

December 6, 2021

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Re: United Healthcare Commercial Medical Policy, #2021T0126FF; effective August 8, 2021

Dear Drs. Migliori and Stettler-Davis:

On behalf of the undersigned organizations we are writing to express concern regarding the [United Healthcare \(UHC\) Commercial Medical Policy](#), number 2021T0126FF, which came into effect August 8th, 2021. The policy dictates the coverage rationale for patients in need of functional and neuromuscular electrical stimulation (FES and NMES respectively) for spinal cord injuries or disuse muscle atrophy. What it fails to cover, due to what UHC deems as “not medically necessary,” are neuromodulation treatments that include dorsal root ganglion stimulation (DRG-S) and percutaneous peripheral nerve stimulation (PNS). Both of these treatments have a proven track record of safety and efficacy despite what the UHC policy states.

Examining the ongoing global health crisis of the COVID-19 pandemic, which has collided with the preexisting opioid epidemic that has plagued the United States, it is evident that DRG-S and PNS coverage is essential. By overwhelming the healthcare system, the pandemic impacted patients who required continued mental health services, treatment of chronic pain, and management of ongoing substance use disorders.¹ Limitations in resources increased social isolation and decreased access to care contributing to a “new wave” of the opioid overdose crisis.² Undoubtedly, the COVID-19 pandemic has fueled the overdose crisis with a record high 96,719 overdose deaths from March 2020-March 2021, according to the Centers for Disease Control and Prevention ([CDC](#)). The data also show a 29.7% increase in drug overdose deaths between February 2020 and February 2021. Unfortunately, these individuals suffer an array of ailments, including but not limited to chronic pain that can be medically treated not by opioid prescriptions but by safe and effective procedures such as DRG-S and PNS.

Neuromodulation utilizes therapeutic electrical stimulation of the nervous system and is used by physicians specializing in pain medicine for the treatment of neuropathic pain— pain that occurs from a damaged or malfunctioning nervous system. Overall, neuromodulation reduces the opioid burden in the chronic pain population.³ These are safe and effective treatments for patients with chronic pain after surgery, including complex regional pain syndrome (CRPS), a disease that entails prolonged pain and inflammation following an injury to an arm or leg and failed back surgery syndrome. They are also useful in treating a myriad of other painful conditions.

DRG-S is a form of SCS and differs slightly by the selective method of treating intractable focal pain in the trunk and limbs, specifically in patients with CRPS, diabetic peripheral neuropathy, and phantom pain by achieving stimulation to the targeted regions of pain versus an entire region as SCS does. DRG-S was

¹ Becker WC, Fiellin DA. When Epidemics Collide: Coronavirus Disease 2019 (COVID-19) and the Opioid Crisis. *Ann Intern Med.* 2020 Jul 7;173(1):59-60. doi: 10.7326/M20-1210. Epub 2020 Apr 2. PMID: 32240291; PMCID: PMC7138333.

² American Medical Association. Issue brief: reports of increases in opioid-related overdose and other concerns during COVID pandemic. Updated November 12, 2021. Available from <https://www.ama-assn.org/system/files/issue-brief-increases-in-opioid-related-overdose.pdf>

³ Cohen S, Gilmore C, Kapural L, Hopkins T, Desai M, DePalma M, Li S, Burgher A, Deer T, Plunkett T, McGee M, Boggs J. Reductions in Opioid Consumption with Percutaneous Medial Branch Peripheral Nerve Stimulation for Chronic Low Back Pain as presented at the Military Health Research Symposium August 21, 2019, Kissimmee, FL.

approved by the Food and Drug Administration (FDA) in February 2016 and stimulates cell bodies of sensory neurons that correlate with the exact dermatome of the painful regions, providing a more specific, targeted treatment compared to SCS, with a more meaningful significant clinical benefit. The DRG is an ideal target for neurostimulation and requires significantly less electrical dosage delivered to the central nervous system than traditional dorsal column stimulation.

The ACCURATE Trial by Deer *et al.* demonstrates that compared to tonic stimulation with SCS, DRG-S avoids patient perceived stimulation or paresthesia with the added benefit of decreased battery consumption. DRG-S yielded higher treatment success rates for CRPS at 3 and 12 months in this randomized comparative trial. The percentage of subjects receiving greater than 50% of pain relief was greater in the DRG-S patients (81.2%) versus the SCS patients (55.7%) at 3 months ($P < 0.001$).⁴

These findings are also consistent with those of Hunter *et al.* who showed that DRG-S is most effective in treating focal neuropathic pain, particularly in patients with pain that is distributed in a specific peripheral nerve. Among the 113 patients who had CRPS, the mean reduction in pain with DRG-S was 66.2%, with a 92% success rate for treatment.⁵

PNS is also used to treat chronic pain by placing small electrodes next to a peripheral nerve (nerves beyond the brain and spinal cord) and applying pulsed neurostimulation to the area of pain to block nerve signals from reaching the brain. Like DRG-S, PNS also provides a localized and highly targeted treatment. PNS has been FDA approved since 2018 with the goal of providing non-opioid alternatives to treating pain especially during the ongoing opioid epidemic.

Nayak and Banik describe PNS as a novel treatment of chronic pain from trauma, nerve injuries, or post cerebral vascular accident. With its minimally invasive, sometimes solely percutaneous, implantation technique they describe it as being a tremendous step forward in nonmedication treatment for chronic pain.⁶ A couple years after, Deer *et al.* conducted a systematic review evaluating PNS for pain. They critically analyzed 14 randomized controlled trials for a variety of painful disorders and concluded that PNS offers moderate-to-strong evidence for effective treatment of pain and improvement in quality of life.⁷ Thus, there is extensive level 1 evidence that DRG-S and PNS are effective for treating acute and chronic pain from multiple etiologies.

The impact of these highly targeted forms of neurostimulation, both DRG-S and PNS, are consistent with a growing body of evidence for neuromodulation and how it can reduce opioid use in chronic pain patients, improving function, disability, and quality of life. While an emphasis is on the use of these devices on CRPS and nerve injury, an array of evidence exists in support of these devices for other ailments. DRG-S has been shown to help patients with other nerve injury, post amputation pain, discogenic back pain, post-thoracotomy (surgery of the chest) pain, and more. PNS has been studied in patients with post-stroke shoulder pain, phantom limb pain, migraines, eye pain, fibromyalgia, and chronic muscle pain. There is growing evidence supporting the utilization of these non-opioid therapies, and patients should be able to have access from their insurance company to receive this care. With the benefit of these advanced therapies, patients are improving functionally and can decrease the reliance on opioids as well as create significant cost avoidance for insurance companies like UHC.

⁴ Deer TR, Levy RM, Kramer J, et al. Dorsal root ganglion stimulation yielded higher treatment success rate for complex regional pain syndrome and causalgia at 3 and 12 months: a randomized comparative trial. *Pain Journal*. 158(2017) 669-681.

⁵ Hunter CW, Sayed D, Lubenow T, et al. DRG Focus: A multicenter study evaluating dorsal root ganglion stimulation and predictors for trial success. *Neuromodulation Journal*. 2019; 22:61-79.

⁶ Nayak R, Banik RK. Current Innovations in Peripheral Nerve Stimulation. *Pain Res Treat*. 2018; doi: 10.1155/2019/9091216.

⁷ Deer TR, Esposito MF, McRoberts WP, et al. A systematic literature review of peripheral nerve stimulation therapies for the treatment of pain. *Pain Med*. 2020;21:1590-1603. doi: 10.1093/pm/pnaa030.

We appreciate your consideration of our comments on the UHC Medical Policy and urge UHC to immediately reevaluate and overturn the lack of coverage for PNS and DRG-S that this policy creates. If you have any questions or comments about our feedback, please do not hesitate to contact Ashley Walton at the American Society of Anesthesiologists via email: a.walton@asahq.org.

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

North American Neuromodulation Society

North American Spine Society

Society of Interventional Radiology

Spine Intervention Society

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