



September 22, 2022

Juan L. Schaening-Perez, MD
First Coast Service Options
Attn: Medical Policy and Procedures
532 Riverside Ave
ROC 19T
Jacksonville, FL 32202-4914

Delivered via email to: medical.policy@fcsso.com

Re: Proposed Local Coverage Determination (LCD): *Nerve Stimulators for Chronic Intractable Pain (DL39406)*

Dear Dr. Juan Schaening-Perez:

The International Society for the Advancement of Spine Surgery (ISASS) is a global, scientific and educational society organized to provide an independent venue to discuss and address fundamental topics to restore and improve motion and function of the spine for: surgeons, scientists, inventors, and of course--spine patients. ISASS is dedicated to advancing major evolutionary steps in spine surgery and is an active member of the AMA House of Delegates and AMA Mobility Caucus.

We have reviewed First Coast Service Options (FSCO) proposed Local Coverage Determination (LCD) 39406, *Nerve Stimulators for Chronic Intractable Pain*. We commend FSCO and the Contractor Medical Directors for taking steps to refine the criteria for two important technologies in the spine care domain, Spinal Cord Stimulators (SCS) and Peripheral Nerve Stimulators (PNS). After examination of the proposed LCD, we support the existing criteria for use in Section A, which outlines requirements for the use of SCS devices. In Section B, requirements for PNS devices, we believe changes are warranted based on clinical evidence that may not have been considered as part of the policy development process. Our comments will focus on Section B, and we have recommended changes that should be made. We also encourage Novitas to perform an updated literature search that is more comprehensive in its approach to cite the appropriate literature to substantiate coverage for specific indications for use. We will provide a recommended reference list for your consideration as well.

Section B: Peripheral Nerve Stimulators

Criteria 1: Pain must have a neuropathic cause

We disagree with Criteria 1 as it is overly limiting to PNS devices that can treat chronic low back pain (CLBP) that is not solely neuropathic. A systematic review evaluating the morphological changes of the paraspinal muscles has been produced and there is documented correlation of CLBP that is non-neuropathic and non-surgical with loss of neural drive to the key stabilizer of the lumbar spine, the multifidus muscle. This pain would not be classified as "neuropathic" and thus this criterion would eliminate access to proven treatments addressing multifidus dysfunction. Multifidus dysfunction is characterized by loss of neuromuscular control due to arthrogenic inhibition which results in functional instability of the lumbar spine. This is the underlying cause of CLBP in patients who have been diagnosed with this condition



through provocative test maneuvers and or MRI findings. PNS treatments that address this must remain available to Medicare beneficiaries. Our recommended change to this criterion is:

Pain must have a neuropathic cause OR RELATED TO MULTIFIDUS DYSFUNCTION.

Criteria 5: Pain is caused by a diagnosis with evidence of efficacy to support peripheral nerve stimulation is an effective treatment for pain relief. Based on current evidence-based literature, these use cases include:

Subsection 4: Medial branch nerve stimulation for the treatment of chronic low back pain, including that related to failed back surgery syndrome (FBSS).

We agree that medial branch nerve stimulation should be identified as a specific use case for PNS devices. There is a PNS device on the market today that stimulates the medial branch nerve for the treatment of chronic low back pain, specifically for patients who have been diagnosed with the previously described multifidus dysfunction. The clinical evidence proving safety and efficacy of this treatment is robust and will support the addition of this modification. This subsection should be clarified, we recommend the following change to Subsection 4:

Medial branch nerve stimulation for the treatment of chronic low back pain, including that related to *MULTIFIDUS DYSFUNCTION OR* failed back surgery syndrome (FBSS).

Criteria 6: Performance and documentation of a successful stimulation trial precedes permanent neurostimulator placement. A successful trial is characterized by:

- Greater than or equal to 50% reduction in patient pain from baseline AND/OR
- Substantial objective improvement in functional ability measures (eg, walking tolerance, performance of ADLs, sleep, etc.) from baseline.

We agree that setting trial requirements should be clarified as part of the proposed LCD to ensure patient response to the treatment is validated. In the context of using PNS devices for neuropathic pain that utilize a sensory-based analgesia, the current criterion as constructed is appropriate. However, for PNS therapies that engage motor control of the nerve to stimulate anatomical targets (ie, multifidus muscle) as part of the therapeutic response, this is not an appropriate criterion. We recognize there should be some process to support the validation of stimulation. In the case of PNS devices that target motor control of the nerve, we recommend that trial language be added to establish that mechanism as a vehicle for satisfying the coverage requirements. We recommend the following addition to the existing language in Criterion 6:

- Add *OR* to the second bullet point under Criteria 6.
- *VALIDATION OF PHYSIOLOGIC RESPONSE OF MOTOR CONTROL SHOULD BE PERFORMED BEFORE PERMANENT IMPLANTATION OF A NEUROSTIMULATOR.*

The associated Billing and Coding Article, DA59190, that was drafted with this proposed LCD will require changes as well. In the Group 2 Codes, CPT code 64590 was not included in the article and this needs to be added as clinicians report 64590 when implanting a PNS system. Also, as part of the listing of covered ICD-10-CM codes for PNS devices (Group 2 Codes), M62.5A2 needs to be included to capture the diagnosis of muscle wasting and atrophy of muscles in the back, lumbosacral as part of the diagnosis of multifidus dysfunction. M54.59 should also be included to report the concomitant pain condition with the atrophy and wasting



of the muscles of the back (ie, multifidus muscle). A consideration around a dual diagnosis requirement would be appropriate to ensure proper reporting of this particular use of PNS for patients suffering from multifidus dysfunction.

On behalf of the International Society for the Advancement of Spine Surgery and our members, we thank the Contractor Medical Directors for the opportunity to comment. The need for novel treatments that focus on rehabilitative approaches to restoring spine function is critical for the Medicare population. This not only allows for improved care for these patients, but it also builds the armamentarium of treatments that will allow for clinicians to avoid the use of opioids to manage pain conditions related to the spine. Please see the list of references to support our recommendations as well as those that should be considered for the development of Section B for Peripheral Nerve Stimulators.

If you have any questions or wish to engage in any follow up, please do not hesitate to contact Morgan Lorio, MD at mloriomd@gmail.com.

Respectfully,

A handwritten signature in black ink that reads 'Morgan P. Lorio MD'.

Morgan Lorio, MD, FACS

ISASS Chair of Coding and Reimbursement Task Force

References:

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5. Deckers K, De Smedt K, Mitchell B, et al. New Therapy for Refractory Chronic Mechanical Low Back Pain-Restorative Neurostimulation to Activate the Lumbar Multifidus: One Year Results of a Prospective Multicenter Clinical Trial. *Neuromodulation*. 2018;21(1):48-55. doi:10.1111/ner.12741
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