IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF OREGON

MELINDA BROOME,

Plaintiff,

v.

SILVIA MATHEWS BURWELL, Secretary, United States Department of Health and Human Services,

Defendant.

Case No. 6:14-cv-01248-MC

OPINION AND ORDER

MCSHANE, Judge:

Plaintiff Melinda Broome brings this action for judicial review of a decision by the Medicare Appeals Council (MAC) denying her continued Medicare Part D coverage for fentanyl citrate lozenges for breakthrough pain (pain that "breaks through" the pain medication she regularly takes) associated with her chronic, severe back pain. This Court has jurisdiction under 42 U.S.C. § 405(g). *See* 42 U.S.C. § 1395ff(b)(1)(A).

This Court is asked to consider whether the clause "and such term includes" in the third paragraph of 42 U.S.C. § 1395w–102(e)(1) is illustrative (it introduces several examples of coverage) or definitional (it imposes additional conditions on coverage). If this clause is interpreted as illustrative, then the broad language of 42 U.S.C. § 1395w–102(e)(1)(A) endorses coverage for Broome's lozenges under Medicare Part D. In contrast, if this clause is interpreted as definitional, then Broome's lozenges are not covered because she does not use them for their

"medically accepted indication" as defined in 42 U.S.C. § 1395w–102(e)(4). Because the use of the conjunctive "and" in the third paragraph of 42 U.S.C. § 1395w–102(e)(1) is definitional, this Court finds that Broome's use of fentanyl citrate lozenges for breakthrough back pain is not covered under Medicare Part D. Thus, defendant's motion for summary judgment, ECF No. 6, is GRANTED.

PROCEDURAL AND FACTUAL BACKGROUND

Broome qualified for Social Security Disability benefits on June 27, 2008, based on chronic back pain stemming from multiple back surgeries. In order to control this back pain, Broome currently receives fentanyl injections through a spinal pump, which she supplemented with oral fentanyl citrate lozenges to control her breakthrough pain. In 2013, following an audit performed by the Centers for Medicare & Medicaid Services, Broome received notification that coverage for her fentanyl citrate lozenges prescription would be discontinued, but the Medicare Part D plan would still cover the use of fentanyl in her spinal pump. Broome exhausted her administrative appeals up to the MAC, which determined on June 2, 2014, that Broome's fentanyl citrate lozenges use did not match the definition of a "medically accepted indication" as defined in 42 U.S.C. § 1395w–102(e)(4). Broome now seeks judicial review.

STANDARD OF REVIEW

Under the Administrative Procedure Act, a district court may set aside an agency decision that is "'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Palomar Med. Ctr. v. Sebelius*, 693 F.3d 1151, 1159 (9th Cir. 2012) (quoting 5 U.S.C. § 706(2)(A)). 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). "Substantial evidence" is "more than a mere scintilla but less than a preponderance; it

is such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Sandgathe v. Chater*, 108 F.3d 978, 980 (9th Cir. 1997) (citation and internal quotations marks omitted).

DISCUSSION

The Medicare Act, established under Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395–1395lll, is a federally funded health insurance program for the elderly and disabled. *See Maximum Comfort Inc. v. Sec. of Health & Human Servs.*, 512 F.3d 1081, 1083 (9th Cir. 2007). At issue here is Part D, a voluntary prescription drug benefit program established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. No. 108–173, 117 Stat. 2066 (2012). The MMA identifies three types of drugs covered by Part D, including: (1) certain prescription drugs; (2) certain biological products; and (3) certain insulin and supplies used to inject insulin. *See* 42 U.S.C. § 1395w–102(e)(1).

The MMA further specifies, in the third paragraph of 42 U.S.C. § 1395w–102(e)(1), that the definition of a covered Part D drug includes "a vaccine licensed under section 262 of this title . . . and any use of a covered Part D drug for a medically accepted indication (as defined in paragraph (4))." Because Broome's lozenges are not licensed vaccines, the issue before this Court is whether Broome's fentanyl citrate lozenges must be used solely for their "medically accepted indication," as defined in 42 U.S.C. § 1395w–102(e)(4), in order to qualify for coverage. The disputed provision of the MMA reads 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),

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)).*

. . .

(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) (emphasis added).

Because Broome does not use fentanyl citrate lozenges as part of an anticancer chemotherapeutic regimen, *see* 42 U.S.C. § 1395w–102(e)(4)(A)(i), her use must satisfy the "medically accepted indication" criteria listed in 42 U.S.C. § 1396r–8(k)(6), *see* 42 U.S.C. §

1395w–102(e)(4)(A)(ii). Under § 1396r–8(k)(6), the "medically accepted indication" is defined as (1) a use approved by the Food and Drug Administration (FDA), or (2) "the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in section (g)(1)(B)(i) of this section." 42 U.S.C. § 1396r–8(k)(6). The compendia include:

> (I) the American Hospital Formulary Service Drug Information;
>
> (II) the United States Pharmacopeia–Drug Information (or its successor publications); and
>
> (III) the DRUGDEX Information Systems.

42 U.S.C. § 1396r–8(g)(1)(B)(i).

Broome does not argue that treatment for back pain is an FDA-approved use for fentanyl citrate lozenges, or that she satisfies the compendia requirement. Instead, she argues that the phrase "any use of a covered Part D drug for a medically accepted indication" is merely illustrative, not definitional.

The United States District Court for the Northern District of California properly rejected the same argument in *Nievod v. Sebellius*, No. C11-4134 SBA, 2013 WL 503089, at *7 (N.D. Cal. Feb. 8, 2013). In *Nievod*, the court relied on four findings.

First, the *Nievod* court examined the structure of 42 U.S.C. § 1395w–102(e)(1), comparing the disjunctive term "or" between subparagraphs (e)(1)(A) and (e)(1)(B), and the conjunctive term "and" at the beginning of the third paragraph to (e)(1). *Id.* at *6–7. The *Nievod* court concluded that "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)." *Id.* at *7 (emphasis in original).

Second, the *Nievod* court considered the context in which "and such term includes" was used in the statute. *Id.* at *7–8. The court noted that subparagraphs (e)(1)(A) and (e)(1)(B) both cross-reference 42 U.S.C. § 1396r-8(k)(2), which "identifies each of the aforementioned items as defining what constitutes a 'covered outpatient drug.'" *Id.* at *7. Specifically excluded from the definition of a "covered outpatient drug" is any drug "used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(3). Put differently, "all of the drugs identified in the definition of a covered Part D drug must . . . satisfy the medically accepted indication requirement." *Nievod*, 2013 WL 503089, at *7. As a result, the court concluded "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." *Id.*

Third, the *Nievod* court determined that its interpretation of "and such term includes" was further supported "by the interplay between the reference to 'biological product' and 'vaccines' in the second and third paragraphs of section 1395w–102(e), respectively." *Id.* at *8. The second paragraph of section 1395w–102(e) defines "biological product." That definition cross-references 42 U.S.C. 1396r –8(k)(2)(B), which "specifically ***excludes*** vaccines." *Id.* (emphasis in original). In contrast, the third paragraph of section 1395w–102(e) provides: "***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)(1) (emphasis added). The court explained that "[g]iven that the definition of a 'biological product' does not include a vaccine, it would be illogical to construe the reference to vaccines as [illustrative], when, in the preceding paragraphs, vaccines are expressly excluded." *Nievod*, 2013 WL 503089, at *8.

Fourth, the *Nievod* court emphasized that an illustrative interpretation of "includes" under the third paragraph of (e)(1) "cannot be reconciled with the . . . lengthy and detailed definition of 'medically accepted indication' within the statutory definition of 'covered Part D drug." *Id.* The definition of "medically accepted indication" under section 1395w–102(e) is divided into two parts. *See* 42 U.S.C. § 1395w–102(e)(4)(A). The first part, which applies to Part D drugs "used in an anticancer chemotherapeutic regimen," incorporates the definition of "medically accepted indication" in Medicare Part B, codified at 42 U.S.C. § 1395x(t)(2)(B). *See* 42 U.S.C. § 1395w–102(e)(4)(A)(i). The second part, which applies to any other covered Part D drug, incorporates a narrower definition of "medically accepted indication" codified at 42 U.S.C. § 1396r–8(k)(6). *See* 42 U.S.C. § 1395w–102(e)(4)(A)(ii); *Nievod*, 2013 WL 503089, at *9 n.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.'" (citation omitted)). The court found that this detailed definitional framework "belie[d] Plaintiff's assertion that the reference to the medically accepted indication requirement [in the third paragraph of (e)(1)] is merely 'illustrative' and not restrictive." *Nievod*, 2013 WL 503089, at *9.

Because of these findings, the *Nievod* court held that, "[i]n 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." *Nievod*, 2013 WL 503089, at *9. This Court is persuaded by the reasoning in *Nievod*. *See also Rickoff v. United States Sec'y for the Dep't of Health & Human Servs.*, No. CV-11-2189-PHX-DGC, 2012 WL 6177411, at *2 (D. Ariz. Dec. 11, 2012) ("Fentanyl in lozenge form is not a 'medically accepted indication' for non-cancer patients and

this is not a covered Part D drug."); *Kilmer v. Leavitt*, 609 F. Supp. 2d 750, 753 (S.D. Ohio 2009) (concluding that "the medically accepted indication clause must be read as a limitation").[1]

CONCLUSION

For these reasons, defendant's motion for summary judgment, ECF No. 6, is GRANTED.

IT IS SO ORDERED.

DATED this 1st day of April, 2015.

Michael J. McShane
United States District Judge

[1] *But see Layzer v. Leavitt*, 770 F. Supp. 2d 579, 587 (S.D. N.Y. 2011) (holding that "Congress did not intend to impose the Compendia Requirement").