

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
DEPARTMENTAL APPEALS BOARD

DECISION OF MEDICARE APPEALS COUNCIL  
Docket Number: M-11-1799

In the case of

Claim for

R.S.  
\_\_\_\_\_  
(Appellant)

Prescription Drug Benefit  
(Part D)  
\_\_\_\_\_

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\_\_\_\_\_  
(Enrollee)

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\_\_\_\_\_  
(HIC Number)

Connecticut General Life  
Insurance Co./Cigna Medicare  
Rx  
\_\_\_\_\_

(Part D Plan/Part D Sponsor)

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(ALJ Appeal Number)

The Medicare Appeals Council has decided, on its own motion, to review the Administrative Law Judge's (ALJ's) decision dated April 20, 2011, because there is an error of law material to the outcome of the claim. 42 C.F.R. § 423.2110. The ALJ issued a fully favorable decision directing the Medicare Part D prescription drug plan (PDP) to cover the brand-name drug Geodon (ziprasidone 20 mg.) to treat the enrollee's mood and behavioral deficits associated with a traumatic brain injury.

By memorandum dated June 10, 2011, Maximus Federal Services, the Part D Independent Review Entity (IRE), on behalf of the Centers for Medicare & Medicaid Services (CMS) asked the Council to review the ALJ's decision on its own motion. The IRE's referral memorandum (submitted with attachments) is entered into the record as Exhibit (Exh.) MAC-1. Subsequently, by letter dated June 13, 2011, CMS submitted a memorandum issued by CMS on March 18, 2011, which was inadvertently omitted from the original referral submission. The March 18, 2011, memorandum pertains to CMS policy guidance in light of the district court's decision in *Layzer v. Leavitt*, 770 F.Supp.2d 579 (S.D.N.Y. March 7, 2011). The Council admits the CMS's supplemental submission into the

administrative record as Exh. MAC-2. The appellant did not submit a response to the IRE's memorandum.<sup>1</sup>

For the reasons explained below, the Council reverses the ALJ's decision. The PDP may not be required to cover Geodon for the enrollee.

#### BACKGROUND

The enrollee requests PDP coverage of Geodon, 20 mg., which his physician prescribed to manage ongoing physical, cognitive, mood, and behavioral deficits experienced as the result of a traumatic brain injury in August 1981. Exh. 4, at 213. The enrollee's treating physician indicated that other medications, such as Abilify and Risperdal, have been trialed and resulted in side effects which include increased falls and cognitive confusion. *Id.*

The appellant requested pre-authorization from the PDP for coverage of Geodon. The PDP did not issue a timely decision on the authorization request and, therefore, the matter was forwarded to the IRE for reconsideration. Exh. 5, at 219.

On reconsideration, the IRE denied the enrollee's request. Exh. 5. The IRE concluded that Geodon, as prescribed, was not being provided "for a medically accepted indication as defined by Medicare law." *Id.* at 239. The IRE also concluded that an exception based on the medical necessity of Geodon may not be considered in that, as prescribed, the drug does not satisfy the definition of a Part D drug. *Id.*

The enrollee requested an ALJ hearing. The ALJ held a hearing on March 10, 2011. In the hearing decision which followed, the ALJ found that the PDP was required to cover the cost of Geodon as prescribed for the enrollee. The ALJ relied, primarily, on a recent decision of the United States District Court for the Southern District of New York holding that the Social Security Act (Act) does not impose a "Compendia Requirement" as a part of the definition of a "covered Part D drug." Decision (Dec.) at 6-7, citing *Layzer v. Leavitt*, 770 F. Supp. 2d 579 (S.D.N.Y. March 7, 2011).

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<sup>1</sup> In response to a request for an extension of time to file a supplemental statement dated July 15, 2011, the appellant's representative was given until August 31, 2011, for the Council's receipt of any supplemental submissions. The request for an extension of time and correspondence granting the request for an extension have been entered into the record as Exh. MAC-3 and Exh. MAC-4, respectively.

The ALJ considered and gave weight to the treating physician's statement that it had been the physician's experience that --

. . . Geodon on patients with traumatic brain injuries has been effective to help them process and respond to information in a more appropriate manner and helps them to regain control of their behavior.

*Id.* at 7. Further, the ALJ opined on an internet search result which indicated that "Geodon is prescribed with some regularity to people with traumatic brain injury." *Id.* Thus, the ALJ concluded that the appellant established the medical necessity for the Geodon for treatment of traumatic brain injuries and therefore satisfied the statutory definition of a Part D drug. *Id.*

On June 10, 2011, CMS referred the ALJ's decision for the Council's own motion review, citing as bases "an error of law material to the outcome of the case" and "broad policy or procedural issue that may affect the public interest." Exh. MAC-1, at 1. Generally, CMS argues that the ALJ erred in granting coverage for a prescription drug that was not being used for a medically accepted indication. *Id.* at 2. CMS also argues that the ALJ erred in relying on the non-precedential *Layzer* decision, as applicable regulations are binding on the ALJ and "clearly and unambiguously require a covered Part D drug to be used for a 'medically accepted indication' as defined in section 1927(k)(6)" of the Act. *Id.* CMS further asserts that, by disregarding indications in the FDA label and Medicare compendia and permitting the "off-label use" in this case, the ALJ "challenges the integrity of FDA drug oversight authority and drug compendia evidence-based expertise." *Id.* at 1.

#### **LEGAL AUTHORITIES**

Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)(Pub. L. 108-173) established the Voluntary Medicare Prescription Drug Benefit Program (Medicare Part D), to be effective January 1, 2006. Implementing regulations were issued on January 28, 2005, codified at 42 C.F.R. Part 423, effective March 22, 2005. As of January 1, 2006, enrollees were eligible to receive drug benefits under a PDP in which they were enrolled. 70 Fed. Reg. 4194 (Jan. 28, 2005).

Section 1860D-2(e)(1) of the Social Security Act (Act) defines the term "covered Part D drug" as "a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1927(k)(2)" of the Act, "and any use of a covered Part D drug for a medically accepted indication (as defined in section 1927(k)(6))." Section 1927(k)(2)(A)(i) of the Act defines a "covered part D drug" as a drug that may be dispensed only upon a prescription and which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act, or which is approved under section 505(j) of such Act. The drug must be used for a "medically accepted indication" (as defined in section 1927(k)(6)). Section 1860D-2(e)(1) of the Act. Section 1927(k)(6) defines a "medically accepted indication" as "any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i)."

Section 182 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275, enacted July 15, 2008) revised the definition of a Part D drug found in section 1860D-2(e)(1) of the Act. The change was effective January 1, 2009. On January 16, 2009, the Centers for Medicare and Medicaid Services published an interim final rule, effective January 16, 2009, which revised the definition of a Part D drug, and, specifically, the definition of "medically accepted indication" in 42 C.F.R. § 423.100. 74 Fed. Reg. 2881 (January 16, 2009).<sup>2</sup>

The implementing regulations in 42 C.F.R. Part 423 are, in large part, identical to the language of the Act. Specifically, 42 C.F.R. § 423.100 provides that a Part D drug is a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1927(k)(2) of the Act. It must be used for a "medically accepted indication" as defined in section 1927(k)(6) of the Act; a "medically accepted indication" is limited to FDA-approved uses or those uses supported by citation in the section 1927(g)(1)(B)(i) drug compendia. A medically accepted indication, for this purpose, does not include references in peer-reviewed medical literature as prescribed by section 1927(g)(1)(B)(ii) of the Act. See Final Rule, 70 Fed. Reg. 4194 at 4228-4229 and 4261 (Jan. 28, 2005). A Part D drug also

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<sup>2</sup> The definition of a "medically accepted indication" differs for Part D drugs used as part of an anti-cancer chemotherapy regimen. See 74 Fed. Reg. 2881.

excludes any drug for which payment as so prescribed or dispensed or administered to an individual is available for that individual under Part A or Part B. 42 C.F.R. § 423.100.

The regulations at 42 C.F.R § 423.578 implement the Part D exceptions process. Limitations to the exceptions process are found at 42 C.F.R § 423.578(e), which provides: "Nothing in this section may be construed to allow an enrollee to use the exceptions process set out in this section to request or be granted coverage for a prescription drug that does not meet the definition of a Part D drug."

The Medicare Prescription Drug Benefit Manual (PDBM), Pub. 100-18, Chapter 6, Section 10 largely repeats the language in the implementing regulations.

### **DISCUSSION**

At the outset, the Council acknowledges that the enrollee and the ALJ have presented compelling arguments that the enrollee's use of Geodon is medically reasonable and necessary in this case. We do not question that the enrollee has received significant relief with Geodon, nor do we question his physician's judgment in prescribing Geodon.

However, the determinative legal issue is whether the use of Geodon as prescribed meets the criteria in the statute and regulations for a medically accepted indication. As explained below, we find reversible legal error in the ALJ's decision. The ALJ erred in not applying the regulatory requirements for whether a drug is being used for a "medically accepted indication" and, therefore, may be eligible for Part D coverage.

#### Medically Accepted Indication

The regulations provide that "[a]ll laws and regulations pertaining to the Medicare program including, but not limited to, Titles XI, XVIII, and XIX of the Social Security Act and implementing regulations, are binding on ALJs," as well as the Council. 42 C.F.R. § 423.2063(a). Further, ALJs and the Council must also give substantial deference to CMS program guidance such as program memoranda and manual instructions. 42 C.F.R. § 423.2062(a). If an ALJ or the Council declines to follow the applicable guidance material in a particular case, the ALJ or the Council must explain the reasons why it was not followed. 42 C.F.R. § 423.2062(b). The ALJ did not cite any

authority for his decision to order the plan to cover the enrollee's Geodon, a decision that was contrary to the law, regulations, and program guidance which the ALJ and the Council must follow.

The Act and implementing regulations limit the definition of a Part D drug to a prescription drug which has been approved by the FDA for safety and efficacy. The drug must be prescribed for an FDA-labeled indication, or for a use which is supported by a citation included or approved for inclusion in any of the recognized compendia. Act, section 1927(k)(6).

The FDA has approved Geodon for treatment of schizophrenia and bipolar disorders. See Beneficiary Claim File, FDA Label Description.<sup>3</sup> Further, the Medicare-approved compendia, DRUGDEX and AHFS-DI, do not support the use of Geodon to treat the enrollee's condition. DRUGDEX describes one off-label use for ziprasidone (generic for Geodon), which is for the treatment of schizoaffective disorder. Beneficiary Claim File, DRUGDEX at 77. The AHFS-DI describes only the FDA-approved indications. *Id.*, AHFS-DI at 1-19. The enrollee's diagnosis, traumatic brain injury, is not included in either compendium.

The record establishes that the enrollee did not require or use Geodon for a medically accepted indication, because he does not have schizophrenia, bipolar disorder, or schizoaffective disorder. Moreover, a physician's statement (see Exh. 4, at 213; Exh. 6, 243-244) that a drug is effective for an enrollee, or is the preferred treatment option, or even that the drug is medically necessary for an enrollee, may not be the basis for ordering a PDP to cover a drug that does not meet the definition of a Part D drug.

Further, the plan's Evidence of Coverage (EOC) and formulary indicate that the plan does not cover this drug for the enrollee's intended use. The formulary lists Geodon as a tier 4 non-preferred brand drug, with quantity limitations and prior authorization required. Exh. 2, at 187. Additionally, the plan's EOC provides explicitly: "We will generally cover a drug on the plan's Drug List [Formulary] as long as you follow the other coverage rules . . . and the drug is medically necessary, meaning reasonable and necessary for treatment of your illness or injury. *It also needs to be an accepted treatment for your*

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<sup>3</sup> The FDA label, as well as the DRUGDEX and American Hospital Formulary Service Drug Information (AHFS-DI), are included in the record but have not been marked as exhibits.

medical condition." Exh. 1, at 111 (emphasis added). The EOC further addresses non-coverage of "off-label" uses of prescription drugs as follows:

- "Off-label use" is any use of the drug other than those indicated on a drug's label as approved by the Food and Drug Administration.
- Sometimes "off-label use" is allowed. Medicare sometimes allows us to cover "off-label uses" of a prescription drug. Coverage is allowed only when the use is supported by certain reference books. These reference books are the American Hospital Formulary Service Drug Information, the DRUGDEX Information System, and the USPDI or its successor. If the use is not supported by any of these reference books, then our plan cannot cover its "off-label use."

*Id.* at 104-105.

The Council therefore concludes that Geodon is not a covered Part D drug for the use for which it was prescribed for the enrollee.

*Layzer v. Leavitt*

We acknowledge the ALJ's analysis concerning statutory construction. Citing the United States District Court decision in *Layzer v. Leavitt*, the ALJ noted that coverage of the enrollee's prescription had been declined on grounds that "all Part D drugs must be used for a medically accepted indication as defined in § 1927(k)(2) of the Act and 42 C.F.R. § 423.100." Dec. at 6. The ALJ concluded that "the [District] Court did a thorough interpretation of 42 U.S.C. 1395w-102(e) and concluded that Congress did not intend to limit coverage of Part D drugs to the indications listed on their labels and in certain compendia." *Id.* at 6; see 770 F. Supp. 2d at 584. The ALJ concluded that ". . . it is possible for Geodon to meet the definition of a Part D drug as long as its use in patients with traumatic brain injuries can be established as efficacious." *Id.* at 7.

In *Layzer*, the court determined that two beneficiaries, one diagnosed with ovarian cancer and the other with myotonic muscular dystrophy type 2, may not be denied Part D coverage of the drugs Cetrotide and Increlex, respectively, on the basis

that the beneficiaries' uses of these drugs were not supported by compendia. As the court noted, the dispute between the Secretary and the beneficiaries centered on interpretation of the language of sections 1860D-2(e)(1)(A) and (B) of the Act. 770 F. Supp. 2d at 583.

Sections 1860D-2(e)(1)(A) and (B) state (emphasis supplied) -

(1) IN GENERAL.- Except as provided in this subsection . . . the term 'covered part D drug' means -

- (A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1927(k)(2); or
- (B) a biological product described in clauses (i) through subparagraph (iii) of subparagraph (B) of such section . . . *and such term includes* a vaccine licensed under section 351 of the Public Health Service Act . . . *and any use of* a covered part D drug for a medically accepted indication (as defined in section 1927(k)(6)).

The *Layzer* beneficiaries argued that sections 1860D-2(e)(1)(A) and (B) are written in the disjunctive and require only FDA approval for coverage. The parties disagreed on whether to construe the words "and such term includes" as merely illustrative (introducing examples), or definitional (introducing additional factors required to meet the definition). 770 F. Supp. 2d at 583. The court rejected the latter (in other words, rejected the Secretary's "medically accepted indication" argument, to which the court referred as the "Compendia Requirement") as "unsound interpretation of the law." *Id.* at 587. The court determined that statutory language and canons of statutory construction make clear that Congress did not intend to impose a Compendia Requirement for the purposes of defining what is meant by a "covered Part D drug." *Id.* at 583-84. As the court stated, "[e]ven if the Definition [of covered Part D drug] does not provide a model of clarity, the Secretary's regulation is not a reasonable interpretation." *Id.* at 584.<sup>4</sup>

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<sup>4</sup> Even so, the *Layzer* court acknowledged the contrary district court opinion in *Kilmer v. Leavitt*, 609 F.Supp.2d 750, 754 (S.D. Ohio 2009), which, like the *Layzer* opinion, is not binding precedent. *Id.* The *Kilmer* court concluded that the plain language of the statute indicates the "medically accepted indication" clause must be construed as a limitation.



However, the ALJ must follow the Secretary's regulations. "All laws and regulations pertaining to the Medicare program, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJs and [the Council]." 42 C.F.R. § 423.2063(a). See also 14 U.S. Op. Off. Legal Counsel, 1990 WL 750326 (ALJs do not have authority to invalidate regulations or to interpret regulations contrary to the Secretary's interpretation).

The definition of "Part D drug" set forth in 42 C.F.R. § 423.100 provides, in pertinent part (emphasis supplied):

- (1) Unless otherwise excluded under paragraph (2) of this definition, any of the following *if used for a medically accepted indication (as defined in section 1860D-2(e)(4) of the Act)*-

- (i) A drug that may be dispensed only upon a prescription and that is described in section 1927(k)(2)(A)(i) through (iii) of the Act.

The use of the word "if" in the regulation requires that, in order to meet the regulatory definition of "Part D drug," the drug *must* be used for a medically accepted indication as defined by statute. As relevant here, section 1860D-2(e)(4)(A)(ii) defines "medically accepted indication," "in the case of any other covered part D drug" (i.e., a covered part D drug that is not used in an anti-cancer chemotherapy regimen, as defined in section 1860D-2(e)(4)(A)(i)), in accordance with the language in section 1927(k)(6). Therefore, to meet the section 1927(k)(6) definition, the drug must meet at least one of two requirements - its use must be approved under the Federal Food, Drug, and Cosmetic Act, or, its use must be supported by a statutorily recognized compendium (or compendia).

There is no question that the enrollee's use of Geodon in this case is not FDA approved (i.e., not "on label"). Therefore, the enrollee's "off-label" use of Geodon must be supported by a statutorily recognized compendium. The Council has determined, as explained earlier, that this requirement has not been met. Notwithstanding the district court's decision in *Layzer v. Leavitt*, the Council is bound to follow the Secretary's implementing regulations. The Council also notes that, subsequent to the *Layzer* and *Kilmer* decisions, on March 18, 2011, the Secretary, through CMS, reaffirmed that "Part D sponsors should continue to follow existing CMS coverage policy

as outlined in 42 C.F.R. § 423.100. Thus, [the *Layzer* and *Kilmer*] decisions shall have no effect on plan coverage determinations and redeterminations, nor are the decisions applicable to reconsiderations or higher level Part D appeals." Exh. MAC-2.

#### DECISION

It is the decision of the Medicare Appeals Council that the enrollee's use of Geodon is not for a "medically accepted indication" as defined in the Act and regulations. It is therefore not covered under Medicare Part D and the PDP is not required to pay for it.

The ALJ's decision is reversed.

MEDICARE APPEALS COUNCIL

/s/ Gilde Morrisson  
Administrative Appeals Judge

/s/Constance B. Tobias, Chair  
Departmental Appeals Board

Date: September 8, 2011