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New Medicare Part B Immunosuppressant Drug Benefit

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Implementation Date: January 3, 2023
Related CR Title: New Medicare Part B Immunosuppressant Drug Benefit (PBID) - Implementation

Note: We revised this Article due to a revised CR 12804. The CR revision didn't change the substance of the Article. We did revise the CR release date, transmittal numbers, and web addresses of the transmittals. All other information is the same.

Provider Types Affected

This MLN Matters Article is for physicians, providers, and suppliers billing claims to Medicare Administrative Contractors (MACs) for immunosuppressant drugs they provide to Medicare ESRD patients.

Provider Action Needed

Make sure your billing staff knows about the new benefit effective January 1, 2023:

- Extension of Medicare coverage for immunosuppressant drugs beyond 36 months for certain patients with kidney transplants
- Coverage of premiums and cost sharing for some of these patients

Background

Most individuals with ESRD are eligible for Medicare, regardless of age. CMS considers a kidney transplant as the best treatment for ESRD. When a patient gets a kidney transplant, Medicare coverage extends for 36 months after the month in which the patient gets a transplant.

Medicare Part B patients who had Medicare coverage when they had their transplant have coverage for immunosuppressive drug therapy for as long as they remain eligible and enrolled in Part B. After the 36 months, Medicare coverage ends unless the patient is otherwise entitled to Medicare (for example, if they're now eligible based on age or disability). Once ESRD-only patients exhaust their 36 months of Medicare eligibility, they lose Part B coverage for immunosuppressive drugs and must pay for the medications out of pocket, through other insurance, or with third-party assistance. The cost of paying for this drug therapy could be

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impossible for those who lose Medicare coverage after 36 months and who don't have another source of healthcare coverage.

If an individual doesn't take these immunosuppressive drugs, it's possible that the transplant rejects and the individual will be at risk of developing ESRD again. This would lead to further Medicare coverage, dialysis, and potentially another transplant.

Section 402 of the Consolidated Appropriations Act (CAA) makes an exception for eligibility for enrollment under Part B solely for the purposes of coverage of immunosuppressive drugs described in Section 1861(s)(2)(J) of the Social Security Act (the Act). Effective January 1, 2023, this provision allows individuals whose Medicare coverage based on ESRD ends 36 months after the month of a successful kidney transplant to keep enrollment under Part B only for the immunosuppressive drugs described in section 1861(s)(2)(J) of the Act with no time limit.

We refer to this benefit as the Part B immunosuppressive drug benefit or Part B-ID or PBID. The PBID benefit is unique because it's classified as a Part B benefit, but it provides coverage limited to immunosuppressive drugs. Only a small number of Medicare patients are eligible. Most rules and requirements applicable to Part B also apply to the PBID benefit. Patients entitled to the PBID benefit wouldn't get Medicare coverage for any other items or services. They're only eligible for the immunosuppressive drug coverage if they aren't enrolled in certain other types of coverage (for example, a group health plan, TRICARE, or a Medicaid state plan that covers immunosuppressive drugs).

Section 402 of the CAA doesn't make changes to payment limits for applicable billing and payment codes associated with immunosuppressive drugs, supplying fees to pharmacies (as described in Section 1842(o)(6) of the Act), or applicable patient deductible and coinsurance amounts. Section 402 of the CAA also amends the Medicare Savings Programs (MSP) under Sections 1905(a)(1)(A) and 1902(a)(10)(E) of the Act to pay some of the Part B premiums and, in some cases, all the cost sharing for certain low-income individuals under the MSP.

A small number of individuals will enroll in the PBID benefit each year. We anticipate that most will also qualify for the Qualified Medicare Beneficiary group, the MSP group that covers PBID premiums, deductibles, and coinsurance.

PBID enrollees will get a new Medicare card that will identify them as only eligible for immunosuppressant drugs under the PBID benefit. Coverage is limited to those drugs medically necessary and appropriate for the specific purpose of preventing or treating the rejection of a transplanted organ or tissue.

Drugs used for the treatment of conditions that may result from an immunosuppressive drug regimen (for example, antibiotics, antihypertensives, analgesics, vitamins, and other drugs that aren't directly related to organ rejection) aren't covered under this benefit.

The drugs must be FDA-approved, be available only through a prescription, and belong to 1 of the following 3 categories:

- A drug approved for marketing and labeled as an immunosuppressive drug
- A drug, such as a corticosteroid, approved and labeled for use in conjunction with immunosuppressive drugs to treat or prevent the rejection of a patient's transplanted organ or tissue
- A drug that a Part B MAC decides is reasonable and necessary or for use in conjunction with those immunosuppressive drugs for the purpose of preventing or treating the rejection of a patient's transplanted organ or tissue.

Chapter 15, Section 50.5.1, of the Medicare Benefit Policy Manual states the covered immunosuppressive drugs labeled as such and FDA-approved for marketing include (The list below isn't all inclusive):

- Sandimmune (cyclosporine), Sandoz Pharmaceutical
- Imuran (azathioprine), Burroughs Wellcome
- Atgam (antithymocyte globulin), Upjohn
- Orthoclone OKT3 (Muromonab-CD3), Ortho Pharmaceutical
- Prograf (tacrolimus), Fujisawa USA, Inc
- Celicept (mycophenolate mefetil, Roche Laboratories
- Daclizumab (Zenapax)
- Cyclophosphamide (Cytoxan)
- Prednisone
- Prednisolone

Note: This is an exception to the standing drug policy which allows coverage of FDA-approved drugs for nonlabelled uses, where the uses are reasonable and necessary in an individual case.

More Information

We issued CR 12804 to your MAC as the official instruction for this change. The CR consists of 3 transmittals:

- R11764BP updates the Medicare Benefit Policy manual
- R11764CP updates the Medicare Claims Processing manual
- R11764GI updates the Medicare General Information, Eligibility, and Entitlement manual

For more information, find your MAC's website.

Document History

Date of Change	Description
December 23, 2022	We revised this Article due to a revised CR 12804. The CR revision didn't change the substance of the Article. We did revise the CR release date, transmittal numbers, and web addresses of the transmittals. All other information is the same.
December 16, 2022	Initial article released.