

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 783	Date: March 30, 2018
	Change Request 10544

SUBJECT: Proof of Delivery Exceptions for Immunosuppressant Drugs Paid Under the Durable Medical Equipment (DME) Benefit

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to permit immunosuppressant drugs paid under the DME benefit to be delivered to a beneficiary's home address, up to 2 days preceding discharge from an inpatient stay. While the date of service on the claim should not precede the date of discharge, this exception to typical proof of delivery requirements helps ensure beneficiary access to life-sustaining medications upon discharge to their home location.

EFFECTIVE DATE: August 1, 2016

**Unless otherwise specified, the effective date is the date of service.*

IMPLEMENTATION DATE: April 30, 2018

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

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SUBJECT: Proof of Delivery Exceptions for Immunosuppressant Drugs Paid Under the Durable Medical Equipment (DME) Benefit

EFFECTIVE DATE: August 1, 2016

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IMPLEMENTATION DATE: April 30, 2018

I. GENERAL INFORMATION

A. Background: This CR will permit immunosuppressant drugs paid under the DME benefit to be delivered to a beneficiary's home address, up to 2 days preceding discharge from an inpatient stay. While the date of service on the claim should not precede the date of discharge, this exception to typical proof of delivery requirements helps ensure beneficiary access to life-sustaining medications upon discharge to their home location.

B. Policy: This CR does not involve any legislative or regulatory policies.

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	
10544.1	Contractors shall permit DME, prosthetics, or orthotics item—but not supplies—to be delivered to a patient in an inpatient facility that does not qualify as the beneficiary’s home up to two (2) days prior to the patient’s anticipated discharge, for the purpose of fitting or training the patient in the proper use of the item.				X					CERT, RACs, SMRC, UPICs, ZPICs
10544.2	Contractors shall ensure the date of service on the claim is the date of discharge.				X					CERT, RACs, SMRC, UPICs, ZPICs
10544.2.1	Contractors shall ensure the item is medically necessary on the date of discharge.				X					CERT, RACs, SMRC, UPICs, ZPICs
10544.2.2	Contractors shall not permit billing for any dates prior to discharge.				X					CERT, RACs, SMRC,

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Note- See 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 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.									UPICs, ZPICs
10544.3	Contractors shall permit payment for the first immunosuppressive drug claim after a beneficiary is discharged from an inpatient stay (if all other Medicare payment requirements are met) if the drugs were mailed up to 2 days prior to discharge to a valid place of service that does not qualify as the beneficiary's home and the date of discharge is used as the date of service on the claim. Note: See Pub. 100-04, Chapter 17, Section 80.3.3 for additional billing instructions.				X					CERT, RACs, SMRC, UPICs, ZPICs
10544.4	Contractors shall 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, contractors shall follow all applicable Medicare and DME MAC rules for immunosuppressive drug billing (for example, the date				X					CERT, RACs, SMRC, UPICs, ZPICs

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	of service will be the date of delivery).									

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): Lisa Sullivan, 410-786-2841 or Lisa.Sullivan@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.783; Issued: 03-30-18; Effective: 04-01-16; Implementation: 04-30-18)

This section applies to ZPICs/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 patient in *an inpatient facility that does not qualify as the beneficiary's home*, for the purpose of fitting or training the patient in the proper use of the item. This *delivery* may be done up to *two (2)* days prior to the patient'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 for subsequent use in the patient's home. No billing may be made for the item on those days the patient was receiving training or fitting in the hospital or nursing facility.

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 patient's home. No billing may be made for any day prior to the date of discharge. (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.)

A supplier may not bill for drugs or other DMEPOS items used by the patient prior to the patient'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 patient 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 days before a beneficiary is discharged from an inpatient facility. Delivery must be to a valid place of service (e.g., home, custodial facility), and not another facility (e.g., inpatient or skilled nursing) that does not qualify as the beneficiary's home. 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).