UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

THERESE M. WATERS,
on behalf of KELLY E. WATERS,

Plaintiff,

v.

XAVIER BECERRA, Secretary, United States Department of Health & Human Services,

Defendant.
_____/

Hon. Sally J. Berens

Case No. 1:21-cv-170

OPINION

Plaintiff, Therese M. Waters, on behalf of Kelly E. Waters, seeks judicial review pursuant to 42 U.S.C. §§ 405(g) and 1395ff(b)(1)(A) of a final decision of the Medicare Appeals Council denying Kelly's claim for reimbursement under Medicare Part B for her orally-consumed enteral nutrition formula, Vitaflo Homocystinuria Cooler (HCU Cooler).

This matter is now before the Court on the parties' cross Motions for Summary Judgment.[1] (ECF Nos. 29 and 31.) The motions are fully briefed and ready for decision. For the following reasons, the Court will **grant** the Secretary's motion, **deny** Plaintiff's motion, and **affirm** the Secretary's final decision.[2]

[1] Pursuant to 28 U.S.C. § 636(c), the parties have consented to have the Court conduct all further proceedings in this case, including entry of judgment.

[2] Because Plaintiff requested oral argument only if Defendant did so, the Court will decide the matter on the briefs and the administrative record, as Defendant did not request oral argument.

I. Background

A. Kelly's Genetic Disorder and the Medicare Claims

Kelly, the Medicare beneficiary at issue in this matter, suffers from Homocystinuria (HCU), a rare condition that interferes with the body's ability to break down protein from food that is consumed. More specifically, HCU is an inborn metabolic disease that prevents the body from metabolizing the amino acid methionine. It also prevents the production of the amino acid L-cysteine, the end product of normally-metabolized methionine. (ECF No. 13 at PageID.301.) The disorder can lead to vision issues, brittle bones and other skeletal abnormalities, cognitive impairment and other mental abnormalities, and stroke. (*Id.*; *see also* PageID.304, 306.) Kelly, who is now an adult, was diagnosed with HCU at age 6. (*Id.* at PageID.303.)

HCU is treated primarily through restricting the individual's protein intake. (*Id.*) In addition to limiting Kelly's protein intake, her treating physician prescribed HCU Cooler, a methionine-free protein formula containing L-cysteine, to provide nutrition that she cannot obtain from her low-protein diet. (*Id.* at PageID.301.) She drinks four HCU Coolers orally each day, and "tube feeding is not necessary in [her] case." (*Id.*) Use of "a methionine-free amino acid formula supplying the other amino acids," such as HCU Cooler, is the recognized medical standard of care in treating HCU. (*Id.* at PageID.310.)

Plaintiff submitted claims for Medicare reimbursement for HCU Cooler covering the periods December 18, 2018–January 12, 2019; February 18, 2019–March 17, 2019; March 21, 2019–April 20, 2019; and August 12, 2019–September 11, 2019, totaling at least $22,034.70. (*Id.* at PageID.129, 331, 338–39.) CGS Administrators, LLC (CGS), the Medicare Administrative Contractor (MAC), denied the claim initially and on redetermination. CGS concluded that the claims were not covered by Medicare and that Kelly was responsible for the cost of the HCU Cooler. (*Id.* at PageID.280–82.) On December 10, 2019, Plaintiff requested reconsideration of the

denial by a Qualified Independent Contractor (QIC). (*Id.* at PageID.327.) On February 3, 2020, MAXIMUS Federal Services, the QIC, denied coverage on the basis that the enteral formula, or HCU Cooler, does not meet Medicare coverage guidelines for parenteral/enteral nutrition. The QIC also found the supplier, OCT Pharmacy LLC, responsible for the charges. (*Id.* at PageID.229–33.) On March 26, 2020, Plaintiff requested a hearing before an Administrative Law Judge (ALJ). (*Id.* at PageID.216–17.) Following a May 4, 2020 telephone hearing, (*id.* at PageID.375–91), ALJ Lynette Gohr issued an unfavorable decision on May 15, 2020, concluding that Kelly's HCU Cooler did not meet the coverage requirements for enteral nutrition and that Kelly was responsible for the non-covered costs. (*Id.* at PageID.370–74.) On July 1, 2020, Plaintiff requested that the Medicare Appeals Council (Appeals Council) review ALJ Gohr's decision. (*Id.* at PageID.125.) The Appeals Council issued a decision on December 22, 2020, adopting ALJ Gohr's decision. Therefore, Plaintiff fully exhausted her administrative appeals. *See* 42 C.F.R. § 405.904.

B. Statutory and Regulatory Provisions at Issue

The Medicare Act, set forth in Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, was enacted in 1965 to establish a national program of health insurance for the aged and disabled. At issue in this case is Medicare Part B, which provides coverage for "medical and other health services." 42 U.S.C. § 1395k(a)(1). The Act "does not contain a comprehensive list" of items or services covered or excluded by Medicare. 68 Fed. Reg. 55634, 55635 (Sept. 26, 2003). "Rather, it lists categories of items and services, and vests in the Secretary the authority to make determinations about which specific items and services within these categories can be covered under the Medicare program." *Id.* Payment depends upon a determination "that a service meets a benefit category, is not specifically excluded from coverage, and the item or service is 'reasonable and necessary.'" *Id.*; *see also* 42 U.S.C. § 1395y(a)(1)(A).

The benefit category at issue covers "prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices . . . ." 42 U.S.C. § 1395x(s)(8). To determine whether an item or service is reasonable and necessary under the Act and to promote consistency in coverage determinations, Congress has authorized the Secretary to issue generally applicable rules through National Coverage Determinations (NCD). 42 U.S.C. § 1395y(*l*)(6)(A). An NCD is a determination "whether or not a particular item or service is covered nationally under . . . [Medicare]." 42 U.S.C. § 1395ff(f)(1)(B); 42 C.F.R. § 405.1060(a)(1). NCDs are binding at all levels during administrative claim adjudication. *Id.* at § 405.1060(a)(4).

The NCD at issue is 180.2 (retired January 1, 2022) for Enteral and Parental Nutritional Therapy.[3] NCD 180.2 applies to individuals "who, because of chronic illness or trauma, cannot be sustained through oral feeding" and "must rely on either enteral or parenteral nutritional therapy, depending upon the particular nature of their medical condition."[4] *Id.* Enteral nutrition therapy is covered if the individual meets the requirements of the prosthetic device benefit under Part B. "Enteral nutrition is considered reasonable and necessary for a patient with a functioning gastrointestinal tract who, due to pathology to, or non-function of, the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition." Such therapy may be "given by nasogastric, jejunostomy, or gastrostomy tube[]." *Id.*

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[3] Available at https://www.cms.gov/medicare-coverage-database/view/ ncd.aspx?ncdid=242&ncdver=1& (last visited Sept. 14, 2022).

[4] Enteral nutrition delivers nutrition directly to an individual's stomach or small intestine via a feeding tube. *See* https://www.mayoclinic.org/tests-procedures/home-enteral-nutrition/about/pac-20384955 (last visited Sept. 14, 2022). Parenteral nutrition involves infusing liquid nutrients intravenously. *See* https://www.mayoclinic.org/tests-procedures/total-parenteral-nutrition/about/pac-20385081 (last visited Sept. 14, 2022).

In addition to NCDs, Congress also authorized Local Coverage Determinations (LCDs). LCDs are issued by MACs. 42 U.S.C. §§ 1395kk-1(a)(1), (4), 1395y(*l*)(5)(D). LCDs govern claim determinations only by the issuing MAC. 42 U.S.C. § 1395ff(f)(2)(B). In contrast to NCDs, LCDs are not binding at higher levels of administrative review by a QIC, an ALJ, or the Appeals Council, *see* 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. §§ 405.968(b)(2)–(3), 405.1062(a)–(b), but those adjudicators will give "substantial deference" to LCDs. If they decline to apply a relevant LCD, they must explain the reasons why it was not followed. 42 C.F.R. §§ 405.968(b)(2)–(3), 405.1062(a)–(b). The relevant LCD here, adopted by CGS, is L33783 (retired November 12, 2020), covering Enteral Nutrition.[5] L33783 provides that covered "[e]nteral nutrition may be administered by syringe, gravity, or pump," and medical records must document the medical necessity for enteral formulas and supplies. *Id.*

In connection with L33783, CGS adopted Policy Article A52493 (retired November 12, 2020).[6] Policy Article A52493 states that enteral nutrition, which is covered under the prosthetic device benefit, "is the provision of nutritional requirements through a tube into the stomach or small intestine." In addition, the beneficiary's condition must require "tube feedings." The article further states that "[e]nteral nutrition products that are administered orally and related supplies are noncovered, no benefit." *Id.*

Finally, Section 1879 of the Act may limit a beneficiary's liability for expenses incurred for items and services not covered by Medicare. 42 U.S.C. § 1395. Such limitation may arise if the services are not found to be reasonable and necessary, and the beneficiary could not reasonably

[5] Available at https://localcoverage.cms.gov/mcd_archive/view/lcd.aspx?lcdInfo=33783:23 (last visited Sept. 14, 2022).

[6] Available at https://localcoverage.cms.gov/mcd_archive/view/article.aspx?articleInfo=52493:21 (last visited Sept. 14, 2022).

have been expected to know that the services were not covered. *Id.* § 1395(a). In other words, for the limitation to apply, the administrative reviewer must find under Section 1862(a)(1)(A) that the items or services were not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. 42 U.S.C. § 1395y(a)(1)(A).

C. Administrative Decisions

1. ALJ Decision

The ALJ found that Kelly does not meet the requirements for enteral nutrition under LCD L33783 and Policy Article A52493 because she consumes the HCU Cooler orally and does not require tube feedings. (ECF No. 13 at PageID.373.) Although the ALJ observed that the facts could perhaps support deviating from the LCD and Policy Article, she noted that NCD 180.2 requires that enteral nutrition therapy be given by nasogastric, jejunostomy, or gastrostomy tubes and that the letter of medical necessity from Kelly's physician indicated that she does not rely on a feeding tube into the stomach or small intestine, but instead consumes it orally. The ALJ concluded that, without use of a feeding tube, Kelly did not meet the coverage requirements of NCD 180.2. (*Id.*) As for the Section 1879 limitation, the ALJ found that, because her finding of non-coverage was not pursuant to Section 1862(a)(1)(A) of the Act, the Section 1879 limitation of liability was inapplicable. (*Id.*)

2. Appeals Council Decision

The Appeals Council rejected Plaintiff's contentions the HCU Cooler was a covered prosthetic device; that the ALJ improperly applied NCD 180.2, LCD L33783, and Policy Article A52493 in requiring Kelly to use a feeding tube as a condition of coverage; and that the feeding tube requirement was inconsistent with the Social Security Act. The Appeals Council stated:

> Upon review, the Council does not find that the enteral nutrition falls into a Medicare benefit category. Also, the Council does not find the coverage determinations and policy article were improperly applied. Here; [sic] the question

> is whether the record sufficiently documents the prosthetic device benefit is met and the medical necessity of the formula supplied to the beneficiary. Contrary to assertions that the appellant belongs to a dissimilar group and the relevant NCD, LCD and Policy Article do not apply, the coverage determinations and policy article contemplate beneficiaries that require use of enteral nutrition but only allow Medicare coverage when certain criteria are met consistent with the Act. Here, the medical evidence consists of the May 2018 letter and April 2019 letter of medical necessity that contain summary descriptions of the beneficiary's disability and the course of treatment through the use of the HCU cooler for the beneficiary's diet. File 7 at 48-52. The summary descriptions are not substantiated by contemporaneous, clinical documentation of the beneficiary's disability and do not evidence a feeding tube. *Id.* The record does not include any contemporaneous medical documents such as hospital records or physician visit notes substantiating that the beneficiary has permanent non-function of all or part of an internal body organ, and that enteral nutrition therapy is medically necessary. NCD 180.2. Accordingly, the Council finds that the supplies at issue do not fall into the prosthetic benefit category and are not covered under §1861(s)(8) of the Act.
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> The Council acknowledges the ALJ stated that "the facts of this case could perhaps support deviating from the applicable LCD and Policy Article." Dec. at 4. Here, the Council gives substantial deference to the LCD and Policy Article and finds there is no evidence to support deviation from the LCD and Policy Article. 42 C.F.R. § 405.1062(a). The method by which the appellant takes the enteral therapy is not in dispute and the Policy Article makes clear that enteral nutrition products that are administered orally and related supplies are not covered. Policy Article A52493. As stated above, NCD 180.2 explicitly states that the record must include medical documentation substantiating that the beneficiary's condition "meets the requirements of the prosthetic device benefit and that enteral nutrition therapy is medically necessary." Thus, without contemporaneous medical documentation showing the beneficiary has permanent non-function of all or part of an internal body organ, the Council cannot find that Medicare covers the enteral nutrition and supplies at issue.

(*Id.* at PageID.121–22.) Regarding limitation of liability, the Appeals Council stated:

> The ALJ found the items at issue are non-covered, but non-coverage is not pursuant to § 1862(a)(1)(A) of the Act; therefore § 1879 does not apply. The Council agrees with the ALJ. Financial relief is available to a beneficiary under § 1879, if the beneficiary did not know or could not reasonably have been expected to know that the items were not medically reasonable or necessary. However, § 1879 is only applicable when a service or item is eligible for coverage, but coverage is denied on the basis that the item is not medically reasonable and necessary for the beneficiary under § 1862(a)(1) of the Act. In this case, coverage is denied pursuant to § 1861(s)(8), because the record does not demonstrate that the requirements for the prosthetic device benefit category are satisfied. Thus, § 1879 is not applicable in this case. See CMS Ruling No. 96-3. Accordingly, we find that the beneficiary is financially responsible for the non-covered costs.

(*Id.* at PageID.122.)

D. Procedural History

Plaintiff filed her complaint in this case on February 22, 2021. On August 18, 2021, at the parties' request in their joint status report, the Court stayed this matter while the Centers for Medicare & Medicaid Services (CMS) completed its review of NCD 180.2. (ECF No. 17 at PageID.465; ECF No. 19.) On December 9, 2021, the Court lifted the stay after the parties informed it that CMS published its final rule on November 19, 2021, which removed NCD 180.2. (ECF No. 25.) Thereafter, the parties filed their instant motions.

II. Standard of Review

Although the parties have filed motions for summary judgment pursuant to Federal Rule of Civil Procedure 56(a), the same judicial standard that applies in Social Security disability insurance benefit appeals governs this Court's review of the Secretary's denial of Plaintiff's claim for Medicare benefits. *See EPI Corp. v. Chater*, No. 95-5069, 1996 WL 428409, at *5-6 (6th Cir. July 30, 1996). Section 205(g) of the Social Security Act limits the Court to review of the administrative record and provides that if the Secretary's decision is supported by substantial evidence, it shall be conclusive. 42 U.S.C. § 405(g). The scope of judicial review in this matter is thus limited to determining whether the Secretary applied the proper legal standards and whether substantial evidence supports that decision. *See Brainard v. Sec'y of Health & Human Servs.*, 889 F.2d 679, 681 (6th Cir. 1989). The decision of the Appeals Council is considered the Secretary's "final decision" on Plaintiff's claim. *See Heckler v. Ringer*, 466 U.S. 602, 605 (1984) (citing 42 U.S.C. 405(g)).

Substantial evidence is more than a scintilla but less than a preponderance. *See Cohen v. Sec'y of Dept. of Health & Human Servs.*, 964 F.2d 524, 528 (6th Cir. 1992). It is such relevant

evidence as a reasonable mind might accept as adequate to support a conclusion. *See Richardson v. Perales*, 402 U.S. 389, 401 (1971); *Bogle v. Sullivan*, 998 F.2d 342, 347 (6th Cir. 1993).

III. Discussion

A. Claim Denial

Plaintiff contends that the Appeals Council erred in applying NCD 180.2, LCD L33783, and Policy Article A52493 to her claim and situation for several reasons. She first asserts that the decision was arbitrary and capricious because LCD L33783 and Policy Article A52493 were rescinded or retired on November 12, 2020, prior to the Appeals Council's December 22, 2020 decision. Plaintiff is correct that CGS retired LCD L33783 and Policy Article A52493 as of November 12, 2020, but she fails to acknowledge that they remain effective for claims with dates of service prior to that date. In fact, they remain effective for services performed between October 1, 2015, and November 12, 2020.[7] *See supra* nn.5 and 6. Because Kelly's claims arose prior to the retirement date, the Appeals Council properly applied the LCD and Policy Article in reaching its decision.

Next, Plaintiff contends that the decision was erroneous because Policy Article A52493's requirement that enteral nutrition be administered through a feeding tube conflicts with the Medicare Act, 42 U.S.C. § 1395x(s)(8), and Section 120 of Chapter 15 of the Medicare Benefits Policy Manual.[8] The Court disagrees. NCD 180.2 and Policy Article A52493 both expressly refer to the Part B prosthetic device benefit in Section 1861(s)(8) of the Act and thus require that enteral nutrition be administered by tube or some other means via a prosthetic device. They are thus

[7] NCD 180.2 was rescinded after the Appeals Council issued its decision. Therefore, there is no question that it was effective as of that date.

[8] Available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/ Downloads/bp102c15.pdf (last visited Sept. 15, 2020).

consistent with the Medicare Act. In the same vein, the LCD references the requirement that enteral nutrition products be administered via prosthetic device, noting that "[e]nteral nutrition may be administered by syringe, gravity, or pump." Plaintiff notes, correctly, that the Medicare Benefits Policy Manual includes parenteral and enteral nutrition as examples of prosthetic devices, and she contends that this reference supports that the Medicare Act does not require that HCU Cooler be administered through a feeding tube. However, the Medicare Benefits Policy Manual "is a guide for intermediaries in applying the Medicare statute and reimbursement regulations and does not have the binding effect of law or regulation." *National Med. Enters. v. Bowen*, 851 F.2d 291 (9th Cir. 1988). Hence, the general statements in the manual must be considered in light of the binding authority of NCD 180.2, as well as LCD L33783 and Policy Article A52493, to which the Appeals Council gave substantial deference. (PageID.122.)

Third, Plaintiff contends that the NCD, the LCD, and the Policy Article do not govern her claim because all address a dissimilar group that does not include Kelly. She asserts that NCD 180.2 applies only to patients who suffer with chronic illness or trauma and therefore cannot receive adequate nutrition through oral feeding, while Policy Article A52493 and LCD L33783 apply only to patients with permanent non-function or disease of the structures that normally permit food to reach the small bowel or disease of the small bowel which impairs digestion and absorption of an oral diet. Plaintiff contends that none of these authorities covers a patient like Kelly, "who suffers from a genetic defect that results in an error in metabolism." (ECF No. 29 at PageID.502–04.) While it is true that the NCD, the LCD, and the Policy Article do not describe a beneficiary with Kelly's condition, it is clear, as the Appeals Council observed, that they apply to all beneficiaries who require use of enteral nutrition but provide coverage only in situations where the coverage criteria, *i.e.*, administration by means of a prosthetic device, are met. Plaintiff's

attempt to draw an artificial distinction between beneficiaries who can consume and metabolize regular protein and those who cannot is unavailing. Plaintiff also cites no support for her suggestion that the Secretary is precluded from applying a generally applicable rule or policy to a beneficiary's specific circumstances absent any medical or scientific basis for limiting coverage. Because the decision as to whether a particular item or service is reasonable and necessary under the Act is a matter committed to the Secretary's discretion, *see Heckler*, 46 U.S. at 617, Plaintiff fails to show that the Appeals Council's application of the NCD, LCD, and Policy Article to Kelly's circumstances was arbitrary and capricious.[9] *See Atrium Med. Ctr. v. HHS*, 766 F.3d 560, 568 (6th Cir. 2014) ("[I]n the Medicare context, 'broad deference is all the more warranted when, as here the regulation concerns a complex and highly technical regulatory program, in which the identification and classification of relevant criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.'" (quoting *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994))).

Plaintiff's primary contention, as it appears to the Court, is that HCU Cooler is itself a stand-alone prosthetic device that meets the coverage requirements of the Act because it replaces part of, or a function performed by, Kelly's liver. Plaintiff asserts that HCU Cooler omits methionine and contains L-cysteine, which her liver cannot produce, thereby replacing a function of her liver. Plaintiff contends that supplying an amino acid fulfills the requirements of a prosthetic device under Section 1395x(s)(8). (ECF No. 29 at PageID.498–500.) The Secretary responds that

[9] To the extent Plaintiff seeks to challenge the validity of the NCD, the LCD, and the Policy Article, that issue is not before the Court as Plaintiff has not pursued the matter through the administrative process. 42 U.S.C. § 1395ff(f)(1) and (2); 42 C.F.R. Part 426, subpart E; *see Woodfill v. Sec'y of Health & Human Servs.*, No. 3:11CV2236, 2013 WL 2153247, at *5 (N.D. Ohio May 15, 2013), *aff'd* 557 F. App'x 473 (6th Cir. 2014) ("Plaintiff had ample opportunity to challenge the validity of the NCD through administrative means . . . She instead chose to pursue this claim here, knowing that this Court can only review the *application* of the NCD to her case.").

the HCU Cooler that Kelly consumes for nutrition is a medical food according to the Food and Drug Administration, not a prosthetic device, (ECF No. 32 at PageID.621 (citing PageID.182–83, 188)), and Plaintiff's assertion is nothing more than lawyer's argument, unsupported by applicable legal authority or medical documentation in the administrative record, as required by NCD 180.2. (*Id.* at PageID.622.) The Secretary further notes that the Medicare statue and regulations, 42 U.S.C. § 1395m(h)(4)(B) and 42 C.F.R. § 414.202, specifically exclude enteral nutrients, such as HCU Cooler, from the definition of prosthetic devices.

> As set forth above, the Medicare Act provides coverage for
>
> prosthetic devices (other than dental) which replace all or part of an internal body organ (including colostomy bags and supplies directly related to colostomy care), including replacement of such devices, and including one pair of conventional eyeglasses or contact lenses furnished subsequent to each cataract surgery with insertion of an intraocular lens[.]

42 U.S.C. § 1395x(s)(8). By the plain language of this provision, an item qualifies for coverage if it: (1) is a "prosthetic device"; and (2) "replace[s] all or part of an internal body organ." The statute does not further define "prosthetic device," *see Currier v. Thompson*, 369 F. Supp. 2d 65, 67 (D. Maine 2005), although the regulations implementing the special payment rules for particular items and services under the Act, 42 U.S.C. § 1395m, define prosthetic devices as "[d]evices that replace all or part of an internal body organ, including ostomy bags and supplies directly related to ostomy care, and replacement of such devices and supplies." 42 C.F.R. § 414.202. When, as here, a statutory term is undefined, courts will give the term its "ordinary meaning." *United States v. Santos*, 553 U.S. 507, 511 (2008). A court may consult a dictionary for this purpose. *Id.; see also Keeley v. Whitaker*, 910 F.3d 878, 883 (6th Cir. 2018). "Device" is defined as "an apparatus or article of manufacture." *Device*, Black's Law Dictionary (11th ed. 2019). Other definitions of "device" from general usage dictionaries include "a piece of equipment or a mechanism designed to serve a special purpose of perform a special function," Merriam-Webster Dictionary, available

at https://www.merriam-webster.com/dictionary/device (Sept. 19, 2022); "[a] contrivance or an invention serving a particular purpose, especially a machine used to perform one or more relatively simple tasks," The American Heritage Dictionary (4th ed.); and "an invention, contrivance; *esp.* a mechanical contrivance (usually of a simple character) for some particular purpose." Oxford English Dictionary Online, available at https://www.oed.com/view/Entry/51464?redirectedFrom=device#eid (Sept. 19, 2022). "Prosthetic" is defined as "an artificial substitute or replacement of a part of the body such as a tooth, eye, a facial bone, the palate, a hip, a knee or another joint," Medical Definition of Prosthetic, available at https://www.medicinenet.com/prosthetic/definition.htm (Sept. 19, 2022).

Contrary to Plaintiff's argument, the HCU Cooler that Kelly consumes is liquid nutrition that cannot be considered a prosthetic device. As set forth above, a device is a piece of equipment or mechanism having some permanence. Liquid nutrition that a patient consumes lacks this quality. A feeding tube clearly is a prosthetic device. The statutory language, which expressly refers to colostomy bags, eyeglasses, and contacts—items that have some degree of permanence but may require replacement—underscores that Kelly's liquid nutrition is not a prosthetic device; it is not equipment or a mechanism that could be replaced.

Plaintiff's related argument based on the definition of "prosthetic devices" in 42 U.S.C. § 1395m(h)(4)(B) is unpersuasive. This section states that "the term 'prosthetic devices' has the meaning given such term in section 1395x(s)(8) of this title, except that such term does not include parenteral and enteral nutrition nutrients, supplies, and equipment." Plaintiff contends that this provision confirms that enteral nutrition, alone, is covered as a prosthetic device. As noted, however, Section 1395m only provides special payment rules for particular items and services covered under Medicare, and NCD 180.2 makes clear that enteral nutrition is covered only if is

administered through a feeding tube. Moreover, the regulation governing payment for parenteral and enteral (PEN) items and services provides that "[p]ayment for PEN items and services is made in a lump sum for nutrients and supplies that are purchased and on a monthly basis for equipment that is rented." 42 C.F.R. § 414.104(a). This provision thus makes clear that enteral nutrition is covered when used in conjunction with a prosthetic device, but payment for the liquid nutrients is made in a different manner for the equipment used to administer the nutrition.[10]

B. Limitation of Liability

Plaintiff contends that the Appeals Council erred in finding that Kelly is financially responsible and in not applying the Section 1879 limitation of liability. This argument lacks merit. The Appeals Council did not deny coverage because it found that Plaintiff failed to show that HCU Cooler was not reasonable and necessary to treat Kelly's condition. Rather, the Appeals Counsel expressly noted that "coverage is denied pursuant to § 1861(s)(8), because the record does not demonstrate that the requirements for the prosthetic device benefit category are satisfied." (ECF No. 13 at PageID.122.) Therefore, the Appeals Council correctly concluded that Section 1879 is inapplicable in this case.

[10] The Court does not address Plaintiff's constitutional claim as Plaintiff states that she "does not intend to rely upon her Equal Protection and Due Process violation claims unless the Secretary responds to her claims with an argument that forecloses any review of her claims." (ECF No. 29 at PageID.508.) Here, the Secretary has not responded with such an argument.

IV. Conclusion

In sum, the Court finds that the Secretary's final decision denying Medicare benefits was supported by substantial evidence in the record and contained no legal error. Therefore, the Secretary's motion will be **granted,** and Plaintiff's motion will be **denied**.

A separate order will enter.

Dated: September 21, 2022

/s/ Sally J. Berens
SALLY J. BERENS
U.S. Magistrate Judge