive diagnosis with the algorithm to avoid inappropriate surgical treatment. In other clinical research, a group of experts reached a consensus which indicated a lack of a "gold standard" for the diagnosis and treatment of stenosis because of the variable signs and symptoms, physicians' history-taking and physical methods, and diagnostic tests (Sandella et al. 2013).

Minimally invasive lumbar decompression (MILD) is a percutaneous procedure that treats LSS by removing small but adequate portions of the interlaminar bone (laminotomy) and partial excision (debulking) of the ligamentum flavum (LF) to restore space in the spinal canal while minimizing trauma to the surrounding tissue and bony structure. In the procedure, a *mild®* Device Kit may be used, which contains a specialized cannula and surgical tools. The *mild®* Device Kit is used under fluoroscopic guidance for bone and tissue sculpting near the spinal canal. The procedure and device kit function as a minimally invasive alternative to conservative treatment or open/endoscopic lumbar decompression (Dallas Neurosurgical & Spine Associates). Before surgical treatment is used, there are more conservative treatments, including medication, physical therapy, or epidural injections (Mekhail et al. 2012). If the conservative treatments have failed, the following open/endoscopic surgical procedures are recommended:

- Open decompressive laminectomy is the classic surgical treatment for LSS; it creates space by totally removing the lamina – the back part of a vertebra that covers the spinal canal (Malik, 2014). In other words, the procedure enlarges the spinal canal to relieve pressure on the spinal cord or nerves (Mayo Clinic). Although a laminectomy may cause spinal instability, other surgical techniques involving minimal decompression are subject to higher rates of restenosis (recurrence of stenosis).
- Open decompressive laminotomy functions, in part, the same way a laminectomy functions. The only difference is that the laminotomy is a partial removal of the lamina.
- Micro-endoscopic laminectomy and Micro-endoscopic laminotomy are two types of minimally invasive spinal surgeries. The two procedures have several benefits, including smaller incisions, shorter operative time, lower operative complication rate, and less blood loss (Polikandriotis, 2013).
- Interspinous spacer implantation is a minimally invasive procedure that offers patients with LSS distinct advantages. There are several FDA-approved interspinous spacers, including Vertiflex® and X-STOP®.

Many of the MILD determinations have been concluded based on trials and studies. There were two randomized controlled trials (RCT) that compared the MILD procedure and *mild®* Device Kit with epidural

steroid injection (ESI) and identified the benefits of the *mild®* procedure of ESI; however, with only two eligible studies, the consistency of these results cannot be determined.

- MIDAS ENCORE: Staats et al. (2016) reported the six-month results of a RCT comparing the treatment outcomes of the MILD procedure (n=149) and ESI (n=153) for LSS. At six months, all primary and secondary efficacy proportion results provided statistically significant evidence that MILD is superior to the active control of ESI. The authors are continuing to obtain outcomes extending to two years post procedure. Limitations of the study noted by the authors included lack of blinding and the possibility of a higher non-responder rate vs. standard of care in both groups due to restrictions of the study for use of adjunctive therapies.
- Brown (2012) conducted a double-blind randomized study of ESI vs. the *mild®* procedure in patients with symptomatic LSS (n=38). It included patients who had painful lower limb neurogenic claudication, with hypertrophic ligamentum flavum as a contributing factor, and had failed conservative treatment. At six weeks, 17 of 21 patients in the ESI group crossed over to the *mild®* procedure. Comparative 12-week outcome data were therefore not available. It is difficult to draw conclusions from this study due to the small number of participants and lack of data on long-term outcomes. In addition, patients in the ESI group were treated with a single interlaminar injection, which is generally not typical of ESI treatment.

A study conducted in 2014 examined the literature that may support the use of the MILD procedure to reduce pain and improve function in patients with symptomatic degenerative LSS. The study was designed as an evidence-based review of available data. Studies were identified from PubMed, Embase, and the Cochrane Library. Articles were evaluated using the Grading of Recommendations Assessment, Development and Evaluation Working Group system. Results were compiled assessing short- (4-6 weeks), medium- (3-6 months), and long-term (>1 year) outcomes. The literature search revealed one RCT and 12 other studies (seven prospective cohort, four retrospective, and one case series) that provided information on the use of MILD in patients with degenerative LSS. Categorical data were not provided; thus, the proportion of patients who experienced minimal clinically meaningful outcomes is unknown. The current body of evidence addressing MILD is of low quality. High-quality studies that are independent of industry funding and provide categorical data are needed to clarify the proportions of patients who benefit from MILD and the degree to which these patients benefit. Additional data at up to 2 years are needed to determine the overall utility of the procedure (Kreiner et al., 2014).

Coding Requirements

Non-covered Procedure Code

These procedure codes will not be reimbursed without Medical Director approval.

CPT 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

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

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