

April 7, 2021

Elizabeth Richter  
Acting Administrator  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Acting Administrator Richter,

On behalf of the organizations below and the patients and healthcare stakeholders we serve, we are writing to reiterate the growing concern within the healthcare community regarding the expanding use of prior authorization by the Centers for Medicare & Medicaid Services (CMS).

Prior authorization is a tool that Medicare has traditionally reserved for use in very limited circumstances, when evidence of widespread unnecessary utilization is sufficient to outweigh concerns about the adverse impact on timely access for beneficiaries to medically necessary care and the administrative burden imposed on providers. Recent actions by CMS, however, suggest the agency has begun moving away from that long-established position. In the calendar year (CY) 2020 Medicare Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Final Rule (CMS-1717-FC), CMS established a nationwide prior authorization process for five hospital outpatient department (OPD) services that have cosmetic uses in addition to therapeutic indications, with an implementation date of July 1, 2020. Then, just months after that implementation, CMS expanded prior authorization to two new service categories in the CY 2021 OPPS/ASC Final Rule (CMS-1736-FC)—Cervical Fusion with Disc Removal and Implanted Spinal Neurostimulators. That action was taken despite evidence that Medicare Administrative Contractors (MACs) were failing to process prior authorization requests within the time period mandated by the agency, and the fact, as CMS has acknowledged, that the agency has “minimal data to track [the effectiveness of] this issue.”

In response to the CY 2021 OPPS/ASC proposed rule to expand prior authorization to cervical fusion and implanted spinal neurostimulators, 50 bipartisan Members of Congress wrote then-Administrator Seema Verma. In their letter, Members of Congress wrote:

*“If finalized, we believe this policy could negatively impact beneficiary access to medically necessary procedures, and we ask you to reconsider.... We are concerned that CMS is proposing to move forward with this expansion of prior authorization without the necessary guardrails to ensure beneficiary access to care is protected. This proposal comes only a few months after implementing prior authorization for five other service categories. When CMS proposed this policy, despite it agreeing with prior authorization being appropriate for those particular services, MedPAC noted it had a number of concerns about this proposed policy: a lack of experience in using prior authorization in fee-for-service Medicare, a lack of administrative structure for implementing this proposed policy, and a lack of guidelines through which providers would obtain prior authorization. In addition, the Commission is concerned that access to necessary care could be adversely affected. Therefore, MedPAC notes, CMS should proceed carefully in*

*using prior authorization and consider the potential burden on providers, the agency's resources, beneficiaries, and tax payers..... Due to all of these concerns, we respectfully ask that CMS does not move forward with any expansion of prior authorization under OPSS until it has thoroughly examined its experiences with the five procedures that have recently established prior authorization and shared the results of this audit publicly.”*

Over two dozen health care stakeholders, including many of the signatories to this letter, also responded to the proposed rule, expressing similar concerns as the Members of Congress or, in many cases, outright opposition to the proposed expansion of prior authorization. The list of organizations questioning the agency's actions far exceeded the very few that submitted supportive comments. In addition, a number of impacted stakeholders met directly with agency officials, providing data demonstrating that increases in utilization reflected legitimate medical need and raising questions about the methodology used by CMS to determine “unnecessary utilization.” Those questions remain unanswered.

We continue to have serious concerns that beneficiaries will experience significant barriers to access to medically necessary procedures as a direct result of the CY 2021 policy. We also worry that future expansions of prior authorization will unnecessarily delay access to care for even more beneficiaries and add administrative and cost burden for providers unless appropriate and transparent regulatory processes are established.

CMS should suspend the prior authorization requirements generally or for a particular service at any time by issuing a notification on the CMS website. We urge the agency to delay prior authorization requirements for the new two service categories past July 1, 2021 and withhold action on any further expansion of prior authorization requirements until:

- CMS has conducted a thorough analysis of the impact of prior authorization for the five procedures for which it was implemented in July 2020, including the extent to which the MACs have been able to meet the timeframes for processing prior authorization requests, and the cost and other burdens imposed upon providers and beneficiaries relative to the benefit to the Medicare program from reductions in inappropriate utilization; and
- the agency has established specific criteria, through a transparent process incorporating feedback from beneficiaries and other stakeholders, to guide its decision-making related to the use of prior authorization.

We appreciate your attention to these concerns and look forward to working with you and the incoming Administrator on meeting the healthcare needs of all Medicare beneficiaries.

Sincerely,

American Academy of Family Physicians  
American Academy of Ophthalmology  
American Association of Neurological Surgeons  
American Association of Orthopaedic Surgeons  
American College of Cardiology

American College of Osteopathic Surgeons  
American College of Surgeons  
American Gastroenterological Association  
American Medical Association  
American Orthopaedic Foot & Ankle Society  
American Society for Radiation Oncology  
American Society of Anesthesiologists  
American Society of Cataract and Refractive Surgery  
American Society of Colon & Rectal Surgeons  
American Society of Pain and Neuroscience  
American Society of Plastic Surgeons  
Association for Clinical Oncology  
BioOhio  
BioUtah  
California Life Sciences Association (CLSA)  
Center for Medicare Advocacy  
Coalition of State Rheumatology Organizations  
Congress of Neurological Surgeons  
Federation of American Hospitals  
Florida Medical Manufacturers Consortium  
Healthcare Financial Management Association  
HealthCare Institute of New Jersey (HINJ)  
Life Science Washington  
Life Sciences Pennsylvania  
Medical Device Manufacturers Association (MDMA)  
Michigan Biosciences Industry Association (MichBio)  
National Association for Proton Therapy  
North American Spine Society  
North Carolina Biosciences Organization (NCBIO)  
Physician Fee Schedule Pathology Payment Coalition  
Texas Medical Association  
The International Society for the Advancement of Spine Surgery  
The Medical Alley Association  
The North American Neuromodulation Society  
The Society of Thoracic Surgeons