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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](http://www.regulations.gov)

**Subject: CMS-1772-P Medicare Program: Calendar Year (CY) 2023 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star**

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 and quality provisions of the above-referenced notice of proposed rulemaking.

## **EXECUTIVE SUMMARY**

### **Reimbursement Issues**

#### ***Outpatient Prospective Payment System***

- **Inpatient Only List.** The AANS and the CNS believe the site of service should be determined by the surgeon in consultation with the patient. We were concerned about the agency's plan to eliminate the Inpatient Only (IPO) list two years ago. We supported the reversal of that policy in favor of a more measured approach. Even when a procedure comes off the IPO list, inpatient admission should remain an option for patients who require that level of care. For CY 2023, we agree with the agency's proposals to remove the arthrodesis CPT code 22632 from the list and to add the new CPT code 228XX additional level total disc arthroplasty procedures.
- **Prior Authorization Issues.** The AANS and the CNS continue to be disappointed that CMS has not rescinded the action of the previous administration to require prior authorization for cervical fusion with disc removal (CPT codes 22551 and 22552) and implanted spinal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). This 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burden and confusion and remains a barrier to timely access to care for these critical spine procedures and should be rescinded. In our detailed

comments below, we provide data from a recent survey of neurosurgeons on this issue, highlighting the delayed patient care, administrative burden and cost of useless prior authorization requirements.

- **APC Assignment for Magnetic Resonance guided Focused Ultrasound (MRgFUS).** The AANS and the CNS recommend that MRgFUS, CPT code 0398T, be assigned to APC 5464.
- **OPSS Payment for Software.** The AANS and the CNS ask the agency to consider exempting the EyeBOX concussion detection device from bundling requirements, as the agency has for several other software-dependent services.
- **Transitional Pass-Through Payment Applications for CY 2023.** The AANS and the CNS support the pass-through payment application process to foster innovation in patient care. For CY 2023, we note two applications of particular promises for neurosurgery: The EVOKE compound action potential (ECAP) closed-loop Spinal Cord Stimulation (SCS) system and the Aprevo custom intervertebral body fusion device.

## **Quality Issues**

### ***Outpatient Prospective Payment System Quality Issues***

- **Hospital Outpatient Quality Reporting (OQR) Program.** The AANS and the CNS strongly oppose the future reimplementations of the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP–26) measure or the adoption of another volume indicator for quality improvement and accountability.

### ***Ambulatory Surgery Center Quality Issues***

- **Ambulatory Surgical Center Quality Reporting Program.** The AANS and the CNS strongly oppose the future reimplementations of the ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC–7) measure or the adoption of another volume indicator for quality improvement and accountability.

## **DETAILED COMMENTS**

### **Reimbursement Issues**

#### ***Outpatient Prospective Payment System***

- **Changes to 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 were pleased to see CMS reiterate the principle that “the absence of a procedure from the list should not be interpreted as identifying that procedure as appropriately performed only in the hospital outpatient setting.” Two years ago, we supported 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 supported 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 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. **Therefore, we urge CMS to work closely with the physician community to help develop best practices for determining the IPO and the ASC lists.**

For CY 2023 specifically, CMS is proposing to remove CPT 22632 (Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; each additional interspace (list separately in addition to code for primary procedure)) off the list, stating that it makes sense since it is an add-on code to CPT 22630 and CPT 22630 was removed from the IPO List in CY 2021. We agree with this recommendation, as this is a procedure that can safely be in the outpatient setting for appropriately selected Medicare patients. Again, we emphasize that the inpatient setting should still be permitted for those beneficiaries for whom that setting is best.

CMS has also proposed to add to the IPO list the new CPT Code 228XX (Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)). We believe this is appropriate, as Medicare data shows that the base code for single-level total disc arthroplasty (CPT code 22857) is performed over 75% of the time in the inpatient setting, and we would expect the inpatient percentage for a two-level arthroplasty to be greater than that.

- **Impact of Prior Authorization for Spine and Neurostimulator Procedures.** Three years ago, CMS began requiring prior authorization for select medical procedures performed in the hospital outpatient department. Two years ago, CMS expanded this requirement to include two new categories of services reimbursed under the Hospital Outpatient Prospective Payment System (OPSS) — cervical fusion with disc removal (CPT codes 22551 and 22552) and 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 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.

The AANS and the CNS recently 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 they may. This has caused confusion, frustration and harm to patients.

Our survey results show:

- + **Significant Delays in obtaining prior authorization from Medicare Administrative Contractors.** 66% of survey respondents have experienced delays over 10 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 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 Patients Over Paperwork initiative, 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 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 can often be 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 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 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, a joint initiative by the AANS and the American Academy of Orthopaedic Surgeons. 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). 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 health care 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 two years post-implant.
  - 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. 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 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.** The agency’s baseline for counting the number of spinal cord stimulation procedures two years ago began before 2010 — more than a decade ago. As evidenced by listing several peer-reviewed studies above, the last decade has seen unprecedented 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.

Importantly, neurosurgeons have worked diligently for several years in concert with the AMA, CMS, the Department of Health and Human Services (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 denied a more significant number of 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. 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 and the new facet joint procedures added for CY 2023. 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; and
  - + Suspend the use of prior authorization for all Medicare fee-for-service programs.
- **APC Assignment for Magnetic resonance-guided focused ultrasound.** Magnetic resonance-guided focused ultrasound is a non-invasive acoustic surgical procedure that uses magnetic resonance imaging with high-power, focused ultrasound energy (non-ionizing radiation) to provide a single-day treatment. Neurosurgeons use this technology to treat patients suffering from essential tremor and Parkinson's Disease in a procedure reported with CPT code 0398T (Magnetic resonance image-guided high intensity focused ultrasound (MRgFUS), stereotactic ablation lesion, intracranial for movement disorder including stereotactic navigation and frame placement when performed). We are concerned that the proposal to assign CPT code 0398T to APC 5463 (Level 3 Neurostimulator and Related Procedures) may not account for the hospital resources required for this procedure. Our understanding is that the underlying claims data are maturing and continue to show a rise in the geometric mean cost for the procedure that may be better reflected with an assignment to APC 5464 (Level 4 Neurostimulator and Related Procedures). **The AANS and the CNS ask CMS to review data submitted by the manufacturer and consider assigning CPT code 0398T to APC 5464 for CY 2023.**
  - **OPPS Payment for Software as a Service.** CMS points out that new clinical software, which includes clinical decision support software, clinical risk modeling, and computer-aided detection (CAD), is becoming increasingly available to providers. These technologies often perform data analysis of diagnostic images from patients. While many of these technologies are new, clinical software, particularly CAD, has been used to aid or augment clinical decision-making for decades. These technologies rely on complex algorithms or statistical predictive modeling to aid in diagnosing or treating a patient's condition. CMS refers to these algorithm-driven services that assist practitioners in making clinical assessments as Software as a Service (SaaS).

In CY 2021, CMS began paying for CPT code 0615T (Eye-movement analysis without spatial calibration, with interpretation and report), which involves the use of the EyeBOX system as an aid in the diagnosis of concussion. CMS assigned EyeBOX to APC 5734 with the status indicator "Q1" to indicate that the code is bundled when performed with another service on the same day. However, this is inappropriate because the EyeBOX service is always provided in conjunction with a clinical exam, which is included in the FDA labeling for the device. CMS is proposing to pay separately for several other new SaaS add-on codes that are more expensive than the imaging services with which they are billed. Although these codes are reported with imaging services, the logic that compels the agency to exempt these services from bundling would also apply to the EyeBOX. A service already performed with a visit should not be bundled into payment for another, lower-cost service that happens to be reported on the same day. **We urge the agency to consider the payment structure for this important promising technology to aid physicians in the diagnosis of concussion.**

Given the distinct nature of the EyeBOX evaluation, we believe that payment for this service should not be bundled with another same-day service.

- **Transitional Pass-Through Payment Applications for CY 2023.** CMS has received applications for device pass-through payments for several neurosurgical products. We support both the traditional program and the expedited FDA Breakthrough Device Designation path for pass-through payment when innovative and promising products are introduced. For CY, 2023, we would like to highlight two technologies that we believe offer encouraging early clinical improvement data for appropriately selected neurosurgical patients.
  - + **The AANS and the CNS support the application for pass-through payment for the EVOKE compound action potential (ECAP) closed-loop Spinal Cord Stimulation (SCS) system submitted by Saluda Medical.** This first-in-class neurostimulation system employs novel technology to sense actionable potentials from the nervous system and self-adjust in response to these to optimize patient outcomes. The device and technology differ substantially from other existing neurostimulation devices marketed for spinal cord stimulation. The results have been validated in peer-reviewed randomized controlled trials published in respected journals such as the *Journal of the American Medical Association*, *Neurology* and *Lancet*. These publications document the effectiveness of the novel EVOKE closed-loop technology and the durability of these results. We urge CMS to support the introduction of this therapy through a pass-through payment.
  - + **The AANS and the CNS support the FDA Breakthrough Pathway Device Pass-through applications for the Aprevo intervertebral body fusion device.** This is a custom three-dimensional printed interbody cage system for patients with unusual bone morphology such as spinal deformity and is different from traditional “off-the-shelf” options. With new developments in personalized medicine moving forward, the innovation in products uniquely suited to an individual patient's anatomy offers a promising future for patient care. We urge the agency to support this device's application for pass-through payment.

## Quality Issues

### ***Hospital Outpatient Quality Reporting (OQR) Program***

- **Reimplementing Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP–26) Measure or Adoption of Another Volume Indicator.** CMS previously adopted the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures measure (OP–26), beginning with the CY 2012 reporting period. This structural measure collected surgical procedure volume data on eight categories of procedures frequently performed in the hospital outpatient setting: cardiovascular, eye, gastrointestinal, genitourinary, musculoskeletal, nervous system, respiratory, and skin. In the CY 2018 OPPS/ASC final rule, CMS removed OP–26 due to a lack of evidence regarding the measure's link to improved clinical quality.

Due to the migration of procedures from the inpatient setting to the outpatient setting, CMS seeks comment on the potential inclusion of a volume measure in the Hospital OQR Program, either by re-adopting the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP–26) measure or adopting another volume indicator. CMS also seeks comment on what volume data hospitals currently collect and if it is feasible to submit this data to the Hospital OQR Program to minimize the collection and reporting burden of an alternative, new volume measure.

While the AANS and the CNS appreciate the agency's desire to provide patients with more complete information to inform health care decisions, **we strongly oppose using volume measures for quality improvement and accountability.** As we have expressed in previous comments, we are concerned about the accuracy of utilization data and the potential misinterpretation or misuse of such data. High volume is not, in all situations, a clear indicator of high-quality or high-value care.

We are also concerned that the dataset would only reflect Medicare volume and not include utilization data related to other Medicare Advantage, Medicaid, Veteran Affairs or private payers. As a result, this measure could erroneously suggest that facilities have little to no experience with certain procedures they regularly perform on other beneficiary types. Furthermore, it is not so simple to report volume by procedure type. Many services and diagnoses are distributed over large groups of procedure codes or diagnostic codes respectively. Therefore, even if a facility regularly performs a service, a volume measure may incorrectly identify it as having little to no experience if no single code exceeds a minimum threshold.

In general, we do not believe that volume data is well understood by the average Medicare consumer or an appropriate metric for facility accountability. **If CMS insists on adopting a volume measure for surgical procedures, then we strongly recommend that it only use this measure for confidential facility-level feedback and not tie it to payment or public reporting.**

## **Ambulatory Surgery Center Quality Issues**

### ***Ambulatory Surgical Center Quality Reporting Program***

- **Request for Comment on Potential Future Reimplementation of ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC-7) Measure or Other Volume Indicator.** Similar to the discussion above regarding the potential adoption of a surgical procedure volume measure under the Hospital OQR Program, CMS is considering reimplementation of ASC-7 measure — a structural measure of facility capacity that collects surgical procedure volume data on six categories of procedures frequently performed in the ASC setting (gastrointestinal, eye, nervous system, musculoskeletal, skin, and genitourinary) — or another volume measure. CMS is also considering a potential future facility-level volume measure on ASC procedures related to pain management. CMS believes a volume measure would provide Medicare beneficiaries and other interested parties with information on the numbers and proportions of ASC procedures by category performed by individual facilities.

**The AANS and the CNS oppose using procedural volume measures for accountability due to their tenuous tie to quality.** We refer to CMS our previous comments regarding its consideration of a similar measure for the Hospital OQR Program.

## **CONCLUSION**

The AANS and the CNS appreciate the opportunity to comment on the CY 2023 Medicare Hospital OPSS ASC proposed rule. We continue to support the agency's plan to maintain the IPO list and use 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. Our recent member survey on the impact of prior authorization requirements shows significant interference with access to essential, life and ability-saving spine procedures, hurting patients and causing unnecessary suffering.

Thank you for considering our comments. We appreciate the expertise, hard work and dedication of CMS leaders and staff. We look forward to collaborating on these and other policy matters to ensure timely patient access to quality care.

Sincerely,



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***Payment-Related Issues***

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