KAISER PERMANENTE®

Kaiser Foundation Health Plan of Washington

Clinical Review Criteria

Minimally Invasive Lumbar Decompression (MILD)

also known as Percutaneous image-guided lumbar decompression (PILD)

Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	Percutaneous image-guided lumbar decompression (PILD) for lumbar spinal stenosis (150.13)
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	Decision Memo for PERCUTANEOUS IMAGE-GUIDED LUMBAR DECOMPRESSION for Lumbar Spinal Stenosis (CAG-00433R) ***PILD procedure is non-covered when furnished outside of a CMS approved CED study***

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Lumbar spinal stenosis (LSS) is one of the most common degenerative diseases of the lumbar spine, and the most common indication for spinal surgery in elderly patients. LSS is a condition 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. In LSS the space within the spinal canal narrows leading to asymptomatic compression of the nerves and ultimately symptomatic neurogenic claudication, which is described as pain, paresthesia, weakness or heaviness radiating to lower extremities that occurs with walking or prolonged standing. The severity of these symptoms varies widely among patients, and may be disabling in some (Deer 2011, Brown 2012, Popov 2012, Wong 2012).

Conservative therapies for LSS include rest, pain medication, and physical therapy with or without epidural steroid injections. If these therapies fail, the patient may be advanced to more invasive surgical procedures. The goal of any surgical treatment of LSS is the relief of symptoms by adequate neural decompression while preserving as

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much of the anatomy, stability, and biomechanics of the lumbar spine as possible. Until the last decade, open spinal surgery was the standard treatment of LSS. The traditional surgical approach involves performing a wide, bilateral decompression laminectomy and resection of the medial portion of the facet joints to decompress the affected neural elements. This can successfully alleviate nerve compression symptoms but has the drawback of the open approach including the amount of soft tissue dissection, blood loss, postoperative pain, muscular atrophy, and potential for iatrogenic instability of the spinal segment (Popov 2012).

A number of less-invasive surgical techniques have been developed in recent years as an alternative to the traditional spine surgeries to limit the injury to the patient's native anatomy and reduce complication rates. These procedures are particularly attractive to spine surgeons for their small-skin incision, minimization of soft tissue injury, reduction of blood loss, infection rates, hospitalization time, narcotic usage, and minimization of physiological stress on the patient. Minimally invasive lumbar decompression techniques include the unilateral lumbar laminotomy for bilateral decompression, micro-endoscopic decompressive laminectomy, and lumbar micro-decompression (Deer 2010, Payer 2011, Smith 2012).

The *mild* ® (Minimally Invasive Lumbar Decompression) procedure (Vertos Medical Inc., Aliso Viejo, California) is a minimally invasive alternative to open or endoscopic lumbar decompression in the treatment of lumbar spinal stenosis. *Mild* ® 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. The procedure is typically performed under intravenous sedation monitored anesthesia and fluoroscopic guidance. The *mild* ® device kit is comprised of a single-use 6 gauge (5.1 mm diameter) *mild*® portal cannula with trocar to access into the soft tissue of the posterior lumbar spine, followed by a Bone Sculptor Ronguer which is used to precisely sculpt small pieces of lamina prior to tissue resection of the hypertrophic ligamentum flavum, then the *mild*® Tissue Sculpture is used to remove ligamentous and fibrous tissues from the hypertrophic ligamentum flavum (Deer 2010, 2011, Wong 2012).

The Vertos Medical *mild* ® Device Kit was FDA approved 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 (FDA website accessed June 26, 2012).

Medical Technology Assessment Committee (MTAC)

Minimally Invasive Lumbar Decompression

08/20/2012: MTAC REVIEW

Evidence Conclusion: There is insufficient published evidence to determine that *mild* ® Vertos procedure leads to similar or better outcomes than traditional surgery among in patients with symptomatic spinal stenosis who failed conservative therapy. There is limited published literature on the procedure. No published randomized controlled trials compared the procedure to the traditional surgical approach, or to other less invasive surgical techniques. The only published RCT to date was a small study that compared the outcomes of *mild* ® procedure to epidural steroid injection (ESI) in patients with symptomatic spinal stenosis and painful lower limb neurogenic claudication. The authors indicated that patients had to fail conservative therapy to be included in the trial, yet the procedure was compared to epidural steroid injection (ESI), which is considered a conservative management. In addition, the epidural steroid was delivered through interlaminar injections and not the preferable transforaminal route to maintain blinding (according to the author). The other published studies were prospective or retrospective case series with potential biases and were all funded by Vertos Medical the manufacturer of *mild*® *device*.
Articles: The literature search revealed one small RCT that compared the *mild*® procedure with epidural steroid injection, two multicenter observational studies with no control group, and few small prospective and retrospective case series. The RCT and the prospective multicenter observational study with one-year follow-up were selected for critical appraisal: Brown LL. A double-blind, randomized, prospective study of epidural steroid injection vs. the *mild* ® procedure in patients with symptomatic lumbar spinal stenosis. *Pain Practice*. 2012; 12:333-341. See Evidence Table. Mekhail N, Vallejo R, Coleman MH, et al. Long-term results of percutaneous lumbar decompression *mild* ® for spinal stenosis. *Pain Practice*.2012;12:184-193. See Evidence Table.

The use of minimally invasive lumbar decompression for treatment of spinal stenosis does not meet the *Kaiser Permanente Medical Technology Assessment Criteria.*

mild® Procedure for Lumbar Spinal Stenosis
June 2023: MTAT REVIEW
Evidence Conclusion: The Interregional New Technologies Committee (INTC) reviewed the evidence assessment provided by TPMG New Medical Technology on June 30, 2023. The assessment concluded: There is

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insufficient evidence regarding the efficacy and safety of the mild® procedure by Vertos Medical, Inc. (mild®) for lumbar spinal stenosis (LSS), compared with treatment alternatives. The certainty of the body of evidence is low, given the limitations of the available studies. Rationale: Two randomized controlled trials (RCTs), one retrospective comparative study, and three clinical series – with a total of 757 patients – suggest that mild® is efficacious and safe for treating LSS and achieves greater improvement in pain and function compared with no mild® and epidural steroid injection (ESI). However, the certainty of this body of evidence is low, given notable limitations across studies. Overall, INTC members and guests agreed with the assessment and low-certainty evidence conclusion by TPMG New Medical Technology. A low-certainty evidence rating does not preclude (1) use of mild® in select patients – for instance, those who are not surgical candidates or who refuse surgery or (2) its deployment into PMG clinical practice. The INTC discussion with clinical expert input noted MAPMG and TPMG use mild® for select patients and report good results. A pilot study conducted by SCPMG found mild® more difficult to complete than anticipated, requiring longer operating rooms times than expected and longer radiation exposure with fluoroscopy, and challenging to judge if its outcomes were superior to other modalities. The INTC noted the potential benefit of collecting additional data on the use of mild® within KP.

Interregional New Technologies Committee

MILD PROCEDURE FOR LUMBAR SPINAL STENOSIS

INTC Review: June 30, 2023

Evidence Conclusion:

There is insufficient evidence regarding the efficacy and safety of the mild® procedure by Vertos Medical, Inc. (MILD) for lumbar spinal stenosis (LSS), compared with treatment alternatives. The certainty of the body of evidence is low, given limitations of the available studies. Additional details on the studies can be found in the TPMG New Medical Technology assessment report.

Applicable Codes

Medicare - Considered Medically Necessary when criteria in the applicable policy statements listed above are met

Non-Medicare - Considered Not Medically Necessary

CPT® Codes	Description
62287	Decompression procedure, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle-based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar
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

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

****To verify authorization requirements for a specific code by plan type, please use the **Pre-authorization Code Check**. 2023

Creation Date	Review Dates	Date Last Revised
09/04/2012	09/04/2012[MPC], 10/02/2012[MPC], 08/06/2013[MPC], 06/03/2014[MPC], 04/07/2015[MPC], 02/02/2016[MPC], 12/06/2016[MPC], 10/03/2017[MPC], 09/04/2018[MPC], 09/03/2019[MPC], 09/01/2020[MPC], 09/07/2021[MPC], 09/06/2022[MPC], 09/05/2023[MPC], 06/04/2024[MPC], 06/03/2025[MPC]	12/19/2024

[MPC] Medical Policy Committee

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Revision History	Description
09/01/2020	Removed CPT code 0274T
06/15/2022	Added 62287 CPT code (per neurosurgery consultation this is more accurate than 62380); 62380 will no longer require review after 11/1/2022
11/20/2023	Added June 2023 MTAT Review for mild® Procedure for Lumbar Spinal Stenosis
12/19/2024	Updated applicable code

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