



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Office of Audit Services, Region IX
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

October 5, 2010

Report Number: A-09-10-02042

Mr. Mike Barlow
Vice President
Palmetto GBA
4249 Easton Way, Suite 400
Columbus, OH 43219

Dear Mr. Barlow:

Enclosed is the U.S. Department of Health & Human Services (HHS), Office of Inspector General (OIG), final report entitled *Review of Medicare Part B Carrier Payments for Neulasta Injections in California and Hawaii 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 Lorralli Herrera, Senior Auditor, at (619) 557-6131, extension 105, or through email at Lorralli.Herrera@oig.hhs.gov, or contact Alice Norwood, Audit Manager, at (415) 437-8360 or through email at Alice.Norwood@oig.hhs.gov. Please refer to report number A-09-10-02042 in all correspondence.

Sincerely,

Lori A. Ahlstrand
Regional Inspector General
for Audit Services

Enclosure

Direct Reply to HHS Action Official:

Ms. Nanette Foster Reilly
Consortium Administrator
Consortium for Financial Management & Fee for Service Operations
Centers for Medicare & Medicaid Services
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Department of Health & Human Services

**OFFICE OF
INSPECTOR GENERAL**

**REVIEW OF MEDICARE PART B
CARRIER PAYMENTS FOR
NEULASTA INJECTIONS IN
CALIFORNIA AND HAWAII FOR
CALENDAR YEARS
2004 THROUGH 2007**



Daniel R. Levinson
Inspector General

October 2010
A-09-10-02042

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.

Before 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 Claims 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. Providers inject patients with pegfilgrastim (Neulasta), usually in 6-milligram doses, to stimulate bone marrow and promote the growth of white blood cells. Before January 1, 2004, CMS assigned Healthcare Common Procedure Coding System (HCPCS) code Q4053 to Neulasta injections and defined one service unit as 1 milligram. Effective January 1, 2004, CMS changed the HCPCS code for Neulasta to J2505 and defined one service unit as 6 milligrams, which represented a standard dose.

During calendar years (CY) 2004 through 2007, National Heritage Insurance Company (NHIC) and Noridian Mutual Insurance Company (Noridian) were the Medicare Part B carriers for California and Hawaii, respectively. During this period, NHIC and Noridian processed and paid more than 292 million Part B claims, of which 75,587 claims included Neulasta injections in these two States. In September 2008, Palmetto GBA (Palmetto) assumed full responsibility as the Medicare administrative contractor for Jurisdiction 1, which includes California and Hawaii. Although Palmetto did not process or pay any of the claims we reviewed in our audits of selected providers, it is responsible for resolving any issues identified in this report.

OBJECTIVE

Our objective was to consolidate the results of our reviews of seven selected Medicare Part B providers in California and Hawaii that billed Medicare for Neulasta injections. Those reviews determined whether the seven providers billed Medicare for the correct number of service units of Neulasta.

SUMMARY OF RESULTS

For 105 Medicare claims reviewed, 7 providers in California and Hawaii billed Medicare for the incorrect number of service units of Neulasta. Consequently, during CYs 2004 through 2007, NHIC and Noridian paid these providers \$398,704 instead of \$204,751, resulting in overpayments totaling \$193,953. NHIC and Noridian made these overpayments because the providers billed for more than one service unit for every 6 milligrams of Neulasta administered.

RECOMMENDATION

We recommend that Palmetto consider reviewing Neulasta claims with the incorrect number of service units that were not part of this review.

PALMETTO COMMENTS

In its comments on our draft report, Palmetto concurred with the results of our reviews at the seven providers in California and Hawaii and stated that it will take our recommendation under advisement. Palmetto's comments are included in their entirety as 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

Before 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 providers' Part B claims, Medicare contractors use the Medicare Multi-Carrier Claims 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 that 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 claims, over 1 million claims for pegfilgrastim (Neulasta)³ injections resulted in payments of approximately \$1.7 billion.

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 (December 8, 2006), a "medically unlikely edit" tests claim lines for the same beneficiary, procedure code, date of service, and billing provider against a specified number of service units. Medicare contractors must deny the entire claim line when the service units 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 the fiscal intermediary, carrier, or Medicare administrative contractor, whichever is applicable.

² Pursuant to 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. Providers inject patients with Neulasta, usually in 6-milligram 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 milligram. Providers billed for six units because they usually administer the drug in 6-milligram doses (generally from a prefilled syringe). Effective January 1, 2004, the HCPCS code changed to J2505 and identified a 6-milligram 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 service unit under HCPCS code J2505 as “injection, pegfilgrastim [Neulasta] 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: “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 dose of 6 milligrams was published three times in the Federal Register in 2004, beginning on January 6, 2004.

Medicare Contractors for California and Hawaii

During CYs 2004 through 2007, National Heritage Insurance Company (NHIC) and Noridian Mutual Insurance Company (Noridian), which administered the Medicare program under contracting arrangements with CMS, were the Medicare Part B carriers for California and Hawaii, respectively. During this period, NHIC and Noridian processed and paid more than 292 million Part B claims, of which 75,587 claims included Neulasta injections in these two States.

In September 2008, Palmetto GBA (Palmetto) assumed full responsibility as the Medicare administrative contractor for Jurisdiction 1. California and Hawaii are part of Jurisdiction 1. Although Palmetto did not process or pay any of the claims we reviewed as part of our audits of selected providers, it is responsible for resolving any issues identified in this report.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to consolidate the results of our reviews of seven selected Medicare Part B providers in California and Hawaii that billed Medicare for Neulasta injections. Those reviews determined whether the seven providers billed Medicare for the correct number of service units of Neulasta.

Scope

To select the providers, we identified paid Medicare Part B claims for Neulasta injections for which providers billed more than one service unit and had potential overpayments greater than \$5,000. We identified and reviewed 105 claims billed by 7 providers in California and Hawaii that NHIC and Noridian processed and paid during CYs 2004 through 2007.

We did not review the seven providers' internal controls because our objective did not require an understanding of controls over the submission of claims. However, we performed a limited review of internal controls applicable to the processing and paying of claims for Neulasta injections at the current Medicare contractor, Palmetto. Our review allowed us to establish reasonable assurance of the authenticity and accuracy of the data obtained from CMS's National Claims History file, but we did not assess the completeness of the file.

We conducted our fieldwork from February to October 2009, which included contacting the seven providers in California and Hawaii that received payments for Neulasta injections. In addition, we contacted officials from Palmetto located in Columbus, Ohio, from March through August 2010.

Methodology

To determine whether the selected providers billed Medicare for the correct number of service units of Neulasta, we:

- reviewed applicable Medicare laws, regulations, and guidance;
- used CMS's National Claims History file to identify paid Medicare Part B claims with more than one service unit of Neulasta that had not been reviewed in other audits;
- contacted the providers to determine whether the service units of Neulasta were billed correctly and, if not, why the service units were billed incorrectly;
- reviewed Medicare claim forms, patient medical records, and providers' additional supporting documentation that supported the identified claims;
- used the Medicare Part B drug fee schedules, published by CMS, to calculate overpayments identified in CYs 2004 and 2005; and
- confirmed with the providers that overpayments occurred.

We issued a restricted report to each of the seven providers in November and December 2009.

We also interviewed staff from Palmetto to determine whether it had issued guidance to its providers and had any policies, system edits, or other claims processing controls to prevent overpayments for Neulasta.

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.

RESULTS OF REVIEWS AND RECOMMENDATION

For 105 Medicare claims reviewed, 7 providers in California and Hawaii billed Medicare for the incorrect number of service units of Neulasta. Consequently, during CYs 2004 through 2007, NHIC and Noridian paid these providers \$398,704 instead of \$204,751, resulting in overpayments totaling \$193,953.⁴ NHIC and Noridian made these overpayments because the providers billed for more than one service unit for every 6 milligrams of Neulasta administered.

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 maximum allowable payment amount; the beneficiary pays the remaining 20 percent.

CMS's Transmittal 54, Change Request 3022, defined a service unit under HCPCS code J2505 as "injection, pegfilgrastim [Neulasta] 6mg." Therefore, during our audit period, for every 6 milligrams of pegfilgrastim administered to a patient, providers should have billed Medicare for one service unit. The transmittal instructed Medicare contractors to inform providers of this requirement.

INCORRECT NUMBER OF SERVICE UNITS BILLED

For all 105 claims reviewed, the 7 providers billed Medicare for the incorrect number of service units of Neulasta. Rather than billing one service unit for every 6 milligrams of Neulasta administered, as Medicare required, providers billed more than one service unit for every 6 milligrams. Specifically, for 93 of the 105 claims, 6 providers incorrectly billed for 6 service units rather than 1 service unit for every 6 milligrams of Neulasta. For the 12 remaining claims, 1 provider billed for 10 service units rather than 1 service unit for every 6 milligrams of

⁴ All overpayments were for services provided during CYs 2004 and 2005.

Neulasta. Consequently, NHIC and Noridian paid these providers \$398,704 instead of \$204,751, resulting in overpayments totaling \$193,953.

The table below summarizes the results for all seven providers reviewed.

Neulasta Overpayments at the Seven Providers

Provider	State	Calendar Year(s)	No. of Claims	Medicare Payment	Correct Payment	Overpayment
1	CA	2004–2005	13	\$108,890	\$25,704	\$83,186
2	CA	2005	12	62,400	19,949	42,451
3	CA	2004–2005	49	123,844	96,915	26,929
4	CA	2004	13	41,418	26,078	15,340
5	CA	2004	4	18,893	8,024	10,869
6	CA	2004	5	17,040	10,030	7,010
7	HI	2004	9	26,219	18,051	8,168
Total			105	\$398,704	\$204,751	\$193,953

All seven providers agreed with our findings that they billed for the incorrect number of service units of Neulasta and refunded the overpayments to Medicare. The providers attributed the incorrect billing primarily to the change in the number of milligrams per service unit of Neulasta from 1 milligram to 6 milligrams.

MEDICARE SYSTEM EDITS

The medically unlikely edits that CMS required Medicare contractors to use starting in January 2007 did not include Neulasta injections. Therefore, during our audit period, NHIC and Noridian processed claims submitted by providers for more than one service unit of Neulasta.⁵

RECOMMENDATION

We recommend that Palmetto consider reviewing Neulasta claims with the incorrect number of service units that were not part of this review.

PALMETTO COMMENTS

In its comments on our draft report, Palmetto concurred with the results of our reviews at the seven providers in California and Hawaii and stated that it will take our recommendation under advisement. Palmetto's comments are included in their entirety as the Appendix.

⁵ In October 2006, Palmetto implemented a system edit that suspended all claims for which the provider billed for more than one unit of Neulasta.

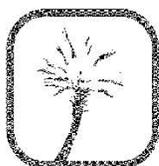
OTHER MATTER

We reviewed CMS's National Claims History file to determine whether there were paid Medicare Part B claims with more than one service unit of Neulasta after our audit period. We identified one claim for a California provider that billed Medicare for more than one service unit in May 2008 with potential overpayments greater than \$5,000. Based on the Medicare Part B drug fee schedules published by CMS, we estimate that this provider received approximately \$7,000 in potential overpayments for five service units of Neulasta.

In its comments on our draft report, Palmetto provided information on actions taken to recoup the overpayment for this claim.

APPENDIX

APPENDIX: PALMETTO GBA COMMENTS



Palmetto GBA

Mike Barlow

September 29, 2010

Lori A. Ahlstrand
Regional Inspector General for Audit Services
Office of Audit Services, Region IX
90 – 7th Street, Suite 3-650
San Francisco, CA 94103

Re: Draft Report number: A-09-10-02042

Dear Ms. Ahlstrand,

We have reviewed the letter dated September, 2010 detailing the draft report entitled *Review of Medicare Part B Carrier Payments for Neulasta Injections in California and Hawaii for calendar Years 2004 through 2007*.

We understand the objective of the audit was to determine whether seven selected providers billed Medicare for the correct number of service units of Neulasta. During the selection period of calendar years 2004 through 2007, the National Heritage Insurance Company (NHIC) and Noridian Mutual Insurance Company (Noridian) for California and Hawaii were the Medicare Part B carriers for California and Hawaii respectively. In September 2008, Palmetto GBA assumed full responsibility as the Medicare Administrative Contractor for Jurisdiction I, which includes California and Hawaii.

Based upon your review, NHIC and Noridian processed and paid more than 292 million Part B claims, of which 75,587 claims included Neulasta injections in these two states. The review concluded that NHIC and Noridian paid 7 providers \$398,704 instead of \$204,751, resulting in overpayments totaling \$193,953. Palmetto GBA concurred with these findings at the time. The 7 providers identified during the review were contacted by the OIG and the providers agreed with the findings and refunded the overpayments to Medicare. We understand your recommendation to consider reviewing additional Neulasta claims with the incorrect number of service units and will take this under advisement. The claims and history for the period in question have been purged from the Medicare claims system and will require significant effort.

The one additional California claim outside the review period identified by the OIG as a potential overpayment greater than \$5,000 has been referred to the Palmetto GBA financial department for recoupment of the overpayment.

Palmetto GBA has maintained edits and other processing controls since 2006 to ensure appropriate payments of Neulasta injections, HCPCS Code J2505 fro the claims it processed for payment. Upon the transition of the J1 workload from NHIC and Noridian in the 3rd quarter of FY 2008, the edit for the Neulasta J code caused any claim submitted to be systematically

Ahlstrand
September 29, 2010

rejected as unprocessable when submitted with a quantity greater than one (1) unit. Effective July 7, 2010, the code was added to the CMS controlled Medical Unlikely Editing (MUE) and now systemically denies when more than one unit is submitted per claim line. In addition, Palmetto has a Local Coverage Decision (LCD 28259) in place for additional medical coverage review.

Feel free to contact me or Ms. Glenda Piatt at (740) 574-4089 with any questions.

Sincerely,

Mike
Barlow

Mike Barlow
Palmetto GBA
Vice President
J1 Project Manager