September 12, 2022

Ms. Chiquita Brooks-Lasure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention:
Mail Stop 1753-P; C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1772-P; Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs;

Dear Ms. Brooks-Lasure:

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:

- Prior Authorization for Neurostimulator Implantation and
- APC Placement for New CPT Codes 0627T-0630T

Prior Authorization for Neurostimulator Implantation and Cervical Fusion

In CY 2020, 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.

In CY 2021, the agency finalized a 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.

In the Proposed Rule for CY 2023, CMS proposes to maintain these services for pre-authorization and expand prior authorization requirements to including facet treatment by

injection or ablation (CPT codes 64490-64495 and 64633-64636) under the Prior Authorization requirements in the ASC and OPPS setting.

ISASS strongly disagrees with this proposal and the rationale provided by the agency. We strongly urge CMS to not apply the prior authorization requirement for cervical fusion specifically. 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.

We dispute the CMS claim that prior authorization will reduce unnecessary utilization. There is evidence that prior authorization has little impacts on unnecessary authorization but mostly causes a delay in appropriate care (leading patients toward alternative pain relief options like opioids).[1] There is not sufficient evidence that utilization is increasing at significant rates for these procedures but there is considerable evidence to illustrate the costs for patients and practices from prior authorization policies used by private payers.[2][3][4]And even to the extent utilization is increasing, 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.[5] Furthermore, Morley et al. reaffirmed that preauthorization is a measurable burden on physician and staff time.[6] 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.[7] A 2019 AMA survey that prior

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[1] 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.

[2] 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.

[3] 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

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

[5] 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,

[6] 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

[7] 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.

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.[8] A study from the Cleveland Clinic estimated their annual costs for prior authorization activities to exceed $10 million a year.[9]

We believe it is essential to continue to increase access to non-opioid surgical options and cervical fusion is an important alternative to opioid prescriptions.[10] We urge CMS to revise their proposal to decrease access to cervical fusion the imposition of a costly and burdensome prior authorization process.

APC Placement for New CPT Category III codes 0627T and 0629T

ISASS agrees with the proposed APC designation for CPT codes 0627T and 0629T and applauds CMS for adjusting the assignment in the final OPPS/ASC rule to APC 5115 (Level 5 Musculoskeletal Procedures).

However, in addition to the APC assignment, we also support the designation of both codes as "device intensive" and the addition of device-intensive payment status for both services. The average device related costs for Viadisc are $8257.09 based on a review of CMS approved claims (median costs for Viadisc were $8212.81), which is 66% of the APC fee for APC 5115. CMS defines a device as "device intensive" if the device itself accounts for at least 65% of the fee assigned, which Viadisc does. Furthermore, the 66% device cost for Viadisc is well above the average device cost percentage of 46.6% for other devices in the APC 5115 classification group, thereby highlighting the device intensive status for Viadisc within APC 5115.

Based on these costs, we request both services be assigned device intensive in the facility setting and qualified for the device intensive offset payment.

We appreciate CMS' careful review of comments and look forward to discussing the matter further.

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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

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

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

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

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