



American Society for  
Transplantation and Cellular Therapy

Ms. Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

March 13, 2023

*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](mailto:amaloney@astct.org).

A handwritten signature in blue ink, appearing to read "M. A. P." followed by a horizontal line.

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### **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 authorization 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



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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.

#### 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.



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### 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. Payers 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.

### 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.

### 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,



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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.

#### *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.

#### *Requirements for Prior Authorization Decision Timeframes and Communications*



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- 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.

#### *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.

#### 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.