

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**PROVIDERS DID NOT CORRECTLY BILL
MEDICARE PART B FOR THE ORAL FORM
OF THE DRUG EMEND**

*Inquiries about this report may be addressed to the Office of Public Affairs at
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Deputy Inspector General

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Office of Inspector General

<https://oig.hhs.gov>

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

EXECUTIVE SUMMARY

BACKGROUND

Pursuant to Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance coverage to people aged 65 and over, people with disabilities, and people with permanent kidney disease. The Centers for Medicare & Medicaid Services (CMS), which administers the program, contracts with Medicare administrative contractors (Medicare contractors) to process and pay Medicare claims submitted for outpatient services. The Medicare contractors use the Fiscal Intermediary Standard System and CMS's Common Working File (CWF) to process claims. The CWF can detect certain improper payments during prepayment validation.

Medicare guidance requires providers to submit accurate claims to Medicare contractors for outpatient services. Each submitted Medicare claim contains details about each provided service (called a line item in this report).

This report focuses on aprepitant, one of three drugs in a regimen of oral anti-emetic drugs that are prescribed to help reduce nausea and vomiting in chemotherapy patients. In this report we refer to aprepitant by its brand name, Emend. The second anti-emetic drug in this regimen, called a 5-HT₃ antagonist, also helps reduce nausea and vomiting. The third anti-emetic drug, dexamethasone, is an anti-inflammatory and immunosuppressant.

Prior to the Balanced Budget Act of 1997, Medicare Part B covered anti-emetic drugs that were administered intravenously, but it did not cover anti-emetic drugs that were administered orally. The Balanced Budget Act of 1997 amended the Act to provide coverage under Medicare Part B for oral anti-emetic drugs that are approved by the Food and Drug Administration and administered under certain conditions. The revised section of the Act generally authorizes Medicare contractors to pay providers if the oral anti-emetic drug was administered under an anticancer chemotherapy regimen and prescribed as a full replacement for other anti-emetic drugs that would have been administered intravenously.

CMS stated, in a National Coverage Determination, that a three-drug oral anti-emetic regimen consisting of Emend, a 5-HT₃ antagonist, and dexamethasone meets the "reasonable and necessary" standard for Medicare Part B payment only when prescribed for beneficiaries who are also receiving at least one of nine specified anticancer chemotherapeutic agents.

CMS guidance in the *Medicare Claims Processing Manual* states that, for the oral form of Emend to be payable as an outpatient service under Medicare Part B, providers must administer or prescribe the oral three-drug regimen described above, along with at least one of the nine specified anticancer chemotherapeutic agents, for use immediately before, at, or within 48 hours of administering the anticancer chemotherapeutic agent. CMS guidance also states that the oral anti-emetic drugs must fully replace anti-emetic intravenous therapy and, for drugs billed to the Medicare contractor, be billed on the same claim for Emend to be allowable for a Medicare Part B payment.

For calendar year (CY) 2010, Medicare contractors paid 725 providers a total of \$3,410,359 under Medicare Part B for the oral form of Emend. Five providers, who received the highest amounts of payments on claims for the oral form of Emend, billed 3,555 line items and were paid \$923,003 under Medicare Part B. For these 5 providers, we reviewed 2,105 billed line items totaling \$580,626 that were paid by Medicare contractors under Medicare Part B. (A single Medicare claim from a provider typically includes more than one line item. In this audit, we did not review entire claims; rather, we reviewed specific line items on claims for the oral form of Emend.)

OBJECTIVE

Our objective was to determine whether providers correctly billed Medicare Part B for the oral form of Emend.

SUMMARY OF FINDINGS

In general, the five selected providers that we reviewed did not correctly bill Medicare Part B for the oral form of Emend. Of the 2,105 selected line items for which Medicare contractors made payments to providers for the oral form of Emend during CY 2010, only 193 were correct. The remaining 1,912 line payment amounts were incorrect because providers did not bill for all of the required drugs in the regimen on the same claim as required; these errors resulted in overpayments totaling \$530,769. (During our fieldwork, the five selected providers informed us that they had returned the overpayments after we showed them the improper payments.)

The five selected providers billed incorrectly because they were not aware of the Federal requirements for the three-drug oral anti-emetic regimen until we made them aware of them during our fieldwork. The Medicare contractors made incorrect payments because the CWF did not have sufficient edits in place during our audit period to prevent or detect the overpayments in cases where providers did not bill, on the same claim, all of the required drugs in the regimen.

RECOMMENDATIONS

We recommend that CMS:

- verify that the \$530,769 in identified overpayments made to the five selected providers has been refunded to the Federal Government;
- direct the five selected providers to review the remaining CY 2010 line items on claims for the oral form of Emend that were not reviewed as part of this audit, as well as all subsequent claims, and refund any overpayments;
- develop and implement system edits to prevent payments for the oral form of Emend when providers do not bill for all of the required drugs in the regimen on the same claim; and
- use the results of this audit to educate providers.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS concurred with three of our four recommendations and described corrective actions that it had taken or planned to take.

CMS did not concur with our third recommendation, pointing to instances when a patient may already be receiving the oral 5-HT₃ antagonist and dexamethasone at home for emesis (that is, nausea and vomiting) related to the cancer but not related to chemotherapy. In such cases, CMS stated, “it is likely that any edit would not in fact identify erroneous billing.” CMS added that it would continue to investigate this issue and would provide an update on its planned course of action at a later date.

CMS’s comments are included in their entirety as the Appendix.

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing CMS’s comments, we maintain that all of our findings and recommendations remain valid. According to CMS guidance, for an oral anti-emetic drug such as Emend to be allowable under Medicare Part B, it must be billed on the same claim as the other drugs in the prescribed regimen. Although CMS raises important clinical issues in its comments on our draft report, we maintain that an edit is appropriate to prevent improper Medicare Part B payments for the oral form of Emend when providers do not bill in accordance with CMS’s instructions. We support CMS’s continued evaluation of this issue and look forward to receiving an update on CMS’s planned course of action in the future.

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INTRODUCTION

BACKGROUND

Medicare Program

Pursuant to Title XVIII of the Social Security Act (the Act), the Medicare program provides health insurance coverage to people aged 65 and over, people with disabilities, and people with permanent kidney disease. The Centers for Medicare & Medicaid Services (CMS), which administers the program, contracts with Medicare contractors to process and pay Medicare claims submitted for outpatient services. The Medicare contractors use the Fiscal Intermediary Standard System and CMS's Common Working File (CWF) to process claims. The CWF can detect certain improper payments during prepayment validation.

Medicare guidance requires providers to submit accurate claims to Medicare contractors for outpatient services. Each submitted Medicare claim contains details about each provided service (called a line item in this report).

Medicare Part B Coverage of Oral Anti-emetic Drugs

This report focuses on aprepitant, one of three drugs in a regimen of oral anti-emetic drugs that are prescribed to help reduce nausea and vomiting in chemotherapy patients. In this report we refer to aprepitant by its brand name, Emend. The second anti-emetic drug in this regimen, called a 5-HT₃ antagonist, also helps reduce nausea and vomiting. The third anti-emetic drug, dexamethasone, is an anti-inflammatory and immunosuppressant.

Prior to the Balanced Budget Act of 1997, Medicare Part B covered anti-emetic drugs that were administered intravenously, but it did not cover anti-emetic drugs that were administered orally. The Balanced Budget Act of 1997, P.L. No. 105-33, amended section 1861(s)(2) of the Act to provide coverage under Medicare Part B for oral anti-emetic drugs that are approved by the Food and Drug Administration and administered under certain conditions. This section of the Act generally authorizes Medicare contractors to pay providers if the oral anti-emetic drug was administered under an anticancer chemotherapy regimen and prescribed as a full replacement for other anti-emetic drugs that would have been administered intravenously.

CMS stated, in a National Coverage Determination (CAG-00248N, April 4, 2005), that a three-drug oral anti-emetic regimen consisting of Emend, a 5-HT₃ antagonist, and dexamethasone meets the "reasonable and necessary" standard for Medicare Part B payment only when prescribed for beneficiaries who are also receiving at least one of nine specified anticancer chemotherapeutic agents.

CMS guidance in section 80.2 of chapter 17 of the *Medicare Claims Processing Manual* (the Manual) states that, for the oral form of Emend to be payable as an outpatient service under Medicare Part B, providers must administer or prescribe the oral three-drug regimen described above for use immediately before, at, or within 48 hours of administering one of the nine specified anticancer chemotherapeutic agents. The Manual also states that the oral anti-emetic drugs must fully replace anti-emetic intravenous therapy and, for drugs billed to the Medicare

contractor, be billed on the same claim for Emend to be allowable for a Medicare Part B payment.

Further, the Manual and related CMS guidance state that, for drugs billed to the Medicare contractor, all three drugs in the oral anti-emetic regimen (Emend, a 5-HT₃ antagonist, and dexamethasone), as well as the qualifying anticancer chemotherapeutic agent, should be billed on the same claim for Emend to be allowable for payment under Medicare Part B.

OBJECTIVE, SCOPE, AND METHODOLOGY

Objective

Our objective was to determine whether providers correctly billed Medicare Part B for the oral form of Emend.

Scope

For calendar year (CY) 2010, Medicare contractors paid 725 providers a total of \$3,410,359 under Medicare Part B for the oral form of Emend. Our review covered the five providers who received the highest amounts of payments on claims for the oral form of Emend. The 5 selected providers billed 3,555 line items and were paid \$923,003 for line items on claims for the oral form of Emend.¹ Of these 3,555 line items, we judgmentally selected and reviewed 2,105 line items for which 3 Medicare contractors paid the 5 selected providers \$580,626.^{2, 3}

We limited our review of internal controls to the billing controls of the five providers who billed for the oral form of Emend and to the existing CWF edits. Our objective did not require an understanding of all internal controls over the submission and processing of claims. Our audit provided us with reasonable assurance that the data we obtained from the National Claims History file was authentic and accurate. However, we did not assess the completeness of the file.

We performed our fieldwork from October 2011 to March 2012, which included contacting the five selected providers who billed for the oral form of Emend.

Methodology

To accomplish our objective, we:

- reviewed applicable Federal laws, coverage determinations, and guidance;

¹ A single Medicare claim from a provider typically includes more than one line item. In this audit, we did not review entire claims; rather, we reviewed specific line items on claims for the oral form of Emend.

² The three Medicare contractors that processed these line items were Cigna Government Services, National Health Insurance Company, and TrailBlazer Health Enterprises, LLC.

³ The 2,105 line items generally consisted of those with the highest dollar amounts.

- used CMS's National Claims History file to identify outpatient claims that included the oral form of Emend (procedure code J8501) but that did not include the other required procedure codes associated with the oral anti-emetic regimen;⁴
- identified the five providers that received the highest amounts of Medicare Part B payments for the oral form of Emend during CYs 2007 through 2010;
- for the five providers, reviewed 2,105 line items paid in CY 2010 that included outpatient claims billed for the oral form of Emend;
- contacted the five providers that received Medicare payments for the line items selected to determine whether the payment information for those items was correct and, if not, why the information was incorrect;
- reviewed documentation for the line items selected to determine whether billed drugs were actually administered, spreadsheets from providers that identified the amount of overpayments, and letters from the providers to their Medicare contractors explaining why the selected line items were billed incorrectly;
- evaluated the CWF edits;
- discussed the results of our review with CMS officials on April 3, 2012; and
- provided the results of the overpayments to CMS officials on May 22, 2012.

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.

FINDINGS AND RECOMMENDATIONS

In general, the five selected providers that we reviewed did not correctly bill Medicare Part B for the oral form of Emend. Of the 2,105 selected line items for which Medicare contractors made payments to providers for the oral form of Emend during CY 2010, only 193 were correct. The remaining 1,912 line payment amounts were incorrect because providers did not bill for all of the required drugs in the regimen on the same claim as required; these errors resulted in overpayments totaling \$530,769. (During our fieldwork, the five selected providers informed us that they had returned the overpayments after we showed them the improper payments.)

The five selected providers billed incorrectly because they were not aware of the Federal requirements for the three-drug oral anti-emetic regimen until we made them aware of them during our fieldwork. The Medicare contractors made incorrect payments because the CWF did

⁴ Procedure code J8501 is assigned for billing the oral form of Emend. Identifying billing based on the presence of this procedure code and the absence of the other required procedure codes allowed us to identify cases when providers did not bill for all of the required drugs in the regimen on the same claim.

not have sufficient edits in place during our audit period to prevent or detect the overpayments in cases where providers did not bill, on the same claim, all of the required drugs in the regimen.

FEDERAL REQUIREMENTS

Section 4557 of the Balanced Budget Act of 1997, P.L. No. 105-33, amended section 1861(s)(2) of the Act to provide coverage under Medicare Part B for oral anti-emetic drugs that are approved by the Food and Drug Administration and administered under certain conditions. This section of the Act generally authorizes Medicare contractors to pay providers if the oral anti-emetic drug was administered under an anticancer chemotherapy regimen and prescribed for use as a full replacement for other anti-emetic drugs that would have been administered intravenously.

In the Manual, chapter 17, section 80.2, and in a National Coverage Determination (CAG-00248N, April 4, 2005), CMS stated that the three-drug oral anti-emetic regimen consisting of Emend, a 5-HT₃ antagonist, and dexamethasone meets the “reasonable and necessary” standard for Medicare Part B payment only when prescribed for beneficiaries who are also receiving at least one of nine specified anticancer chemotherapeutic agents.⁵

The Manual and related Change Request 5655 (dated July 6, 2007) state that, for drugs billed to the Medicare contractor, all three drugs in the oral anti-emetic regimen (Emend, a 5-HT₃ antagonist, and dexamethasone), as well as the qualifying anticancer chemotherapeutic agent, should be billed on the same claim for Emend to be allowable for payment under Medicare Part B.

OVERPAYMENTS FOR SELECTED LINE ITEMS

Oral Three-Drug Regimen and at Least One of Nine Anticancer Chemotherapeutic Agents Not Present on Same Claim

Four providers incorrectly billed Medicare Part B for 1,098 line items on claims for the oral form of Emend. These providers did not bill for all of the drugs that make up the three-drug oral anti-emetic drug regimen, and did not bill at least one of the nine specified anticancer chemotherapeutic agents, on the same claim. This error resulted in overpayments to the four providers totaling \$301,701.

All Drugs in Oral Three-Drug Regimen Not Present on Same Claim

Four providers incorrectly billed Medicare Part B for 185 line items on claims for the oral form of Emend. These providers did not bill all of the drugs that make up the three-drug oral anti-emetic drug regimen on the same claim. This error resulted in overpayments to the four providers totaling \$54,857.

⁵ National Coverage Determinations are binding on all Medicare contractors and, based on 42 CFR §§ 405.732 and 405.860, are also binding on administrative law judges during the claim appeal process. The title of the relevant National Coverage Determination is “Decision Memo for Aprepitant for Chemotherapy-Induced Emesis.”

At Least One of Nine Anticancer Chemotherapeutic Agents Not Present on Claim

Four providers incorrectly billed Medicare Part B for 629 line items on claims for the oral form of Emend. Although these providers billed for all of the drugs that make up the three-drug anti-emetic drug regimen on the same claim, those claims did not include any of the nine specified anticancer chemotherapeutic agents. This error resulted in overpayments to the four providers totaling \$174,211.

CAUSES OF INCORRECT MEDICARE PAYMENTS

The five selected providers billed incorrectly because they were not aware of the Federal requirements for the three-drug oral anti-emetic regimen until we made them aware of them during our fieldwork. The Medicare contractors made incorrect payments because the CWF did not have sufficient edits in place during our audit period to prevent or detect the overpayments in cases where providers did not bill, on the same claim, all of the required drugs in the regimen.

CMS guidance designates the procedure codes that should be billed on each claim for the oral form of Emend. CMS guidance in the Manual also states that “[t]he CWF edits claims with these codes to assure that the beneficiary is receiving the oral anti-emetic(s) as part of a cancer chemotherapeutic regimen by requiring a diagnosis of cancer.” However, not all of the procedure codes for the three-drug anti-emetic regimen are in the Manual.

Moreover, although the existing edits require a diagnosis code of cancer, they do not ensure that the required combination of procedure codes (that correctly reflects all of the drugs in the three-drug oral anti-emetic regimen and one of the nine required anticancer chemotherapy agents) is billed on the same claim pursuant to Federal requirements.

During our fieldwork, the five selected providers informed us that they had returned the overpayments after we showed them the improper payments.

RECOMMENDATIONS

We recommend that CMS:

- verify that the \$530,769 in identified overpayments made to the five selected providers has been refunded to the Federal Government;
- direct the five selected providers to review the remaining CY 2010 line items on claims for the oral form of Emend that were not reviewed as part of this audit, as well as all subsequent claims, and refund any overpayments;
- develop and implement system edits to prevent payments for the oral form of Emend when providers do not bill for all of the required drugs in the regimen on the same claim; and
- use the results of this audit to educate providers.

CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

In written comments on our draft report, CMS concurred with three of our four recommendations and described corrective actions that it had taken or planned to take.

CMS did not concur with our third recommendation, pointing to instances when a patient may already be receiving the oral 5-HT₃ antagonist and dexamethasone at home for emesis (that is, nausea and vomiting) related to the cancer but not related to chemotherapy. In such cases, CMS stated, “it is likely that any edit would not in fact identify erroneous billing.” CMS added that it would continue to investigate this issue and would provide an update on its planned course of action at a later date.

CMS’s comments are included in their entirety as the Appendix.

OFFICE OF INSPECTOR GENERAL RESPONSE

After reviewing CMS’s comments, we maintain that all of our findings and recommendations remain valid. According to CMS guidance, for an oral anti-emetic drug such as Emend to be allowable under Medicare Part B, it must be billed on the same claim as the other drugs in the prescribed regimen. Although CMS raises important clinical issues in its comments on our draft report, we maintain that an edit is appropriate to prevent improper Medicare Part B payments for the oral form of Emend when providers do not bill in accordance with CMS’s instructions. We support CMS’s continued evaluation of this issue and look forward to receiving an update on CMS’s planned course of action in the future.

APPENDIX

APPENDIX: CENTERS FOR MEDICARE & MEDICAID SERVICES COMMENTS

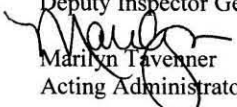
DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: OCT 02 2012

TO: Gloria L. Jarmon
Deputy Inspector General for Audit Services

FROM: 
Marilyn Tavenner
Acting Administrator

SUBJECT: Office of Inspector General Draft Report: "Providers Did Not Correctly Bill Medicare Part B for the Oral Form of the Drug Emend" (A-07-11-04181)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General (OIG) Draft Report entitled, "Providers Did Not Correctly Bill Medicare Part B for the Oral Form of the Drug Emend" (A-07-11-04181). The objective of this study was to determine whether providers correctly billed Medicare Part B for the oral form of Emend.

This report focused on aprepitant, one of three drugs in a regimen of oral anti-emetic drugs that are prescribed to help reduce nausea and vomiting in chemotherapy patients. In this report, the audit referred to aprepitant by its brand name, Emend. The second anti-emetic drug in this regimen, called a 5-HT₃ antagonist, also helps reduce nausea and vomiting. The third anti-emetic drug, dexamethasone, is an anti-inflammatory and immunosuppressant.

The CMS issued Medicare Claims Processing instructions on July 7, 2007, stating that the three drug combination protocol requires the first dose be administered before, during, or immediately after the anti-cancer chemotherapy administration. The second day is defined as within 24 hours and the third day is defined as within 48 hours of the chemotherapy administration. To facilitate coverage reviews, providers should bill all three drugs in the oral anti-emetic combinations as well as the qualifying highly emetogenic anti-cancer agents on the same claim. The OIG audit identified five providers that billed Medicare B incorrectly for the oral form of Emend.

The CMS appreciates OIG's efforts in working with us to help identify Emend billing issues. Our response to each of the OIG recommendations follows.

OIG Recommendation

Verify that the \$530,769 in identified overpayments made to the five selected providers has been refunded to the Federal Government.

CMS Response

The CMS concurs with this recommendation. Upon receipt of the data from OIG, CMS will contact the appropriate contractors to determine if the five selected providers refunded the federal government. OIG should furnish CMS with information related to each of the five providers including, at a minimum, the provider number, the overpayment amount, the Medicare contractor number, and the claims information (including the paid date, HIC numbers, etc.).

OIG Recommendation

Direct the five selected providers to review the remaining CY 2010 line items on claims for the oral form of Emend that were not reviewed as part of this audit, as well as all subsequent claims, and refund any overpayments.

CMS Response

The CMS concurs with the recommendation. CMS requests that the OIG furnish the overpayment data (Medicare contractor numbers, provider numbers, claims information including the paid date, HIC numbers, etc.) for each of the five providers referenced in the audit report in order for CMS to begin the review and recovery process. In addition, we ask that the OIG provide CMS with the contractor specific data on separate CD-ROMs, separate hardcopy worksheets, or transmit the data to CMS electronically using the secure HHS/OIG web portal to better facilitate the transfer of information to the appropriate contractors.

OIG Recommendation

Develop and implement system edits to prevent payments for the oral form of Emend when providers do not bill for all of the required drugs in the regimen on the same claim.

CMS Response

The CMS non-concurs with this recommendation. There are incidences when a patient may already have oral 5-HT₃ and dexamethasone at home for emesis related to the cancer as opposed to the chemotherapy, so it is likely that any edit would not in fact identify erroneous billing. We will continue to investigate this issue and will provide an update on our planned course of action at a later date.

OIG Recommendation

Use the results of this audit to educate providers.

CMS Response

The CMS concurs with this recommendation. Since 2000, CMS has produced national provider education materials for Medicare fee-for-service (FFS) providers under the brand name of the Medicare Learning Network® (MLN). One of the most popular of these materials are national articles, referred to as MLN Matters®, designed to inform Medicare FFS providers about the latest changes to the Medicare Program.

The CMS released two such articles related to this report's topic.

- The first was MM 5655, "*Clarification on Billing for the Oral Three Drug Combination Anti-Emetic (Aprepitant)*" released on March 5, 2008. This article was subsequently revised on March 18, 2008, to add additional clarifying language to "Provider Action Needed" and "Background" (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM5655.pdf>).
- The second article was SE0910, "*Clarification for Billing Part B versus Part D for the Anti-emetic Aprepitant (Emend®)*" released on June 11, 2009 (<http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE0910.pdf>).

All MLN Matters® articles are heavily marketed to the provider community through the MLN Matters® electronic mailing list, which currently has over 25,500 subscribers. We also market MLN products and articles through other electronic mailing lists, ultimately reaching over 4 million subscribers.

The CMS will be happy to re-market the MLN Matters® articles mentioned above. In addition, we will determine if additional types of educational materials are warranted, and will proceed from there with the development of these materials, as necessary.

The CMS thanks the OIG for the opportunity to review and comment on this report.