

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 1448</b>	<b>Date: FEBRUARY 15, 2008</b>
	<b>Change Request 5916</b>

**NOTE: We are re-communicating Transmittal 1448, dated February 15, 2008. In BR 5916.1.1, we inadvertently left the X in the VMS column. The X has been deleted with this release. All other material remains the same.**

**SUBJECT: Adjudicating Claims for Immunosuppressive Drugs When Medicare Did Not Pay for the Original Transplant**

**I. SUMMARY OF CHANGES:** This instruction implements an automated process for adjudicating claims for immunosuppressive drugs when the beneficiary was enrolled in Medicare Part A at the time of their transplant, but Medicare did not make payment for the transplant.

**New / Revised Material**

**Effective Date: July 1, 2008**

**Implementation Date: July 7, 2008**

*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	17/80.3/Billing for Immunosuppressive Drugs

**III. FUNDING:**

**SECTION A:** For Fiscal Intermediaries and Carriers:

Not Applicable.

**SECTION B:** 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**

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

# Attachment - Business Requirements

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**SUBJECT: Adjudicating Claims for Immunosuppressive Drugs When Medicare Did Not Pay for the Original Transplant**

**Effective Date:** July 1, 2008

**Implementation Date:** July 7, 2008

## **I. GENERAL INFORMATION**

**A. Background:** Medicare covers immunosuppressive drugs for a beneficiary who has received an organ transplant, provided that the beneficiary receiving the drug was enrolled in Medicare Part A at the time of the organ transplant. Medicare will make payment for medically necessary immunosuppressive drugs for such a beneficiary regardless of whether Medicare made payment for the transplant itself.

Prior to April of 2006, the Durable Medical Equipment (DME) Regional Carriers (DMERCs) received information regarding the date of a beneficiary's transplant through a DMERC Information Form (DIF), which included a field where the supplier could enter a transplant date. However, on February 17, 2006, the Centers for Medicare and Medicaid Services (CMS) issued Transmittal 867, Change Request (CR) 4241, which eliminated the DIF. The CR also implemented an edit at the Common Working File (CWF) to search the Master Beneficiary Record (MBR) for a transplant upon receipt of a claim for an immunosuppressive drug. If the CWF does not find evidence of a transplant in the MBR, the claim line for such a drug is rejected.

Because CWF does not have a transplant record for a beneficiary if Medicare did not actually pay for the procedure, the DME Medicare Administrative Contractors (DME MACs) have been inappropriately denying claims even when such beneficiaries were enrolled in Medicare Part A at the time of their transplant.

This instruction implements an automated process for adjudicating claims for immunosuppressive drugs when the beneficiary was enrolled in Medicare Part A at the time of their transplant, but where Medicare did not make payment for the transplant.

**B. Policy:** For claims filed on and after July 1, 2008, suppliers that furnish an immunosuppressive drug to a Medicare beneficiary, when such drug has been prescribed due to the beneficiary having undergone an organ transplant, shall: 1) secure from the prescriber the date of such organ transplant, 2) retain documentation of such transplant date in its files, and 3) annotate the Medicare claim for such drug with the "KX" modifier to signify both that the supplier retains such documentation of the beneficiary's transplant date and that such transplant date precedes the Date of Service (DOS) for furnishing the drug.

For claims received on and after July 1, 2008, contractors shall accept claims for immunosuppressive drugs without a KX modifier but shall deny such claims unless a query of the Master Beneficiary Record (MBR) shows that Medicare has made payment for an organ transplant on a date that precedes the DOS of the immunosuppressive drug claim.

In the context of a claim for an immunosuppressive drug that is submitted to Medicare in order to receive payment, the use of the KX modifier signifies that the supplier has documentation on file to the effect that the

beneficiary has undergone an organ transplant on a date certain and that the immunosuppressive drug has been prescribed incident to such transplant.

If a supplier has not determined (or does not have documentation on file to support a determination) that either the beneficiary did not receive an organ transplant or that the beneficiary was not enrolled in Medicare Part A as of the date of the transplant, then the supplier may not, with respect to furnishing an immunosuppressive drug: 1) bill Medicare, 2) bill or collect any amount from the beneficiary, or 3) issue an Advance Beneficiary Notice (ABN) to the beneficiary.

## II. BUSINESS REQUIREMENTS TABLE

Use “Shall” to denote a mandatory requirement

Number	Requirement	Responsibility (place an “X” in each applicable column)									
		A / B  M A C	D M E  M A C	F I  M A C	C A R I  I E R	R H H I  I S S	Shared-System Maintainers				OTH ER
						F I S S	M C S	V M S	C W F		
5916.1	For claims received on or after July 1, 2008, contractors shall process claims for immunosuppressive drugs with modifier “KX” present on the immunosuppressive drug claim line.		X						X	X	
5916.1.1	The shared system maintainer shall automatically override the CWF reject for no matching transplant date when the “KX” modifier is present on the claim.									X	
5916.1.2	Contractors shall consider the presence of the “KX” modifier on an immunosuppressive claim line to be an attestation by the supplier that it has documentation on file that proves that the beneficiary had the transplant for which the immunosuppressive drug was prescribed while the beneficiary was enrolled in Medicare Part A.		X								
5916.1.3	Contractors shall continue to follow existing procedures and edits for immunosuppressive drug claims that do not have a “KX” modifier attached.		X					X	X		

## III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an “X” in each applicable column)									
		A / B  M A C	D M E  M A C	F I  M A C	C A R I  I E R	R H H I  I S S	Shared-System Maintainers				OTH ER
						F I S S	M C S	V M S	C W F		

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B  M A C	D M E  M A C	F I  M A C	C A R I E R	R H I  S S	Shared-System Maintainers				OTH ER
						F I S	M C S	V M S	C W F		
5916.2	<p>A provider education article related to this instruction will be available at <a href="http://www.cms.hhs.gov/MLNMattersArticles/">http://www.cms.hhs.gov/MLNMattersArticles/</a> shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv.</p> <p>Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your 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.</p>		X								

**IV. SUPPORTING INFORMATION**

**A. For any recommendations and supporting information associated with listed requirements, use the box below:**

*Use "Should" to denote a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:

**B. For all other recommendations and supporting information, use this space: N/A**

**V. CONTACTS**

**Pre-Implementation Contact(s):** Angela Costello at (410) 786-1554 or [angela.costello@cms.hhs.gov](mailto:angela.costello@cms.hhs.gov)

**Post-Implementation Contact(s):** Angela Costello at (410) 786-1554 or [angela.costello@cms.hhs.gov](mailto:angela.costello@cms.hhs.gov)

## **VI. FUNDING**

**Section A: For *Fiscal Intermediaries (FIs), Carriers, and Regional Home Health Carriers (RHHs)* use only one of the following statements: N/A**

**Section B: For *Medicare Administrative Contractors (MACs)*, use the following statement:**

The contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the Statement of Work (SOW). 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.

### **80.3 - Billing for Immunosuppressive Drugs**

*(Rev. 1448; Issued: 02-15-08; Effective: 07-01-08; Implementation: 07-07-08)*

Beginning January 1, 1987, Medicare pays for FDA approved immunosuppressive drugs and for drugs used in immunosuppressive therapy. (See the Medicare Benefit Policy Manual, Chapter 15 for detailed coverage requirements.) Generally, contractors pay for self-administered immunosuppressive drugs that are specifically labeled and approved for marketing as such by the FDA, or identified in FDA-approved labeling for use in conjunction with immunosuppressive drug therapy. This benefit is subject to the Part B deductible and coinsurance provision.

Contractors are expected to keep informed of FDA additions to the list of the immunosuppressive drugs and notify providers. Prescriptions for immunosuppressive drugs generally should be nonrefillable and limited to a 30-day supply. The 30-day guideline is necessary because dosage frequently diminishes over a period of time, and further, it is not uncommon for the physician to change the prescription from one drug to another. Also, these drugs are expensive and the coinsurance liability on unused drugs could be a financial burden to the beneficiary. Unless there are special circumstances, contractors will not consider a supply of drugs in excess of 30 days to be reasonable and necessary and should deny payment accordingly.

Entities that normally bill the carrier bill the DME **MAC**. Entities that normally bill the FI continue to bill the FI, except for hospitals subject to OPPS, which must bill the DME **MAC**.

Prior to December 21, 2000 coverage was limited to immunosuppressive drugs received within 36 months of a transplant. ESRD beneficiaries continue to be limited to 36 months of coverage after a Medicare covered kidney transplant. For all other beneficiaries, BBA '97 increased the length of time a beneficiary could receive immunosuppressives by a sliding method. So for the period 8/97 thru 12/00 a longer period of time MAY apply for a transplant. Effective with immunosuppressive drugs furnished on or after December 21, 2000, there is no time limit, but an organ transplant must have occurred for which immunosuppressive therapy is appropriate. That is, the time limit for immunosuppressive drugs was eliminated for transplant beneficiaries that will continue Medicare coverage after 36 months based on disability or age. The date of transplant is reported to the FI with occurrence code 36.

CWF will edit claim records to determine if a history of a transplant is on record. If not an error will be returned. See Chapter 27 for edit codes and resolution.

*For claims filed on and after July 1, 2008, suppliers that furnish an immunosuppressive drug to a Medicare beneficiary, when such drug has been prescribed due to the beneficiary having undergone an organ transplant, shall: 1) secure from the prescriber the date of such organ transplant, 2) retain documentation of such transplant date in its files, and 3) annotate the Medicare claim for such drug with the “KX” modifier to signify both that the supplier retains such documentation of the beneficiary’s transplant date and that such transplant date precedes the Date of Service (DOS) for furnishing the drug.*

*For claims received on and after July 1, 2008, contractors shall accept claims for immunosuppressive drugs without a KX modifier but shall deny such claims unless a query of the Master Beneficiary Record (MBR) shows that Medicare has made payment for an organ transplant on a date that precedes the DOS of the immunosuppressive drug claim.*

*In the context of a claim for an immunosuppressive drug that is submitted to Medicare in order to receive payment, the use of the KX modifier signifies that the supplier has documentation on file to the effect that the beneficiary has undergone an organ transplant on a date certain and that the immunosuppressive drug has been prescribed incident to such transplant.*

*If a supplier has not determined (or does not have documentation on file to support a determination) that either the beneficiary did not receive an organ transplant or that the beneficiary was not enrolled in Medicare Part A as of the date of the transplant, then the supplier may not, with respect to furnishing an immunosuppressive drug: 1) bill Medicare, 2) bill or collect any amount from the beneficiary, or 3) issue an Advance Beneficiary Notice (ABN) to the beneficiary.*