December 29, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: **CMS-1736-P**
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

December 29, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: **CMS-1736-FC, CMS-1736-IFC**
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1736-FC, CMS-1736-IFC; CY 2021 Proposed Rule Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician-owned Hospitals

Dear Administrator Verma:

ISASS is a multi-specialty association dedicated to the development and promotion of the must current surgical standards, as well as the highest quality, most cost-efficient, patient-centric, and proven cutting-edge technology for the diagnosis and treatment of spine and low back pain.

This letter includes ISASS recommendations and comments regarding the following:

- Pre-Approval for Neurostimulator Implantation and Cervical Fusion
- Elimination of the Inpatient Only Procedure (IPO) List
- APC Placement for New CPT Codes 0627T-0630T

- APC Placement for CPT codes for MILD procedure

Pre-Approval for Neurostimulator Implantation and Cervical Fusion

ISASS is very disappointed with CMS' decision to move forward with the proposal to implementation pre-authorization for spinal neurostimulator procedures. ISASS and many other stakeholders provided extensive comments to the agency in regards to the proposed changes by CMS in the August proposed rule. Yet, despite the compelling and voluminous input, CMS moved forward with the implementation for CY 2021. We believe this is a mistake and will lead to reduced access to efficacious and cost-effective treatment for pain for Medicare patients. It will lead to increased opioid use (not reduced opioid use) and to negative physical and clinical outcomes for patients.

Last year, CMS finalized a proposal to establish a process through which hospitals must submit a prior authorization request for a provisional affirmation of coverage before a covered outpatient service is furnished to the beneficiary and before the claim is submitted for processing. The change applied to five categories of services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation.

This year, the agency finalized their proposal to expand prior authorization requirements for two additional services: implanted spinal neurostimulators and cervical fusion with disc removal to curb what they state may be unnecessary utilization.

ISASS strongly disagrees with this action and the rationales provided by the agency. We strongly urge CMS to revise the policy at its earliest possibility and not apply the prior authorization requirement to both of these procedures as this requirement creates an improper and unnecessary burden on physicians and physician practices. This is in direct opposition to numerous other CMS initiatives to decrease administrative burdens for medical practices and is redundant to already existing National Coverage Decisions (NCDs) and Local Coverage Decisions (LCDs) that exist for Spinal Cord Stimulation.[1]

We dispute the CMS claim that prior authorization will reduce unnecessary utilization. There is evidence that prior authorization has little impact on unnecessary authorization but instead causes a delay in appropriate care (leading patients toward alternative pain relief options like opioids).[2] There is not sufficient evidence that utilization is increasing at significant rates for these procedures. For example, CPT code 63650 (Implant Neuroelectrodes) saw only a 1% increase in Medicare utilization from 2018 to 2019 and CPT code 63655 (Laminectomy for Implantation…) saw a decrease in Medicare utilization. CPT code 22610 (Cervical Fusion) saw only a 2% increase in utilization, but there is considerable evidence to illustrate the costs

[1] Centers for Medicare and Medicaid Services. NCD 160.7 Electrical Nerve Stimulators.
[2] Morley, C. P., Badolato, D. J., Hickner, J., & Epling, J. W. (2013). The impact of prior authorization requirements on primary care physicians' offices: report of two parallel network studies. *The Journal of the American Board of Family Medicine*, *26*(1), 93-95.

for patients and practices from prior authorization policies used by private payers.[3][4][5] There are multiple factors that could affect utilization changes such as innovation, awareness, payment policy, legislative policy and clinical factors.

For example, Karrison et al in a 2009 study found that when time spent in acquiring prior authorization is converted to dollars, they estimated that the national time cost to practices of interactions with plans is at least $23 billion to $31 billion each year.[6] Furthermore, Morley et al. reaffirmed that preauthorization is a measurable burden on physician and staff time.[7] This financial burden and cost has only increased in the ensuing seven to twelve years and we believe this cost to be an unnecessary and unjustified burden for physicians performing neurostimulator implantation procedures.

Other studies have confirmed and added to the body of evidence showing the detrimental impact of prior authorization burdens to patient access.[8] A 2019 AMA survey demonstrated that prior authorization efforts add 14.4 hours of staff time per week to their workload with 30% of respondents reporting to have a Full Time Employee (FTE) dedicated to prior authorization. The same survey found the prior authorization burden to have increased significantly over the past 7 years, with 86% of respondents reporting increased prior authorization costs to their practice in the previous five years.[9] A study from the Cleveland Clinic estimated their annual costs for prior authorization activities to exceed $10 million a year.[10]

We believe it is essential to continue to increase access to non-opioid pain treatment. Spinal cord stimulation and cervical fusion surgery are especially important alternatives to opioid prescriptions.[11] We urge CMS to revise their policy to decrease and delay access to these procedures through the imposition of a costly and burdensome prior authorization process.

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[3] Casalino, L. P., Nicholson, S., Gans, D. N., Hammons, T., Morra, D., Karrison, T., & Levinson, W. (2009). What Does It Cost Physician Practices To Interact With Health Insurance Plans? A new way of looking at administrative costs—one key point of comparison in debating public and private health reform approaches. *Health Affairs*, *28*(Suppl1), w533-w543.

[4] American Board of Pain Medicine. Second Annual Survey of Pain Medicine Specialists Highlights Continued Plight of Patients with Pain, And Barriers to Providing Multidisciplinary, Non-Opioid Care. Article. 2019. http://abpm.org/component/content/article/296

[5] American Board of Pain Medicine. Second Annual Survey of Pain Medicine Specialists Infographic. 2019. http://abpm.org/uploads/files/abpm%20survey%202019-v3.pdf .

[6] Health Affairs, 28, no.4 (2009):w533-w543 What Does It Cost Physician Practices To Interact With Health Insurance Plans? Theodore Karrison and Wendy Levinson Lawrence P. Casalino, Sean Nicholson, David N. Gans, Terry Hammons, Dante Morra,

[7] Morley, C. P., Badolato, D. J., Hickner, J., & Epling, J. W. (2013). The impact of prior authorization requirements on primary care physicians' offices: report of two parallel network studies. *The Journal of the American Board of Family Medicine*, *26*(1), 93-95

[8] Casalino, L. P., Nicholson, S., Gans, D. N., Hammons, T., Morra, D., Karrison, T., & Levinson, W. (2009). What Does It Cost Physician Practices To Interact With Health Insurance Plans? A new way of looking at administrative costs—one key point of comparison in debating public and private health reform approaches. *Health Affairs*, *28*(Suppl1), w533-w543.

[9] https://www.ama-assn.org/system/files/2020-06/prior-authorization-survey-2019.pdf

[10] https://www.ama-assn.org/practice-management/sustainability/inside-cleveland-clinic-s-10-million-prior-authorization-price

[11] Adil SM, et al. Impact of Spinal Cord Stimulation on Opioid Dose Reduction: A Nationwide Analysis. *Neurosurgery.* nyaa353. August 31, 2020.

Elimination of Inpatient Only Procedure (IPO) List

The Inpatient Only (IPO) List was created to identify services that require inpatient care. Because of the invasive nature of the procedure, the need for postoperative recovery time or the underlying physical condition of the patient. CMS concluded in the final rule that the list is not necessary to identify services that require inpatient care because of changes in medical practice, including new technologies and innovations. As a result, beginning in 2021, CMS will start to eliminate the IPO list over three calendar years, starting with the removal of 300 musculoskeletal-related services in 2021. CMS also proposed a three-year period of implementation with different procedures phased out across the three years.

In regards to Lumbar Total Disc Replacement, Revision, and Replacement in particular (CPT codes 0163T, 0164T, 0165T, 22857, 22862, and 22865 respectively) we would again strongly recommend that CMS consider these codes as a distinct category as there is Medicare National Coverage Decision that does not allow the procedure on Medicare patients. Therefore, the volume of Medicare patients is at or near zero already, and any changes in site-of-service could lead to drastic changes in APC and DRG classifications that are the result of miscoding by definition. Yet, the payment impacts would be profound, detrimental, and subject to tremendous annual fluctuation.

Because CMS chose to not treat procedures with low Medicare volumes like CPT 22857, 22862, and 22865 separately and in a way that maintains stability and consistently we would recommend CMS reconsider the NCD itself. The NCD is over 15 years old, and significant literature and data have been developed since the initial establishment and a review is overdue and warranted. In the interim CMS should address low volume and NCD covered procedures in a separate fashion moving forward. ISASS is disappointed the final rule did not implement this action and recommends CMS consider it in early 2021.

APC Placement for New CPT Category III codes 0627T-0630T

ISASS agrees with the proposed APC designation for CPT codes 0627T and 0630T and applauds CMS for adjusting the assignment in the final rule to APC 5115 (Level 5 Musculoskeletal Procedures) with a proposed facility fee of $12,558.56.

The Total Estimated Cost of 0627T and 0629T is the addition of the non-device related costs of APC 5114 ($4,524) plus the device related costs ($8,000) or $12,524 and is closest to APC 5115 with a CY 2021 Projected Payment Rate of $12,500.50.

We appreciate CMS' careful review of comments and change of assignment and support the APC assignment.

Device Offset Payment Rate for MILD CPT Category III code 0275T

ISASS does not agree with the proposed device offset assignment for CPT code 0275T, Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements, (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method, under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar. ISASS believes the revised payment, which equals a 41% increase in the ASC setting will result in increased utilization of MILD by physicians and we believe this has the potential to have negative consequences for patients.

The MILD procedure represents a relatively unproven treatment option for patients with low back pain to other more well established and higher quality surgical options, yet the increased payment provides increased incentives for facilities to encourage the use of MILD. CMS states their rationale for the payment as reflective of device and related costs; however, we urge CMS to consider the potential impact on patients who may be steered toward MILD. ISASS is disappointed the agency took this step without consulting expert stakeholders like ISASS on the evidence for the procedure. ISASS strongly recommends that CMS engage in outreach with stakeholder organizations on matters related to appropriate spine care moving forward.

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Thank you for your time and consideration of the International Society for Advancement of Spine Surgery's comments. We greatly appreciate the opportunity to participate in efforts to more efficiently and accurately capture current care delivery. We commend CMS on its comments, please do not hesitate to contact Morgan Lorio, MD at mloriomd@gmail.com.

Sincerely,

Morgan Lorio, MD
Chair, ISASS Coding and Reimbursement Task Force