September 22, 2022

Leslie Stevens, MD
Contractor Medical Director
Novitas Solutions, Inc.
2020 Technology Parkway, Ste. 100
Mechanicsburg, PA 17050
Via Electronic Submission to ProposedLCDComments@novitas-solutions.com

Dear Dr. Stevens,

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 Novitas Solutions Inc.'s proposed Local Coverage Determination (LCD) 39404, *Nerve Stimulators for Chronic Intractable Pain*. We commend Novitas 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 the 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, DA59188, 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 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,

Morgan Lorio, MD, FACS
ISASS Chair of Coding and Reimbursement Task Force

**References:**


1. Seyedhoseinpoor, T et al. Alteration of lumbar muscle morphology and composition in relation to low back pain: a systematic review and meta-analysis. The Spine Journal. 2022;22:660-676. doi.org/10.1016/j.spinee.2021.10.018
2. Russo M, et al. Muscle Control and Non-specific Chronic Low Back Pain. Neuromodulation. 2018;21(1):1-9.
3. Hebert JJ, Koppenhaver SL, Teyhen DS, Walker BF, Fritz JM. The evaluation of lumbar multifidus muscle function via palpation: reliability and validity of a new clinical test. Spine J. 2015 Jun 1;15(6):1196-202. doi: 10.1016/j.spinee.2013.08.056. Epub 2013 Oct 4. PMID: 24314767; PMCID: PMC3976459.
4. Deckers K, De Smedt K, van Buyten J-P, et al. Chronic Low Back Pain: Restoration of Dynamic Stability. Neuromodulation. 2015;18(6):478-486. doi:10.1111/ner.12275
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
6. Gilligan C, Volschenk W, Russo M, et al. On Behalf of the ReActiv8-B Investigators. Refractory Mechanical Chronic Low Back Pain: A Randomized Sham-Controlled Clinical Trial. Pain. 2021;162(00):2486-2498.

7. Mitchell B, Deckers K, De Smedt K, et al. Durability of the Therapeutic Effect of Restorative Neurostimulation for Refractory Chronic Low Back Pain. Neuromodulation. 2021;24(6):1024-1032. doi:10.1111/ner.13477

8. Gilligan C., Volschenk W., Russo M., et al. On Behalf of the ReActiv8-B Investigators. 2021. Long-Term Outcomes of Restorative Neurostimulation in Patients With Refractory Chronic Low Back Pain Secondary to Multifidus Dysfunction: Two-Year Results of the ReActiv8-B Pivotal Trial. Neuromodulation 2021; 1–11. doi.org/10.1016/j.neurom.2021.10.011

9. Thomson S, Chawla R, Love-Jones S, Sharma M, Vajramani G, Williams A, Eldabe S; ReActiv8 PMCF Investigators. Restorative Neurostimulation for Chronic Mechanical Low Back Pain: Results from a Prospective Multi-centre Longitudinal Cohort. Pain Ther. 2021 Dec;10(2):1451-1465. doi: 10.1007/s40122-021-00307-3. Epub 2021 Sep 3. PMID: 34478115; PMCID: PMC8586272.