August 31, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1770-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-4203-NC; Medicare Program; Request for Information on Medicare

Dear Administrator Brooks-LaSure:

The North American Neuromodulation (NANS) appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Notice of Proposed Rule Making (*Proposed Rule*) on the request for information on Medicare Advantage.

NANS is a multi-specialty association of more than 1,600 physicians dedicated to the development and promotion of the highest standards for the practice of neuromodulation procedures in the diagnosis and treatment of the nervous system, including neurosurgeons, orthopedic spine surgeons, anesthesiologists, physiatrists, psychologists, urologists, and neurologists. We are committed to working with CMS and other stakeholders to promote the highest quality, most efficient, patient care for patients dealing with chronic neuromuscular pain.

We are writing to address several aspects of the Medicare Advantage program and how to better align and collaborate with the provider community. We believe the most important thing CMS do to improve the Medicare Advantage program and ensure and encourage partnership with patients and providers is to remove pre-authorization requirements. These are a tremendous obstacle to quality care provided in an efficient and accessible manner.

The Request for Information (RFI) specified five areas for input and comment.

A. Access Equity
B. Coverage & Accessibility to Care (including prior authorization)
C. Payment Reform Models Enabling Personalized Health Care (including value based contracting and data management)
D. Affordability & Sustainability of the Medicare Trust (including technical adjustments and MAO competition)
E. Expanded Stakeholder Engagement & Collaborations

We believe that the obstacles created by the Medicare Advantage Pre-Authorization requirements negatively impacts all five of these areas, but our comments focus particularly on Coverage and Accessibility to Care.

Coverage and Accessibility to Care (including prior authorization)

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 many covered services is furnished for Medicare beneficiaries and before the claim is submitted for processing.

The change applied most particularly 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. These mirrored Prior Authorization requirements in the OPPS/ASC and the overall combination has been deleterious to access to important care, particularly for non-opioid pain management treatment.

In the OPPS/ASC Proposed Rule for CY 2023, CMS proposes to 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.

We strongly urge CMS to remove the prior authorization requirements under Medicare Advantage particularly on these services. Prior Authorization 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 several services currently subject to Prior Authorization.

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 many of the procedures CMS has included for OPPS/ASC Prior Authorization (for example, CPT code 63650, Implant Neuroelectrodes, saw only a 1% increase in Medicare utilization from 2018 to 2019 and 63655 saw a decrease in Medicare utilization, and in the proposed rule CMS acknowledged the rate of utilization increase for facet interventions is slowing not increasing). However, 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

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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 .

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 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]

Many of these interventions, such as SCS and Facet Interventions are key alternatives to opioid prescription for the management of pain symptoms and reducing access to this non-opioid alternative will only increase opioid prescriptions and opioid dependence and ultimately result in higher addiction rates, higher costs to Medicare and to society as a whole. SCS has been shown to prevent, stabilize or decrease the use of opioids. In addition, earlier consideration of SCS before escalated opioid use has the potential to improve clinical outcomes.[10][11] Studies have demonstrated that prior authorization creates specifically negative impacts for non-opioid pain procedures and that these increased delays and denials have led to increased opioid prescription rates.[12] We urge CMS to follow the recommendation of their Pain Taskforce[13] and increase access to non-opioid treatments. Requiring prior authorization of interventions such as SCS and Facet Interventions does the exact opposite of what CMS' own medical and public health officials have urged and represents a massive cost to society, patients, and providers, without offering anything other than overestimated cost savings.[14]

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[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.

[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] Sharan AD, Riley J, Falowski S, et al. Association of Opioid Usage with Spinal Cord Stimulation Outcomes. *Pain Med*. 2018;19(4):699-707. doi:10.1093/pm/pnx262

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

[12] https://www.ama-assn.org/practice-management/sustainability/prior-authorization-nonopioid-pain-care-prolongs-patient

[13] I. Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations published May 9, 2019

[14] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49.

We believe it is essential for Medicare Advantage beneficiaries to continue to increase access to non-opioid pain treatment as especially important alternatives to opioid prescriptions.[15] We urge CMS to revise their prior authorization requirements for services provided for Medicare Advantage patients.

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Thank you for your time and consideration of NANS comments. We greatly appreciate the opportunity to participate in efforts to more efficiently and accurately capture current care delivery. We commend CMS on its continued efforts to improve care quality and access. If you have any questions on our comments, please do not hesitate to contact Chris Welber, MBA, NANS Executive Director, at cwelber@neuromdoulation.org.

Sincerely,

President
North American Neuromodulation Society (NANS)

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