APPENDIX TABLE OF CONTENTS

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File Name: 23a0211p.06

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

THERESE M. WATERS, obo Kelly E. Waters, *Plaintiff-Appellant*, v. XAVIER BECERRA, Secretary of Health and Human Services, *Defendant-Appellee.*	No. 22-1997

Appeal from the United States District Court for the Western District of Michigan at Grand Rapids. No. 1:21-cv-00170—Sally Berens, Magistrate Judge.

Argued: June 13, 2023

Decided and Filed: September 11, 2023

Before: GILMAN, BUSH, and READLER, Circuit Judges.

COUNSEL

ARGUED: Thomas J. Waters, THE RUNNING WISE LAW FIRM, Traverse City, Michigan, for Appellant. Nicole Mazzocco, UNITED STATES ATTORNEY'S OFFICE, Grand Rapids, Michigan, for Appellee. **ON BRIEF:** Thomas J. Waters, THE RUNNING WISE

LAW FIRM, Traverse City, Michigan, for Appellant. Nicole Mazzocco, UNITED STATES ATTORNEY'S OFFICE, Grand Rapids, Michigan, for Appellee.

BUSH, J., delivered the opinion of the court in which GILMAN and READLER, JJ., joined. READLER, J. (pg. 16), delivered a separate concurring opinion.

OPINION

JOHN K. BUSH, Circuit Judge. Therese Waters, on behalf of her daughter Kelly Waters, sought judicial review of the Medicare Appeals Council's denial of Waters's Medicare Part B claim. Her claim was for Vitaflo Homocystinuria Cooler, an orally consumed enteral nutrition formula that provides her with necessary protein to compensate for her limited liver functionality. The Council's decision is considered the final decision of the Secretary of Health and Human Services. That ruling affirmed the denial of Waters's claim by an Administrative Law Judge, which in turn affirmed decisions of a Medicare Administrative Contractor and a Qualified Independent Contractor. On judicial review, the district court granted summary judgment for the Secretary—holding that the Secretary's decision was based on substantial evidence and contained no legal error. We AFFIRM.

I.

A. Acronyms and Abbreviations

Because of the variety of acronyms and abbreviations throughout the opinion, we begin with this table that includes summary information about relevant terms for this appeal:

Acronym/Abbreviation	Term (explanation)
HCU Cooler	Vitaflo Homocystinuria Cooler (item denied coverage at issue on appeal)
Secretary	Secretary of Health and Human Services
MAC	Medicare Administrative Contractor (initial reviewer of a Medicare claim)
QIC	Qualified Independent Contractor (initial administrative appeal)
ALJ	Administrative Law Judge (intermediate administrative appeal)
Council	Medicare Appeals Council (final administrative appeal)

NCD	National Coverage Determination (issued by the Secretary, nationally binding)
Policy Manual	Medicare Benefits Policy Manual (issued by the Secretary, non-binding)
LCD	LCD Local Coverage Determination (issued by the MAC, locally binding)
Article	Policy Article (issued by the MAC, locally binding)

B. Waters's Condition & Claim

Waters was born with homocystinuria and diagnosed with that condition at the age of six. Homocystinuria is a genetic attribute that causes metabolic issues that prevent Waters from metabolizing methionine, an amino acid, that produces L-cysteine, another amino acid. Typically, the liver does this metabolization, but Waters's liver is unable to do so.

To address this, her physician prescribed HCU coolers. The prescription is for a medical food containing a methionine-free protein formula that helps with the dietary management of her homocystinuria by providing most of the protein she consumes. Waters

ingests an HCU cooler orally because she has a fully functioning gastrointestinal tract.

Pursuant to the Medicare Act, Title XVIII of the Social Security Act (Medicare Act), 42 U.S.C. § 1395 *et seq.*, Waters submitted a Medicare claim seeking reimbursement for the HCU coolers purchased during four separate periods spanning from December 2018 to September 2019. But Medicare benefit payments are available only for claims that meet certain criteria. The claimed benefit must fall within a benefit classification, cannot be specifically excluded from coverage, and must be reasonable and necessary. Medicare Program; Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. 55,634, 55,635 (Sept. 26, 2003); 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1). The Secretary has broad authority to decide what benefits will be covered under each category. *See* 42 U.S.C. § 1395ff(a)(1).

Waters sought coverage under the prosthetic-device benefit of Medicare Part B. 42 U.S.C. § 1395k(a)(2)(I); 42 U.S.C. § 1395x(s)(8). That benefit covers the following:

> 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). In addition, the Secretary and the regional Medicare Administrative Contractor explain prosthetic-device benefit coverage through various documents. Those documents include a National Coverage Determination, a Local Coverage Determination, and a Policy Article, which all provide guidance for understanding that benefit category in relation to Waters's HCU cooler claims.

First, an "NCD is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare." 42 C.F.R. § 405.1060(a)(1). The NCD binds all levels of the administrative review process when making coverage decisions, which includes initial coverage decisions by the MAC, review by the Qualified Independent Contractor, review by the Administrative Law Judge, and review by the Council. 42 C.F.R. §§ 405.1060(a)(4), 405.1063.

NCD 180.2 was instrumental to the coverage determinations made throughout the administrative review process for Waters's claim.[1] *See* Enteral and Parenteral Nutrition Therapy, Ctrs. for Medicare and Medicaid Servs. Pub. 100-3, National Coverage Determinations

[1] During the district-court proceedings, the Centers for Medicare and Medicaid Services (CMS) retired NCD 180.2. But NCD 180.2 continues to bind Waters's claim because the final rule issued by CMS that retired NCD 180.2 states that NCD 180.2 applies to all claims with dates of service before January 1, 2022. CY 2022 Payment Policies, 86 Fed. Reg. at 64,996, 65,241-44.

Manual, § 180.2.[2] Importantly, NCD 180.2 explains that, as part of the prosthetic-device benefit, enteral nutrition is considered reasonable and necessary when a patient "cannot maintain weight and strength commensurate with his or her general condition" because food does not reach the digestive tract. *Id.* This NCD specifies that "[e]nteral therapy may be given by nasogastric [nose], jejunostomy [small intestine], or gastrostomy [stomach] tubes" and that the documentation provided by the patient should "permit an independent conclusion that the patient's condition meets the requirements of the prosthetic device benefit." *Id.* Also relevant to Waters's claim, the NCD acknowledges "[s]ome patients require supplementation of their daily protein and caloric intake," but "[n]utritional supplementation is not covered under Medicare Part B" *Id.*

To implement NCD 180.2, a MAC can issue its own guidance, via an LCD or Article, or both, to apply to all Medicare coverage decisions within a region—Michigan in this case. 42 U.S.C. §§ 1395y(*l*)(6)(B), 1395ff(f)(2)(B). Although the MAC's guidance policies bind only coverage determinations within the MAC itself, and no other region, any review of the MAC's coverage determination (including by the ALJ and the Council) must give "substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.968(b), 405.1062(a). Here, the MAC that oversaw Waters's initial claim—CGS

[2] Available at https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=242&ncdver=1& (last visited Aug. 17, 2023).

Administrators—adopted LCD L33783[3] and Article A52493[4], both of which relate to enteral nutrition.

Those MAC guidance policies, along with NCD 180.2, were referenced at each level of review.[5] LCD L33783 states that "[e]nteral nutrition may be administered by syringe, gravity, or pump" and that medical records need to demonstrate medical necessity for the enteral formulas and related equipment. And Article A52493 explains that "[e]nteral nutrition is the provision of nutritional requirements through a tube into the stomach or small intestine," meaning that the "beneficiary must require tube feedings." Article A52493. Further, the Article plainly declares that "[e]nteral nutrition products that are administered orally and related supplies are noncovered, no benefit." *Id.*

C. Coverage Determinations

With the applicable guidance in mind, CGS Administrators (as the MAC for Michigan) denied coverage

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[3] Enteral Nutrition, Ctrs. for Medicare and Medicaid Servs., LCD ID L33783. Available at Enteral Nutrition, https://localcoverage.cms.gov/mcd_archive/view/lcd.aspx?lcdInfo=33783:23 (last visited Aug. 17, 2023).

[4] Enteral Nutrition – Policy Article, Ctrs. for Medicare and Medicaid Servs., Article ID A52493. Available at Enteral Nutrition – Policy Article, https://localcoverage.cms.gov/mcd_archive/view/article.aspx?articleInfo=52493:21 (last visited Aug. 17, 2023).

[5] CGS Administrators has since retired LCD L33783 and Article A52493 for any claims after November 12, 2020. Because Waters's claims occurred before these retirement dates, the retirements do not impact the previous coverage denials or this appeal.

for Waters's claims and affirmed the denial after Waters sought redetermination. Waters then appealed that decision to MAXIMUS Federal Services (the QIC), which also denied coverage. Following that denial, Waters sought an ALJ hearing and review, which led to the ALJ's conclusion that the HCU cooler was not covered. Exhausting the last level of administrative review, Waters appealed the ALJ's decision to the Council, which agreed with the ALJ's denial of coverage.

Waters then sought judicial review of the Secretary's decision by filing a complaint in federal court. *Waters v. Becerra*, No. 1:21-cv-170, 2022 WL 4363900 (W.D. Mich. Sept. 21, 2022). The district court determined that the Secretary had not erred in analyzing or applying NCD 180.2, LCD L33783, or Article A52493. *Waters*, 2022 WL 4363900, at *5. The court also found the Medicare Benefits Policy Manual to be not sufficiently persuasive authority, noting that although it "is a guide for intermediaries in applying the Medicare statute and reimbursement regulations," the Policy Manual "does not have the binding effect of law or regulation." *Id.* (quoting *Nat'l Med. Enters. v. Bowen*, 851 F.2d 291 (9th Cir. 1988)). Finally, the court agreed with the administrative rulings that an HCU cooler is not a stand-alone prosthetic device based on the plain meaning of prosthetic "device" and because an HCU cooler is a medical food according to the Food and Drug Administration. *Id.* at *6.

As a result, the district court granted summary judgment for the Secretary. Waters timely appealed.

II.

This court reviews a district court's grant, or denial, of summary judgment de novo. *Williams v. Maurer*, 9 F.4th 416, 430 (6th Cir. 2021). In doing so, we review the Council's decision to deny coverage anew to determine whether the district court erred by granting the Secretary's motion for summary judgment.

The Council's decision is considered the Secretary's final decision for Waters's claim. *Heckler v. Ringer*, 466 U.S. 602, 605 (1984) (citing 42 U.S.C. § 405(g)). The Medicare Act limits judicial review to determining whether the Secretary's decision was supported by substantial evidence and whether the Secretary applied the correct legal standards. 42 U.S.C. § 405(g); *Brainard v. Sec'y of Health & Hum. Servs.*, 889 F.2d 679, 681 (6th Cir. 1989). Substantial evidence falls somewhere between more than a scintilla but less than a preponderance. *Cohen v. Sec'y of Dept. of Health & Hum. Servs.*, 964 F.2d 524, 528 (6th Cir. 1992). And Waters "bears the burden of proving her entitlement to Medicare coverage." *Keefe ex rel. Keefe v. Shalala*, 71 F.3d 1060, 1062 (2d Cir. 1995) (citing *Friedman v. Sec'y of Dep't of Health & Hum. Servs.*, 819 F.2d 42, 45 (2d Cir.1987)).

III.

NCD 180.2, which, again, was issued by the Secretary and binding on the Council, supported the denial of coverage as to Waters's claims. As NCD 180.2 explains, "[i]f the coverage requirements for enteral or

parenteral nutritional therapy are met under the prosthetic device benefit provision, related supplies, equipment and nutrients are also covered." This is a direct reference to the prosthetic device benefit in 42 U.S.C. § 1395x(s)(8) and makes coverage for enteral nutritional therapy dependent on satisfying the prosthetic-device provision.

There is no dispute about the method that Waters used to consume the HCU cooler for which she sought coverage—she consumed it orally. She makes no claim about the use of a prosthetic device beyond using the HCU cooler itself. And as the Secretary's decision held, "[e]nteral nutrition products that are administered orally and related supplies are noncovered, no benefit." R. 13, PageID 121 (quoting Article A52493). That alone is enough to determine that the Secretary's decision was based on substantial evidence. NCD 180.2 binds the Secretary's decisions, and the Secretary articulated this rationale in its original decision. *See SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947).

The definition in § 1395x(s)(8) of a prosthetic device—a device replacing all or part of an internal body organ—also shows that the denial of coverage had a sufficient legal basis. 42 U.S.C. § 1395x(s)(8). Although Waters does not contest that she has a liver, she does argue that the HCU cooler replaces the function of part of her liver because her liver cannot break down certain amino acids. But her argument goes against the plain reading of the definition, which indicates that a device is not to be eliminated through consumption, but rather has some degree of lasting permanence

outside one's body. The HCU cooler lacks any degree of lasting permanence because Waters drinks four HCU coolers every day. In contrast, colostomy bags, feeding tubes, pumps, and other devices mentioned in these contexts, by the statutory definition and other guidance, would last weeks if not months or years. *See id.*; *see also* NCD 180.2.

Permanence is also an attribute implicit in the definition of the word "device" in *Black's Law Dictionary.* It describes a device as "an apparatus or an article of manufacture," and lists "machine" as a synonym. *Device, Black's Law Dictionary* (11th ed. 2019). Similarly, *Merriam-Webster's Collegiate Dictionary* defines a device to be "a piece of equipment or a mechanism designed to serve a special purpose or perform a special function." *Device, Merriam-Webster's Collegiate Dictionary* (11th ed. 2019). These definitions underscore that the Secretary did not err in concluding that the nonpermanent nature of the ingestible HCU cooler renders it outside the category of a device, apparatus, piece of equipment, mechanism, or other object that would qualify for coverage under the plain reading of § 1395(x)(s)(8).

Waters relies on 42 U.S.C. § 1395m and 42 C.F.R. § 414.104 to argue that HCU coolers are an independently covered benefit, but this argument fails as well because those provisions are payment rules. It is uncontested that "Medicare will cover and pay for enteral nutrition formula when it is used in conjunction with a prosthetic device." Appellee's Br. At 28. Even with that concession by the Secretary, the payment

provisions do not alter the definition of prosthetic devices, but rather describe how payment will be made for enteral nutrition items that are covered because those items are used in tandem with a prosthetic device.

We are also unpersuaded by Waters's appeal to the Policy Manual[6] to argue that HCU cooler is a covered benefit. Ctrs. for Medicare and Medicaid Servs., Ch. 15, § 120, p. 137–40. As noted, the Policy Manual is not binding on the Secretary. And in any event, the Policy Manual does not call for coverage of the HCU cooler. It merely describes enteral nutrition as one of many items covered under the prosthetic-device benefit. This description is consistent with the binding guidance found in NCD 180.2, which explains that enteral nutrition is covered *only* when taken through a prosthetic device, as discussed earlier.[7]

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[6] Available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673 (last visited Aug. 17, 2023).

[7] Waters's attempt to use Justice Brennan's dissent in *Cruzan v. Director, Missouri Department of Health*, 497 U.S. 261 (1990), to establish enteral nutrition as a covered benefit independent of a prosthetic device is equally unavailing. Justice Brennan's dissent does not address the precise coverage issue on appeal here, but he does specify that the "Federal Government permits the cost of the medical devices and formulas used in enteral feeding to be reimbursed under Medicare." *Id.* at 308 (Brennan, J., dissenting) (citations omitted). He goes on to clarify that "formulas are regulated by the Food and Drug Administration as 'medical foods' and the feeding tubes are regulated as medical devices." *Id.* (citations omitted). If anything, his dissent highlights the distinctions separating enteral formulas, like the HCU cooler,

During her administrative appeal, Waters asserted that NCD 180.2 did not apply to her claim, arguing that she belonged to a dissimilar group of individuals whose coverage decisions would not be governed by that binding guidance. But the Council disagreed, and we are of the same mind as the council. Medicare Part B coverage extends to enteral nutrition only when used with a prosthetic device. *See* NCD 180.2.

To that end, Waters needed to document the permanent non-function of all or part of her liver. *See* 42 U.S.C. § 1395x(s)(8). Waters provided two letters of medical evidence, but those letters included only summary descriptions of Waters's disability and the course of her treatment with HCU cooler. Those high-level descriptions were not substantiated by any other medical documentation such as physician visit notes or hospital records. And without contemporaneous medical documentation showing the beneficiary has permanent non-function of all or part of an internal body organ, Medicare coverage will be denied. *See* NCD 180.2. Had the Secretary decided to grant coverage, that decision would not have been based on substantial evidence because it would have contradicted NCD 180.2's requirement that Waters provide sufficient medical documentation.Denial of coverage was therefore the correct decision.

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from the prosthetic device one would use to consume the enteral formulas, rather than strengthens the argument that the HCU cooler is itself a prosthetic device.

Waters cannot skirt the requirement to provide adequate documentation for her claim by alleging that NCD 180.2 simply established an exception to the general rule. Because NCD 180.2 is an interpretation of statutory language rather than a standalone substantive rule, it falls within the Secretary's discretion. *Heckler*, 466 U.S. at 617; *Friedrich v. Sec'y of Health & Hum. Servs.*, 894 F.2d 829, 837 (6th Cir. 1990). And the Secretary used that discretion to explain that all beneficiaries seeking coverage for enteral nutrition are covered by the provisions in NCD 180.2, with no one exempt from its scope.

Finally, Waters invoked *Motor Vehicle Manufacturers Association v. State Farm Mutual Auto. Insurance Company*, 463 U.S. 29 (1983), to argue that the Secretary should have provided a rationale for promulgating NCD 180.2 in the first instance. But that issue is not properly before us. As the district court correctly noted, Waters failed to exhaust her administrative remedies in challenging the validity of NCD 180.2 or any other statute or provision. *Waters*, 2022 WL 4363900, at *5 n. 9. Thus, we do not address that argument as part of this appeal.

IV.

As the concurrence observes, this court is mindful of the difficult circumstances of Waters and her family—facts that may warrant a change in regulation to address Waters's situation and that of others like her. But such redress is the responsibility of administrators

and legislators, not the court. We can only interpret the law in this case, not change it.

For the foregoing reasons, we AFFIRM the district court's grant of summary judgment for the Secretary.

CONCURRENCE

CHAD A. READLER, concurring. Justice Antonin Scalia famously observed that "the judge who always likes the results he reaches is a bad judge." Justice Clarence Thomas, *A Tribute to Justice Scalia*, 126 Yale L.J. 1600, 1601 (2017). Assuming the opposite is true for a good judge, today's outcome, which properly applies the regulatory framework before us, is one we can relish as jurists. But it is otherwise difficult to celebrate this result.

The realities of this outcome are not lost on us, just as they likely were not lost on the tribunals that previously considered the matter. Keep in mind the family before us. A daughter suffering from a rare, life-threatening genetic condition. A mother seeking Medicare reimbursement to cover the staggering costs to treat the condition. And a father, ill himself, litigating the case on his daughter's behalf, with his life, as he explained at oral argument, all that stands in the way of his daughter losing her eligibility for future reimbursement for her lifesaving treatment.

As judges, we may do no more than resolve the matter before us, applying the law as we understand it. *Williams-Yulee v. Fla. Bar*, 575 U.S. 433, 445 (2015) (quoting The Federalist No. 78 (A. Hamilton)). Policymakers we are not. This is true as a matter of constitutional design. *See id.* ("Unlike the executive or the legislature, the judiciary 'has no influence over either the sword or the purse; . . . neither force nor will but merely judgment.' "). It also reflects the practical reality that we are not policy experts. On that score, we are the first to acknowledge that there are no doubt many policy considerations on both sides of the scale well beyond our purview. But for those who do craft our laws, they would not be faulted for giving their decisions here a second look. One family, perhaps others as well, would welcome that effort.

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

No. 22-1997

THERESE M. WATERS, obo Kelly E. Waters,

Plaintiff - Appellant,

v.

XAVIER BECERRA, Secretary of Health and Human Services,

Defendant - Appellee.

Before: GILMAN, BUSH, and READLER, Circuit Judges.

JUDGMENT

(Filed Sep. 11, 2023)

On Appeal from the United States District Court for the Western District of Michigan at Grand Rapids.

THIS CAUSE was heard on the record from the district court and was argued by counsel.

IN CONSIDERATION THEREOF, it is ORDERED that the judgment of the district court is AFFIRMED.

ENTERED BY ORDER OF THE COURT

/s/ Deborah S. Hunt
Deborah S. Hunt, Clerk

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

(Filed Sep. 21, 2022)

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

[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.

grant the Secretary's motion, **deny** Plaintiff's motion, and **affirm** the Secretary's final decision.[2]

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 Lcysteine, 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

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[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.

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

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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://

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.*

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

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www.mayoclinic.org/tests-procedures/total-parenteral-nutrition/about/pac-20385081 (last visited Sept. 14, 2022).

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

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 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).

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

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 noncoverage 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.
>
> 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 noncovered 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

[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.

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 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

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

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 nonfunction 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 the HCU Cooler that Kelly consumes for nutrition is a medical food

[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.").

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.

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

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[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.

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

No. 22-1997

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

THERESE M. WATERS, OBO KELLY E. WATERS, Plaintiff-Appellant, v. XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES, Defendant-Appellee.	)	ORDER (Filed Nov. 1, 2023)

BEFORE: GILMAN, BUSH, and READLER, Circuit Judges.

The court received a petition for rehearing en banc. The original panel has reviewed the petition for rehearing and concludes that the issues raised in the petition were fully considered upon the original submission and decision of the case. The petition then was circulated to the full court. No judge has requested a vote on the suggestion for rehearing en banc.

Therefore, the petition is denied.

ENTERED BY ORDER OF THE COURT

/s/ Kelly L. Stephens
Kelly L. Stephens, Clerk

STATUTES AND REGULATIONS

A. Statutes

1. 42 U.S.C. §1395x(s)(8) provides:

"For purposes of this title – (s) the term "medical and other health services means any of the following items or services;

(8) 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."

2. 42 U.S.C. §1395m(h)(4)(B) provides:

"Payment for Prosthetic Devices and Orthotics and Prosthetics. –

(4) Definitions. – In this subsection –

(B) the term 'prosthetic devices' has the given such term in section1861(s)(8), except that such term does not include parenteral and enteral nutrition nutrients, supplies, and equipment and does not include an implantable item for which payment may be made under section 1833(t);"

3. 42 U.S.C. §1395u(s)(1)(A) provides:

"(s) Application of Fee Schedule

(1)(A) Subject to paragraph (3), the Secretary may implement a statewide or other areawide fee schedule to be used for payment of any item or service described in paragraph (2) which is paid on a reasonable charge basis.

* * *

(2) The items and services described in this paragraph are as follows:

* * *

(D) Parenteral and enteral nutrients, equipment and supplies."

4. 42 U.S.C. §1395y(a)(1)(A) provides:

"(a) Items or services specifically excluded –

notwithstanding any other provision of this subchapter, no payment may be made under part A or part B for any expenses or services –

(1) (A) which except for items and services described in a succeeding subparagraph or additional preventative services (as described in section 1395(x)(ddd)(1) of this title), are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member,"

5. 42 U.S.C. §1395y(l)(1) provides:

> "(l) National and local coverage determination process
>
> (1) Factors and evidence used in making national coverage determinations
>
> The Secretary shall make available to the public the factors considered in making national coverage determinations of whether an item or service is reasonable and necessary. The Secretary shall develop guidance documents to carry out this paragraph in a manner similar to the development of guidance documents under section 371(h) of title 21."

6. 42 U.S.C. §1395y(l)(6) provides:

> "(6) National and local coverage determination defined: for purposes of this subsection
>
> (A) National coverage determination
>
> The term 'national coverage determination' means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this subchapter."

7. 21 U.S.C. §360ee provides:

> "(a) Authority of Secretary
>
> The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist

in (1) defraying the costs of developing drugs for rare diseases or conditions, including qualified testing expenses, (2) defraying the costs of developing medical devices for rare diseases or conditions, (3) defraying the costs of developing medical foods for rare diseases or conditions, and (4) developing regulatory science pertaining to the chemistry, manufacturing, and controls of individualized medical products to treat individuals with rare diseases or conditions.

(b) Definitions

For purposes of subsection (a):

(3) The term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation."

B. Regulations

1. 42 C.F.R. §414.104 provides:

§ 414.104 PEN Items and Services.

"(a) *Payment rules.* Payment 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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
DEPARTMENTAL APPEALS BOARD
Medicare Appeals Council
Docket No. M-20-2568

T.W. o/b/o K.W., Appellant
ALJ Appeal No. 3-9128750051

DECISION

The Administrative Law Judge (ALJ) issued a decision dated May 15, 2020, which concerned Medicare Part B coverage of enteral formula and supplies furnished to the appellant-beneficiary (appellant) from December 13, 2018 to September 11, 2019 (dates of service). The appellant has asked the Medicare Appeals Council (Council) to review this decision.

The Council reviews the ALJ's decision *de novo.* 42 C.F.R. § 405.1108(a). The Council enters the appellant's request for review into the administrative record as Exhibit (Exh.) MAC-1, and attached brief as Exh. MAC-2. As set forth below, the Council agrees with the ALJ that the supplies are not covered by Medicare.

DISCUSSION

After carefully considering the record and the appellant's contentions. the Council finds the enteral nutrition at issue is not covered under § 1861(s)(8) of the Social Security Act (Act). We also find that § 1879 does not apply and the appellant is financially responsible for the non-covered costs.

The Medicare contractor and Qualified Independent Contractor (QIC) denied coverage because the evidence failed to satisfy the requirements set forth in the relevant Policy Article A52493 to the Local Coverage Determination (LCD) L33783. *See* File 7 at 33; File 2 at 6. The ALJ also found the beneficiary does not require tube feedings and does not meet the criteria for enteral nutrition therapy under Policy Article A52493. The ALJ indicated the facts of the case could support deviating from the applicable LCD, but concluded "National Coverage Determination (NCD) 180.2 requires that enteral therapy may be given by nasogastric, jejunostomy. or gastronomy tubes" and the documentation reflects the appellant does not met the requirements for Medicare coverage. *See* Decision (Dec.) at 4.

Before the Council, the appellant asserts the enteral nutrition is a covered prosthetic device which replaces all or part of an internal body organ or all or part of the function of a permanently inoperative or malfunctioning internal body organ. (Exh.) MAC-2. She asserts NCD 180.2. LCD L33783, and A52493 were improperly applied to require her to use a feeding tube to receive Medicare coverage, and that the Policy Article, LCD, and NCD apply to an unrelated and dissimilar patient group. *Id.* The appellant asserts she is not required to use a feeding tube to meet the criteria under NCD 180.2 to receive Medicare coverage, and requiring a feeding tube to receive Medicare coverage for the prescribed and medically necessary enteral nutrition is a violation of her constitutional rights. *Id.*

As a preliminary matter, the Council acknowledges the appellant's assertion that her constitutional rights have been violated under the 5th and 14th amendments of the United States Constitution by her inclusion within a group of unrelated and dissimilar patients. requiring her to undergo invasive and risky surgery to receive a feeding tube for Medicare coverage. *Id* at 18-20. Further, the appellant contends the application of the NCD and Policy Article is arbitrary and capricious under the Administrative Procedures Act (APA) because the requirements lack an adequate determining principle, is inconsistent with the determining medical principles set forth in the Enteral Nutrition Policy, and reflects an absence of consideration of significant medical principles regarding the appellant's disability. *Id* at 16. The Council, however, has no authority to ignore or create exceptions to Medicare law based on those arguments. 42 C.F.R. § 405.1063 (providing that all laws and regulations pertaining to the Medicare program are binding on Administrative Law Judges and the Council).

Medicare Coverage

Medicare is a defined benefits program. Medicare Part B only covers an item or service if Congress has established a covered benefit for that item in section 1861(s) of the Act. Relevant here. the Act defines the benefit category, prosthetic devices, as those that "replace all or part of an internal body organ." Act § 1861(s)(8); 42 C.F.R. § 411.351. Medicare covers enteral nutrition supplies when the beneficiary qualifies for the

prosthetic device benefit under section 1861(s)(8) of the Act.

An ALJ and the Council are bound by statutes, regulations, NCDs and Medicare Rulings. 42 C.F.R. §§ 405.1060(a)(4). 405.1063. Neither an ALJ nor the Council is bound by a LCD or Medicare program guidance such as program memoranda and manual instructions. "but will give substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062(a).

Relevant here, NCD 180.2, Enteral and Parenteral Nutritional Therapy, provides coverage of nutritional therapy under the Part B prosthetic benefit for those beneficiaries who have, "a permanently inoperative internal body organ or function thereof." NCD 180.2. The NCD also specifies requirements for coverage of enteral therapy:

> Enteral nutrition is considered reasonable and necessary for a patient with a functioning gastrointestinal tract who, due to pathology to, or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition. Enteral therapy may be given by nasogastric, jejunostomy, or gastrostomy tubes. . . .

Medicare National Coverage Determinations Manual. CMS Pub. 100-3. Chapter 1, § 180.2.

The NCD requires that "[e]ach claim must contain a physician's written order or prescription and sufficient

medical documentation . . . to permit an independent conclusion that the patient's condition meets the requirements of the prosthetic device benefit and that enteral nutrition therapy is medically necessary." NCD 180.2. In addition to the NCD. the contractor issued LCD L33783 for further guidance on coverage and documentation for enteral nutrition and associated supplies. The LCD states that the patient's medical records must indicate the need for the enteral nutrition and supplies. *See* LCD L33783. The LCD also directs the contractor to Policy Article A52493 for the statutory coverage criteria. *Id.* Policy Article A52493 provides. in pertinent part, "Enteral nutrition products that are administered orally and related supplies are noncovered, no benefit."

The appellant asserts the enteral nutrition is a covered prosthetic device. Exh. MAC-2. The appellant also contends the national and local coverage determinations and policy article were improperly applied in requiring the beneficiary to use a feeding tube, a contraindicated treatment. *Id.* The appellant argues NCD 180.2 allows, but does not require a feeding tube, and that the feeding tube requirement is inconsistent with the Social Security Act. *Id.*

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; 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.

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.

Financial Responsibility

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.

DECISION

For the above reasons, the Council agrees with the ALJ's decision that the enteral nutrition therapy furnished to the beneficiary on the dates of service, are not covered by Medicare. The beneficiary is responsible for the non-covered costs. The Council adopts the ALJ's decision.

MEDICARE APPEALS COUNCIL

/s/ Jeffrey Sacks
Jeffrey Sacks
Administrative Appeals Judge

Date: December 22, 2020

US Government References:

https://www.ncbi.nlm.nih.gov/books/NBK1524/

National Library of Medicine:

NLM Citation: Sacharow Si, Picker JD, Levy HL. Homocystinuria Caused by Cystathionine Beta-Synthase De ciency. 2004 Jan 15 [Updated 2017 May 18]. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2019

Relevant excerpts:

SUMMARY

Clinical characteristics Homocystinuria caused by cystathionine 13-synthase (CBS) de ciency is characterized by involvement of the eye (ectopia lentis and/or severe myopia), skeletal system (excessive height, long limbs, scolioisis, and pectus excavatum), vascular system (thromboembolism), and CNS (developmental delay/intellectual disability). All four – or only one – of the systems can be involved; expressivity is variable for all of the clinical signs. It is not unusual for a previously asymptomatic individual to present in adult years with only a thromboembolic event that is often cerebrovascular. Two phenotypic variants are recognized, B6-responsive homocystinuria and B6- nonresponsive homocystinuria. B6-responsive homocystinuria is usually milder than the non-responsive variant. Thromboembolism is the major cause of early death and morbidity. IQ in individuals with untreated homocystinuria

ranges widely, from 10 to 138. In B6-responsive individuals the mean IQ is 79 versus 57 for those who are B6-non-responsive. Other features that may occur include: seizures, psychiatric problems, extrapyramidal signs (e.g., dystonia), hypopigmentation of the skin and hair, malar flush, livedo reticularis, and pancreatitis.

TREATMENT

The diet for homocystinuria is very complex and the skills of an experienced metabolic dietician must be utilized. Dietary treatment reduces methionine intake by restricting natural protein intake. However, to prevent protein malnutrition, a methionine-free amino acid formula supplying the other amino acids (as well as cysteine, which may be an essential amino acid in CBS deficiency) is provided. The amount of methionine required is calculated by a metabolic dietician and supplied in natural food and special low-protein foods and monitored on the basis of plasma concentrations of total homocysteine as well as methionine.

Kelly Waters, DOB [redacted]1989
MEDICARE #[redacted]JC43

U.S. Department of Health and Human Services Food and Drug Administration Center for Food Safety and Applied Nutrition May 2016

Frequently Asked Questions About Medical Foods; Second Edition Guidance for Industry
https://www.fda.gov/media/97726/download

from page 4:

A medical food, as defined in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)), is "a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation." FDA considers the statutory definition of medical foods to narrowly constrain the types of products that fit within this category of food (21 CFR 101.9(j)(8)). Medical foods are distinguished from the broader category of foods for special dietary use by the requirement that medical foods be intended to meet distinctive nutritional requirements of a disease or condition, used under medical supervision, and intended for the specific dietary management of a disease or condition. Medical foods are not those simply recommended by a physician as part of an overall diet to manage the symptoms or reduce the risk of a disease or condition. Not all foods fed to patients with a disease, including diseases that

require dietary management, are medical foods. Instead, medical foods are foods that are specially formulated and processed (as opposed to a naturally occurring foodstuff used in a natural state) for a patient who requires use of the product as a major component of a disease or condition's specific dietary management.

The following criteria that clarify the statutory definition of a medical food can be found in FDA's regulations at 21 CFR 101.9(j)(8). A medical food is exempt from the nutrition labeling requirements of 21 CFR 101.9 only if: a. It is a specially formulated and processed product (as opposed to a naturally occurring foodstuff used in its natural state) for the partial or exclusive feeding of a patient by means of oral intake or enteral feeding by tube, meaning a tube or catheter that delivers nutrients beyond the oral cavity directly into the stomach or small intestine;2 b. It is intended for the dietary management of a patient who, because of therapeutic or chronic medical needs, has limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone; 2 Enteral feeding can be achieved by oral intake or by tube. Enteral feeding by tube refers to a tube or catheter that delivers nutrients beyond the oral cavity directly into the stomach or small intestine. These enteral feedings should not be confused with parenteral (or intravenous) nutrient formulations. 5 c. It

provides nutritional support specifically modified for the management of the unique nutrient needs that result from the specific disease or condition, as determined by medical evaluation; d. It is intended to be used under medical supervision; and e. It is intended only for a patient receiving active and ongoing medical supervision wherein the patient requires medical care on a recurring basis for, among other things, instructions on the use of the medical food.

from page 9:

Does FDA generally consider inborn errors of metabolism (IEMs) to be diseases or conditions that a medical food could be used to manage? Yes. FDA generally considers IEMs to be diseases or conditions that a medical food could be used to manage. IEMs include inherited biochemical disorders in which a specific enzyme defect interferes with the normal metabolism of protein, fat, or carbohydrate. As a result of diminished or absent enzyme activity in these disorders, certain compounds accumulate in the body to toxic levels, and levels of other compounds that the body normally makes may become deficient (Ref. 1). Without appropriate and accessible management, these metabolic disturbances can lead to a host of medical and developmental consequences ranging from intellectual disability to severe cognitive impairment and even death (Ref. 1). Management may include one or a combination of the following: drug therapy, modification of the normal diet, or use of a medical food. Some of these disorders can be managed with modification of the normal diet alone (e.g., reduction of galactose and

lactose for galactosemia). However, others cannot be managed solely with diet modification. For these IEMs, a medical food is required in addition to a specific dietary modification in order to obtain adequate levels of essential nutrients (e.g., essential amino acids, essential fatty acids) that are restricted by modifying the normal diet. Medical foods become indispensable for individuals with these IEMs in order to meet the daily requirements of essential nutrients and to limit the metabolic disturbances associated with the particular IEM Medical foods may also include infant formulas used for IEM which are regulated as exempt infant formulas under section 412(h)(1) of the FD&C Act; 21 CFR 107.50. Some examples of specific IEMs that medical foods could be used to manage involve amino acid/protein, organic acid, or fatty acid metabolism. These IEMs primarily require significant restriction of particular amino acids and/or total protein such as in phenylketonuria (phenylalanine restriction), ornithine transcarbamylase deficiency (nonessential amino acid restriction), methylmalonic acidemia (isoleucine, methionine, threonine, and valine restriction), or significant modification of fatty acids/total fat such as in very long-chain acyl-CoA dehydrogenase deficiency (long chain fatty acid restriction with an increase in medium chain fatty acid levels).

from page 12:

References include:

1. Camp, K., Lloyd-Puryear, M., Huntington, K. Nutritional treatment for inborn errors of metabolism:

Indications, regulations, and availability of medical foods and dietary supplements using phenylketonuria as an example. Molecular Genetics and Metabolism, 107:3-9, 2012. Available: http://www.ncbi.nlm.nih.gov/pubmed/22854513.

Medicare National Coverage Determinations Manual
Chapter 1, Part 3 (Sections 170 – 190.34)
Coverage Determinations

Table of Contents
(Rev. 181, 03-27-15)

Transmittals for Chapter 1, Part 3

190.8 - Lymphocyte Mitogen Response Assays

190.9 - Serologic Testing for Acquired Immunodeficiency Syndrome (AIDS)

190.10 - Laboratory Tests - CRD Patients

190.11 - Home Prothrombin Time/International Normalized Ratio (PT/INR) Monitoring for Anticoagulation Management – (Effective March 19, 2008)

190.12 - Urine Culture, Bacterial

190.13 - Human Immunodeficiency Virus (HIV) Testing (Prognosis Including Monitoring)

190.14 - Human Immunodeficiency Virus (HIV) Testing (Diagnosis)

190.15 - Blood Counts

190.16 - Partial Thromboplastin Time (PTT)

necessary and covered if the treating physician determines that there is a change in medical condition, diagnosis, or treatment regimen that requires a change in MNT and orders additional hours during that episode of care.

Effective October 1, 2002, if the treating physician determines that receipt of both MNT and DSMT is medically necessary in the same episode of care, Medicare will cover both DSMT and MNT initial and subsequent years without decreasing either benefit as long as DSMT and MNT are not provided on the same date of service. The dietitian/nutritionist may choose how many units are performed per day as long as all of the other requirements in the NCD and 42 CFR 410.130-410.134 are met. Pursuant to the exception at 42 CFR

410.132(b)(5), additional hours are considered to be medically necessary and covered if the treating physician determines that there is a change in medical condition, diagnosis, or treatment regimen that requires a change in MNT and orders additional hours during that episode of care.

180.2 - Enteral and Parenteral Nutritional Therapy (Rev. 173, Issued: 09-04-14, Effective: Upon Implementation: of ICD-10, Implementation: Upon Implementation of ICD-10)

Covered As Prosthetic Device

There are patients who, because of chronic illness or trauma, cannot be sustained through oral feeding. These people must rely on either enteral or parenteral nutritional therapy, depending upon the particular nature of their medical condition.

Coverage of nutritional therapy as a Part B benefit is provided under the prosthetic device benefit provision which requires that the patient must have a permanently inoperative internal body organ or function thereof. Therefore, enteral and parenteral nutritional therapy are normally not covered under Part B in situations involving temporary impairments.

Coverage of such therapy, however, does not require a medical judgment that the impairment giving rise to the therapy will persist throughout the patient's remaining years. If the medical record, including the judgment of the attending physician, indicates that the

impairment will be of long and indefinite duration, the test of permanence is considered met.

If the coverage requirements for enteral or parenteral nutritional therapy are met under the prosthetic device benefit provision, related supplies, equipment and nutrients are also covered under the conditions in the following paragraphs and the Medicare Benefit Policy Manual, Chapter 15, "Covered Medical and Other Health Services," § 120.

Parenteral Nutrition Therapy Daily parenteral nutrition is considered reasonable and necessary for a patient with severe pathology of the alimentary tract which does not allow absorption of sufficient nutrients to maintain weight and strength commensurate with the patient's general condition.

Since the alimentary tract of such a patient does not function adequately, an indwelling catheter is placed percutaneously in the subclavian vein and then advanced into the superior vena cava where intravenous infusion of nutrients is given for part of the day. The catheter is then plugged by the patient until the next infusion. Following a period of hospitalization, which is required to initiate parenteral nutrition and to train the patient in catheter care, solution preparation, and infusion technique, the parenteral nutrition can be provided safely and effectively in the patient's home by nonprofessional persons who have undergone special training. However, such persons cannot be paid for their services, nor is payment available for any

services furnished by non-physician professionals except as services furnished incident to a physician's service.

For parenteral nutrition therapy to be covered under Part B, the claim must contain a physician's written order or prescription and sufficient medical documentation to permit an independent conclusion that the requirements of the prosthetic device benefit are met and that parenteral nutrition therapy is medically necessary. An example of a condition that typically qualifies for coverage is a massive small bowel resection resulting in severe nutritional deficiency in spite of adequate oral intake. However, coverage of parenteral nutrition therapy for this and any other condition must be approved on an individual, case-by-case basis initially and at periodic intervals of no more than three months by the Medicare Administrative Contractor (A/B MAC (B)) medical consultant or specially trained staff, relying on such medical and other documentation as the A/B MAC (B) may require. If the claim involves an infusion pump, sufficient evidence must be provided to support a determination of medical necessity for the pump. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation.

Nutrient solutions for parenteral therapy are routinely covered. However, Medicare pays for no more than one month's supply of nutrients at any one time. Payment for the nutrients is based on the reasonable charge for the solution components unless the medical record,

including a signed statement from the attending physician, establishes that the beneficiary, due to his/her physical or mental state, is unable to safely or effectively mix the solution and there is no family member or other person who can do so. Payment will be on the basis of the reasonable charge for more expensive premixed solutions only under the latter circumstances.

Enteral Nutrition Therapy

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. Enteral therapy may be given by nasogastric, jejunostomy, or gastrostomy tubes and can be provided safely and effectively in the home by nonprofessional persons who have undergone special training. However, such persons cannot be paid for their services, nor is payment available for any services furnished by nonphysician professionals except as services furnished incident to a physician's service.

Typical examples of conditions that qualify for coverage are head and neck cancer with reconstructive surgery and central nervous system disease leading to interference with the neuromuscular mechanisms of ingestion of such severity that the beneficiary cannot be maintained with oral feeding. However, claims for Part B coverage of enteral nutrition therapy for these

and any other conditions must be approved on an individual, case-by-case basis. Each claim must contain a physician's written order or prescription and sufficient medical documentation (e.g., hospital records, clinical findings from the attending physician) to permit an independent conclusion that the patient's condition meets the requirements of the prosthetic device benefit and that enteral nutrition therapy is medically necessary. Allowed claims are to be reviewed at periodic intervals of no more than 3 months by the A/B MAC (B) medical consultant or specially trained staff, and additional medical documentation considered necessary is to be obtained as part of this review.

Medicare pays for no more than one month's supply of enteral nutrients at any one time. If the claim involves a pump, it must be supported by sufficient medical documentation to establish that the pump is medically necessary, i.e., gravity feeding is not satisfactory due to aspiration, diarrhea, dumping syndrome. Program payment for the pump is based on the reasonable charge for the simplest model that meets the medical needs of the patient as established by medical documentation.

Nutritional Supplementation

Some patients require supplementation of their daily protein and caloric intake. Nutritional supplements are often given as a medicine between meals to boost protein-caloric intake or the mainstay of a daily

nutritional plan. Nutritional supplementation is not covered under Medicare Part B.

190 - Pathology and Laboratory
(Rev. 1, 10-03-03)

190.1 - Histocompatibility Testing
(Rev. 1, 10-03-03)
CIM 50-23

Histocompatibility testing involves the matching or typing of the human leucocyte antigen (HLA). This testing is safe and effective when it is performed on patients:

- In preparation for a kidney transplant;
- In preparation for bone marrow transplantation;

Local Coverage Article:
Enteral Nutrition – Policy Article (A52493)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands

				Virginia West Virginia
Noridian Health-care Solu-tions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont

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Article Guidance

Article Text:

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

Enteral nutrition is covered under the Prosthetic Device benefit (Social Security Act § 1861(s)(8)). In order for a beneficiary's nutrition to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met). In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

GENERAL:

Enteral nutrition is the provision of nutritional requirements through a tube into the stomach or small intestine.

Enteral nutrition is covered for a beneficiary who has (a) permanent non-function or disease of the structures that normally permit food to reach the small bowel or (b) disease of the small bowel which impairs digestion and absorption of an oral diet, either of which requires tube feedings to provide sufficient nutrients to maintain weight and strength commensurate with the beneficiary's overall health status.

The beneficiary must have a permanent impairment. Permanence does not require a determination that there is no possibility that the beneficiary's condition may improve sometime in the future. If the judgment of the treating practitioner, substantiated in the medical record, is that the condition is of long and indefinite duration (ordinarily at least 3 months), the test of permanence is considered met. Enteral nutrition will be denied as non-covered in situations involving temporary impairments.

The beneficiary's condition could be either anatomic (e.g., obstruction due to head and neck cancer or reconstructive surgery, etc.) or due to a motility disorder (e.g., severe dysphagia following a stroke, etc.). Enteral nutrition is non-covered for beneficiaries with a functioning gastrointestinal tract whose need for enteral nutrition is due to reasons such as anorexia or nausea associated with mood disorder, end-stage disease, etc.

The beneficiary must require tube feedings to maintain weight and strength commensurate with the beneficiary's overall health status. Adequate nutrition must not be possible by dietary adjustment and/or oral supplements. Coverage is possible for beneficiaries with partial impairments – e.g., a beneficiary with dysphagia who can swallow small amounts of food or a beneficiary with Crohn's disease who requires prolonged infusion of enteral nutrients to overcome a problem with absorption.

Enteral nutrition products that are administered orally and related supplies are noncovered, no benefit.

If the coverage requirements for enteral nutrition are met, medically necessary nutrients, administration supplies, and equipment are covered.

Enteral nutrition provided to a beneficiary in a Part A covered stay must be billed by the SNF to the fiscal intermediary. No payment from Part B is available when enteral nutrition services are furnished to a beneficiary in a stay covered by Part A. However, if a beneficiary is in a stay not covered by Part A, enteral nutrition is eligible for coverage under Part B and may

be billed to the DME MAC by either the SNF or an outside supplier.

NUTRIENTS:

Food thickeners (B4100), baby food, and other regular grocery products that can be blenderized and used with the enteral system will be denied as noncovered.

Codes B4102 and B4103 describe electrolyte-containing fluids that are noncovered by Medicare.

Self-blenderized formulas are noncovered by Medicare.

Code B4104 is an enteral formula additive. The enteral formula codes include all nutrient components, including vitamins, mineral, and fiber. Therefore, code B4104 will be denied as not separately payable.

SUPPLIES:

The unit of service (UOS) for the supply allowance (B4034, B4035, or B4036) is one (1) UOS per day. Claims that are submitted for more than one UOS per day for HCPCS codes B4034, B4035, or B4036 will be rejected.

National Coverage Determination (NCD)

Enteral and Parenteral Nutritional Therapy

180.2

Tracking Information

Publication Number
100-3
Manual Section Number
180.2

Manual Section Title
Enteral and Parenteral Nutritional Therapy

Version Number
2
Effective Date of this Version
01/01/2022

Implementation Date
07/05/2022

Description Information

Benefit Category
Prosthetic Devices

Please Note: This may not be an exhaustive list of all applicable Medicare benefit categories for this item or service.

Item/Service Description
Effective January 1, 2022, the Centers for Medicare & Medicaid Services determined that no national coverage determination (NCD) is appropriate at

this time for Enteral and Parenteral Nutritional Therapy in the absence of an NCD, coverage determinations will be made by the Medicare Administrative Contractors under 1862(a)(1)(A) of the Social Security Act.

Indications and Limitations of Coverage

Claims Processing Instructions
TN 11272 (Medicare Claims Processing)

Transmittal Information

Transmittal Number
11272

Coverage Transmittal Link
https://www.cms.gov/files/document/r11272NCD.pdf

Revision History
02/2022 - The purpose of this Omnibus change request is to make Medicare contractors aware of the updates to remove two National Determination NCDs, updates to the Medical Nutritional Therapy (MNT) policy and updates to the Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR), and Intensive Cardiac Rehabilitation (ICR) resulting from changes specified in the calendar year 2022 Physician Fee Schedule (PFS) final rule published on November 19, 2021. (TN 11272 E) (CR12613)

Additional Information

Other Versions

Title	**Version**	**Effective Between**	
Enteral and Parenteral Nutritional Therapy	2	01/01/2022 - N/A	You are here
Enteral and Parenteral Nutritional Therapy	1	07/11/1984 - 01/01/2022	View

October 12, 2020

Retired: Retirement of Enteral Nutrition Local Coverage Determination (LCD) and Related Policy Article – Effective November 12, 2020

Joint DME MAC Article

Chapter 13, Section 13.3 of the CMS *Program Integrity Manual* (CMS Pub. 100-08) grants Medicare Administrative Contractors (MACs) the discretion to revise or retire their Local Coverage Determinations (LCDs) at any time on their own initiative. The DME MACs will be retiring the Enteral Nutrition LCD (L33783) and related Policy Article (A52493), effective for claims with dates of service on or after November 12, 2020, due to the evolution of enteral nutrition clinical paradigms.

Enteral nutrition is covered under the Prosthetic Device benefit (Social Security Act §1861(s)(8)), and coverage is further outlined in the *National Coverage Determinations (NCD) Manual* EXT (CMS Pub. 100-03), Chapter 1, Section 180.2. With the retirement of the LCD and Policy Article, providers and suppliers should refer to the CMS NCD 180.2 – Enteral and Parenteral Nutritional Therapy, which addresses coverage criteria for enteral and parenteral nutrition. In addition, providers and suppliers should review the recently published joint DME MAC correct coding article entitled "Enteral Nutrition – Correct Coding and Billing" for more information regarding coverage and Billing of enteral nutrition.

For claims with dates of service prior to November 12, 2020, please visit the Medicare Coverage Database (MCD) to access the retired LCD and Policy Article.

Note: LCDs and Policy Articles that have been retired for less than one year are housed on the EXT *MCD. LCDs and Policy Articles that have been retired for one year or more are accessible on the MCD Archive* EXT .

Publication History

December 16, 2021	Retired due to information no longer current.
October 8, 2020	Originally Published