

American Society of Interventional Pain Physicians®

"The Voice of Interventional Pain Management"

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Re: National Coverage Analysis (NCA) for Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis (CAG-00433R)

Dear Ms. Syrek-Jensen and Ms. Gilbreath:

On behalf of the Board of Directors of the American Society of Interventional Pain Physicians (ASIPP) and 51 state societies including Puerto Rico, and the membership of all these societies, we appreciate the opportunity to comment on the Proposed Decision Memorandum for Percutaneous Image-guided Lumbar Decompression (PILD).

We are disappointed and oppose the proposed extension of Coverage with Evidence Development (CED) and the introduction of new requirements for coverage. The recently completed CMS-approved study (MiDAS ENCORE¹) fulfilled the original requirements for CED as stated in the Decision Memo for Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis (CAG-00433N). The results of this study and the existing body of literature clearly establish *mild*® as reasonable and medically necessary. Efficacy and safety are comparable or exceed currently covered surgical, interventional, and conservative therapies. As such, unrestricted coverage without the need for additional studies under CED should be granted. We therefore respectfully request that you change your draft coverage policy on PILD to a final coverage policy that grants full coverage for the *mild*® procedure without the requirement of doing another study. Not reversing this illogical and inappropriate decision is deleterious to patient access and investment in innovations.

¹ Benjamin RM, Staats, MiDAS Encore I. MILD® is an effective treatment for lumbar spinal stenosis with neurogenic claudication: MiDAS ENCORE randomized controlled trial. *Pain Physician* 2016; 19:229-242.

Interventional pain management is defined as the discipline of medicine devoted to the diagnosis and treatment of pain-related disorders principally with the application of interventional techniques in managing subacute, chronic, persistent, and intractable pain, independently or in conjunction with other modalities of treatment.²

Interventional pain management techniques are minimally invasive procedures including percutaneous precision needle placement, with placement of drugs in targeted areas or ablation of targeted nerves; and some surgical techniques such as laser or endoscopic discectomy, intrathecal infusion pumps and spinal cord stimulators, for the diagnosis and management of chronic, persistent, or intractable pain.³

ASIPP is a not-for-profit professional organization founded in 1998 now comprising over 4,500 interventional pain physicians and other practitioners who are dedicated to ensuring safe, appropriate, and equal access to essential pain management services for patients across the country suffering with chronic and acute pain. There are approximately 8,500 appropriately trained and qualified physicians practicing interventional pain management in the United States.

We are commenting on all relevant issues as follows:

- **The mild[®] Procedure has Fulfilled the Original CED Requirements**
The Medicare National Coverage Determinations Manual Chapter 1, Part 2 Section 150.13 – Percutaneous Image-guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS) states the requirements for an approvable study under the Coverage with Evidence Policy. Specifically:
 1. A clinical study must address one or more aspects in a prospective, randomized, controlled design using current validated and reliable measurement instruments and clinically appropriate comparator treatments.
 2. The study protocol must specify a statistical analysis and a minimum length of patient follow-up time that evaluates the effect of beneficiary characteristics on patient health outcomes as well as the duration of benefit.
 3. The study protocol must produce data that demonstrate whether PILD provides clinically meaningful improvement in function and reduction in pain as well as whether PILD affects management of LSS compared to other treatments.

The MiDAS ENCORE Study met all three requirements. Specifically:

1. The design of the study was prospective, randomized, and controlled. It used validated and reliable measurement instruments such as the Oswestry Disability Index (ODI), Numeric Pain Rating Scale (NPRS), and Zurich Claudication Questionnaire (ZCQ). These are all clinically accepted outcome measures. Epidural steroid injections (ESIs) are a widely accepted treatment for these

² The National Uniform Claims Committee. Specialty Designation for Interventional Pain Management-09.

www.cms.hhs.gov/transmittals/Downloads/r1779b3.pdf

³ Medicare Payment Advisory Commission. Report to the Congress: Paying for interventional pain services in ambulatory settings. Washington, DC: MedPAC. December. 2001.

<http://www.medpac.gov/documents/reports/december-2001-report-to-the-congress-paying-for-interventional-pain-services-in-ambulatory-settings.pdf?sfvrsn=0>

patients and meet the definition of a clinically appropriate comparator.^{4,5} The Centers for Medicare and Medicaid Services (CMS) approved the outcomes measures and comparator treatment.

2. The statistical plan and sample size were designed to power the study and were deemed to be more than adequate for the protocol-defined endpoint analysis. The statistical plan and sample size were approved by CMS. The one-year endpoint is appropriate for an interventional pain management treatment comparative efficacy study and was approved by CMS, however, follow-up continues beyond one year.
3. The study's outcome measures address the need to collect validated outcomes in function (ODI and ZCQ Physical Function) and pain (NPRS and ZCQ Symptom Severity). The selection of an active control (ESI) and requirement to demonstrate statistical superiority on endpoints provides the necessary information to assess the effect of *mild*[®] on clinical management of LSS compared to other treatments.

The MiDAS ENCORE study clearly met the CED requirements and the CMS approval of the study protocol validates this position. The clinical results on endpoints demonstrated statistical superiority at one year for ODI responder rates (58.0% for *mild*[®] vs. 27.1% for the control, $P < 0.001$), NPRS responder rates (57.3% for *mild*[®] vs. 27.1% for the control, $P < 0.001$), ZCQ Symptom Severity (51.7% for *mild*[®] vs. 31.8% for the control, $P = 0.001$), ZCQ Physical Function (44.1% for *mild*[®] vs. 17.8% for the control, $P < 0.001$), and Patient Satisfaction (61.5% for *mild*[®] and 33.3% for the control, $P < 0.001$). Endpoints of a CED-approved study were successfully achieved, so it is logical to conclude that the CED data requirements are met and CED should end. If a study was not intended to provide the necessary data to make an affirmative coverage decision, then the protocol should not have been approved.

The “Guidance for the Public, Industry, and CMS Staff Coverage with Evidence Development” issued by your department provides additional support for why *mild*[®] should exit CED now that the study has been successfully completed.

- ***Section IV. Principles governing the application of CED*** stipulates three areas that are relevant to this Draft Policy:
 1. CED will not be used when less restricted coverage is justified by the available evidence.
 2. CED will generally expand access to medical technologies for beneficiaries.
 3. CED will lead to the production of evidence complementary to existing medical evidence.

Continuing CED by adding a new requirement for a prospective cohort study contradicts these principles.

⁴ Manchikanti L, Knezevic NN, Boswell MV, Kaye AD, Hirsch JA. Epidural injections for lumbar radiculopathy and spinal stenosis: A comparative systematic review and meta-analysis. *Pain Physician* 2016; E365-E410.

⁵ Manchikanti L, Kaye AD, Manchikanti KN, Boswell MV, Pampati V, Hirsch JA. Efficacy of epidural injections in the treatment of lumbar central spinal stenosis: A systematic review. *Anesth Pain Med* 2015; 5:e23139.

1. A requirement for a new study violates the precept that CED will not be used when less restricted coverage is justified by the available evidence. The MiDAS ENCORE study was approved by CMS and statistical superiority was established on all endpoints, so less restricted coverage is justified by the evidence and CED should not be used moving forward per this guideline.
 2. A requirement for a new study limits patient access since only investigators from the MiDAS ENCORE study and can enroll patients in the new study, which violates the intent of expanding access to medical technologies for beneficiaries.
 3. The new study will not produce evidence complementary to the existing medical evidence since the data required will be duplicative of data already collected in the MiDAS ENCORE study and the published cohort studies conducted to date. The fact that the requested data is duplicative also goes against the NCD, which states that “The research study does not unjustifiably duplicate existing studies.”
- ***Section VIII. Ending CED***, states “We expect that the studies conducted under a CED NCD will produce evidence that will lead to revisions to Medicare coverage policies, such as to the NCD that included CED as a component of the decision.” CMS approved the MiDAS ENCORE protocol and the study demonstrated clinically significant and statistically superior outcomes so a meaningful revision to the policy should result. The proposal to do another study does not constitute a meaningful revision.

In summary, the *mild*[®] procedure has clearly met the requirements set by CED. The study protocol was approved by CMS and the study successfully demonstrated significant statistical superiority on protocol-defined endpoints, so the therapy should be covered without needing to do another study under CED.

- **The *mild*[®] Procedure Body of Evidence is Comparable to Current Medicare Covered Procedures**

The Draft Policy issued by CMS requires a level of evidence to which no other therapy in the category has ever been subjected.

The *mild*[®] procedure now has:

- Two published randomized controlled trials (RCTs),^{1,6} with one high quality trial as designed by CMS for coverage development, providing Level I evidence (340 total patients / 164 *mild*[®] patients)
- As shown in systematic reviews,⁷ an additional 7 prospective single-arm and 2 retrospective published studies (382 *mild*[®] patients)
- 668 *mild*[®] patients have been studied in all *mild*[®] clinical trials
- Five studies report 1Y follow-up of patients treated with *mild*[®] (326 patients)
- One study reports 2Y follow-up of patients treated with *mild*[®] (45 patients)
- All studies show statistically significant efficacy using validated outcomes measures.

⁶ Brown LL. A double-blind, randomized, prospective study of epidural steroid injection vs. the *mild*[®] procedure in patients with symptomatic lumbar spinal stenosis. *Pain Pract* 2012; 12:333-341.

⁷ Levy R, Deer TR. Systematic safety review and meta-analysis of procedural experience using percutaneous access to treat symptomatic lumbar spinal stenosis. *Pain Med* 2012; 13:1554-1561.

All eleven of these published studies,⁷ including two RCTs,^{1,6} with one high quality trial as designed by CMS for coverage development, report that *mild*[®] provided statistically significant improvement in functional mobility and reduced pain compared to baseline. In addition, two RCTs demonstrated superiority of *mild*[®] versus the active control for all primary and secondary outcome measures. There were no reports of device-related adverse events in any of these studies.

These reports are consistent regarding significant improvement in patient outcomes generated through high quality studies, including one high quality RCT providing Level I evidence of the effectiveness and safety of *mild*[®]. The strength of this evidence, which combines high quality study designs with significantly improved outcomes in all studies, surpasses that available for many common back treatments currently covered by CMS.

- **Multiple covered therapies have similar or weaker evidence:**

Surgery for Spinal Stenosis

- A 2016 Cochrane Review by Zaina et al⁸ reviewed the evidence that compares surgery versus non-surgical treatment for lumbar spinal stenosis (LSS). After reviewing almost 13,000 citations, only three high-quality RCTs related to open surgery were identified (Amundsen 2000, Malmivaara 2007, Weinstein 2008). This review reports that there is low quality evidence from the meta-analysis performed on two trials that used ODI to compare direct decompression with or without fusion versus multi-modal non-operative care. The evidence showed no significant differences at 6 months and 1 year. At 2 years, significant differences favored decompression. Low-quality evidence from one small study revealed no difference in pain outcomes between decompression and usual conservative care at 3 months, four years and 10 years. Further, the rate of side effects ranged from 10% to 24% in surgical cases, and no side effects were reported for any conservative treatment. This Cochrane Review concluded that no clear benefits were observed with surgery versus non-surgical treatment, and that current evidence comparing surgical versus non-surgical care for LSS is of low quality.

Lumbar Fusion:

- Phillips et al⁹ concluded that the body of literature supports fusion surgery as a viable treatment option for reducing pain and improving function in patients with chronic low back pain refractory to nonsurgical care when a diagnosis of disc degeneration can be made. Bydon et al¹⁰ concluded that despite the significant improvement in Oswestry Disability Index (ODI) scores in the lumbar fusion groups in 3 studies, pooled data revealed no significant difference when compared to the nonoperative groups. Saltychev

⁸ Zaina F, Tomkins-Lane C, Carragee E, Negrini S. Surgical versus non-surgical treatment for lumbar spinal stenosis. *Cochrane Database Syst Rev* 2016; (1):CD010264.

⁹ Phillips FM, Slosar PJ, Youssef JA, Andersson G, Papatheofanis F. Lumbar spine fusion for chronic low back pain due to degenerative disc disease: a systematic review. *Spine (Phila Pa 1976)* 2013; 38:E409-E422.

¹⁰ Bydon M, De la Garza-Ramos R, Macki M, Baker A, Gokaslan AK, Bydon A. Lumbar fusion versus nonoperative management for treatment of discogenic low back pain: A systematic review and meta-analysis of randomized controlled trials. *J Spinal Disord Tech* 2014; 27:297-304.

et al¹¹ also reached similar conclusions regarding the lack of strong evidence for lumbar fusion compared to conservative treatment.

Manchikanti et al¹² suggested fluoroscopically directed epidural injections provide long-term improvement in back and lower extremity pain for patients with lumbar discogenic pain. They showed only limited evidence for the potential effectiveness of surgical interventions compared to nonsurgical treatments.

Neurostimulation

- National coverage for spinal cord stimulation (SCS) was established in 1995. However, the first RCT was not published until 2005, with a second trial in 2006, and a third trial in 2015.¹³
- In 2016 Grider et al¹³ conducted a systematic review of RCTs of spinal cord stimulation (SCS) in chronic spinal pain. The authors identified 6 RCTs, however only 3 of those studies assessed efficacy. Of the three randomized trials evaluating SCS, all reported effectiveness for short- and long-term relief. The authors concluded that the indicated level of evidence for SCS is Level I to II based on 2 high-quality RCTs and one moderate-quality RCT.
- **Additional study requirement is unjust**
Additional requirements for coverage are unprecedented and inconsistent with coverage policies for other therapies. Additionally, a prospective cohort study with an inferior design will provide weaker quality data than the MiDAS ENCORE study and won't achieve the stated goal of collecting "real world" information since the data will be collected in a controlled study format (similar to the MiDAS ENCORE study). In fact, the MiDAS ENCORE study from multiple academic and real-world practice settings with an active-control design has provided the best possible "real world data." In addition, the additional study requirement puts an unreasonable demand on the interventional pain management specialty to continue to produce evidence when the current evidence already is sufficient. We understand that there will always be an interest in gathering more data on a therapy, but it cannot come at the cost of eliminating broad patient access to therapies that have already demonstrated therapeutic efficacy and safety.

In summary, at a time when pain management has become a significant public health issue and strong pressures to reduce health care costs exist, it is essential to preserve options like *mild*[®] that are inexpensive and have demonstrated efficacy and safety. This is a very important interventional pain treatment that can benefit thousands of patients that currently don't have multiple options. Establishing a policy that requires a promising therapy like this to do more studies after successful completion of a CED study is counterintuitive to innovation and patient access. Support for access to promising technologies is not enabled by this policy. It not only

¹¹ Saltychev M, Eskola M, Laimi K. Lumbar fusion compared with conservative treatment in patients with chronic low back pain: A meta-analysis. *Int J Rehabil Res* 2014; 37:2-8.

¹² Manchikanti L, Staats PS, Nampiaparampil DE, Hirsch JA. What is the role of epidural injections in the treatment of lumbar discogenic pain: A systematic review of comparative analysis with fusion and disc arthroplasty. *Korean J Pain* 2015; 28:75-87.

¹³ Grider JS, Manchikanti L, Carayannopoulos A, Sharma ML, Balog CC, Harned ME, Grami V, Justiz R, Nouri KH, Hayek SM, Vallejo R, Christo PJ. Effectiveness of spinal cord stimulation in chronic spinal pain: A systematic review. *Pain Physician* 2016; 19:E33-E54.

defies logic, but also violates ethical principles. Further, such an attitude discourages investment in innovative technologies, apart from the grave injustice done to needy patients, sending them to ineffective and expensive treatments. Further, this also creates a significant credibility issue for the CED program. We respectfully ask you to issue a final policy granting coverage for this therapy without the requirement of doing another study.

Thank you and if you have any questions, please feel free to contact us.

Sincerely,

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