CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11646	**Date: October 19, 2022**
	Change Request 12804

Transmittal 11520, dated July 28, 2022, is being rescinded and replaced by Transmittal 11646, dated, October 19, 2022 to remove business requirement 12804-04.7 and to add business requirements 12804-04.15 and 12804-04.16. This correction does not make any revisions to the companion Pubs. 100-01 or 100-02; all revisions are associated with Pub. 100-04. All other information remains the same.

NOTE: This Transmittal is no longer sensitive and is being re-communicated November 2, 2022. The Transmittal Number, date of Transmittal and all other information remains the same. This instruction may now be posted to the Internet.

SUBJECT: New Medicare Part B Immunosuppressant Drug Benefit (PBID) - Implementation

I. SUMMARY OF CHANGES: The purpose of this is to update certain sections in Pub. 100-02 with policy information regarding the new Part B-ID benefit.

EFFECTIVE DATE: January 1, 2023
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 3, 2023

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	15/ 50/ 50.5.1/ Immunosuppressive Drugs

III. FUNDING:

For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements
Manual Instruction

Attachment - Business Requirements

Pub. 100-02	Transmittal: 11646	Date: October 19, 2022	Change Request: 12804

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EFFECTIVE DATE: January 1, 2023
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I. GENERAL INFORMATION

A. Background: The majority of individuals with End-Stage Renal Disease (ESRD) are eligible for Medicare, regardless of age. A kidney transplant is ultimately considered the best treatment for ESRD. When an individual receives a kidney transplant, Medicare coverage extends for 36 months after the month in which the individual receives a transplant. Currently, Medicare Part B beneficiaries have coverage for immunosuppressive drug therapy for as long as they remain eligible and enrolled in Medicare Part B. After the 36th month, Medicare coverage will end unless the individual is otherwise entitled to Medicare (i.e., if they would now be eligible based on age or disability). Once ESRD-only beneficiaries 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 immunosuppressive drug therapy could be prohibitive for individuals who lose Medicare coverage at the 36th month and who do not have another source of healthcare coverage. If an individual does not take these immunosuppressive drugs, however, it is possible that the transplant will be rejected and the individual will be at risk of developing ESRD again, which would lead to further Medicare entitlement, dialysis, and potentially another transplant.

In 2020, section 402 of the Consolidated Appropriations Act (CAA) amended sections 226(a), 1836, 1837, 1838, 1839, 1844, 1860-D-1, 1902, and 1905 of the Act to make an exception for eligibility for enrollment under Medicare Part B solely for the purposes of coverage of immunosuppressive drugs described in section 1861(s)(2)(J) of the Act. Effective January 1, 2023, this provision allows individuals whose Medicare entitlement based on ESRD ends 36 months after the month in which they received a successful kidney transplant to continue enrollment under Medicare Part B only for the coverage of immunosuppressive drugs described in section 1861(s)(2)(J) of the Act without a time limit. This benefit will be referred to as the Part

B immunosuppressive drug benefit or "Part B-ID" or "PBID". The PBID benefit, is unique in that it is classified as a Part B benefit, but it provides coverage limited to immunosuppressive drugs for which only a select subset of Medicare beneficiaries would be eligible. Because it is considered a part of the Part B benefit, most rules and requirements applicable to Part B also apply to the PBID benefit. Individuals entitled to Part B for coverage of immunosuppressive drugs, would not receive Medicare coverage for any other items or services, and would only be eligible for the immunosuppressive drug coverage if they are not enrolled in certain other types of coverage (e.g., group health plan, TRICARE, or a Medicaid state plan that covers immunosuppressive drugs). Section 402 of the CAA does not 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 beneficiary 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 eligibility groups. The Office of the Actuary (OACT) estimates that a small number of individuals (250) will enroll in the Part B-ID benefit each year, and it is anticipated that most will also qualify for the Qualified Medicare Beneficiary group (QMB), the MSP group that covers Part B-ID premiums, deductibles, coinsurance and copayments. Under MSP Part B-ID coverage, states will pay Part B-ID premiums and cost sharing for QMBs, and Part B-ID premiums for Specified Low-Income Beneficiaries (SLMBs) and Qualifying Individuals (QIs). The Centers for Medicare & Medicaid Services (CMS) anticipates enrollment in MSP Part B-ID mainly occurring in the 12 states that, as of December 2021, have elected to not expand Medicaid eligibility to adults with income up to 133 percent Federal Poverty Level (FPL) ("non-expansion states") because individuals in the expansion states will likely be eligible for the adult group under 42 CFR § 435.119. Those 12 states are Alabama, Florida, Georgia, Kansas, Mississippi, North Carolina, South Carolina, South Dakota, Tennessee, Texas, Wisconsin and Wyoming.

The CAA established criteria which make an individual eligible for the PBID benefit. In new § 410.184(a) an individual is eligible to enroll in, be deemed enrolled, or re-enroll in, the PBID benefit if their Part A entitlement ends under § 406.13(f)(2). Section 402 of the CAA also requires that an individual attest that they do not have other health coverage. This requirement is established at new § 410.188 (Attestation). Individuals whose 36-month post-transplant period ends before January 2023 can enroll starting in October 2022 and their coverage will start the later of January 2023 or the month after the month in which they enroll. Individuals whose Part A entitlement ends on or after January 1, 2023, and is not deemed enrolled, can enroll at any time, and their coverage will start in accordance with the articulated time frames. Beneficiaries are not required to have the PBID benefit and can terminate their benefit by filing notice that they no longer wish to participate in the PBID benefit program.

For any individual enrolled in the PBID program, there will be a new enrollment code that will be provided by the Social Security Administration (SSA) to identify them as separate Medicare enrollees. The effort conducted by SSA is an EPIC in Jira, project MEPS-1419. This effort is currently scheduled for implementation in October 2022. PBID enrollees will also receive a new Medicare card that will identify them as only eligible for immunosuppressant drugs under the PBID benefit.

Section 1861(s)(2)(J) of the Act provides for coverage of only prescription drugs used in immunosuppressive therapy furnished to an individual who receives an organ transplant for which payment is made by Medicare. Therefore, coverage is limited to those drugs that are medically necessary and appropriate for the specific purpose of preventing or treating the rejection of a transplanted organ or tissue by suppressing a patient's natural immune responses. Accordingly, drugs that are used for the treatment of conditions that may result from an immunosuppressive drug regimen (for example, antibiotics, antihypertensives, analgesics, vitamins, and other drugs that are not directly related to organ rejection) are not covered under this benefit. A drug must be approved by the Food and Drug Administration (FDA), be available only through a prescription, and belong to one of the following three categories:

- It is a drug approved for marketing by the FDA and is labeled as an immunosuppressive drug.

- It is a drug, such as a corticosteroid, that is approved by the FDA and is labeled for use in conjunction with immunosuppressive drugs to treat or prevent the rejection of a patient's transplanted organ or tissue.
- It is a drug that a Part B carrier, in processing a Medicare claim, determined to be reasonable and necessary for the specific purpose of preventing or treating the rejection of a patient's transplanted organ or tissue, 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.

Per the Medicare Benefit Policy Manual, Chapter 15, Section 50.5.1, covered drugs include those immunosuppressive drugs that have been specifically labeled as such and approved for marketing by the FDA. (This is an exception to the standing drug policy which permits coverage of FDA approved drugs for nonlabelled uses, where such uses are found to be reasonable and necessary in an individual case.)

The FDA has identified and approved for marketing the following specifically labeled immunosuppressive drugs. They are: 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; and Prednisolone. The CMS expects contractors to keep informed of FDA additions to the list of the immunosuppressive drugs. So, the above list is not all inclusive.

This new implementation change request instructs downstream systems to make the necessary system changes, activities, and efforts to ensure that processes are implemented accordingly. These changes include directives that contractors shall be able to properly identify PBID eligible beneficiaries in their systems, be able to accept and store effective and termination dates for PBID eligible beneficiaries, and accept updated screens with a new PBID indicator. A more extensive list of necessary system changes for proper implementation are outlined in the Business Requirements sections below.

Finally, this change request provides updates to Publication (Pub.) 100-02. The specific modification is outlined below:

- Pub. 100-02, Chapter 15, Section 50.5.1 'Immunosuppressive Drugs' revised to include Part B-ID policy information

B. Policy: This Change Request (CR) instructs contractors to conduct implementation activities, necessary system changes, and levels of effort required to implement the new Part B-ID benefit. ThIS (CR) also instructs contractors to refer to designated Internet Only Manual (IOM) Publications for detailed information related to the new Part B-ID benefit.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12804 - 02.1	The contractor shall refer to Publication 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 50.5.1 for updates regarding the new Part B-ID benefit.	X	X		X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Sarah Shirey-Losso, Sarah.SHIREY-LOSSO@cms.hhs.gov (For questions related to the Medicare Benefit Policy Manual 100-02) , Kelechi Anyatonwu, kelechi.anyatonwu@cms.hhs.gov (For PBID policy-related questions)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to

be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare Benefit Policy Manual

Chapter 15 – Covered Medical and Other Health Services

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(Rev. 11646; 10-19-22)

50.5.1 - Immunosuppressive Drugs

(Rev.11646; Issued: 10-19-22; Effective: 01-01-23; Implementation: 01-03-23)

A3-3112.4.B.3, HO-230.4.B.3, AB-01-10

Until January 1, 1995, immunosuppressive drugs were covered under Part B for a period of one year following discharge from a hospital for a Medicare covered organ transplant. The CMS interpreted the 1-year period after the date of the transplant procedure to mean 365 days from the day on which an inpatient is discharged from the hospital. Beneficiaries are eligible to receive additional Part B coverage **within** 18 months after the discharge date for drugs furnished in 1995; **within** 24 months for drugs furnished in 1996; **within** 30 months for drugs furnished in 1997; and **within** 36 months for drugs furnished after 1997.

For immunosuppressive drugs furnished on or after December 21, 2000, this time limit for coverage is eliminated.

The Consolidated Appropriations Act of 2021 amended section 1836(b) of the Social Security Act to add a new form of coverage that provides solely for coverage of immunosuppressive drugs beginning January 1, 2023, for eligible individuals whose entitlement to Medicare based on End-Stage Renal Disease (ESRD) ends the 36th month after the month in which the individuals receive a successful kidney transplant. This new benefit is referred to as the Part B immunosuppressive drug benefit or "Part B-ID." Refer to Pub. 100-01, Chapter 2, Section 40.9 for more information on Part B-ID.

Covered drugs include those immunosuppressive drugs that have been specifically labeled as such and approved for marketing by the FDA. (This is an exception to the standing drug policy which permits coverage of FDA approved drugs for **nonlabeled** uses, where such uses are found to be reasonable and necessary in an individual case.)

Covered drugs also include those prescription drugs, such as prednisone, that are used in conjunction with immunosuppressive drugs as part of a therapeutic regimen reflected in FDA approved labeling for immunosuppressive drugs. Therefore, antibiotics, hypertensives, and other drugs that are not directly related to rejection are not covered.

The FDA has identified and approved for marketing the following specifically labeled immunosuppressive drugs. They are:

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; and
Prednosolone.

The CMS expects contractors to keep informed of FDA additions to the list of the immunosuppressive drugs.