

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

Decision of the Administrator

IN THE MATTER OF: *
* **Appeals CGDP0000902012**
*
Novartis Pharmaceutical Corporation *
*
P1008 - Quarter 3 Appeal *
* **Date: June 20, 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 decision. Comments were timely received from the Center for Medicare (CM). Accordingly, this case is now before the Administrator for final agency review.

ISSUE AND INDEPENDENT REVIEW ENTITY DECISION

In this appeal, the issue involves the IRE’s decisions concerning whether Novartis was properly invoiced for the quantities dispensed. The IRE denied the appeal

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.)

finding that the quantity dispensed was not aberrant, and the invoiced amounts were appropriate within the parameters of the Discount Program. The IRE reviewed the appealed National Drug Codes (NDCs) to determine whether the days' supply dispensed exceeded the CMS-specified threshold of three times the FDA approved maximum dose included in the appeals guidance. As a result of the IRE's review of the dispute file, the statements from the Part D sponsor, and its own analysis of the FDA maximum within the context of quantities dispensed, the IRE determined that Novartis was properly invoiced. The IRE stated that the applicable drugs were appropriately billed for the coverage gap discount dollars associated with the NDCs and the corresponding Detail Reference Numbers (DRNs), and denied Novartis' appeal based on Excessive Quantity.²

COMMENTS

Novartis requested review of the IRE's decision based on the exceeding the maximum recommended dosage of applicable drugs, in the instant case.

CM submitted comments stating, with respect to this appeal, that Novartis argued that the discounts must have been in error because the drugs dispensed exceeded the maximum FDA labeled dose. However, CM contended that Novartis failed to demonstrate that such doses and quantities associated with such doses, were errors either because they were three times higher than the FDA maximum labeled dosing, represented a severe threat to the health of beneficiaries, were inconsistent with the packaging, or otherwise represented an unlikely dose in the Medicare population. Moreover, the Part D sponsor confirmed to the IRE that the drugs were dispensed as specified by the beneficiaries' physicians and the IRE determined that the drugs were appropriately invoiced. 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.

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.

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 drugs³ 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.⁴ Beneficiaries then receive the manufacturer discount on applicable drugs at the point-of-sale, and the Part D sponsors subsequently submit prescription drug event (PDE) data to CMS.⁵ 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.⁶

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.

³ 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).

⁴ See, CMS guidance published on May 21, 2010.

⁵ 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.

⁶ 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.

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.⁷ 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 (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.⁸ 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 this appeal, it stated in pertinent part:

Aberrant Quantity: A quantity is considered aberrant if it represents a clearly excessive quantity for a given days' supply or is inconsistent with packaging of the product. Legitimate variations in patient characteristics and the therapeutic characteristics of drugs often warrant appropriate dosing in excess of FDA approved labeling. Therefore, appeals should be based on quantities that likely represent errors and not medically appropriate variation in dosing.

⁷ 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.

⁸ See, Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011.

Generally, the IRE will further review and validate appeals based on the manufacturer's representation that the quantities represent greater than three times the maximum FDA labeled daily dose. To justify further review and validation by the IRE, manufacturers that appeals quantities that represent less than three times the maximum FDA labeled dose, or for any quantity-related appeal if there is no maximum FDA labeled daily dose, will need to demonstrate that the dose represents a severe threat to the health of beneficiaries, is inconsistent with the packaging of the product, or otherwise represents an unlikely dose in the Medicare population.⁹

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 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.¹⁰

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.¹¹

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,

⁹ See, Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011.

¹⁰ See, e.g. Medicare Coverage Gap Discount Program – Dispute Resolution, dated March 5, 2012.

¹¹ See, Medicare Coverage Gap Discount Program – Dispute Resolution, dated March 5, 2012, and Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011 at p. 2.

00998, 42515, 42826, 43068, 46028, 58768, 61314, 63851, 66521, 66685, and 66758.¹²

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 was due to be paid by December 9, 2011.¹³ 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).¹⁴ 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.

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."¹⁵

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.¹⁶ On March 28 and 29, 2012 Novartis filed three appeals with the IRE which included this appeal in the instant case. Novartis challenged discounts for 10 DRNs having 7 NDC's which included the following drugs: Diovan® 160mg, Diovan®320mg, Diovan® HCT 160mg/25mg, Stalevo® 50mg/200mg/200mg, Vivelle® 0.1mg.¹⁷ The IRE requested that all involved Part D sponsors affirm that the drug quantities included on the invoices were indeed dispensed. The IRE also reviewed the appealed NDCs to see if the days' supply dispensed exceeded the CMS-specified guidance.

¹² See, CM's Comments, Exhibit 6, Health Plan Management System Screen Shot of Novartis Labeler Codes.

¹³ See, CM's Comments, Exhibit 7, Coverage Gap Discount Program Manufacturer Invoice for Quarter 3, 2011, Novartis Pharmaceuticals Corporation, P1008.

¹⁴ See, CM's Comments, Exhibit 8, Novartis Pharmaceutical Corporation Quarter 3 Aggregated Dispute Report.

¹⁵ See, CM's Comments, Exhibit 9, Novartis Pharmaceutical Corporation Quarter 3 Dispute Summary.

¹⁶ See, CM's Comments, Exhibit 10, Novartis Quarter 3 IRE Appeal Submission.

¹⁷ See, Independent Review Entity's Decision, Appeal CGDP0000602012, pgs. 3-5.

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.

The CMS Discount Program appeals guidance specifically stated that, “a discount payment is in error only if it is not accurately calculated or if it is not calculated based upon accurate data that represents the dispensing event that actually occurred.”¹⁸ It further explains that “it is not an error if the discount payment is accurately calculated based upon accurate data for dispensing events that actually occurred, even if the amount calculated appears to indicate that the dispensing event may not have been clinically appropriate.”¹⁹ In other words, the appeal process is not intended to “look behind” or second guess the clinical decision of the prescriber Part D plan.

In addition, relevant to this appeal, the Administrator notes that the March 5, 2012 Dispute Resolution Guidance also further provides an explanation of the dispute reason codes, and specifically states in pertinent part, consistent with the earlier guidance, that:

D04, Excessive Quantity:

Manufacturers who file a dispute on the basis that the quantity is excessive should demonstrate that the quantity is inconsistent with the packaging of the product and that the quantity is considered excessive given the days’ supply. Legitimate variations in patient characteristics often warrant approximate dosing in excess of the Food and Drug Administration (FDA) approved labeling. When there is a maximum FDA labeled daily dose, CMS will generally not uphold disputes for quantities that represent doses less than three times the maximum. Disputes should be based on quantities that likely represent errors that are not medically appropriate under any circumstances and may represent a threat to the health of a Medicare beneficiary.

Thus, the dispute and appeals 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. The guidance noted that legitimate variation in patient characteristics and therapeutic characteristics of

¹⁸See, Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011, pg. 2.

¹⁹ *Id.* at pg. 3.

drugs often warrant appropriate dosing in excess of FDA approved labeling and consequently established a threshold of three times the maximum FDA labeled daily dose as warranting further review unless the manufacturer demonstrates that lower doses represent “a severe threat to the health of beneficiaries, is inconsistent with packaging of the product, or otherwise represents an unlikely dose in the Medicare population.”²⁰

Novartis argued that the discounts were in error because the drugs dispensed exceeded the maximum dose listed on the FDA-approved label. The record shows that Novartis failed to demonstrate that such doses, and the quantities associated with such doses, were likely errors either because they were three times higher than the FDA maximum labeled dosing, represented a severe threat to the health of beneficiaries, or were inconsistent with the packaging or otherwise represent an unlikely dose in the Medicare population. The Part D sponsors provided coverage for appealed drugs for these beneficiaries because they have determined that the quantities dispensed represent medically appropriate variations in dosing.

In the instant case, the Part D sponsor confirmed to the IRE that the drugs were dispensed as specified by the beneficiaries’ physicians²¹ and the IRE determined that all quantities dispensed were under the threshold specified in the CMS guidance.²² For example, Novartis appealed the DRN for Stalevo® 50mg/200mg/200mg. The Maximum dosage for 90 days is 720 units. The prescription drug event was validated by the plan sponsor, and it explained that “the prescription was written for Stalevo 200mg tabs with directions ‘Take 1 tablet 6 to 7 times daily.’ According to these directions, the quantity of 630 tablets and days’ supply of 90 are correct.”²³ The dosing information for this drug is eight (8) 50mg/200mg/200mg tablets per day.²⁴ The calculation for the maximum FDA-approved dose based on quantity dispensed was 720 tablets for a 90 day supply, and the quantity equal to 3 times the FDA-approved Maximum Dose is 2160 tablets for 90 days. The actual quantity dispensed was 630 tablets for 90 days, which although is higher than the maximum FDA-approved amount, is still lower than 3 times the maximum dose amount.²⁵ The Administrator notes that “legitimate

²⁰ *Id.*

²¹ See, Independent Review Entity Decision, Appeal CGDP0000902012, Table 2: Part D Sponsor Verification Response for Dispensing Information, pgs. 4-5.

²² See, Independent Review Entity Decision, Appeal CGDP0000902012, dated June 20, 2012, pgs. 6-7.

²³ See, Independent Review Entity Decision, Appeal CGDP0000902012, Table 2: Part D Sponsor Verification Response for Dispensing Information, pg. 5.

²⁴ See, Independent Review Entity Decision, Appeal CGDP0000902012, Table 3: FDA Dosing Information, pg. 7.

²⁵ *Id.*

variations in patient characteristics and the therapeutic characteristics of drugs often warrant appropriate dosing in excess of FDA approved labeling.”²⁶ Thus, the actual quantity filled and days’ supply for this drug, along with the 7 other DRNs appealed in this case, were not aberrant and appropriately dispensed within the parameters of the program.²⁷

For Vivelle® Dot 0.1 mg (DRN 0007800000003076181), and Diovan® 320mg (DRN 0007800000006255038), Novartis argued that the dose dispensed exceeded the maximum dose available. The Part D sponsors have provided coverage for the appealed drugs for these beneficiaries because they have determined that the quantities dispensed represent medically appropriate variations in dosing. Specifically, the Part D sponsors provided coverage for the dispensed quantity because the prescriptions were written with the requested quantities.²⁸ For Vivelle® Dot 0.1 mg, the Part D Sponsor explained “The member... has been using the Vivelle® Dot patch at this quantity/day since June 2007. In all instances, the physician wrote the prescriptions for the amounts shown and pharmacist agreed to dispense as written. In addition, the plan does not have a quantity limit on the drug.”²⁹ For Diovan® 320mg, The Part D Sponsor explained that “The claim is valid as grandfathered prior authorization exists. The member has historical usage at this dose and has been allowed to continue the dosing regimen as directed by prescribing physician.”³⁰ Moreover, the Administrator notes that legitimate variations in patient characteristics and the therapeutic characteristics of drugs often warrant appropriate dosing in excess of FDA approved labeling, and the appeals should be based on quantities that likely represent errors and not medically appropriate variation in dosing. Accordingly, the Administrator finds that Novartis failed to provide supporting information that the quantity prescribed per day supply was a clearly excessive quantity for a given day’s supply, represented a severe threat to the health of the beneficiary, was inconsistent with packaging of the

²⁶ See, Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011, pg. 3.

²⁷This includes Diovan® 160 mg (DRNs 0007800000003050437, 0007800000003305469, and 0007800000002091369), Diovan® 160mg (DRNs 00078000000002300855, and 00078000000004167119), Diovan® 320mg (DRN 00078000000002273736), Diovan® HCT 160mg/25mg (DRN 0007800000002726637), and Stavelo® 50mg/200mg/200mg (DRN 00078000000002966095).

²⁸ See, Independent Review Entity Decision, Appeal CGDP0000902012, Table 2: Part D Sponsor Verification Response for Dispensing Information, pgs. 4-5.

²⁹ *Id.* at pg. 5.

³⁰ *Id.*

product, or otherwise represented an unlikely dose in the Medicare population, as described in CMS guidance from May 31, 2011, for these two DRNs at issue.³¹

In this case, 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 this appeal.

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

DECISION

In light of the foregoing and based on the record, the Administrator hereby upholds the decision of the Independent Review Entity in this Appeal CGDP0000902012.

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