

AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS

KATHLEEN T. CRAIG, CEO
5550 Meadowbrook Drive
Rolling Meadows, IL 60008
Phone: 888-566-AANS
Fax: 847-378-0600
info@aans.org



American
Association of
Neurological
Surgeons



Congress of
Neurological
Surgeons

CONGRESS OF
NEUROLOGICAL SURGEONS

REGINA SHUPAK, CEO
10 North Martingale Road, Suite 190
Schaumburg, IL 60173
Phone: 877-517-1CNS
FAX: 847-240-0804
info@cns.org

President
REGIS W. HAID, JR., MD
Atlanta, Georgia

President
BRIAN L. HOH, MD
Gainesville, Florida

September 17, 2021

Ms. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-1751-P
P.O. Box 8013 Baltimore, MD 21244-1850

Submitted electronically via www.regulations.gov

Subject: CMS-1753-P Medicare Program: Calendar Year 2022 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals

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 in the United States, we appreciate the opportunity to comment on the payment provisions of the above-referenced notice of proposed rulemaking.

EXECUTIVE SUMMARY

Outpatient Prospective Payment System Issues

- **Inpatient Only List.** The AANS and the CNS believe the site of service should be determined by the surgeon in consultation with the patient. Last year we were concerned about the agency's plan to eliminate the Inpatient Only List (IPO). We support the reversal of that policy in favor of a more measured approach. Even when a procedure comes off the IPO, inpatient admission should remain an option for patients who require that level of care.
- **Prior Authorization for Spine and Neurostimulator Procedures.** The AANS and the CNS were pleased to see that CMS did not propose additional procedures for prior authorization. However, we were disappointed to see that CMS did not rescind 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 codes 63650, 63685 and 63688). The requirement has caused a significant burden and confusion and remains a barrier to timely access to care for these critical spine procedures and should be rescinded.
- **Removal of Non-Opioid Pain Relief from OPPS Bundling Policy.** The AANS and the CNS supported the CMS policy to pay separately for the non-opioid pain drug Exparel in the ambulatory surgery center (ASC) setting, removing it from the packaging or bundling policy. We would also support an expansion of the ASC policy of allowing separate payment for non-opioid pain treatment in the hospital outpatient setting

Ambulatory Surgery Center Issues

- **Expansion of the ASC List.** The AANS and the CNS again emphasize that the site of service should be determined by the operating surgeon in consultation with the patient. We support the agency's plan to reconsider the methodology proposed for the ASC list last year.

DETAILED COMMENTS

OPPS Issues

Eliminating the IPO List

The AANS and the CNS believe the site of service should be determined by the operating surgeon in consultation with the patient, carefully considering the individual's clinical status. However, we have heard from some of our members that they have had retrospective denials of payment for inpatient admissions for elderly patients for whom that setting was medically necessary. Therefore, we support CMS rescinding the elimination of the IPO list. Without a clear CMS policy to ensure that physician and patient choice are paramount and payment for inpatient care will be honored based on clinician judgment, rather than retroactive review, we support a more measured process for taking procedures off the IPO list.

Given that the inpatient setting is generally the most expensive treatment environment, the AANS and the CNS agree that patients should be offered the option of receiving care in the outpatient and ambulatory surgery center settings — provided safety and effectiveness can be assured. However, safety in one outpatient environment does not guarantee universal safety, and elements of care that are demonstrated to promote safe outpatient treatment need to be cataloged and disseminated. CMS proposes to codify in regulation the five longstanding criteria used to determine whether a procedure or service should be removed from the IPO list. CMS should involve stakeholders in reviewing criteria for the annual IPO review process. **We, therefore, urge CMS to work closely with the physician community to help develop best practices for determining both the IPO and the ASC lists.**

Prior Authorization for Spine and Neurostimulator Procedures

Two years ago, CMS began requiring prior authorization for select medical procedures performed in the hospital outpatient department. Last year, 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 implanted spinal neurostimulators (CPT codes 63650, 63685, and 63688). **The AANS and the CNS continue to object to expanding prior authorization in the Medicare fee-for-service program — particularly for these neurosurgical procedures.** This expansion was adopted without adequate transparency regarding the standards used to select the services subject to these burdensome new requirements. Furthermore, CMS had no data evaluating the program's first year before expanding the program to include these additional services.

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 they may. This has caused confusion, frustration and harm to patients.

CMS has seen fit to reverse previous year's policies for other provisions of the OPSS program, and the agency should eliminate the prior authorization program as well. CMS should be working 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 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 are contrary to the agency's stated goal of reducing opioid prescriptions. Non-pharmacological treatment by neurosurgeons for Medicare beneficiaries with chronic pain offers significant improvement in appropriately selected patients. Finally, prior authorization is particularly inappropriate during the COVID-19 crisis.

The AANS and the CNS offered some of the following comments on the specific technologies identified for prior authorization in the proposed rule last year. We believe they are worth repeating.

- **Cervical Fusion with Disc Removal (CPT codes 22551 and 22552).** We objected to the agency's proposal to require prior authorization for cervical fusion with disc removal — CPT codes 22551 and 22552 last year. We again urge the agency to remove these procedures from the list of 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 can often be of the utmost importance. CMS Recovery Audit Contractor (RAC) policies often push these procedures into the outpatient setting, yet when there is a resulting volume increase, the growth rate is deemed inappropriate. 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 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 then 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 collected several years of data, it would obtain 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. Last year, our comments provided details about the American Spine Registry (ASR), a joint initiative by the AANS and the American Academy of Orthopaedic Surgeons (AAOS). Consistent with the ASR's operating procedures, we would be happy to share additional data from this excellent resource with CMS.

- **Implanted Spinal Neurostimulators. (CPT codes 63650, 63685, and 63688).** The AANS and the CNS continue to object to prior authorization requirements for 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 healthcare utilization. Over the last several years, many high-quality studies have been published demonstrating the effectiveness of neuromodulation in treating 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) 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.
- + A follow-up study published in 2017 shows the durability of substantial 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 to treat 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) could stabilize their opioid requirements despite undergoing dose escalation at the time of implantation.
- + Finally, SCS allowed chronic pain patients on high-dose opioid regimens to reduce their opioid intake after device implantation (Pilitsis, et al., 2018).

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.

Last year the agency's baseline for counting the number of spinal cord stimulation procedures began before 2010 — more than a decade ago. As evidenced by listing several peer-reviewed studies above, the last decade has seen an unprecedented level of innovation in this field. 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.

Although we noted that CPT code 63650, Implant Neuroelectrodes, experienced only a 1% increase in Medicare utilization from 2018 to 2019 and 63655 saw a decrease in Medicare utilization, we acknowledged the volume of these procedures had increased dramatically. Much of this is due to innovation and patient needs. However, some volume increases may be attributable to incorrect coding. Neurosurgery continues to offer our expertise to ensure appropriate reporting for new devices. During the rapid innovation of neuromodulation, the AANS and the CNS continue to work closely with the AMA CPT Editorial Panel to ensure correct coding for new devices and accurate coding advice.

Importantly, neurosurgeons have been diligently working for several years in concert with the AMA, CMS, HHS, National Academy of Medicine and numerous other government organizations, private payors, 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 delayed and denied a larger number

of Medicare patients from 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 they are 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. 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.” **The AANS and the CNS urge CMS to adhere to the task force’s recommendations and rescind the requirement for prior authorization for implanted spinal neurostimulators.**

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

- Immediately halt the prior authorization requirements for the seven clinical areas currently subject to this new program. At the very least, CMS must closely monitor the implementation of the current PA requirements to ensure that decisions are made promptly and, if they are not, clarify that the PA requirements are not barriers to payment for these services;
- Release the MACs’ PA data to improve transparency;
- Clarify the process for removing services from the PA requirements; and
- Suspend the use of PA for any additional services under all Medicare FFS programs.

Removal of Non-Opioid Pain Relief from OPPS Bundling Policy

The AANS and the CNS supported the CMS policy to pay separately for the non-opioid pain drug Exparel in the ASC setting, removing it from the packaging or bundling policy. We would also support expanding the ASC policy of allowing separate payment for non-opioid pain medications used as surgical supplies to the hospital outpatient setting. CMS is required to review payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) to ensure that there are no financial incentives to use opioids instead of non-opioid alternatives. This year CMS again will continue permitting separate payment in the ASC setting and not in the OPPS setting. **We urge CMS to allow for separate payment for non-opioid pain management in all surgery settings.** As we mentioned above, we support coverage and reimbursement policy for innovative nonpharmacologic options such as neurostimulators for appropriately selected patients to improve pain control

Ambulatory Surgery Center Issues

Reversal of the Expansion of the ASC List.

The AANS and the CNS reiterate that the site of service should be determined by the operating surgeon in consultation with the patient. We urge CMS to carefully consider stakeholder comments on the optimal methodology for proposed additions to the ASC list. As with the IPO list policy, the AANS and

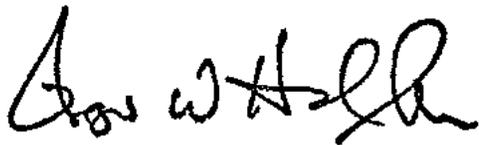
the CNS have emphasized the importance of patient selection in determining the site of service for individual Medicare beneficiaries. Inpatient admission should always remain an option for patients who require that level of care, and the ASC should be permitted for patients for whom that setting is optimal.

CONCLUSION

The AANS and the CNS appreciate the opportunity to comment on the CY 2022 Medicare Hospital OPPTS ASC proposed rule. We support the agency's decision to maintain the IPO list and develop a more measured process for selecting procedures for the IPO and ASC lists. Above all, we continue to object vigorously to the requirement for prior authorization. We urge CMS to take all necessary steps to reduce stress on our overburdened health care system, including rescinding the hospital outpatient department prior authorization requirements.

Thank you for considering our comments. We appreciate the expertise, hard work and dedication of CMS leaders and staff, especially during the continuing COVID-19 public health emergency. We look forward to collaborating on these and other policy matters to ensure timely patient access to quality care.

Sincerely,



Regis W. Haid, Jr., MD, President
American Association of Neurological Surgeons



Brian L. Hoh, MD, President
Congress of Neurological Surgeons

Staff Contact:

Catherine Jeakle Hill
Senior Manager, Regulatory Affairs
AANS/CNS Washington Office
25 Massachusetts Ave., NW
Washington, DC 20005
Phone: 202-446-2026
E-mail: chill@neurosurgery.org