DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services

Decision of the Administrator

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IN THE MATTER OF:	*	**Appeals CGDP0000882012**
	*	**and CGDP0000892012**
Novartis Pharmaceutical Corporation	*	
	*	
P1008 - Quarter 3 Appeals	*	
	*	**Date: June 6, 2012**
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This case is before the Administrator, Centers for Medicare & Medicaid Services (CMS), for review of the decisions entered by Provider Resources, Inc. (PRI), the Medicare Coverage Gap Discount Program (Discount Program) Independent Review Entity (IRE). The review is pursuant to Section 1860D-14A(c)(1)(A)(vii) of the Affordable Care Act of 2010 and section V(g) of the Medicare Coverage Gap Discount Program Agreement (the Agreement).[1] The Novartis Pharmaceutical Corporation (Novartis) timely requested review of the IRE's decisions. Comments were timely received from the Center for Medicare (CM). Accordingly, these cases are now before the Administrator for final agency review.

ISSUES AND INDEPENDENT REVIEW ENTITY DECISIONS

In Appeal CGDP0000882012, (hereinafter Appeal 1), the issue involves the IRE's decision concerning whether the drugs at issue are not applicable drugs for

[1] Section 1860D-14A(c)(1)(A)(vii) of the Act requires CMS to provide a reasonable mechanism to resolve manufacturer disputes involving the discounts provided under the Discount Program and section V of the Agreement specifies the rights and obligations of both CMS and manufacturers for resolving such disputes. A copy of the agreement can be found on the CMS website at: http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/CGDPMfrAgrmtOriginal.pdf. See, also 75 Fed Reg. 29555 (May 26, 2010), "Medicare Program; Medicare Coverage Gap Discount Program Model Manufacturer Agreement and announcement of the Jan. 11, 2010 Public Meeting. (CMS explained that "the model manufacturing agreement will be finalized and posted on the CMS website after we have considered the public comments and consult with manufacturers as required by Section 1860D-14(A)(a) of the Act." *Id.* at 29556.)

purposes of the Medicare Coverage Gap Discount Program (Discount Program) because they are covered under Medicare Part B, and not Medicare Part D. Novartis is appealing forty-four (44) Detail Reference Numbers (DRNs)[2] having one (1) National Drug Codes (NDCs) with dates of service ranging from April 6, 2011 through September 15, 2011.[3] The appealed DRNs were for Reclast® 5mg. In Appeal CGDP0000892012, (hereinafter Appeal 2) the issue also concerns whether the drugs dispensed applicable drugs for purposes of the Discount program because it is covered under Medicare Part B, and not Medicare Part D. Novartis appealed fifteen (15) DRNs having one (1) NDC with dates of service ranging from April 12, 2011 through September 22, 2011, however, the IRE noted that six of the fifteen DRNs were duplicate submissions from Appeal 1 (CGDP0000882012).[4] The appealed DRNs were for Reclast® 5mg.

In Appeal 1 and Appeal 2, the IRE denied the appeals and found the drugs at issue were applicable drugs within the parameters of the Discount Program. The IRE noted that Novartis failed to show that the service providers dispensing the drugs were non-pharmacy providers. Therefore, the IRE determined that the drugs were covered under Part D because they were not dispensed by a physician provider incident to a physician's service.

COMMENTS

Novartis requested review of the IRE's decisions based on the Part B infusion or injectable drugs in both appeals.

CM noted with respect to Appeal 1 and Appeal 2, that Novartis alleged that the drug Reclast® should be covered under Medicare Part B, rather than Part D, because the drugs are generally not self-administered. CM argued that Medicare Part B pays for "not usually self-administered drugs" only when provided incident to a physician service. In order to be incident to a physician service, the physician must actually provide the drug from his or her own stock, and bill for the drug. CM noted that in this case, the IRE confirmed that all appealed DRNs were dispensed

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[2] DRNs are unique identifiers used by CMS for the Discount program when invoicing manufacturers to represent a pharmacy transaction and all subsequent actions including invoicing, payment, and appeals.

[3] Novartis initially appealed forty-five DRNs however, the IRE noted that one of the DRNs was invalid (000005171972) and Novartis was notified by the IRD on March 30, 2012 of the submission error, however, Novartis did not submit a new appeal with the correct DRN.

[4] Novartis submitted the following DRNs on both appeals: 00078000000002436438, 00078000000004554792,00070000000002570049,00078000000004153079,00078000000002693947, 00078000000004416549.

through pharmacies. Thus, CM argued that all the claims for Reclast® would not qualify for Medicare Part B coverage as incident to a physician service and could only be covered under Medicare Part D with applicable discounts for coverage gap claims.

In summary, CM argued that Novartis failed to demonstrate at any level of the dispute and appeal processes that the invoiced discount amounts were incorrect. Based on the information provided in the IRE decisions, CM requested that the Administrator uphold the IRE's decision that Novartis was appropriately billed for quarter three coverage gap discount payments.

DISCUSSION

The entire record furnished by the Independent Review Entity has been examined, including any written documents submitted. All comments timely received are included in the record and have been considered.

Section 101 of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108-173) amended the Social Security Act (the Act) to, among other things, create a Medicare drug benefit program (Medicare Part D). The Patient Protection and Affordable Care Act and the Health Care Education and Reconciliation Act, collectively known as the Affordable Care Act (ACA) established the Discount program by adding §1860D-43 and §1860D-14A to the Act. Under the program, the ACA made manufacturer discounts available to applicable Medicare beneficiaries receiving applicable drugs[5] while in the coverage gap. The Coverage Gap, according to Chapter 5 of the Prescription Drug Benefit Manual, is defined as the gap phase in prescription drug coverage occurring between the initial coverage limit and the out-of-pocket threshold.

Generally, the discount on each applicable drug is 50 percent of an amount equal to the negotiated price. However, applicable drugs may be covered under Part D only if the manufacturer has a signed Medicare Coverage Gap Discount Program Agreement (Agreement) with CMS to provide the discount on coverage gap claims for all of its applicable drugs.[6] Beneficiaries then receive the manufacturer discount on applicable drugs at the point-of-sale, and the Part D sponsors

[5] An applicable drug, as defined in §1860D-14A(g)(2) of the Act, is a covered Part D drug that is either approved under a new drug application (NDA) under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under §351 of the Public Health Service Act (BLA).

[6] See, CMS guidance published on May 21, 2010.

subsequently submit prescription drug event (PDE) data to CMS.[7] Each Part D sponsor calculates the applicable discount for an applicable coverage gap claim and advances the discount to the beneficiary on behalf of the manufacturer.[8]

Through the use of a third-party administrator (TPA), CMS invoices manufacturers on a quarterly basis for those discounts provided by Part D sponsors. The invoices provide claim-level Manufacturer Data Reports containing Medicare Part D Discount Information along with each invoice that details the manufacturers liability for each coverage gap discount advanced to beneficiaries by Part D sponsors. The Agreement requires manufacturers to pay the Part D sponsor within 38 days of receipt of the quarterly invoice.

Section 1860D-14A(c)(1)(A)(vii) of the Affordable Care Act, established a mechanism to resolve manufacturer disputes involving the discounts provided under the Discount Program. Section V of the Discount Program Agreement specifies the rights and obligations of both CMS and the manufacturers for resolving such disputes. Manufacturers have the opportunity to file a dispute with the third party administrator about any of the invoiced amounts based on the Medicare Part D Discount Information received on the Manufacturer Data report after payment is made. Within 60 days of receipt of the information that is the subject of the dispute, manufacturers must electronically submit all disputes to the TPA. To the extent a manufacturer receives an unfavorable dispute determination from the third party administrator; it has the right to appeal to the Independent Review Entity.[9] Manufacturers must demonstrate why the disputed discount payment likely is in error in order for the IRE to further review and validate a disputed discount payment.

CMS issued guidance on May 31, 2011, that outlines the standards that manufacturer's appeals must satisfy in order for the IRE to further review and validate a disputed discount program. The guidance identifies four bases upon which a manufacturer may challenge a discount payment: National Drug Code

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[7] 42 CFR §423.4 defines Part D plan sponsor or Part D sponsor as a plan (PDP sponsor, MA organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualified prescription drug coverage and/or a cost plan) offering qualified prescription drug coverage.

[8] Each Part D sponsor calculates the applicable 50 percent discount off of its negotiated price with the pharmacy and reports the discount payment amount to CMS through its normal Part D prescription drug event submission process.

[9] Manufacturers may only appeal disputes that have received a timely unfavorable determination from the TPA, or were not resolved by the TPA within 60 days of submission. See, Section V(g) of the Medicare Coverage Gap Discount Program Agreement.

(NDC) Not on Market, Aberrant Quantity, Not Part D Covered Drug – Part B Ineligible for Discount, and High price of the Drug/Excessive Gap Discount.[10] Manufacturers bear the burden of proof in meeting these standards.

The May 2011 appeals guidance noted that there were several primary dispute reasons that may reasonably be appealed and clarified the expectations that manufacturers were to demonstrate on these appeals to justify further review and validation by the IRE. Relevant to Appeal 2, the May 2011 guidance states:

> Not Part D Covered Drug – Part B Drug Ineligible for Discount: Many prescription drug products that are covered under Medicare Part B may also be covered under Medicare Part D depending upon the patient and/or provider setting. For example, an injectible drug product that is covered under Medicare Part B when provided in a physician office from the physician's stock might be covered under Medicare Part D when dispensed by a pharmacy. Conversely, other drug products, such as oral anticancer drugs or IVIG, may be covered under Medicare Part B or Part D when dispensed by a pharmacy depending upon the indication and/or patient setting.
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> Manufacturers that appeal a discount payment on the basis that the drug product is covered under Medicare Part B must specify which Medicare Part B coverage category is the basis for their appeal to justify further review and validation by the IRE. If the appeal is based upon an injectable drug product being covered under Medicare Part B when provided incident to a physician's service, the Service Provider indicated on the detailed Manufacturer Data Report cannot be a pharmacy because pharmacies do not provide drugs in this particular Medicare Part B benefit category. If the appeal is based upon a Medicare Part B benefit category that may be dispensed from a pharmacy, the manufacturer must demonstrate that the claim likely should have been covered under Medicare Part B. The IRE may use Part D sponsors' previous B versus D coverage determinations as the basis for determining these appeals.[11]

In March 2012, CMS provided additional industry guidance for the Discount Program disputes. CMS specified the standards that manufacturers must satisfy in order for the TPA to review and validate a disputed discount payment. The

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[10] See, Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011.

[11] See, Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011.

document gives general guidance for disputes and also gives dispute submission requirements by dispute reason for Duplicate Invoice Item, Closed Pharmacy, Not a Part D Drug, Excessive Quantity, Days Supply, High Price of the Drug, Last Lot Expiration Date, Early Fill, Marketing Category Not a Biologic License Application (BLA) or New Drug Application (NDA) and Other.[12]

Moreover, the dispute guidance states that "CMS will deny disputes if the discount payment is accurately calculated, even if the dispensing event may not have been clinically appropriate." In other words, the dispute process is not intended to be a retrospective utilization management review where the clinical decision making of the prescriber, provider, or Part D plan is called into question. Manufacturers are expected to pay discounts on all applicable drugs which were dispensed to applicable beneficiaries even if the manufacturer believes that the dosages dispensed were inappropriate.[13]

The 2012 Dispute guidance reiterates the importance of looking at the setting in which the drug was dispensed for drugs disputed for Medicare Part B versus Part D. It states that "manufacturers wishing to dispute for this reason should first confirm that the Service Provider ID field on the invoiced PDE in question does not represent a pharmacy. Absent any clinical review, if a drug that can be covered under Part B or Part D is dispensed through a pharmacy, we can only assume that the indication or patient setting supports being billed correctly under Part D.[14]

In the instant cases, Novartis contracted with CMS to participate in the Discount program beginning in January 2011. Under the terms of the Discount Program Agreement, Novartis submitted the following labeler codes for applicable drugs to be covered under Part D: 00028, 00065, 00067, 00078, 00083, 00185, 00781, 00998, 42515, 42826, 43068, 46028, 58768, 61314, 63851, 66521, 66685, and 66758.[15]

On September 1, 2011 Novartis received its third quarter 2011 invoice covering discounts provided to Medicare Part D beneficiaries in the coverage gap from July 1, 2011 through September 30, 2011. The total invoice was for $19,133,614.08 and

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[12] See, e.g. Medicare Coverage Gap Discount Program – Dispute Resolution, dated March 5, 2012.

[13] See, Medicare Coverage Gap Discount Program – Dispute Resolution, dated March 5, 2012.

[14] See, Medicare Coverage Gap Discount Program – Dispute Resolution, dated March 5, 2012.

[15] See, CM's Comments, Exhibit 6, Health Plan Management System Screen Shot of Novartis Labeler Codes.

was due to be paid by December 9, 2011.[16] Novartis paid the invoice through electronic funds transfer on November 30, 2011. On December 22 and 23, 2011, Novartis submitted to Palmetto, CMS' TPA, disputes for 26,134 detail reference numbers (DRNs) using six dispute reason codes (D01-Duplicate Claim, D02-Closed Pharmacy, D03 – Not a Part D drug, D04 – Excessive Quantity, D06 – High Price of Drug and D99 – Other).[17] The great majority of Novartis' disputes fell into the following two categories:

> D04, "Excessive Quantity" was used to dispute 1,085 DRNs. Novartis included "Max Dosage" amounts for each drug in the notes section of the dispute file.
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> D03, "Not a Part D drug" was used to dispute 24,335 DRNs. The dispute notes stated "product Service ID is not eligible for Coverage Gap Discount. Part B drug, Infusion Drug. Not usually self administered.[18]

On February 29, 2012 the TPA sent Novartis notification that 1,054 (97%) of its D04 – "Excessive Quantity" disputes and 100% of its D03 – "Not a Part D drug" disputes had been denied.[19] On March 28 and 29, 2012 Novartis filed three appeals with the IRE which included the two Appeals in the instant case. In these appeals, Novartis contended that their drug Reclast®, was not an applicable drug for purposes of the Discount program because it is covered under Medicare Part B. Novartis claimed that the drug is administered by intravenous infusion, and therefore must be administered by qualified healthcare professionals. As a result, Novartis argued that the drug is covered under Medicare Part B, and not Part D. The IRE concluded that the drug was dispensed by pharmacies rather than physicians, and therefore, covered under Part D.

The Administrator finds that the regulations at §1860D-43 and §1860D-14A of the Act delineate the parameters of the Discount Program. The May 2011 appeals guidance provided standards that manufacturer appeals must meet in order for the IRE to review and validate a disputed discount program claim. In addition, relevant to this appeal, the Administrator notes that the March 5, 2012 Dispute Resolution Guidance further provides an explanation of the dispute reason codes, and specifically states in pertinent part, consistent with the earlier guidance, that:

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[16] See, CM's Comments, Exhibit 7, Coverage Gap Discount Program Manufacturer Invoice for Quarter 3, 2011, Novartis Pharmaceuticals Corporation, P1008.
[17] See, CM's Comments, Exhibit 8, Novartis Pharmaceutical Corporation Quarter 3 Aggregated Dispute Report.
[18] See, CM's Comments, Exhibit 9, Novartis Pharmaceutical Corporation Quarter 3 Dispute Summary.
[19] See, CM's Comments, Exhibit 10, Novartis Quarter 3 IRE Appeal Submission.

> D03, Not Part D Covered Drug:
> …The purpose of this code is for manufacturers to indicate that an NDC should not be covered under the Part D program under any circumstances. Manufacturers should not use the dispute reason code of "Not Part D Covered Drug" to file a dispute on the basis that the drug is potentially a non-applicable CGDP drug, but otherwise would be covered under Medicare Part D. … Additionally, we note that drugs disputed for Medicare Part B vs. Part D coverage are largely dependent on indication and/or patient setting. Manufacturers wishing to dispute for this reason should first confirm the Service Provider ID field on the invoiced PDE in question does not represent a pharmacy. Absent any clinical review, if a drug that can be covered under Part B or Part D is dispensed through a pharmacy, we can only assume that the indication or patient setting supports being billed correctly under Part D. Therefore, disputed PDEs meeting these criteria will be denied.

Novartis asserted that its drug Reclast® should be covered under Medicare Part B, rather than Part D, as it is generally not self-administered drugs. Manufacturers that have signed Agreements are required to provide discounts for "applicable drugs" to "applicable beneficiaries." An applicable drug, as defined in §1860D-14A(g)(2) of the Act, is a covered Part D drug that is either approved under a new drug application (NDA) under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under §351 of the Public Health Service Act (BLA). The CMS Medicare Benefit Policy Manual, at Chapter 15, §50.2 and §50.3, explains that Medicare Part B covers drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients. The charge for the drug, if any, must be included in the physician's billing. The cost of the drug charged must represent an expense to the physician in order to be considered "incident to" the physician's service.

The Medicare Prescription Drug Benefit Manual, in Chapter 6, Appendix C, also states that drugs are covered under Medicare Part B if furnished "incident to" a physician's service. More specifically, injectable or intravenous drugs, administered predominantly by a physician or under a physician's direct supervision as "incident to" a physician's professional service, qualify as covered under Medicare Part B. In order to meet all the general requirements for coverage under the "incident to" provision, an FDA-approved drug or biological unit must:

- Be of a form that is not usually self-administered;
- Be furnished by a physician; and

- Be administered by the physician, or by auxiliary personnel employed by the physician and under the physician's personal supervision.

The Chapter 6 guidance also states, "if a network pharmacy supplies the drug directly to the beneficiary, the drug must be accounted for under its Part D benefits."

The Administrator notes that Medicare Part D pays for drugs that otherwise meet the definition of a Part D drug, including "not usually self-administered drugs," if not covered under Medicare Part A or Part B, as prescribed and dispensed or administered with respect to that individual. Medicare Part B pays for "not usually self-administered drugs," such as Reclast®, only when provided "incident to a physician service." As explained in the manuals, in order to be "incident to a physician service," inter alia, the physician must meet the criteria to bill for the drug. Consequently, if a pharmacy dispenses and bills for a "not usually self-administered drug," it does not meet the Medicare Part B "incident to physician services" requirements and therefore can only be covered under Part D.

The record shows that all the appealed DRNs were dispensed through pharmacies.[20] The table listing the Service Provider Identifier Qualifier, the Service Provider Identifiers, and the Classification clearly show that the drugs were dispensed by a pharmacy, mail order pharmacy, long term care pharmacy, specialty pharmacy, clinic pharmacy, home infusion therapy pharmacy, or community/retail pharmacy.[21] Consequently, all of these claims for Reclast® would not qualify for Medicare Part B coverage as "incident to a physician service" and could only be covered under Medicare Part D with applicable discounts for coverage gap claims. As a result, the claims in Appeals 1 and 2 were appropriately billed under the coverage gap discount program.

In these cases, the Administrator finds that Novartis failed to demonstrate at any level of the dispute and appeal process that the invoiced discount amounts were incorrect. Therefore, the Administrator finds that the IRE properly determined that Novartis was appropriately billed for Quarter three coverage gap discounts, with respect to Appeal 1 and Appeal 2.

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[20] See, Independent Review Entity Decision, Appeal 1, CGDP0000882012, Attachment A, pgs. 6-8, and Appeal 2, CGDP0000892012, Attachment A, pg. 6.
[21] *Id.*

DECISION

In light of the foregoing and based on the record, the Administrator hereby upholds the decision of the Independent Review Entity in Appeal 1 - CGDP0000882012, and Appeal 2 - CGDP0000892012.

THIS CONSTITUTES THE FINAL ADMINISTRATIVE DECISION OF THE SECRETARY OF HEALTH AND HUMAN SERVICES

Date: 3/13/13

/s/

Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services