



## TRANSPLANT PHARMACY COMMUNITY OF PRACTICE

### Medicare Part B Immunosuppressive Drug Benefit Is Now Open for Enrollment!

AST Transplant Pharmacy Community of Practice/ACCP Immunology/Transplant Practice and Research Network Medication Access Workgroup and the AST Transplant Pharmacy Community of Practice Public Policy Workgroup\*

#### Background:

- The Omnibus Budget Reconciliation Act of 1986 established immunosuppressive drug coverage for one-year post transplant and CMS extended this coverage to 36 months in the 1990s. In 2000, the 36-month duration terminated with immunosuppressants then covered by Part B for eligible individuals for as long as they have Medicare.
- Previously, Medicare coverage (including immunosuppressive drug coverage) ended 36 months after kidney transplantation for patients that had Medicare **due to a diagnosis of ESRD** and were not otherwise eligible based on age or disability.
- Per the 2018 US Renal Data System Annual Report, 32 percent of kidney transplant recipients aged 45-64 have no known or other creditable prescription drug coverage.
- Medicare loss, both early (before 3 years post-transplant) and late (after 3 years post-transplant) has been significantly associated with graft failure in kidney transplant recipients.
- The Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act [H.R. 5534 and S. 3353]; (also known as the Immuno bill) passed in December 2020 and is now law!
- Beginning January 1, 2023, Medicare will offer a new Part B Immunosuppressive Drug benefit that helps continue to pay for immunosuppressive drugs beyond 36 months in eligible kidney transplant recipients **that do not have other health coverage**.
- An analysis by the Department of Health and Human Services estimated that this coverage will prevent approximately 375 allograft failures annually and is estimated to save American taxpayers approximately \$400 million dollars.
- The [Final Rule](#) outlining the details of this new benefit was published on November 3, 2022.

#### Who is Eligible for the Medicare Part B Immunosuppressive Drug Benefit?

- **Kidney transplant recipients previously or currently enrolled in Medicare based on ESRD eligibility and**
- **Medicare eligibility has terminated (or will soon terminate) since 36 months have passed since the time of the kidney transplant and**
- **Upon Medicare termination, the patient will not have ongoing coverage by any other entity including:**
  - Group health plans, individual health plans (including Marketplace), or national health plans
  - TRICARE for Life
  - Medicaid or State Children's Health Insurance Program (CHIP) coverage that includes immunosuppressive drugs
  - Department of Veteran Affairs and eligible to receive immunosuppressive drugs
  - Other programs that cover immunosuppressive drugs

## How do patients enroll?

- **By Telephone:** Patients should call the Social Security Administration (SSA) at 1-877-465-0355 to sign up. This is a special phone number just for this program.
  - The patient must provide a verbal attestation that they are not enrolled in and do not expect to enroll in any insurance that covers the immunosuppressive drugs. The patient also must agree to notify SSA within 60 days of enrollment in any alternate source of drug coverage (e.g. Medicaid, insurance through an employer, full Medicare).
- **In Writing:** Patients can also enroll by completing and filing the Application for Enrollment in Part B Immunosuppressive Drug Coverage Form CMS-10798. This form can be dropped off at a Social Security Field Office or by mailing it to the following address:
  - SOCIAL SECURITY ADMINISTRATION  
OFFICE OF CENTRAL OPERATIONS  
PO Box 32914  
BALTIMORE, MARYLAND 21298-2703

## When should patients enroll?

- Patients whose **Part A entitlement ends prior to January 1, 2023, may enroll in the Part B-ID benefit any time after October 1, 2022.**
- Patients whose Part A entitlement ends on or after January 1, 2023 can enroll at any time AFTER such entitlement ends.
- Patients can also re-enroll in the Part B-ID benefit at any time if they meet eligibility requirements.
  - For instance, if an individual lost Part B-ID benefits because the individual obtained health coverage under a health program or insurance plan, but then later lost that other coverage, the individual can re-enroll in the Part B-ID benefit.

## When does coverage become effective?

- It depends on when Part A entitlement based on ESRD status ends and when attestation is provided:
  - **Prior to January 1, 2023:** If an attestation is submitted as part of the enrollment process from October 1, 2022 through December 31, 2022, **Part B-ID coverage begins January 1, 2023.**
  - **On or after January 1, 2023:** If an attestation is submitted before the end of the 36th month after the month in which they receive kidney transplant, Part B-ID coverage begins with the month their Part A benefits would end.
  - **For patients that provide an attestation later after their Part A entitlement has ended,** Part B-ID coverage begins the month following the month in which the patient provides the required attestation.

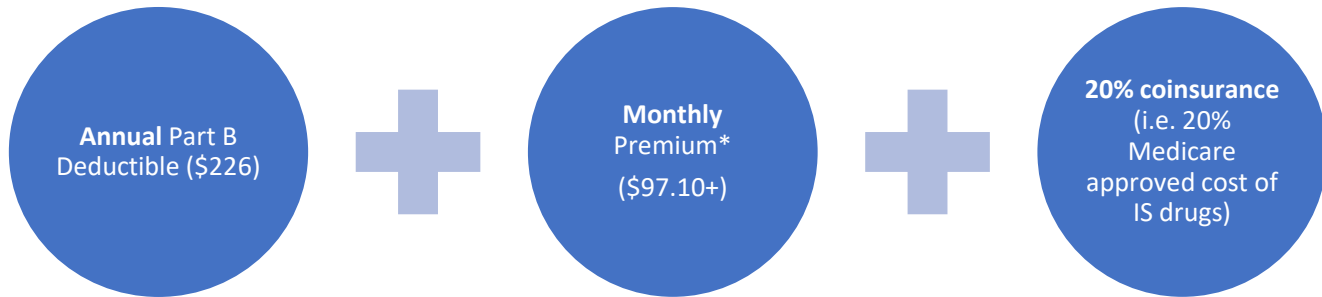
## How do patients terminate coverage?

- To voluntarily terminate their Part B-ID benefit, patients must provide notification to SSA by calling 1-877-465-0355, by visiting an SSA field office, or in writing, by completing a [CMS-1763 termination form](#) and mailing to [SSA](#), indicating that they no longer wish to participate in the Part B-ID benefit (even if the individual does not have other health insurance coverage).
- When a patient enrolls in other health coverage that would make them ineligible for the Part B-ID benefit, they must notify SSA of this within 60 days (up to 6 months in advance)
  - Part B-ID benefit would then be terminated effective the first day of the month after the month of notification **OR**
  - A patient may request a different, prospective termination date up to 6 months in the future for the Part B-ID benefit to align with the coverage period under the other insurance plan or government program. This allows the patient to retain the benefit up to the effective date of their new coverage, which will alleviate potential gaps or overlaps in coverage.

**What does this benefit cover?**

- This new benefit only covers medications that prevent or treat rejection and no other items or services (like other medications, labs, doctor visits, imaging, and vaccines).
- It does not cover compounded formulations of immunosuppressive drugs or the cost of administration for infused or injectable immunosuppressive drugs.

**What does this benefit cost in 2023?**



- **Monthly Premium will be higher than \$97.10 if modified adjusted gross income, as reported on IRS tax return from 2 years ago, is more than:**
  - \$97,000 in 2023, if you file an individual tax return or are married and file separately
  - \$194,000 in 2023, if you are married and file a joint tax return

Yearly income in 2021 (for what you pay in 2023) was			Monthly Premium (2023)
File individual tax return	File joint tax return	File married & separate tax return	
\$97,000 or less	\$194,000 or less	\$97,000 or less	<b>\$97.10</b>
Above \$97,000 up to \$123,000	Above \$194,000 up to \$246,000	Not applicable	<b>\$161.80</b>
Above \$123,000 up to \$153,000	Above \$246,000 up to \$306,000	Not applicable	<b>\$258.90</b>
Above \$153,000 up to \$183,000	Above \$306,000 up to \$366,000	Not applicable	<b>\$356.00</b>
Above \$183,000 and less than \$500,000	Above \$366,000 and less than \$750,000	Above \$97,000 and less than \$403,000	<b>\$453.10</b>
\$500,000 or above	\$750,000 or above	\$403,000 or above	<b>\$485.50</b>

**Is there extra help available to patients for these costs?**

- **Patients may be eligible for state associated Medicare Savings Plans (MSPs) depending on income and must contact their [State](#) to apply. MSPs include:**
  - Qualified Medicare Beneficiary (QMB) group
  - Specified Low-Income Beneficiary (SLMB) group
  - Qualifying Individuals (QI) group

## References:

- 1) "What's the Part B Immunosuppressive Drug benefit?" <https://www.medicare.gov/basics/end-stage-renal-disease>. Accessed 3 Oct 2022.
- 2) Medicare and You Handbook 2023: <https://www.medicare.gov/publications/10050-Medicare-and-You.pdf>. Accessed 3 Oct 2022.
- 3) Final Rule Medicare Program: Implementing Certain Provisions of the Consolidated Appropriations Act and other Revisions to Medicare Enrollment and Eligibility Rules, 3 November 2022, <https://www.federalregister.gov/documents/2022/11/03/2022-23407/medicare-program-implementing-certain-provisions-of-the-consolidated-appropriations-act-2021-and>
- 4) HI 00805.400 Medicare Part B Immunosuppressive Drug Coverage (Part B-ID), Effective Date 8/17/2022-present. <https://secure.ssa.gov/apps10/poms.nsf/lnx/0600805400>
- 5) United States Renal Data System: 2018 USRDS Annual Data Report: Epidemiology of Kidney Disease in the United States, Bethesda, MD, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, 2018, from <https://cjasn.asnjournals.org/content/14/3/327>.
- 6) Hart A, Gustafson SK, Wey A, et al. The association between loss of Medicare, immunosuppressive medication use, and kidney transplant outcomes. Am J Transplant 2019;19(7):1964-71.

\*AUTHORSHIP TEAM ON BEHALF OF: American Society of Transplantation Transplant Pharmacy Community of Practice/American College of Clinical Pharmacy Immunology/Transplant Practice and Research Network Medication Access Workgroup & American Society of Transplantation Transplant Pharmacy Community of Practice Public Policy Workgroup

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