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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	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 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

[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.

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

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 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 for Waters's claims and affirmed the denial after Waters sought

[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.

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 non-permanent 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

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.

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

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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, 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.

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.