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September 24, 2022

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

Subject: Proposed Local Coverage Determination (LCD): Nerve Stimulators for Chronic Intractable Pain (DL 39406).

Dear Dr. Schaening-Perez:

The AANS and the CNS appreciate the opportunity to comment on the above referenced First Coast Service Options (FCSO) proposed local coverage determination (LCD) policy for spinal cord (SCS) and peripheral nerve stimulation (PNS) for pain (DL 39406). These procedures are increasingly important for reducing pain, disability and opioid use among the Medicare population. The AANS and the CNS are keenly interested in these proposed policies, given their importance to our patients with chronic pain. However, we are concerned that these proposed policies have multiple issues that require correction as they may adversely affect patient care if implemented as they currently stand.

The proposed LCDs contain definitions of various types of pain, neurostimulation therapies and stimulation waveforms. Several of these are not fully accurate. First, spinal cord stimulation does not involve placing an electrode in the spinal canal "adjacent to the area of pain." These electrodes are placed at locations in the spine that have been determined physiologically and neuroanatomically to treat pain in certain body regions. **We request that the description of spinal cord stimulation be edited to read "at the spinal level and laterality appropriate for the bodily area of pain to be treated."**

The description of burst neurostimulation states that the stimulation patterns "mimic the firing patterns of neurons in the spinal cord (which allow communication between spinal cord and brain)." This is incorrect. **We request that the description of burst neurostimulation be edited to read "mimic the firing patterns of neurons in the thalamus".**

Additionally, the description of "high-frequency neurostimulation states that the frequency range of this therapy is "500-10,000 Hz" but also states that this is "also called 10 kHz stimulation." The designation "10 kHz stimulation" is reserved only for stimulation at this specific frequency, not the range described. **We request that the phrase "also called 10 kHz stimulation" be removed from this paragraph.**

The listing of criteria under which SCS and PNS would be considered medically reasonable and necessary is one of the most crucial sections of the proposed LCDs. We disagree with this section for both PNS and SCS, as it is too narrow and would exclude too many people from accessing the therapy who would otherwise benefit. Neuropathic pain due to etiologies such as sciatic nerve or brachial plexus injury, radiation plexopathy, chemotherapy-related neuropathy along with SCS for phantom limb pain, painful small fiber neuropathy would not be covered despite the scientific literature to support these indications and its accepted use. Importantly, there are many neuropathic pain conditions that benefit

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from SCS and PNS but for which specific FDA approval labeling has not been sought. **We request that point 4 in both the SCS and PNS sections be removed from the proposed LCD. In addition, we request that point 5 in both the SCS and PNS sections be revised to state "include but are not only limited to" or add "other chronic neuropathic pain states" in the bullet point list.**

The coverage limitations section is overly restrictive and does not take into account the clinical scenarios under which SCS and PNS procedures are performed. The first limitation states that SCS and PNS are not covered for patients with "a correctable pathology." This completely neglects situations in which the procedure to correct the pathology might be unsafe or undesirable for the patient. For instance, an elderly frail individual might have spinal pathology that could be corrected with a very large thoracolumbar fusion. However, for this person, that procedure might pose unacceptably high morbidity and mortality risks, as compared to a trial of SCS or PNS, and corrective surgery may not be offered to the patient. Moreover, the patient may choose not to accept those risks, even if corrective surgery was offered. A trial of neurostimulation is less invasive and may be better tolerated than corrective surgery. Similarly, someone who has had multiple brachial plexus explorations and neurolysis procedures might still have scarring/entrapment but the chance of yet another neurolysis relieving the pain is much lower than the chance of a trial of neurostimulation providing significant pain relief. Again, the presence of a "correctable pathology" such as in these scenarios should not exclude patients from trials of SCS and PNS. **We request that this clause be deleted from the proposed LCD.**

The AANS and the CNS are dismayed that limitation number 9 specifically excludes post-herpetic neuralgia (PHN) from SCS and PNS coverage. Neurostimulation can significantly and durably reduce pain from PHN. Patients suffering from the neuropathic pain of PHN often fail medical therapy and interventional therapy (blocks, etc) rarely provide lasting relief. **We request that the clause "including post-herpetic neuralgia" be removed from limitation #9.**

There is a cohort of patients who have neuropathic pain in more than one body area (e.g. cervical and lumbar spine or spinal and cranial). Some of these individuals require separate neurostimulation systems for treatment of each region of pain. The proposed limitation #10 of only one SCS or PNS implant per patient (both at any one time and per lifetime) cruelly asks these patients to choose which pain to treat and from which pain they would like to continue to suffer. This is both unfair to these people and will result in an overall lesser degree of pain relief, opioid reduction and quality of life improvement by leaving important areas of pain untreated. While requiring more than one device is uncommon, it should not be blanketly denied for all. **We request that limitation #10 be removed from the proposed LCD.**

These proposed policies have drawn interest from several medical device manufacturers. While the AANS and the CNS agree with the spirit of adding an "evergreen" clause to the LCDs to streamline the process of coverage modernization over time as new indications for spinal cord and peripheral nerve stimulation are proven, we are concerned that the wording to "update" the diagnosis lists could result in removal of previously covered diagnoses without consultation with physician organizations. **Given this concern, we would propose that either this clause not be adopted, or it be edited to remove the words "or update." In contrast, the AANS and the CNS would support addition of the proposed language for the "limitations" section, as we agree that careful patient selection is key for optimizing outcomes from these procedures.**

The AANS and the CNS agree that spinal cord stimulation has been demonstrated to be an effective treatment for painful diabetic neuropathy and coverage for this indication should be included in the new LCDs as well as updates to previous LCDs. However, we disagree that this coverage should be limited

to one specific neurostimulation device (high frequency). As described in the LCD reconsideration request from Medtronic, there is ample literature supporting the effectiveness of conventional frequency spinal cord stimulation in treating painful diabetic neuropathy. Limiting coverage for spinal cord stimulation for this indication to only one device jeopardizes access for patients to the therapy, as some hospitals/surgical centers may not have this device on contract. Moreover, while the results from the high frequency randomized trial for painful diabetic neuropathy were impressive, chronic pain tends to be a complex issue and one device or stimulation waveform may not be appropriate for all patients with a single diagnosis. For instance, some patients do not want or cannot handle a rechargeable neurostimulator. Under the proposed revisions to the LCD, all patients would be forced to have a rechargeable generator implanted. Those patients who cannot reliably recharge the device or do not want to do so on a daily basis (as these generators require) would lose the therapy, thus rendering the procedure and costs of the device a total loss. **We request that coverage for spinal cord stimulation for painful diabetic neuropathy be added to the new LCD DL39406 without limiting the group 1 HCPCS codes to only C1822 and including codes C1767 and C1820 for other types of neurostimulator generators.**

Thank you for your consideration of our comments.

Sincerely,

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American Association of Neurological Surgeons

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Congress of Neurological Surgeons

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