



New York Society of Interventional Pain Physicians

NYSIPP
1991 Marcus Ave, M217
Lake Success, NY 11042
(516) 492-3100
NYSIPP.org

Sudhir Diwan MD
CEO

Robert Tiso MD
President

Karina Gritsenko MD
President-Elect

Hemant Kalia MD
Vice-President

Edward Rubin MD
Treasurer

Neel Mehta MD
Secretary

NYSIPP POSITION STATEMENT

mild® Procedure

January 31, 2024

The leadership and membership of NYSIPP endorses this position statement in support of the *mild*® Procedure.

The *mild* Procedure is a minimally invasive decompression procedure used to treat lumbar spinal stenosis (LSS). Over two million LSS patients nationwide are diagnosed and treated annually (1) and the likelihood of developing LSS increases with age. The *mild* Procedure restores space in the spinal canal, allowing patients to stand longer and walk farther with less pain (2). This outpatient procedure is performed through an incision smaller than the size of a baby aspirin (5.1mm), and requires no general anesthesia, stitches, implants, steroids, or opioids. The *mild* Procedure has a clinically proven safety profile equivalent to epidural steroid injections (3), with durability out to 5 years (4), and patients typically resume normal activity within 24 hours with no restrictions (5).

Performed on over 85,000 patients nationwide, the *mild* device is FDA cleared and the procedure's safety and outcomes are supported by >30 peer-reviewed publications, and 17 clinical studies, including Level 1 data from two multi-center randomized controlled trials and no device/procedure related serious adverse events in any study publications. Treatment algorithm positions the *mild* Procedure after conservative care but before surgery/implant intervention (6).

The *mild* Procedure is covered under Medicare's National Coverage Determination (NCD) for Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis 150.13. Additional federal health insurance programs include the Veterans Administration, Department of Defense, and Indian Health Service.

Physician Qualification and Patient Selection

- Physician Qualifications
 - *mild* should be performed only by qualified physicians, trained in the management of patients suffering from lumbar spinal stenosis and comfortable with performing procedures using image guidance.
- Patient Selection
 - Pain, numbness, tingling, or heaviness is present in back, legs, or buttocks when standing or walking.
 - LSS at levels L1-S1.
 - Hypertrophic ligamentum flavum ≥ 2.5 mm.
 - Spinal stability: \leq grade 2 spondylolisthesis.



New York Society of Interventional Pain Physicians

NYSIPP
1991 Marcus Ave, M217
Lake Success, NY 11042
(516) 492-3100
NYSIPP.org

Sudhir Diwan MD
CEO

Robert Tiso MD
President

Karina Gritsenko MD
President-Elect

Hemant Kalia MD
Vice-President

Edward Rubin MD
Treasurer

Neel Mehta MD
Secretary

- Patients who are non-surgical candidates due to factors like a high BMI, intolerance to anesthesia, or those with medical and spinal comorbidities (e.g., Grade 1-2 spondylolisthesis, foraminal narrowing, degenerative disc disease, lateral recess narrowing, etc.) may still be eligible for the mild procedure.

Conclusions & Recommendations

It is the position of the New York Society of International Pain Physicians that policymakers and payers take immediate action towards positive coverage for *mild* and align with Medicare's NCD 150.13. Doing so would recognize the breadth of data supporting the safety and efficacy of the *mild* Procedure and provide remedy to the unmet clinical need affecting a large and debilitated patient population.

References

1. 2012 data from Health Market Sciences report for Vertos Medical 2013.
2. Mekhail N, Costandi S, Abraham B, Samuel SW. Functional and patient-reported outcomes in symptomatic lumbar spinal stenosis following percutaneous decompression. *Pain Pract.* 2012;12(6):417-425. doi:10.1111/j.1533-2500.2012.00565.x.
Benyamin RM, Staats PS, MiDAS ENCORE Investigators. *mild*® is an effective treatment for lumbar spinal stenosis with neurogenic claudication: MiDAS ENCORE Randomized Controlled Trial. *Pain Physician.* 2016;19(4):229-242.
3. Mekhail N, Costandi S, Nageeb G, Ekladios C, Saied O. The durability of minimally invasive lumbar decompression procedure in patients with symptomatic lumbar spinal stenosis: Long-term follow-up [published online ahead of print, 2021 May 4]. *Pain Pract.* 2021;10.1111/papr.13020. doi:10.1111/papr.13020
4. Jain S, Deer TR, Sayed D, et al. Minimally invasive lumbar decompression: a review of indications, techniques, efficacy and safety. *Pain Manag.* 2020;10(5). <https://doi.org/10.2217/pmt-2020-0037>. Accessed June 1, 2020.
5. Deer T, Grider J, Pope J et al. Best Practices for Minimally Invasive Lumbar Spinal Stenosis Treatment 2.0 (MIST): Consensus Guidance from the American Society of Pain and Neuroscience (ASPN). *Journal of Pain Research* 5 May 2022, p 1325-1354.