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March 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-0057-P

RE: Autoimmune Association Comments to CMS Proposed Rule on Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes (CMS-0057-P) [RIN 0938-AU87]

Dear Administrator Brooks-LaSure:

On behalf of tens of millions of Americans who live every day with serious and chronic illnesses, including autoimmune diseases, the Autoimmune Association appreciates the opportunity to comment on the proposed rule regarding *Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes* (CMS-0057-P) (Proposed Rule), issued by the Department of Health and Human Services (HHS) Centers for Medicare and Medicaid Services (CMS or the agency).¹ We are pleased that CMS is focused on improving prior authorization processes, and we are eager to work with the agency on these important efforts.

The Autoimmune Association is the world's leading nonprofit organization dedicated to autoimmune awareness, advocacy, education, and research. Autoimmune diseases are a major cause of serious and chronic health conditions for millions of individuals. The Autoimmune Association leads the fight against autoimmune disease by collaborating to improve healthcare, advance research, and support the community through every step of the journey. The Autoimmune Association is also the founder and facilitator of the National Coalition of Autoimmune Patient Groups (NCAPG), a coalition of approximately 50 organizations representing numerous diseases, such as lupus, psoriasis, rheumatoid arthritis, multiple sclerosis, Sjögren's, celiac disease, relapsing polychondritis, and many others. The NCAPG's mission is to convene, support, and amplify the voice of autoimmune disease patients and patient groups to enhance capacity, collaboration, and impact through advocacy, education, awareness, and research concerning all aspects of autoimmune disease.

In addition, consistent with this collaborative approach and our recognition of the important role of clinician-patient relationships in our health care system, the Autoimmune Association convenes the national Let My Doctors Decide (LMDD) initiative, a national partnership of leaders across health care working in support of a simple goal: treatment decisions should always be made by patients and trusted health care professionals, not insurance companies or pharmacy benefit managers (PBMs).²

Regarding prior authorization practices and processes, a recent poll commissioned by LMDD found that a majority of healthcare consumers/patients oppose prior authorization policies imposed by health insurance companies and PBMs, which often result in access restrictions, increased patient costs, and delayed health and wellness.³

¹ 87 Fed. Reg. 76,238 (Dec. 13, 2022).

² See <https://letmydoctorsdecide.org/>.

³ See <https://letmydoctorsdecide.org/resources>.

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We are concerned that prior authorization policies are a harmful utilization management practice that interferes with patients' access to care and with the physician-patient relationship. Indeed, time-consuming prior authorization processes require health care providers to take valuable time away from patients and can lead to negative health outcomes.

We appreciate the proposed rule's efforts to address the burdensome nature of prior authorization processes and to "help[] patients remain at the center of their own care."⁴ We also support efforts to better integrate prior authorization into the clinical workflow through the incorporation of electronic prior authorization (e-PA) functionalities into Electronic Health Records (EHRs). The inclusion of e-PA functionalities can substantially improve the efficiency of prior authorization processes efficiency, and, most importantly, can help reduce delays in patient care and patient abandonment of medically necessary services.

We remain concerned, however, that prior authorization processes continue to prioritize insurers' cost control objectives and mechanisms over patient care, thereby undermining—instead of facilitating—patient-centered policies and decision making. Accordingly, while we support certain aspects of the proposed rule, such as ensuring that patients and providers have timely access to prior authorization information, including the status of requests and payor determinations, and requiring prompt turnaround times for providing prior authorization information to patients and providers,⁵ we believe additional steps are needed to reduce the extent to which prior authorization practices are employed and to mitigate the utilization and impact of prior authorization practices that currently operate to restrict and delay access to care for patients.

For example, the recent nationwide poll commissioned by LMDD, which was conducted by Lake Research Partners and the Tarrance Group, found that:

- 75% of health care consumers are concerned that prior authorization can delay or block patients' access to treatment.
- 71% are worried that prior authorization will increase patient costs.
- 74% expressed concern that prior authorization can require patients to substitute less effective or ineffective treatments for what their doctors prescribed.
- 72% said they are concerned that such policies can override doctors' recommendations by allowing insurance companies to control treatment decisions.⁶

Similarly, a recent American Medical Association (AMA) survey of 1,000 practicing physicians found that more than nine in ten respondents (greater than 90%) said that prior authorization had a significant or somewhat negative clinical impact on a patient in their care. In the survey, which focused on the impact of prior authorization on physicians' ability help their patients, 28% of responding doctors reported that prior authorization had led to a serious adverse event for a patient, such as death, hospitalization, disability, permanent bodily damage or other life-threatening issues.⁷ This is simply unacceptable—but it is unfortunately representative of the costly, yet avoidable, medical issues that arise when decision making is made for economic instead of clinical reasons.

The burden of prior authorizations in terms of additional time, unnecessary paperwork, and negative health outcomes is significant. In the AMA survey, the vast majority (85%) of physician responders reported that the administrative burden of prior authorization is "high or extremely high," taking time away from patients and adding significantly to physician expenses.

In light of these significant concerns, we urge CMS to propose and implement the following additional policies in connection with prior authorization practices and processes:

⁴ 87 Fed. Reg. 76,240.

⁵ E.g., 87 Fed. Reg. 76,242–76,244.

⁶ See https://static1.squarespace.com/static/59a55aa28dd041cc6f74be62/t/64014bb874bd6834e33e863c/1677806522068/LMDD+-+Patients+and+Providers+Oppose+Prior+Authorization+-+Infographic_v6.pdf; see also <https://letmydoctorsdecide.org/resources>.

⁷ Andis Robeznieks, *1 in 4 Doctors Say Prior Authorization Has Led to a Serious Adverse Event* (Feb. 5, 2019), available at <https://www.ama-assn.org/practice-management/sustainability/1-4-doctors-say-prior-authorization-has-led-serious-adverse> (last visited Mar. 13, 2023).

- ⇒ Consider potential criteria for situations when prior authorization requirements are not appropriate and would be prohibited in light of patient care circumstances and needs.
- ⇒ Where prior authorization is permitted, require use of standard prior authorization forms, electronic filing, minimum response times, and other standard protocols that plans must adopt.
- ⇒ Prohibit the practice of non-medical switching of treatment regimens. For persons with complex conditions who are already stabilized on a therapy, it is not appropriate to impose automatic substitutions or non-medical switching made by a payor without the intervention of or consultation with the prescriber and consent of the patient.
- ⇒ Establish mandatory policies that exempt patients, once stable on therapy, from step therapy or other prior authorization requirements to continue on their current therapeutic regimen. CMS should adopt a single, standard form that meets any documentation required to establish stability on therapy and require that patient coverage continue without additional requirements. These requirements also should follow the patient regardless of a change in clinician or insurer.

By adopting these recommendations, CMS would not only relieve the significant administrative burdens, but also would facilitate improved beneficiary decision-making and coverage transparency.

We believe that a truly patient-centered approach requires policies that reduce administrative burdens and that do not interfere with the patient-physician relationship. Patient-centered policies facilitate the effective management of serious and chronic conditions, leading to improved outcomes and increased health care system efficiency.

We appreciate the opportunity to provide comments regarding these important issues, and we share CMS's goals to reduce unnecessary burdens, increase efficiencies, and improve patients' experience. We urge CMS to support and advance policies that put patients first, and that do not place unnecessary administrative burdens and barriers to access between patients and their health care providers.

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Thank you for your consideration of our comments. We look forward to continuing to work with you on these important issues.

Sincerely,



Molly Murray
President and Chief Executive Officer
Autoimmune Association