CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 4189	**Date: December 31, 2018**
	Change Request 11072

SUBJECT: Updates to Immunosuppressive Guidance

I. SUMMARY OF CHANGES: This CR updates guidance in Chapter 17 of the Medicare Claims Processing Manual.

EFFECTIVE DATE: April 3, 2019
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 3, 2019

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/Table of Contents
R	17/80/80.3.3/Special Requirements Limited to 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: Inpatient facilities (for example hospitals) are responsible for providing drugs during a beneficiary's inpatient stay. However, once the beneficiary has returned home, Part B suppliers (including pharmacies) provide immunosuppressive drugs, and the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) make payments for Part B covered immunosuppressive drugs.

B. Policy: In certain cases, a beneficiary who has received a transplant does not return home immediately after the procedure. In order to ensure timely beneficiary access to prescribed immunosuppressive medications at the time of discharge, suppliers may deliver the initial prescriptions of a beneficiary's immunosuppressive drugs to an alternate address, such as the transplant facility or alternative location where the beneficiary is temporarily staying, e.g., temporary housing, instead of delivering the drugs to the patient's home address. Note that this is an optional, not mandatory, process. If the supplier ships immunosuppressive drugs to an alternate address, all parties involved, including the beneficiary and the transplant facility, must agree to the use of this approach. All other applicable Medicare and DME MAC billing requirements continue to apply. This provision may be used with the early delivery provision described in the preceding paragraphs of this section and is also limited to prescriptions that will be billed on the first claim that the supplier submits for the beneficiary after the beneficiary is discharged from an inpatient facility.

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	
11072.1	Contractors shall be aware of these manual updates.	X	X	X	X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
11072.2	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the "MLN Matters" listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.	X	X		X	

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): Susan Janeczko, 703-999-7807 or susan.janeczko@cms.hhs.gov

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. 4189, 12-31-18)

80.3.3 – Special Requirements *Limited to* Immunosuppressive Drugs
(Rev. 4189, Issued: 12-31-18, Effective: 04-03-19, Implementation: 04-03-19)

Inpatient facilities (for example hospitals) are responsible for providing drugs during a beneficiary's inpatient stay. However, once the beneficiary has returned home, Part B suppliers (including pharmacies) provide immunosuppressive drugs, and the DME MACs make payments for Part B covered immunosuppressive drugs. Under normal circumstances, the date of service listed on a supplier's claim must be the date the supplier actually delivered or mailed the item. However, suppliers that utilize mail-order delivery may wish to mail immunosuppressive drug prescriptions one or two days prior to the date that a beneficiary *is anticipated to* be discharged from an inpatient facility, so that the drugs will be available immediately *to* the beneficiary *after discharge*. In this situation, the systems will reject the supplier's immunosuppressive drug claim because the date of service precedes the beneficiary's date of discharge; the hospital remains responsible for the provision of immunosuppressive drugs while the beneficiary is still an inpatient.

In order to obtain payment in these *specific* instances where immunosuppressive drug prescriptions have been mailed so that they arrive before a beneficiary's *anticipated date of* discharge so that the drugs will be available for beneficiary use *after discharge*, the supplier may enter the date of discharge as the date of service on the first claim it submits for the beneficiary after the beneficiary is discharged from an inpatient facility. Note that this is an optional, not mandatory, process. If the supplier chooses not to mail the immunosuppressive drug(s) prior to the beneficiary's date of discharge from the hospital, they may wait for the beneficiary to be discharged before delivering the drugs, and follow all applicable Medicare and DME MAC rules for immunosuppressive drug billing (for example, the date of service will be the date of delivery).

In certain cases, a beneficiary who has received a transplant does not return home (i.e., his/her own dwelling, an apartment, a relative's home, a home for the aged, or some other type of institution (such as an assisted living facility, or an intermediate care facility for individuals with intellectual disabilities (ICF/IID) but not a hospital or skilled nursing facility) immediately after discharge. In order to ensure timely beneficiary access to prescribed immunosuppressive medications at the time of discharge, suppliers may deliver the initial prescriptions of a beneficiary's immunosuppressive drugs to an alternate address, such as the inpatient hospital that performed the transplant or alternative location where the beneficiary is temporarily staying, e.g., temporary housing, instead of delivering the drugs to the patient's home address. Note that this is an optional, not mandatory, process. If the supplier ships immunosuppressive drugs to an alternate address, all parties involved, including the beneficiary and the transplant facility, must agree to the use of this approach. The supplier will not receive additional payment for delivery to an alternate location. Separate payment will also not be available from either Medicare or the beneficiary if, for any reason, redelivery is necessary. All other applicable Medicare and DME MAC billing requirements continue to apply. This provision may be used with the early delivery provision described in the preceding paragraphs of this section and is also limited to prescriptions that will be billed on the first claim that the supplier submits for the beneficiary after the beneficiary is discharged from an inpatient hospital.
Early and/or direct delivery to the transplant facility does not change the facility's responsibility to provide all immunosuppressive drugs required by the beneficiary for the duration of the beneficiary's inpatient stay.

Note that the following conditions also apply:

1) The inpatient hospital performing the transplant remains responsible for all immunosuppressive drugs required by the beneficiary for the duration of the beneficiary's inpatient stay. The supplier must not receive separate payment for immunosuppressive drugs prior to the beneficiary's discharge.
2) The supplier must not mail or otherwise dispense the drugs any earlier than *two* days before the *anticipated date of the* beneficiary*'s* discharge. It is the supplier's responsibility to confirm the beneficiary's anticipated discharge date.
3) The supplier must not submit a claim for payment prior to the beneficiary's *actual* date of discharge.

4) The immunosuppressive drug must be medically necessary on the date of discharge, i.e., there is a valid prescription for an immunosuppressive drug that is reasonable and necessary and is clinically required to be available no later than the date of discharge for home use.
5) The option to deliver to the inpatient hospital performing the transplant is available only if the supplier and the inpatient hospital agree on an approach for ensuring the beneficiary is discharged with the immunosuppressive medications furnished by the supplier.
6) The supplier must not claim additional payment for any costs that the supplier incurs in ensuring that the immunosuppressive medications are delivered to the alternative location.
7) The supplier must not bill Medicare or the beneficiary for redelivery if it is necessary.