

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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June 14, 2022

Ms. Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
ATTN: CMS-1771-P
P.O. Box 8013 Baltimore, MD 21244-1850

Submitted electronically via <https://www.regulations.gov/>

SUBJECT: Fiscal Year (FY) 2023 Medicare Hospital Inpatient Prospective Payment System (IPPS) Proposed Rule (CMS-1771-P)

Dear Administrator Brooks-LaSure:

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), we appreciate the opportunity to comment on the above-referenced CMS hospital inpatient prospective payment system proposed rule.

SUMMARY OF COMMENTS

MS-DRG Assignments

- **Laser Interstitial Thermal Therapy (LITT) procedures.** The AANS and the CNS support the proposal by CMS to change the MS-DRG Assignment for Laser Interstitial Thermal Therapy (LITT) procedures.
- **MS-DRG Assignment for Gene Therapy and Rare Diseases.** The AANS and the CNS urge the agency to consider appropriate reimbursement for hospital costs for gene therapy intracerebral infusion therapies, given the rapid development and potential for these innovative therapies to help patients. In addition, we appreciate CMS' request for feedback on MS-DRG assignment for rare diseases and note that gene therapy represents an area of significant innovation in treating these conditions.

FY 2023 Applications for New Technology Add-On Payments

- **Spinal Implants.** The AANS and the CNS support new technology add-on payment for four spinal devices approved under the FDA Breakthrough Devices Pathway.
- **Neuromodulation Devices.** The AANS and the CNS support new technology add-on payment for two neurostimulator devices.

Hospital Promoting Interoperability Program

Query of Prescription Drug Monitoring Program (PDMP) Measure. The AANS and the CNS appreciate the intent of this measure and support efforts to curb opioid abuse and harm. However, we do not believe this measure should be mandatory.

DETAILED COMMENTS

DRG Assignments

- **Laser Interstitial Thermal Therapy (LITT).** In the FY 2022 IPPS final rule, CMS reassigned ICD-10 PCS codes describing laser interstitial thermal therapy (LITT) of the brain and brain stem from MS-DRGs 023, 024, 025, 026, 027 to MS-DRGs 040, 041, and 042. We were concerned that CMS implemented this change without an adequate notice and comment period.

While we were disappointed that CMS did not address this procedural error for FY 2022, we are pleased that in the FY 2023 IPPS proposed rule, the agency plans to reassign new ICD-10 PCS codes for LITT of the brain to MS-DRGs 025 through 027. **We support reassigning the LITT procedure to MS-DRS 025-027, and we urge the agency to finalize the proposal.** This change reflects that the use of LITT in the brain is aligned in terms of cost and clinical considerations with the other neurosurgical procedures grouped to MS-DRGs 025-027.

However, we question the need for CMS to re-evaluate the assignment of other neurosurgical procedures within the craniotomy MS-DRGs 023-027 in future proposed regulations. The procedures in these MS-DRGs have been well established from a clinical homogeneity perspective, and the procedures' costs have been stable. **We disagree that the reassignment of LITT procedures back to the craniotomy MS-DRGs for FY 2023 should trigger the realignment of other procedures currently assigned to the craniotomy MS-DRGs.** The surgical approach, percutaneous via a smaller opening vs. open, does not equate to less resource use and lower cost. In addition, we note that CMS has asked whether the LITT procedures should be separated based on the diagnosis of epilepsy vs. oncology. We believe the procedures are similar regarding resource requirements and post-operative care for the patient regardless of the specific diagnosis. When the new LITT CPT codes were developed, we evaluated this topic and determined that separate codes based on diagnosis were unnecessary.

In summary, once the LITT procedures are reassigned to the craniotomy MS-DRGs as proposed by CMS, we believe that the neurosurgical procedures grouped to MS-DRGs 023-027 are appropriate and do not require further refinement. Should CMS consider future changes to the procedures assigned to MS-DRGs 023-027, we respectfully request the agency provide adequate notice so that all stakeholders can help the agency assess the impact of the proposals before implementing any changes. The neurosurgeons who perform LITT procedures to treat epilepsy and brain tumors are intensely interested in ensuring that Medicare adequately reimburses hospitals for these services to safeguard timely access to these vital treatments.

- **Neurosurgical Gene Therapies and Rare Disease MS-DRG Assignment.** We appreciate concerns expressed by CMS that the MS-DRG system as currently structured may be inadequate to ensure access to rapidly expanding gene therapies, many of which will provide transformative treatments for rare and ultra-rare diseases with low Medicare claims volume. For example, several intracerebral infusion therapies potentially significantly improve patient care. **We urge the agency to carefully consider MS-DRG assignment for procedures involving the intracerebral infusion of gene therapy and stem cell products in development for many neurologic disorders, both common (Parkinson's) and very rare (i.e., aromatic L-amino acid decarboxylase deficiency).** Intracerebral infusion therapies are unique procedures requiring vastly different hospital resources compared to more traditional neurosurgical procedures. Given this, appropriate MS-DRG assignment — including considering creating new MS-DRG categories — will be essential to assuring access to these promising therapies.

Proposed New Technology Add-On Payments for New Services/Technologies

CMS has received requests for New Technology Add-on Payment (NTAP) for five neurosurgical products with FDA Breakthrough Device designation and one product for which the designation is pending before the FDA. The AANS and the CNS support the streamlined process for NTAP status for devices with FDA breakthrough device designation. **To foster innovation and bring life and ability-saving devices to patients, we urge the agency to finalize its proposal to grant NTAP status to the following devices.**

- **Spine devices/products.** We support new technology add-on payments (NTAPS) for four products for spinal surgery:
 - + CERAMENT® G Injectable bone-void filler to treat osteomyelitis.
 - + IFuse Bedrock Granite Implant System implant to provide sacropelvic fusion of the sacroiliac joint and fixation to the pelvis when used with pedicle screw fixation systems as a foundational element for segmental spinal fusion.
 - + LigaPASS 2.0 PJK Prevention System polyester band and titanium alloy medial open connector with two set screws to mitigate the risk of post-operative proximal junctional kyphosis and failure in patients with spinal deformities.
 - + TOPS System motion preserving device comprised of a titanium construct with an interlocking polycarbonate urethane articulating core inserted into the lumbar vertebral joint and anchored using pedicle screws after posterior spinal decompression surgery.
- **Neurostimulation Devices.** We support the NTAP designation for the two devices for stimulation of the vagus nerve listed below:
 - + Vitaria System's implantable neuromodulation system that uses vagus nerve stimulation to deliver autonomic regulation therapy.
 - + ViviStim Paired VNS System to stimulate the vagus nerve during rehabilitation therapy to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe arm impairment.

Hospital Promoting Interoperability Program

In the FY 2022 IPPS/LTCH PPS final rule, CMS confirmed that the Query of Prescription Drug Monitoring Program (PDMP) measure under the Promoting Interoperability Program would remain optional and eligible for bonus points. However, in this year's rule, CMS proposes to require the measure beginning with the CY 2023 reporting period. Eligible hospitals would be required to attest "yes" or "no" to the following expanded measure:

For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using Certified EHR Technology (CEHRT) during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history.

CMS also proposes exclusions to the measure to account for 1) any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances that include drugs from Schedules II, III, and IV and is not located within 10 miles of

any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period; and 2) any eligible hospital or CAH that cannot report on this measure in accordance with applicable law.

The AANS and the CNS oppose the agency’s proposal to require hospitals to report the Query of PDMP measure and urge CMS to maintain it as an optional measure eligible for bonus points.

While we recognize that progress has been made over the last few years to make the use of PDMPs more feasible and widespread, there are still ongoing challenges related to the use of PDMPs. For example, some of our members have reported not having seen an increased availability of interstate data through their PDMP. Other members have pointed to the ongoing patchwork of state laws and adopted processes. In Michigan, for example, providers are not required to search the PDMP unless supplying more than three days of scheduled drugs.

Requiring this measure would impose additional burdens on providers and create confusion and conflicts with processes adopted in individual states. Another ongoing challenge we have highlighted in the past is how frequently the information is updated. If a patient receives an opioid prescription today, it may take 30 days to appear in the PDMP, depending upon the state. This significantly hampers the ability of the PDMP to provide meaningful information and is an issue that goes beyond the system's functionality. It also is unclear to what extent this measure would recognize reporting by other non-physician providers. It is critical that CMS permit query and reporting requirements to be fulfilled by a surgeon’s delegate (e.g., resident, PA, NP) if they are the one doing the prescribing. Finally, we remind CMS that neurosurgeons see a number of patients that reasonably require a short course of opioids post-operation. Measures and other regulatory requirements in this space should be aimed only at safety and abuse and should not impede the efforts of clinicians to access these medications when appropriate.

CONCLUDING REMARKS

The AANS and the CNS appreciate the opportunity to comment on this proposed regulation. We look forward to working with CMS to improve Medicare’s IPPS program to ensure our patients have timely access to quality neurosurgical care. In the meantime, if you have any questions or need further information, please contact us.

Thank you.

Sincerely,



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