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Dear Dr. Dhuria,

We are writing on behalf of the more than 95,000 members our undersigned societies represent. Our members include anesthesiologists, neurologists, neurosurgeons, orthopedic surgeons, physiatrists, psychologists, radiologists, engineers, scientists, and health care professionals. We are all dedicated to improving the care patients receive when dealing with chronic neurologic disorders, including severe debilitating pain.

Now that your Humana Medicare Advantage plan removed closed-loop spinal cord stimulation therapy as "experimental, investigational, and/or unproven," we write to you in hopes that your commercial plan will follow suit. We express our profound objection to the current characterization by your commercial coverage policy of closed-loop spinal cord stimulation therapy as experimental, as it is our firm belief that such a classification does a disservice to patients and neglects the scientific research, rigorous clinical trials, and evidence supporting the efficacy of closed-loop SCS therapy.

Closed-loop technology is an evolutionary approach to SCS compared to the traditional open-loop technology. As opposed to a standard neurostimulator, a closed-loop device actively monitors the spinal cord responses to the delivered electrical stimulation. The device then rapidly and automatically adjusts the strength of stimulation in response to the evoked activity in the spinal cord based on patient-specific values for comfort and pain relief. This represents a significant evolution in SCS technology. Closed-loop SCS has been studied in high-level peer-reviewed publications, including randomized, blinded clinical trials. The outcomes of these trials demonstrated substantial improvements in pain in patients suffering from back and leg pain with three-year follow up (Evoke study). Furthermore, closed-loop SCS has enabled a considerable number of patients in both the Evoke and Avalon studies to successfully taper off opioid therapy, underscoring its effectiveness and impact on public health. It is also important to note the holistic responses to closed-loop therapy that are observed in these studies. Specifically, drastic improvements in sleep, function (as measured by Oswestry Disability Index), mood and quality of life. As such, the secondary benefits of closed-loop spinal cord stimulation will likely have profound impacts on multiple aspects of our patients' lives and not only subjective pain relief.

It is important to note that closed-loop SCS devices allow the patient to choose between traditional open-loop stimulation and the newer stimulation modality, depending on their preference. Chronic neuropathic pain is a complicated disorder and no two patients' pain is alike. The availability of more stimulation modalities in a single device increases the chance that clinicians can provide a patient with pain relief and continue to reduce their pain over time as the patient's condition changes.

All of the available FDA-approved SCS devices are able to deliver several different stimulation waveforms and closed-loop devices are no different in that respect. We believe closed-loop SCS devices should be covered under similar provisions as other SCS devices.

In the Evoke study, the use of a single device allowed a true comparison between the current technology (open-loop) and the technological advancement (closed-loop) while being able to blind the patient to the stimulation modality used. This makes the study methodology stronger than if the patient knew they were receiving either a newer device or one that was already on the market, which would unblind the patient, and possibly, the evaluator. Importantly, open-loop stimulation used in the study is the same stimulation waveform delivered by all other SCS systems currently on the market, making this trial one comparing a standard of care stimulation paradigm to a novel paradigm. The quality of this study and the results have been subjected to rigorous peer review and published in both The Lancet and the Journal of the American Medical Association (JAMA), two respected journals with exceptional standards and high impact factors.
Moreover, the closed-loop technology has been acknowledged and validated by federal payers. Closed-loop SCS received transitional pass through (TPT) designation from CMS, enabling temporary enhanced reimbursement due to the therapy's meeting the requirement of demonstrating "substantial clinical improvement." This recognizes the therapy's ability to significantly enhance clinical outcomes for patients, reaffirming its status as a groundbreaking and validated therapeutic option.

Closed-loop technology may be new to SCS, but it is rapidly proliferating through other neuromodulation modalities. Closed-loop brain stimulation is already in practice for the treatment of medication-refractory epilepsy (the NeuroPace RNS system). It is being actively studied for such disorders as Parkinson's disease, tremor, obsessive-compulsive disorder, depression and obesity. The idea of a neurostimulation device sensing the nervous system and independently responding and adjusting therapy is certainly not "experimental, investigational, and/or unproven."

The efficacy of closed-loop SCS therapy has been studied out to three years of follow up, which is substantial for neuromodulation therapies for pain, and the outcomes have been presented at national meetings, such as the 2023 North American Neuromodulation Society Annual Meeting.

Additionally, closed-loop SCS therapy was shown to be at least as good, if not better than, open-loop SCS, a treatment modality in use for more than four decades and proven to be superior to multiple conservative treatment modalities as well as repeat spinal surgery. In light of this compelling body of evidence, we strongly suggest you reconsider your current coverage policy for closed-loop devices. The scientific community at large recognizes closed-loop SCS as an evolutionary and proven advancement, offering patients a level of personalized care that was once unimaginable. Dismissing it as "experimental, investigational, and/or unproven" not only undermines the years of dedicated research but also restricts patient access to a treatment that has the potential to transform lives.

In conclusion, we urge you to reevaluate your commercial position and acknowledge the overwhelming evidence supporting closed-loop SCS therapy. By doing so, you will be aligning your policies and ensuring that patients suffering from chronic pain have access to the most advanced and effective treatments available.

We appreciate your attention to this matter and look forward to a positive response.

Sincerely,
American Academy of Pain Medicine
American Academy of Physical Medicine and Rehabilitation

American Association of Neurological Surgeons
American Society of Anesthesiologists
American Society of Neuroradiology
American Society of Regional Anesthesia and Pain Medicine
American Society of Spine Radiology
Congress of Neurological Surgeons
International Pain and Spine Intervention Society
North American Neuromodulation Society
North American Spine Society
Society for Interventional Radiology

cc: Suzy Shannon
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