

AMERICAN ASSOCIATION OF  
NEUROLOGICAL SURGEONS

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Centers for Medicare & Medicaid Services  
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**Subject: Proposed National Coverage Determination (NCD) for Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis (CAG-00433R)**

Dear Ms. Jensen,

On behalf of the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), and the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves, we appreciate the opportunity to comment on the recently released proposed national coverage determination (NCD) for percutaneous image-guided lumbar decompression (PILD) for lumbar spinal stenosis (LSS) patients experiencing neurogenic claudication. We share the agency's dedication to patient safety, and as such, we provide the following comments.

PILD represents novel technology in the treatment of patients with lumbar stenosis who experience neurogenic claudication. As such, we agree on the need to evaluate this technology in a prospective randomized trial. The current literature on this procedure at this time appears discordant. Some industry-sponsored trials have demonstrated clinical efficacy while others have shown limited clinical efficacy requiring reoperation.<sup>1,2</sup> Mekhail and colleagues report a series of 58 patients who underwent the procedure demonstrating benefit at six weeks from the procedure. However, in another industry-sponsored trial, Wilkinson and Fourney found limited efficacy at six months with 60 percent of the patients in their series of 24 requiring reoperation in that time frame. The authors hypothesize a placebo effect and increased narcotic use as a potential explanation for the short term benefit. A reoperation rate of 60 percent is concerning.

In an independent analysis of the procedure, Kreiner and colleagues surmised that the "current body of evidence addressing MILD (PILD) is of low quality. High-quality studies that are independent of industry funding and provide categorical data are needed to clarify the proportions of patients who benefit from MILD (PILD) and the degree to which these patients benefit."<sup>3</sup>

In keeping with the need for high-quality studies, we are concerned with the current design of two prospective randomized controlled studies for which CMS is considering an NCD. One study has the investigative cohort being compared to patients undergoing a sham procedure; the second study is

comparing the investigative arm patients to epidural injection therapy. The former study is designed to address the issue of a placebo effect; the latter study is to compare PILD to nonoperative measures, specifically epidural injection therapy. One of the criteria of the study design for approval established by CMS is the “study results are not anticipated to unjustifiably duplicate existing knowledge.” The study by Staats and colleagues appears to have already compared this procedure to epidural steroid therapy.<sup>4</sup> The question that beckons to be answered is the efficacy of PILD compared with laminectomy. Such a study would be a meaningful contribution to the literature and further define the role of this technology.

Along with the alarming rate of reoperation with this procedure, we remain concerned with the safety profile. No device-associated complications have been reported in the industry sponsored trials. However, Tumialán and colleagues published their concern regarding the safety profile of this procedure reporting eight patients who needed additional surgery, two patients with a cerebrospinal fluid leak, one of whom had transected nerve roots from this procedure resulting in complete loss of bowel and bladder function.<sup>5</sup>

A thoughtful and independent analysis of data collected from a well-conceived randomized controlled trial will undoubtedly further define the role of this procedures. However, procedures that have demonstrated efficacy and a positive impact on patient care seldom await the result randomized control studies for a trend to surface showing a sustained utilization of a procedure. After all, surgeons and interventionalists migrate to procedures that achieve excellent and reliable clinical outcomes. Analysis of Medicare data for the tracking code (0275T) demonstrates that the PILD procedure peaked in 2013 with 2,623 procedures. In 2014, the procedure appeared to have been performed 187 times precipitously declining 22 procedures in 2015. It seems that as surgeons and interventionalists alike observed the efficacy of this technique over that period, enthusiasm for employing it waned. The current trend in utilization of the PILD procedure raises the question as to why CMS would want to extend coverage to this procedure when so few Medicare beneficiaries are having the procedure done in the setting of a disease state that is widely prevalent among Medicare beneficiaries — particularly if there are concerns regarding safety.

Thank you for considering our views. We appreciate the opportunity to comment on this coverage decision and look forward offering further guidance relating to the role of this technology in the treatment of lumbar stenosis with neurogenic claudication. If you have any questions or need additional information, please don't hesitate to contact us.

Sincerely,



Frederick A. Boop, MD, President  
American Association of Neurological Surgeons



Alan M. Scarrow, President  
Congress of Neurological Surgeons



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### **Footnotes**

1. Mekhail N, Vallejo R, Coleman MH, Benyamin RM. Long-term results of percutaneous lumbar decompression mild((R)) for spinal stenosis. *Pain practice: the official journal of World Institute of Pain*. Mar 2012;12(3):184-193.
2. Wilkinson JS, Fourny DR. Failure of percutaneous remodeling of the ligamentum flavum and lamina for neurogenic claudication. *Neurosurgery*. Jul 2012;71(1):86-92.
3. Kreiner DS, MacVicar J, Duszynski B, Nampiaparampil DE. The mild(R) procedure: a systematic review of the current literature. *Pain Med*. Feb 2014;15(2):196-205.
4. Staats PS, Benyamin RM. MiDAS ENCORE: Randomized Controlled Clinical Trial Report of 6-Month Results. *Pain physician*. Feb 2016;19(2):25-38.
5. Tumialan LM, Marciano FF, Theodore N. Regarding: long-term results of percutaneous lumbar decompression mild for spinal stenosis. *Pain practice: the official journal of World Institute of Pain*. Mar 2012;12(3):252; author reply 252-253.