DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Office of the Attorney Advisor

MAY 2 2014

Mr. Felim Buckley
Novartis Pharmaceutical Corporation
One Health Plaza
East Hanover, NJ 07936-1080

Re: Novartis Pharmaceutical Corporation, Appeal CGDP0001162013

Dear Mr. Buckley:

Enclosed is a copy of the Administrator's decision in the above case upholding the decision of the Independent Review Entity. This constitutes the final administrative decision of the Secretary of Health and Human Services.

Sincerely yours,

Jacqueline R. Vaughn
Attorney Advisor

Enclosure

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

Decision of the Administrator

IN THE MATTER OF:	*	**Appeals CGDP0001162013**
Novartis Pharmaceutical Corporation	*	
P1008-Quarter 2-2012 Appeal	*	
	*	**Date: April 19, 2013**

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This case is before the Administrator, Centers for Medicare & Medicaid Services (CMS), for review of the decision 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)(l)(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.[2] Comments were timely received from the Center for Medicare (CM). Accordingly, this case is now before the Administrator for final agency review.

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[1] Section 1860D-14A(c)(l)(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/PrescriptionDrugCovGenln/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). Provisions of the Manufacturer Agreement were codified in the final rule at 77 Fed Reg 22079 (April 12, 2012) effective June 1, 2012.

[2] *See* n. 1, The administrative review process was codified in the regulation at 42 CFR §423.2330(c), 77 Fed Reg 22072 (April 12, 2012).

ISSUE AND INDEPENDENT REVIEW ENTITY DECISION

In this appeal, the issue involves the IRE's decision concerning whether Novartis was properly invoiced for the quantities dispensed. The IRE denied the appeal finding that the quantities dispensed were not aberrant, and the invoiced amounts were appropriate and within the parameters of the Discount Program. The IRE determined that the information provided by the third party administrator (TPA) establishes that the Prescription Drug Event (PDE) data was valid as entered and that the Part D sponsor provided coverage for the appealed Detail Reference Numbers (DRNs). The record reflected the FDA dosing information, the regular FDA dose based on quantity dispensed, quantity equal to three times the FDA regular dose, and actual quantity filled and day supply for each DRN. The IRE compared the FDA product information for the drug at issue to the TPA Dispute File listing of "Day's Supply" and "Quantity Dispensed" for the drug, and verified that the daily quantity invoiced was within the dosage and administration guidelines contained in the FDA product information. The IRE noted that for the National Drug Code (NDC) {TOBI 300 mg/5mL) at issue in this appeal, there are no well-established maximum doses.

Moreover, the CMS guidance from May 31, 2011, states that the IRE will further review and validate appeals when the quantities represent greater than three times the maximum FDA-labeled daily dose. In this case, Novartis argued that the quantities dispensed were excessive, however it did not provide additional explanation to support this assertion nor provide the FDA-approved label or other accompanying documentation. Under CMS guidance, the manufacturer bears the burden of proof to demonstrate that the gap discount was excessive or calculated incorrectly and Novartis did not offer evidence to meet that burden. The IRE found that Novartis failed to provide information that the quantities prescribed per day supply was clearly an excessive quantity for a given day's supply or was inconsistent with packaging of the product for the DRNs at issue. 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 product information 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 NDC and the corresponding DRNs, and denied Novartis' appeal based on Excessive Quantity.[3]

[3] 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.

COMMENTS

Novartis requested review of the IRE's decision based on the argument that the amounts invoiced were for excessive/aberrant quantities, and therefore it was not responsible for the amount invoiced.

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. CM noted that the Part D sponsors confirmed to the IRE that the drugs were accurate and represent actual dispensing events that occurred, in all but one DRN, the latter of which was corrected. Novartis' failed to submit any further evidence to support its claims, and the arguments presented were similar to the ones made in prior appeals to the Administrator, which were upheld. CM stated that CMS guidance issued on May 30, 2011 states that manufacturers bear the burden of proof on appeal to demonstrate that the discount payment was made in error. CM contended 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 second quarter 2012 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[4] while in the coverage gap. The Coverage Gap, according to Chapter 5 of the Prescription Drug Benefit

[4] 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 Publc Health Service Act (BLA).

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.[5] 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.[6] 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.[7]

Through the use of a third-party administrator or 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 manufacturer's 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)(l)(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

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[5] *See,* CMS Memorandum "Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance" issued on May 21, 2010.

[6] 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.

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

Review Entity.[8] 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 primary 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.[9] Manufacturers bear the burden of proof in meeting these standards.

The May 31, 2011 appeals guidance noted that there were several primary dispute , reasons that may reasonably be appealed. CMS clarified its expectations of manufacturers as to what must be demonstrated for 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.
>
> 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 appeal 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

[8] 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.

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

> inconsistent with the packaging of the product, or otherwise represents an unlikely dose in the Medicare population.[10]

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."[11] 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."[12] 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. 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." 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]

Pursuant to a March 5, 2012 Dispute Resolution Guidance memorandum, 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.[14]

The March 5, 2012 memorandum again emphasized that CMS will deny disputes if the discount payment is accurately calculated, even if the dispensing event may not have been clinically appropriate. The dispute is not intended to be a retrospective utilization management review where the clinical decision making of 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, at 2.

[12] *Id.* at 3. .,

[13] *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 2.

[14] *See, e.g.,* Medicare Coverage Gap Discount Program – Dispute Resolution, dated March 5, 2012, at 1-2.

prescriber, provider, or Part D plan is called into question. In explaining the basis for disputes generally, CMS explained that manufacturers must explain why they believe that the invoiced gap discount amount is likely in error. The Dispute Resolution Guidance 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. [15]

The Attached "Summary of Dispute Submission Guidance by Reason Code" set forth the expected supporting Documentation stating for "Excessive Quantity" that:

> **REQUIRED:**
> The ADDITIONAL INFORMATION field should provide supporting evidence that:
> • The quantity is inconsistent with the packaging of the product;
> • The quantity is unlikely in the Medicare population;
> • The gap discount is based on an inaccurate calculation; and/or,
> • The gap discount was based upon inaccurate data that does not represent the dispensing event that occurred.
>
> Please provide the proprietary benchmark used to identify excessive quantity.

In the instant case, Novartis contracted with, CMS to participate in the Discount program and is appealing 29 DRNs for one NDC (TOBI 300mg/5mL), with dates of service ranging from May 16, 2011 through June 21, 2012. [16] Novartis received its second quarter 2012 invoice 922012 covering discounts provided to Medicare

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[15] *See*, Medicare Coverage Gap Discount Program Appeals Guidance, dated March 5, 2012, at 1-2.
[16] *See*, IRE Appeal CGDP00011620l3, dated April 19, 2013, at 1.

Part D beneficiaries in the coverage gap. Novartis was invoiced for all drugs having NDCs with the manufacturer's labeler code(s). The Invoice Report 201202, showed Novartis was charged for NDC 00078049471.[17] Novartis filed a dispute with the TPA on October 30, 2012, stating that the amount invoiced were for excessive and aberrant quantities. The TPA denied Novartis's disputes on December 28, 2012, reaffirming the drugs at issue were dispensed appropriately. Novartis subsequently filed an IRE appeal on January 22, 2013.

Novartis argued that the discounts were in error because the drugs dispensed exceeded the maximum dose listed on the FDA-approved label. However, the record shows that Novartis failed to demonstrate that such doses, and the quantities associated with such doses, were likely errors either because the quantities were three times the maximum dose, or they represented a severe threat to the health of beneficiaries, were inconsistent with the packaging, or otherwise represent an unlikely dose in the Medicare population.

The Administrator finds that, as a preliminary matter, in order to initiate further review of the matter, the manufacturer must demonstrate that the quantities dispensed likely represent errors and, thus, that the invoiced gap discount amount is likely in error. The method of doing that is for the manufacturer to document that the appealed quantities: 1) represent three times the maximum FDA labeled dose; or 2) where the dose represents less than three times the maximum FDA labeled dose, or for any quantity-related appeal if there is no maximum FDA labeled daily dose, 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.[18] However, even if such a threshold burden is met, CMS will still deny disputes if it is subsequently confirmed, as a result of further review once this threshold burden is met, that the discount payment was accurately calculated and represented an actual dispensing event that occurred.

In this case, the manufacturer did not establish that there was an FDA labeled maximum dose. Thus, in the alternative, for the manufacturer to justify further review, it must submit supporting documentation that the quantity dispensed 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.

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[11] *Id.* at 3.

[18] *See,* Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011, at 3.

Although there was no FDA labeled maximum dose for this NDC, the IRE verified that the daily quantity invoiced was within the regular dosage and administration guidelines contained in the FDA product information of the drug.[19] The IRE reasonably concluded that, as the quantities dispensed for the respective DRNs were consistent with the regular FDA-approved dose, they did not represent aberrant quantities. The Attachment B of the IRE decision listed for each DRN the FDA dosing information, the regular FDA-approved dose based on quantity dispensed, the quantity equal to three times the FDA-approved regular dose (and that there was FDA maximum indicated) and the actual quantity filled and days' supply.[20] The labeling information on TOBI 300mg/5mL included in pertinent part:

> **Dosage**
> The 300 mg/5mL dose of TOBI® is the same for patients regardless of age or weight.... Doses should be inhaled as close to 12 hours apart as possible and not less than 6 hours apart.
>
> **Treatment Schedule**
> You should take TOBI® in repeated cycles of 28 days on drug followed by 28 days off drug. You should take TOBI® **twice** a day during the 28-day period on drug.[21]

Upon examining of the information provided, the record supports that the actual quantity filled was either equal to, or less than, the regular FDA-approved dose for all of the DRNs listed, with the exception of two DRNs (DRN 00078000000032499796 and 00078000000032798451).[22] For example, the FDA Dosing Information is "1 single use ampule (300 mg/5mL) administered twice per

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[19] *See,* IRE Decision, Appeal CGDP0001162013, dated April 19, 2013, at 4.

[20] *See,* IRE Decision, Appeal CGDP0001162013, dated April 19, 2013, Attachment B, at 7-12.

[21] *See,* IRE administrative record, FDA Labels "Tobramycin Solution for Inhalation" from "Facts&Comparison@eAnswers" , http://online.factsandcomparison.com and Tobramycin "Nebulizer Solution – For Inhalation Use Only" at http://www.accessdata.fda.gov/spl/data/
see also Novartis TOBI Label at http://www.pharma.us.novartis.com/cs/www.pharma.us.novartis.com/product/pi/pdf/tobi.pdf.

[22] *See,* IRE Decision, Appeal CGDP0001162013, dated April 19, 2013, Attachment A, at. 6.

day for 28 days."[23] The calculation for the regular FDA-approved dose based on quantity dispensed is "28 mL for a 28-day supply," which is approximately l OmL per day. The actual quantity filled and days' supply was 280 mL for a 28.:.day supply which was consistent with the FDA-approved regular dose. (Administering a single use ampule (300/5mL) twice a day would equal to 10mL per day x number of days (28) = 280 mL). Since the medication should be taken in repeated cycles of 28 days on drug followed by 28 days off the drug, the actual quantity filled and days' supply of 280 mL for a 28 day supply AND 280 mL for a 56 day supply are both consistent with the FDA-approved regular dose, in this case. . The Administrator finds that the actual quantity filled and days' supply for this drug, were clearly not aberrant for 27 out of the 29 DRNs at issue, as each was equal to or less than 1OmL per day which represented the recommended daily dose as there was no maximum dose indicated.[24]

Further, the record shows that for the two remaining DRNs the quantities dispensed also were not aberrant. For DRNs 00078000000032499796 and 00078000000032798451, the amount of 280mL was filled for a 14 day supply. The regular FDA approved dose based on quantity dispensed would have been 140 mL for a 14-day supply. Although this amount is higher than the regular FDA approved dose, it is still lower than three times the FDA approved regular dose (as there was no maximum dose indicated) which would be 420mL for a 14-day supply. Further, the plan sponsor validated the DRN 00078000000032798451, explaining that "Max Dose warning generated at POS (Rx dosage exceeds ESI's Maximum Daily Dose (MDD), but not FDA's MDD)."[25] The Administrator notes that legitimate variations in patient characteristics and the therapeutic characteristics of drugs often warrant differences in dosage amounts."[26]

In addition, despite the fact that the quantities dispensed for the 28 DRNs were not aberrant or excessive and therefore did not require further investigation by the TPA or IRE, the IRE further requested and received information provided by the Part D sponsor to validate the dispensing for DRN 00078000000032798451 along with those DRNs with quantities other than the standard recommended dose of 280

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[23] *See,* IRE Decision, Appeal CGDP000l162013, dated April 19, 2013, Attachment B, at 7.

[24] *See,* IRE Decision, Appeal CGDP0001162013, dated April 19, 2013, Attachment A, at 6.

[25] *See,* IRE Decision, Appeal CGDP000l162013, dated April 19, 2013at Attachment D, at 14.

[26] *See,* Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011, at. 3.

ml/28 day, which represented dosing of 70mL/7days, 100 mL/10 days, 140 mL/14 days, and 110mL/30 days.[27]

Novartis, in contrast, did not provide additional explanation to support the assertion for all of the DRNs that the "max dosage 90 days is 3.00 units." Novartis failed to provide supporting information that the quantity prescribed per day supply was clearly excessive quantity (three times the FDA labeled Maximum dose), posed risk to the beneficiaries, was inconsistent with packaging, or an unlikely dose for the Medicare population for the DRNs at issue. Thus, the Administrator finds that the IRE properly determined that Novartis was appropriately invoiced for the discounts with respect to this appeal.

[27] *See*, IRE Decision, Appeal CGDP000l 162013, dated April 19, 2013, Attachment A, at 6.

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.

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

Date: 4/29/14

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTERS FOR MEDICARE & MEDICAID SERVICES

Office of the Attorney Advisor

MAY - 2 2014

Mr. Felim Buckley
Novartis Pharmaceutical Corporation
One Health Plaza
East Hanover, NJ 07936-1080

Re: Novartis Pharmaceutical Corporation, Appeal CGDP0001172013

Dear Mr. Buckley:

Enclosed is a copy of the Administrator's decision in the above case upholding the decision of the Independent Review Entity. This constitutes the final administrative decision of the Secretary of Health and Human Services.

Sincerely yours,

Jacqueline R. Vaughn
Attorney Advisor

Enclosure

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

Decision of the Administrator

IN THE MATTER OF:	*	**Appeals CGDP0001172013**
Novartis Pharmaceutical Corporation	*	
P1008 - Quarter 2 - 2012 Appeal	*	
	*	**Date: April 19, 2013**

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This case is before the Administrator, Centers for Medicare & Medicaid Services (CMS), for review of the decision 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)(l)(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.[2] Comments were timely received from the Center for Medicare (CM). Accordingly, this case is now before the Administrator for final agency review.

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[1] Section 1860D-14A(c)(l)(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/PrescriptionDrugCovGenln/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). Provisions of the Manufacturer Agreement were codified in the final rule at 77 Fed Reg 22079 (April 12, 2012) effective June 1, 2012.

[2] *See* n. 1, The administrative review process was codified in the regulation at 42 CFR §423.2330(c), 77 Fed Reg. 22072 (April 12, 2012).

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 for all drugs except one Detail Reference Number (DRN) 00078000000031976487 for Comtan 200mg,[3] finding that the quantities dispensed were not aberrant, and the invoiced amounts were appropriate within the parameters of the Discount Program. The IRE reviewed the appealed eight 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.

The IRE determined that the information provided by the third party administrator (TPA) establishes that the Prescription Drug Event (PDE) data was valid as entered , and that the Part D sponsor provided coverage for the appealed Detail Reference Numbers (DRNs). The record reflected the FDA dosing information, the regular FDA dose based on quantity dispensed, quantity equal to three times the FDA regular dose, and actual quantity filled and days' supply for each DRN. The IRE compared the FDA product information for the drug at issue to the TPA Dispute File listing of "Day's Supply" and "Quantity Dispensed" for the drug, and verified that the daily quantity invoiced was within the dosage and administration guidelines contained in the FDA product information.

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.[4]

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

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[3] For that DRN for Comtan 200 mg, the IRE affirmed Novartis's appeal and found the initial quantities submitted by the pharmacy for the prescription drug event (PDE) records were inaccurate which caused an incorrect Discount calculation.

[4] 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, an appeals.

the maximum FDA labeled dose. CM noted that the Part D sponsors confirmed to the IRE that the drugs were accurate and represented actual dispensing events that occurred in all but one DRN (Comtan® 200 mg). The Part D sponsor stated, for this drug, that the quantity dispensed was correct but adjusted the days supply for the drug. CM stated that this change did not alter the discount amount invoiced to the manufacturer. CM noted that Novartis failed to submit any further evidence to support its claims, and the arguments presented were similar to the ones made in prior appeals to the Administrator, which were upheld. CM argued that CMS guidance issued on May 30, 2011 states that manufacturers bear the burden of proof on appeal to demonstrate that the discount payment was made in error. CM contended 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 second quarter 2012 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

[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).

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 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 or 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 manufacturer's 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)(l)(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. 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.

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[6] *See:J.* CMS Memorandum "Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance" issued on May 21, 2010.

[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 based on the 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.

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 primary 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.[10] Manufacturers bear the burden of proof in meeting these standards.

The May 31, 2011 appeals guidance noted that there were several primary dispute reasons that may reasonably be appealed. CMS clarified its expectations of manufacturers as to what must be demonstrated for these appeals to justify further review and validation by the IRE. Relevan 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.
>
> 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 appeal 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.[11]

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

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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.

occurred."[12] 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."[13] 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. 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." 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.[14]

Pursuant to a March 5, 2012 Dispute Resolution Guidance memorandum, 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.[15]

The March 5, 2012 memorandum again emphasized that CMS will deny disputes if the discount payment is accurately calculated, even if the dispensing event may not have been clinically appropriate. The dispute 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. In explaining the basis for disputes generally, CMS explained that manufacturers must explain why they believe that the invoiced gap discount amount is likely in error. The Dispute Resolution Guidance provides an explanation of the dispute reason codes, and specifically states in pertinent part, consistent with the earlier guidance, that:

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[12] *See,* Medicare· Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011, at 2.

[13] *Id.* at 3.

[14] *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 2.

[15] *See, e.g.* Medicare Coverage Gap Discount Program – Dispute Resolution, dated March 5, 2012, at 1-2.

> 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. [16]

The Attached "Summary of Dispute Submission Guidance by Reason Code" set forth the expected supporting Documentation stating for "Excessive Quantity" that:

> **REQUIRED:**
> The ADDITIONAL INFORMATION field should provide supporting evidence that:
> • The quantity is inconsistent with the packaging of the product;
> • The quantity is unlikely in the Medicare population;
> • The gap discount is based on an inaccurate calculation; and/or,
> • The gap discount was based upon inaccurate data that does not represent the dispensing event that occurred.
>
> Please provide the proprietary benchmark used to identify excessive quantity.

In the instant appeal, Novartis contracted with CMS to participate in the Discount program. Novartis received its second quarter 2012 Invoice Report 201202, covering discounts provided to Medicare Part D beneficiaries in the coverage gap from February 19, 2011 through June 21, 2012. On October 30, 2012, Novartis submitted to CMS' TPA, disputes for 20 detail reference numbers or DRNs using the dispute reason code D04 – Excessive Quantity. On December 28, 2012, the TPA sent Novartis notification that the disputes had been denied.[17] On January 22, 2013, Novartis filed an appeal with the IRE and challenged discounts for 20 DRNs having eight national drug codes. or NDC's which included the following drugs:

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[16] *See,* Medicare Coverage Gap Discount Program Appeals Guidance, dated March 5, 2012, at. 1-2.

[17] *See*, IRE Decision, Appeal CGDP0001172012, at 3.

Elidel Cream 1%® lOmg, Tegretol® 100mg/5mL, Diovan® HCT 160mg/12.5mg, Stalevo® 200, Sandimmune® 25mg, Neoral® 25mg, Comtan® 200 mg, and Exelon® 9.5mg.[18]

The IRE reviewed the Part D Sponsor's verification responses as applicable. For Comtan® 200 mg (DRN 00078000000031976487), the Part D Sponsor stated that the PDE was initially submitted with incorrect information which resulted in an error. However, the Part D Sponsor confirmed that the PDE was adjusted and corrected so that accurate quantities were ultimately supplied for the days indicated.[19] The IRE affirmed the appeal for Comtan® 200 mg and found that the initial quantities submitted by the pharmacy for the PDE records were inaccurate, and based on the submitted PDE data, caused an incorrect Discount calculation. Accordingly, the Part D sponsor noted the PDE was adjusted affecting the invoiced coverage gap dollars.[20]

For the remaining DRNs, the IRE reviewed Novartis's statements from both the initial dispute and the subsequent appeals. The actual quantities dispensed were compared with the FDA dosing information, maximum FDA dose based on quantity dispense, and quantity equal to three times the FDA-approved maximum dose.2[1] The IRE also reviewed the FDA product information to determine the appropriate dosage and administration, and compared it to the information provided in the TPA Dispute File listing of "Days' Supply" and "Quantity Dispensed." By comparing this information, the IRE verified that the daily quantity invoiced was within the dosage and administration guidelines contained in the FDA product information.[22] The IRE found that the appellant did not provide any additional explanation to support its assertion that the quantities dispensed were excessive, and the Manufacturer did not provide the FDA-approved label or other accompanying documentation. The IRE found that the Manufacturer failed to meet the burden of proof to demonstrate that the gap discount was excessive or calculated incorrectly. Novartis failed to show that the quantity prescribed per day was "clearly excessive quantity for a given day's supply or is inconsistent with the packaging of the product." The IRE denied Novartis' appeal for the DRNs at issue and found the quantities dispensed were not aberrant, as they did not represent greater than three times the FDA labeled daily dose.

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

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[111] *See*, IRE Decision, Appeal CGDP000l 172012, Attachment A, at 7.
[19] *See*, IRE Decision, Appeal CGDP000l 172012, Attachment D, at 12.
[20] *See*, IRE Decision, Appeal CGDP000l 172012, at pg. 4.
[21] *See*, IRE Decision, Appeal CGDP000l 172012, Attachment B, at 8-9.
[22] *Id.* at 4.

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 Administrator finds that, as a preliminary matter, in order to initiate further review of the matter, the manufacturer must demonstrate that the quantities dispensed likely represent errors and, thus, that the invoiced gap discount amount is likely in error. The method of doing that is for the manufacturer to document that the appealed quantities: 1) represent three times the maximum FDA labeled dose; or 2) where the dose represents less than three times the maximum FDA labeled dose, or for any quantity-related appeal if there is no maximum FDA labeled daily dose, 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.[23] However, even if such a threshold burden is met, CMS will still deny a dispute if it is subsequently confirmed, as a result of further review once this threshold burden is met, that the discount payment was accurately calculated and represented an actual dispensing event that occurred.

For Comtan® 200 mg (DRN 00078000000031976487), the record shows that the initial days' supply for the quantities invoiced were inaccurate. The Plan Sponsor's verification response for the dispensing information was that the claim information was incorrect. The Plan Sponsor specifically stated that "the claim in question was submitted with 781 QTY and 32 DS [day supply]. As a result of a previous audit, this claim was reversed and resubmitted on 9/10/2012 with 781 Qty and 48 DS."[24] The manufacturer did not dispute this event. The prescription read "Take one tab every hour while awake, with each Carbidopa/Levodpa dose."[25] The Plan Sponsor verified with the pharmacy that the member takes 1.5 tablets of Carbidopa/Levodpa every hour while awake and sleeps 8 hours per day resulting in 16 doses of medicine per day. Thus, the member would take Comtan® 16 times a day along with Carbidopa/Levodpa, resulting in a supply of 48 DS. The FDA-approved labeled Dosing information for this drug is eight tablets per day.[26] Since the calculation for the maximum FDA-approved dose based on quantity dispensed was

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[23] *See* Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011, at 3. ·-

[24] *See* IRE Decision, Appeal CGDPOOO1172012, Attachment D, at 12.

[25] *Id.*

[26] *See* IRE Decision, Appeal CGDPOOO1172012, Attachment B, FDA Dosing Information, at 9. *See,* IRE Record, FDA Label Comtan®"Facts&Comparison@eAnswers", http://online.factsandcomparison.com

256 tablets for a 32 day supply, the quantity equal to three times the FDA-approved maximum dose is 768 tablets for 32 days.[27] The actual quantity dispensed as reflected in the adjustment was 781 tablets for 48 days, which although is higher than the maximum FDA-approved amount, is still lower than three times the maximum dose amount.[28] Thus, the Administrator finds that the initial error was corrected and the quantity dispensed for Comtan® 200 mg, as reflected in this corrected claim, was not aberrant. CMS has verified that the adjustment did not alter the calculation of the amount of the discount.[29]

For the remaining 19 DRNs, the Administrator finds that the quantities dispensed did not represent greater than three times the FDA-approved maximum labeled daily dose. By way of example, Novartis appealed the DRN for Stalevo® 200, which has a Maximum dosage of 540 tablets for 90 days. (The FDA Dosing information for this drug is 6 tablets daily).[30] Since the calculation for the maximum FDA-approved dose based on quantity dispensed was 540 tablets for a 90 day supply, the quantity equal to three times the FDA-approved Maximum Dose is 1620 tablets for 90 days. The actual quantity dispensed for certain of the DRNs was 720 tablets for 90 days, which although is higher than the maximum FDA-approved amount, is still lower than 3 times the maximum dose amount.[31] Even for DRN 00078000000029853926 where the actual quantity dispensed of Stalevo® 200 was 720 tablets for a 60 day supply, the quantity per day is still less than the three times FDA labeled approved maximum dose of 1620 tablets for a 90 day supply. The actual quantity filled would result in approximately 12 tablets per day, whereas, in contrast, three times the FDA-approved maximum dose would result in approximately 18 tablets per day. In addition, although the threshold was not met to require further investigation for any of the DRNS involving Stavelo, the PDE for DRN 00078000000029853926 was validated as correct and confirmed by pharmacist.

For the drugs with no FDA maximum labeled dose established in the record,[32] the Part D Sponsor verified that the claim information was correct. For example, for

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[27] *Id.*

[28] *See* IRE Decision, Appeal CGDP00011720l3, Attachment D, at 12.

[29] CM Comments, dated July 13, 2013 at 3.

[30] *See* IRE Decision, Appeal CGDP00011720l2, Attachment B, FDA Dosing Information, at 8. *See,* IRE administrative record, FDA Label for Stalevo at http://www:-accessdata.fda.gov/spl/data/

[31] *Id.*

[32] For Sandimmune® 25 mg there is, no well-established maximum, as dosage is based upon patient's weight, and for and Elidel Cream 1% (100 mg) there is no well-established maximum dose for the approved indication according to the prescribing information. *See,* IRE administrative record, FDA Labels for

Sandimmune® 25 mg, DRN 00078000000031318040, the Plan Sponsor stated that "dosing is highly variable and dependent on patient weight and clinical response. Based on the submitted claim info, .member is taking 6 capsules per day and does not seem excessive considering that there is no established maximum dose."[33] For Elidel Cream 1% (100 mg) the Plan Sponsor provided that the prescription instructions were to "apply a thin film topically to affected areas twice daily" and the prescription was filled accordingly. The Administrator recognizes that different circumstances warrant variations in dosage according to the needs to each patient in these cases. Where there is no FDA labeled approved maximum dose, the manufacturer must establish that the dispensed doses represent 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, which the Manufacturer failed to do here.

The Administrator also notes that "legitimate variations in patient characteristics and the therapeutic characteristics of drugs often warrant appropriate dosing in excess of FDA approved labeling."[34] Thus, the actual 'quantity filled and days' supply for this drug, along with the other DRNs appealed in this case, were not aberrant or excessive. In addition, even though the quantities dispensed for the DRNs were not aberrant or excessive and therefore did not require further investigation by the TPA or IRE, the IRE requested and received information provided by the Part D Sponsor validating, *inter a/ia,* the dispensing for those DRNs without an FDA labeled maximum dose threshold (Sandimmune 25 mg and Elidel cream 1%).

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 the second Quarter of 2012 coverage gap discounts, with respect to this appeal.

Sandimmune Soft Gelatin Capsules(cyclosporine capsules, USP)Sandimmune Oral Solution(cyclosporine oral solution, USP)Sandimmune Injection(cyclosporine injection, USP) and Elidel (pimecrolimus) Cream 1%
at http://www.accessdata.fda.gov/spl/data/

[33] *See* IRE Decision, Appeal CGDPOOO1172013, Attachment D, at 12.

[34] *See* Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011, at 3.

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 as modified herein.

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

Date: 4/29/14

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTERS FOR MEDICARE & MEDICAID SERVICES

Office of the Attorney Advisor

MAY - 2 2014

Mr. Felim Buckley
Novartis Pharmaceutical Corporation
One Health Plaza
East Hanover, NJ 07936-1080

Re: Novartis Pharmaceutical Corporation, Appeal CGDP0001182013

Dear Mr. Buckley:

Enclosed is a copy of the Administrator's decision in the above case upholding the decision of the Independent Review Entity. This constitutes the final administrative decision of the Secretary of Health and Human Services.

Sincerely yours,

Jacqueline R. Vaughn
Attorney Advisor

Enclosure

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

Decision of the Administrator

IN THE MATTER OF:	*	**Appeals CGDP0001182013**
Novartis Pharmaceutical Corporation	*	
P1008 - Quarter 2 - 2012 Appeal	*	
	*	**Date: April 19, 2013**

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This case is before the Administrator, Centers for Medicare & Medicaid Services (CMS), for review of the decision 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)(l)(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.[2] Comments were timely received from the Center for Medicare (CM). Accordingly, this case is now before the Administrator for final agency review.

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[1] Section 1860D-14A(c)(l)(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.ems.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenln/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). Provisions of the Manufacturer Agreement were codified in the final rule at 77 Fed Reg 22079 (April 12, 2012) effective June 1, 2012.

[2] *See* n. 1, The administrative review process was codified in the regulation at 42 CFR §423.2330(c), 77 Fed Reg. 22072 (April 12, 2012).

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 finding that the quantity dispensed was not aberrant, and the invoiced amounts were appropriate within the parameters of the Discount Program. The record reflected the FDA dosing information, the regular FDA dose based on quantity dispensed, quantity equal to three times the FDA regular dose, and actual quantity filled and days' supply for each DRN. The IRE compared the FDA product information for the drug at issue to the TPA Dispute File listing of "Day's Supply" and "Quantity Dispensed" for the drug, and verified that the daily quantity invoiced was within the dosage and administration guidelines contained in the FDA product information.

The IRE reviewed the appealed 13 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. Regarding 12 of the NDCs, the IRE found that the Manufacturer did not provide any additional explanation to support its assertion that the quantities dispensed were excessive, and the Manufacturer did not provide the FDA-approved label or other accompanying documentation. It is the manufacturer's burden of proof to demonstrate that the gap discount was excessive or calculated incorrectly and to explain "why they believe that the invoiced gap -discount is likely in error." The IRE found that the quantities dispensed did not represent greater than three times the FDA labeled daily dose. Accordingly, the Manufacturer failed to provide supporting documentation information that the quantities prescribed per day supply was a "clearly excessive quantity for a given day's supply or is inconsistent with the packaging of the product" as described in CMS guidance for the DRNs at issue. The IRE stated that the applicable drugs were appropriately billed for the coverage gap discount dollars associated with the 12 NDCs and the corresponding Detail Reference Numbers (DRNs), and denied Novartis' appeal based on Excessive Quantity.[3]

With respect to the NDC for Vivelle-Dot 0.1mg/day for three DRNs, The IRE denied the appeal finding that the quantity dispensed was not aberrant, and the invoiced amounts were appropriate within the parameters of the Discount Program.

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[3] 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.

Following the same process of review the IRE determined that the quantities for the DRNs exceeded three times the FDA-approved maximum dose. The IRE reviewed the information provided by the Part D Sponsors for the respective DRNs. CMS acknowledged that legitimate variations in patient characteristics often warrant appropriate dosing in excess of the FDA approved labeling. The Part D Sponsors provided coverage for this NDC because they determined that the quantities dispensed represented medically appropriate variations in dosing. The Part D Sponsors provided information that the pharmacist verified the prescribed dose/quantities as valid. The IRE thus denied the manufacturers file disputes finding that the quantities dispensed were not aberrant. The applicable drug was appropriately billed for the coverage gap discount dollars associated with the one NDC and the corresponding DRNs, and within the parameters of the Discount Program.

COMMENTS

Novartis requested review of the IRE's decision based on a challenge that the DRNS exceeded the maximum recommended dosage of applicable drugs.

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. CM noted that the Part D sponsors confirmed to the IRE that the drugs were accurate and represented actual dispensing events that occurred, and the IRE determined that the drugs were appropriately invoiced. CM stated that Novartis failed to submit any further evidence to support its claims, and the arguments presented were similar to the ones made in prior appeals to the Administrator, which were upheld. CM argued that CMS guidance issued on May 30, 2011 states that manufacturers bear the burden of proof on appeal to demonstrate that the discount payment was made in error. CM contended 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 second quarter 2012 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 §l 860D-43 and §l 860D-l 4A to the Act. Under the program, the ACA made manufacturer discounts available to applicable Medicare beneficiaries receiving applicable drugs[4] 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.[5] 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.[6] 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.[7]

Through the use of a third-party administrator or 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 manufacturer's 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.

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[4] An applicable drug, as defined in §l 860D-l 4A(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).

[5] *See*, CMS Memorandum "Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance" issued on May 21, 2010.

[6] 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.

[7] Each Part D sponsor calculates the applicable 50 percent discount based on the 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)(l)(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. 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 primary 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.[9] Manufacturers bear the burden of proof in meeting these standards.

The May 31, 2011 appeals guidance noted that there were several primary dispute reasons that may reasonably be appealed. CMS clarified its expectations of manufacturers as to what must be demonstrated for these appeals to justify further review and validation by the IRE. Relevant to this appeal, it stated in pertinent part:

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[8] 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.

[9] *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 appeal 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. [10]

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." [11] 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."[12] 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. 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." 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]

Pursuant to a March 5, 2012 Dispute Resolution Guidance memorandum, 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

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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, at 2.

[12] *Id.* at 3.

[13] *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 2.

Fill, Marketing Category Not a Biologic License Application (BLA) or New Drug Application (NDA) and Other.[14]

The March 5, 2012 memorandum again emphasized that CMS will deny disputes if the discount payment is accurately calculated, even if the dispensing event may not have been clinically appropriate. The dispute 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. In explaining the basis for disputes generally, CMS explained that manufacturers must explain why they believe that the invoiced gap discount amount is likely in error. The Dispute Resolution Guidance 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. [15]

The Attached "Summary of Dispute Submission Guidance by Reason Code" set forth the expected supporting Documentation stating for "Excessive Quantity" that:

> **REQUIRED:**
> The ADDITIONAL INFORMATION field should provide supporting evidence that:
> • The quantity is inconsistent with the packaging of the product;
> • The quantity is unlikely in the Medicare population;
> • The gap discount is based on an inaccurate calculation; and/or,

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[14] *See, e.g.,* Medicare Coverage Gap Discount Program – Dispute Resolution, dated March 5, 2012, at 1-2.

[15] *See,* Medicare Coverage Gap Discount Program Appeals Guidance, dated March 5, 2012, at. l-2.

> • The gap discount was based upon inaccurate data that does not represent the dispensing event that occurred.
>
> Please provide the proprietary benchmark used to identify excessive quantity.

In the instant appeal, Novartis contracted with CMS to participate in the Discount program. Novartis received its second quarter 2012 Invoice Report 201202, covering discounts provided to Medicare Part D beneficiaries in the coverage gap from April 4, 2011 through June 21, 2012. On October 30, 2012, Novartis submitted to CMS' TPA, disputes for 19 detail reference numbers (DRNs) using the dispute reason code D04 – Excessive Quantity. On December 28, 2012, the TPA sent Novartis notification that the disputes had been denied.[16] On January 23, 2013, Novartis filed an appeal with the IRE and challenged discounts for 19 DRNs having 13 NDC's which included the following drugs: Diovan® 40mg, Diovan® 80mg, Diovan® HCT 80mg/12.5mg, Stalevo® 75, Stalevo® 100, Stalevo® 150, Stalevo® 200, Tegretol® 200 mg, Tegretol® XR 100 mg, Tegretol® XR 200 mg, Tegretol® XR 400 mg, Trileptal suspension 300 mg/5mL, and Vivelle® 0.1mg.[17]

The Administrator finds that, as a preliminary matter, in order to initiate further review of the matter, the manufacturer must demonstrate that the quantities dispensed likely represent" errors and, thus, that the invoiced gap discount amount is likely in error. The method of doing that is for the manufacturer to document that the appealed quantities: 1) represent three times the maximum FDA labeled dose; or 2) where the dose represents less than three times the maximum FDA labeled dose, or for any quantity-related appeal if there is no maximum FDA labeled daily dose, 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.[18] However, even if such a threshold burden is met, CMS will still deny a dispute if it is subsequently confirmed, as a result of further review once this threshold burden is met, that the discount payment was accurately calculated and represented an actual dispensing event that occurred.

The IRE reviewed Novartis' statements from both the initial dispute - and the subsequent appeals. The actual quantities dispensed were compared with the FDA dosing information, maximum FDA dose based on quantity dispense, and quantity

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[16] *See,* IRE Decision, Appeal CGDP0001182012, at pg. 3.
[17] *See,* IRE Decision, Appeal CGDP0001182012, Attachment A, at 7.
[18] *See,* Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011, at 3.

equal to three times the FDA-approved maximum dose.[19] The IRE also reviewed the FDA product information to determine the appropriate dosage and administration, and compared it to the information provided in the TPA Dispute File listing of "Days' Supply" and "Quantity Dispensed." By comparing this information, the IRE verified that the daily quantity invoiced was within the dosage and administration guidelines contained in the FDA product information for 12 of the NDCs [20] and 16 related DRNs.[21] The IRE denied Novartis' appeal for these DRNs and found the quantities dispensed were not aberrant,[22] as they did not represent greater than three times the FDA labeled daily dose.

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, for the 12 NDCs 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 Administrator finds that the quantities dispensed did not represent greater than three times the maximum FDA-labeled daily dose. By way of example, Novartis appealed the DRN for Diovan® 80mg, which has a Maximum dosage of 360 (80 mg) tablets for 90 days. (The FDA Dosing information for this drug is 80 mg up to four times daily).[23] Since the calculation for the maximum FDA-approved labeled dose based on quantity dispensed was 360 tablets for a 90 day supply, the quantity equal to three times the FDA-approved Maximum Dose is 1080 tablets for 90 days. The actual quantity dispensed was 540 tablets for 90 days, which although is higher than the recommended FDA-approved amount, is still lower than three times the maximum FDA-labeled dose amount.[24] The Administrator notes that "legitimate variations in patient characteristics and the therapeutic characteristics of drugs

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[19] *See* IRE Decision, Appeal CGDP0001182012, Attachment B, at 8-9.

[20] Diovan® 40mg, Diovan® 80mg, Diovan® HCT 80mg/12.5mg, Stalevo® 75, Stalevo® 100, Stalevo® 150, Stalevo® 200, Tegretol® 200 mg, Tegretol® XR 100 mg, Tegretol® XR 200 mg, Tegretol® XR 400 mg, Trileptal suspension 300 mg/5mL.

[21] *Id.* at 4. .,

[22] *See also* IRE administrative record and related FDA labels for respective drugs.

[23] *See*, IRE Decision, Appeal CGDP0001182012, Attachment B, FDA Dosing Information, at 8. *See also* IRE Administrative record FDA label for Diovan® at http://www.accessdata.fda.gov/spl/data

[24] *Id.*

often warrant appropriate dosing in excess of FDA approved labeling."[25] Thus, the actual quantity filled and days' supply for this drug, along with the other specified DRNs appealed in this case for those NDCs were similarly not aberrant and appropriately dispensed within the parameters of the program.[26]

However, for Vivelle® Dot 0.1 mg DRNs 00078000000030327326, 00078000000030550805, and 00078000000031340855), Novartis also argued that the dose dispensed exceeded the maximum dose available. The IRE found that the DRNs represented greater than three times the FDA labeled daily dose. The IRE verified that the Part D sponsors had provided coverage for the appealed drug for these beneficiaries and verified that the quantities dispensed represented actually dispensed variations in dosing. Specifically, the Part D sponsors provided coverage for the dispensed quantity and verified that the prescriptions were written and dispensed with the requested quantities.[27] For example, for DRN 00078000000031340855, Vivelle® Dot 0.1 mg, the Part D Sponsor explained, in pertinent part, 'The pharmacy has confirmed that the medication was filled as prescribed calling for 3 patches per day for a 90 day supply based upon the prescribing [doctor's] orders. The claim was [dispensed] as prescribed therefore valid. The Vivelle-Dot package size is four patches per box. In this case a quantity of 272 patches were dispensed, which is equal to 68 boxes. The dispensed quantity is correct."[28] For DRN 00078000000030327326, the sponsor stated that "the claim was processed for a 73 year old male member with cancer. There is a compendia support for use of transdermal estrogen patches....."[29] The Plan Sponsor also validated the dispensing information was correct for D R N 00078000000030550805.

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[25] *See,* Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011, at 3.

[26] This includes Diovan® 40mg (DRNs 00078000000031676617 and 00078000000033303094, Diovan® 80mg (DRN 00078000000031040673), Diovan® HCT 80mg/12.5mg (DRN 00078000000031030361), Stalevo® 75 (DRNs 00078000000029556433 and 00078000000029557527), Stalevo® 100 (DRN 00078000000033140520), Stalevo® 150 (DRN 00078000000032783191), Stalevo® 200 (DRNs 00078000000032917543 and 00078000000033307673), Tegretol® 200 mg (DRN 00078000000032995847), Tegretol® XR 100 mg (DRN 00078000000028128745), Tegretol® XR 200 mg (DRN 00078000000032827340), Tegretol® XR 400 mg (DRN 00078000000030318414), and Trileptal suspension 300 mg/5mL (DRNs 00078000000029288028 and 00078000000029288044).

[27] *See,* IRE Decision, Appeal CGDP0001182013, Attachment D, at 12.

[28] *Id.*

[29] *Id.*

Thus, although the amounts dispensed for these three DRNs for the Vivelle-Dot (272 patches for a 90-day supply, 192 patches for an 84-day supply, and 176 patches for an 88-day supply, respectively) was higher than three times the FDA approved daily dose for those days supplies each PDE/DRN dosage was validated and verified as properly invoiced and dispensed in accordance with the prescriber's instructions.[30] As noted, CMS recognizes that legitimate variations in patient characteristics and the therapeutic characteristics of the drugs warrant appropriate dosing in excess of FDA approved labeling. In this instance, the respective PDEs have been verified as occurring and dispensed in accordance with the prescribers instructions for the quantities invoiced. Thus, the record does not support that the appealed PDEs and related DRNs represented errors.

Accordingly, 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 the second Quarter of 2012 coverage gap discounts, with respect to this appeal.

[30] *See* IRE Decision, Appeal CGDP0001182013, Attachment B, at 9. *See also* IRE administrative record containing FDA label for Vivelle-Dot.

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.

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

Date: 4/29/14

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services