AMERICAN SOCIETY OF TRANSPLANTATION

Submitted electronically via http://www.regulations.gov

June 27, 2022

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-4199-P: Medicare Program: Implementing Certain Provisions of the Consolidated Appropriations Act and other Revisions to Medicare Enrollment and Eligibility Rules

Dear Administrator Brooks-LaSure:

The American Society of Transplantation (AST) represents over 4,000 medical professionals dedicated to the field of organ transplantation. We are thrilled to see the long-awaited lifelong immunosuppressive drug coverage for kidney transplant recipients benefit take shape, and we look forward to its implementation. We have read your draft regulation with great interest, and wish to share the following comments and suggestions:

- In several locations, the draft regulation refers to "successful" kidney transplantation. We recommend striking the term "successful" and simply stating that the new Part B-ID benefit is extended to kidney transplant recipients, as stated in the U.S. Code. This will ensure patients continue to have coverage for immunosuppressive drugs even in the event of failed kidney transplantation. Ongoing immunosuppression in the setting of failing allografts is important to prevent anti-HLA antibody development and preserve the opportunity for kidney re-transplantation.

- We strongly encourage creating an electronic option for submitting the Part B-ID benefit attestation (in addition to the telephone and pen-and-ink options). Likewise, we strongly encourage offering an electronic option for requesting termination of Part B-ID should an individual gain alternate insurance coverage. We strongly oppose only accepting attestations in writing with pen-and-ink.

- Consider clarifying that enrollment in a charity program (e.g., manufacturer-based free drug programs) does not constitute "a program that covers immunosuppressive drugs" and would not preclude eligibility for the new Part B-ID benefit. This is important since a patient may be eligible for a manufacturer-based patient assistance program to obtain one of their immunosuppressant medications, but these programs may not be available for other immunosuppressant medications that make up a well-rounded regimen. Likewise, for other coverage to render a patient ineligible for Part B-ID, the "other coverage" must cover immunosuppressive drugs. It will be very important that individuals enrolled in programs such as a Medicaid program with limited coverage (e.g., mental health coverage only) or a group plan the provides limited coverage (e.g., medical coverage only without a corresponding prescription drug benefit) ***would*** be eligible to enroll in Part B-ID for immunosuppressive drug coverage.

- Please clarify how coverage determination/eligibility will be handled for individuals who were eligible for Medicare at the time of kidney transplant but elected alternate coverage (e.g., a patient with commercial coverage through an employer who became eligible for but decided not to enroll in Medicare at the time of kidney transplantation). If such an individual were to later lose the elected alternate coverage and therefore become uninsured, would he/she be eligible for the Part B-ID benefit?

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- These regulations acknowledge that individuals will be seeking to enroll in the new Part B-ID option when it becomes active (i.e., enroll starting October 2022 for coverage starting January 2023) as well as when their Medicare eligibility through the ESRD benefit terminates. Please add detail regarding special enrollment periods for individuals who will seek to enroll outside of these time points (e.g., when a group health plan terminates, when state Medicaid benefits terminate, upon release from a corrections facility). Alternately, please clearly state that individuals who meet enrollment criteria for Part B-ID will be allowed to enroll/re-enroll at any time and without penalty.

- In order to prevent kidney allograft rejection and maintain kidney allograft function, immunosuppressive drugs must be taken every day, without exception. Therefore, it is essential that Part B-ID enrollment processes are straightforward, the steps are efficient, and that coverage be activated immediately upon enrollment (i.e., and not the first day of the month that follows).

- We appreciate the requirement that states maintain individuals in the appropriate MSP eligibility groups for payment of Part B-ID premiums and cost-sharing. Please specify how Medigap (Medicare supplemental plans) will behave in the context of this new Part B-ID benefit. It will be important that individuals enrolled in Part B-ID have the option of enrolling in some version of a Medigap plan to assist with the Part B-ID deductibles and coinsurance.

- Regarding the request for comments about what CMS can do to assist beneficiaries and promote awareness of coverage choices upon loss of the ESRD Medicare benefit: Please create a detailed booklet (like Medicare & You) as well as a one-pager highlighting the essential details. Please create streamlined/simple web-based education specific to the new Part B-ID coverage. We recommend disseminating this information to kidney transplant recipients, transplant centers, and general nephrology practices. Please be sure to include:
    - qualification criteria,
    - benefit details (i.e., that Part B-ID covers immunosuppressive drugs only and not physician visits, routine laboratory testing, etc.),
    - simplified cost details (i.e., that enrollees will be expected to pay monthly premiums, annual deductibles, and copays; please include approximate costs),
    - instructions for enrolling including how to complete the attestation,
    - instructions for enrolling in Medigap to supplement this coverage (if possible),
    - turnaround time between enrollment and the ability to use the coverage, and
    - instructions for terminating coverage.

  We suggest these educational efforts be developed and rolled out as soon as possible, and at least one month prior to enrollment eligibility (i.e., by September 2022).

- The proposed rule states “Medicare Administrative Contractors have issued Local Coverage Determinations on this topic and, generally speaking (using Local Coverage Determination #L33824 as an example), covered immunosuppressive drugs are oral tablets or capsules. However, certain immunosuppressive drugs may be intravenously infused or intramuscularly injected.” Please note that some immunosuppressive drugs are commercially manufactured or compounded oral solutions or suspensions; these formulations should also be listed as covered.

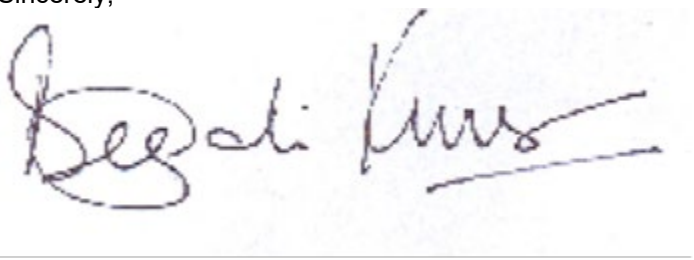
- For patients using immunosuppression that is given via intravenous infusion or injection, the Part B-ID coverage states it would extend to the drug only (not the service of administration). Please extend the coverage to both the drug and the drug administration. Without covered administration, it will be difficult if not impossible to identify infusion centers or facilities willing to administer these therapies, thereby limiting access to certain immunosuppressive drugs that may be considered necessary based on patient tolerability.

- The proposed rule language states that individuals enrolled in the new Part B–ID benefit would not receive Medicare coverage for any other items or services, other than coverage of immunosuppressive drugs. It is important to note that several immunosuppressant drugs have a narrow therapeutic index, the margin between efficacy and toxicity is small, and therapeutic drug monitoring is critical for safe use. We suggest covering select immunosuppressant drug-related laboratory monitoring that is standard-of-care to guide dosage adjustments for tacrolimus, cyclosporine, everolimus, and sirolimus.

- Chapter 15 of the Medicare Benefit Policy Manual, and the excerpt taken for this regulation, requires correction and updating. Specifically:
    - Clarify the generic name of Sandimmune as cyclosporine, non-modified
    - Add Neoral (cyclosporine, modified)
    - Add Gengraf (cyclosporine, modified)
    - Clarify the generic name of Atgam as anti-thymocyte globulin, equine
    - Add Thymoglobulin (anti-thymocyte globulin, rabbit)
    - Remove orthoclone OKT3; this drug is no longer manufactured
    - Remove daclizumab; this drug is no longer manufactured
    - Correct the spelling of Cellcept
    - Correct the spelling of mycophenolate mofetil
    - Correct the spelling of prednisolone
    - Add Envarsus XR and Astagraf XL (tacrolimus extended release formulations)
    - Add Myfortic (mycophenolate sodium)
    - Add Rapamune (sirolimus)
    - Add Zortress (everolimus)
    - Add Nulojix (belatacept)
    - Add Campath (alemtuzumab)

On behalf of the AST, thank you for this opportunity to share our thoughts. Please do not hesitate if we can be of further assistance or provide any clarification to our comments.

Sincerely,



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