



American Society of Hematology

Helping hematologists conquer blood diseases worldwide

2026

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June 15, 2026

Mehmet Oz, MD

Administrator

Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges (CMS-0062-P)

Dear Dr. Oz:

On behalf of the American Society of Hematology (ASH), thank you for the opportunity to submit comments on the Interoperability Standards and Prior Authorization for Drugs proposed rule. We support the Centers for Medicare & Medicaid Services' (CMS) and the Office of the National Coordinator for Health Information Technology efforts to update and propose policies that streamline the use of prior authorization for drugs, and non-drug items and services in plans administered by the Agency.

ASH represents more than 18,000 clinicians and scientists worldwide committed to studying and treating blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as classical hematology (non-malignant) conditions like sickle cell disease, bleeding and clotting disorders. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the fields of stem cell biology, transfusion medicine, and gene and cell therapies. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians providing care to patients.

Electronic Prior Authorization for Drugs

Citing an overwhelming response from comments received on the 2024 interoperability rule as well citing the need to improve patient care and reduce provider burden, CMS proposes to include drugs in prior authorization interoperability requirements and processes. As one of the stakeholders who made that request, ASH appreciates the Agency's efforts to modernize electronic prior authorization (ePA) processes with proposed policy that reduces the administrative burden associated with current manual workflows. ASH members reported continued reliance on fax machines, phone calls, and payer-specific portals to complete prior authorizations. Navigating these different

processes and modalities creates delays and poses significant administrative and financial challenges for physicians, practices, and health systems. We believe that adopting standardized ePA processes and improving interoperability has the potential to make the prior authorization system more efficient for patients and providers, which will ultimately support more timely access to the drugs and therapies that patients need.

Additionally, ASH encourages the Agency to ensure that there is improved documentation and standardization across plans to allow for greater interoperability. The Society notes that providers must routinely navigate payer and plan specific forms, submission requirements, and documentation standards. This constant battle of navigating varying expectations for payer and plan specific documentation requirements, submission portals, and other administrative tasks often cause care delays, takes valuable time away from patient care and presents a financial burden to practitioners. As CMS considers ePA for drugs, ASH cautions that this change may only shift the burden of prior authorization rather than meaningfully reducing it unless there is greater consistency of documentation requirements across plans. True interoperability can only be achieved when the data elements and the exchange of that information are standardized across operating systems, including EHRs and application programming interfaces, and are then applied consistently across health plans. CMS should promote alignment around core clinical data elements, which are essential to efficient workflows, and to allow for prompt decisions on prior authorization requests. Core clinical data elements for drug prior authorization requests may include diagnoses, biomarker and laboratory test results, prior treatment history and therapy failures, contraindications, and adverse reactions.

Given the assumed ease of electronic prior authorization of drugs, we also suggest CMS establish guardrails to ensure plans do not use electronic submissions as a basis for requesting additional documentation beyond what is reasonably necessary for review. This may be viewed by many as a delay tactic, particularly when that documentation may be unnecessary and would only serve to delay patient access to clinically appropriate drugs and therapies. Providers are concerned that this will create unnecessary delays which may then lead to adverse patient outcomes.

Finally, CMS must ensure these changes do not unintentionally create overreliance on artificial intelligence (AI) decision-making tools. The Society sees the value of using AI within the healthcare system, understanding that automation may help expedite prior authorization processes. AI may be most valuable when used to review treatment approvals for cases that are straightforward, generally uncomplicated without much room for alternate interpretations of an appropriate treatment protocol, and when there are established clinical pathways and treatment guidelines that can be consulted prior to a payer or plan making a prior authorization determination. However, AI tools should support and not replace the clinical judgment of providers. Human review remains especially important for complex hematologic cases, the use off-label therapies, treating rare diseases, when using genomic-driven treatments, and other circumstances that may not fit neatly within standardized criteria but that are commonly seen in hematology practice. Providers and patients need accessible escalation pathways like peer-to-peer reviews when automated systems simply cannot appropriately address and respond accordingly to the clinical situation.

Reporting Metrics and Decision Timeframes

ASH supports CMS's proposed timelines for prior authorization decisions, requiring that standard requests be turned around in 72 hours and expedited requests in 24 hours. The Society also encourages

CMS to ensure these timelines operate on a true 24-hour, 7-day a week basis. However, ASH members have raised that certain clinical situations may require even faster decisions. Patients with aggressive leukemias or lymphomas, urgent bleeding or clotting complications, transplant-related issues, or discharge-related treatment needs require treatment decisions in less than 24 hours to avoid serious health consequences. CMS should consider requiring that plans develop electronic pathways that allow greater flexibility or exceptions for clearly urgent clinical circumstances. While ASH supports the proposed turnaround times of prior authorization decisions, the Society urges the Agency- in collaboration with stakeholders like the plans and EHR vendors- to continue working toward real-time approval or denial decisions. Real-time decisions, while the patient and provider are in the same room, will increase shared decision-making, improve patient care, and improve timely access to needed therapies and drugs.

Additionally, our members report that the appeals process is one of the most burdensome and time-consuming aspects of the prior authorization process. Our members note that some of the longest care delays are created when they appeal a prior authorization decision, with plans asking for additional documentation, chart notes, or other types of information to reach a determination. ASH recommends that CMS strengthen requirements for appeal timeliness, require timely escalation to qualified clinical reviewers, and provide transparency regarding appeal outcomes.

Finally, ASH supports CMS's efforts to improve transparency through public reporting of prior authorization metrics. Information on approval rates, denial rates, appeal outcomes, and turnaround times can help improve accountability and identify barriers to patient access. Timeliness measures such as same-day approvals or approvals completed within 24 hours would also be particularly meaningful for providers and patients.

Request for Information: Step Therapy

We appreciate the Agency's interest in gathering information on ways to improve the use of step therapy protocols through integration into the electronic prior authorization process. Step therapy protocols, used by many payers, are an administratively complex and clinically sensitive form of utilization management. While we do not support the use of step therapy generally, and our preference would be its elimination for hematologic treatments and therapies given the often complex and sensitive nature of hematologic conditions and malignancies, we do support the use of interoperability processes to make improvements within the system and encourage the Agency to require that payers and plans maintain consistent documentation requirements. Improved interoperability and portability of treatment history across plans would be especially important for continuity of care and could help prevent treatment disruption as well as reduce delays in care.

The Society believes that step therapy protocols must be clinically relevant to the disease process and allow for physician autonomy to make decisions that are in the best interest of the patient. Patients should not be required to retry therapies that were previously ineffective, poorly tolerated, highly toxic, or clinically inappropriate simply because they changed health plans, or when the electronic record failed to capture data of previously tried and failed therapies. This is the point at which the provider must have the autonomy to "skip a step" and make clinically appropriate recommendations based on what is needed for an improved patient outcome.

ASH supports CMS's efforts to modernize prior authorization processes and improve interoperability across the healthcare system. Successful implementation will depend on creating consistent standards across plans, reducing unnecessary administrative burden, preserving meaningful human clinical review, and ensuring patients can access needed therapies without avoidable delays. If you have questions or need additional information, please contact Carina Smith, Manager of Health Care Access Policy (casmith@hematology.org).

Sincerely,

A handwritten signature in black ink, appearing to read "R. Negrin". The signature is stylized and cursive.

Robert Negrin, MD
American Society of Hematology, President