New York Society of Interventional Pain Physicians

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June 26, 2026

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

Dear Medical Policy Leaders and Committee Members,

On behalf of the leadership and membership of the New York Society of Interventional Pain Physicians (NYSIPP), we respectfully submit this position statement in support of the mild® Procedure for patients with symptomatic lumbar spinal stenosis (LSS) with associated neurogenic claudication (NC) and hypertrophic ligamentum flavum (HLF). We strongly recommend payors adopt favorable coverage policies aligned with the newly approved Category I CPT® codes, effective January 1, 2026, to ensure equitable access to this minimally invasive therapy with a well-established safety and effectiveness profile. Our recommendation is grounded in a robust and ever-growing body of clinical evidence which includes level 1 randomized controlled trials (RCTs), real-world outcomes, and broad utilization across interventional pain practices. Through this letter, NYSIPP aims to provide evidence-based guidance to inform coverage decision-making and to advocate for timely access to appropriate care for a deserving patient population who stand to benefit from this therapy.

## LSS Overview

Lumbar spinal stenosis (LSS) is the narrowing of the spinal canal in the lower back, specifically in the lumbar region. Repeated spinal wear and tear can lead to degenerative changes in the spinal canal such as HLF, disc herniation, facet hypertrophy, and lateral recess/foraminal narrowing[1]. This can result in symptoms which may profoundly affect a patient's quality of life (QoL), such as severe pain, altered sensation, and weakness in the legs and buttocks. Standing and walking will often exacerbate the NC symptoms and forward flexion, sitting, or reliance on walking aids will typically provide relief. Untreated/improperly managed LSS puts patients at risk of developing several complications, including decreased mobility and function, limited exercise tolerance, muscle atrophy, depression and reduced quality of life[1].

While the lack of universal diagnostic criteria for LSS makes its exact prevalence difficult to determine, the condition is reported to affect more than 200,000 individuals in the US[1]. The radiological prevalence of moderate and severe stenosis in patients older than 40 years can be as high as 80% and 40%, respectively[1].

## mild® Procedure Overview

The mild procedure, sometimes referred to as percutaneous image-guided lumbar decompression (PILD), is an FDA-cleared, minimally invasive technique which aims to restore space in the spinal canal. This procedure is typically conducted on an outpatient basis, through an incision just 5.1mm wide[2].

The mild device kit contains specialized surgical instruments designed to access the interlaminar space from the posterior lumbar spine, enabling the user to remove small portions of the lamina and debulk the thickened ligamentum flavum under fluoroscopic guidance.

This procedure is implant free and typically does not require general anesthesia or stitches. Patients can generally be discharged within 24 hours[3].

**Patient Selection**

Procedure suitability is identified based on both clinical presentation and radiographic criteria to ensure treatment is targeted to those most likely to benefit. The following clinical and radiographic factors outline the typical patient profile considered for this intervention[4]:

- Symptomatic LSS (i.e., presence of neurogenic claudication).
- Confirmation of central canal stenosis on imaging.
- HLF measuring ≥2.5 mm.
- Without contraindications: Grade 3 or higher spondylolisthesis, signs of local inflammation or infection[4].

Multifactorial etiologies such as disc disease, facet hypertrophy, lateral recess/foraminal stenosis are not contraindicated as debulking the ligamentum flavum with mild has successfully treated LSS narrowing due to multiple etiologies in the clinical setting[3].

Clinical evidence supporting the mild procedure includes a wide range of patient ages, from 37 to 102 years[5,6], demonstrating its applicability across the adult population commonly impacted by LSS. Analysis of the evidence found that approximately 42% of mild publications include participants under 65 years old. This breadth of representation underscores the procedure's relevance to real-world clinical practice and coverage populations.

**Reimbursement**

New CPT Category I codes for the mild procedure have been approved and effective on January 1, 2026[7,8].

- **62330** Decompression, percutaneous, with partial removal of the ligamentum flavum, including laminotomy for access, epidurography, and imaging guidance (i.e., CT or fluoroscopy), bilateral; one interspace, lumbar
- **62331** additional interspace(s), lumbar (List separately in addition to code for primary procedure)

These codes replaced the Category III code (0275T)[9]. This transition reflects the procedure's established clinical utility, widespread adoption, and specialty society support. Category I status affirms that the procedure is no longer investigational and warrants standardized coverage and payment. We encourage payors to align coverage policies with this AMA determination to ensure timely and equitable access for eligible patients.

**mild® Clinical Evidence Overview: Peer-Reviewed Publications & Clinical Consensus Guidelines**

A growing body of clinical evidence, spanning prospective RCTs, case series, and real-world longitudinal studies, supports the safety, efficacy, and durability of mild. These studies utilize both objective outcome measures (e.g. validated walking tolerance tests [WTT]) as well as patient-reported outcome measures (PROMs), for example the Oswestry Disability Index (ODI), Numeric Pain Rating Scale (NPRS), and Zurich Claudication Questionnaire (ZCQ). These scales are widely validated PROMS used in LSS research to assess disability, pain, and disease-specific symptoms, respectively[10]. Together, these instruments provide a comprehensive framework for assessing patient outcomes in LSS research.

Below we provide a summary of key findings from published clinical literature that highlights how this body of evidence has informed current clinical guidelines.

MIDAS ENCORE RCT

The MIDAS ENCORE prospective, multicenter, RCT compared outcomes for 143 patients treated with mild versus 131 treated with epidural steroid injections (ESIs). Follow-up occurred at 6 months and at 1 year for the randomized phase and at 2 years for PILD subjects only[11,12,13]. ODI, NPRS, and ZCQ were used to evaluate function and pain. Safety was evaluated by assessing incidence of device-/procedure-related adverse events (AEs). All outcome measures demonstrated clinically meaningful and statistically significant improvement from baseline through 6-month, 1-year, and 2-year follow-ups[11,12,13]. There were no serious device-/procedure-related AEs, and 1.3% experienced a device-/procedure-related adverse event. The procedure showed excellent long-term durability, with no evidence of spinal instability through 2-year follow-up[13]. Given the minimally invasive nature of this procedure, its robust success rate, and durability of outcomes, the authors concluded that mild is an excellent choice for first-line therapy for select patients with central spinal stenosis suffering from NC with HLF[11,12,13].

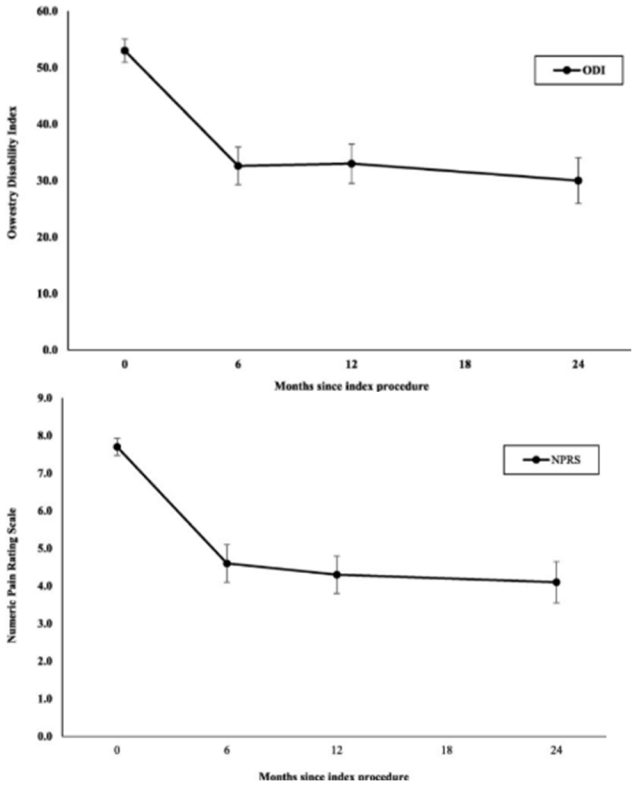



*Figure 1: ODI and NPRS mean improvement at all follow-up intervals were clinically meaningful and statistically significant (P < 0.001) using modified intent-to-treat statistical analysis method. The modified intent-to-treat analysis includes all observed data for each follow-up visit reported. Subjects who missed a given follow-up, or who withdrew prior to that follow-up, are not included in the analysis for that visit*[13]

MOTION RCT

The MOTION prospective, multicenter RCT compares the outcomes of mild in combination with conventional medical management (CMM) to the use of CMM alone for the treatment of LSS with NC secondary to HLF[3,14,15,16]. The study includes extended follow-up for patients in both the treatment group and for those who crossed over from the control group to the treatment group. The treatment group received mild in combination with nonsurgical CMM, while the active control group received CMM alone. There were no restrictions for either group regarding access to real-world CMM therapies. Patients reported outcomes using ODI, ZCQ, and NPRS. Objective outcomes were measured using a validated WTT, the incidence of subsequent lumbar spine interventions (SLSIs), and AEs[3,14,15,16]. Forty-eight patients initially receiving mild + CMM consented to extended follow-up and were available for 3-year follow-up. All outcomes for this group were significantly improved over baseline (p-values ranging from <0.0001 to 0.0001)[16]. WTT demonstrated 274 % improvement from baseline, and only 4 (5.6 %) patients had received SLSIs[16].

The recently published five-year follow-up results from the MOTION RCT further reinforce the long-term durability of the mild procedure. At five years, all primary and secondary outcome measures, including ODI, NPRS, and ZCQ, remained significantly improved compared to

baseline ($p < 0.0001$) [26], demonstrating sustained functional and symptomatic benefit over time. Objective outcomes also remained durable, with walking tolerance increasing by 387% from baseline[26]. The rate of subsequent lumbar spine interventions remained low, with only a small number of additional interventions observed between years 3 and 5. Importantly, no device- or procedure-related AEs were reported. These results demonstrate the safety and durability of the mild combined with CMM for early interventional treatment of symptomatic LSS. The absence of device or procedure-related AEs further underscores the robust safety profile of the procedure across an extended time horizon[26].

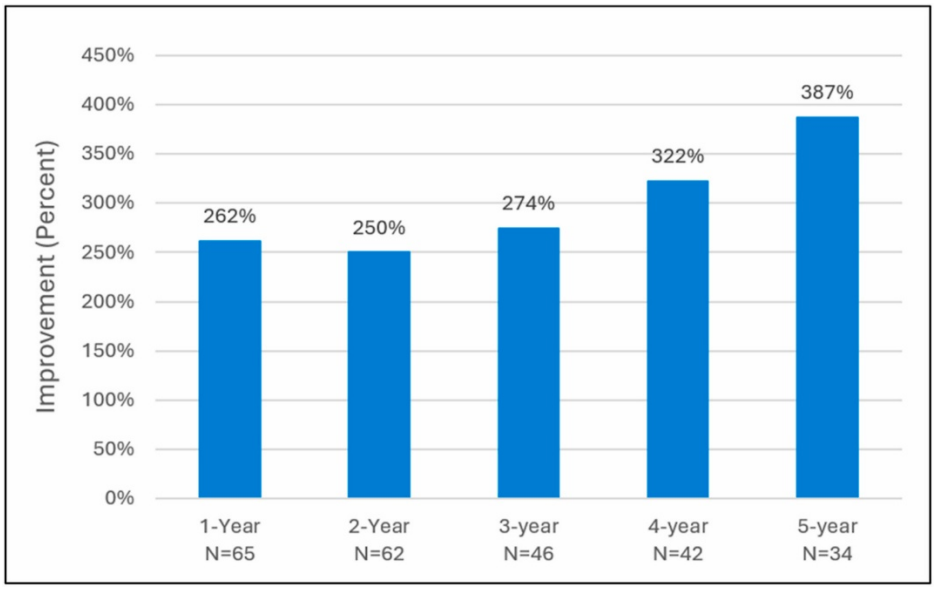



*Figure 2: 15-Minute Walking Tolerance Test (WTT) mean percent improvement for the mild + CMM group*[26]

Cleveland Clinic Prospective Case Series

A prospective case series conducted by the Cleveland clinic reported changes in functional abilities and pain for the first 40 consecutive LSS patients treated with mild[17]. Efficacy was evaluated using the Pain Disability Index (PDI) and Roland-Morris Disability Questionnaire (RMDQ). Pre- and post-procedure Standing Time, Walking Distance, and Visual Analog Score (VAS) were also monitored. Significant device- or procedure-related AEs were reported[17]. At 12 months, both PDI and RMDQ showed significant improvement of 22.6 points and 7.7 points (both $P<0.0001$), respectively. Walking Distance, Standing Time, and VAS improvements were also statistically significant, increasing from 246 to 3,956 feet, 8 to 56 mins, and 7.1 to 3.6 points (all $P<0.0001$), respectively[17]. No significant device- or procedure-related AEs were reported. This study demonstrated significant functional improvement as well as decreased disability secondary to NC after mild[17].

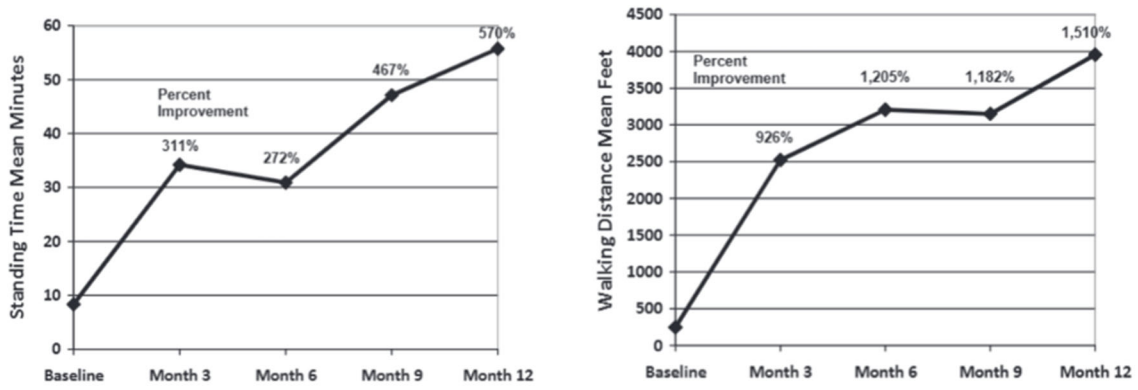



*Figure 3: Mean standing time and walking distance at each follow-up (N = 34)*[17]

Cleveland Clinic Retrospective Longitudinal Study

A retrospective longitudinal study conducted at the Cleveland Clinic examines the long-term durability of mild through 5-year follow-up in patients diagnosed with LSS secondary to HLF[18]. The primary outcome was the incidence of open lumbar decompression surgery at the same level(s) as the mild during 5-year follow-up. Secondary outcome measures were change in pain levels using the NPRS and opioid utilization using Morphine Milligram Equivalent (MME) dose per day from baseline to 3-, 6-, and 12-months post-mild[18]. Postprocedural complications were also collected. Seventy-five patients received mild in this study. Only 9 of 75 required lumbar surgical decompression during the 5-year follow-up. Patients experienced statistically significant pain relief and reduction of opioid utilization at 3, 6, and 12 months compared to baseline[18]. There were no major complications recorded[18].

2-year Medicare Claims Study: mild versus interspinous spacers

A 2-year prospective longitudinal Medicare Claims Benchmark Study compared outcomes between Medicare patients receiving mild and a control group receiving interspinous spacers[19]. Outcomes include a cohort comparison of the incidence of harms, the rate of subsequent interventions, and the overall rate of harms and subsequent interventions during 2-year follow-up after the index procedure. The study included 2229 patients in the mild group and 3401 in the spacers group[19]. The rate of harms with mild was less than half that of patients with a spacer (5.6% vs. 12.1%; $p < 0.0001$). The rate of subsequent interventions was not significantly different (24.9% for mild vs. 26.1% for spacer; $p = 0.7679$)[19]. This comprehensive study of real-world Medicare claims data demonstrated a significantly lower rate of harms for mild compared to interspinous spacers, an important element of decision making for treatment of patients early in the LSS continuum of care[19].

2-year Medicare claims benchmark study: mild versus outpatient laminectomy

Another prospective longitudinal study compares outcomes for Medicare beneficiaries receiving mild to patients undergoing outpatient laminectomy[20]. Similarly to above, the rate of subsequent surgical procedures and incidence of harms were used as study outcomes. Cohorts included 2197 mild and 7416 laminectomy patients. Mild patients were significantly older (76.7 years vs. 73.4 years, respectively; $p < 0.0001$) and presented with significantly more baseline comorbidities compared to laminectomy patients ($p < 0.0001$)[20]. Subsequent surgical procedure rate of 9.0 % for mild was significantly higher than 5.5 % for laminectomy ($p < 0.0001$), which may be attributable to its position earlier in the LSS treatment algorithm[20]. mild experienced harms at a significantly lower rate than laminectomy (1.9 % vs. 5.8 %, respectively; $p < 0.0001$)[20]. Overall composite rate of subsequent surgical procedures and harms was similar between groups at 10.8 % for mild and 11.0 % for laminectomy[20].

Best Practices for Minimally Invasive Lumbar Spinal Stenosis Treatment 2.0 (MIST): Consensus Guidance from the American Society of Pain and Neuroscience (ASPN)

Building on this robust evidence base, expert consensus guidelines have formalized the role of mild in LSS management. In 2019, the first version of the MIST (Minimally Invasive Spine Treatment) guidelines was published[21]. A consensus group of physician leaders encompassing multiple disciplines was formed and evaluated the literature regarding diagnosis and minimally invasive treatment of LSS. The authors provided 11 wide-ranging consensus points and concluded that minimally invasive spine treatments should be used algorithmically in a multimodal fashion[21]. Given the rapidly evolving LSS treatment landscape, a second expert consensus group was formed to update and expand the 2019 MIST guidelines. The objectives of these second MIST guidelines were to review the published literature since the first MIST guidelines, modify existing consensus points based on the latest research, describe a treatment algorithm, and provide new consensus points where new evidence exists[22]. Consensus Point 6 recommends that PILD should be considered for the treatment of mild-to-moderate LSS in the presence of NC, with less than or equal to a grade 2 spondylolisthesis, and with a contribution of spinal narrowing with at least 2.5 mm of HLF (Grade A; Level of certainty high; Level of evidence 1-A)[22].

Impact of Age on mild outcomes

This analysis retrospectively compared clinical outcomes of the mild procedure in two age groups: adults (age<65) and older adults (age≥65)[23]. All prospective studies of the mild procedure with a 1-year follow-up completed since the beginning of 2012 that allowed the inclusion of adult patients of all ages were reviewed and outcomes were compared for adults and older adults. Four studies met the inclusion criteria, resulting in an analysis of 49 adults and 16 older adults[23]. Patients in both age groups experienced significant mean improvements in all but one outcome measure at 6- and 12-month follow-up. Differences between the two age groups in all scores at 6 and 12 months were not statistically significant (see Figure 4). These results illustrate that mild can be an effective treatment for LSS due primarily to HLF, regardless of the adult patient age[23].

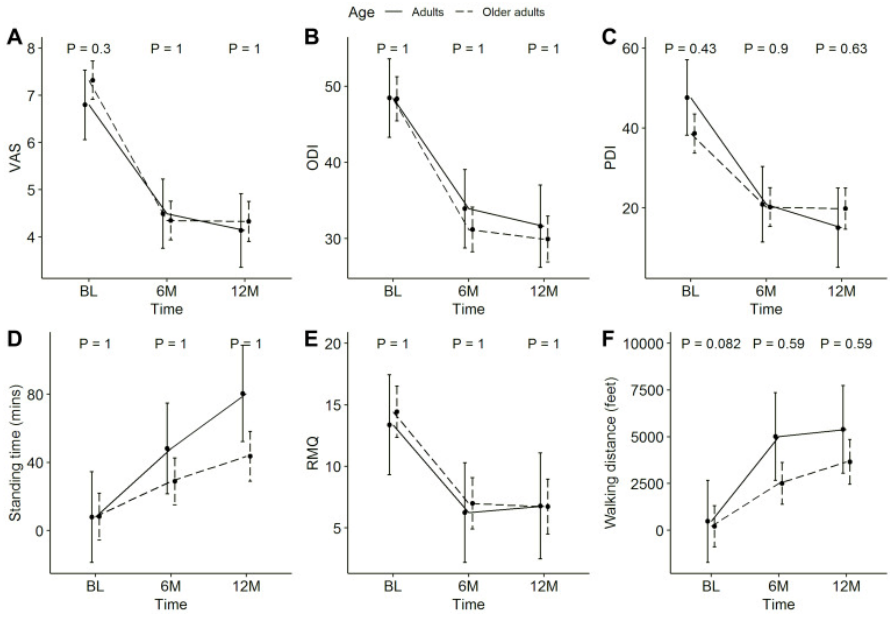



*Figure 4: Change in outcomes across adult and older adult groups for (A) VAS, (B) ODI, (C) PDI, (D) Standing time, (E) RMQ, and (F) Walking distance.*

## Cost Effectiveness Data

In addition to clinical value, the mild procedure has demonstrated favorable economic value compared with more invasive surgical options, offering superior cost effectiveness, as measured by cost per quality adjusted life year (QALY), when compared with epidural steroid injections and decompression laminectomy[24]. Moreover, patients treated with mild have been shown to require fewer downstream health care resources, including reductions in subsequent specialty care visits and interventional pain procedures[25], supporting its role as a clinically and economically responsible treatment option.

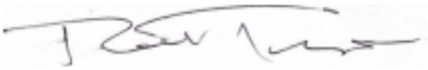
## Conclusions & Recommendations

From both a clinical and economic perspective, a large body of evidence demonstrates that the mild procedure has proven an effective option for the management of LSS with NC when identified using clinical examination and radiological findings of HLF ≥ 2.5 mm. Published evidence supporting mild includes real-world patient populations, comparative analyses, follow-up periods of up to five years, and a broad age range, with approximately 42% of mild publications including participants under 65 years old.

NYSIPP strongly urges payors to adopt favorable coverage policies for the mild procedure in recognition of its clinical efficacy, cost-effectiveness, and alignment with the new Category I CPT® coding. Doing so will address a significant unmet need among patients suffering from debilitating spinal conditions who deserve access to evidence-based interventional pain

management solutions. We would welcome the opportunity to meet and engage in any dialogue pertaining to this important matter.

Sincerely,



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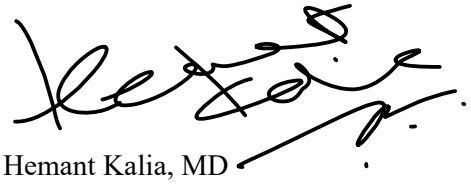

Hemant Kalia, MD
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7. AMA CPT Panel Meeting September 2024 Summary of Panel Actions
8. *CPT Changes: An Insider's View* 2026
9. Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy),

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