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September 9, 2024

Ms. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
US Department of Health and Human Services
ATTN: CMS-1809-P
PO Box 8010
Baltimore, MD 21244-8010

Submitted electronically via www.regulations.gov

Subject: CMS-1809-P Medicare Program: Calendar Year (CY) 2025 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

Dear Administrator Brooks-LaSure:

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), representing more than 4,000 neurosurgeons nationwide, we appreciate the opportunity to comment on the payment provisions of the above-referenced notice of proposed rulemaking.

EXECUTIVE SUMMARY

- **Prior Authorization Issues**. We continue to be disappointed that CMS has not rescinded the action of the previous administration to require prior authorization for cervical fusion with disc removal (CPT codes 22551 and 22552) and implanted spinal neurostimulators (CPT code 63650) in the Hospital Outpatient Department (HOD). This requirement has caused a significant burden and confusion and remains a barrier to timely access to care for these critical spine procedures, which should be rescinded. A survey of our members conducted two years ago showed delayed patient care, administrative burden, and significant cost of useless prior authorization requirements. We have provided details from the survey for your consideration.

- **APC Placement for New Category III CPT Codes for Vagus Nerve Integrated Stimulation System**. We urge the agency to assign the new Vagus Nerve Integrated Stimulator CPT codes 0908T and 0909T to APC 5465.

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- **Payment for Non-Opioid Drugs.** We support CMS' proposal to make separate payments for certain drugs and one pain-pump device in the ASC and the OPPS setting setting for CY 2025. While we are pleased to see reimbursement for a pain device, we urge the agency to expand reimbursement for neurological devices such as pain pumps and spinal cord stimulators to treat pain. These innovative alternatives to opioids are a positive development in the response to the opioid epidemic.

DETAILED COMMENTS

PRIOR AUTHORIZATION FOR SPINE AND NEUROSTIMULATOR AND CERVICAL FUSION PROCEDURES

CMS began requiring prior authorization for select medical procedures performed in the hospital outpatient department five years ago. Four years ago, CMS expanded this requirement to include two new categories of services reimbursed under the Hospital Outpatient Prospective Payment System (OPPS) — cervical fusion with disc removal (CPT codes 22551 and 22552) and percutaneously implanted spinal neurostimulators (CPT codes 63650). **The AANS and the CNS continue to object to expanding prior authorization in the Medicare fee-for-service program — particularly for neurosurgical procedures.** The expansion of prior authorization to cervical fusion and spinal cord stimulators was adopted without adequate transparency regarding the standards used to select the services subject to these burdensome new requirements. Reports from our members and recent survey data confirm that the implantation of prior authorization has caused catastrophic disruption to patient care.

A few years ago, the AANS and the CNS surveyed our members to better determine their experience with prior authorization for these codes. The results reinforce our assertion that extending burdensome prior authorization requirements has unnecessarily delayed patient care and increased administrative costs without benefitting the Medicare program. We have received numerous reports from neurosurgeons and their staff who have had Medicare Administrative Contractors (MACs) tell them that they may not initiate a request for prior authorization when CMS instructions clearly state that this is required. This discrepancy has caused confusion, frustration, and harm to patients.

Our survey results showed significant delays in obtaining prior authorization from Medicare Administrative Contractors. 66% of survey respondents have experienced delays over ten days. Of these, 55% experienced delays from 11-20 days, 25% experienced delays from 21-30 days, and 10% experienced delays of more than 30 days.

Neurosurgical practices have experienced the following issues related to prior authorization for these procedures:

- Initial denial requiring additional documentation (63%);
- Initial denial requiring peer-to-peer or other higher-level review (42%);
- Final denial requiring the patient to appeal (21%);
- Final denial resulting in the patient abandoning this treatment option (21%);
- Final denial resulting in procedure to be performed at another site of service (8%);
- No denials, and the prior authorization process is not overly burdensome (4%); and
- No denials, but the prior authorization process adds unnecessary practice burdens (46%).

Widespread Delays and Disruption and Lack of Awareness from Hospital Staff

Written comments from our survey respondents emphasized that they have sometimes received denials for prior authorization for the pickiest of bureaucratic reasons that could easily be cleared up with a phone call or e-mail to the practice, such as failure to include a hospital fax number. They note a significant lack of education and support from hospital staff on this issue, and neurosurgeons' office staff have wasted valuable time that would be better spent helping patients. In addition, survey comments note that some MACs do not reimburse the neurosurgeon until the hospital has submitted its claim and CMS has processed it, punishing the neurosurgeon who has complied with all requirements. The agency's prior authorization policy for outpatient spine procedures hurts patients, limits access to needed care, complicates operating room scheduling, and reduces hospital efficiency.

In summary, CMS should eliminate the prior authorization program. Given its stated goal of reducing physician regulatory burden, the agency must strive to reduce burdensome prior authorization requirements, which have increased significantly over the last several years — delaying or preventing time-sensitive surgical care. Moreover, ongoing studies and our survey described above demonstrate that excessive and unnecessary prior authorization results in:

- Delays in medically necessary treatment;
- Patients abandoning treatment;
- Negative impacts on clinical outcomes; and
- Serious adverse events, such as death, disability, or other life-threatening outcomes.

Furthermore, these prior authorization burdens contradict the agency's goal of reducing opioid prescriptions. Non-pharmacological treatment by neurosurgeons for Medicare beneficiaries with chronic pain offers significant improvement in appropriately selected patients. The AANS and the CNS reiterate our previous comments, which we believe are worth repeating.

Cervical Fusion with Disc Removal (CPT codes 22551 and 22552)

We previously objected to the agency's proposal to require prior authorization for cervical fusion with disc removal — CPT codes 22551 and 22552, and again urge the agency to remove these procedures from the codes requiring prior authorization. This procedure can reduce pain and restore mobility for appropriately selected patients, allowing patients a significantly better quality of life. Requiring prior authorization has added additional burdens and delays without any benefits for patients for whom timely access is often of the utmost importance. CMS Recovery Audit Contractor (RAC) policies often push these procedures into the outpatient setting, yet the growth rate is deemed inappropriate when there is a resulting volume increase. Some of these changes are driven by CMS contractors, with admissions for cervical fusion with disc removal denied *a priori* by some Medicare contractors. This approach denies surgeons the opportunity to choose the best site of service for each patient.

Demanding prior authorization for cervical fusion with disc removal is performed in an outpatient setting, rather than allowing surgeons the option to choose the appropriate site of service for each patient, has delayed care. A better approach would be to enable each surgeon to select the site of service that s/he believes is appropriate for the patient and study the outcomes. CMS should adopt this approach and review several years of data to analyze volume growth and quality of care before implementing prior authorization requirements for these and other Medicare services. We understand this would require a

change in CMS contractor policy. However, if the agency had collected several years of data, it would have obtained more useful information on cost and quality.

One mechanism to support this data collection and review is for CMS to recognize and support participation in physician-led clinical registry programs. In previous years, we have provided details about the American Spine Registry (ASR), a joint initiative by the AANS and the American Academy of Orthopaedic Surgeons. Consistent with the ASR's operating procedures, we would happily share additional data from this excellent resource with CMS.

Implanted Spinal Neurostimulators (CPT code 63650)

The AANS and the CNS continue to object to prior authorization requirements for percutaneously implanted spinal neurostimulators. Innovation and strong evidence for effectiveness have increasingly made these procedures excellent choices for patients in pain. They offer effective, nonpharmacologic options for appropriately selected patients to treat chronic pain and have been shown to significantly improve pain control and decrease pain-related disability and opioid use. Furthermore, effective pain control achieved through interventional care has also substantially reduced long-term health care utilization. Over the last several years, many high-quality studies have been published demonstrating the effectiveness of neuromodulation in treating chronic pain.

We continue to disagree with the agency's assertion that the increase in the volume of spinal cord stimulation trials and device implantation procedures has been unnecessary. The agency's baseline for counting the number of spinal cord stimulation procedures two years ago began before 2010 — more than a decade ago. Numerous peer-reviewed studies indicate that this field has seen unprecedented innovation in the last decade. New stimulation waveforms have been developed to give patients better pain control without perceptible paresthesia. New targets — such as the dorsal root ganglion and dorsal horn of the spinal cord — have been investigated and validated. Moreover, new devices allow patients to run multiple stimulation waveforms simultaneously, thus improving their chances for significant long-term pain relief. Appropriate increased utilization of spinal cord stimulation represents a positive alternative to opioid use and an important tool to help address the opioid epidemic.

Importantly, neurosurgeons have worked diligently for several years in concert with the American Medical Association (AMA), CMS, Department of Health and Human Services (HHS), National Academy of Medicine, and numerous other government organizations, private payers, and health care organizations to devise solutions to the opioid crisis and the epidemic of opioid-related morbidity and mortality. As stated above, neuromodulation procedures such as spinal cord stimulation are proven to reduce pain, pain-related disability, and opioid use. These are non-pharmaceutical, reversible, adjustable, and minimally invasive procedures that clearly play an increasing role in managing patients with various chronic pain diagnoses. Imposing prior authorization requirements has resulted in delayed care and denied many Medicare patients the benefits of these procedures, leaving them to continue with ineffective opioid therapies or, worse, to leave them without any good options for managing their chronic pain disability.

Evidence shows that neurostimulation procedures are more effective if employed earlier in the pain syndrome. Delaying utilization of these devices through unnecessary and burdensome prior authorization processes will likely result in patients not obtaining the optimal relief from the therapy as the treatment will be delayed as the pain syndrome progresses and becomes more refractory. As a result, patients will continue to have more pain-related disability and incur higher healthcare costs over time.

The HHS "Pain Management Best Practices Inter-Agency Task Force Report" emphasizes the importance of multidisciplinary chronic pain care and highlights barriers to accessing optimal pain care.[1] The task force recognizes both the high level of evidence for neurostimulation and barriers "requiring patients and health care professionals to navigate burdensome and variable coverage policies may contribute to slow development, adoption, and implementation of timely and effective pain treatments and may force providers to treat patients in a less-than-optimal fashion. Consistently forcing providers to try a series of non-first-line treatments before authorizing treatment plans can be problematic, hindering appropriate patient care, creating tremendous inefficiency, and resulting in a loss of time and resources." We believe that placing more roadblocks in the way of patients with chronic pain who wish to access effective opioid-sparing procedures such as neurostimulation only prolongs the opioid crisis, which continues to damage patient lives while not relieving them of their chronic pain. **The AANS and the CNS urge CMS to adhere to the task force's recommendations and rescind the requirement for prior authorization for percutaneously implanted spinal neurostimulators.**

In summary, we urge CMS to take the following actions:

- Immediately halting the prior authorization program. At the very least, CMS must closely monitor the implementation of the current prior authorization requirements to correct documented cases of delay and disruption that this policy has caused for hospitals and surgeons, but most of all for patients.
- Release the MACs' prior authorization data to improve transparency.
- Clarify the process for removing services from the prior authorization requirements.
- Suspend the use of prior authorization for all Medicare fee-for-service programs.

APC Placement for Integrated Vagus Nerve Stimulation System

In February, 2024, the AMA CPT Editorial Panel created new category III CPT codes, 0908T, 0909T, to report implantation and replacement services for integrated neurostimulator system for vagus nerves. CMS is proposing to assign these codes to APC 5462, Level 2 Neurostimulator and Related Procedures, with a payment rate of $6,557. We believe that this assignment is inappropriate. The surgical technique, time and risk of implanting, revising, and removing and integrated vagus nerve stimulator is very similar to the procedures described by CPT codes 64568 and 64569 for the placement and revision of a traditional (non-integrated) vagus nerve stimulation system. Moreover, the hospital resource costs (operating room time, instrumentation, anesthesia and nursing) required for integrated vagus nerve stimulation procedures are identical to those required for traditional VNS system procedures. Given this, we disagree with the proposed APC assignment and request that CPT codes 0908T, and 0909T. be assigned to the same category as traditional VNS system procedures (APC 5465). The clinical complexity and resource use for these codes are most analogous to procedures currently captured under APC 5465, Level 5 Neurostimulator and Related Procedures and we request the agency to assign them to APC 5465. It is important to note that this new device offers significant hope to patients with few, if any, adequate treatment alternatives. There is a small but important group of functional neurosurgeon experts who manage these patients and adequate facility reimbursement is essential to maintaining access for appropriate patients.

Separate Payment for Non-Opioid Drugs and Devices

[1] US Department of Health and Human Services, Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations (Final Report), May 9, 2019, https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf?language=es.

CMS is proposing to provide temporary additional payment for specific non-opioid pain control devices and drugs in the hospital outpatient department (HOPD) and ASC settings for the years 2025–2027. **T**he AANS and the CNS support CMS' proposal to continue to pay separately for these drugs and one device in both the ASC and OPPS setting. We are particularly pleased that CMS has included a pain pump device for separate payment. The AANS and the CNS have long supported adequate coverage and funding for neurological devices such as pain pumps and spinal cord stimulators that offer short and long-term non-opioid pain relief.

Neurosurgeons evaluate and manage patients with various chronic pain conditions, such as postsurgical spinal pain syndrome, chronic regional pain syndrome, and others. Neurostimulation procedures, such as spinal cord stimulation (SCS), peripheral nerve stimulation, and deep brain stimulation, provide significant pain relief while allowing patients to reduce the use of opioid medications. These procedures often involve a trial period, allowing the physician and patient to evaluate the level of effectiveness before deciding on a permanent implant. Neurostimulation therapies are adjustable by the patient and physician to adapt the therapy as the patient's condition changes over time.

We provide some additional specific comments on neurostimulation below. We are eager to work with CMS to help promote innovative and safe non-opioid devices and hope CMS will look forward to providing more information over the coming year and in our future comments on the CY 2025 proposed rule.

Potential Future Qualifying Devices. As we have often stated in our many comments regarding spinal cord stimulators, innovation and strong evidence for effectiveness have increasingly made these procedures excellent choices for patients in pain. They offer effective, nonpharmacologic options for appropriately selected patients to treat chronic pain and have been shown to significantly improve pain control and decrease pain-related disability and opioid use. Furthermore, effective pain control achieved through interventional care has also substantially reduced long-term health care utilization. We believe spinal cord stimulators should be considered qualifying devices for non-opioid pain treatment as the agency moves forward with innovation in the development of alternatives to opioids for pain.

Evidence Requirement for Medical Devices. We are eager to work with the agency to review clinical data and real-world evidence for neurological devices that treat pain and give patients truly effective alternatives to opioids. Over the last several years, many high-quality studies have been published demonstrating the effectiveness of neuromodulation in treating pain, including those below:

- The SENZA Trial, published in 2015, reports the results of a large, prospective, randomized, controlled trial of high-frequency spinal cord stimulation (SCS) to treat 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 reductions in disability scales were also seen.[2] A follow-up study published in 2017 shows the durability of substantial treatment effects two years post-implant.[3]

[2] Kapural L, Yu C, Doust MW, Gliner BE, Vallejo R, Sitzman BT, Amirdelfan K, Morgan DM, Brown LL, Yearwood TL, Bundschu R, Burton AW, Yang T, Benyamin R, Burgher AH, Novel 10-kHz High-frequency Therapy (HF10 Therapy) Is Superior to Traditional Low-frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: The SENZA-RCT Randomized Controlled Trial, *Anesthesiology*, 2015 Oct;123(4):851-60, doi: 10.1097/ALN.0000000000000774. PMID: 26218762.

[3] Kapural L, Yu C, Doust MW, Gliner BE, Vallejo R, Sitzman BT, Amirdelfan K, Morgan DM, Yearwood TL, Bundschu R, Yang T, Benyamin R, Burgher AH, Comparison of 10-kHz High-Frequency and Traditional Low-Frequency Spinal Cord Stimulation for the Treatment of Chronic Back and Leg Pain: 24-Month Results From a Multicenter, Randomized,

- The ACCURATE study, another randomized trial published in 2017, pitted the newer technical of dorsal root ganglion stimulation against traditional SCS to treat lower limb chronic regional pain syndrome.[4] 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.[5]

- An observational study demonstrated that chronic pain patients who undergo SCS could stabilize their opioid requirements despite undergoing dose escalation at the time of implantation.[6]

- Finally, SCS allows chronic pain patients on high-dose opioid regimens to reduce their opioid intake after device implantation.[7]

Again, as the agency continues to consider appropriate reimbursement and increased availability of non-opioid pain treatment going forward, the AANS and the CNS are uniquely positioned to help, as we have a long history of innovation in chronic and acute pain care.

CONCLUSION

Thank you for the opportunity to share our comments on these topics. The AANS and the CNS appreciate the dedication and professionalism of the CMS staff. We urge the agency to do all it can to maintain appropriate reimbursement for neurosurgical services and reduce burdensome regulations.

Sincerely,

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Alexander A. Khalessi, MD
President
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[6] Sharan AD, Riley J, Falowski S, Pope JE, Connolly AT, Karst E, Dalal N, Provenzano DA, Association of Opioid Usage with Spinal Cord Stimulation Outcomes, *Pain Med,* 2018 Apr 1;19(4):699-707. doi: 10.1093/pm/pnx262. PMID: 29244102.

[7] Gee L, Smith HC, Ghulam-Jelani Z, Khan H, Prusik J, Feustel PJ, McCallum SE, Pilitsis JG, Spinal Cord Stimulation for the Treatment of Chronic Pain Reduces Opioid Use and Results in Superior Clinical Outcomes When Used Without Opioids, *Neurosurgery*, 2019 Jan 1;84(1):217-226, doi: 10.1093/neuros/nyy065. PMID: 29538696.

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