

AMERICAN ASSOCIATION OF
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American
Association of
Neurological
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Congress of
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CONGRESS OF
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September 27, 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 www.regulations.gov

**Subject: CMS-1717-P Medicare Program: Calendar Year 2020 Hospital Outpatient
Prospective Payment and Ambulatory Surgical Center Payment Systems and
Quality Reporting Programs**

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 notice of proposed rulemaking.

EXECUTIVE SUMMARY

Outpatient Prospective Payment System Issues

- **Consideration of Removal of Spine Procedure from the Inpatient Only (IPO) List.** The AANS and the CNS support the removal of CPT codes 63265-63268 (laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural) and CPT codes 22633 and 22634 (combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/ or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar) from the IPO. **However, we emphasize the importance of patient selection in determining the site of service. Inpatient admission should remain an option for patients who require that level of care.**
- **Magnetic Resonance-guided Focused Ultrasound (MRgFUS) for Essential Tremor (ET).** The AANS and the CNS urge CMS to reverse its decision from last year to reassign MRgFUS to a lower-paying APC and restore appropriate reimbursement for this promising new technology.
- **Pass-through Status for VNS for Treatment-Resistant Depression (TRD).** The AANS and the CNS support pass-through designation for VNS for TRD.
- **Expedited "Pass-through" eligibility for Breakthrough Devices.** We commend the agency for efforts to expedite the process for pass-through payment eligibility for breakthrough devices.

Ambulatory Surgery Center Issues

- ***New C-APC 5461 (Level 1 Neurostimulator and Related Products)***. We note that CMS has created a new comprehensive APC (C-APC) for *Neurostimulator and Related Products*. We urge the agency to closely monitor payments in the new C-APC to be sure the payment reflects the costs of the elements in the bundle.

DETAILED COMMENTS

Outpatient Prospective Payment System Issues (OPPS) Issues

- ***Consideration of Removal of Spine Procedures from the Inpatient Only (IPO) List***. The AANS and the CNS appreciate the agency's request for feedback on consideration of possible removal of CPT codes 63265-63268 (laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural) and CPT codes 22633 and 22634 (combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/ or discectomy sufficient to prepare interspace (other than for decompression), single interspace and segment; lumbar) from the IPO. We believe these procedures meet the requirements for removal from the list. **However, we emphasize the importance of patient selection in determining the site of service for any individual Medicare beneficiary. Inpatient admission should always remain an option for patients who require that level of care.** We are eager to work with the agency to intelligently and cooperatively promote high-quality surgical care in all health care settings, and we urge CMS to carefully consider objective data as the agency reviews site of service issues related to surgical procedures.

All health care stakeholders must work to promote safe, effective and affordable surgical care. As the inpatient setting is generally the most expensive treatment environments, we should offer patients the option of receiving care in the outpatient and ambulatory surgery center settings, when safety and effectiveness can be assured. Of course, 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. Ultimately, the AANS and the CNS believe the site of service should be determined by the operating surgeon in consultation with the patient, with careful consideration of the individual's clinical status. 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 more appropriate and medically necessary. Again, our support for the removal of the six spine procedures from the IPO in no way suggests that procedures should not be performed and paid for in the hospital for Medicare patients who need that level of care.

- ***Magnetic Resonance-guided Focused Ultrasound for Essential Tremor (MRgFUS)***. The AANS and the CNS support fair, adequate and stable reimbursements for Magnetic Resonance-guided Focused Ultrasound for Essential Tremor (MRgFUS), and the ability of neurosurgeons to offer this innovative, noninvasive therapy for essential tremor to appropriately selected patients. We are concerned that the proposed APC assignment for CPT code 0398T could significantly impede the development of this technology. MRgFUS is still in the early stages of adoption, limiting claims data needed for CMS to appropriately value the technology to reflect the hospital resources necessary to furnish the service. The proposed payment rate could discourage hospitals from adopting this breakthrough therapy, which ultimately means patient access will be jeopardized. We respectfully ask that CMS consider assigning CPT 0398T to a higher New Technology APC for CY2020 instead of continuing to assign it to APC 1575, as proposed.

- **Pass-through Status for VNS for TRD.** The AANS and the CNS support pass-through status for VNS for TRD. We note that CMS has stated concern, “that the clinical utility of the technology has not been well demonstrated.” As we noted in our comments to the agency regarding the recent National Coverage Decision (NCD) for this technology, we believe that the clinical benefits of VNS for TRD have been demonstrated by the medical literature submitted during the review of VNS for TRD and the device meets the clinical improvement requirement for pass-through status.
- **Pass-through Status for Innovative Devices.** CMS proposes an alternative pathway for qualifying for device “pass-through” payment status for transformative devices that meet the FDA Breakthrough Device designation. Specifically, for new medical devices approved through this expedited process, CMS would not require applicants to separately prove that “substantial clinical improvement” criterion has been met. Our specialty — which is highly dependent on medical technology — is one of rapid innovation. We share the common goal of enhancing efficiency in bringing lifesaving improvements to our patients and, therefore, we commend CMS for moving forward with common-sense policies to improve access to new technology. We support this initiative, as we did for the similar program proposed in the Fiscal Year (FY) Medicare Hospital Inpatient Prospective Payment System (IPPS) proposed rule for new technology add-on payments, and we refer the agency to our previously submitted comments.

Ambulatory Surgical Center (ASC) Issues.

- ***New C-APC 5461 (Level 1 Neurostimulator and Related Products).*** We note that CMS proposes to continue the Comprehensive APC (C-APC) payment methodology implemented in CY 2015 and has created a C-APC for *Neurostimulator and Related Products* as part of that program. We urge the agency to closely monitor payments in the new C-APC relative the actual costs of the procedures bundled together to assure they are fairly compensated and available to appropriate patients in the ASC setting.

CONCLUSION

The AANS and the CNS appreciate the opportunity to provide feedback on these specific provisions on the 2019 Medicare Hospital OPPTS ASC proposed rule. 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
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