



INLAND EMPIRE HEALTH PLAN

**IEHP UM Subcommittee Approved Authorization Guidelines**  
***Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis (PILD), Including the Commercial Procedure Known as Minimally Invasive Lumbar Decompression (mild®-Vertos Medical)***

**Policy:**

Based on a review of the currently available literature, there is insufficient evidence to support PILD or *mild*® as reasonable and necessary procedures for the relief of the signs and symptoms of lumbar spinal stenosis. Therefore, the IEHP UM Subcommittee concurred to consider PILD or *mild*® a non-covered benefit.

**CMS: CAG-(00433N). October 17, 2013:**

**CMS proposes that PILD for LSS is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act. Therefore, CMS proposes that PILD for LSS is non-covered by Medicare.**

**Summary of CMS Findings Regarding PILD/*mild*®:**

CMS identified a number of studies related to the PILD procedure for LSS. The majority of studies were case series which have inherent limitations in providing a level of reliable evidence for benefit for a procedure, especially a procedure addressing pain. The case series for the PILD procedure suffered from additional limitations in failing to report information important for anyone to assess the clinical utility of this procedure for a particular patient. The one RCT had a small enrollment and major design flaws that called into question the results of the trial.

In reviewing the evidence of PILD we are confronted with weak studies, questions about missing information, questions about adverse events and conflicts of interest. After thoroughly reviewing the evidence for PILD for LSS, we determined the evidence does not support a conclusion of improved health outcomes for Medicare beneficiaries.

**CMS Analysis: Research Review and Summary:**

The following research review and summary is obtained from a CMS literature search on 5/3/13, which utilized PubMed for randomized controlled trials (RCT's) and nonrandomized controlled trials, cohort or other case-controlled studies, case series studies and systemic reviews for "Percutaneous image-guided lumbar decompression for lumbar spinal stenosis". Evidence for PILD for LSS comes from the *mild*® literature and includes one randomized study, seven case

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series, one meta-analysis and one systematic review. The studies evaluated by CMS are listed in the bibliography under the “Published Studies” section of reference number one.

The CMS review of the literature was intended to see if the following question could be answered regarding the PILD/ *mild*® procedure: ***Is the evidence sufficient to conclude that PILD improves health outcomes in Medicare beneficiaries with lumbar spinal stenosis?*** The answer to this question was: no. This decision was based on the following issues identified with the available literature that was reviewed:

1. **The reliance of the majority of the studies on case series rather than robust randomized sham-controlled clinical trials with explicit protocol driven criteria.**
2. **Concerns regarding the subjective nature of patient’s symptoms with regard to back pain and the failure to adequately account for the biases and confounding that arise from placebo effects and spontaneous symptom improvement in the natural history of the condition.**
3. **Questions regarding the safety profile of the procedures:**

Some studies reported serious adverse events including: refractory neurogenic claudication that required additional surgery, cerebrospinal leaks, dural tears, DVT, PE, and transected nerve roots requiring revision surgery.

4. **Concerns regarding research study bias:**

Much of the *mild*® evidence appears to have authorship or other relationships to the manufacturer. A number of the authors of these studies have had a financial relationship with Vertos Medical and the manufacturer provided funding for some of the studies. Shah’s retrospective review of articles published in the journal *Spine* identified, “industry supported studies had a greater frequency of positive results than studies with any other funding sources.” (Shah, Albert et al. 2005).

Per the review by CMS, no evidence-based guidelines on the use of PILD/ *mild*® were found.

### **ECRI Institute Opinion:**

Based on our review of 17 publications (15 reviewed as abstracts, 1 full-text article review, and 1 meeting conference abstract), the overall reported results suggest that the *mild* procedure is safe and provides symptom relief for up to 24 months compared with previous conservative therapy in a select group of patients. However, the reported results may not be reliable because the large majority of studies are observational (uncontrolled) and may reflect the natural waxing and waning of LSS symptoms. Also, studies differed in the diagnostic criteria used for LSS, which affects interpretation of results because patients in studies may have differences that affect the results. Some of the treatment effect may be a placebo effect or spontaneous recovery not related to treatment (regression to the mean). One study found the *mild* procedure to be ineffective and recurrence of neurogenic claudication to be 60%. According to the company website, no major adverse events associated with this procedure have been reported in clinical trials. However,

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MAUDE contains reports of at least two dural tears, one of which required open surgical repair. **One or more well-designed randomized controlled trials comparing the mild procedure to laminectomy or laminotomy are needed to determine the true treatment effect and to define the extent of LSS best treated by the mild procedure.** Anyone interested in using the mild procedure should also review the CMS decision and the concerns raised regarding this technology.

### **Anthem (2013):**

Anthem considers percutaneous or endoscopic surgical techniques, including image-guided minimally invasive lumbar decompression for Spinal Stenosis (*mild*®), to be investigational and not medically necessary.

### **Aetna (2013):**

Aetna considers minimally invasive lumbar decompression (MILD) procedure (percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements under indirect image guidance) for lumbar canal stenosis or other indications to be experimental and investigational.

### **Background:**

Procedure Description:

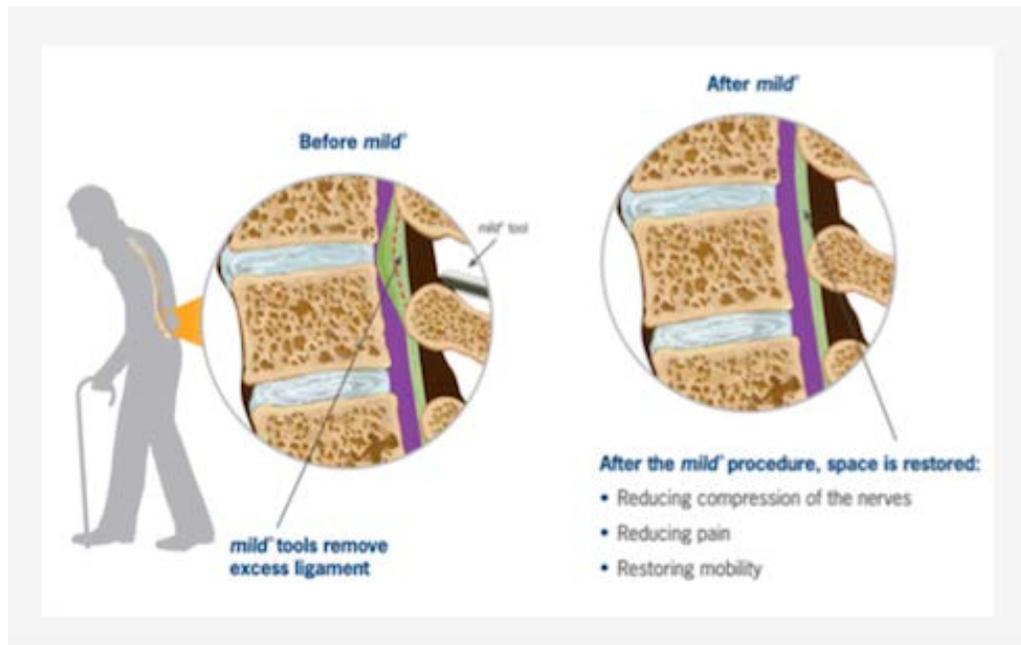
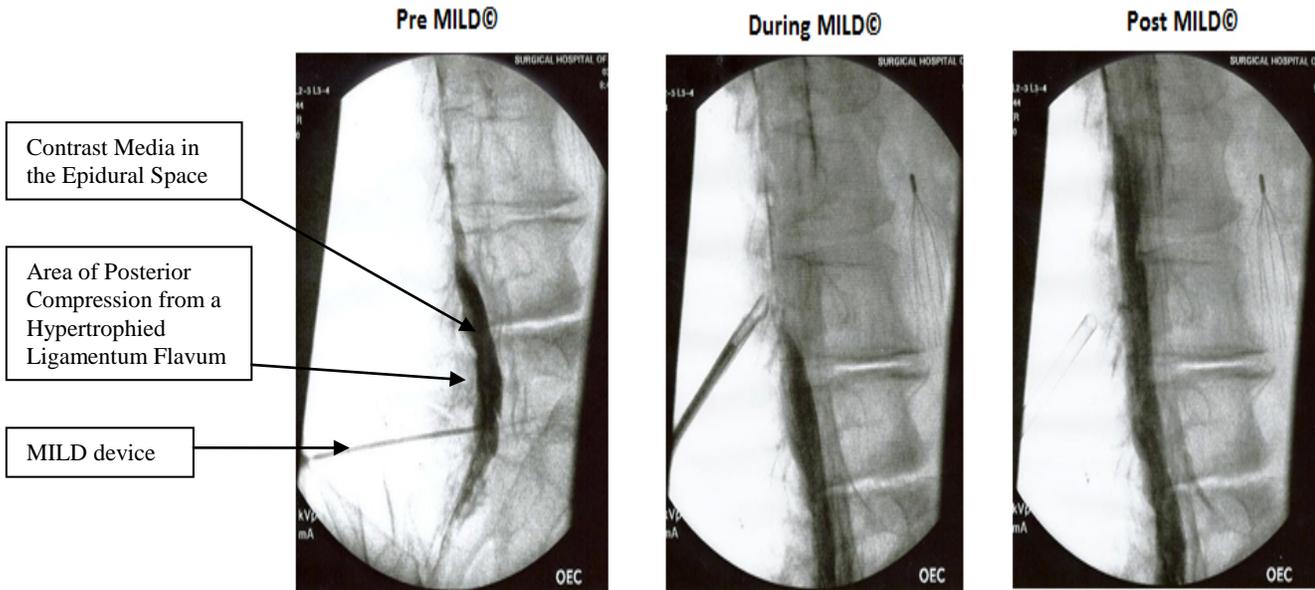
- Percutaneous image-guided lumbar decompression (PILD) describes a minimally invasive laminotomy/laminectomy procedure (using a posterior interlaminar approach) for decompression of the lumbar spine for a primary diagnosis of
- lumbar spinal stenosis (LSS) under indirect image guidance (eg. fluoroscopic, CT)
- with or without the use of an endoscope.
- PILD involves a posterior decompression of the lumbar spine under indirect image guidance without any direct visualization of the surgical area. The patient lies prone and the use of a cannula and trocar provide a portal that allows access to the anatomic area for instruments used for resection. Indirect visualization of the surgical area is achieved with the assistance of injection of contrast medium into the epidural space and fluoroscopic guidance (epidurography). This allows the surgeon to identify the compressed area and to subsequently remove small portions of the lamina and preferentially resect and debulk the thickened ligamentum flavum, thus accomplishing a lumbar decompression.
- This procedure does not involve a discectomy.
- The procedure can be performed on an outpatient basis under local anesthesia.
- The proprietary/commercial name for this procedure is *mild*®.

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- Note: PILD/mild® procedures do NOT describe endoscopically assisted laminotomy/laminectomy, which requires open and direct visualization.



<https://www.treatingpain.com/diagnosis-treatments/mild-procedure-for-lumbar-spinal-stenosis-lss>

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### **Purpose of the Procedure:**

The purpose of the PILD/*mild*® procedure is to remove portions of the posterior spinal elements that comprise the roof of the spinal canal (including the lamina and ligamentum flavum). This results in an increase in the critical diameter of the stenosed spinal canal. In theory, this decompression of the canal relieves pressure being exerted on the neural elements, thus improving the symptoms typically associated with lumbar spinal stenosis such as radiating pain, weakness and paresthesias (eg. numbness and tingling).

PILD/ *mild*® is proposed as a treatment for symptomatic LSS that is unresponsive to conservative (non-surgical) therapy such as: physical therapy, pharmacotherapy (NSAIDs, opiates, oral steroids), and epidural steroid injections.

LSS is the narrowing of the space around the spinal cord and the spinal nerve roots. The most common symptom of LSS is back pain with neurogenic claudication (i.e., pain, numbness, or weakness in the legs that worsens when standing or walking and is alleviated by sitting or leaning forward).

**Effective Date:** *November 13, 2013*

**Reviewed Annually:** *November 9, 2016*

<b>Revised:</b>

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