UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

JILL A. WHITCOMB,

Plaintiff,

v. **Case No. 17-CV-14**

ERIC D. HARGAN,[1]
Acting Secretary of Health and Human Services,

Defendant.

DECISION AND ORDER

Jill A. Whitcomb is a Type I diabetic who is unable to detect sudden drops in her blood sugar levels. To manage her symptoms, she sought coverage for a continuous glucose monitor, a device that would alert her when her blood sugar drops below a certain level. After her insurance plan denied her claim, Ms. Whitcomb requested and received a hearing before an administrative law judge. The ALJ determined that the plan was required to cover the continuous glucose monitor. On appeal, however, the Medicare Appeals Council—acting on behalf of the Secretary of the U.S. Department of Health and Human Services—found that continuous glucose monitors are not entitled to Medicare coverage because they are not primarily and customarily used to serve a medical purpose. Ms. Whitcomb now seeks judicial review of that decision.

[1] Eric D. Hargan assumed the position of Acting Secretary of the U.S. Department of Health and Human Services in October 2017 and, therefore, should be substituted as the named defendant in this action. *See* Fed. R. Civ. P. 25(d).

Ms. Whitcomb argues that the Secretary erred in finding that a continuous glucose monitor does not serve a medical purpose. She further maintains that the Secretary's coverage denial is arbitrary and capricious because it conflicts with the agency's own policies and prior decisions. The Secretary contends that its decision is supported by substantial evidence and is free from legal error. For the reasons that follow, the Court agrees with Ms. Whitcomb and therefore will reverse the Secretary's decision denying her coverage for a continuous glucose monitor.

I. Background

Jill A. Whitcomb was born on May 4, 1966. *See* Transcript 472, ECF No. 12-1–12-3. She is diagnosed with Type 1 diabetes and has suffered from this condition for over forty years. Tr. 148, 285, 472. Ms. Whitcomb also has a complication known as hypoglycemic unawareness, which means that she does not experience a nervous system response (e.g., palpitations, sweating, or anxiety) prior to sudden drops in her blood glucose levels. Tr. 247–48, 283–84. As of April 2011, Ms. Whitcomb was experiencing on average twenty-two hypoglycemic events per month. Tr. 472. Her caregiver often would find her unresponsive due to low blood glucose levels, and, despite monitoring, Ms. Whitcomb would frequently require emergency medical attention. *See* Tr. 148, 249, 254, 290–91, 472, 1176–77, 1180. In short, her diabetes is uncontrolled.

Due to the nature of her symptoms, in 2011, Ms. Whitcomb's treatment providers prescribed her a continuous glucose monitor. Tr. 148, 285–86. A continuous glucose monitor is a sensor system that is designed to continuously and

automatically monitor interstitial glucose values in the subcutaneous tissue (i.e., the fluid that surrounds the cells of the tissue beneath the skin). *See* Tr. 6, 285–90, 472. The monitor consists of three parts: a sensor, a transmitter, and a receiver. The disposable sensor is inserted under the skin to measure glucose levels in tissue fluid. It is connected to a transmitter that sends the information to a receiver where a user can view her glucose levels in real time. A continuous glucose monitor therefore is a method of estimating blood glucose. If glucose levels are high or low, the monitor alerts the user so she can confirm those levels through the traditional finger-stick method. The continuous glucose monitor also tracks trends in glucose levels.

Ms. Whitcomb's six-month trial with the monitor was "remarkably" successful. *See* Tr. 148, 290–92, 472. She experienced hypoglycemic events much less frequently, and she required emergency medical attention on only two occasions, both of which resulted from her using expired supplies. Tr. 1177–80. Given the success of the trial, Ms. Whitcomb sought coverage for her own continuous glucose monitor, the Medtronic MiniMed. *See* Tr. 472–74, 1186–87.

Ms. Whitcomb is an enrollee of a Medicare Advantage plan offered by United Healthcare of Wisconsin (Secure Horizons). *See* Tr. 3. On April 14, 2011, Ms. Whitcomb sought pre-authorization to obtain a continuous glucose monitor. Tr. 474. Secure Horizons denied the request initially, Tr. 549, and upon reconsideration, Tr. 568–69, concluding that continuous glucose monitors are precautionary and therefore not covered by Medicare as durable medical equipment. A qualified

independent contractor agreed with Secure Horizons' decision to deny coverage. Tr. 585–86.

Ms. Whitcomb appealed the denial of coverage to an administrative law judge. After conducting two hearings, on February 6, 2013, the ALJ issued a decision fully favorable to Ms. Whitcomb, finding that Secure Horizons was required to provide coverage for the monitor because Ms. Whitcomb met the Medicare coverage criteria of National Coverage Determination 40.2 and the Medicare coverage guidelines of Local Coverage Determination L27231.[2] Tr. 356–66. Secure Horizons appealed, and on August 25, 2013, the Medicare Appeals Council reversed the ALJ's decision. Tr. 322–30. Relying on Local Coverage Article A47238, a document setting forth the agency's own policy interpretation, the Appeals Council determined that continuous glucose monitors are not covered by Medicare because they are precautionary.

Ms. Whitcomb exercised her right to judicial review by filing a federal lawsuit in the United States District Court for the Eastern District of Wisconsin. On May 26, 2015, United States Magistrate Judge William E. Duffin issued a decision remanding the matter to the Secretary for further proceedings. Tr. 212–21; *see* ECF No. 51 in *Whitcomb v. Burwell*, Case No. 13-CV-990. Judge Duffin determined that neither NCD 40.2 nor LCD L27231 provided coverage for the continuous glucose monitor. Tr. 217–18. He concluded, however, that the Appeals Council erred in

[2] NCD 40.2 and L27231 provide coverage for home blood glucose monitors and their associated supplies.

relying on A47238. Tr. 218–20. Judge Duffin remanded the matter to the Secretary to assess the case "under the proper legal standard." Tr. 220.

The Appeals Council remanded the matter to the ALJ to address the preliminary issue of whether the glucose monitor is eligible for coverage under a defined benefit category. Tr. 199–203. After conducting another hearing, on October 14, 2015, the ALJ issued a second decision fully favorable to Ms. Whitcomb. Tr. 54–69. The ALJ determined that the monitor qualified as durable medical equipment. Tr. 64. He further determined that the device was medically reasonable and necessary for Ms. Whitcomb. Tr. 65–67. The ALJ concluded that Secure Horizons was required to provide Ms. Whitcomb coverage for the continuous glucose monitor. Tr. 68.

Secure Horizons appealed again, and on November 8, 2016, the Appeals Council reversed the ALJ's second fully favorable decision. Tr. 1–12. The Appeals Council first determined that the components of a continuous glucose monitor are not listed in the items automatically classified as durable medical equipment. Tr. 10 (citing section 1861(n) of the Social Security Act, 42 U.S.C. § 1395x(n)). The Appeals Council also determined that continuous glucose monitors do not meet the regulatory definition of durable medical equipment. Tr. 10 (citing 42 C.F.R. § 414.202). Secure Horizons therefore was not required to authorize coverage for Ms. Whitcomb's monitor. Tr. 12. The Appeals Council's decision is the final decision of the Secretary of Health and Human Services. *See Bowen v. New York*, 476 U.S. 467, 482 (1986).

Ms. Whitcomb filed this action on January 4, 2017, seeking judicial review of the Secretary's decision under 42 U.S.C. § 405(g). Complaint, ECF No. 1. The matter was reassigned to this Court after both parties consented to magistrate judge jurisdiction. *See* Consent to Proceed Before a Magistrate Judge, ECF Nos. 2 & 6 (citing 28 U.S.C. § 636(c) and Fed. R. Civ. P. 73(b)). It is now fully briefed and ready for disposition. *See* Plaintiff's Brief, ECF No. 15; Defendant's Response, ECF No. 16; and Plaintiff's Reply, ECF No. 17. The Court heard oral argument from the parties on October 10, 2017. *See* Minute Sheet for Oral Argument, ECF No. 18.

II. Standard of Review

"Judicial review of Administration decisions under the Social Security Act is governed by 42 U.S.C. § 405(g)." *Allord v. Astrue*, 631 F.3d 411, 415 (7th Cir. 2011) (citing *Jones v. Astrue*, 623 F.3d 1155, 1160 (7th Cir. 2010)). Pursuant to sentence four of § 405(g), federal courts have the power to affirm, reverse, or modify the Secretary's decision, with or without remanding the matter for a rehearing. *See* 42 U.S.C. § 1395ff(b)(1)(A) (explaining that references to the "Commissioner" in § 405(g) shall be considered a reference to the Secretary).

This Court reviews the Secretary's decision "with the deference due to final decisions of agencies." *Wood v. Thompson*, 246 F.3d 1026, 1029 (7th Cir. 2001). The Secretary's factual findings are conclusive if they are supported by "substantial evidence." *Id.* (quoting *Johnson v. Heckler*, 741 F.2d 948, 952 (7th Cir. 1984)). "'Substantial evidence' is 'more than a scintilla' but less than a preponderance of the evidence, and is 'such relevant evidence as a reasonable mind might accept as

adequate to support a conclusion.'" *Wood*, 246 F.3d at 1029 (quoting *Kapusta v. Sullivan,* 900 F.2d 94, 96 (7th Cir. 1990)).

In reviewing the record, this Court "may not decide the facts anew, reweigh the evidence, or substitute [its] own judgment for that of the Secretary." *Delgado v. Bowen*, 782 F.2d 79, 82 (7th Cir. 1986) (citing *Garfield v. Schweiker*, 732 F.2d 605, 610 (7th Cir. 1984)). But the Court should not simply "rubber stamp" the Secretary's decision. *Id.* Rather, the Court must ensure that the Secretary considered the entire record and that "the reasons for his conclusions [were] stated in a manner sufficient to permit an informed review." *Delgado*, 782 F.2d at 82–83 (citing *Garfield*, 732 F.2d at 610).

The Secretary's denial of coverage may be reversed if the denial was based on legal error. *Wood*, 246 F.3d at 1029. When interpreting the Social Security Act, this Court must

> first determine whether the intent of Congress is unambiguous. *See Chevron U.S.A., Inc. v. Nat'l Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984)). "If the meaning of the statute is clear, no deference is due an agency's interpretation. If the meaning of the statute is ambiguous, an agency's interpretation will be deferred to if it is reasonable. *See id.* at 844. If the agency's interpretation conflicts with its prior interpretation, the current interpretation is "'entitled to considerably less deference' than a consistently held view." *INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 n.30 (1987) (quoting *Watt v. Alaska*, 451 U.S. 259, 273 (1981)).

Id. Absent legal error, the Secretary's decision must be affirmed if it is supported by substantial evidence, even if the reviewing court would have decided the matter differently. *See Delgado*, 782 F.2d at 83.

III. Discussion

Ms. Whitcomb asks the Court to set aside the Appeals Council's decision and to order Secure Horizons to provide coverage for her continuous glucose monitoring system.

A. Legal framework

"Administration of the Medicare program is governed by title XVIII of the [Social Security] Act." Procedures for Making National Coverage Decisions, 64 Fed. Reg. 22619, 22620 (Apr. 27, 1999). "Under the Medicare program, the benefits available to eligible beneficiaries are called 'covered' services." *Id.* "Medicare is a defined benefit program—the services covered are broadly defined in the Act[] in . . . benefit categories." *Id.* "Specific health care services must fit into one of these benefit categories to be eligible for coverage under Medicare." *Id.* To be covered, the item or service must also be "reasonable and necessary" and not otherwise excluded from coverage. *See* 42 U.S.C. § 1395y(a)(1).

The Act provides coverage for "medical and other health services," 42 U.S.C. § 1395k(a), which is defined to include "durable medical equipment," 42 U.S.C. § 1395x(s)(6). Section 1861(n) of the Act contains a non-exhaustive list of certain items that are automatically classified as durable medical equipment. *See* § 1395x(n). Included within this list are blood glucose monitors for individuals with diabetes.

An item not included within that list may still qualify as durable medical equipment if it satisfies the following regulatory definition:

> Durable medical equipment means equipment, furnished by a supplier or a home health agency that meets the following conditions:
>
> (1) Can withstand repeated use.
>
> (2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.
>
> (3) Is primarily and customarily used to serve a medical purpose.
>
> (4) Generally is not useful to an individual in the absence of an illness or injury.
>
> (5) Is appropriate for use in the home.

42 C.F.R. § 414.202.

B. The Appeals Council's Decision

The Medicare Appeals Council concluded that Secure Horizons was not required to authorize coverage for Ms. Whitcomb's monitor because the device does not fall within Medicare's durable medical equipment benefit category. Tr. 10–11. The Appeals Council first determined that continuous glucose monitors are not "blood glucose monitors" because they measure glucose in the interstitial fluid, not the blood. The Appeals Council further determined that continuous glucose monitors are merely "precautionary" and therefore are not primarily and customarily used to serve a medical purpose.

The Appeals Council acknowledged that precautionary "is not a statutorily defined term." Tr. 10. It nevertheless explained, "Where an enrollee must still use another device to accomplish the medical purpose at issue, the device is essentially used as an additional precaution, but not for a primary medical purpose." Tr. 10. According to the Appeals Council, the medical purpose at issue—measuring blood

glucose levels—cannot be accomplished with a continuous glucose monitor; rather, this medical purpose is achieved through the traditional finger-stick method. Because the Appeals Council found that Ms. Whitcomb's monitor did not fall within a benefit category, it never addressed whether the monitor was reasonable and necessary or otherwise excluded from coverage. *See* Tr. 11.

C. Legal Analysis

Ms. Whitcomb maintains that the Appeal Council's decision is contrary to the law and facts. She first contends that the Appeals Council erroneously concluded that a continuous glucose monitor does not serve a medical purpose and, therefore, does not satisfy the regulatory definition of durable medical equipment. Pl.'s Br. 15–20; Pl.'s Reply 3–6. Second, she asserts that the Appeals Council's decision is arbitrary and capricious because the agency failed to follow its own policies and has provided coverage for continuous glucose monitors for "medically indistinguishable beneficiaries." Pl.'s Br. 15, 22; Pl.'s Reply 6–8. Ms. Whitcomb further maintains that her monitor satisfies the other requirements for coverage under the Act. Pl.'s Br. 20–22; Pl.'s Reply 1–2. The Court will address her arguments in turn.

1. Whether the Appeals Council erred in denying coverage for Ms. Whitcomb's continuous glucose monitor

Ms. Whitcomb first argues that the Appeals Council erred in concluding that continuous glucose monitors are not primarily and customarily used to serve a medical purpose. The Court agrees. The device at issue is used by diabetics to continuously and automatically monitor glucose levels in the tissue beneath their skin. Such a function clearly constitutes a medical purpose.

In seeking affirmance of the Appeals Council's decision, the Secretary asks this Court to give substantial deference to the interpretative guidance found in the agency's Medicare Benefit Policy Manual and A47238. *See* Def.'s Resp. 18–19. According to the Manual, "precautionary-type equipment" is presumptively considered to be non-medical. *See* United States Centers for Medicare & Medicaid Services Pub. 100-02, *Medicare Benefit Policy Manual*, Ch. 15, § 110.1(B)(2). And the agency stated in A47238 that continuous glucose monitors are considered precautionary. Where the meaning of a regulation is clear, however, this Court is not required to give any deference to an agency's interpretation. *See Wood*, 246 F.3d at 1029 (citing *Chevron*, 467 U.S. at 844); *see also Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (holding that courts must defer to agency interpretations of their own regulations unless they are "plainly erroneous or inconsistent with" those regulations) (citations omitted).

The regulation defining durable medical equipment, as that term is used in the Act, is clear on its face. To qualify as durable medical equipment, a device must be, among other requirements, "primarily and customarily used to serve a medical purpose." *See* 42 C.F.R. § 414.202. That is, the device's primary and customary purpose must be medical as opposed to non-medical. *See Medicare Benefit Policy Manual*, Ch. 15, § 110.1(B)(2) ("Equipment which is primarily and customarily used for a nonmedical purpose may not be considered 'medical' equipment for which payment can be made under the medical insurance program.") The Secretary has never articulated what non-medical purpose it believes a continuous glucose

monitor primarily and customarily serves. That is likely because the monitor does not serve a non-medical purpose. The medical community seems to agree. *See* Pl.'s Br. 4–5 (citing Tr. 18 (attachments 1, 4 & 6), 148–49).

Moreover, to the extent the regulatory definition of durable medical equipment is ambiguous, the agency's interpretation of "primarily and customarily used to serve a medical purpose" is unreasonable. *First*, the agency's interpretation defies the syntax of this definitional phrase. As written, the terms "primarily" and "customarily" refer to the "equipment" in question. That is, does the equipment primarily and customarily serve a medical purpose rather than a non-medical one? The agency's interpretation transposes these terms, asking whether the equipment serves a primary (as opposed to a secondary) medical purpose. *See, e.g.*, Tr. 10 ("[Continuous glucose monitoring] systems, however, do not have a primary medical purpose."). If the agency did not intend to provide coverage for secondary medical equipment, then the regulatory definition of durable medical equipment must be revised to reflect that ideal.

Second, the agency's interpretation does not provide any guidance on what type of equipment will satisfy its reformulated definition. Neither the Act nor the regulations use the term "precautionary." *See* 42 U.S.C. § 1395x; 42 C.F.R. § 414.202; *see also* Tr. 10 ("'[P]recautionary' is not a statutorily defined term."). The term does appear in NCD 280.1, the Medicare Benefit Policy Manual, and in A47238. The Appeals Council's decision, however, does not reference any of those policy interpretations in attempting to explain non-coverage of Ms. Whitcomb's

glucose monitor. And the interpretations themselves are unhelpful. A47238 indicates, without any explanation, that continuous glucose monitors are considered precautionary and therefore non-covered. This putative policy interpretation is a tautology, not an explanation. The only examples of (non-covered) precautionary equipment listed in NCD 280.1 and the Manual are preset portable oxygen systems/units, which are used in emergency response or first-aid situations, and spare tanks of oxygen. Continuous glucose monitors are not of a piece with these purely emergency or back-up devices.

Generally speaking, a continuous glucose monitor has two functions: it measures interstitial glucose levels and it tracks trends in those levels. These functions are particularly crucial for diabetics like Ms. Whitcomb who suffer from hypoglycemic unawareness. The device, in the first instance, alerts the user when her glucose falls below a certain level. That the FDA advises users not to make therapeutic decisions without confirming the result using the traditional finger-stick method does not negate the device's primary purpose. After all, a user cannot prick her finger and take corrective action while she is sleeping or after she has already lost consciousness due to severely low glucose levels.

In sum, the Appeals Council committed legal error when it concluded that continuous glucose monitors are not primarily and customarily used to serve a medical purpose. The regulatory definition does not on its face require equipment to serve a primary medical purpose. Nor does the definition exclude coverage for equipment that must be used in conjunction with another device. Rather, such

equipment—including, for example, oxygen humidifiers, which expressly are covered according to NCD 280.1 only "for use in connection with" other covered durable medical equipment—is eligible for coverage if its primary purpose is medical. The record contains no reason as to why a different outcome should obtain for continuous glucose monitors, devices that unquestionably are "primarily and customarily used to serve a medical purpose." The glucose monitor at issue here indisputably satisfies that unambiguous definitional phrase.

Ms. Whitcomb also argues that the Appeals Council's decision is arbitrary and capricious. Again, the Court agrees. The decision conflicts with NCD 280.1, a reference tool that lists the coverage status of certain pieces of durable medical equipment. The list includes several devices that are purely adjunctive but nevertheless covered by Medicare. For example, NCD 280.1 indicates that a self-contained pacemaker monitor—a device that serves a secondary medical purpose—is covered as durable medical equipment. The decision not to cover continuous glucose monitors, which arguably do serve a primary medical purpose, is therefore arbitrary and capricious.

The Appeals Council's decision also is contrary to numerous final decisions of the Secretary in which coverage was provided for the same device at issue here. *See* Pl.'s Br. 12 & n.25 (citing http://dparrishlaw.com/medicare-acknowledges-dexcoms-g5-as-a-covered-medicare-benefit/), 22; Pl.'s Reply 6–7. The Secretary maintains that those decisions are not precedential and are fact-specific. *See* Def.'s Resp. 21–22. That may be true with respect to whether a continuous glucose monitor is

reasonable and necessary for an individual enrollee. But the threshold question of whether such monitors satisfy the regulatory definition of durable medical equipment should not vary from enrollee to enrollee. It is arbitrary and capricious for the Secretary to find that other enrollees' monitors were primarily and customarily used to serve a medical purpose while also concluding that Ms. Whitcomb's monitor is not eligible for coverage because it is precautionary.

2. Whether Ms. Whitcomb's continuous glucose monitor satisfies the other requirements for coverage under the Act

Because the Appeals Council determined that Ms. Whitcomb's glucose monitor was not primarily and customarily used to serve a medical purpose, it never addressed whether the device otherwise satisfied the definition of durable medical equipment or was medically reasonable and necessary for Ms. Whitcomb. *See* Tr. 11. The ALJ, however, did undertake that analysis, and he determined that Ms. Whitcomb's monitor met all of the requirements for coverage under the Act. *See* Tr. 65–67. Those findings are supported by substantial evidence. Moreover, at oral argument, the Secretary indicated through counsel that it was not contesting the ALJ's findings as to the remaining statutory elements. *See* Minute Sheet 2. Accordingly, Ms. Whitcomb is eligible for coverage of her continuous glucose monitor.

IV. Conclusion

For all the foregoing reasons, the Court finds that the Appeals Council erred when it denied coverage for Ms. Whitcomb's continuous glucose monitor. The record demonstrates that the monitor meets the statutory and regulatory requirements for

coverage under the Act. Accordingly, the Court reverses the Appeals Council's decision and remands the matter to the Secretary with instruction to authorize Secure Horizons to provide coverage for Ms. Whitcomb's monitor.

NOW, THEREFORE, IT IS HEREBY ORDERED that the Secretary's decision is **REVERSED**.

IT IS FURTHER ORDERED that this action is **REMANDED** to the Secretary pursuant to sentence four of section 205(g) of the Social Security Act, 42 U.S.C. § 405(g), with instruction to authorize Secure Horizons to provide coverage for Ms. Whitcomb's continuous glucose monitoring system.

FINALLY, IT IS ORDERED that the Clerk of Court enter judgment accordingly.

Dated at Milwaukee, Wisconsin, this 26th day of October, 2017.

BY THE COURT:

s/ David E. Jones
DAVID E. JONES
United States Magistrate Judge