AMERICAN SOCIETY OF TRANSPLANTATION

TO: Center for Medicare & Medicaid Services (CMS), Department of Health and Human Services

FROM: Dr. Deepali Kumar, President
on behalf of the AST Board of Directors

RE: CMS-0057-P

87 FR 76238: 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

DATE: March 10, 2023

The American Society of Transplantation (AST) represents over 4,200 medical professionals dedicated to the field of organ transplantation. We applaud efforts to improve health information exchange, improved access to information in health records, and proposals to reduce payer, provider, and patient burden to improve prior authorization processes for items and services.

While we recognize that the proposals in this proposed rule do not apply to any drugs, we appreciate the request for comments on whether policies should be considered to require impacted payers to include information about prior authorizations for drugs, when the payer covers drugs, via the patient access Application Programming Interface (API), the provider access API, and the payer-to-payer API. We also appreciate the request for comments on how future rulemaking to convey information about prior authorizations for drugs available through these APIs might interact with existing prior authorization requirements and standards.

Prior authorizations requirements by payers for drugs have increased over time and can cause delays in life sustaining medication access as well as add to healthcare administrative costs and clinician inefficiency[1-3]. Prior authorizations are currently required for many solid organ transplant-related medications including immunosuppressants and anti-infective agents. Several inefficiencies and lack of standardization exist among payers regarding prior authorizations of drugs. In addition, within the same payer, prior authorization processes are applied uniformly, regardless of the clinical condition which is inappropriate. Immunosuppressant drugs in solid organ transplant are critical medications of which doses cannot be missed or delayed for the organ transplant to function properly (ultimately to prevent transplant allograft rejection and subsequent death of the patient), yet prior authorization

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processes are routinely applied to these life-sustaining medications delaying vital access.

- Regarding this request for comments on whether policies should be considered to require impacted payers to include information about prior authorizations for drugs, we suggest that the proposed requirements of payers listed within this rule applied to items and services also be expanded to drugs including: Impacted payer requirements for transparency in Patient and Provider Access API about prior authorization requests and decisions (and related administrative and clinical documentations), including, as applicable:
    - The status of the prior authorization
    - The date the prior authorization was approved or denied
    - The date or circumstance under which the authorization ends
    - The items and services approved
    - The quantity used to date
    - If the prior authorization was denied, a specific reason why the request was denied, *no later than 24 hours or 1 calendar day* after the payer receives a prior authorization request or there is another type of status change for the prior authorization.
- Regarding notice of prior authorization decision time, we agree with shortening decision times for both standard and expedited requests and appreciate adding the wording “as expeditiously as a patient’s health condition requires”, however feel it is important for certain conditions of which delaying medication access may have deleterious consequences, to be clearly and uniformly defined among payers.
- Specifically, we would advocate that for solid organ transplant recipients, CMS should consider rules to exempt prior authorization requirements of select specialty medications including immunosuppressants which are required to sustain life in solid organ transplant recipients.
- If this is not possible, at a minimum, we suggest implementing a payer requirement for all immunosuppressant drug prior authorizations to be considered “expedited” necessitating web-based solutions with set criteria algorithms to allow for real-time decision or priority review with a maximum time to decision of 24 hours or 1 calendar day (rather than current state of up to 72 hours for expedited requests) regardless of payer type (currently differences exist for Part B versus D drugs, although immunosuppressants could be covered by either depending on transplant date in relation to Medicare Part A and Part B date).
- In addition, for existing maintenance therapies requiring a coverage redetermination prior authorization (an example of this is Medicare Part B vs D determination); there should be requirement for the payer to continue authorizing a short-term ongoing supply during the prior authorization process pending decision to not interrupt therapy given the deleterious clinical consequences that can result with missed immunosuppressant drug doses, including allograft rejection requiring hospital readmission and associated excess cost.

Additional comments that we have specific to prior authorization of drugs and special considerations for solid organ transplant related medications include the following:

- **Both the patient and provider access API should have transparency regarding payer prior authorization criteria, covered formulary alternatives, quantity limits, appeal information and process (rather than a separate notice after denial), and preferred/in-network pharmacies:**
    - Regarding prior authorization notification, it would be helpful to have a requirement for the payer to list the specific drug criteria and covered conditions within the need for prior authorization notification in both provider and patient access API. This is important for transparency and efficiency in completing the request.
    - Standardization within provider access API is needed and important to submit acceptable supportive evidence/medical literature/documentation for the request as these processes vary depending on payer.
    - For off-label drug use in Medicare Advantage or Medicare Part D plans, API should have the ability to interface with CMS approved Compendia (Micromedex® and AHFS Clinical Drug Information®) to determine if use is endorsed since this is standardly used by payers to approve or deny requested off-label drugs.
    - It is important for quantity limits for all drugs be listed within provider and patient access API as well as notifications to filling pharmacies (to advise prescribers) and have clear detail regarding criteria for quantity limit exceptions to be approved.
    - Further, payers should be required to list preferred formulary alternatives and tier hierarchy within the prior authorization required notification. This clarity may impact decision making or guide clinical reasoning for specific medication being prescribed/requested and prevent additional clinician workload.
    - For payers that require specific in-network pharmacies to be utilized, including specialty pharmacies, this information should be listed within payer and patient access API under each drug as applicable. This will ensure that prescriptions are sent to the correct filling pharmacies the first time preventing additional provider workload.

- **Payers may require annual redetermination of coverage, meaning, providers must continually complete prior authorizations regardless of condition. Some clinical conditions are lifelong, such as the need for lifelong immunosuppression following solid organ transplant. Certain chronic conditions requiring lifelong drug therapy should be exempt from annual prior authorizations, and rather have a one-time prior authorization for the requested drug.**

- **During the prior authorization and/or appeal process for drugs, there should be a requirement for improved access for providers to directly reach payer decision makers to improve efficiency.**

    - Existing processes direct providers to payer call centers, with representatives often rerouting calls incorrectly leading to lengthy call times and provider inefficiency.
    - A solution would be a requirement for payers to have a direct line of communication available to the assigned reviewer for prior authorizations. This

could be via the provider access API as electronic communication or via a direct phone line.
    - Similarly, a solution would be for payers to have a direct line of communication for peer-to peer medical reviews for drug appeals. This could be via the provider access API as electronic communication or via a direct phone line.

- **Transplant Specific Prior Authorization Inefficiencies and Proposed Solutions for Medicare Advantage Plans:**

    - Currently one type of prior authorization, Medicare Part B versus D determination, requires knowledge of the transplant date as well as Medicare Part A and B activation dates to determine which portion pays. It is already required that the transplant date be entered on the prescription. A real-time solution to avoid clinician time completing a prior authorization is for this information to then be submitted at the dispensing pharmacy during claim processing rather than clinicians being required to then call or electronically submit this information to the plan after prescriptions are sent. Medicare Advantage plans already have access to Part A and B activation dates. This would reduce provider burden for completing prior authorizations for necessary life sustaining medications and increase efficiency.
    - These types of prior authorizations (B versus D determination) also require annual renewal which is cumbersome and time consuming for clinicians. We propose for immunosuppressant medications needed lifelong for this to be a one-time prior authorization and the determination to last as long as the patient has the same plan. If the patient requires re-transplantation, the new transplant date would be on the prescription and this information could be shared between the pharmacy API and payer API, removing the clinician and associated inefficiency completing additional prior authorizations.

References:

1. Resneck JS Jr. Refocusing medication prior authorization on its intended purpose. *JAMA* 2020;323:703-4.
2. Choi DK, Patel S, Muran C, et al. Prior authorization burden on the use of LCP-tacrolimus in abdominal solid organ transplant recipients. Ann Pharmacother 2022;56:856-57.
3. Fuglesten Biniek J, Sroczynski N. (2023, February 2). Over 35 million prior authorization requests were submitted to Medicare advantage plans in 2021. Kaiser Family Foundation. https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021/