

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**CMS AND ITS CLAIMS
PROCESSING CONTRACTORS
ISSUED CONFLICTING GUIDANCE
ON THE PROPER USE OF THE
KX MODIFIER FOR PART B
IMMUNOSUPPRESSIVE DRUG
CLAIMS**

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Office of Inspector General

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The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

Report in Brief

Date: August 2017

Report No. A-06-15-00018

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL



Why OIG Did This Review

Medicare Part B covers immunosuppressive drugs for beneficiaries who receive an organ transplant for which Medicare payment has been made. A record of fee-for-service (FFS) transplant claims should be retained in the beneficiary's claims history. For circumstances when Medicare cannot locate an FFS claim in a beneficiary's history, a pharmacy can submit an immunosuppressive drug claim with a KX modifier to indicate that it has records showing the beneficiary is eligible for Medicare coverage. In Federal fiscal year 2014, Part B paid almost \$353 million for immunosuppressive drugs, and nearly 100 percent of the claims were submitted with the KX modifier.

Our objective was to determine whether Part B should have paid for immunosuppressive drugs billed with a KX modifier for beneficiaries for whom Medicare did not have a transplant record.

How OIG Did This Review

We reviewed immunosuppressive drug claims billed with the KX modifier for beneficiaries for whom Medicare did not have a transplant record. Our target frame consisted of 126,551 paid claims, totaling \$35 million of which we reviewed a random sample of 75 claims. We contacted the pharmacies and requested copies of documentation.

CMS and Its Claims Processing Contractors Issued Conflicting Guidance on the Proper Use of the KX Modifier for Part B Immunosuppressive Drug Claims

What OIG Found

Part B paid for some immunosuppressive drugs billed with the KX modifier that were not eligible for Part B payment. Of the 75 claims in our random sample, pharmacies had documentation to support the KX modifier for 65 claims but did not have support for the remaining 10.

The Centers for Medicare & Medicaid Services' (CMS) intention for the KX modifier was to signify an attestation by the pharmacy that it had documentation proving that a beneficiary's organ transplant occurred when the beneficiary was eligible for Medicare coverage. However, guidance in the *Medicare Claims Processing Manual* (the Manual) is not clearly written and additional guidance issued by claims processing contractors conflicted with the guidelines in the Manual by indicating that claims without the KX modifier would be denied.

Pharmacies improperly received \$3,973 in Part B reimbursement for the immunosuppressive drugs on the 10 claims. On the basis of our sample results, we estimated that Part B paid \$4.6 million in reimbursement for immunosuppressive drugs billed with the KX modifier that did not comply with Medicare requirements.

What OIG Recommends and CMS Comments

We recommend that CMS (1) clarify language in the Manual to be consistent with its intent, as described above, and (2) instruct the claims processing contractors to process immunosuppressive drug claims without the KX modifier and educate pharmacies on the correct use of the modifier.

CMS concurred with our recommendations and provided separate technical comments on our report. We incorporated the technical comments where appropriate.

TABLE OF CONTENTS

INTRODUCTION.....	1
Why We Did This Review	1
Objective	1
Background	1
The Medicare Program.....	1
Durable Medical Equipment Medicare Administrative Contractors.....	1
Immunosuppressive Drugs Submitted With the KX Modifier	2
How We Conducted This Review	3
FINDINGS.....	4
RECOMMENDATIONS	5
CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE	5
APPENDICES	
A: Audit Scope and Methodology	6
B: Statistical Sampling Methodology	7
C: Sample Results and Estimates	9
D: CMS Comments	10

INTRODUCTION

WHY WE DID THIS REVIEW

Immunosuppressive drugs are designed to prevent an individual's body from rejecting a donor organ. Medicare Part B (Part B) covers immunosuppressive drugs for beneficiaries who receive an organ transplant for which Medicare payment has been made.¹ When Medicare fee-for-service (FFS) pays for a transplant, a record of the transplant claim should be maintained in the beneficiary's Master Beneficiary Record (MBR) claim history. However, to accommodate certain circumstances in which Medicare cannot locate an FFS claim for a transplant in a beneficiary's MBR that would confirm that Medicare paid for the transplant, a pharmacy can submit an immunosuppressive drug claim with a KX modifier.² The modifier was intended to indicate that the beneficiary was eligible for Medicare benefits at the time of a transplant that preceded the date of service for furnishing the drug and thus is eligible for Part B drug coverage. In Federal fiscal year (FFY) 2014, Part B paid almost \$353 million for immunosuppressive drugs, and nearly 100 percent of the claims were submitted with the KX modifier.

OBJECTIVE

Our objective was to determine whether Part B should have paid for immunosuppressive drugs billed with a KX modifier for beneficiaries for whom Medicare did not have a transplant record.

BACKGROUND

The Medicare Program

Title XVIII of the Social Security Act established the Medicare program, which provides health insurance coverage to people aged 65 and over, people with disabilities, and people with permanent kidney disease. Part A helps cover inpatient care in hospitals, including coverage for organ transplants and hospital care related to transplants. Part B helps cover doctors' services and outpatient care, as well as a limited number of drugs.

Durable Medical Equipment Medicare Administrative Contractors

The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program and contracts with private organizations to process and pay claims for services provided to eligible

¹ Section 1861(s)(2)(J) of the Social Security Act provides that Medicare covers "prescription drugs used in immunosuppressive therapy furnished to an individual who receives an organ transplants for which payment is made under this title."

² A modifier is a two-position code designed to give Medicare and commercial payers additional information needed to process a claim.

beneficiaries. During our audit period, CMS contracted with four Durable Medical Equipment Medicare Administrative Contractors (DME MACs, also known as claims processing contractors) to process and pay Part B immunosuppressive drug claims. Each DME MAC processed claims for one of four jurisdictions.³

DME MACs issued local policy regarding immunosuppressive drug coverage in their jurisdictions. A local policy may consist of two separate but closely related documents: a local coverage determination and an associated local coverage article. CMS's *Medicare Program Integrity Manual* states that DME MACs should apply the coverage requirements documented in local coverage policies on either a prepayment or postpayment basis (chapter 13, § 13.10).⁴

Immunosuppressive Drugs Submitted With the KX Modifier

In early 2006, CMS implemented a prepayment edit in the Common Working File (CWF) system to search the MBR for evidence of an organ transplant when adjudicating immunosuppressive drug claims.⁵ If the CWF system did not find evidence of a transplant in the MBR, the claim was denied. Because the CWF did not have a transplant record for a beneficiary in certain circumstances, such as a beneficiary who received a transplant through the Medicare Advantage (MA) program, DME MACs were denying immunosuppressive drug claims for beneficiaries who were entitled to coverage.⁶

Effective July 1, 2008, CMS implemented an automated process for adjudicating immunosuppressive drug claims to ensure that such claims are not denied. DME MACs started accepting claims with a KX modifier, which overrides the CWF rejection when evidence of a transplant is not found in the MBR. CMS intended the modifier to signify an attestation by the supplier (e.g., pharmacy) that it has documentation on file that proves the beneficiary had a transplant that preceded the date of service for furnishing the drug and while eligible for Medicare benefits.⁷

³ Currently there are two DME MACs with two jurisdictions each.

⁴ Prepayment edits are programming logic within a claim processing system that is designed to evaluate claims and prevent payment for errors such as noncovered, incorrectly coded, or inappropriately billed lines of service within a claim.

⁵ The CWF comprises nine localized databases, called Hosts, that maintain claim history and entitlement information for the beneficiaries in their jurisdictions. Each beneficiary is assigned to one Host based on where he or she signed up for Social Security Administration benefits.

⁶ CMS's MA program offers beneficiaries a managed care option by allowing them to enroll in private health plans rather than having their care covered through Medicare's traditional fee-for-service program. According to CMS officials, as a general rule, claims for MA beneficiaries are not maintained within the MBR.

⁷ This intent was expressed in CMS Manual System, Publication 100-04 Medicare Claims Processing, Transmittal 1448 (Change Request 5916, Feb. 15, 2008); CMS, Medicare Learning Network (MLN) Matters Number MM5916; and discussions with CMS officials.

In reference to the July 2008 change, chapter 17, section 80.3 of the *Medicare Claims Processing Manual* (the Manual) states:

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.

This section of (the Manual) also indicates that pharmacies that furnish an immunosuppressive drug to a beneficiary who underwent an organ transplant shall (1) secure from the prescriber the date of the transplant, (2) retain documentation of the transplant date in their files, and (3) annotate the claim for the drug with the KX modifier to signify both that the pharmacy retains the documentation of the beneficiary's transplant date and that the transplant date precedes the prescription date. CMS also instructed the DME MACs to continue following existing procedures and edits for claims without a KX modifier (i.e., deny claims if the CWF did not find evidence of a transplant).

HOW WE CONDUCTED THIS REVIEW

Our review covered Part B immunosuppressive drug claims billed with the KX modifier for beneficiaries without a transplant history in the MBR. We identified 126,551 paid claims for prescriptions filled during FFY 2014 that were associated with this condition, totaling \$34,983,227. We sampled 75 claims, totaling \$36,585, in Part B payments.⁸ For each sample item, we contacted the pharmacies where the prescriptions were filled and requested copies of their documentation showing that the beneficiary was enrolled in Part A and that the prescription was written after a transplant.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology, Appendix B contains our statistical sampling methodology, and Appendix C contains our sample results and estimates.

⁸ Our statistical sample and the corresponding statistical estimate covers 120,382 of the 126,551 claims associated with the target population. The target population was restricted to FFY 2014 claims for the top seven immunosuppressive drugs.

FINDINGS

Part B should not have paid for some immunosuppressive drugs billed with the KX modifier. Pharmacies had documentation to support the use of the KX modifier for 65 of the 75 claims in our sample. The remaining 10 claims were not allowable for Part B payment because the pharmacy:

- had documentation that showed the beneficiary received an organ transplant before his or her Medicare eligibility (6 instances),
- did not have a transplant date to verify that the beneficiary was eligible for Medicare at the time of the transplant (2 instances), and
- did not have any supporting documentation (2 instances).

CMS guidance in the Manual is not clearly written and does not agree with CMS's intent that the KX modifier signify an attestation by the pharmacy that it had documentation proving the beneficiary is eligible for Part B immunosuppressive drug coverage because the transplant occurred before the date of service for furnishing the drug and while the beneficiary was eligible for Medicare benefits. This intent was expressed in CMS Change Request 5916 and MLN Matters Number MM5916 and by CMS officials in their discussions with us. The Manual language includes a double negative that is unclear, indicating that if a pharmacy has *not* determined that either the beneficiary did not receive an organ transplant or that the beneficiary was not enrolled in Part A, then it cannot bill Medicare.

In addition, during our audit period, all four DME MACs had local coverage policies that mandated that pharmacies add the KX modifier to an immunosuppressive drug claim only if the beneficiary was enrolled in Part A at the time of the organ transplant.⁹ However, the DME MACs also issued local coverage articles indicating that pharmacies must submit all immunosuppressive drug claims with the KX modifier or they will be denied. The local coverage articles conflict with the Manual, which indicates that claims may be processed without the modifier.

Pharmacy staff added the KX modifier to the claim in only two of the eight errors for which some supporting documentation was provided to us. For the remaining six errors, the KX modifier was added after the pharmacies submitted a claim (e.g., by a third-party billing company). In these instances, the pharmacies did not attest to having the required supporting documentation because they did not add the KX modifier. The local coverage articles from the DME MACs, which conflict with CMS's guidance, may have contributed to the errors because the claims would not have been paid without the KX modifier.

⁹ Local Coverage Determination for Immunosuppressive Drugs, numbers L68, L11521, L11531, and L27036; Local Coverage Article for Immunosuppressive Drugs, numbers A23662, A25366, A25526, and A47058.

Pharmacies improperly received \$3,973 in Part B reimbursement for the immunosuppressive drugs on the 10 claims. On the basis of our sample results, we estimated that Part B paid \$4,648,125 for immunosuppressive drugs billed with the KX modifier that did not comply with Medicare requirements.

RECOMMENDATIONS

We recommend that CMS (1) clarify language in the Manual to be consistent with its intent and (2) instruct DME MACs to process immunosuppressive drug claims without the KX modifier and educate pharmacies on the correct use of the modifier.

CMS COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS concurred with our recommendations and provided separate technical comments on our report. We incorporated the technical comments where appropriate. See Appendix D for CMS comments in their entirety.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our review covered Part B immunosuppressive drug claims with the KX modifier for prescriptions that were filled during FFY 2014. We included only claims for the top seven paid immunosuppressive drugs. We excluded claims (1) for beneficiaries for whom the MBR had a transplant record, (2) when the diagnosis code was not related to an organ transplant or a transplant complication, and (3) with payment amounts of less than \$50. We identified 126,551¹⁰ claims billed with the KX modifier, totaling \$34,983,227, during FFY 2014. We extracted these claims from CMS's National Claims History file.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Medicare laws, regulations, and guidance;
- interviewed Medicare officials to obtain an understanding of the Medicare requirements related to immunosuppressive drugs;
- obtained from CMS a list of beneficiaries for whom the MBR had a transplant record;
- identified 126,551 paid claims billed with the KX modifier during FFY 2014, totaling \$34,983,227;
- selected a random sample of 75 immunosuppressive drug claims;
- requested and reviewed, when provided, pharmacy documentation to determine whether the claim billed with the KX modifier complied with Medicare requirements; and
- discussed the results of our review with CMS officials.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

¹⁰ Our statistical sample and the corresponding statistical estimate covers 120,382 of the 126,551 claims associated with the target population. The target population was restricted to FFY 2014 claims for the top seven immunosuppressive drugs.

APPENDIX B: STATISTICAL SAMPLING METHODOLOGY

TARGET POPULATION

The population consisted of Part B immunosuppressive drug claims (1) with prescription fill dates in FFY 2014, (2) billed with a KX modifier, (3) for beneficiaries for whom CMS did not have a transplant record, and (4) related to an organ transplant or an organ transplant complication. In addition, the population was restricted to claims of \$50 or more for the top seven paid immunosuppressive drugs.

SAMPLING FRAME

Our sample was pulled from a list that contained 127,198 paid claims. This list contained 6,816 claims that were not part of the target population and excluded 6,169 claims that were part of the target population. We calculated a statistical estimate for the 120,382 paid claims (127,198 - 6,816) that were part of the target population and within the list used to pull the sample. No improper payments were calculated for the remaining 12,985 claims (6,816 + 6,169).

To identify the 126,551 claims associated with the target population, we:

- isolated the immunosuppressive drug claims that were billed with a KX modifier;
- identified and excluded claims for immunosuppressive drugs for beneficiaries for whom the MBR had a transplant record;
- excluded claims for immunosuppressive drugs not related to an organ transplant or an organ transplant complication using local policies issued by the DME MACs;
- narrowed our review to claims for the top seven paid Healthcare Common Procedure Coding System (HCPCS) codes: J7502, J7507, J7515, J7517, J7518, J7520, and J7527;¹¹ and
- excluded all claims with payment amounts of less than \$50.

The difference between the target population and the sampling frame was due to a limitation in the analytic procedure that was used to develop the sampling frame.

SAMPLE UNIT

The sample unit was one claim.

¹¹ The HCPCS is a medical code set used throughout the health care industry as a standardized system for describing and identifying health care procedures, equipment, and supplies in health care transactions.

SAMPLE DESIGN

We used a stratified random sample containing 3 strata (Table 1).

Table 1: Sample Design

Stratum	Strata Labels	Number of Claims
1	Low Dollar	84,064
2	Moderate Dollar	31,215
3	High Dollar	11,919
Total		127,198

See the Sampling Frame section for the relationship between the sample listing and the target population.

SAMPLE SIZE

We selected 75 claims, 25 from each of the 3 strata.

SOURCE OF THE RANDOM NUMBERS

We generated the random numbers with the Office of Inspector General (OIG), Office of Audit Services (OAS), statistical software.

METHOD FOR SELECTING SAMPLE ITEMS

We consecutively numbered the claims in each stratum. After generating the random numbers for each stratum, we selected the corresponding claims in each stratum.

ESTIMATION METHODOLOGY

We used the OIG OAS statistical software to analyze the sample results. We estimated the amount of ineligible Part B payments for immunosuppressive drugs billed with a KX modifier in our sampling frame. Our estimate covers 95.1 percent of the paid claims associated with the target population.¹²

¹² We identified 126,551 paid claims associated with the target population. The 95.1 percent that is listed here represents the number of paid claims covered by our estimate (120,382) divided by the number of paid claims associated with the target population (126,551).

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 2: Sample Results Details

Stratum	Sample Size	Value of Sample	Number of Unallowable Claims	Value of Unallowable Claims
1	25	\$3,338	4	\$500
2	25	9,703	4	1,698
3	25	23,544	2	1,775
Total	75	\$36,585	10	\$3,973

**Table 3: Estimated Value of Unallowable Beneficiary Days
(Limits Calculated for a 90-Percent Confidence Interval)**

Point Estimate	\$4,648,125
Lower Limit	2,295,836
Upper Limit	7,000,415

APPENDIX D: CMS COMMENTS



DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

200 Independence Avenue SW
Washington, DC 20201

DATE: June 5, 2017

TO: Daniel R. Levinson
Inspector General
Office of the Inspector General

FROM: Seema Verma
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: CMS and Its Claim Processing Contractors Issued Conflicting Guidance on the Proper Use of the KX Modifier for Part B Immunosuppressive Drug Claims (A-06-15-00018)

A handwritten signature in blue ink that reads "Seema Verma".

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS strives to provide Medicare beneficiaries with access to high quality health care while protecting taxpayer dollars.

Medicare covers a beneficiary's immunosuppressive drugs following an organ transplant, in accordance with section 1861(s)(2)(J) of the Social Security 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."

A claim for immunosuppressive drugs can be submitted with or without a KX modifier. If the KX modifier is not included on a claim and a check to the Master Beneficiary Record indicates a transplant was paid for by Medicare, the claim is paid. If the check shows the claim was not paid for by fee-for-service Medicare, the claim is denied.

CMS implemented an automated process (i.e., the KX modifier) for adjudicating claims for immunosuppressive drugs when the beneficiary was eligible for Medicare Part A at the time of their transplant, but where Medicare systems cannot identify a claims record indicating the transplant was paid for by fee-for-service Medicare. Use of the KX modifier permits CMS to pay for immunosuppressive drugs in situations when a transplant claim does not appear in the claims database. Suppliers that use the KX modifier on a Medicare claim signify that they attest to retaining documentation on file that the beneficiary has undergone an organ transplant on a date in which the beneficiary was eligible to receive Medicare Part A benefits, that the prescribed immunosuppressive drug is associated with that transplant, and that such transplant date precedes the Date of Service for furnishing the drug.

CMS recognizes the importance of continuing to provide Medicare beneficiaries with access to medically necessary services and, at the same time, working to protect the Medicare Trust Funds from improper payments. CMS has taken actions to prevent Medicare overpayments by

educating providers on proper billing, including with the KX modifier. CMS educates providers on avoiding Medicare billing errors through various channels including the Medicare Learning Network, weekly electronic newsletters, and quarterly compliance newsletters.

In addition to provider education, CMS uses a robust program integrity strategy to reduce and prevent Medicare improper payments, including prepayment and postpayment reviews, prior authorization for certain items and services, and the Comprehensive Error Rate Testing program to identify and address incorrect billing caused by coverage or coding errors made by providers.

OIG's recommendations and CMS' responses are below.

OIG Recommendation

The OIG recommends that CMS clarify the language in the Medicare Claims Processing Manual to be consistent with the intent.

CMS Response

CMS concurs with OIG's recommendation. CMS will review the language in the Medicare Claims Processing Manual, and clarify as necessary.

OIG Recommendation

The OIG recommends that CMS instruct the claims processing contractors to process immunosuppressive drug claims without the KX modifier and educate pharmacies on the correct use of the modifier.

CMS Response

CMS concurs with OIG's recommendation. CMS will instruct the claims processing contractors to process immunosuppressive drug claims without the KX modifier. Additionally, CMS routinely educates providers on avoiding Medicare billing errors through various channels, including the Medicare Learning Network, weekly electronic newsletters and quarterly compliance newsletters. CMS will continue to use channels such as these to educate suppliers (including pharmacies) on the correct use of the modifier.