Clinical Review Criteria
Minimally Invasive Lumbar Decompression

NOTICE: Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc., provide these Clinical Review Criteria for internal use by their members and health care providers. The Clinical Review Criteria only apply to Kaiser Foundation Health Plan of Washington and Kaiser Foundation Health Plan of Washington Options, Inc. Use of the Clinical Review Criteria or any Kaiser Permanente entity name, logo, trade name, trademark, or service mark for marketing or publicity purposes, including on any website, or in any press release or promotional material, is strictly prohibited.

Kaiser Permanente Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Kaiser Permanente reserves the exclusive right to modify, revoke, suspend or change any or all of these Review Criteria, at Kaiser Permanente’s sole discretion, at any time, with or without notice. Member contracts differ in their benefits. Always consult the patient’s Medical Coverage Agreement or call Kaiser Permanente Customer Service to determine coverage for a specific medical service.

Criteria
For Medicare Members

<table>
<thead>
<tr>
<th>Source</th>
<th>Policy</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMS Coverage Manuals</td>
<td>Percutaneous image-guided lumbar decompression (PILD) for lumbar spinal stenosis (150.13)</td>
</tr>
<tr>
<td>National Coverage Determinations (NCD)</td>
<td>None</td>
</tr>
<tr>
<td>Local Coverage Determinations (LCD)</td>
<td>None</td>
</tr>
<tr>
<td>Local Coverage Article</td>
<td>Decision Memo for PERCUTANEOUS IMAGE-GUIDED LUMBAR DECOMPRESSION for Lumbar Spinal Stenosis (CAG-00433R)</td>
</tr>
</tbody>
</table>

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.

The following information was used in the development of this document and is provided as background only. It 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 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 dissection, and lower rates of infection and blood loss.

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 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 Sculpter 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 ligmentous 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 transformainal 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.


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

<table>
<thead>
<tr>
<th>Creation Date</th>
<th>Review Dates</th>
<th>Date Last Revised</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/04/2012</td>
<td>09/04/2012MDCRPC, 10/02/2012MDCRPC, 08/06/2013MPC, 06/03/2014MPC, 04/07/2015MPC, 02/02/2016MPC, 12/06/2016MPC, 10/03/2017MPC</td>
<td>06/03/2014</td>
</tr>
</tbody>
</table>

MDCRPC Medical Director Clinical Review and Policy Committee
MPC Medical Policy Committee

<table>
<thead>
<tr>
<th>Revision History</th>
<th>Description</th>
</tr>
</thead>
</table>

Codes
CPT 0274T, 0275T, 62380