CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 3856	**Date: September 1, 2017**
	Change Request 10235

SUBJECT: Clarification of the Billing of Immunosuppressive Drugs

I. SUMMARY OF CHANGES: This instruction updates the manual to remove a double negative statement in order to provide clear instruction on the billing of immunosuppressive drugs.

EFFECTIVE DATE: October 2, 2017
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: October 2, 2017

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/ 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

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I. GENERAL INFORMATION

A. Background: This instruction updates language in the Claims Processing Manual Publication 100-04, Chapter 17, Section 80.3 to remove a double negative statement and clearly provide guidance on when a supplier may bill Medicare for immunosuppressive drugs.

B. Policy: No change in policy.

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	
10235.1	Medicare contractors shall be aware of the change in language to Publication 100-04, Chapter 17, Section 80.3 and ensure processing of claims for immunosuppressive drugs is in compliance with the manual.				X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
10235.2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5				X	

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.					

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): Wendy Tucker, wendy.tucker@cms.hhs.gov

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

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):
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ATTACHMENTS: 0

80.3 - Billing for Immunosuppressive Drugs

(Rev.3856, Issued: 09-01-17, Effective: 10- 02-17, Implementation: 10-02-17)

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. 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.*

*U*se 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.*