CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 3932	**Date: December 8, 2017**
	Change Request 10370

SUBJECT: Special Requirements for Immunosuppressive Drugs

I. SUMMARY OF CHANGES: The Centers for Medicare & Medicaid Services (CMS) is revising the Part B date of service requirements for the first immunosuppressive drug claim after the beneficiary is discharged from an inpatient stay as follows: in order to allow payment for a claim for an immunosuppressive drug that is mailed by a supplier either one or two days before a beneficiary is discharged from an inpatient facility, the supplier may enter the date of discharge as the date of service. The manual changes in this Change Request (CR) become effective on August 1, 2016.

EFFECTIVE DATE: August 1, 2016
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: March 9, 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
N	17/ 80.3/ 80.3.3 - Special Requirements 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: 3932	Date: December 8, 2017	Change Request: 10370

SUBJECT: Special Requirements for Immunosuppressive Drugs

EFFECTIVE DATE: August 1, 2016
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I. GENERAL INFORMATION

A. Background: Under Medicare Part B, the date of service on a supplier's immunosuppressive drug claim must be the date the supplier actually delivered or mailed the item. Thus, if a supplier mails a prescription shortly before the end of a beneficiary's inpatient stay and uses the mailing date as the date of service, the claim processing system will reject the supplier's claim because the claim's date of service precedes the beneficiary's date of discharge. As a result, beneficiaries whose immunosuppressive drug prescriptions are mailed on the day of discharge from an inpatient facility may be at risk for an interruption in their immunosuppressive drug therapy.

B. Policy: The Centers for Medicare & Medicaid Services (CMS) is revising the date of service requirements for the first immunosuppressive drug claim after the beneficiary is discharged from an inpatient stay as follows: in order to allow payment for a claim for an immunosuppressive drug that is mailed by a supplier either one or two days before a beneficiary is discharged from an inpatient facility, the supplier may enter the date of discharge as the date of service.

The manual update that is associated with this change request (CR) is based on the section titled Special Optional Requirements for Immunosuppressive Drugs in CR 2731, which was issued on June 27, 2003. CR 2731 is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1804B3.pdf. The manual changes in this CR are limited to the date of service requirement for immunosuppressive drugs paid under Medicare Part B and do not alter coverage provisions, claim submission, or delivery requirements for immunosuppressive drugs.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
		A/B MAC			D M E M A C	Shared-System Maintainers				Other
		A	B	H H H		F I S S	M C S	V M S	C W F	
10370.1	Medicare contractors shall be aware of the policy provided with this instruction in Publication 100-04, Chapter 17, Section 80.3.3.				X					
10370.2	Medicare contractors shall adjust previously denied claims that adhere to this policy with dates of service on or after August 1, 2016 if brought to their attention by the supplier.				X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibilit			
		A/B MAC			D M E M A C
		A	B	H H H	
10370.3	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 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.				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): Edmund Kasaitis, Edmund.Kasaitis@cms.hhs.gov (Payment Policy) , Wendy Tucker, Wendy.Tucker@cms.hhs.gov (Claims Processing)

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

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(Rev.3932, Issued: 12-08-17)

80.3.3 - Special Requirements for Immunosuppressive Drugs

80.3.3 – Special Requirements for Immunosuppressive Drugs

(Rev. 3932, Issued: 12-08-17, Effective: 08-01-16, Implementation: 03-09-18)

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 will be discharged from an inpatient facility, so that the drugs will be available at the beneficiary's home immediately after the beneficiary returns. 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 for immunosuppressive drug prescriptions that have been mailed one or two days before a beneficiary's 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).

Note that the following conditions also apply:

1) The facility 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 date the beneficiary is discharged.

2) The supplier must not mail or otherwise dispense the drugs any earlier than 2 days before the beneficiary is discharged. It is the supplier's responsibility to confirm the beneficiary's discharge date if they choose to take advantage of this option.

3) The supplier must not submit a claim for payment prior to the beneficiary's date of discharge.

4) The beneficiary's discharge must be to a qualified place of service (for example, home, or custodial facility), but not to another facility (for example, inpatient hospital or skilled nursing facility) that does not qualify as the beneficiary's home.