CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 875	**Date: April 5, 2019**
	Change Request 11172

Transmittal 872, dated March 29, 2019, is being rescinded and replaced by Transmittal 875, dated April 5, 2019, to change the section number in the "Changes In Manual Instructions" section from 4.26.3 to 4.26.2. All other information remains the same.

SUBJECT: Updates to Immunosuppressive Guidance

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to update Chapter 4 of Publication (Pub.) 100-08 to account for recent updates to policies related to the delivery of immunosuppressive drugs.

EFFECTIVE DATE: April 3, 2019 - Date aligns with policy update per CR 11072
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: April 18, 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	4/4.26/4.26.2/Exceptions

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. 100-08	Transmittal: 875	Date: April 5, 2019	Change Request: 11172

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SUBJECT: Updates to Immunosuppressive Guidance

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IMPLEMENTATION DATE: April 18, 2019

I. GENERAL INFORMATION

A. Background: The instruction updates medical review guidance provided in Chapter 4 of Pub. 100-08 to account for recent updates to policies related to the delivery of immunosuppressive drugs. Inpatient facilities (e.g., 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.

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.

B. Policy: There are no legislative or regulatory policies involved with this CR.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
11172.1	Contractors shall permit delivery of immunosuppressive drugs to places other than a beneficiary's home (e.g., 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				X					CERT, MRAC, RAC, SMRC, UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	facility, or an intermediate care facility for individuals with intellectual disabilities but not a hospital or skilled nursing facility) in those instances in which the beneficiary does not immediately return home after receipt of a transplant and discharge from an acute facility. Note—Alternate addresses may include the inpatient hospital that performed the transplant or alternative locations where the beneficiary is temporarily staying (e.g., temporary housing).									
11172.2	Contractors shall note that this is an optional, not mandatory process.				X					CERT, MRAC, RAC, SMRC, UPICs
11172.3	Contractors shall, if assessing claims in which the supplier used an alternate address, ensure that no billing is made prior to discharge.				X					CERT, MRAC, RAC, SMRC, UPICs
11172.4	Contractors shall continue to assess claims for all other coverage provisions. Note: • 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				X					CERT, MRAC, RAC, SMRC, UPICs

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
	from either Medicare or the beneficiary if, for any reason, redelivery is necessary. • This process 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. Delivery to places other than home, to ensure beneficiary access, may be combined with the authority to delivery early as outlined in this section 4.26.3 in chapter 4 of Pub. 100-08. • 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. • See IOM Pub. 100-04, Chapter 17, Section 80.3.3 for additional information									

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): Marissa Petto, 212-616-2354 or marissa.petto@cms.hhs.gov , Jennifer Phillips, 410-786-1023 or jennifer.phillips@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

4.26.2 – Exceptions

(Rev. 875; Issued: 04-05-19; Effective: 04-03-19; Implementation: 04-18-19)

This section applies to UPICs. This section is applicable to DME MACs, RACs, SMRC, and CERT medical review contractors, as noted in Ch. 5, Section 5.8.

Exceptions to the preceding statements concerning the date(s) of service on the claim occur when the items are provided in anticipation of discharge from an inpatient facility that does not qualify as the beneficiary's home. A supplier may deliver a DME, prosthetics, or orthotics item—but not supplies-- to a *beneficiary* in an inpatient facility that does not qualify as the beneficiary's home, for the purpose of fitting or training the *beneficiary* in the proper use of the item. This delivery may be done up to two (2) days prior to the *beneficiary's* anticipated discharge to their home. The supplier must bill the date of service on the claim as the date of discharge and the supplier must ensure that the beneficiary takes the item home, or the supplier picks up the item at the facility and delivers it to the beneficiary's home on the date of discharge. The item must be medically necessary on the date of discharge, i.e., there is a physician's order and corroborating medical documentation to support a stated initial date of need that is no later than the date of discharge for home use, and the item must be for subsequent use in the *beneficiary's* home. (See IOM Pub. 100-04, Chapter 20, Section 110.3, for the policy and billing procedures regarding the circumstances under which a supplier may deliver durable medical equipment, prosthetics, and orthotics - but not supplies - to a beneficiary who is in an inpatient facility that does not qualify as the beneficiary's home.) (See IOM Pub. 100-04, Chapter 20, Section 110.3.1 for the full list of the conditions that must be met to bill under this policy.)

No billing may be made for any day prior to the date of discharge. A supplier may not bill for drugs or other DMEPOS items used by the *beneficiary* prior to the *beneficiary's* discharge from a stay in an inpatient facility that does not qualify as the beneficiary's home. Billing the DME MAC for surgical dressings, urological supplies, or ostomy supplies that are provided during a stay in an inpatient facility that does not qualify as the beneficiary's home is not allowed. These items are payable to the facility under Part A of Medicare. This prohibition applies even if the item is worn home by the *beneficiary* from the inpatient facility. Any attempt by the supplier and/or facility to substitute an item that is payable to the supplier for an item that, under statute, should be provided by the facility, may be considered to be fraudulent.

To allow payment for the first immunosuppressive drug claim after the beneficiary is discharged from an inpatient stay, the immunosuppressive drug may be mailed by a supplier no earlier than two *(2)* days before a beneficiary is discharged from an inpatient facility. The supplier must enter the date of discharge as the date of service on the claim. (See IOM Pub. 100-04, Chapter 17, Section 80.3.3 for additional billing instructions.) 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).

Delivery of the immunosuppressive drugs may be made to the beneficiary's 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). In certain cases, a beneficiary who has received a transplant does not return home 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 beneficiary'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.

(See IOM Pub. 100-04, Chapter 17, Section 80.3.3 for additional information.)