



Office of Audit Services, Region III
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Philadelphia, PA 19106-3499

July 9, 2010

Report Number: A-03-09-00015

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 Maryland 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-03-09-00015 in all correspondence.

Sincerely,

/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
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Department of Health & Human Services

**OFFICE OF
INSPECTOR GENERAL**

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



Daniel R. Levinson
Inspector General

July 2010
A-03-09-00015

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.

TrailBlazer Health Enterprises, LLC (TrailBlazer), was the Medicare Part B carrier for Maryland. During calendar years (CY) 2004 through 2007, TrailBlazer processed and paid almost 47 million Part B claims, of which 13,844 claims included Neulasta injections in Maryland. 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 Maryland. Although Highmark did not process or pay any of the claims reviewed, it is responsible for resolving any issues identified in the report.

OBJECTIVE

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

SUMMARY OF FINDING

Medicare payments made by TrailBlazer for Neulasta injections in Maryland were not always appropriate. TrailBlazer paid two providers \$66,212 for 20 payments reviewed when it should have paid \$34,330, an overpayment of \$31,882. All overpayments occurred for services performed during CYs 2004 and 2005. TrailBlazer reversed one overpayment of \$1,806 prior to our audit because the provider notified the carrier of the error. However, at the time of our audit, 19 overpayments totaling \$30,076 remained outstanding from one provider.

TrailBlazer made these overpayments because the providers incorrectly claimed excessive units of service on 20 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 \$30,076 in overpayments and
- consider including its Neulasta edit in the “Medically Unlikely Edits.”

HIGHMARK COMMENTS

As a result of the audit, the one provider with overpayments for 19 claims requested that Highmark reopen the claims for adjustment. Highmark recovered \$32,259 (\$30,076 plus interest). 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 comments, without the enclosures, are included in the Appendix.

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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 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 carriers. Of these, over 1 million claims included approximately \$1.7 billion for pegfilgrastim (Neulasta³) injections.

“Medically Unlikely Edits”

In January 2007, during 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, fiscal intermediaries and carriers continue to process claims. For purposes of the report, the term “Medicare contractor” means fiscal intermediary, carrier, or Medicare administrative contractor, 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. 100-4. 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.

TrailBlazer Health Enterprises, LLC, and Highmark Medicare Services

TrailBlazer Health Enterprises, LLC (TrailBlazer), which administered the Medicare program under contracting arrangements with CMS, was the Medicare Part B carrier for Maryland. During CYs 2004 through 2007, TrailBlazer processed and paid almost 47 million Part B claims, of which 13,844 claims included Neulasta injections in Maryland. In December 2005, TrailBlazer implemented a system edit that suspended all claims for Neulasta when the provider billed for more than one unit.

On October 24, 2007, CMS named Highmark Medicare Services (Highmark) as the Medicare administrative contractor for jurisdiction 12.⁴ Maryland is part of jurisdiction 12. Although Highmark did not process or pay any of the claims reviewed, it is responsible for resolving any issues identified in the report.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

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

⁴ Highmark, with headquarters located in Camp Hill, Pennsylvania, did not begin processing carrier claims for Maryland until March 2008.

Scope

We reviewed payments that TrailBlazer processed and paid in Maryland for Neulasta injections provided to Medicare patients during CYs 2004 through 2007. We limited our review of the carriers' 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 through September 2009. Our fieldwork included contacting Highmark, located in Camp Hill, Pennsylvania, and two providers in Maryland 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 six or more units of service with a paid amount greater than \$2,006 not reviewed in other audits;
- identified 20 claims with Neulasta injections totaling \$66,212 that were provided by two physicians to nine Medicare patients;
- reviewed available Common Working File data for the 20 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

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.

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.

FINDING AND RECOMMENDATIONS

Medicare payments made by TrailBlazer for Neulasta injections in Maryland were not always appropriate. TrailBlazer paid two providers \$66,212 for 20 payments reviewed when it should have paid \$34,330, an overpayment of \$31,882.⁶ TrailBlazer reversed one overpayment of \$1,806 prior to our audit because the provider notified the carrier of the error. However, at the time of our audit, 19 overpayments totaling \$30,076 remained outstanding from one provider.

TrailBlazer made these overpayments because the providers incorrectly claimed excessive units of service on 20 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

TrailBlazer overpaid \$31,882 for 20 claims for excessive units of service incorrectly billed by two Maryland providers. For each of the 20 claims, the providers incorrectly billed for six units of service rather than one unit of service for 6 mg of Neulasta. At the time of our audit, 19 overpayments totaling \$30,076 remained outstanding from one provider.

One provider notified the carrier of the error before our audit and TrailBlazer reversed the overpayment of \$1,806. The other provider attributed the incorrectly billed quantities to the change in the Medicare payment methodology beginning January 1, 2004. The provider knew or should have known that the claims were billed in error because they each exceeded the maximum allowable payment for a 6-mg dose of Neulasta by \$1,061 to \$1,698.

TrailBlazer paid the 20 payments for excessive units of service because it did not have edits in place during CYs 2004 or 2005 to ensure that the units of Neulasta billed corresponded to the units administered.

⁶ All overpayments occurred for services performed during CYs 2004 and 2005.

TRAILBLAZER AND HIGHMARK SYSTEM EDITS

In December 2005, TrailBlazer implemented a system edit that suspended all claims for Neulasta when the provider billed for more than one unit. All of the overpayments identified in our review occurred for services performed before CY 2006.

Although 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, Highmark did not begin processing claims for Maryland until March 2008.

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.

RECOMMENDATIONS

We recommend that Highmark:

- recover the \$30,076 in overpayments and
- consider including its Neulasta edit in the “Medically Unlikely Edits.”

HIGHMARK COMMENTS

As a result of the audit, the one provider with overpayments for 19 claims requested that Highmark reopen the claims for adjustment. Highmark recovered \$32,259 (\$30,076 plus interest). 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. Although Highmark refers to a “remaining claim,” TrailBlazer had collected the overpayment for that claim prior to our audit. Highmark’s comments, without the enclosures, are included in the Appendix.

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

APPENDIX

APPENDIX: HIGHMARK MEDICARE SERVICES COMMENTS



June 8, 2010

RE: Report Number A-03-09-00015

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 12, 2010, regarding the draft report number A-03-09-00015, *Medicare Part B Carrier Payments for Neulasta Injections in Maryland for Calendar Years 2004 through 2007*, please consider our written comments concerning the reports' recommendations.

In response to the recommendation to recover the \$30,076 overpayments that were made in Maryland; 19 of the 20 claims in which overpayments occurred were reopened per provider request resulting in a recovery amount of \$32,259. The remaining claim is 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", with a long horizontal flourish extending to the right.

David Vaughan
Vice President, Operations & J12 Project Manager

Enclosures