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

Decision of the Administrator

IN THE MATTER OF:	*	**Appeals CGDP0001252013**
Novartis Pharmaceutical Corporation	*	
P1008 - Quarter 3 - 2012 Appeal	*	
	*	**Date: May 31, 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)(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.[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)(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). 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 reviewed the appealed twenty-three (23) Detail Reference Numbers (DRNs) for twelve (12) National Drug Codes (NDCs) to determine whether the days' supply dispensed, *inter alia*, exceeded the CMS-specified threshold of three times the FDA approved maximum dose included in the appeals guidance. The IRE denied the appeal for all the drugs finding that the quantities dispensed were not aberrant, and the invoiced amounts were appropriate 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 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.

For 17 of the DRNs, some of the NDCs had no maximum dose and others had an FDA maximum dose, The IRE compared the FDA product information for the drugs at issue to the TPA Dispute File listing of "Day's Supply" and "Quantity Dispensed" for the drugs, and verified that for those DRNs either there was no maximum daily dose or that the amount dispensed did not represent greater than three times the FDA labeled daily dose. The IRE consequently found that the Appellant failed to provide supporting information that the quantity prescribed per days' supply represented a severe threat to the health of the beneficiaries, is inconsistent with the package or otherwise represented an unlikely dose in the Medicare population. The IRE also noted that for one DRN that the Appellant appealed, the dosing was within the FDA labeled daily dose.

The IRE also compared the FDA product information for the Vivelle-Dot® 0.1mg related DRNs to the TPA Dispute File listing of "Day's Supply" and "Quantity Dispensed" for the drugs, and verified that for the six DRNs related to the Vivelle-Dot® 0.1mg, the daily quantity invoiced was the quantity exceeded three times the FDA maximum dose. However, the Part D sponsors verified and provided information showing that the quantities dispensed represented medically appropriate variations in dosing. The Part D sponsor provided information that the pharmacist verified the prescribed amount dose/quantity was valid. The IRE consequently found that the Appellant failed to provide supporting information that the quantity prescribed per days' supply was a clearly excessive quantity for a given days' supply or is inconsistent with packaging of the product as described by CMS 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.[3]

COMMENTS

Novartis requested review of the IRE's decisions for the 23 DRNs at issue.

CM incorporated its prior comments in previous decisions since the appeals were so similar in nature to the current appeals. CM noted that Novartis alleged that the amounts invoiced were for excessive/aberrant quantities, and therefore it was not responsible for the excess dollars 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.

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

[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.

[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 Public Health Service Act (BLA).

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.

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

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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.

from the third party administrator; it has the right to appeal to the Independent 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.
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> 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.
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> 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 third quarter 2012 Invoice Report 201203, covering discounts provided to Medicare Part D beneficiaries in the coverage gap from June 15, 2012 through September 5, 2012. On December 31, 2013, Novartis submitted to CMS' TPA, disputes for 23 detail reference numbers or DRNs using the dispute

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

reason code D04 – Excessive Quantity. On March 1, 2013, the TPA sent Novartis notification that the disputes had been denied.[16] On March 19, 2013, Novartis filed an appeal with the IRE and challenged discounts for 23 DRNs having twelve national drug codes or NDC's which included the following drugs: Zigran 0.15%® Miacalcin® 200 [I.U.]/mL, Comtan® 200 mg, Vivelle-Dot® 0.1mg (3 packet in 1 carton), Vivelle-Dot® 0.1mg (8 pouch in 1 packet), Trileptal® 60 mg/mL, Ritalin 20 mg, Tegretol® 100mg/5mL, Tegretol® 200mg, Tegretol® XR 200 mg, Stalevo® 200 (carbidopa 50 mg, levodopa 200 mg, entacapone 200 mg), and Afinitor 5mg.[17]

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.[18] 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.[19] 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 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

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[16] *See*, IRE Decision, Appeal CGDP0001252013, at 3.
[17] *See*, IRE Decision, Appeal CGDP0001252013, Attachment A, at 12.
[18] *See*, IRE Decision, Appeal CGDP0001252013, Attachment B, at 13-14.
[19] *Id.* at 9.

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.[20] 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 Vivelle Dot 0.1 mg patch (DRNs 00078000000037537772, 00078000000037538679, 00078000000036467209, 00078000000036467631, 00078000000036467831, and 00078000000036942578), Novartis 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.[21] For example, for DRNs 00078000000037537772 and 00078000000037538679, Vivelle® Dot 0.1 mg, the Part D Sponsor explained, in pertinent part, "The member was already taking this protected class drug (based upon the diagnosis of prostate cancer) upon his enrollment in January 2011, so coverage was continued. In May 2012, the increased dosage was requested by the prescriber, determined by Coventry to be medical appropriate and was authorized by the plan. The member was being treated for prostate cancer and the compendia supports use of Vivelle for such treatment."[22] For DRN 00078000000036942578, the sponsor stated that "Patient is being treated with Hormonal Therapy for Prostate Cancer as validated with prescriber."[23] The Plan Sponsor also validated the dispensing information was correct for the three remaining DRNs (00078000000036467631, 00078000000036467831, and 00078000000036467209), and stated that "The Pharmacy confirmed that the claim is accurate and they received approval from the prescribing physician to provide dosing as indicated."[24]

Thus, although the amounts dispensed for these six DRNs for the Vivelle-Dot 0.1 mg patch were higher than three times the FDA approved dose for those days supplies each PDE/DRN dosage was validated and verified as properly invoiced

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

[21] *See*, IRE Decision, Appeal CGDP0001252013, Table 1, at 5-6.

[22] *Id.* at 5.

[23] *Id.* at 6.

[24] *Id.* at 5-6.

and dispensed in accordance with the prescriber's instructions.[25] 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.

For the remaining 17 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 00078000000040938664 for Comtan® 200, which has a Maximum dosage of 720 tablets for 90 days. (The FDA Dosing information for this drug is 8 tablets daily).[26] Since the calculation for the maximum FDA-approved dose based on quantity dispensed was 720 tablets for a 90 day supply, the quantity equal to three times the FDA-approved Maximum Dose is 2160 tablets for 90 days. The actual quantity dispensed for this DRNs was 810 tablets for 90 days, which although is higher than the maximum FDA-approved amount, is still lower than 3 times the maximum dose amount.[27] Even for DRN 00078000000035678293 where the actual quantity dispensed of Tregretol® 200 was 900 tablets for a 90 day supply, and the Maximum FDA-approved dose was 720 tablets for 90 days, the quantity per day is still less than the three times the FDA labeled approved maximum dose of 2160 tablets for a 90 day supply. In addition, although the amount dispensed did not exceed three times the maximum dose, the Part D sponsor also confirmed that the dispensing event occurred consistent with the prescription as written."[28]

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[25] *See* IRE Decision, Appeal CGDP0001252013, Table 1 at 5-6, and Attachment B at 13.

[26] *See* IRE Decision, Appeal CGDP0001252013, Attachment B, FDA Dosing Information, at pg. 13. *See*, IRE administrative record, FDA Label for Comtan at http://www.accessdata.fda.gov/spl/data/

[27] *Id.*

[28] *See* IRE Decision, Appeal CGDP0001252013, Table 1, at 6. For example, for Tegretol® 200 mg, DRNs 00078000000035603706, the Plan Sponsor verified that the claim resulted in Max Daily Dose alert and the "edit was reviewed and the claim was processed by the pharmacist based on the member's history and did not represent a safety threat to the Medicare beneficiary." For Tegretol® 200 mg DRN 00078000000035678293, and Tegretol® XR 200 mg DRN 00078000000034100479, the Plan Sponsor stated that "the pharmacy confirmed that the claim is accurate and they received approval from the prescribing physician to provide dosing as indicated."

For the drugs with no FDA maximum labeled dose established in the record,[29] the Part D Sponsor verified that the claim information was correct. For Zirgan 0.15% 5g tube DRN 42826000000040703582, the Plan Sponsor provided that the prescription directions for use are "apply to left eye 4 times daily and were confirmed with the pharmacy… the days' supply per fill are dependent upon the amount of gel applied each time by the member."[30] The Plan Sponsor verified that 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."[31] 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 alia*, the dispensing for those DRNs without an FDA labeled maximum dose threshold (Zirgan 0.15% 5g tube, Miacalcin 200 [I.U.]/mL, Trilptal 60 mg/mL®, Ritalin 20 mg, and Afinitor 5mg).

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

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[29] For Zirgan 0.15% 5g tube, Miacalcin 200 [I.U.]/mL, Trilptal 60 mg/mL® there is no well-established maximum. For Ritalin 20 mg, no maximum dose is established as "dosage should be individualized according to the needs and responses of the patient." For Afinitor 5mg, "maximum dose for hepatic function impairment is 2.5 mg/day, however there are no well-established maximum doses for the other approved indications." *See* IRE Decision, Appeal CGDP0001252013, Attachment B, FDA Dosing Information, at 13-14. *See*, IRE administrative record, FDA Labels for the drugs at http://www.accessdata.fda.gov/spl/data/

[30] *See* IRE Decision, Appeal CGDP0001252013, Table 1, at 6.

[31] *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.

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

Date: 6/24/14

/s/

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services