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

Decision of the Administrator

IN THE MATTER OF:	*	**Appeals CGDP0001272013**
Novartis Pharmaceutical Corporation	*	
P1008 - Quarter 3 - 2012 Appeal	*	
	*	**Date: June 7, 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 five Detail reference Numbers (DRNs) for three National Drug Codes (NDCs) to determine whether the days' supply dispensed were excessive and aberrant.

For three of the appealed DRNs in this case, (00078000000024689614 for Methergine 0.2mg, 00078000000034367340 and 00078000000041195864 for Zortress 0.5mg), the IRE denied the appeals 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) established 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.[3] For the DRNs at issue in this case, the FDA Dosing Information was not available, as there is no well-established maximum dose for the approved indication according to the prescribing information for the drugs.

The IRE found that the quantities dispensed did not have a maximum FDA labeled daily dose established, nor did it represent greater than three (3) times the FDA labeled daily dose. The IRE noted that Novartis failed to provide supporting information that the quantity prescribed per days' supply "represents a severe threat to the health of beneficiaries, is inconsistent with packaging of the product, or otherwise represents an unlikely dose in the Medicare population," for the DRNs at issue.[4] 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 for these three DRNs.[5]

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[3] *See,* IRE Decision, Appeal CGDP0001272013, Attachment B, at 10.

[4] *See,* Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011, and March 5, 2012.

[5] 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.

However for two DRNs in this case, Zortress 0.75mg (00078000000036261247 and 00078000000036261389), the IRE affirmed Novartis's appeal and found that the DRNs at issue were not eligible within the parameters of the Discount Program. The Part D sponsors noted in their dosing explanation that for these two DRNs, the applicable drug, Zortress 0.75mg, was eligible for coverage under Part B and Part D[6] and that in this instance Thus, the IRE found based upon the Part D Sponsor's explanation, that the DRNs were ineligible for coverage under Medicare Part D as member was a transplant patient. The Part D sponsors noted that the PDE will be adjusted to reflect the correct dispensing information.

COMMENTS

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

CM submitted comments stating that Novartis failed to meet the burden of proof necessary to demonstrate that the Discount Program amounts invoiced were in error. CM noted that Novartis argued that the amounts invoiced were for excessive/aberrant quantities and therefore the company was not responsible for the excess dollars invoiced. CM argued that the 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 stated that Novartis failed to demonstrate at any level of the dispute processes that the invoiced discounts amounts were incorrect. Further, CM noted that the IRE confirmed with the Part D sponsors invoiced that the calculations were accurate and represent actual dispensing events that occurred, and thus, recommended that the Administrator uphold the IRE's decisions that Novartis was appropriately billed for third quarter 2-012 Discount Program 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

[6] *See*, IRE Decision, Appeal CGDP0001272013, Table 2, at 5.

Act. Under the program, the ACA made manufacturer discounts available to applicable Medicare beneficiaries receiving applicable drugs[7] 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.[8] 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.[9] 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.[10]

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

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[7] 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).

[8] *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.

[9] 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.

[10] 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.

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.[11] 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.[12] 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

[11] 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.

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

> 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.[13]

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."[14] 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."[15] 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.[16]

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.[17]

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

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

[15] *Id.* at 3.

[16] *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.

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

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.[18]

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.

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

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 July 28, 2011 through August 18, 2012. On December 31, 2012, Novartis submitted to the CMS' TPA, disputes for 5 detail reference numbers or DRNs using the dispute reason code D04 – Excessive Quantity. On March 1, 2013, the TPA sent Novartis notification that the disputes had been denied.[19] On March 25, 2013, Novartis filed an appeal with the IRE and challenged discounts for 5 DRNs having three national drug codes or NDC's which included the following drugs: Methergine 0.2mg, Zortress 0.5mg, and Zortress 0.75mg.[20]

For three of the appealed DRNs in this case, (00078000000024689614 for Methergine 0.2mg, 00078000000034367340 and 00078000000041195864 for Zortress 0.5mg), Novartis argued that the discounts were in error because the drugs dispensed exceeded the maximum dose listed on the FDA-approved label. The record shows that Novartis failed to demonstrate that such doses, and the quantities associated with such doses, were likely errors either because they were three times higher than the FDA maximum labeled dosing, represented a severe threat to the health of beneficiaries, or were inconsistent with the packaging or otherwise represent an unlikely dose in the Medicare population.

The 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.[21] 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.

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[19] *See*, IRE Decision, Appeal CGDP0001272012, at 3.
[20] *See*, IRE Decision, Appeal CGDP0001272012, Table 1, at 4.
[21] *See* Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011, at 3.

These specific drugs have no FDA maximum labeled dose established in the record,[22] however, the Part D Sponsor verified that the claim information was correct. For example, for Methergine® 0.2 mg, DRN 00078000000024689614, 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."[23] With respect to the drug Zortress, it was verified that "There are no well-established maximum doses for the other approved indications according to the prescribing information.[24] 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."[25] Thus, the actual quantity filled and days' supply for the drug Methergine, along with Zortress 0.5mg 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.

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, three of the appealed DRNs in this case, for Methergine 0.2mg (00078000000024689614), and Zortress 0.5mg (00078000000034367340 and

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[22] *See*, IRE Decision, Appeal CGDP0001272013, Attachment B, at 11.
[23] *See* IRE Decision, Appeal CGDP0001272013, Table 2, at 5.
[24] *See* IRE Decision, Appeal CGDP0001272013, Attachment B, at 11. The Part D sponsor stated that the drug Zortress (Everolimus) is used in patients with severe hepatic impairment for the treatment of advanced pancreatic neuroendorcrine tumors, advanced renal cell carcinoma, or renal angiomyolipoma. *But see* when used in conjunction with Medicare covered transplant at Medicare Prescription Drug Benefit Manual, Chapter 6, Appendix C-1, C-1-Attachment 1 and C-2 "Medicare Part B versus Part D Coverage.
[25] *See* Medicare Coverage Gap Discount Program Appeals Guidance, dated May 31, 2011, at 3.

00078000000041195864). Moreover, the IRE also found, for the two DRNs for Zortress 0.75mg (00078000000036261247 and 00078000000036261389), that the quantities dispensed did not have a maximum FDA labeled daily dose or did not represent greater than three times the FDA labeled daily dose. Novartis also failed to show that the dosage represented a severe threat to the health of beneficiaries was inconsistent with the package of the product or otherwise represented an unlikely dose in the Medicare population. However, the IRE found that the part D plan sponsor for the applicable DRNs Zortress 0.5mg (00078000000034367340 and 00078000000041195864). Stated in their dosing explanation that those DRNs are eligible for coverage under Part B and Part D and that upon review the Part D sponsors verified that these two DRNs should have been covered under Part B.

Relevant to the DRNs for Zortress 0.75mg (00078000000036261247 and 00078000000036261389), the May 2011 guidance states:

> Not Part D Covered Drug – Part B Drug Ineligible for Discount: Many prescription drug products that are covered under Medicare Part B may also be covered under Medicare Part D depending upon the patient and/or provider setting. …
>
> Manufacturers that appeal a discount payment on the basis that the drug product is covered under Medicare Part B must specify which Medicare Part B coverage category is the basis for their appeal to justify further review and validation by the IRE. …. The IRE may use Part D sponsors' previous B versus D coverage determinations as the basis for determining these appeals.[26]

In March 2012, CMS provided additional industry guidance for the Discount Program disputes. CMS specified the standards that manufacturers must satisfy in order for the TPA to review and validate a disputed discount payment. The document gives general guidance for disputes and also gives dispute submission requirements by dispute reason for Duplicate Invoice Item, Closed Pharmacy, Not a Part D Drug, Excessive Quantity, Days Supply, High Price of the Drug, Last Lot Expiration Date, Early Fill, Marketing Category Not a Biologic License Application (BLA) or New Drug Application (NDA) and Other.[27] The March 5, 2012 Dispute Resolution Guidance further provides an explanation of the dispute reason codes, and specifically states in pertinent part, consistent with the earlier guidance, that:

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

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

> D03, Not Part D Covered Drug:
> …The purpose of this code is for manufacturers to indicate that an NDC should not be covered under the Part D program under any circumstances. Manufacturers should not use the dispute reason code of "Not Part D Covered Drug" to file a dispute on the basis that the drug is potentially a non-applicable CGDP drug, but otherwise would be covered under Medicare Part D. … Additionally, we note that drugs disputed for Medicare Part B vs. Part D coverage are largely dependent on indication and/or patient setting.

The Medicare Prescription Drug Benefit Manual, in Chapter 6, Appendix C-1, "Medicare Part B versus Part D Coverage" provides that:

> Introduction
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> This document provides an overview of outpatient prescription drug coverage policies under Medicare….. . In general, references are seen to five major categories of Medicare Part B drug spending: ,,,,
> 5. Separately billable End Stage Renal Disease (ESRD) drugs such as erythropoietin (EPO).
> …
>
> Medicare Part A and Part B Covered Drugs, Part A/B Covered Drugs Set by Statute
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> Traditional Medicare (Part A/B) does not cover most outpatient prescription drugs. Medicare bundled payments made to hospitals and skilled nursing facilities generally cover all drugs provided during a stay. Medicare also makes payments to physicians for drugs or biologicals that are not usually self-administered. This means that coverage is usually limited to drugs or biologicals administered by infusion or injection. However, if the injection is generally self-administered (e.g., Imitrex), it is not covered.
>
> Despite the general limitation on coverage for outpatient drugs under Part B, the law specifically authorizes coverage for the following:
> …
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> *Immunosuppressive Drugs*. Drugs used in immunosuppressive therapy (such as cyclosporine) for a beneficiary who has received a Medicare covered organ transplant.

In addition, C-1, Attachment I, "Part B Drugs and Part D Coverage Chart" provides the following:

> Situations in which a billing entity would have to decide whether for a given drug (NDC) to bill Part B or Part D based on characteristics of beneficiary or medical use of the drug.'
>
> Relationship between Part B and Part D Coverage: The same drug (NDC) dispensed by a pharmacy may be covered under Part B or Part D depending on the characteristics of the beneficiary
>
> Categories of Separately Billable Part B Drugs: Drugs used in Immunosuppressive therapy for a transplant covered under Medicare
>
> Comments: Pharmacists would bill Part B or the individual's Part D plan based on information received from the individual or the Part D plan. Part B would be billed if the individual had a Medicare covered transplant; otherwise, the Part D plan would be billed. (Part D plan eligibility systems could contain a marker for members who had a Medicare covered transplant. This information could come from a question included on the Part D plan's enrollment or COB survey form.) In determining whether to pay for an immunosuppressive drug under Part D, it would not be appropriate for a Part D plan to institute a general policy of requiring a Part B claim rejection, as a substitute for maintaining information on transplant status and paying claims based on that information. Such a policy would be disruptive to beneficiaries and pharmacies and would unnecessarily increase Part B contractor costs. Instead a prior authorization requirement would be appropriate.

Finally, Chapter 6 – Appendix C-2, "Medicare Parts B/D Coverage Issues" provides a table which acts as a reference guide for the most frequent B/D coverage determination scenarios facing Part D plans and Part D pharmacy providers and sets forth the following:

> Part B Coverage Categories—Immunosuppressant Drugs
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> Part B Coverage Description--Drugs used in immunosuppressive therapy for beneficiaries that received transplant from Medicare approved facility and were entitled to Medicare Part A at time of transplant (i.e. "Medicare Covered Transplant)

> Retail and Home Infusion Pharmacy Setting B/D Coverage-- B or D: Part B for Medicare
> Covered Transplant, Part D for all other situations
>
> LTC Pharmacy Setting B/D Coverage -- B or D: Part B for Medicare
> Covered Transplant Part D for all other situations
>
> Comments- Participating Part B pharmacies must bill the DMERC in their region when these
> drugs are covered under Part B
>
> Written Prescription Indicators to Highlight B/D: Part B: "*For Medicare covered transplant*" Part D: "*For rheumatoid arthritis* (or other non-transplant use)" or "*Not for Medicare-covered transplant*".

Zortress is a drug used in Immune suppression therapy.[28] In reviewing these two DNRs relating to the drug Zortress 0.75 mg, the IRE found that the record shows the dosing for this drug was correct, however the drug may be covered under Medicare Part B or D, depending upon the circumstances.[29] In the verification information for the dosing explanation, the Part D Sponsor stated that for these two DRNs, (00078000000036261247 and 00078000000036261389),"the claims should have been billed to Part B benefit due to the member being a Transplant patient."[30] Thus, the Administrator finds that based upon the Part D Sponsor's explanation, the IRE correctly found that the DRNs 00078000000036261247 and 00078000000036261389 were ineligible for coverage under Medicare Part D, as long as the transplant was covered under Medicare: that is, the drugs was "used in immunosuppressive therapy for beneficiaries that received transplant from Medicare approved facility and were entitled to Medicare Part A at time of transplant (i.e. "Medicare Covered Transplant)" The Administrator affirms the IREs decision as modified herein, and finds that the DRNs were not eligible within the parameters of the Discount Program, and thus were not appropriately billed for the coverage gap discount dollars.

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[28] *See e.g.* https://www.pharma.us.novartis.com/product/pi/pdf/zortress.pdf.
[29] *See*, IRE Decision, Appeal CGDP0001272013, Table 2, at 5.
[30] *Id.*

DECISION

In light of the foregoing and based on the record, the Administrator hereby upholds the decisions 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: 2/18/15

/s/

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services