This document contains submitted ASTCT comments and response sections from the [CMS Interoperability and Prior Authorization Final Rule](https://www.federalregister.gov/documents/2024/02/08/2024-00895/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability), dated February 8, 2024.

Ms. Chiquita Brooks-LaSure March 13, 2023

Administrator

Centers for Medicare & Medicaid Services

7500 Security Boulevard

Baltimore, MD 21244

*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 Society for Transplantation and Cellular Therapy (ASTCT) is pleased to submit the following comments and references regarding the proposed changes to Prior Authorization requirements.

The ASTCT is a professional membership association of more than 3,700 physicians, scientists, and other health care professionals promoting blood and marrow transplantation and cellular therapy through research, education, scholarly publication, and clinical standards. Our Society’s clinical teams have been instrumental in developing and implementing clinical care standards and advancing cellular therapy science, including participation in trials that led to current Food and Drug Administration approvals for chimeric antigen receptor T-cell (CAR-T) therapy.

For more than 25 years, ASTCT members have focused on innovation in the treatment of hematologic malignancies, hematologic disorders, and other immune system diseases. ASTCT members very much rely on team care for the complex cancers and other disorders requiring hematopoietic stem cell transplants (HSCTs) and newer cell therapies like CAR-T.

If CMS has any questions regarding these comments, please contact Alycia Maloney, the ASTCT’s Director of Government Relations, at amaloney@astct.org.

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**General Summary of the Final Rule**

The rule is focused on MA, Medicaid and CHIP FFS, and Medicaid and CHIP Managed care and Qualified Health Plan Issuers on the Federally Facilitated Exchanges. Commercial and self-funded plans are not impacted but encouraged to participate.

The rule addresses payer requirements for 4 required APIs – effective 2027:

* Patient Access API – impacted payers should have already implemented or begun implementation of the Patient Access and Provider Directory APIs as required in the CMS Interoperability and Patient Access final rule, except for those organizations that have approved exceptions, as applicable.148149 We did not propose a new Patient Access API, but rather additional data requirements for that API, and reporting requirements for use metrics; structured data on status of prior authorizations
* Provider Access API – enables requests/information on prior authorization requirements. Payers can contractually require providers to make changes to access and can charge fees to providers; structured data only
* Payer to Payer Access API – to share up to 5 years of past data on a patient and any prior authorizations for current treatment – structured and unstructured data
* Prior Authorization API **-** the Prior Authorization API will: (1) enable providers to submit a complete prior authorization request faster and easier; (2) support more timely notice to the provider and beneficiary of the disposition of the prior authorization request; and (3) permit improved scheduling of services or filing appeals, depending on the decision.

Payers must begin reporting metrics on prior authorizations in 2026.

The rule also implements requirements for providers (that is, MIPS eligible clinicians, eligible hospitals, and CAHs) and metrics for MIPS and the hospital interoperability program regarding electronic prior authorization. Most notably, beginning in 2026, impacted payers must provide notice to providers and patients of prior authorization decisions as expeditiously as a patient’s health condition requires, but no later than 7 calendar days for standard requests, and no later than 72 hours for urgent requests. They must also provide a specific reason for a denial within their decision timeframe.

**ASTCT Interest in Prior Authorization Issues**

The membership of ASTCT provides care to patients in need of extremely specialized and resource-intensive medical care. Our patient population includes individuals with otherwise fatal blood cancers, metabolic disorders and immunodeficiencies, and severe blood disorders like sickle cell disease. Streamlined prior authorization processes and timely decisions are critical to providing our patients with the care they need. We appreciate the Centers for Medicare & Medicaid Services’ (CMS’) attention to this topic over the past several years and encourage further action in this area.

*Inclusion of drugs in prior authorization requirements*

In Section I.A., CMS noted that this proposed rule does not apply to any type of drugs, including outpatient drugs or those that may be administered by a physician or a hospital. CMS noted that requirements for drugs are addressed in the CMS Interoperability and Patient Access final rule. However, CMS noted later in the document that it seeks comments on how prior authorizations requirements in this rule may interact with those applicable to drugs.

We believe CMS’ intent for its prior authorization proposals is to minimize burden and increase patient access to timely care. Thus, we wish to raise concerns with the exclusion of drugs as a category, and to separately request that cellular and gene therapy products be specifically included in the proposed rule.

The prior authorization process for drugs has long been viewed as one of the most complex processes for providers to navigate, including those drugs utilized for HSCT and CAR-T. Patients who are undergoing any sort of cancer treatment are vulnerable, clinically fragile, and in dire need of smooth and consistent access to their physician-determined care plan. These patients are likely the ones set to benefit the most from the proposed rule—if, and only if, CMS expands the rule to include drugs. We ask that CMS consider physician- or hospital-administered drugs be treated the same as other “items and services” so that prior authorization requests are processed in a streamlined and coordinated manner within and across payers.

As noted in this letter’s preamble, the ASTCT membership provides specialized biologics, like CAR-T, to patients with blood cancers and other conditions. CAR-T is recognized as a novel therapy for patients who have little to no other treatment options. For the rule to exclude cell and gene therapies such as CAR-T from the long-needed advancements would be a severe disservice to the patients most in need of timely access to care. These biologics are regulated and approved as drugs, but they are delivered through a complex set of medical services over an extended episode of care; CAR-T cannot be provided without these services and these services on their own would be futile without the CAR-T biologic product.

Requests for authorization of use of CAR-T are often handled by a payer’s transplant department due to the similar definitions for the phases of care within the clinical episode, as well as the complexities associated with case management, the prior authorization process, and reimbursement. Our members have recently raised examples of long and uncoordinated prior authorization processes during which they are asked to seek an authorization for a CAR-T product from a payer’s pharmacy division, only to be told, later, that they should have sought the authorization from the hospital divisions, and vice versa.

Regardless of the mechanism for prior authorization request (through pharmacy or the hospital division) for the CAR-T product itself, our providers are also required to obtain separate authorizations for the surrounding medical services within the episode of care. On numerous occasions, the provider then receives a varying number of approvals and denials from the same payer in response to the desire to utilize a single authorization for a set of services for a single patient. This results in confusion, additional work by all parties, and delayed care for the patient.

The ASTCT requests that CMS clarify cell and gene therapy products are expressly included in the proposed rule, separate from the general exclusion of drugs.

**CMS response: (p. 29-31)**

*“A few commenters specifically requested that CMS include drugs covered under a medical benefit in the prior authorization process and Prior Authorization API policies in the final rule and explained that the exclusion was troubling because health plans may cover physician-administered drugs and specialty drugs through a patient’s medical benefits, including specialty drugs. A commenter urged CMS to include administered drugs, which are inextricably related to other provider services. Some commenters stated that by failing to include administered drugs throughout the proposed rule, CMS is failing to address the biggest culprit of delay to timely care and administrative burden for cancer patients. Commenters described barriers to access for prescriptions for specialty drugs, cancer drugs, and certain drugs for chronic conditions that require ongoing re-authorizations.”*

*“While we acknowledge the request for reconsideration, when making the decision to exclude prescription drugs from the proposed rule, we believed there would be operational complexities in applying the requirements of this rule to prior authorization for prescription drugs under current conditions and did not anticipate the overwhelming response to that exclusion under current conditions. Based on the scope and breadth of the comments, it is essential for us to conduct a thorough evaluation of both existing policies and standards, and the impact any mandatory changes will have on impacted payers, providers, and patients, as well as on other policies before making a proposal for public consideration. We are committed to ensuring transparency of the process, and the development of the right policy to support all entities who might benefit. We anticipate engaging with the public on this topic in the near future and encourage the public to provide additional feedback.”*

Patient Access Application Programming Interface (API)

The ASTCT agrees with CMS’ proposed Patient Access API requirements, specifically the one business day timeframe for status change information and the inclusion of prior authorization information.

The ASTCT recommends CMS consider the following additional requirements:

* Inclusion of clear instructions on how to appeal a denial, when a prior authorization request is denied.
* Payer support teams that are accessible to patients seeking to reverse a denial—ideally, through immediate synchronous communication with live/human representatives (not ChatBots or Artificial Intelligence programs) with multiple language options and extended hours.
* Denials need to be accompanied by patient-specific information provided in terms that are understandable to individuals with low health literacy levels, along with details on what specific information is missing that may support a successful appeal. When denials are accompanied by vague information or terms that are primarily utilized in the payer community, patients and the family members assisting them are faced with a knowledge barrier in addition to navigating complex and unfamiliar processes.
* For HSCT and CAR-T, which are provided at limited facilities, payers need to clearly outline which facilities are in- vs. out-of-network, any nuances associated with seeking care at an out-of-network facility, and any special handling required for appeals. For example, if a patient has no in-network options for HSCT and they have no out-of-network benefits, it is not uncommon for an exception to be granted for the patient to receive the life-saving care at an appropriate facility.

**CMS Response: (p. 61, 65-66)**

*“A few commenters urged CMS to require payers to include plain language information about appealing a prior authorization decision, including processes to request internal review and external appeal of a decision and information about consumer programs to assist with appeals…We did not propose to make that information available via the Patient Access API.”*

*“Multiple commenters suggested that the Patient Access API should include information regarding whether the requesting provider is in-network or out-of-network, by requiring payers to fully implement the X12 270/271 transaction standards for health plan eligibility benefit inquiry and responses… This rule makes no distinction between in-network and out-of-network providers with regard to making prior authorization information available through the Patient Access API. Regardless of the requesting provider’s network status, the required information must be shared with patients. We understand that it is important for patients to know whether the provider they are seeing is in their payer’s network, but we do not believe that the appropriate place for that information is with prior authorization information. Furthermore, the FHIR API technical specifications and IGs for the Patient Access API are not built to include information on a provider’s network participation.”*

**CMS Final Action: (p. 96)**

* Beginning 2027, impacted payers must make all of following information available about prior authorization requests and decisions (excluding for drugs) available via the Patient Access API:

•The prior authorization status.

•The date the prior authorization was approved or denied.

•The date or circumstance under which the prior authorization ends.

•The items and services approved.

•If denied, a specific reason why the request was denied.

•Related structured administrative and clinical documentation submitted by a provider.

* Information must be available no later than 1 business day after any status change
* Impacted payers must annually report patient access API metrics to CMS by March 31, 2026

Provider Access API

The ASTCT supports CMS’ proposal to require that payers develop and maintain a Provider Access API to share patient data with in-network providers with whom the patient has a treatment relationship. However, it is critical that payers also extend this information to out-of-network providers when requested by the patient or provider. Ultra-specialized care such as HSCT or CAR-T therapy are only available in limited hospitals across the country; thus, the uniqueness of these services results in the provision of care to a high proportion of patients with out-of-network insurance. Patients will benefit tremendously when their treating physician team at the out-of-network facility has full access to their health information from other sites of care.

Additionally, it is important to understand that many governmental and commercial payers utilize HSCT or CAR-T therapy “networks” for these services because of the complexities involved for case management and account reconciliation. This means that, although a patient might have an insurance that is considered out-of-network for traditional medical services, the payer for this same patient might utilize a HSCT or CAR-T therapy network that is in-network with the provider. Payors should be required to build Patient and Provider APIs that consider these nuances. Irrespective of whether CMS requires the exchange of patient data for out-of-network providers, in these instances, the provider should be in-network.

**CMS Response:** There was no response from CMS in the Final Rule.

**CMS Final Action: (p. 218)**

* Beginning 2027, impacted payers must implement and maintain a Provider Access API
* Impacted payers must make available upon request from an in-network provider, via the Provider Access API, claims and encounter data (excluding provider remittances and patient cost-sharing information), all data classes and data elements included in a content standard at 45 CFR 170.213 (USCDI), and certain information about prior authorizations (excluding those for drugs) that the payer maintains
* Information must be made available no later than 1 business day after receiving a request from such a provider
* Payers must update providers within 1 day after a status change
* Payers must establish and maintain an attribution process to associate patients with their in-network or enrolled providers
* Payers must establish and maintain a process for patients to opt out of data exchange via the provider access API
* Payers must provide educational resources in plain language via the provider access API and it must be posted on their website

Payer to Payer Data Exchange on FHIR

ASTCT supports the use of payer-to-payer data exchange as a method to maintain a longitudinal record that follows patients across payers. During the first year following HSCT or CAR-T especially, it is critical for patients to remain with the same dedicated and highly specialized care team. It is not uncommon for these patients to transition to a new payer during this acute timeframe and, when this happens, a disruption or delay in treatment based on an administrative barrier, albeit unacceptable and potentially life threatening, unfortunately occurs.

We therefore recommend that CMS require payers to not only exchange information regarding active prior authorizations but also to require payers in these situations to “continue” or honor the prior authorization from the original payer for HSCT or CAR-T if it is considered a covered benefit. Furthermore, we fear the “opt-in” approach for patients to participate in the payer-to-payer data exchange will result in a low adoption rate that negates the positive effect of this aspect of the rule.

**CMS response: (p. 274/275)**

“*While we did not propose to require payers to review, consider, or honor the active prior authorization decision of a patient’s former payer, payers may gain efficiencies by doing so. We sought comment on the benefits, burdens and considerations of imposing such a requirement. However, we did not make any proposals and therefore are not finalizing any policies in this area. We do note that since we published the proposed rule, the Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly final rule (CY 2024 MA and Part D final rule) was issued, which requires MA coordinated care plans to provide a minimum 90-day transition period when an enrollee switches to a new MA organization, during which the new MA organization may not require prior authorization for an active course of treatment.”*

*“An “active course of treatment” is defined at 42 CFR 422.112(b)(8)(ii) as a course of treatment in which a patient is actively seeing a provider and following a “course of treatment,” which is defined as a prescribed order or ordered course of treatment for a specific individual with a specific condition, outlined and decided upon ahead of time with the patient and provider. A patient can have an active course of treatment to which 42 CFR 422.112(b)(8) will apply that did not require prior authorization by their previous payer. Per 42 CFR 422.112(b)(8)(i)(B), MA organizations offering coordinated care plans must have, as part of their arrangements with contracted providers, policies for using prior authorization that provide for a minimum 90-day transition period for any active course(s) of treatment when an enrollee has enrolled in an MA coordinated care plan, even if the course of treatment was for a service that commenced with an out-of-network provider. Further, the MA plan cannot deny coverage of such active courses of treatment on the basis that the active course of treatment did not receive prior authorization (or was furnished by an out-of-network provider) but may review the services furnished against the MA plan’s coverage criteria when determining payment. This includes enrollees who are new to an MA plan, an enrollee switching from Traditional Medicare to MA, or enrollees new to Medicare and enrolling in an MA plan for the first time.*

**CMS Final Action: (p. 355):**

* Beginning in 2027, payers must:
	+ Implement and maintain a payer-to-payer API
	+ Establish and maintain a process to gather patient permission for payer to payer data exchange within 1 week after the start of coverage
	+ Establish and maintain a process to ID a patient’s previous/concurrent payer(s) no later than 1 week after the start of coverage
	+ Gather permission and previous/concurrent payer(s) information from enrolled patients
	+ Make any of the required information that they maintain available to new or concurrent payers within 1 business day of the request
	+ Make available the following required information:
		- Prior authorization status
		- Date the prior authorization was approved
		- The date the circumstance under which the PA ends
		- The items and services approved
		- Structured and unstructured administration and clinical documentation submitted by the provider
	+ Provide educational resources to patients
* Finalized an opt in framework

Improving Prior Auth Processes

The typical patient journey for HSCT or CAR-T occurs in phases—consultation; evaluation; collection of cells; the transplant or infusion itself; and post-HSCT or CAR-T, which extends for one year. Oftentimes, a prior authorization is granted to cover an episode of care congruent to the clinical phase—i.e., a unique prior authorization is granted for consultation, then for evaluation, and so forth. During each phase, numerous visits and diagnostic and therapeutic services are rendered. Our members report that although prior authorizations might be granted for an episode of care congruent with the clinical phase the patient is in, there are still certain individual, high-cost services within that episode of care that require an additional, separate prior authorization.

ASTCT therefore requests that CMS require payers to authorize *all* related services within the phase of care with one authorization—as opposed to the current practice of obtaining numerous authorizations for services related to care that was already authorized. We outline below how CMS may best modify the proposed rule to achieve optimal and timely access to care for patients.

**CMS response: (p. 374-375)**

“*The CY 2024 MA and Part D final rule also streamlines prior authorization requirements, including adding continuity of care requirements and reducing disruptions for beneficiaries. First, we finalized that prior authorization policies for coordinated care plans may only be used to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations and/or ensure that an item or service is medically necessary based on standards specified in that final rule (see 42 CFR 422.138(b)). Second, we finalized that for MA coordinated care plans, an approval granted through prior authorization processes must be valid for as long as medically necessary to avoid disruptions in care in accordance with applicable coverage criteria, the patient’s medical history, and the treating provider’s recommendation, and that plans provide a minimum 90-day transition period when an enrollee who is currently undergoing an active course of treatment switches to a new MA plan or is new to MA (see 42 CFR 422.112(b)(8)).”*

*Electronic Options for Prior Authorization*

* We recommend CMS enforce the current HIPAA transaction standards to combat the existing low payer adoption rate and ensure the goals of this rule are fully realized. Unfortunately, payers do not consistently utilize the 278 transaction standard which is a prerequisite to implementing any, if not all, of the proposed rule.

*Prior Authorization Requirements, Documentation and Decision (PARDD) API*

* We recommend that CMS require standardization across payers on the criteria for documentation to support the prior authorization request based on nationally recognized clinical criteria for treatment.
* The PARDD API should also take into considerations the unique nuances that exist for HSCT and CAR-T services. Expanding on the previous example where a provider might be in-network for transplant but out-of-network for traditional medical services, the PARDD should capture that the authorization for the episode trumps the requirement to have every single service authorized.

*Requirements for Payers to Provide Status of Prior Authorization and Reason for Denial of Prior Authorization*

* We recommend that CMS elaborate on the specificity of the denial reason communication from payer to provider, to ensure providers understand the rationale for denial and can efficiently address. Our centers report denial reasons that are so vague that they require hours of research, numerous internal and external emails, and an unnecessary amount of time on the phone—all before the provider can draft the appeal and all of which are ‘on the clock’ (i.e., counting against any timeframes under which a provider needs to appeal for the case to proceed). If payers were required to provide detailed reasons for denials, a significant amount of time and frustration would be saved by the patient, payer, and provider.

**CMS response (p. 395, 421, 427):**

*“We did not propose to specifically require payers to make available the references to the clinical research evidence that underlie medical policy determinations when they approve or deny a service, but we did propose that when an impacted payer denies a prior authorization request, the payer must include a specific reason for that denial in a notice to the provider who requested the prior authorization.”*

*“Some commenters recommended that CMS define and provide examples for terms such as “approval,” “denial,” and “specific reason” concerning prior authorization denials in the final rule…We are not adding regulatory definitions for these terms in this rule, as these terms are clear, frequently used in many contexts, and commonly used. For this final rule, these terms mean the following:*

*•Approvals are when the payer authorizes coverage of items or services for which prior authorization has been requested.*

*•Denials are the refusal by a payer to approve the prior authorization for a health care item or service. Denials, or rejection of a prior authorization, may result because the service was not considered medically necessary under the payer’s medical guidelines or the provider did not provide complete or accurate documentation to support the request.*

*•A specific reason for denial could include reference to the specific plan provisions on which the denial is based; information about or a citation to coverage criteria; how documentation did not support a plan of care for the therapy or service; a narrative explanation of why the request was denied, and specifically, why the service is not deemed necessary or that claim history demonstrated that the patient had already received a similar service or item.”*

*“Many commenters described challenges with denials, including the burdens they faced when attempting to appeal those denials on behalf of their patients and delays created in access to care when they did not have information about the reason for the denial, and therefore little information to include in the response back to the payer… We concur with the information in many of the letters that the requirement to provide the specific reason for the denial in a response to the provider has the potential to improve communication between payers and providers for the prior authorization process.”*

*Requirements for Prior Authorization Decision Timeframes and Communications*

* ASTCT members provide lifesaving, highly complex treatments to a patient population that require shorter timeframes for decision-making compared to other services. For example, CAR-T patients should proceed to leukapheresis (the collection of immune cells via apheresis and the first step in the CAR-T treatment process) almost immediately after being deemed to be clinically eligible. Otherwise, there is the risk the patient's disease may progress and render them ineligible for treatment. Therefore, ASTCT requests CMS to consider the following requirements for HSCT- and CAR-T-related care:
	+ Prior authorization decisions must be made within 24 hours for HSCT- or CAR-T-related services.
	+ Eliminate payers’ ability to extend the timeline for decision-making unless a peer-to-peer is needed. In such instances, a decision should be rendered within 48 hours of the original request for authorization. If the PARDD is fully implemented, denials or extensions based on “needs additional information” should be mostly eliminated.
	+ In instances where a denial is received for a prior authorization, appeals must be managed within five days.

**CMS Response:** There was no response from CMS in the Final Rule.

**CMS Final Action: (p. 500)**

P. 500: *“We are finalizing that, beginning in 2026, MA organizations, including applicable integrated plans, and state Medicaid and CHIP FFS programs, must provide notice to providers and patients of prior authorization decisions as expeditiously as a patient’s health condition requires, but no later than 72 hours for expedited requests, unless a shorter minimum timeframe is established under applicable state law. That requirement already exists for Medicaid managed care plans and CHIP managed care entities, but for consistency with Medicaid FFS, we are finalizing that those payers must also send notices to patients and comply with a shorter timeframe, if established by state.”*

*Prior Authorization Metrics and Gold-Carding*

* In addition to aggregated data requirements outlined by CMS, the ASTCT recommends all proposed metrics be provided for a category dedicated specifically to solid organ transplant, HSCT, and CAR-T.
* Payers should be required to implement a “gold-carding” approach for providers that commit to following nationally recognized guidelines for HSCT and CAR-T, and that also demonstrate high rates of prior authorization approvals. This approach would allow these providers to bypass the usual authorization process and proceed to treatment after a notification process.
* Prior authorization metrics and gold-carding should be incorporated in the quality ratings for Medicare Advantage plans to encourage payers to further eliminate barriers to timely care.

**CMS Response: (p. 478, 492)**

 *“Multiple commenters stated that service-specific reporting will aid in identifying services for which there is a high rate of approval and for which prior authorization requirements may no longer be necessary, or for identifying critical services or items being routinely denied… Service-specific and demographic reporting may be very useful to the impacted payers in evaluating their programs and expect that they use such data today and will continue to do so as they implement the policies of this final rule. While we agree that there could be many more reporting requirements, and at more granular levels, and data are an important tool for different evaluation purposes, reporting should serve its intended purposes and not become a burden to the users.”*

Conclusion

ASTCT commends CMS for its proposals aimed at improving care for its beneficiaries and all patients seeking care in the United States. We welcome any opportunity to discuss this letter and its recommendations.