# United States Court of Appeals

**FOR THE DISTRICT OF COLUMBIA CIRCUIT**

---

Argued September 5, 2019 Decided November 26, 2019

No. 18-5222

ARTURO C. PORZECANSKI,
APPELLANT

v.

ALEX MICHAEL AZAR, II, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
APPELLEE

---

Appeal from the United States District Court
for the District of Columbia
(No. 1:16-cv-02064)

---

*Caroline L. Wolverton* argued the cause for appellant. With her on the briefs was *Christopher L. Keough*.

*Jaynie Lilley*, Attorney, U.S. Department of Justice, argued the cause for appellee. With her on the brief was *Alisa B. Klein*, Attorney. *R. Craig Lawrence*, Assistant U.S. Attorney, entered an appearance.

Before: HENDERSON and KATSAS, *Circuit Judges*, and SENTELLE, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* HENDERSON.

KAREN LECRAFT HENDERSON, *Circuit Judge*: Judicial review of claims arising under the Medicare Act is carefully circumscribed. A plaintiff must first present his claims to the Secretary of the United States Department of Health and Human Services (HHS) and exhaust administrative remedies, unless doing so would foreclose access to federal court. In this appeal we consider whether, after properly channeling a single claim for "medical and other health services" benefits, a Medicare beneficiary can obtain prospective equitable relief mandating that HHS recognize his treatment as a covered Medicare benefit in all future claim determinations. The district court concluded it could not issue such relief. For the reasons that follow, we affirm.

## I. BACKGROUND

### A

Medicare is a federally funded health insurance program that serves qualified elderly and disabled individuals. *See* Social Security Amendments of 1965 (Medicare Act), Pub. L. No. 89-97, 79 Stat. 286 (1965) (codified as amended at 42 U.S.C. §§ 1395 *et seq.*). Medicare Part A primarily provides inpatient hospital coverage and Part B covers outpatient services. *See* 42 U.S.C. §§ 1395c, 1395j, 1395k. Eligible Part B beneficiaries may submit claims for "medical and other health services," *id.* § 1395k(a)(2)(B), "including drugs and biologicals . . . furnished as an incident to a physician's professional service," *id.* § 1395x(s)(2)(A). But a drug or biological[1] that otherwise qualifies as a "medical or other

[1] Biological products, also known as biologics, "include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins . . . [and] can be composed of sugars, proteins, or nucleic acids or complex combinations of these

health service" will not be covered under Medicare Part B unless it is also "*reasonable and necessary* for the diagnosis or treatment of illness or injury." *Id.* § 1395y(a)(1)(A) (emphasis added). When a drug or biological is approved by the United States Food and Drug Administration (FDA) but administered for a use "that is not included as an indication" on the official FDA label, the off-label use may be covered if it is "medically accepted" as determined on a case-by-case basis after consideration of "the major drug compendia, authoritative medical literature and/or accepted standards of medical practice." Medicare Benefit Policy Manual § 50.4.2 (Rev. 1, Oct. 1, 2003) https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

The individualized nature of many coverage decisions is reflected in Medicare's elaborate claim determination and review regimen. To start, a Medicare Part B beneficiary must submit a claim for an "initial determination" of whether "the items and services furnished are covered or otherwise reimbursable." 42 C.F.R. § 405.920. Initial coverage determinations are made by contractors HHS hires to manage the preliminary claims administration process in designated geographic areas. *See* 42 U.S.C. §§ 1395ff(a)(1)(C), 1395kk-1(a)(1)–(4); 42 C.F.R. §§ 405.920, 405.924(b). The contractor can either review claims individually or act pursuant to a "local coverage determination" (LCD). An LCD sets forth "whether or not a particular item or service is covered on a contractor-wide basis," Medicare Program Integrity Manual § 13.1.1 (Rev. 863, Feb. 12, 2019),

---

substances, or may be living entities such as cells and tissues." *What Are "Biologics" Questions and Answers*, U.S. FDA, https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers (last updated Feb. 6, 2018).

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf; *see also* 42 U.S.C. § 1395ff(f)(2)(B), and may reflect the LCD's conclusion "that a service is not reasonable and necessary for certain diagnoses." 42 C.F.R. § 400.202.

If the contractor denies the beneficiary's claim, the beneficiary is entitled to appeal his claim to HHS. *See* 42 U.S.C. § 1395ff(b)(1)(A). Initially, he must obtain a "redetermination" from the same contractor. *See id.* § 1395ff(a)(3)(A); 42 C.F.R. § 405.940. If unsuccessful, the beneficiary can seek "reconsideration" by a "qualified independent contractor" who is wholly independent of the initial determination contractor. *See* 42 U.S.C. § 1395ff(c)(1)–(2); 42 C.F.R. § 405.960. If the beneficiary remains unsatisfied, he can request a hearing before an administrative law judge (ALJ). *See* 42 C.F.R. § 405.1000. The ALJ's decision is binding on the parties unless reviewed by the Medicare Appeals Council (Council). *Id.* § 405.1048. If Council review is sought, the Council must either issue a decision, dismiss the case or remand to the ALJ, ordinarily within ninety days of receipt of the request for review. *Id.* § 405.1100(c). If it fails to do so, the beneficiary is entitled to request that his appeal be escalated to federal court. *Id.* § 405.1132(a). Upon receipt of the request, the Council must act within five calendar days or, alternatively, notify the beneficiary that it is unable to issue a decision within the time allotted. *Id.* § 405.1132(a)(1)–(2). The beneficiary then has sixty days to file an action. *Id.* § 405.1132(b).

B

Arturo Porzecanski was diagnosed with systemic capillary leak syndrome (SCLS) in 2005. SCLS, also known as Clarkson's disease, is a rare, life-threatening condition,

"characterized by debilitating episodes in which blood and proteins shift from blood vessels into nearby body cavities and muscles." *Porzecanski v. Azar*, 316 F. Supp. 3d 11, 14 (D.D.C. 2018). SCLS has no known cure. Following his diagnosis, Porzecanski began a preventive course of theophylline and terbutaline but, within a few years, his episodes occurred more frequently. *Id.* at 15.

In 2009 Porzecanski started an experimental regimen of intravenous immune globulin (IVIG), a biological product. *Id.* The FDA has approved IVIG for certain indications; IVIG for the treatment of SCLS, however, is considered an off-label use. Although the body of research at that time comprised only a few published articles, anecdotal reports and unpublished case studies, IVIG showed promising results for controlling SCLS symptoms. The dearth of scientific testing is unsurprising: SCLS's deadliness and rarity render clinical trials virtually impossible. Since starting on IVIG, Porzecanski has been symptom-free. *Id.* at 16. According to the National Institutes of Health, IVIG is now "the best available treatment" for SCLS patients. *Id.* at 19 n.4. Porzecanski's physicians recommend that he continue his IVIG infusion schedule—two consecutive days every four weeks—indefinitely.

On December 16, 2014, Porzecanski underwent a round of IVIG therapy at Georgetown University Medical Center, for which the Medical Center billed $29,860.95. *Id.* at 16. He submitted a Medicare Part B claim for the treatment.[2] The

[2] Since 2009, Porzecanski's private, employer-sponsored health insurance has covered his IVIG infusions and continues to do so. Porzecanski became eligible for Medicare in November 2014. Anticipating retirement—and the resulting loss of his private insurance—he began designating Medicare as his secondary

initial contractor—Novitas Solutions—denied coverage. Novitas' LCD then in effect did not include SCLS as an approved indication for IVIG. *Id.* at 16 & n.2, 20.

As mandated by the regulatory scheme, Porzecanski requested a redetermination and Novitas affirmed its initial denial. *Id.* at 16. He then sought a reconsideration by Maximus Federal Services, a qualified independent contractor. *Id.* Maximus also rejected his claim, in a decision the district court described as "not entirely clear." *Id.* Porzecanski fared no better before an ALJ, who denied coverage as well. *Id.* Porzecanski then appealed to the Council and, after the ninety-day review period lapsed, informed the Council of his desire to escalate the appeal to federal court. *Id.* The Council acknowledged his request and confirmed it could not issue a decision within the required time frame, which permitted Porzecanski to proceed to federal court.

While Porzecanski pursued his claim through the lengthy administrative appeals process, he underwent monthly IVIG therapy and submitted Medicare claims for each treatment. Initial contractors continued to deny coverage. Unlike the December 2014 claim, however, each subsequent denial was eventually overturned by either a qualified independent contractor or an ALJ, obviating the need for judicial review of those claims. *Id.* Yet Porzecanski's success on agency review did not interrupt the initial denials. Because the review generally binds only the parties unless specifically designated as precedential, a favorable determination in one proceeding does not ensure that future claims will be approved. *See* 42 C.F.R. §§ 401.109, 405.1130, 405.1048.

---

insurer. The December 16 treatment was the first IVIG claim submitted to Medicare after Porzecanski became eligible therefor.

Porzecanski filed suit in district court on October 17, 2016. On summary judgment, Porzecanski sought to reverse the denial of benefits for his December 16, 2014 claim and, because HHS's favorable coverage rulings had done nothing to stem the flow of adverse initial determinations, also requested "declaratory and injunctive relief . . . confirming his entitlement to Medicare coverage for his medically necessary and life-saving treatment, and requiring the Secretary, his agency, and its contractors to honor the agency's obligation to provide the Medicare benefits to which he is entitled." Plaintiff's Memorandum in Support of Motion for Summary Judgment at 2–3, *Porzecanski*, 316 F. Supp. 3d 11 (No. 16-2064), ECF No. 15-1. The proposed order accompanying Porzecanski's motion asked the court to order the Secretary to "take all timely and appropriate actions necessary to ensure that [HHS], its contractors, and its administrative review officials will not deny Medicare Part B coverage for . . . *future* IVIG treatments furnished to [Porzecanski] for SCLS pursuant to a physician's order and incident to a physician's service to [Porzecanski]." Proposed Order at 2, *Porzecanski*, 316 F. Supp. 3d 11 (No. 16-2064), ECF No. 15-6 (emphasis added).

On May 30, 2018, the district court granted Porzecanski's motion in part, concluding that the ALJ committed "clear error" by denying the claim even though the IVIG treatment at issue "met all requirements for coverage." 316 F. Supp. 3d at 19. Accordingly, it reversed the denial of benefits and "direct[ed] HHS to take all steps necessary to reflect Medicare coverage for Porzecanski's IVIG treatment of December 16, 2014." *Id.* at 21. But it denied further declaratory and injunctive relief. The district court viewed Porzecanski's proposed remedy as "an advance decision on whether Medicare covers [his] other claims" and declined to make such a determination because:

> For benefits claims "arising under" the Medicare statute, "the sole avenue for judicial review" is 42 U.S.C. § 405(g), which requires beneficiaries to first pursue their claims through the Medicare claims process before seeking review in federal court. *Heckler v. Ringer*, 466 U.S. 602, 615 (1984); *see also* 42 U.S.C. §§ 405(h), 1395ff(b)(1)(A). That is, the Medicare statute "demands the 'channeling' of virtually all legal attacks through the agency." *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000).

*Id.* at 22. Porzecanski was therefore required to "initiate his claims for other IVIG treatments through the Medicare claims process." *Id.* The district court noted, however, that Porzecanski was not "without recourse": he could challenge the LCD "under which contractors have summarily denied his claims"[3] or request that HHS issue a national coverage determination (NCD).[4] *Id.* Porzecanski appeals the denial of his request for declaratory and injunctive relief.

---

[3] A beneficiary who objects to an LCD "provision" can seek administrative review of its reasonableness. 42 C.F.R. § 426.300(a); *see* 42 U.S.C. § 1395ff(f)(2)(A). The beneficiary can also obtain judicial review, 42 U.S.C. § 1395ff(f)(2)(A)(iv), including, in some cases, "without otherwise exhausting other administrative remedies," *id.* § 1395ff(f)(3).

[4] An NCD is "a determination by the Secretary with respect to whether or not a particular item or service is covered nationally," 42 U.S.C. § 1395ff(f)(1)(B), which "ensure[s] that similar claims . . . are covered in the same manner," 78 Fed. Reg. 48,164, 48,165 (Aug. 7, 2013). When no NCD has been made for a particular item or service, an eligible beneficiary may request that the Secretary issue one. 42 U.S.C. § 1395ff(f)(4)(A).

Porzecanski also heeded the district court's advice. After filing this appeal, Porzecanski requested that Novitas revise its LCD to reflect coverage for IVIG when used to treat SCLS. Novitas updated its LCD, effective for services performed on or after September 9, 2018, and added SCLS as a covered indication for IVIG, albeit in limited circumstances. Appellee's Addendum at 8, 13. Although HHS does not argue with the partial grant of summary judgment ordering coverage for the December 16, 2014 IVIG treatment, it does maintain that the revised LCD has mooted Porzecanski's appeal. We must therefore consider whether Porzecanski's appeal is moot before we determine whether the district court correctly declined to grant the requested equitable relief. We address each issue in turn.

## II. MOOTNESS

HHS argues that the appeal "appears to be moot" as a result of Novitas' revised LCD. Appellee's Br. at 11. Although HHS's brief cites no caselaw on this point, we have an "independent obligation" to ensure that cases before us are not moot. *Am. Freedom Def. Initiative v. WMATA*, 901 F.3d 356, 361 (D.C. Cir. 2018) (quotation marks omitted). This duty arises from Article III's requirement that federal courts "only adjudicate actual, ongoing controversies." *Honig v. Doe*, 484 U.S. 305, 317 (1988). In general, "a case becomes moot when the issues presented are no longer live or the parties lack a legally cognizable interest in the outcome." *Conservation Force, Inc. v. Jewell*, 733 F.3d 1200, 1204 (D.C. Cir. 2013) (quotation marks omitted). For example, a case is moot if intervening events make it impossible "to grant any effectual relief," *Church of Scientology of Cal. v. United States*, 506 U.S. 9, 12 (1992) (quotation marks omitted), or if "a party has already obtained all the relief that it has sought,"

*Conservation Force*, 733 F.3d at 1204 (quotation marks and brackets omitted).

This case is not moot. Porzecanski seeks an equitable remedy to stop the nearly automatic coverage denials that have been, and continue to be, issued for his monthly IVIG treatments. The district court's order reversing the denial of the December 16, 2014 claim has done nothing to stop the repetitive denials underlying Porzecanski's claim for declaratory and injunctive relief. Nor has the revised Novitas LCD given Porzecanski the full relief he requested.

Novitas' September 2018 revisions expanded coverage of IVIG for SCLS "on a trial basis when associated with monoclonal gammopathy and used for prophylaxis," although "prophylaxis should be tapered to the lowest dose obtainable." Appellee's Addendum at 13–14. HHS argues the case is moot because coverage is no longer "categorically unavailable." Appellee's Br. at 11–12. But Novitas has continued to deny Porzecanski's claims after Novitas' revised LCD's effective date and he maintains that the "lowest dose obtainable" limitation is arbitrary and dangerous.[5] Appellant's Reply Br. at 12–13. Shortly before oral argument in this case, Novitas again revised its LCD, replacing "lowest dose obtainable" with "lowest effective dose." *Local Coverage Determination (LCD): Intravenous Immune Globulin (IVIG) (L35093)*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35093 (last updated Aug. 22, 2019).[6]

[5] Porzecanski has brought a separate action in district court challenging the revised LCD. *See Porzecanski v. Azar*, No. 19-cv-661 (D.D.C. filed Mar. 8, 2019) [hereinafter *Porzecanski II*].

[6] Both the impetus and the effect of this change are not entirely clear. On March 15, 2019, Porzecanski requested reconsideration of certain language in Novitas' revised LCD. *See*

Although the impact of this most recent change remains to be seen, it appears to support, if anything, coverage for Porzecanski. In any event, neither LCD revision has mooted this case.

Assuming, *arguendo*, that the current Novitas LCD manifests that Porzecanski's IVIG treatments are covered under Medicare Part B, he still would not have "obtained all the relief [he] sought." *Conservation Force*, 733 F.3d at 1204 (quotation marks omitted). An LCD binds only the issuing contractor. *See* 42 U.S.C. § 1395ff(f)(2)(B). That is, if Porzecanski receives treatment in a geographic region administered by another contractor, the Novitas LCD would not control the determination.[7] An LCD is also binding only at the initial determination stage and does not dictate the qualified independent contractor's reconsideration decision. *Id.* § 1395ff(c)(3)(B)(ii)(II). Likewise, notwithstanding LCDs are afforded "substantial deference . . . if they are applicable to a particular case," ALJs and the Council are not bound to follow the determination made by the issuing contractor. 42

---

Attachment, Letter from Jaynie Lilley, Counsel for HHS, to Mark J. Langer, Clerk of Court (Sept. 4, 2019) (pursuant to Fed. R. App. P. 28(j)). Novitas responded on August 16 and rejected his assertion that "lowest dose obtainable" was ambiguous. *Id.* Nevertheless, within a week of its response, Novitas in fact substituted "effective" for "obtainable," a change it described as "non-substantive" and "made for clarification." *Local Coverage Determination (LCD): Intravenous Immune Globulin (IVIG) (L35093)*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=35093 (last updated Aug. 22, 2019).

[7] Indeed, to date Porzecanski has fared better with contractors operating in other jurisdictions. *See* Complaint, Exhibit 2 at 27, *Porzecanski II*, No. 19-cv-661 (D.D.C. filed Mar. 8, 2019), ECF No. 1-3.

C.F.R. § 405.1062(a). In sum, other initial contractors, qualified independent contractors, ALJs and the Council are not bound by the Novitas LCD when deciding whether Porzecanski's IVIG treatments are covered under Medicare Part B. They would, however, be bound by the equitable relief he seeks. Accordingly, Porzecanski's appeal is not moot.

## III. PORZECANSKI'S REQUESTED RELIEF

Porzecanski contends the district court had *authority* to issue equitable relief because the December 16, 2014 claim was properly before it. We note as a preliminary matter that Porzecanski has narrowed the scope of his proposed remedy on appeal. In district court, his proposed order requested, in part, "that [HHS], its contractors, and its administrative review officials will not deny Medicare Part B coverage for . . . future IVIG treatments furnished to [Porzecanski]." Proposed Order at 2, *Porzecanski*, 316 F. Supp. 3d 11 (No. 16-2064), ECF No. 15-6. Before us, however, he contends the requested injunction would not in fact require HHS to approve his future claims. Tr. of Oral Arg. 10:13–10:17. Instead, it would merely effectuate the district court's ruling that his December 16, 2014 claim was a covered Medicare Part B benefit by precluding the Secretary—and any HHS adjudicators and contractors—from denying future claims on the same rejected grounds. However Porzecanski frames his request, we believe the district court correctly declined to grant equitable relief.

### A

Federal jurisdiction is extremely limited for claims arising under the Medicare Act. Generally, a beneficiary must first channel his claim "into the administrative process which Congress has provided for the determination of claims for benefits" before obtaining judicial review. *Heckler v. Ringer*,

466 U.S. 602, 614 (1984). Three statutory provisions elucidate this channeling requirement.

First, 42 U.S.C. § 1395ii—part of the Medicare Act—incorporates the judicial review scheme set forth in 42 U.S.C. § 405(h)[8] and elsewhere in Title II of the Social Security Act, mandating that these provisions "shall also apply" to the Medicare Act "to the same extent as they are applicable with respect to" Title II, with any reference to the "Commissioner of Social Security" deemed a reference to the HHS Secretary as well. In the Medicare context, then, § 405(h) "divests the district courts of federal-question jurisdiction 'on any claim arising under'" the Medicare Act and prohibits judicial review of any decision by the HHS Secretary, "'except as herein provided' in other Title II provisions." *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 825 (D.C. Cir. 2018) (quoting 42 U.S.C. § 405(h)). The judicial review procedure set forth in 42 U.S.C. § 405(g)[9] "creat[es]

[8] "The findings and decision of the Commissioner of Social Security after a hearing shall be binding upon all individuals who were parties to such hearing. No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter." 42 U.S.C. § 405(h). In administering the Medicare review provisions, all references to the "Commissioner of Social Security" in § 405(h) are considered references to the HHS Secretary. *Id.* § 1395ii.

[9] "Any individual, after any final decision of the Commissioner of Social Security made after a hearing to which he was a party, irrespective of the amount in controversy, may obtain a review of such decision by a civil action commenced within sixty days after the mailing to him of notice of such decision . . . ." 42

the exception 'herein provided.'" *Id.* Although § 405(g) is not one of the Title II provisions specifically incorporated by § 1395ii, it has been consistently interpreted as such. *Id.* ("[T]hese decisions treat it as such, presumably on the theory that expressly incorporating the judicial-review bar in § 405(h) also effectively incorporates the exception 'herein provided' in § 405(g).").

In relevant part, § 405(g) provides that any person may "obtain a review" of "any final decision" of the Secretary "made after a hearing to which he was a party," by filing a civil action in federal court. *See also* 42 U.S.C. § 1395ff(b)(1)(A). The United States Supreme Court has interpreted this provision to impose two distinct requirements that a beneficiary must satisfy before obtaining judicial review of a Medicare claim. First, "a claim for benefits shall have been presented to the Secretary." *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976). This precondition is nonwaivable because without presentment "there can be no 'decision' of any type," as is required by § 405(g). *Id.* Presentment is thus "an absolute prerequisite" for jurisdiction. *Nat'l Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1130 (D.C. Cir. 1992). Second, "the plaintiff must fully exhaust all available administrative remedies, though this more demanding requirement is waivable." *Am. Hosp. Ass'n*, 895 F.3d at 826.

Accordingly, § 405(h)'s bar on judicial review, as modified by § 405(g), "demands the 'channeling' of virtually all legal attacks through the agency." *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000). Channeling extends "beyond ordinary administrative law principles of ripeness and exhaustion of administrative remedies" in order to "assure[] the agency greater opportunity to apply, interpret,

---

U.S.C. § 405(g). As noted, "Commissioner of Social Security" refers to the HHS Secretary in the Medicare context. *Id.* § 1395ii.

or revise policies, regulations, or statutes without possibly premature interference by different individual courts." *Id.* at 12–13 (quotation marks omitted). That said, the preconditions do not apply "where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." *Id.* at 19; *see also Am. Hosp. Ass'n*, 895 F.3d at 825 ("[F]ederal-question jurisdiction remains available where necessary to preserve an opportunity for judicial review."). We have held that the exception recognized in *Illinois Council* "applies not only when administrative regulations foreclose judicial review, but also when roadblocks practically cut off any avenue to federal court." *Am. Chiropractic Ass'n v. Leavitt*, 431 F.3d 812, 816 (D.C. Cir. 2005). A party may not circumvent the channeling requirement "by showing merely that postponement of judicial review would mean added inconvenience or cost in an isolated, particular case." *Council for Urological Interests v. Sebelius*, 668 F.3d 704, 708 (D.C. Cir. 2011) (quotation marks and brackets omitted). Rather, the "difficulties must be severe enough to render judicial review unavailable as a practical matter." *Am. Chiropractic Ass'n*, 431 F.3d at 816.

B

We review *de novo* the district court's conclusion that it was precluded by § 405(g) from issuing the requested declaratory and injunctive relief. *See, e.g.*, *Am. Hosp. Ass'n*, 895 F.3d at 825.

A beneficiary seeking to establish a right to future benefit payments must be considered to have brought a claim that "arises under" the Medicare statute. *Ringer*, 466 U.S. at 615. Judicial review is therefore limited by the interplay between § 405(h) and § 405(g), subject to the exception expounded by the Supreme Court in *Illinois Council*. Here, Porzecanski has

not shown that judicial review will be "foreclose[d]" or "practically cut off" if he is forced to channel future claims through the HHS administrative process. *See Am. Chiropractic Ass'n*, 431 F.3d at 816. To the contrary, he can obtain judicial review of any future claim denial just as he has done in this case. And to the extent he desires broader relief outside the case-by-case adjudicatory model, he has a clear administrative path to challenge an LCD or to request an NCD, *see* 42 U.S.C. § 1395ff(f)(2)(A), (f)(4)(A), subject, in both cases, to judicial review after final agency action. 42 U.S.C. § 1395ff(f)(1)(A)(v), (f)(2)(A)(iv). Postponing judicial review would delay—but not deprive—Porzecanski of access to federal court. Until then, he has an adequate remedy that seems to work. Indeed, except for the December 16, 2014 claim, HHS has ultimately approved his IVIG treatments. He understandably wants to end the cycle of initial denials and agency appeals but "occasional individual, delay-related hardship" does not override "the judgment of Congress" encapsulated in § 405(h). *Illinois Council*, 529 U.S. at 13. Accordingly, Porzecanski must present and exhaust each of his future benefit claims.

Porzecanski cannot satisfy § 405(g)'s presentment requirement with respect to future claims because those claims have not yet arisen. Under the Medicare scheme, a claim can be filed "only after the medical service for which payment is sought has been furnished." *Ringer*, 466 U.S. at 621. Moreover, § 405(g) contemplates appeals from "decision[s]" of the Secretary. Here, the Secretary has not decided Porzecanski's future claims because—to state the obvious—none has been submitted. Porzecanski attempts to avoid this conclusion, arguing that he does not in fact seek "a declaration of entitlement to Medicare benefits on specific future claims," even as he admits his requested relief would "preclud[e] the agency from applying its invalidated

conclusions that the treatments for his rare condition are not a Medicare-covered benefit and not medically necessary." Appellant's Br. at 32.

Porzecanski's strained position is at odds with Supreme Court precedent. In *Ringer*, the Court held that § 405(g) barred a patient from obtaining declaratory and injunctive relief compelling the Secretary to conclude that his future surgery was "reasonable and necessary" under the Medicare Act. 466 U.S. at 620–21, 626–27. The equitable nature of the relief did not mean that the claim was different from "essentially one requesting the payment of benefits." *Id.* at 620. Indeed, as the Court explained, "[a]lthough it is true that Ringer is not seeking the immediate payment of benefits, he is clearly seeking to establish a right to future payments" which "must be construed as a 'claim arising under' the Medicare Act because any other construction would allow claimants substantially to undercut Congress' carefully crafted scheme for administering the Medicare Act." *Id.* at 621. And for the three patients who had already had the surgery at issue, the Court affirmed "[i]t is of no importance" that they "sought only declaratory and injunctive relief and not an actual award of benefits as well" because "only essentially ministerial details will remain before respondents would receive reimbursement." *Id.* at 615. In *Illinois Council*, the Supreme Court again declared that a "claim for future benefits is a § 405(h) claim" and that "all aspects" of any future claim "must be channeled through the administrative process." 529 U.S. at 12 (quotation marks and citation omitted); *see also Ringer*, 466 U.S. at 614.

*Ringer* and *Illinois Council* directly foreclose Porzecanski's attempt to recast the requested relief as anything other than a claim for future benefits. An order requiring HHS to conclude that future IVIG treatments are

both a "Medicare-covered benefit" and "medically necessary" runs headlong into the Supreme Court's instruction that "*all* aspects" of a claim be first channeled through the agency. *Illinois Council*, 529 U.S. at 12 (emphasis added). Moreover, the issues Porzecanski attempts to resolve through judicial decree are not merely related to his claim; they *are* his claim. Granted, Porzecanski would still need to provide appropriate documentation in connection with his claims but the ultimate issue of whether his treatments are covered under Medicare Part B would be predetermined by the relief he seeks. In other words, "only essentially ministerial details [would] remain before [he] would receive reimbursement" in the future. *Ringer*, 466 U.S. at 615. Porzecanski "is clearly seeking to establish a right to future payments" outside the appropriate channels and we therefore must reject his request for prospective relief. *Ringer*, 466 U.S. at 621. We believe the district court correctly rejected Porzecanski's attempt to circumvent the Medicare Act's channeling requirement.[10] Because we hold that Porzecanski runs afoul of § 405(g)'s jurisdictional presentment precondition, we need not decide whether he exhausted administrative remedies or whether exhaustion is otherwise waived.

---

[10] The district court did not explicitly state whether it declined to grant equitable relief under the nonwaivable presentment requirement or the waivable exhaustion requirement. It appears, however, that the court based its decision on jurisdictional presentment grounds. *See Porzecanski*, 316 F. Supp. 3d at 22 ("Porzecanski must *initiate* his claims for other IVIG treatments through the Medicare claims process, and the Court cannot provide an advance decision on whether Medicare covers the other claims.") (emphasis added). We read this language, as well as the court's corresponding discussion of channeling, *id.*, to reflect its conclusion that Porzecanski has not yet presented his future claims to the Secretary.

We note that Porzecanski construes his case as one implicating the court's authority to issue equitable relief, not its jurisdiction of the underlying claim. There is no dispute that the December 16, 2014 claim was properly channeled through HHS before reaching the district court. Understandably, then, Porzecanski frames the equitable relief he seeks as "effectuat[ing] the district court's invalidation of the Secretary's conclusions" so that the Secretary and the attendant components of HHS cannot deny his future claims for the same reasons. Appellant's Reply Br. at 5–6. As he sees it, the properly channeled claim secured jurisdiction, thereby authorizing the district court to issue equitable relief. We disagree with his characterization. Properly channeling one claim does not permit a plaintiff to resolve other claims or causes of action that have not been channeled. *See S. Rehab. Grp., P.L.L.C. v. Sec'y of HHS*, 732 F.3d 670, 677–79 (6th Cir. 2013).

Porzecanski cites *Califano v. Yamasaki*, 442 U.S. 682 (1979), where the Supreme Court recognized that § 405(g) authorizes injunctive relief. In *Yamasaki*, the Court upheld class-wide injunctive relief ordering the Secretary to provide class members with an opportunity for a hearing before recouping erroneous overpayments of Social Security benefits. *Id.* at 705. Relevant here, the Court noted that injunctive relief remains available because § 405(g) does not strip federal courts of their equitable power. *Id.* at 705–06. But the fact that equitable relief is not categorically foreclosed under § 405(g) says nothing about *when* it is available. The *Yamasaki* opinion itself provides only two examples of when equitable relief is appropriate: to preserve the status quo *pendente lite* and, in class actions, to protect absent class members and prevent repetitive litigation. *Id.* at 705. Harmonizing *Yamasaki* with *Ringer* and *Illinois Council*, we conclude the fact that a federal court *may* issue equitable

relief in some circumstances does not mean equitable relief is appropriate in all cases. We recognize there may be situations where equitable relief is appropriate and necessary to carry out a decision. But when prospective relief would functionally determine future claims, we cannot ignore the restrictive mandate of the Medicare Act's channeling requirement.

Porzecanski's reliance on *Lion Health Services, Inc. v. Sebelius*, 635 F.3d 693 (5th Cir. 2011), and *Los Angeles Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644 (9th Cir. 2011), is similarly misplaced. In both cases, hospice care providers challenged the so-called "hospice cap regulation," 42 C.F.R. § 418.309, under which they were ordered to repay excess reimbursement amounts. 635 F.3d at 697; 638 F.3d at 649. The respective district courts declared the regulation invalid and enjoined the Secretary from enforcing it. 635 F.3d at 698; 638 F.3d at 649. But the posture of those cases differs considerably from this one. The district courts in *Lion Health* and *Los Angeles Haven Hospice* exercised jurisdiction under 42 U.S.C. § 1395*oo*(f)(1), which sets out a judicial review scheme that deviates from § 1395ii and § 405(g) in important ways. Indeed, § 1395*oo*(f)(1) confers jurisdiction of "any action of the fiscal intermediary which involves a question of law or regulations relevant to the matters in controversy whenever the Board determines . . . that it is without authority to decide the question." The court can then review the regulation "notwithstanding any other provisions in section 405." *Id.* Thus, in both *Lion Health* and *Los Angeles Haven Hospice*, the challenged regulation's validity was squarely presented and properly before the court. Put differently, enjoining enforcement of the hospice cap regulation did not "mak[e] premature refund determinations for unexhausted years"—it simply prevented HHS from relying on an unlawful regulation. *Lion Health*, 635 F.3d at 702. By contrast, Porzecanski's requested remedy would functionally

require HHS to cover claims that have neither been presented to the Secretary nor administratively exhausted.

Accordingly, we also reject Porzecanski's argument that the Administrative Procedure Act (APA), 5 U.S.C. §§ 701 *et seq.*, authorizes the remedy he seeks. Although he frames *Lion Health* and *Los Angeles Haven Hospice* as affirming equitable relief granted pursuant to the APA, neither held that the APA independently permits prospective relief where the Medicare Act's jurisdictional prerequisites have not been satisfied. *See, e.g.*, *Lion Health*, 635 F.3d at 701 ("The district court may only hear a claim and grant relief pursuant to the specific jurisdictional provisions of the Medicare Act."). Indeed, the Fifth Circuit made clear that the APA only provided authority to craft the equitable remedy at issue once the challenged regulation's validity was properly before the district court. *Id.* at 701–02. And in both cases, our sister circuits emphasized that the underlying claim had been channeled through the agency. *See L.A. Haven Hospice*, 638 F.3d at 662 (Haven Hospice "fully complied with the requirements of *Illinois Council*" to challenge the reimbursement regulation); *Lion Health*, 635 F.3d at 701 (Lion Health satisfied the statutory "prerequisites to judicial review"). But Porzecanski's future claims have not "proceed[ed] through the special administrative review procedures set forth in the Medicare statute," *L.A. Haven Hospice*, 638 F.3d at 662, and the APA does not excuse the failure to channel such claims.[11]

[11] Porzecanski's brief invocation of the Declaratory Judgment Act, 28 U.S.C. § 2201, is no different. Without an independent basis for jurisdiction of his future claims, the Declaratory Judgment Act does not authorize the requested equitable remedy. *See Lovitky v. Trump*, 918 F.3d 160, 161 (D.C. Cir. 2019) ("[Section] 2201 . . . 'is not an independent source of federal jurisdiction.'")

Finally, we consider the practical effects of his requested relief. In district court, Porzecanski challenged no generally applicable regulation or policy. Instead, his complaint challenged only a single ALJ decision. The district court reversed the claim denial because the ALJ, despite determining that Porzecanski's IVIG treatment was "reasonable and necessary," nevertheless denied coverage due to multiple interpretative missteps. *Porzecanski*, 316 F. Supp. 3d at 19. And because the ALJ's "reasonable and necessary" decision was conclusive, *see* 42 U.S.C. § 405(g) (on judicial review of a final decision of the HHS Secretary, the Secretary's factual findings, "if supported by substantial evidence, shall be conclusive"), the district court's determination that the IVIG treatment was "reasonable and necessary" was not required for its holding. *See* 316 F. Supp. 3d at 19 & n.4. Therefore, it is not clear how Porzecanski's proposed relief would effectuate the district court's invalidation of the ALJ's reasoning. First, there is no indication that the invalidated reasoning was relied on in any subsequent claim determination. Nor could it have been, as ALJ decisions are non-precedential. *See* 42 C.F.R. § 401.109 ("The Chair of the [HHS] Departmental Appeals Board . . . may designate a final decision of the Secretary issued by the Medicare Appeals Council . . . as precedential."); *id.* § 405.1063 (only "[p]recedential decisions designated by the Chair of the Departmental Appeals Board . . . are binding on all CMS components [and] all HHS components that adjudicate matters under the jurisdiction of CMS"). And, in every subsequent claim appeal, HHS has

---

(quoting *Metz v. BAE Sys. Tech. Sols. & Servs. Inc.*, 774 F.3d 18, 25 n.8 (D.C. Cir. 2014)); *see also Randall D. Wolcott, M.D., P.A. v. Sebelius*, 635 F.3d 757, 767 (5th Cir. 2011) (Declaratory Judgment Act is not "independent basis for subject matter jurisdiction" if there is "no jurisdiction under 42 U.S.C. § 405(g) or 28 U.S.C. § 1331").

found that Porzecanski's IVIG treatment is in fact covered under Medicare Part B.

Second, the injunction is not limited to ensuring coverage for the single claim that was properly before the district court. Rather, it attempts to stretch the outcome of a single claim dispute to foreclose a contrary decision in any future determination. This is at odds with the Medicare regime. Porzecanski wants a declaration that his treatments are "medically necessary" in all future cases but Medicare policy provides that for off-label uses—such as IVIG for the treatment of SCLS—a determination that the treatment is "medically accepted" is to be made on a "case-by-case basis." Medicare Benefit Policy Manual § 50.4.2 (Rev. 1, Oct. 1, 2003) https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf. Medical science changes. An accepted practice may be obsolete in a few years. Ordering HHS to cover Porzecanski's treatments indefinitely can hardly be necessary to effectuate the district court's judgment regarding one treatment at a particular point in time. If Porzecanski disputes a future adverse determination, he has agency review—and, eventually, federal court—to vindicate his position.

Porzecanski's real problem seems to be with Novitas. To the extent he wants the Secretary to instruct Novitas to cover his treatments pursuant to its LCD, he cannot do so through the claim appeals process. There is a distinct path provided for beneficiaries to secure broader coverage determinations and Porzecanski cannot circumvent those procedures by obtaining an injunction as part of a single claim appeal.[12]

[12] An LCD challenge is "distinct from the claims appeal processes," 42 C.F.R. § 426.310, and cannot be used to review "an individual claim determination," *id.* § 426.325(b)(11). Conversely,

For the foregoing reasons, the district court's partial grant of summary judgment to HHS is affirmed.

*So ordered.*

---

a claim appeal is an improper mechanism by which to "set aside or review the validity of an . . . LCD." *Id.* § 405.1062. LCD and NCD review is intended to provide an alternative path for beneficiaries to challenge claim denials, not to replace the claims appeal process. *See Medicare Program: Review of National Coverage Determinations and Local Coverage Determinations*, 68 Fed. Reg. 63,692, 63,693 (Nov. 7, 2003). Accordingly, it would be odd if the separate statutory framework governing LCD and NCD review could be contravened by using equitable relief to effectuate the judgment of a single favorable determination.