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March 13, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G 200
Independence Avenue, SW
Washington, DC 20201

Submitted electronically via regulations.gov

RE: [CMS-0057-P] Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program

Dear Administrator Brooks-LaSure,

The American College of Rheumatology (ACR), representing over 7,700 rheumatologists and rheumatology interprofessional team members, appreciates the opportunity to respond to the proposed rule on improving prior authorizations published in the *Federal Register* on December 13, 2022. The ACR applauds the Center for Medicare and Medicaid Services (CMS) for recognizing the burden of prior authorizations on the providers and their practices. More importantly, prior authorization hinders necessary and appropriate access to care for our patients.

Rheumatologists provide ongoing care for patients with complex chronic and acute conditions that require specialized expertise. Rheumatologists, rheumatology physician assistants, and nurse practitioners provide face-to-face, primarily non-procedure-based care and serve patients with severe conditions that can be difficult to diagnose and treat, including rheumatoid arthritis and other forms of inflammatory arthritis, vasculitis, systemic lupus erythematosus, and multiple other debilitating diseases. Rheumatologists and rheumatology professionals also work closely with physical therapists to maximize the ability of patients to achieve and maintain independence outside of healthcare settings. Compared to treatment and therapies provided solely by primary care, early and appropriate treatment by rheumatologists and rheumatology professionals can control disease activity, prevent or slow disease progression, improve patient outcomes, and reduce the need for costly downstream surgical or interventional procedures.

Impact of Prior Authorization on Care

Patients with rheumatic diseases suffer debilitating and sometimes life threatening complications. Timely care, especially medically appropriate pharmacologic interventions, are essential for rapidly suppressing severe inflammatory conditions, keeping these diseases in remission, saving lives, and improving patients' quality of life. Unfortunately, rheumatology providers, sometimes successfully and sometimes not, are forced to overcome barriers every day in an attempt to prevent delays in the initiation and maintenance of treatment caused by prior authorization. These delays negatively impact our patients and provide unnecessary administrative burdens for providers and their staff. According to a 2021 study by the American Medical Association, 88% of surveyed physicians reported that prior authorization hindered the continuity of care. [1] Additionally, the survey shows that, on average, providers and their staff spend an average of two full days or 13 hours a week completing prior authorizations. [2]

The significant burden of prior authorizations on patients and providers negates what is ostensibly the primary purpose of prior authorizations: to ensure the appropriate treatment or drug is being provided to patients. Theoretically, prior authorizations enhance evidence-based practices to ensure proper treatment without unnecessary costs. Sadly, prior authorizations have become a way to hinder, deter, or prevent the services and treatments that allow providers to treat their patients effectively. Prior authorizations now put an undue burden on providers seeking to do what is in the best interest of their patients.

The ACR commends CMS for recognizing the undue burden of prior authorizations and the delay in care these methods cause for our patients. Accordingly, we offer comments on prior authorization timeline proposals, the policies' scope, and the associated quality measures. We also provide cautious optimism regarding the gold card request for information and practice impacts on the provider API proposals.

Prior Authorization Proposals

Scope of Proposals

The proposed policies regarding prior authorizations represent a positive and significant step forward to reduce undue burden on providers and allow for appropriate access to care. We must note, however, that prior authorizations are only a part of broader utilization management strategies that delay and hinder appropriate care. We appreciate that CMS highlights the negative impact of prior authorizations for delivering appropriate medical services; however, we urge CMS to expand guidance beyond medical services and include policies for all utilization management tools for services *and* therapeutics, including step therapy policies.

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[1] *2021 update measuring progress in improving prior authorization*. (n.d.). Retrieved March 2, 2023, from https://www.ama-assn.org/system/files/prior-authorization-reform-progress-update.pdf

[2] Ibid.

Patients suffering from rheumatic diseases require ongoing treatment with therapeutics to manage their disease and maintain quality of life. Unfortunately, prior authorization and step-therapy hinder or prevent our patients from receiving the needed medications. In a recent study, researchers found that prior authorization requirements extended the time to infusion treatments for patients requiring prior authorizations compared to patients who did not require prior authorizations for infusible medications. [3] Additional delays occurred for prior authorizations that were initially denied but subsequently approved. The data shows that 96% of the prior authorizations that were initially denied were subsequently approved upon appeal. [4] While we recognize the need to ensure services and treatments are medically appropriate to cut wasteful spending, the current utilization management tools have expanded beyond that purpose. They are now delaying or preventing appropriate care and treatments. **We urge CMS to include therapeutics in the prior authorization policies and issue additional sub-regulatory guidance on step therapy policies such that they will not jeopardize our patients' access to the necessary treatments.**

Decision Timelines

The ACR appreciates that CMS has outlined timelines for prior authorization decisions. The prior authorization process is lengthy and unpredictable, placing additional burdens and stress on providers and patients. We applaud CMS for attempting to mitigate these delays. The ACR has long been a proponent of the Improving Seniors' Timely Access to Care Act (S. 3018/H.R. 3173), introduced in the House of Representatives and the Senate in the last Congress. We urge CMS to align the decision timeline with that outlined in the legislation. **Specifically, we urge CMS to shorten the decision time to 24 hours for urgent requests and seven days for non-urgent requests.** When a patient urgently needs care, the proposed 72-hour timeframe is far too long. A 24-hour timeline is still too short in emergent cases but will allow providers to deliver urgent care needed to ensure the health and safety of their patients in most situations. For non-urgent requests, a seven-day approval process allows appropriate care planning without significant delays that would jeopardize the patient's health.

Denial Reasons

The proposed rule will require payers to provide the reason for prior authorization denials. We appreciate that CMS will require additional transparency behind denials, particularly as many of those denials are subsequently approved upon resubmission or appeal. **The ACR supports this proposal as it will provide a better understanding of the reasoning behind the denial and will allow a more straightforward path forward for resubmission or appeal.**

Prior Authorization and MIPS Measures

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[3] Wallace, Z. S., Harkness, T., Fu, X., Stone, J. H., Choi, H. K., & Walensky, R. P. (2020, November). *Treatment delays associated with prior authorization for infusible medications: A cohort study*. Arthritis care & research. Retrieved March 2, 2023, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7062557/

[4] Ibid.

The rule proposes new electronic prior authorization (e-prior authorization) measures for MIPS-eligible providers under the Performance Improvement (PI) category. We urge CMS to reconsider this proposal. Our members are struggling to report on current PI measures that were once optional and are now required. Unfortunately, for most of our members, most electronic health records (EHR) do not offer the capabilities to capture this data. In addition, due to increasing practice costs, our members cannot afford to change EHRs to satisfy this measure. Therefore, **we strongly oppose the inclusion of e-prior authorization in the PI category until EHRs can report this measure without additional burden to providers**.

Request for Information: Gold Cards

The ACR commends CMS for gathering additional information and insight on gold cards to help improve prior authorization issues. While we support the concept of a gold card program, we urge CMS to ensure that operationalization of this program is done thoughtfully and comprehensively. **We especially urge CMS to include treatments in the gold card program**, as a services-only program will benefit procedural specialties without alleviating the burden on cognitive specialties.

A gold card program must include drugs to ensure patients are not forced to postpone treatments based on prior authorization delays. Therefore, we urge CMS to consider physician-administered drugs to be included in any gold card program. These drugs are life-altering for our patients. Unfortunately, these treatments are subject to burdensome prior authorizations before the drug can be given to a patient. **Nevertheless, we are cautiously optimistic about this gold card model and welcome the opportunity to be part of future discussions on this issue.**

Provider API

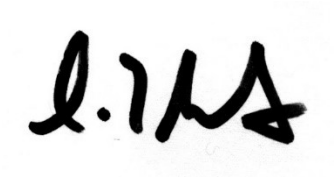
The proposed rule calls upon payers to develop a provider API to share data with providers on their in-network patients. The rule outlines the coordination of care benefits of provider and patient APIs for greater transparency and data exchange. **The ACR supports all efforts for greater transparency and better communication between provider and payer. We urge CMS to go further and require payers to include prior authorization information for services *and* drugs.** Including this information will allow for greater transparency, better care coordination, and more comprehensive care planning.

While we are encouraged to see the increase in transparency between payers and providers, the impacts of the API on everyday practices remain unknown and will not be understood until the APIs are rolled out to practices. We remain optimistic that these programs will increase transparency and alleviate administrative burden; however, the true impact of APIs on prior authorizations and care coordination will not be realized immediately and could bring unintended consequences. We look forward to ongoing dialogue with CMS and payers to refine the provider API to ensure information is shared with providers meaningfully.

Conclusion

The ACR applauds CMS for recognizing the ongoing burdens associated with prior authorizations and the harm these tools have placed on practices and patients. We look forward to continued dialogue with the agency as sub-regulatory guidance is developed, particularly with gold cards and the meaningful impact of APIs. We strongly support the policies related to improving the prior authorization process and hope these policies will provide relief for providers and ensure patients receive the care they need. Please do not hesitate to contact Amanda Grimm Wiegrefe, ACR's Director of Regulatory Affairs, at awiegrefe@rheumatology.org should you have any questions or need clarification.

Sincerely,



Douglas White, MD, PhD
President, American College of Rheumatology