CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	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Transmittal 11520, dated July 28, 2022, is being rescinded and replaced by Transmittal 11646, dated, October 19, 2022 to remove business requirement 12804-04.7 and to add business requirements 12804-04.15 and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, 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 change request is to update certain sections in Pub. 100-04 with policy and claims processing 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	17/ 10/ Payment Rules for Drugs and Biologicals
R	17/ 80.3/ Billing for 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. 100-04	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 100-04. The specific modifications are outlined below:

- Pub. 100-04, Chapter 17, Section 10 'Payment Rules for Drugs and Biologicals' and section 80.3 'Billing for Immunosuppressive Drugs' revised to include Part B-ID policy and claims processing 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 - 04.1	The contractors shall accept and store up to 10 periods of effective and termination dates for PBID eligibility on the beneficiary eligibility screens. Note: New screen BENI to be implemented by September 19, 2022.								X	EDB, HETS
12804 - 04.2	The contractor shall ensure the Common Working File (CWF) claim response files are updated to include the PBID entitlement information and provide the Shared Systems Maintainers with the copybook changes. This includes the Beneficiary Data Streamlining (BDS) response as well as the batch claim responses.								X	
12804 - 04.2.1	The contractors shall make the necessary changes to accept the updated CWF response files.					X	X	X		IDR
12804 - 04.3	The contractor shall update the HUBC, HUDC, HUOP, HUHH and HUHC reply file to return the most current iteration of PBID entitlement date on the Header Portion of HUBC, HUDC, HUOP, HUHH and HUHC reply. The existing 55 bytes of filler can be utilized for this change.								X	
12804 - 04.4	The contractor shall add a PBID IND field to the BENB screen and display an “N” to indicate no PBID periods or “Y” to indicate there are PBID periods of coverage and provide the Shared Systems Maintainers with the copybook changes.								X	
12804 - 04.4.1	The contractors shall make the necessary changes to accept the updated BENB screen with the new PBID indicator.					X	X	X		
12804 - 04.4.1.1	The ViPS Medicare System (VMS) shall modify the HIMR Integration software used by both VMS and Multi-Carrier System (MCS) to account for the addition of the new field to the HIMR BENB screen.						X	X		
12804 - 04.5	The contractor shall check for PBID eligibility when there is no Part B eligibility for the dates of service.								X	

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12804 - 04.5.1	If there is no PBID coverage, the contractor shall reject the Part B claims for non-coverage using the existing reject.								X	
12804 - 04.6	The contractor shall ensure that only Part B immunosuppressive drugs are payable during periods of PBID eligibility.								X	
12804 - 04.7	This business requirement has been deleted.								X	
12804 - 04.8	The contractors shall update the Medicare Summary Notice (MSN) message 5.5 to read: MSN 5.5 - Our records show you didn't have Part A (B) or extended Part B coverage for post-transplant immunosuppressive drugs when you got this service. If you think this is an error, call 1-800-MEDICARE. MSN 5.5 (Spanish) - Nuestros registros indican que usted no tenía cobertura de la Parte A (B) o de la Parte B extendida para medicamentos inmunosupresores posteriores al trasplante cuando recibió éstos servicios. Si cree que es un error, llame al 1-800-MEDICARE.	X	X		X	X				
12804 - 04.9	The contractor shall create an overridable line level edit to reject line items on Part B claims that aren't immunosuppressive drugs billed during periods of PBID eligibility.								X	
12804 - 04.9.1	The contractors shall create MSN message 5.8 to read: MSN 5.8 - Our records show you did not have Part A (B) coverage when you received this service. If you disagree, please contact us at the customer service number shown on this notice. MSN 5.8 (Spanish) - Nuestros archivos indican que usted no tenía la Parte A (B) cuando recibió éstos	X	X		X	X				

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	servicios. Si usted no está de acuerdo favor de llamar al número de Servicios al Cliente indicado en esta notificación.									
12804 - 04.9.2	The contractors shall deny (MCS/VMS) or reject (Fiscal Intermediary Shared System (FISS)) the CWF rejected line items that aren't immunosuppressive drugs billed on Part B claims during periods of PBID eligibility. Note: Part B MACs processing through MCS shall continue to follow their current processes for the payment or non-payment of immunosuppressive drugs during PBID periods of coverage.	X	X		X	X		X		
12804 - 04.9.2.1	The contractors shall use the following codes when denying (MCS/VMS) /rejecting (FISS) claims: Claim Adjustment Reason Codes(CARC) 204 - This service/equipment/drug is not covered under the patient's current benefit plan. MSN 5.8 - Our records show you did not have Part A (B) coverage when you received this service. If you disagree, please contact us at the customer service number shown on this notice. MSN 5.8 (Spanish) - Nuestros archivos indican que usted no tenía la Parte A (B) cuando recibió éstos servicios. Si usted no está de acuerdo favor de llamar al número de Servicios al Cliente indicado en esta notificación. Group Code PR- Patient Responsibility	X	X		X					
12804 - 04.9.3	The contractors shall suppress MSN message 11.21 for QMB PBID beneficiaries regarding denied (MCS/VMS) /denied (FISS) claims.					X	X	X		

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
12804 - 04.10	The contractor shall ensure immunosuppressive drugs covered under PBID are applied to the Part B annual deductible.					X		X	X	
12804 - 04.11	The contractor shall update the HICR application to allow file corrections. Note: Updated to be implemented by September 19, 2022.								X	
12804 - 04.12	The contractor shall perform integrated testing with CWF during the alpha testing window or earlier, when CWF changes have been completed.					X	X	X	X	
12804 - 04.12.1	Integrated testing shall occur before January 2023. The contractors shall attend no more than four calls during the alpha testing period.					X	X	X	X	
12804 - 04.13	The contractor shall refer to Publication 100-04, Medicare Claims Processing Manual, Chapter 17, Section 10 'Payment Rules for Drugs and Biologicals' and section 80.3 'Billing for Immunosuppressive Drugs' for policy and claims processing updates regarding the new Part B-ID benefit.	X	X		X					
12804 - 04.14	Contractors shall allow supply dispensing fees HCPCS codes Q0510, Q0511 and Q0512 when paying for immunosuppressive drugs under the PBID benefit.	X			X				X	
12804 - 04.15	CWF shall update the CABEBCOM copybook to expand the 15 (*)-COMM-CLM-FILLER and (*)-COMM-RESP-PTB fields in CABEBCOM to allow data from CABEBCOM to map correctly to CABEBDSR.						X	X	X	
12804 - 04.16	CWF shall update the CABENGD copybook to include the "current and first prior" PBID entitlement periods as the file currently does for Traditional Part B								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): Bobbett Plummer, bobbett.plummer@cms.hhs.gov (For questions related to Medicare Claims Processing Manual 100-04) , 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 Claims Processing Manual
Chapter 17 - Drugs and Biologicals

Table of Contents
(Rev.11646; 10-19-22)

10 - Payment Rules for Drugs and Biologicals

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

Drugs for inpatient hospital and inpatient skilled nursing facility (SNF) beneficiaries are included in the respective prospective payment system (PPS) rates, except for hemophilia clotting factors for hospital inpatients under Part A.

All hospital outpatient drugs are excluded from SDP because the payment allowance for such drugs is determined by a different methodology. Non pass-through drugs with estimated per day costs less than or equal to the applicable drug packaging threshold that are furnished to hospital outpatients are packaged under the outpatient prospective payment system (OPPS). Their costs are recognized and included but paid as part of the ambulatory payment classification (APC) group payment for the service with which they are billed. Non pass-through drugs with estimated per day costs greater than the applicable drug packaging threshold are paid separately.

Drugs that are granted "pass through" payment status are required by law to be paid at either the amount paid under the physician fee schedule, or, if the drug is included in the Part B drug competitive acquisition program (CAP), at the Part B drug CAP rate. Drugs that have pass-through status may have coinsurance amounts that are less than 20 percent of the OPPS payment amount. This is because pass-through payment amounts, by law, are not subject to coinsurance. CMS considers the amount of the pass-through drug payment rate that exceeds the otherwise applicable OPPS payment rate to be the pass-through payment amount. Thus, in situations where the pass-through payment rate exceeds the otherwise applicable OPPS payment rate, the coinsurance is based on a portion of the total drug payment rate, not the full payment rate.

Hospitals must report all appropriate HCPCS codes and charges for separately payable drugs, in addition to reporting the applicable drug administration codes. Hospitals should also report the HCPCS codes and charges for drugs that are packaged into payments for the corresponding drug administration or other separately payable services. Historical hospital cost data may assist with future payment packaging decisions for such drugs. Drugs are billed in multiples of the dosage specified in the HCPCS code long descriptor. If the drug dose used in the care of a patient is not a multiple of the HCPCS code dosage descriptor, the provider rounds to the next highest unit based on the HCPCS long descriptor for the code in order to report the dose provided.

If the full dosage provided is less than the dosage for the HCPCS code descriptor specifying the minimum dosage for the drug, the provider reports one unit of the HCPCS code for the minimum dosage amount.

OPPS Pricer includes a table of drugs and prices and provides the contractor with the appropriate prices.

Section 90 relates specifically to billing for hospital outpatients. The remainder of this chapter relates to procedures for pricing and paying DME recipients, and to beneficiaries

who receive drugs under special benefits such as pneumococcal, flu and hepatitis vaccines; clotting factors, immunosuppressive therapy, self administered cancer and anti emetic drugs, and drugs incident to physicians‟ services.

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 defines a Specified Covered Outpatient Drug (SCOD) as a covered outpatient drug for which a separate APC has been established and that is either a radiopharmaceutical agent, or a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002. Payment for SCODs is set, by law, at the average acquisition cost. Under the OPPS, a single payment is made for SCODs that represents payment for both the acquisition cost of the drug and any associated pharmacy overhead or nuclear medicine handling costs.

Drugs or biologicals must meet the coverage requirements in Chapter 15 of the Medicare Benefit Policy Manual. Additionally, for end stage renal disease (ESRD) patients, see the Medicare Benefit Policy Manual, Chapter 11. For ESRD patient billing for drugs and claims processing, see Chapter 8 of this manual.

The following chart describes the general payment provisions for drugs.

Table - Drug Payment Methodology

Key to the following Table:

NOTES:

DME MACs do not process claims for blood clotting factors.

Unless noted otherwise, claims for these drugs are submitted to the A/B MAC (B)

† - Drugs & biologicals outside the composite rate and/or ESRD PPS are paid as described in 2 below. Those inside the composite rate and/or ESRD PPS are paid as described in 1. (ESRD PPS effective January 1, 2011)

1 - Included in PPS rate, or other provider-type all inclusive encounter rate

2 – Price taken from CMS drug/biological pricing file effective on the specific date of service.

3 - Based on reasonable cost (101% reasonable cost in CAH)

4 - Lower of cost or 95% AWP paid for drug in addition to PPS rate, or in addition to reasonable cost if excluded from PPS

5 - OPPS-APC, whether pass-thru drug or not

6 - Cannot furnish as that “provider” type

7 - May not bill DME-MAC or MAC for drugs furnished incident-to a physicians’ service

8 - Payment made at the time of cost settlement

A - Bills are submitted to the DME MAC

++ Except in the State of Washington, where CMS permits the ESRD Facility to bill for immunosuppressive drugs due to the unique State assistance to the beneficiary provided only via the ESRD Facility.

Provider/Drug	Hepatitis Vaccine	Pneumococcal & Flu Vaccines	Hemophilia Clotting Factors	Immuno-Suppressive	Erythropoiesis Stimulating Agents ESA's)	Self Admin Anti-Cancer Anti-Emetic for cancer treatment	Other Drugs
Hospital Inpatient (IP) A -Prospective Payment System (IPPS)	3	3	2	1	1	1	1
Hospital IP A - not IPPS	3	3	3	3	3	3	3
Hospital IP B - Outpatient Prospective Payment System (OPPS)	3	3	5	5	5	5	5
Hospital IP B - not OPPS hospital	3	3	3	3	3	3	3
Hospital Outpatient (OP) - OPPS hospital	3	3	5	5 (8 - for 30-day supply)	5	5	5
Hospital OP - not OPPS hospital	3	3	3	3 (8 - for 30-day supply)	3	3	5
Skilled Nursing Facility (SNF) IP	3	3	1	1	1	1	1
SNF OP or IP B	3	3	3	3	6	6	6
End Stage Renal Disease (ESRD) Facility	2	2	6	6++	1 or 2†	6	1 or 2†
Comprehensive Outpatient Rehabilitation Facility (CORF)/ Outpatient Rehabilitation Facility (ORF)	2	2	6	6	6	6	6
Community Mental Health Clinic (CMHC)	6	6	6	6	6	6	6

Rural Health Clinical (RHC)/Federally Qualified Health Clinic (FQHC) -hospital based	1	8	5	5	5	5	5
RHC/FQHC-independent	1	8	6	6	6	6	6
Home Health Agencies	3	3	6	6	6	6	6
Hospice	6	6	6	6	1	1	1
Physicians	2	2	2	2	2	2	2
Pharmacy	2	2	2, 7	2, A	2	2, A	2, 7
Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Supplier	2	2	2	2	2	2	2
Critical Access Hospital (CAH) IP A or B	3	3	3	3	3	3	3
CAH OP-Method I or II	3	3	3	3 (8 - for 30-day supply)	3	3	3

NOTES:

Independent and provider-based RHCs and FQHCs generally do not bill for pneumococcal/influenza vaccines, except when the only service involved is the administration of the vaccine. Instead, RHCs/FQHCs are generally paid for pneumococcal/influenza vaccines at cost settlement via the Medicare cost report. Hepatitis B vaccine payment is bundled into the encounter rate for both Independent and provider-based RHCs and FQHCs.

Influenza, pneumococcal, and Hepatitis B vaccines are paid on a reasonable cost basis in a hospital outpatient department. Neither deductible nor coinsurance apply.

HHAs cannot bill for vaccines, except on TOB 34X, since vaccines are not part of the HH benefit and cannot be paid under HH PPS.

Influenza, PPV, and Hepatitis B vaccines are paid once for the vaccine and once for the administration of the vaccine. The provider or supplier (including physician) must enter each of the HCPCS on separate lines of the claim.

A Part B blood clotting factor claim from a Part B supplier is processed by the A/B MAC (B).

A Part A blood clotting factor claim from a Part A provider, including a hospital-based hemophilia center, is processed by the hospital's Medicare contractor.

80.3 - Billing for Immunosuppressive Drugs

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

Medicare covers a beneficiary's immunosuppressive drugs following a transplant, in accordance with 1861(s)(2)(J) of the Social Security Act, which states that Medicare covers "prescription drugs used in immunosuppressive therapy furnished to an individual who receives an organ transplant for which payment is made under this title."

Medicare pays for FDA approved immunosuppressive drugs and for drugs used in immunosuppressive therapy with specific restrictions. (See 42 CFR 430.10 and the Medicare Benefit Policy Manual, Chapter 15 for detailed coverage requirements.) Generally, contractors pay for self-administered immunosuppressive drugs that are specifically labeled and approved for marketing as such by the FDA, or identified in FDA-approved labeling for use in conjunction with immunosuppressive drug therapy. This benefit is subject to the Part B deductible and coinsurance provision.

Contractors are expected to keep informed of FDA additions to the list of the immunosuppressive drugs and notify providers. Prescriptions for immunosuppressive drugs generally should be non-refillable and limited to a 30-day supply. The 30-day guideline is necessary because dosage frequently diminishes over a period of time, and further, it is not uncommon for the physician to change the prescription from one drug to another. Also, these drugs are expensive and the coinsurance liability on unused drugs could be a financial burden to the beneficiary. Unless there are special circumstances, contractors will not consider a supply of drugs in excess of 30 days to be reasonable and necessary and should deny payment accordingly.

Entities that normally bill the A/B MAC (B) bill the DME MAC. Entities that normally bill the A/B MAC (A) continue to bill the A/B MAC (A), except for hospitals subject to OPPS, which must bill the DME MAC.

Prior to December 21, 2000 coverage was limited to immunosuppressive drugs received within 36 months of a transplant. In practice, ESRD beneficiaries continue to be limited to 36 months of coverage after a Medicare covered kidney transplant because their Medicare entitlement would end 36 months after a successful organ transplant. See 42 CFR 406.13(f)(2). Effective with immunosuppressive drugs furnished on or after December 21, 2000, there is no time limit, but an organ transplant must have occurred for which immunosuppressive therapy is appropriate. That is, the time limit for immunosuppressive drugs was eliminated for transplant beneficiaries that will continue Medicare coverage after 36 months based on disability or age. *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) Act without a time limit. This benefit is referred to as the Part B immunosuppressive drug benefit or*

"Part B-ID" or "PBID". For additional information on PBID eligibility please see section 40.9.1 of IOM publication 100-01, chapter 2.

The date of transplant is reported to the A/B MAC (A) with occurrence code 36.

CWF will edit claim records to determine if a history of a transplant is on record. If not an error will be returned. See Chapter 27 for edit codes and resolution.

As explained below, there are circumstances in which Medicare cannot locate the Medicare claim for the transplant in the claims databases which would have confirmed that Medicare paid for the transplant. In such cases, where the supplier appropriately submits the KX modifier, Medicare makes the assumption that Medicare paid for the transplant, in accordance with the statute, that the supplier has on file documentation that indicates the date of the transplant, and that the services furnished are medically necessary.

The use of the KX modifier is not required. In the case of immunosuppressive drugs, submission of the KX modifier is intended for adjudicating claims when the supplier attests that it maintains documentation that the beneficiary was eligible for Medicare Part A on the date of his/her transplant, but where Medicare cannot identify a claims record indicating the transplant was paid for by fee-for-service Medicare. The additional information provided by the use of the KX modifier permits Medicare to reasonably assume that a Medicare payment for an organ transplant was made.

For claims received on and after July 1, 2008, DME MACs will accept claims for immunosuppressive drugs without a KX modifier but will deny such claims if CMS cannot identify a record of a claim indicating that the transplant was paid for by fee-for-service Medicare.

For claims filed with the KX modifier on and after July 1, 2008, suppliers that furnish an immunosuppressive drug to a Medicare beneficiary, when such drug has been prescribed due to the beneficiary having undergone an organ transplant, must: 1) secure from the prescriber the date of such organ transplant and retain documentation of such transplant date in its files, 2) attest that it has on file documentation that the beneficiary was eligible to receive Medicare Part A benefits at the particular date of the transplant and retain the documentation in its files, and 3) retain such documentation of the beneficiary's transplant date, Medicare Part A eligibility, and that such transplant date precedes the Date of Service (DOS) for furnishing the drug.

Use of the KX modifier permits Medicare to make a reasonable assumption that Medicare paid for the transplant even when the transplant claim does not appear in the claims database. A claim may not appear in the claims database for reasons such as:

1. At the time of the transplant, the beneficiary was enrolled in a Medicare Advantage plan that paid for the transplant. Medicare Advantage data is not included in the Medicare FFS claims database. Although some encounter data may be available, it may be incomplete or may not contain coding information sufficient to identify a transplant claim.

2. There may be instances where claims related to a transplant are old and may not be identifiable in the claims database despite Medicare's payment for the claim.