Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICARE PART B AND BENEFICIARIES PAID FOR XOLAIR THAT JURISDICTION 14 PHYSICIANS DISCARDED WITHOUT DOCUMENTATION

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Acting Regional
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Office of Inspector General

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EXECUTIVE SUMMARY

Medicare Part B and its beneficiaries paid an estimated $69,000 for Xolair that Jurisdiction 14 physicians discarded without documentation in 2010. The physician practices in our sample that billed for undocumented discard were unaware of the requirement to document discard in the medical record.

WHY WE DID THIS REVIEW

When a physician must discard the remainder of a single-use drug vial after administering the prescribed dose to a patient, Medicare Part B will pay for the discarded and the administered drug, up to the amount indicated on the vial's label. Since September 23, 2010, NHIC, Corp. (NHIC), the Medicare administrative contractor (MAC) for Jurisdiction 14, has required physicians to document in the medical record the date, time, and amount of the drug discarded. Xolair is a relatively expensive asthma drug, which is susceptible to discard because of its packaging. Xolair is sold in 150 milligram single-use vials, but two of the four standard dosages are not multiples of 150 milligrams. When beneficiaries receive those dosages, a physician is likely to discard 75 milligrams of Xolair; Medicare Part B and the beneficiaries are responsible for the payment for both the discarded drug and the administered drug.

The objectives of this review were to (1) determine whether Jurisdiction 14 physicians documented in the medical record the discarded Xolair that they billed for in calendar year (CY) 2010 and (2) estimate Medicare Part B and beneficiary payments for undocumented discarded Xolair.

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program and contracts with MACs to process and pay Medicare Part A and Part B claims. NHIC is the MAC for Jurisdiction 14 (Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont).

CMS allows MACs to require physicians to use the "JW" modifier to identify line items billing for discarded drug. For example, if a physician gives a patient 95 milligrams of a drug from a single-use vial labeled to contain 100 milligrams and discards the remaining 5 milligrams, the physician should bill the 95 milligram dose on one claim line and bill the discarded 5 milligrams on another line with the JW modifier. If the JW modifier is not required, then the total amount of the drug administered and discarded would be billed on one claim line. Use of the JW modifier allows MACs to monitor drug waste and identify potential issues in billing and reimbursement.

NHIC does not require use of modifier JW. However, NHIC requires physicians to document discarded drugs in the medical record.

WHAT WE FOUND

For the 30 line items in our sample that included billings for discarded Xolair, physicians did not document the discarded drug. Using our sample results, we estimated that in CY 2010 Medicare and beneficiaries paid $69,000 for Xolair that Jurisdiction 14 physicians discarded but did not document in the medical record. Representatives from all of the physician practices in our sample that billed for undocumented discarded Xolair stated that they were unaware of NHIC's 2010 policy prior to the start of our review in mid-2012.

WHAT WE RECOMMEND

We recommend that NHIC:

- provide additional education to ensure that physicians are aware of the policy to document discarded drugs,
- require the use of the JW modifier for discarded drugs to aid in monitoring of drug waste and identification of potential issues in billing and reimbursement, and
- monitor the use of the JW modifier and address any instances of potential noncompliance with discarded drug requirements.

NHIC COMMENTS

In written comments on our draft report, NHIC concurred with our first recommendation but did not concur with the second and third recommendations.

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INTRODUCTION

WHY WE DID THIS REVIEW

When a physician must discard the remainder of a single-use drug vial after administering the prescribed dose to a patient, Medicare Part B will pay for the discarded and the administered drug, up to the amount indicated on the vial's label. Since September 23, 2010, NHIC, Corp. (NHIC), the Medicare administrative contractor (MAC) for Jurisdiction 14, has required physicians to document in the medical record the date, time, and amount of discarded drugs. Xolair is a relatively expensive[1] asthma drug, which is susceptible to discard because of its packaging. Xolair is sold in 150 milligram single-use vials, but two of the four standard dosages are not multiples of 150 milligrams. When beneficiaries receive those dosages, physicians likely discard 75 milligrams of Xolair at each administration; Medicare Part B and the beneficiaries are responsible for the payment for both the discarded drug and the administered drug.

OBJECTIVES

Our objectives were to (1) determine whether Jurisdiction 14 physicians documented in the medical record the discarded Xolair that they billed for in CY 2010 and (2) estimate Medicare Part B and beneficiary payments for undocumented discarded Xolair.

BACKGROUND

The Medicare Program

Medicare provides health insurance coverage to people aged 65 and over, people with disabilities, and people with end-stage renal disease. The Centers for Medicare & Medicaid Services (CMS) administers the program. CMS contracts with MACs to process and pay Medicare Part A and Part B claims. NHIC is the MAC for Jurisdiction 14 (Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont).

Medicare Part B Coverage for Drugs and Biologicals

Medicare Part B provides limited coverage for drugs and biologicals[2] that are furnished incident to a physician's services and that are not usually self-administered.[3] Medicare Part B uses the average sales price (ASP) methodology to reimburse for most covered drugs. Under this

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[1] In calendar year (CY) 2010, Medicare Part B and a beneficiary paid approximately $1,188 for a 300 milligram dose of Xolair. Nationwide, Part B and its beneficiaries paid approximately $55.4 million for Xolair for CY 2010.

[2] Biologicals are medications made from living organisms or their products. For purposes of this report, the term "drug" means drug or biological.

[3] The *Medicare Benefits Policy Manual*, Pub. No. 100-02, ch. 15, §50.

methodology, the Medicare allowance is 106 percent of the ASP.[4] Part B reimburses physicians 80 percent of the allowance and beneficiaries are responsible for the remaining 20 percent.

Billing for Discarded Drugs

For drugs in single-use vials, Medicare reimburses for both the administered drug and discarded drug up to the amount indicated on the vial's label.[5] Physicians bill Medicare by creating a line item on a claim that specifies the drug and the amount of the drug billed. Providers may use modifier codes to supply additional information for a specific claim line item. CMS allows MACs to require physicians to use the "JW" modifier to identify line items billing for discarded drug. For example, if a physician gives a patient 95 milligrams of a drug from a single-use vial labeled to contain 100 milligrams and discards the remaining 5 milligrams, the physician should bill the 95 milligram dose on one claim line with no JW modifier and should bill the discarded 5 milligrams on another line with the JW modifier. However, if the JW modifier is not required (and not used voluntarily), the total amount of drug administered and discarded should be billed on one claim line.[6]

CMS instructed each MAC to notify Medicare providers of their local requirements concerning the use of the JW modifier. On September 23, 2010, NHIC issued a policy stating that NHIC does not require use of the JW modifier. This policy also requires physicians to document drug wastage in the medical record with date, time, and amount of drug discarded.[7]

Xolair

Xolair (omalizumab) is a drug approved by the Food and Drug Administration (FDA) to treat individuals 12 years and older for allergy-induced asthma. It is manufactured by Genentech and supplied in 150 milligram single-use vials. FDA approved two presentations for Xolair, a 75 milligram single-use vial and a 150 milligram single-use vial, but Genentech has never marketed the 75 milligram vial in the United States.

Xolair is administered by injection in one of four standard dosages every 2 or 4 weeks with the dosage and frequency based on the patient's body weight and the results of a blood test performed at the start of treatment. The standard dosages are 150 or 300 milligrams every 4 weeks or 225 or 375 milligrams every 2 weeks. Because Xolair is available only in a 150

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[4] The Social Security Act § 1847A(c) defines ASP as the value of a manufacturer's quarterly sales of a drug to purchasers in the United States (with certain exceptions), net of any price concessions, divided by the total number of units of the drug sold by the manufacturer in that quarter. CMS reviews and updates the ASP on a quarterly basis.

[5] Medicare does not reimburse physicians for discard from multiuse vials.

[6] The *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 17, § 40, covers CMS's policies on payment for discard and the JW modifier.

[7] *Clarification on Use of Modifier JW and Billing Drug Wastage Based on (CMS) Change Request 6711,* issued September 23, 2010, by NHIC, and available at http://www.medicarenhic.com/providers/articles/MDJWBillingDrugWastageBasedCR6711.pdf.

milligram vial, physicians are likely to discard 75 milligrams of the drug when administering doses of 225 or 375 milligrams.

HOW WE CONDUCTED THIS REVIEW

We used CMS's National Claims History file to identify Medicare Part B line items processed and paid by NHIC for Xolair furnished during CY 2010. We identified 806 line items for more than 150 milligrams of Xolair, which represented $831,976 in Medicare payments to physicians and $209,987 in beneficiary deductibles and copayments. We reviewed the medical and payment records for a random sample of 100 line items. When examining the medical records, we checked to see whether physicians had documented the discarded drug. To identify the undocumented discarded drug, we compared the amount of Xolair billed on each line item to the administered dose in the medical record and asked the physician whether Xolair had been discarded. We determined how much Medicare and beneficiaries paid for the undocumented discard in our sample and used our sample results to estimate how much Medicare and beneficiaries paid in total for undocumented discarded Xolair furnished in CY 2010.

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 scope and methodology, Appendix B contains the details of our sample design and methodology, and Appendix C contains the details of our sample results and estimates.

FINDINGS

For the 30 line items in our sample that included billings for discarded Xolair, physicians did not document the discarded drug. Using our sample results, we estimated that in CY 2010 Medicare and beneficiaries paid $69,000 for Xolair that Jurisdiction 14 physicians discarded but did not document in the medical record. Representatives from all of the physician practices in our sample that billed for undocumented discarded Xolair stated that they were unaware of NHIC's 2010 policy prior to the start of our review in mid-2012.

DISCARDED XOLAIR NOT DOCUMENTED IN MEDICAL RECORD

Thirty line items in our random sample of 100 included billing for discarded Xolair, and for those items physicians did not document the discarded drug in the medical record. Of the 20 physician practices in our sample, representatives of 13 practices (including the 8 practices that billed for undocumented discarded Xolair) stated that they had been unaware of NHIC's 2010 policy until receiving our audit notification letter in 2012. Representatives of four practices

stated that they were aware of NHIC's policy,[8] and representatives of three practices indicated that because their practices do not bill for discarded drugs, they would likely have considered the policy inapplicable.

MEDICARE AND BENEFICIARIES PAID $69,000 FOR DISCARDED XOLAIR

Using our sample results, we estimated that Medicare paid $55,181 and beneficiaries paid $14,016 for Xolair discarded in CY 2010. Medicare and beneficiaries made these payments because the packaging of the drug does not accommodate all standard dosages and because Medicare allows charges for the discarded drug. In each of the 30 instances in our sample in which discarded Xolair was paid, physicians administered 225 or 375 milligram doses and discarded 75 milligrams.

In addition, for 16 line items in our sample, physicians discarded 75 milligrams of Xolair but did not bill for it because they (1) were not aware that billing for the discarded drug was allowable, (2) had a policy not to bill for discarded drugs, or (3) inadvertently neglected to bill for the discarded drug. As a result, in total, 46 of the 100 line items in our sample represented treatments in which physicians discarded 75 milligrams of Xolair.[9] However, physicians billed Medicare for the discarded Xolair only about two-thirds of the time (30 line items out of 46).

CONCLUSION

Most of the physician practices that we contacted in 2012 were unaware of NHIC's 2010 policy requiring documentation of discarded drugs. Payments for undocumented discarded Xolair may continue if physicians remain unaware of the policy and if NHIC does not monitor compliance with the policy. Requiring physicians to use the JW modifier would allow NHIC to monitor drug waste and identify potential issues in billing and reimbursement, such as billing for undocumented discard.

RECOMMENDATIONS

We recommend that NHIC:

- provide additional education to ensure that physicians are aware of the policy to document discarded drugs,

- require the use of the JW modifier for discarded drugs to aid in monitoring of drug waste and identification of potential issues in billing and reimbursement, and

[8] None of the practices that said they were aware of the policy had billed discarded Xolair that appeared in our sample.

[9] The remaining 54 line items represented treatments in which physicians administered doses of 300 milligrams with no discard.

- monitor the use of the JW modifier and address any instances of potential noncompliance with discarded drug requirements.

NHIC COMMENTS

In written comments on our draft report, NHIC concurred with our first recommendation but did not concur with the second and third recommendations.

NHIC's comments are included in their entirety as Appendix D.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered 806 line items for more than 150 milligrams of Xolair[10] furnished during CY 2010, which represented $831,976 in Medicare payments to physicians and $209,987 in beneficiary deductibles and copayments. In this audit, we did not review entire claims; rather, we reviewed specific line items within claims.

We limited our review of NHIC's internal controls to those applicable to the 806 line items of service because our objectives did not require an understanding or assessment of NHIC's complete internal control structure. Our review allowed us to establish reasonable assurance of the authenticity and accuracy of the data obtained from the National Claims History file, but we did not assess the completeness of the file.

Our fieldwork consisted of contacting the physicians who billed for the items we sampled. We also contacted NHIC and FDA officials. We conducted our fieldwork from May 2012 through August 2012.

METHODOLOGY

To accomplish our objectives, we:

- reviewed applicable Medicare laws, regulations, and guidance;
- interviewed NHIC staff members;
- reviewed NHIC educational materials;
- interviewed FDA officials for background information;
- used CMS's National Claims History file to identify Part B line items where payments were made for Healthcare Common Procedure Coding System code J2357 (Xolair) furnished during CY 2010;
- identified 806 line items with unit counts representing more than 150 milligrams of Xolair;
- selected a simple random sample of 100 Xolair line items paid by NHIC (Appendix B);

[10] We did not include line items for 150 milligrams because it was unlikely that a standard dose of 150 milligrams would result in discard. The only other line items we excluded were a small number of lines for 5 milligrams because those line items were likely to have been billed incorrectly.

- reviewed available claims history from the Common Working File for the sampled items to determine whether the claims had been canceled and superseded by revised claims;

- obtained medical and payment records for the sampled items from the 20 physician practices which had provided the Xolair;

- reviewed the medical and payment records;

- determined whether physicians had documented discard in the medical record;

- identified undocumented discard by comparing each amount billed to the administered dose in the medical record and by asking the physicians whether Xolair had been discarded;

- used our sample results to estimate the amount that Medicare and beneficiaries paid for the undocumented discarded Xolair (Appendix C); and

- held an exit conference with NHIC to discuss the results of our review.

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 B: SAMPLE DESIGN AND METHODOLOGY

POPULATION

The population consisted of nationwide paid Medicare Part B physician services (claim line items) for the drug Xolair with dates of service in CY 2010.

SAMPLING FRAME

The sampling frame was an Access database table of 806 Xolair line items processed by NHIC having more than 30 units of service (equivalent to more than 150 milligrams).[11] Those 806 line items totaled $831,976 in Medicare payments to physicians and $209,987 in beneficiary deductibles and copays.

SAMPLE UNIT

The sample unit was a line item of service.

SAMPLE DESIGN

Our sample design was a simple random sample.

SAMPLE SIZE

We selected a sample of 100 line items.

SOURCE OF RANDOM NUMBERS

We used the Office of Inspector General, Office of Audit Services (OAS) statistical software to generate the random numbers.

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the sample units in the sampling frame. After generating the 100 random numbers, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We used the OAS statistical software to estimate the dollar value of payments for undocumented discarded Xolair.

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[11] We did not include line items for 150 milligrams because it was unlikely that a standard dose of 150 milligrams would result in discard. The only other line items we excluded were a small number of lines for 5 milligrams because those line items were likely to have been billed incorrectly.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Medicare Payment for Undocumented Discarded Xolair Sample Results

Frame Size	Value of Frame	Sample Size	Value of Sample	Items with Undocumented Discard	Total Amount of Undocumented Discard
806	$ 831,976	100	$ 100,612	30	$ 6,846

Estimates of Medicare Payment for Undocumented Discarded Xolair

(Limits Calculated for a 90-Percent Confidence Interval)

Point Estimate	$ 55,181
Lower Limit	$ 41,997
Upper Limit	$ 68,366

Beneficiary Payment for Undocumented Discarded Xolair Sample Results

Frame Size	Value of Frame	Sample Size	Value of Sample	Items with Undocumented Discard	Total Amount of Undocumented Discard
806	$ 209,987	100	$ 25,345	30	$ 1,739

Estimates of Beneficiary Payment for Undocumented Discarded Xolair

(Limits Calculated for a 90-Percent Confidence Interval)

Point Estimate	$ 14,016
Lower Limit	$ 10,657
Upper Limit	$ 17,374

APPENDIX D: NHIC COMMENTS

Phone: (781) 741-3255

May 24, 2013

Mr. David Lamir
Acting Regional Inspector for Audit Services
Office of Audit Services, Region 1
JFK Federal Building
15 New Sudbury St, Room 2425
Boston, MA 02203

RE: A-01-12-00508 (*Medicare Part B and Beneficiaries Paid for Xolair That Jurisdiction 14 Physicians Discarded Without Documentation*)

Mr. Lamir:

As the MAC for Jurisdiction 14, NHIC is submitting our response to the OIG's report cited above. Our response to each specific recommendations appears on the next page. We appreciate the efforts of the OIG in identifying areas of potential vulnerability in the program, and will continue to support such efforts in any way that we can.

Sincerely,

/s/ Robert Harrington

Robert Harrington
Program Director, NHIC J14, Corp.

cc: Anne Bockhoff-Dalton (NHIC Vice President)

Recommendation 1: *Provide additional education to ensure that physicians are aware of the policy to document discarded drugs*

Response: NHIC concurs with this recommendation, and we will republish our original instructions, with a summary of this audit's results or Xolair, and further emphasize the requirements by CMS to "document wastage", while noting that wastage is a still an allowable expense. This may increase reimbursement for those providers who are unaware of the allowability of wastage.

Recommendation 2: *Require the use of the JW modifier for discarded drugs to aid in monitoring of drug waste and identification of potential issues in billing and reimbursement*

Response: NHIC does not concur with this recommendation. Though we currently permit this modifier to be used (and anecdotal claims history shows that some have), a *requirement* would imply penalties or sanctions for non-compliance. Since payment of the unavoidable wastage is allowed by CMS policy—whether on a single line (for the entire vial), or split into two claim lines to show the "actual" and "wastage" amounts - to require all providers to document wastage at the claim level would be nearly unenforceable, since:

a. *Wastage is not known from other claims-level information*, and the presence of a full vial dose (or a whole multiple of a vial) is not sufficient to assume that an additional JW claim line must occur and therefore must be investigated, and
b. *Obtaining accurate wastage information would require identifying and suspending each claims containing a "suspected" wastage amount* (e.g., a full-vial dose or a whole multiple of a vial), and then requesting information from each provider about whether any drug wastage had actually occurred, and how much. Since there would be no change in the net payment of the claim, the effort associated with this recommendation may not be cost effective.

We do understand that undocumented wastage could be construed as a program payment risk (it should be denied if undocumented—even though this still represents a cost to the physician practice), but feel that our ability to effectively enforce this may be limited.

Recommendation 3: M*onitor the use of the JW modifier and address any instances of potential noncompliance with discarded drug requirements*

Response: While we acknowledge the audit's intent to increase compliance with CMS expectations regarding physician practice documentation of Xolair drug wastage, NHIC does not concur with this recommendation, mostly for reasons expressed in our response to the second recommendation. Monitoring on a prepayment basis would introduce claims processing delays and likely denials for non-responsiveness (with the costs of processing a corrected claim, plus possible appeals or inquiries to Customer Service, etc.), while providing no net savings to the program nor the beneficiaries involved if the documentation was confirmed. Likewise, monitoring on a postpayment basis for this potential error may not be encompassed within our overall medical review strategy.