



Office of Audit Services, Region III
Public Ledger Building, Suite 316
150 S. Independence Mall West
Philadelphia, PA 19106-3499

August 2, 2010

Report Number: A-03-09-00014

Mr. David Vaughan
Program Manager, MAC Jurisdiction 12
Highmark Medicare Services, Inc.
1800 Center Street
Camp Hill, PA 17011

Dear Mr. Vaughan:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled *Medicare Part B Carrier Payments for Neulasta Injections in Pennsylvania for Calendar Years 2004 Through 2007*. We will forward a copy of this report to the HHS action official noted on the following page for review and any action deemed necessary.

The HHS action official will make final determination as to actions taken on all matters reported. We request that you respond to this official within 30 days from the date of this letter. Your response should present any comments or additional information that you believe may have a bearing on the final determination.

Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site. Accordingly, this report will be posted at <http://oig.hhs.gov>.

If you have any questions or comments about this report, please do not hesitate to call me at (215) 861-4470, or contact Bernard Siegel, Audit Manager, at (215) 861-4484 or through email at Bernard.Siegel@oig.hhs.gov. Please refer to report number A-03-09-00014 in all correspondence.

Sincerely,

/Bernard Siegel/ for
Stephen Virbitsky
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Nanette Foster Reilly
Consortium Administrator
Consortium for Financial Management & Fee for Service Operations (CFMFFSO)
Centers for Medicare & Medicaid Services
601 East 12th Street, Room 235
Kansas City, MO 64106

Department of Health & Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE PART B CARRIER
PAYMENTS FOR
NEULASTA INJECTIONS IN
PENNSYLVANIA FOR
CALENDAR YEARS 2004
THROUGH 2007**



Daniel R. Levinson
Inspector General

August 2010
A-03-09-00014

Office of Inspector General

<http://oig.hhs.gov>

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

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.

EXECUTIVE SUMMARY

BACKGROUND

Pursuant to Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance for people aged 65 and over and those who are disabled or have permanent kidney disease. The Centers for Medicare & Medicaid Services (CMS) administers the program.

Prior to October 1, 2005, section 1842(a) of the Act authorized CMS to contract with carriers. For purposes of this report, the term “Medicare contractor” means the fiscal intermediary, carrier, or Medicare administrative contractor, whichever is applicable.

Medicare contractors process and pay Medicare Part B claims submitted by physicians and medical suppliers (providers). Medicare contractors also review provider records to ensure proper payment and assist in applying safeguards against unnecessary utilization of services. To process providers’ Part B claims, Medicare contractors use the Medicare Multi-Carrier System and CMS’s Common Working File. These systems can detect certain improper payments during prepayment validation.

Individuals receiving chemotherapy often suffer from a low white blood cell count. Physicians inject patients with pegfilgrastim (Neulasta), usually in 6-milligram doses, to stimulate bone marrow and promote the growth of white blood cells. Prior to January 1, 2004, CMS assigned Healthcare Common Procedure Coding System (HCPCS) code Q4053 to Neulasta injections and defined one unit of service as 1 milligram. On January 1, 2004, CMS changed the HCPCS code for Neulasta to J2505 and defined one unit of service as 6 milligrams, which represented a standard dose.

Highmark Medicare Services (Highmark) was the Medicare Part B carrier for Pennsylvania. During calendar years (CY) 2004 through 2007, Highmark processed and paid more than 145 million Part B claims, of which 49,579 claims included Neulasta injections in Pennsylvania. On October 24, 2007, CMS named Highmark Medicare Services as the Medicare administrative contractor for jurisdiction 12, which includes the Part B carrier services for Pennsylvania.

OBJECTIVE

Our objective was to determine whether Medicare payments made by Highmark for Neulasta injections in Pennsylvania were appropriate.

SUMMARY OF FINDING

Medicare payments made by Highmark for Neulasta injections in Pennsylvania were not always appropriate. We found that Highmark paid four providers \$21,515 for 6 of the 25 payments reviewed when it should have paid \$10,913, an overpayment of \$10,602. All overpayments occurred for services performed during CY’s 2004 through 2007. At the time of our audit, these overpayments remained outstanding from the providers. During the audit, Highmark recovered additional overpayments totaling \$6,949 for four payments. For the remaining 15 payments, Highmark recovered overpayments prior to our audit.

Highmark made the overpayments because the providers incorrectly claimed excessive units of service on the 25 claims. In addition, the Medicare claim processing systems did not have sufficient edits in place to detect and prevent payments for this type of erroneous claim.

RECOMMENDATIONS

We recommend that Highmark:

- recover the \$10,602 in overpayments and verify that it had recovered additional overpayments totaling \$6,949 during the review, and
- consider including its Neulasta edit in the “Medically Unlikely Edits.”

HIGHMARK COMMENTS

As a result of the audit, Highmark recovered overpayments totaling \$17,551: \$10,602 as a result of the audit and \$6,949 during the audit. In addition, Highmark stated that it implemented a “Clinically Unlikely Edit” in June 2010 that will deny a claim when the billed quantity is greater than one. Highmark’s final comments are included in Appendix A and Highmark’s initial comments, without the enclosures, are included in Appendix B.

TABLE OF CONTENTS

	<u>Page</u>
INTRODUCTION	1
BACKGROUND	1
Medicare Part B Contractors.....	1
“Medically Unlikely Edits”	1
Payment for Neulasta.....	2
Highmark Medicare Services.....	2
OBJECTIVE, SCOPE, AND METHODOLOGY	2
Objective.....	2
Scope.....	2
Methodology.....	3
FINDING AND RECOMMENDATIONS	4
MEDICARE REQUIREMENTS	4
EXCESSIVE UNITS OF SERVICE	4
HIGHMARK SYSTEM EDITS	5
RECOMMENDATIONS	5
HIGHMARK COMMENTS	5
APPENDIXES	
A: HIGHMARK MEDICARE SERVICES FINAL COMMENTS	
B: HIGHMARK MEDICARE SERVICES INITIAL COMMENTS	

INTRODUCTION

BACKGROUND

Pursuant to Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance for people aged 65 and over and those who are disabled or have permanent kidney disease. The Centers for Medicare & Medicaid Services (CMS) administers the program.

Medicare Part B Contractors

Prior to October 1, 2005, section 1842(a) of the Act authorized CMS to contract with carriers.¹ Medicare contractors process and pay Medicare Part B claims submitted by physicians and medical suppliers (providers). Medicare contractors also review provider records to ensure proper payment and assist in applying safeguards against unnecessary utilization of services. To process Medicare Part B providers' claims, Medicare contractors use the Medicare Multi-Carrier System and CMS's Common Working File. These systems can detect certain improper payments during prepayment validation.

CMS guidance requires Medicare contractors to pay for certain drugs based on the published average sales price.² CMS guidance also requires providers to bill accurately and to report units of service as the number of times the provider performed a service or procedure. During CYs 2004 through 2007, providers nationwide submitted approximately 3.2 billion Part B claims, totaling over \$294 billion, to Medicare contractors. Of these, over 1 million claims included approximately \$1.7 billion for pegfilgrastim (Neulasta³) injections.

“Medically Unlikely Edits”

In January 2007, after our audit period, CMS required Medicare contractors to implement units-of-service edits referred to as “medically unlikely edits.” CMS designed these edits to detect and deny unlikely Medicare claims on a prepayment basis. According to the CMS *Medicare Program Integrity Manual*, Pub. No. 100-08, Transmittal 178, Change Request 5402, a “medically unlikely edit” tests claim lines for the same beneficiary, procedure code, date of service, and billing provider against a specified number of units of service. Medicare contractors must deny the entire claim line when the units of service billed exceed the specified number.

¹ Section 911 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. No. 108-173, required CMS to transfer the functions of fiscal intermediaries and carriers to Medicare administrative contractors between October 2005 and October 2011. Most, but not all, of the Medicare administrative contractors are fully operational; for jurisdictions where the Medicare administrative contractors are not fully operational, the fiscal intermediaries and carriers continue to process claims. For purposes of this report, the term “Medicare contractor” means the fiscal intermediary, carrier, or Medicare administrative contractors, whichever is applicable.

² In accordance with 42 CFR § 414.707(a)(1), the payment allowance limit in calendar year (CY) 2004 was 85 percent of the average wholesale price. However, beginning January 1, 2005, 42 CFR § 414.904(a) established the payment allowance limit as 106 percent of the average sales price.

³ Neulasta is Amgen's registered trademark for the medication pegfilgrastim.

Payment for Neulasta

Individuals receiving chemotherapy often suffer from a low white blood cell count. Physicians inject patients with Neulasta, usually in 6-milligram (mg) doses, to stimulate bone marrow and promote the growth of white blood cells. For Part B drugs, including Neulasta, Medicare contractors determine the provider payment amount as the lesser of the Part B drug fee schedule amount times the number of units billed or the claimed amount.

In 2003, CMS assigned the administration of Neulasta injections the Healthcare Common Procedure Coding System (HCPCS) code Q4053, which defined the unit size as 1 mg. Providers billed for six units because they usually administer the drug in 6-mg doses (generally from a pre-filled syringe). Beginning January 1, 2004, the HCPCS code changed to J2505 and identified a 6-mg dose as one unit.

CMS documented the new HCPCS code J2505 for Neulasta with changes to its *Medicare Claims Processing Manual*, Pub. No. 100-04. On December 24, 2003, CMS issued Transmittal 54, Change Request 3022, to Medicare contractors that defined a unit of service under HCPCS code J2505 as “injection, pegfilgrastim 6mg.” On May 12, 2006, CMS issued Transmittal 949, Change Request 4380, to Medicare contractors (fiscal intermediaries but not carriers) clarifying the billing procedures for Neulasta. The change request stated that “Claims for Pegfilgrastim J2505 [Neulasta] shall be submitted to Medicare contractors so that the units billed represent the number of multiples of 6MG provided, not the number of MGs.” Similarly, notification of the description of HCPCS code J2505 as one single dose of 6 mg was published three times in the Federal Register in 2004, beginning on January 6, 2004.

Highmark Medicare Services

Highmark Medicare Services (Highmark), which administers the Medicare program under contracting arrangements with CMS, was the Medicare Part B carrier for Pennsylvania. During CYs 2004 through 2007, Highmark processed and paid almost 145 million Part B claims, of which 49,579 claims included Neulasta injections in Pennsylvania. On October 24, 2007, CMS named Highmark Medicare Services (Highmark) as the Medicare administrative contractor for jurisdiction 12. Pennsylvania is part of jurisdiction 12.⁴

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether Medicare payments made by Highmark for Neulasta injections in Pennsylvania were appropriate.

Scope

We reviewed payments that Highmark processed and paid in Pennsylvania for Neulasta injections provided to Medicare patients during CYs 2004 through 2007. We limited our review

⁴ Highmark’s headquarters is located in Camp Hill, Pennsylvania.

of Highmark's internal controls to those applicable to processing and paying for Neulasta injections because our objective did not require an understanding of all internal controls over the submission of claims. 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.⁵

We performed our fieldwork from August 2009 through May 2010. Our fieldwork included contacting Highmark, located in Camp Hill, Pennsylvania, and 16 providers in Pennsylvania that received payments for Neulasta injections.

Methodology

To accomplish our objective, we:

- reviewed applicable Medicare laws, regulations, and guidance;
- used CMS's National Claims History file to identify Part B claims for Neulasta injections for two or more units of service with a paid amount greater than \$2,006 that were not reviewed in other audits;
- identified 25 claims with Neulasta injections totaling \$86,382 that were provided by 16 physicians to 21 Medicare patients;
- reviewed available Common Working File data for the 25 claims to determine whether the claims had been canceled and superseded by revised claims and whether the payments remained outstanding at the time of our audit;
- analyzed Common Working File data for canceled claims for which revised claims had been submitted to determine whether the provider received overpayments for the initial claims;
- contacted providers to determine whether claims for Neulasta were billed correctly and, if not, why the claims were billed incorrectly; and
- coordinated our claim review, including a review of system edits and manual processing controls, and the calculation of any overpayments, with Highmark.

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 objective.

⁵ When the Common Working File history was not available due to the age of the claim, we obtained a claim history from Highmark that contained comparable information.

FINDING AND RECOMMENDATIONS

Medicare payments made by Highmark for Neulasta injections in Pennsylvania were not always appropriate. We found that Highmark paid four providers \$21,515 for 6 of the 25 payments reviewed when it should have paid \$10,913, an overpayment of \$10,602.⁶ At the time of our audit, these overpayments remained outstanding from the providers. During the audit, Highmark recovered additional overpayments totaling \$6,949 for four payments. For the remaining 15 payments, Highmark recovered overpayments prior to our audit.

Highmark made the overpayments because the providers incorrectly claimed excessive units of service on the 25 claims. In addition, the Medicare claim processing systems did not have sufficient edits in place to detect and prevent payments for this type of erroneous claim.

MEDICARE REQUIREMENTS

CMS's *Carriers Manual*, Pub. No. 14, part 2, section 5261.1, requires that Medicare contractors process claims accurately in accordance with Medicare program laws, regulations, and instructions. Section 5261.3 of the manual requires Medicare contractors to develop a medical review program that "effectively and continually analyzes data that identifies aberrancies, emerging trends and areas of potential abuse, overutilization or inappropriate care and focusing on areas where the trust fund is most at risk, i.e., highest volume and/or highest dollar codes."

CMS's *Medicare Claims Processing Manual*, Pub. No. 100-04, chapter 17, section 20, requires Medicare contractors to pay for certain drugs based on the published average sales price. The maximum allowable payment equals the lesser of the Part B drug fee schedule amount times the number of units billed or the claimed amount. The Medicare contractor pays the provider 80 percent of the payment amount; the beneficiary pays the remaining 20 percent.

EXCESSIVE UNITS OF SERVICE

Highmark overpaid \$10,602 for six claims for excessive units of service incorrectly billed by four Pennsylvania providers. For two of the six claims, one provider incorrectly billed for six units of service rather than one unit of service for 6 mg of Neulasta. For the remaining four claims, three providers incorrectly billed for two units of service rather than one unit of service.

Prior to our audit, Highmark identified and recovered overpayments for 15 of the 25 payments we reviewed. For the remaining four payments, providers billed and Medicare paid for two units of Neulasta; however, Highmark recovered \$6,949, the amount Medicare paid for the second units billed.

The providers attributed the incorrectly billed quantities to the change in the Medicare payment methodology beginning January 1, 2004. The providers knew or should have known that the claims were billed in error because they exceeded the maximum allowable payment for a 6-mg dose of Neulasta by \$1,729 to \$1,834.

⁶ All overpayments occurred for services performed during CYs 2004 and 2007.

Highmark paid claims for excessive units of service because it did not have edits in place to ensure that the units of Neulasta billed corresponded to the units administered.

HIGHMARK SYSTEM EDITS

In January 2007, CMS required Medicare contractors to implement units-of-service edits referred to as “medically unlikely edits.” These edits detect and deny unlikely Medicare claims on a prepayment basis by testing claim lines for the same beneficiary, procedure code, date of service, and billing provider against a specified number of units of service. However, the medically unlikely edits did not include Neulasta injections. Highmark stated that sometime during CY 2004,⁷ it implemented a system edit that suspended all claims for which the provider billed for more than two units of Neulasta.

Prior to our audit, Highmark performed medical reviews of some Neulasta injection claims and recovered overpayments for 11 of the 25 claims included in our review. For seven of the claims, the provider billed for excessive units of service; for four claims, Highmark determined that medical records did not support the units of service billed.

RECOMMENDATIONS

We recommend that Highmark:

- recover the \$10,602 in overpayments and verify that it had recovered additional overpayments totaling \$6,949 during the review, and
- consider including its Neulasta edit in the “Medically Unlikely Edits.”

HIGHMARK COMMENTS

As a result of the audit, Highmark recovered overpayments totaling \$17,551: \$10,602 as a result of the audit and \$6,949 during the audit.⁸ In addition, Highmark stated that it implemented a “Clinically Unlikely Edit” in June 2010 that will deny a claim when the billed quantity is greater than one. Highmark’s final comments are included in Appendix A and Highmark’s initial comments, without the enclosures, are included in Appendix B.

⁷ Highmark was unable to identify the specific date when it implemented its Neulasta edit.

⁸ Although Highmark’s comments stated that the overpayments of \$6,949 related to five claims, they actually related to only four claims. Highmark’s comments stated that it processed 14 payments correctly; however, Highmark had recovered overpayments for these 14 payments, plus an additional payment, prior to our review.

APPENDIXES

APPENDIX A: HIGHMARK MEDICARE SERVICES FINAL COMMENTS



July 21, 2010

Mr. Stephen Virbitsky
Regional Inspector General
Office of Audit Service, Region III
Public Ledger Building, Suite 316
150 S. Independence Mall West
Philadelphia, PA 19106-3499

Re: Report Number A-03-09-00014

Dear Mr. Virbitsky:

We initially provided information relative to the referenced report on June 3, 2010. Subsequent discussions have transpired with [REDACTED] OIG, and have served to clarify and delineate details pertaining to the adjustment and recovery processes. As a result of acting upon the report recommendations, we recovered \$10,601.93 associated with six (6) claims. Five (5) additional claims representing \$6,948.92 in payments were recovered previously. The remaining fourteen (14) claims were processed correctly so recovery activity was not necessary.

Please contact Barshaunna Windom (717-302-3614) or me if you have further inquiry.

Sincerely,

A handwritten signature in black ink, appearing to read "David B. Vaughan", written in a cursive style.

David B. Vaughan
Vice President & J12 Project Manager
Highmark Medicare Services Inc.

APPENDIX B: HIGHMARK MEDICARE SERVICES INITIAL COMMENTS



June 8, 2010

RE: Report Number A-03-09-00014

Mr. Stephen Virbitsky
Regional Inspector General
Office of Audit Service, Region III
Public Ledger Building, Suite 316
150 S. Independence Mall West
Philadelphia, PA 19106-3499

Dear Mr. Virbitsky,

In response to your letter dated May 27, 2010, regarding the draft report number A-03-09-00014, *Medicare Part B Carrier Payments for Neulasta Injections in Pennsylvania for Calendar Years 2004 through 2007*, please consider our written comments concerning the reports' recommendations.

In response to the recommendation to recover the \$10,602 overpayments that were made in Pennsylvania; 22 of the 25 claims in which overpayments occurred were reopened per provider request resulting in a recovery amount of \$4,584. The remaining claims are outside of the four year timeframe guidance provided in 42 CFR 405.980 *Reopenings of initial determinations redeterminations, and reconsiderations, hearings and reviews* (Enclosure (1)).

In response to the recommendation to include the Neulasta edit in the "Medically Unlikely Edits;" the Highmark Medicare Services, Medicare Integrity Program Committee met on June 2, 2010 to review recommended edits and approved the Neulasta procedure code J2505 as a Clinically Unlikely Edit (see enclosure (2)). Implementation of the edit is expected by the end of June 2010.

If there are any other questions or concerns, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "David Vaughan", is written over a printed name and title.

David Vaughan
Vice President, Operations & J12 Project Manager

Enclosures