UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

ABRAHAM NIEVOD,

Plaintiff,

vs.

KATHELEEN SEBELLIUS, in her official capacity as SECRETARY OF THE UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES and DOES 1-10,

Defendants.

Case No: C 11-4134 SBA

ORDER ON CROSS-MOTIONS FOR SUMMARY JUDGMENT

Docket 20, 21

Plaintiff Abraham Nievod filed the instant action against Defendant Katheleen Sebellius ("Secretary") in her capacity as Secretary of the United States Department of Health and Human Services ("DHHS"), seeking judicial review of an adverse decision by the Medicare Appeals Council ("MAC"). Plaintiff seeks to overturn the MAC's decision that Medicare Part D does not cover his off-label use of the prescription medication known as CellCept (Mycophenolate Mofetil).

The parties are presently before the Court on cross-motions for summary judgment, pursuant to Federal Rule of Civil Procedure 56. Dkt. 20, 21. Having read and considered the papers filed in connection with this matter and being fully informed, the Court hereby GRANTS the Secretary's motion and DENIES Plaintiff's motion, and thus AFFIRMS the decision of the MAC. The Court, in its discretion, finds this matter suitable for resolution without oral argument. See Fed. R. Civ. P. 78(b); N.D. Cal. Civ. L.R. 7-1(b).

I. BACKGROUND

The instant action arises from a dispute between Plaintiff and the Secretary over whether Medicare should cover Plaintiff for the cost of CellCept, which he uses to treat his autoimmune conditions. To resolve this dispute, it is helpful to first review Medicare's statutory and regulatory framework for subsidizing the cost of certain prescription drugs under its Part D Prescription Drug Benefit Program.

A. MEDICARE PART D

Medicare is a federally funded health insurance program for the elderly and disabled which was established pursuant to Title XVIII of the Social Security Act ("SSA"), 79 Stat. 291, as amended 42 U.S.C. § 1395, et seq. Thomas Jefferson Univ. v. Shalala, 512 U.S. 504, 506 (1994). Congress has delegated general rulemaking authority with respect to Medicare to the Secretary. 42 U.S.C. § 1395hh(a)(1) ("The Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter."). The Secretary administers the Medicare program through the Centers for Medicare and Medicaid Services ("CMS"). Palomar Medical Center v. Sebelius, 693 F.3d 1151, 1154-55 (9th Cir. 2012).

1. Coverage Under Part D

Benefits under Medicare are divided into four parts: Parts A, B, C and D. 42 U.S.C. §§ 1395 to 1395kkk-1. At issue here is Part D, a voluntary prescription drug benefit program that became effective on January 1, 2006, pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("Medicare Modernization Act"), Pub. L. No. 108-173, 117 Stat. 2066. Part D drug benefits are provided, inter alia, by private entities (typically insurance providers) which contract with the CMS to offer approved prescription drug plans ("PDP") to qualified Medicare enrollees. See 42 C.F.R. §§ 423.4, 423.30.

The SSA, as amended by the Medicare Modernization Act, expressly defines the types of drugs covered by Part D as: (1) a prescription drug; (2) a biological product;

(3) insulin and supplies used to inject insulin; and (4) certain vaccines. See 42 U.S.C. § 1395w-102(e). The statute states, in relevant part, as follows:

> **(e) Covered part D drug defined**
>
> **(1) In general**
>
> Except as provided in this subsection, for purposes of this part, 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 1396r-8(k)(2) of this title; or
>
> (B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary),[1]
>
> ***and such term includes*** a vaccine licensed under section 262 of this title (and, for vaccines administered on or after January 1, 2008, its administration) and ***any use of a covered part D drug for a medically accepted indication (as defined in paragraph (4)).***
>
> . . . .
>
> **(2) Exclusions**
>
> . . . .
>
> **(3) Application of general exclusion provisions**
>
> . . . .
>
> **(4) Medically accepted indication defined**
>
> **(A) In general**
>
> For purposes of paragraph (1), the term "medically accepted indication" has the meaning given that term—
>
> (i) in the case of a covered part D drug used in an anticancer chemotherapeutic regimen, in section 1395x(t)(2)(B) of this title, except that in applying such section—

[1] The cross-reference in subparagraphs (A) and (B) is to 42 U.S.C. § 1396r-8(k)(2)(A)-(C), which defines the meaning of a "covered outpatient drug." However, "[t]he term 'covered outpatient drug' does not include . . . a drug or biological [product] used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(3).

(I) "prescription drug plan or MA-PD plan" shall be substituted for "carrier" each place it appears; and

(II) subject to subparagraph (B), the compendia described in section 1396r-8(g)(1)(B)(i)(III) of this title shall be included in the list of compendia described in clause (ii)(I) section 1395x(t)(2)(B) of this title; and

(ii) ***in the case of any other covered part D drug, in section 1396r-8(k)(6) of this title***.

(B) Conflict of interest.

On and after January 1, 2010, subparagraph (A)(i)(II) shall not apply unless the compendia described in section 1927(g)(1)(B)(i)(III) meets the requirement in the third sentence of section 1861(t)(2)(B).

(C) Update

For purposes of applying subparagraph (A)(ii), the Secretary shall revise the list of compendia described in section 1927(g)(1)(B)(i) as is appropriate for identifying medically accepted indications for drugs. Any such revision shall be done in a manner consistent with the process for revising compendia under section 1861(t)(2)(B).

42 U.S.C. § 1395w-102(e) (emphasis added).

The above definition of "medically accepted indication" in subparagraph (4) varies depending on the purpose for which the medication is used. For drugs used as part of an anticancer chemotherapeutic regimen, the term medically accepted indication is defined by cross-reference to the definition of that term for purposes of Medicare Part B. Id. § 1395w-102(e)(4)(i) (cross-referencing 42 U.S.C. § 1395x(t)(2)(B)). For all other drugs, such as CellCept, however, the meaning of medically accepted indication is defined by cross-reference to 42 U.S.C. § 1396r-8(k)(6), which states:

(6) Medically accepted indication.

The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.] 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) of this section.

42 U.S.C. § 1396r-8(k)(6) (emphasis added). The "compendia" referenced above consists of: (1) the American Hospital Formulary Service Drug Information; (2) United States Pharmacopeia-Drug Information (or its successor publications); and (3) the DRUGDEX Information System. Id. § 1396r-8(g)(1)(b)(i).

Regulations promulgated by the Secretary further clarify the scope of what is considered a Part D drug. Title 42, Code of Federal Regulations, section 423.100, states, in relevant part:

> Part D drug means—
>
> (1) Unless 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 sections 1927(k)(2)(A)(i) through (iii) of the Act.
>
> (ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act.
>
> (iii) Insulin described in section 1927(k)(2)(C) of the Act.
>
> (iv) Medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze.
>
> (v) A vaccine licensed under section 351 of the Public Health Service Act and for vaccine administration on or after January 1, 2008, its administration.
>
> (vi) Supplies that are directly associated with delivering insulin into the body, such as an inhalation chamber used to deliver the insulin through inhalation.

42 C.F.R. § 423.100 (emphasis added).

2. Administrative Review

The Secretary's decisions regarding Part D coverage are subject to an administrative review process. 42 U.S.C. § 1395w-104(g), (h). A coverage determination includes a decision not to provide or pay for a Part D drug, the failure to provide a timely coverage determination when delay would adversely affect the enrollee's health, or a decision concerning an exceptions request. 42 C.F.R. § 423.566(b). An enrollee dissatisfied with a

Plan D sponsor's coverage determination may request a redetermination of the decision. Id., §§ 423.580, 423.582. If the Plan D sponsor upholds its original decision, the enrollee may request reconsideration by an independent review entity ("IRE") that contracts with the CMS. Id., § 423.600.

If the IRE upholds the Part D plan sponsor's adverse decision and the amount in controversy equals the threshold amount established annually by the Secretary, the enrollee can request a hearing before an administrative law judge ("ALJ"). Id., §§ 423.610(a), 423.612. If the enrollee is dissatisfied with the ALJ's decision, the enrollee may request additional review by the MAC. Id., § 423.620. If the CMS or its contractor is dissatisfied with the ALJ's decision, it may petition the MAC to accept the case for review. Id., § 405.1110.

The MAC may review a case on its own motion if the MAC finds: (1) an error of law material to the outcome of the case; (2) an abuse of discretion by the ALJ; (3) that the decision is inconsistent with the preponderance of evidence of record; or (4) that there is a broad policy or procedural issue that may affect the general public interest. Id. If the amount in controversy meets the threshold amounts established annually by the Secretary, the enrollee may request judicial review of the MAC's decision, or if the MAC declines review of the ALJ decision, the enrollee may seek judicial review of the ALJ's decision. Id., § 423.630.

B. PLAINTIFF'S REQUEST FOR COVERAGE

1. Initial Requests to the PDP

Plaintiff is an attorney afflicted with various auto-immune medical conditions, who, since 2005, has relied on CellCept to treat his conditions. Administrative Record ("AR") 00073. Though Plaintiff has found CellCept medically effective, the medication is not approved by the Food and Drug Administration ("FDA") for such treatment.

On June 23, 2010, Plaintiff's physician sought authorization from Plaintiff's PDP, United Healthcare, for treatment of his interstitial lung disease. AR 00005. The PDP denied the request on the ground that CellCept is not approved by the FDA for the

treatment of that particular condition. Id. Plaintiff's physician requested redetermination and expanded upon the conditions for which the CellCept was to be used. Id. The PDP denied the request. Id. Plaintiff then appealed the decision to an IRE, which determined that the PDP was not required to cover CellCept because the medication was not prescribed for a medically accepted indication. Id.

2. Appeal to the ALJ

Plaintiff appealed the denial of coverage to an ALJ, who conducted a hearing on January 6, 2011. AR 00072. On February 9, 2011, the ALJ rendered a "Fully Favorable Decision" for Plaintiff. AR 00069. In reaching his decision, the ALJ acknowledged that to qualify for coverage under Part D, the drug must, among other requirements, be one "dispensed only upon a prescription [and] is being used for a medically-accepted indication as defined by section 1927(k)(6) of the Act." AR 00079. He further noted that to qualify as a medically accepted indication, the drug must be approved for the specific use by the FDA or be "supported by one or more citations included or approved for inclusion in any of the compendia described in section 1927(g)(1)(B)(i) of the Act." Id. Nonetheless, the ALJ concluded that Plaintiff "has such a rare disease that it may not appear in the approved references and drug compendia." Id. In addition, citing Plaintiff's physician's opinion that alternative therapies were not effective, the ALJ found that "the Medicare Part D drug plan must contemplate the use of drugs for conditions other than those approved by the FDA, such as rare diseases, as in the case of the [Plaintiff]'s condition." Id.

3. Reversal by the MAC

On June 28, 2011, the MAC "decided, on its own motion, to review the . . . [ALJ's] decision because there [was] an error of law material to the outcome of the claim." AR 00003. The MAC found, inter alia, that the ALJ had no legal basis upon which to disregard the plain language of the statute and its implementing regulations, which require that a covered Part D drug be either one that is approved for the particular use by the FDA or approved for inclusion in any of the authorized compendia. AR 00008. With regard to the ALJ's finding that Plaintiff's use of CellCept was medically necessary, the MAC found that

medical necessity was not a cognizable exception to the compendia requirement. AR 00010.

C. THE INSTANT ACTION

Following the MAC's decision, Plaintiff filed the instant action under the Administrative Procedures Act ("APA"), 42 U.S.C. §§ 701-706, to obtain a reversal of the MAC's decision and an order finding that he is entitled to Medicare Part D coverage for his CellCept prescription. Compl., Dkt. 1. The parties each have filed cross-motions for summary judgment which are fully briefed and now ripe for adjudication. Dkt. 21, 22.

II. LEGAL STANDARD

Judicial review of a final decision by the Secretary lies in the United States district courts, pursuant to 42 U.S.C. § 405(g). See 42 U.S.C. § 1395ff(b)(1)(A) (authorizing judicial review of the Secretary's decisions in accordance with 42 U.S.C. § 405(g)); Heckler v. Ringer, 466 U.S. 602, 615 (1984). Under the APA, the Court may set aside an agency decision that is "'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" Palomar Medical Center v. Sebelius, 693 F.3d 1151, 1159 (9th Cir. 2012). A district court must affirm the decision if it is "supported by 'substantial evidence' and if the proper legal standards were applied." Mayes v. Masanari, 276 F.3d 453, 458-59 (9th Cir. 2001).

III. DISCUSSION

A. OVERVIEW

The instant dispute centers on what requirements a drug must satisfy in order to qualify for coverage under Part D—and more specifically—whether an off-label use of a drug must meet the compendia requirement in order to qualify for coverage under Part D. In overruling the ALJ's decision, the MAC relied on both the plain language of the statutory definition of a covered Part D drug, as set forth in 42 U.S.C. § 1395w-102(e), and the Secretary's implementing regulation, 42 C.F.R. § 423.100, to support its conclusion that coverage under Part D is dependent on whether the drug is used for a "medically accepted indication" under 42 U.S.C. § 1396r-8(k)(6). See AR 0007-0009.

Plaintiff contends that nothing in section 1395w-102(e) requires that a Part D drug satisfy the medically accepted indication requirement, and by extension, the compendia requirement where an off label use is implicated. According to Plaintiff, the reference to such requirement is intended merely for illustrative purposes, and not to "cut off coverage." Pl.'s Mot. at 13. As for the Secretary's implementing regulation, Plaintiff argues that the regulation is "arbitrary, capricious and otherwise unlawful" on the grounds that it is contrary to the plain terms of the statute. Id. at 11. In contrast, the Secretary asserts that Congress unambiguously intended that the medically acceptable indication requirement restrict the scope of covered Part D drugs. In addition, the Secretary contends that her interpretation of the statute is valid and entitled to deference under Chevron USA, Inc. v. Natural Res. Defense Council, Inc., 467 U.S. 837 (1984).

B. STATUTORY INTENT

"'The starting point in interpreting a statute is its language, for if the intent of Congress is clear, that is the end of the matter.'" United States v. Turner, 689 F.3d 1117, 1119 (9th Cir. 2012) (quoting Good Samaritan Hosp. v. Shalala, 508 U.S. 402, 409 (1993)). In construing a statute, a court must give effect "to all the words used by Congress" and "avoid an interpretation of a statute that renders any part of it superfluous[.]" Center for Biological Diversity v. Salazar, 695 F.3d 893, 903 (9th Cir. 2012 (internal quotations and citation omitted). A court must "consider the language itself, the specific context in which that language is used, and the broader context of the statute as a whole." United States v. Olander, 572 F.3d 764, 768 (9th Cir. 2009) (internal quotations and alterations omitted).

Applying the aforementioned canons of statutory construction, the Court finds that 42 U.S.C. § 1395w-102(e)—though perhaps inartfully drafted—requires a drug to be used for a "medically accepted indication" in order to qualify for coverage under Part D. The statute provides, in pertinent part:

> [T]he 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 1396r-8(k)(2) of this title; ***or***
>
> (B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary),
>
> ***and such term includes*** a vaccine licensed under section 262 of this title (and, for vaccines administered on or after January 1, 2008, its administration) and ***any use of a covered part D drug for a medically accepted indication*** (as defined in paragraph (4)).

42 U.S.C. § 1395w-102(e)(1) (emphasis added). As noted, medically accepted indication (for uses other than an anticancer chemotherapeutic regimen) is defined to mean either (1) an FDA-approved use or (2) a use supported by a least one citation in an approved compendia. 42 U.S.C. § 1395w-102(e)(4).

Plaintiff's contention that the medically accepted indication requirement is merely illustrative is inconsistent with the language and structure of the statute. The statutory definition of a covered Part D drug is comprised of three paragraphs. The first two paragraphs, identified as subparagraphs (A) and (B), are separated by the disjunctive term "or," meaning that any of the drugs listed in those two paragraphs may qualify as a covered Part D drug. See In re Pacific-Atlantic Trading Co., 64 F.3d 1292, 1302 (9th Cir. 1995) ("In construing a statute, a court should interpret subsections written in the disjunctive as setting out separate and distinct alternatives.") (citations omitted). In contrast, the third paragraph, which contains the reference to the medically accepted indication requirement, is neither denoted by a letter or number nor is it introduced by the term "or." Instead, the text of the paragraph is introduced by the phrase "***and such term includes*** . . . ." 42 U.S.C. § 1395w-102(e) (emphasis added).

The use of the conjunctive "and" connotes that the third paragraph was intended by Congress to impose ***additional*** conditions on the two preceding paragraphs, while the use

of "such term" is intended to refer back to "the term 'covered Part D drug.'" Thus, taken together, the provisions of the third paragraph logically convey that the medically accepted indication requirement applies generally ***and in addition to*** the provisions of subsections (A) and (B). See Kilmer v. Leavitt, 609 F. Supp. 2d 750, 754 (S.D. Oh. 2009) ("The last paragraph of § 1395w-102(e)(1) . . . adds a third condition, specifically that any use of a drug (a drug that satisfies the first two requirements for a covered part D drug) be for a medically accepted indication."); accord Rickhoff v. U.S. Sec'y ex rel. Dept. of Health and Human Servs., No. CV-11-2189-PHX-DGC, 2012 WL 6177411, at *1 (D. Ariz. Dec. 11, 2012) ("To qualify as a covered Part D drug, a drug must be used for a "medically accepted indication.'").

Plaintiff ignores the phrase "and such term" and instead focuses on the word "includes," which he claims demonstrates Congress's intent that the subsequent reference to "any use of a covered part D drug for a medically accepted indication" be construed as ***illustrative*** of what may be covered under Part D, and not as a ***restriction*** on such coverage. In other words, Plaintiff's view is that, under Part D, a drug may—but is not required to—be used for a medically accepted indication. That contention is untenable. It is true that "includes" sometimes is intended as a term of enlargement as opposed to one of limitation. See 42 U.S.C. § 1301(b) ("The terms 'includes' and 'including' when used in a definition contained in this chapter shall not be deemed to exclude other things otherwise within the meaning of the term defined."). At the same time, however, "[t]he term can also be used and construed as restrictive and definitional." Cashman v. Dolce Int'l/Hartford, Inc., 225 F.R.D. 73, 84 (D. Conn. 2004). The key to whether "includes" is intended to be used in an illustrative or a definitional manner is determined by its placement and context within the statute. See Adams v. Dole, 927 F.2d 771, 777 (4th Cir. 1991). The Court must harmonize the term with the overall statute. See Olander, 572 F.3d at 768.

The context in which "includes" is used in the statute does not support Plaintiff's contention that such term is being used illustratively. The first two paragraphs of section 1395w-102(e)(1) collectively specify coverage for a prescription drug, biological product

and insulin, by cross-reference to 42 U.S.C. § 1396r-8(k)(2). That cross-referenced provision, in turn, identifies each of the aforementioned items as defining what constitutes a "covered outpatient drug." 42 U.S.C. § 1396r-8(k)(2). Notably, the definition of a "covered outpatient drug" excludes drugs "used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(3).[2] Stated another way, all of the drugs identified in the definition of a covered Part D drug must, by definition, satisfy the medically accepted indication requirement. Yet, under Plaintiff's interpretation, the use of a drug for a ***non***-medically accepted indication would be entirely permissible under Part D, despite the fact that the cross-referenced provision defining a covered outpatient drug, 42 U.S.C. § 1396r-8(k)(2)-(3), states precisely the opposite. Consequently, it would be incongruous to construe section 1395w-102(e)'s reference to "any use of a covered Part D drug for a medically accepted indication" as anything other than a specific circumscription on the definition of a covered Part D drug.

Further support for the conclusion that "includes" is intended to introduce definitional as opposed to illustrative terms is shown by the interplay between the reference to "biological product" and "vaccines" in the second and third paragraphs of section 1395w-102(e), respectively. As noted, the second paragraph of section 1395w-102(e) specifically identifies a biological product (as defined by cross-reference to 42 U.S.C. § 1396r-8(k)(2)(B)) as an item qualifying as a covered Part D drug. 42 U.S.C. § 1395w-102(e)(4)(B). The cross-referenced definition of biological product specifically ***excludes*** vaccines. 42 U.S.C. § 1396r-8(k)(3). However, to ensure that certain vaccines qualify as covered Part D drugs, the third paragraph of section 1395w-102(e) states that: "***and such term includes a vaccine*** licensed under section 262 of this title (and, for vaccines administered on or after January 1, 2008, its administration) . . . ."). 42 U.S.C. § 1395w-102(e) (emphasis added). Given that the definition of a "biological product" does not

[2] Section 1396r-8(k)(3) provides, in part, that "such term [i.e., covered outpatient drug] also does not include any such drug or product . . . used for a medical indication which is not a medically accepted indication."

include a vaccine, it would be illogical to construe the reference to vaccines as nothing more than an example of what could be covered under Part D, when, in the preceding paragraphs, vaccines are expressly excluded. Rather, the more logical interpretation is to construe the term "includes" in this context as definitional. See Adams, 927 F.2d at 777 (explaining by analogy: "[T[he term 'including' can also introduce restrictive or definitional terms. If we say that 'all licensed drivers, including applicants for driver's licenses, shall take an eye exam,' the word 'including' means 'and' or 'in addition to.' That meaning is derived from the fact that a 'licensed driver,' by definition, excludes an 'applicant,' and therefore if we intend to include applicants we must say so.").

Finally, Plaintiff's contention that "includes" is meant to be illustrative cannot be reconciled with the fact that Congress included a lengthy and detailed definition of "medically accepted indication" within the statutory definition of "covered Part D drug." That definition states:

> **(e) Covered part D drug defined**
>
> . . . .
>
> **(4) Medically accepted indication defined**
>
> **(A) In general**
>
> For purposes of paragraph (1), the term "medically accepted indication" has the meaning given that term—
>
> (i) ***in the case of a covered part D drug used in an anticancer chemotherapeutic regimen***, in section 1395x(t)(2)(B) of this title, except that in applying such section—
>
> (I) "prescription drug plan or MA-PD plan" shall be substituted for "carrier" each place it appears; and
>
> (II) subject to subparagraph (B), the compendia described in section 1396r-8(g)(1)(B)(i)(III) of this title shall be included in the list of compendia described in clause (ii)(I) section 1395x(t)(2)(B) of this title; and
>
> (ii) ***in the case of any other covered part D drug, in section 1396r-8(k)(6) of this title***.

42 U.S.C. § 1395w-102(e)(4) (emphasis added).

As set forth above, the definition of a medically accepted indication is divided into two parts under section 1395w-102(e). The first part applies only to Part D drugs used as part of an "anti-cancer chemotherapeutic regimen," and incorporates by reference the definition of a "medically accepted indication" in Medicare Part B, codified at 42 U.S.C. § 1395x(t)(2)(B). See id. § 1395w-102(e)(4)(A)(i). The second part of the definition applies to all other Part D drugs, and incorporates a narrower definition of a "medically accepted indication" codified at 42 U.S.C. § 1396r-8(k)(6). See id. § 1395w-102(e)(4)(A)(ii).[3] The fact that Congress provided a detailed framework and different definitions for "medically accepted indication" depending on the nature of the drug use, belies Plaintiff's assertion that the reference to the medically accepted indication requirement is merely "illustrative" and not restrictive. C.f., Burlington N. and Santa Fe R.R. Co. v. White, 548 U.S. 53, 63 (2006) ("We normally presume that, where words differ as they differ here, Congress acts intentionally and purposely in the disparate inclusion or exclusion.") (internal quotations and citation omitted); Center for Biological Diversity, 695 F.3d at 903 ("It is a fundamental rule of statutory construction that we should avoid an interpretation of a statute that renders any part of it superfluous and does not give effect to all of the words used by Congress.") (internal quotations and citation omitted).

In sum, the Court concludes that it is clear from the plain terms of the statute that a covered Part D drug is one that comports with the medically accepted indication requirement. In the case of an off label use of a Part D drug, coverage under Part D is dependent upon whether the Medicare enrollee is able to satisfy the compendia requirement. The statute is unambiguous in that regard, and for that reason, the Court finds that the MAC's decision is correct.

[3] Unlike section 1396r-8(k)(6), the definition for medically accepted indication set forth in Medicare Part B is broader in that it permits the use of certain "peer reviewed medical literature." See 42 U.S.C. § 1395x(t)(2)(B)(ii)(II).

C. DEFERENCE TO THE SECRETARY

As an alternative matter, the Secretary contends that her determination that a covered Part D drug must be one used for a medically accepted indication, as embodied in 42 C.F.R. § 423.100, is entitled to deference. Under Chevron, there are two steps to a court's review of an agency's construction of a statute. 467 U.S. at 842. The court first determines "whether Congress has spoken to the precise question at issue[.]" Id. at 843. If the language of the statute is clear and unambiguous, resort to the agency's interpretation is unnecessary. Los Angeles Haven Hospice, Inc. v. Sebelius, 638 F.3d 644, 660 (9th Cir. 2011).

If the statute is ambiguous or silent on the issue, the court proceeds to the second step, which requires the court to defer to the agency's interpretation "so long as it is reasonable." Id. "The court need not conclude that the agency construction was the only one it permissibly could have adopted to uphold the construction, or even the reading the court would have reached if the question initially had arisen in a judicial proceeding." Chevron, 467 U.S. at 843 n.11. Rather, this part of the test "is satisfied if the agency's interpretation reflects a plausible construction of the statute's plain language and does not otherwise conflict with Congress' expressed intent." Or. Trollers Ass'n v. Gutierrez, 452 F.3d 1104, 1116 (9th Cir. 2006) (internal quotations omitted).

While the statute at issue certainly is not a model of clarity, the Court has determined above that there is no ambiguity as to whether a covered Part D drug must be used for a medically accepted indication.[4] But even if there were, the Secretary's

[4] Plaintiff urges the Court to follow Layzer v. Leavitt, 770 F. Supp. 2d 579 (S.D.N.Y. 2011), which ruled that the plaintiff was entitled to coverage under Part D for an off label use of medication, even though he lacked a supporting compendia citation. The court reasoned that under 42 U.S.C. § 1301(b), the statute's use of "includes" conveyed that the reference to medically accepted indication was illustrative and not restrictive. Ultimately, the court concluded that "Congress did not intend to import the definition of 'medically accepted indication' in § 1396r-8(k)(6) as a limiting element of the Definition [for a covered Part D drug]," and for that reason, ruled that the Secretary's reliance on 42 C.F.R. § 423.100 was entitled to no deference under the first step of the Chevron inquiry. Id. As discussed above, the Court has found that the term "includes," when construed in its proper context, was intended by Congress to restrict the scope of a covered Part D drug. Therefore, the Court respectfully declines to follow Layzer.

interpretation of section 1395w-102(e) is both permissible and reasonable. As discussed above, the language, structure and context of the terms presented in the statutory definition of a covered Part D drug, as well as the other statutory provisions incorporated by reference, persuade the Court that 42 C.F.R. § 423.100 represents a justifiable interpretation of the statute. Moreover, Plaintiff has failed to identify any particular provision of the statute demonstrating that it mandates Part D coverage for the use of a drug which does not comport with the compendia requirement, even if such use is medically necessary. Given Plaintiff's failure to make such a showing, the Court is not inclined to find that the Secretary's regulation is arbitrary, capricious or not in accordance with the law.

IV. CONCLUSION

The Court concludes that under 42 U.S.C. § 1395w-102(e), an off label use that does not comport with the medically accepted indication requirement is not covered by Medicare Part D. The MAC thus did not err in its decision. Accordingly,

IT IS HEREBY ORDERED THAT:

1. The Secretary's motion for summary judgment is GRANTED and Plaintiff's motion for summary judgment is DENIED.

2. Final judgment shall be entered in favor of the Secretary.

3. The Clerk shall close the file and terminate any pending matters.

IT IS SO ORDERED.

Dated: February 7, 2013

Saundra B Armstrong

SAUNDRA BROWN ARMSTRONG
United States District Judge