



# FSIPP

FLORIDA SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS

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Feb 17, 2023

Dear Dr. Schaening-Perez:

We have reviewed proposed LCD published by the JN Jurisdiction, FCSO, for Spinal Cord Stimulation (SCS) and Peripheral Nerve Stimulation (PNS) for Chronic Intractable Pain (DL39406) dated Feb 7, 2023. As the leading interventional pain group in the state, the Florida Society of Interventional Pain Physicians (with CAC representation since 2007) appreciates your dedication to ensure that all Medicare beneficiaries have access to much needed technology to treat intractable pain.

However, we are very alarmed that the Florida Society of Interventional Pain Physicians (FSIPP) comments submitted to FCSO/Novitas as outlined on September 7, 2022 to request specific changes in the coverage policy were not addressed (see attachment). The proposed LCD demonstrates lack of due diligence on the part of the contractor, particularly regarding PNS. FCSO has concluded that the clinical evidence regarding PNS devices for specific indications does not meet “reasonable and necessary” standards, despite the information provided.

Specifically, we are concerned that FCSO has completely omitted the literature and indications for:

- Peripheral nerves in upper and lower extremities affected by complex regional pain syndromes (type 1 and 2), pain due to peripheral nerve injury, post-surgical scar formation, nerve entrapment, and painful mono-neuropathies.
- Intercostal and ilioinguinal nerves for post-surgical and post-traumatic neuropathic pain involving these nerve distributions.

Omitted also were the recent systematic review by Helms et al<sup>1</sup> and the recent PNS guidelines.<sup>2</sup> Please note that these devices are FDA approved for all named peripheral nerves from the neck down.

It also appears that you have confused percutaneous (implanted) and transcutaneous (on or through the skin) therapies. For instance, in the systematic review by Zhou, they found “high quality evidence supportive of tSNS [transcutaneous supraorbital] ... as well as nVNS

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[noninvasive vagus nerve stimulation]”. However, since these do not use the 64555 or 64575 codes, they would not be appropriate to discuss in this LCD.

We believe that this proposed LCD should not be approved as it is in direct conflict with current standards of care, as well as recent actions by the AMA CPT determinations. The LCD states that there will be “no comment period,” which is a violation of policy development. We and our experts request a conference call with you and leadership to address more specifically the catastrophic consequences and adverse impact this policy will have on patient care, including a concomitant increase in opioid use and deaths and additional strain on the beneficiary fund.

Sincerely,

*Deborah H. Tracy MD, MBA*

FSIPP, CAC Representative, FCSO

Andrea Trescot MD

FSIPP founder and Board of Directors Member at Large

Former CAC Representative, FCSO

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<sup>1</sup> Helm S, Shirsat N, Calodney A, Abd-Elsayed A, Kloth D, Soin A, et al. Peripheral Nerve Stimulation for Chronic Pain: A Systematic Review of Effectiveness and Safety. Pain Ther. 2021;10(2):985-1002.

<sup>2</sup> Strand N, D'Souza RS, Hagedorn JM, Pritzlaff S, Sayed D, Azeem N, et al. Evidence-Based Clinical Guidelines from the American Society of Pain and Neuroscience for the Use of Implantable Peripheral Nerve Stimulation in the Treatment of Chronic Pain. Journal of pain research. 2022;15:2483-504.

Attachments:

1). FSIPP comments

cc: Tamara Syrek Jensen

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