

American Society of Interventional Pain Physicians®

"The Voice of Interventional Pain Management"

81 Lakeview Drive, Paducah, KY 42001

Phone: (270) 554-9412 - Fax: (270) 554-5394

www.asipp.org

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Re: Coverage Consideration for the mild® Procedure for Lumbar Spinal Stenosis with Neurogenic Claudication

On behalf of the Board, 49 state societies of Interventional Pain Physicians, and membership of the American Society of Interventional Pain Physicians (ASIPP), we respectfully submit our support of the mild® Procedure for patients suffering from lumbar spinal stenosis (LSS) with associated neurogenic claudication (NC) and hypertrophic ligamentum flavum (HLF). This support is based on clinical evidence, FDA clearance, real-world outcomes, and broad utilization across interventional pain practices. We urge Elevance Health to adopt favorable coverage policies aligned with the evidence coinciding with newly approved Category I CPT® codes, effective January 1, 2026, to ensure equitable access to this safe, effective, and minimally invasive therapy.

Established in 1998, ASIPP is a non-profit professional organization that currently with membership of over 4,500 interventional pain physicians and other practitioners dedicated to Safe, Appropriate, Fiscally Neutral, Effective (SAFE) treatments in managing patients with chronic pain. Its mission is to promote safe, appropriate, fiscally neutral and effective pain management services for patients nationwide who grapple with chronic pain. The United States is home to approximately 8,500 proficient physicians with the requisite training and qualifications in interventional pain management. ASIPP is composed of 49 state societies of Interventional Pain Physicians, encompassing Puerto Rico, and includes the affiliated Texas Pain Society.

Lumbar Spinal Stenosis Overview

Lumbar spinal stenosis (LSS) is a condition in which there is a narrowing in the lumbar spine for neural and vascular structures. This is typically due to age-related degenerative changes in the spinal canal such as HLF, disc herniation, facet hypertrophy, and lateral recess/foraminal narrowing. This often manifests in symptoms which can profoundly affect a patient's quality of life (QoL), such as pain, tingling, numbness, and weakness in the legs and buttocks. Function can be greatly reduced in the LSS patient, able to walk only a couple hundred feet or stand for less than 10 minutes without experiencing pain (1). Standing and walking will often exacerbate the NC symptoms and forward flexion, sitting, or reliance on walking aids will typically provide relief.

The prevalence of LSS is reported to be as high as 8% of the general US population (2); however, in those 60 years of age or older, the prevalence is approximately 20% (3). A cross-sectional population-based cohort study utilizing data from the Framingham Heart Study found the prevalence of LSS to be 8.4%. Acquired LSS was found in 7.3% of patients, while congenital LSS is less common at a prevalence of 2.6% (3).

mild® Procedure Evidence Base

Lumbar spinal stenosis is one of the leading causes of disability in older adults and a major contributor to longitudinal healthcare expenditures. While conservative treatments are appropriate initial measures, many patients continue to experience disabling neurogenic claudication. Historically, these patients often proceed to open decompressive surgery—an intervention associated with significantly higher rates of complications, rehospitalization, and postoperative care utilization.

The MILD/PILD procedure offers a proven, low-risk, minimally invasive alternative that can reduce or eliminate the need for more invasive surgery. Its safety profile and cost-effectiveness have been extensively validated in the medical literature. To date, **dozens of peer-reviewed studies**, including **randomized controlled trials, multicenter prospective investigations, systematic reviews, and large Medicare claims analyses**, support the clinical effectiveness and safety of this procedure (4).

The ENCORE (5) and MOTION (6,7) studies—both high-quality, well-controlled prospective trials—demonstrate that MILD/PILD delivers durable improvements in pain, function, and mobility without the adverse events associated with open surgery. Importantly, both studies showed **no evidence of spinal instability**, an issue that often drives downstream utilization after laminectomy.

These findings are reinforced by Medicare claims data, including the Staats et al (8) analysis, which provides compelling real-world evidence highly relevant to insurer decision-making. Across tens of thousands of beneficiaries:

- The adverse event rate for MILD was **1.9%**, compared with **5.8%** for open laminectomy ($p < 0.0001$).
- Life-threatening complications—including myocardial infarction, pneumonia, and stroke—occurred at **twice the rate** in laminectomy patients.
- There were **no recorded spinal cord, nerve root, or dural injuries** in MILD patients.
- **Eighty-eight percent of MILD patients avoided open surgery** over five-year follow-up, representing substantial savings in surgical costs, postoperative care, and surgical complications.

These findings are not only clinically meaningful—they are financially significant. Reduced complication rates, avoidance of inpatient surgery, preservation of spinal stability, and minimal recovery time translate into lower total cost of care and reduced downstream utilization. For payers seeking value-based care, few spine interventions provide such compelling evidence of both safety and cost-effectiveness (9-11).

Given the weight of evidence, ASIPP recommends the MILD/PILD procedure as an appropriate, medically necessary, and cost-efficient treatment option for patients with lumbar spinal stenosis who have not achieved adequate relief from conservative management. ASIPP further supports its use as an intermediate step **prior to open decompressive surgery**, when clinically appropriate, in alignment with a stepwise, evidence-based treatment algorithm that prioritizes safety and resource stewardship.

For these reasons, ASIPP encourages continued—and where applicable, expanded—coverage of the MILD/PILD procedure. Ensuring patient access to this minimally invasive alternative promotes safer care, reduces complications, prevents unnecessary surgical escalation, and supports the delivery of high-value, evidence-based treatment for patients with lumbar spinal stenosis.

We appreciate your commitment to supporting safe, effective, and cost-responsible care, and we remain available to provide any additional data or clarification that may assist in coverage decisions.

Laxmaiah Manchikanti, MD

Chairman of the Board and Chief Executive Officer, ASIPP, SIPMS
Director, Pain Management Centers of America
Ambulatory Surgery Center and Pain Care Surgery Center
Clinical Professor
Anesthesiology and Perioperative Medicine
University of Louisville, KY
Professor of Anesthesiology-Research
Department of Anesthesiology, School of Medicine
LSU Health Sciences Center, Shreveport, LA
drcm@asipp.org

Mahendra Sanapati, MD

President, ASIPP
Vice-President, SIPMS
AMA CPT Advisory Committee
Director, Pain Management Centers of America
Evansville, IN
Assistant Professor of Anesthesiology, University of Louisville
Louisville, KY
msanapati@gmail.com; drs@apccweb.com

Annu Navani, MD

President-Elect, ASIPP
Chief Medical Officer, Boomerang Health Care
Walnut Creek, CA
Medical Director, Clinical Research and Applications, Le Reve Regenerative Wellness
Campbell, CA
Adjunct Clinical Associate Professor, Stanford University School of Medicine
Stanford, CA
annu@navani.net

Amol Soin, MD

Lifetime Director, ASIPP
President, SIPMS
CEO, Ohio Society of Interventional Pain Physicians
Medical Director, Ohio Pain Clinic
Clinical Assistant Professor of Surgery, Wright State University
Dayton, OH
drsoin@gmail.com;

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