



## Clarification of the Billing of Immunosuppressive Drugs

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Related Change Request (CR) Number: 10235

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Effective Date: October 2, 2017

Related CR Transmittal Number: R3856CP

Implementation Date: October 2, 2017

Note: This article was revised on March 28, 2018, to add a link to a related article, [MM10370](#). MM10370 is based on CR 10370 that revised the date of service requirements for the first immunosuppressive drug claim after the beneficiary is discharged from an inpatient stay. All other information is unchanged.

### PROVIDER TYPE AFFECTED

This MLN Matters Article is intended for suppliers billing Durable Medical Equipment Medicare Administrative Contractors (DME MACs) for services provided to Medicare beneficiaries.

### PROVIDER ACTION NEEDED

Change Request (CR) 10235 updates language in the “Medicare Claims Processing Manual,” Chapter 17 (Drugs and Biologicals), Section 80.3 (Billing for Immunosuppressive Drugs) to remove a double negative statement and provide clear guidance to suppliers for when you may bill Medicare for immunosuppressive drugs. It provides no change in policy.

### BACKGROUND

This section provides details to the updated manual section, which is a part of CR10235.

Following a beneficiary’s organ transplant, Medicare covers their immunosuppressive drugs in accordance with 1861(s)(2)(J) of the Social Security Act (the 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.”

In the billing for immunosuppressive drugs, there are circumstances in which Medicare cannot locate, in Medicare’s claims database, the claim that would have confirmed that Medicare paid for the transplant. The claim may not appear in the database for reasons such as:

- 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 Fee-For-Service (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.

- There may be instances in which claims related to a transplant are old and may not be identifiable in the claims database despite Medicare's payment for the claim.

In these circumstances, your submission of the KX modifier (Specific Required Documentation on File) in the claim permits Medicare to make a reasonable assumption that: 1) You have documentation on file that indicates the date of the transplant, 2) The services furnished are medically necessary, and 3) Medicare paid for the transplant in accordance with the statute.

The use of the KX modifier is not required, but you should be aware that your DME MACs will accept claims for immunosuppressive drugs, received on and after July, 2008, without a KX modifier; but will deny the claim if the Centers for Medicare & Medicaid Services (CMS) cannot identify a record of a claim indicating that the transplant was paid for by Medicare FFS.

Further, if you furnish an immunosuppressive drug to a Medicare beneficiary, prescribed because the beneficiary had undergone an organ transplant; and, on and after July 1, 2008, submit a claim for this service that contains the KX modifier, you must:

1. Secure from the prescriber the date of such organ transplant and retain documentation of such transplant date in your files.
2. Attest that you have documentation on file that the beneficiary was eligible to receive Medicare Part A benefits at the particular date of the transplant and retain the documentation in your files.
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.

## ADDITIONAL INFORMATION

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The official instruction, CR10235, issued to your MAC regarding this change, is available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R3856CP.pdf>.

If you have any questions, please contact your MAC at their toll-free number. That number is available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Review-Contractor-Directory-Interactive-Map/>.

## DOCUMENT HISTORY

Date of Change	Description
March 28, 2018	This article was revised to add a link to a related article, <a href="#">MM10370</a> . MM10370 is based on CR 10370 that revised the date of service requirements for the first immunosuppressive drug claim after the beneficiary is discharged from an inpatient stay.
November 20, 2017	This article was revised to add a link to a related article, <a href="#">SE17032</a> . That article reminds pharmacy billing staff of the appropriate process for billing Medicare for immunosuppressive drugs using the KX modifier.
September 1, 2017	Initial article released.

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