

AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS

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American
Association of
Neurological
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Congress of
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CONGRESS OF
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October 11, 2019

Seema Verma, MPH, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Submitted electronically via PainandSUDTreatment@cms.hhs.gov

Subject: Request for Information (RFI) on the Development of a CMS Action Plan to Prevent Opioid Addiction and Enhance Access to Medication-Assisted Treatment

Dear Administrator Verma:

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), representing more than 4,000 neurosurgeons in the United States, we appreciate the opportunity to comment on the above-referenced request for information (RFI) to assist the Centers for Medicare & Medicaid Services (CMS) in its efforts to address opioid addiction.

Amid the nationwide opioid epidemic, physicians are under significant pressure to reduce opioid prescribing in an effort to help resolve this widespread crisis. Yet patients continue to suffer from undertreated chronic pain. Neurosurgeons stand ready to immediately address the opioid crisis by providing several evidence-based and effective therapies to reduce the dependence of chronic pain patients on opioid medications. Unfortunately, Medicare, Medicaid, and many private insurers often deny the use of these treatments such as spinal cord stimulation, peripheral nerve stimulation, deep brain stimulation, peripheral neurectomy, cordotomy and others despite substantial high-quality peer-reviewed evidence supporting their efficacy in reducing chronic pain and patients' dependence on opioid medications. As a result of this dichotomy, neurosurgeons are thrust into situations in which they must treat patients in pain while having fewer options available due to inadequate insurance coverage policies.

Electrical neuromodulation has been recognized for over 40 years as an effective treatment to manage chronic pain and reduce the need for chronic opioids. Spinal cord stimulation, the most common technique used, involves the outpatient implantation under intravenous sedation of thin stimulating electrodes into the spinal epidural space, often via simple minimally invasive needles. Patients typically undergo a five to seven-day trial of stimulation, after which a permanent implant with a subcutaneous pulse generator is placed should the trial be deemed a success via demonstration of at least 50 percent reduction in pain, increased level of daily functioning, or both. Patients can adjust their stimulation in real-time and take control of their pain relief via a small handheld remote control.

Over the last several years, several high-quality studies have been published demonstrating the effectiveness of neuromodulation in the treatment of chronic pain. The SENZA Trial, published in 2015,

reports the results of a large, prospective, randomized, controlled trial of high-frequency spinal cord stimulation (SCS) for the treatment of low back and leg pain. In this study SCS delivered at both standard (60Hz) and high frequency (10Khz) levels produced significant reductions in chronic back and leg pain, with the high-frequency stimulation outperforming lower frequency stimulation. Concomitant significant reductions in disability scales were also seen. A follow-up study, published in 2017, shows the durability of significant treatment effects at two years post-implant. The ACCURATE study, another randomized trial published in 2017, pitted the newer technical of dorsal root ganglion (DRG) stimulation against traditional SCS for the treatment of lower limb chronic regional pain syndrome (CRPS). Once again, both therapies significantly reduced patients' chronic pain. The SunBURST study detailed successful results from a large clinical trial of SCS pulses delivered in short "bursts" rather than constant stimulation. A recent observational study (Sharan, et al., 2018) demonstrated that chronic pain patients who undergo spinal cord stimulation (SCS) were able to stabilize their opioid requirements despite undergoing dose escalation at the time of implantation. Further, SCS allowed chronic pain patients on high dose opioid regimens to actually reduce their opioid intake after device implantation (Pilitsis, et al., 2018).

All of these studies are a product of tremendous interest in the capabilities of neuromodulation to reduce chronic pain. This has also led to the introduction of multiple new devices to increase the number of patients we can effectively treat. For most of the first 30 years of neuromodulation, there were very few device options — one or two types of leads to be inserted either percutaneously or through an open surgical approach. Stimulation was delivered via tonic 40-80hz pulses. Smaller rechargeable implanted generators now exist that can last a decade or more before replacement is required. As previously mentioned, stimulation may be delivered via an ever-widening variety of waveforms that improve the probability of reducing a patient's pain now and maintain that reduction in future years. Smaller stimulation systems have come to market that eliminate the need for the implantation of a pulse generator and are well suited for treating chronic pain of the head and face.

Neurosurgeons continue to educate our non-surgical colleagues and the community on evidence-based alternatives to long-term opioid prescribing. This ranges from perioperative, polyanalgesic therapy (Wick, et al. JAMA 2017), to surgical options such as intrathecal medication delivered by implanted pumps (Deer, et al. PACC: Recommendations on ITP, 2017), as well as lesioning procedures such as cordotomy (Neurosurgical Guidelines for Cancer Pain, in progress), all of which have been shown to reduce the use of opioids by patients. Unfortunately, all of this innovation is wasted if these procedures are not supported by appropriate coverage policies from Medicare and other third-party payors. Without these options, patients have few other choices except to remain on escalating doses of chronic opioids that are marginally effective at best for neuropathic pain.

Neurosurgeons believe in supporting treatments that are evidence-based, cost-effective, and improve the quality of our patients' lives. Long before the opioid crisis made daily headlines, neurosurgeons were working hard to develop neuromodulation therapies and obtain the data to justify their use. In fact, the evidence base supporting neuromodulation for a variety of chronic pain conditions is better than the evidence behind many of the pharmaceuticals that are commonly used for this purpose.

In light of the current milieu surrounding chronic pain treatment, we ask that CMS perform a comprehensive examination of coverage policies for surgical pain therapies for both benign and malignant pain. These therapies include a variety of neurostimulation modalities (spinal cord, deep brain, peripheral, dorsal root ganglion and cortical stimulation), intrathecal medication infusion, as well as destructive procedures such as cordotomy, DREZ lesioning and midline myelotomy. Americans suffering

from chronic pain deserve to have access to the most effective treatments that avoid or reduce the use of chronic opioid medications.

The AANS and the CNS appreciate the opportunity to provide feedback on the CMS RFI for this important issue. If you have any additional questions or need additional information, please feel free to contact us.

Sincerely,



Christopher I. Shaffrey, President
American Association of Neurological Surgeons



Ganesh Rao, MD, President
Congress of Neurological Surgeons

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