UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ARTURO C. PORZECANSKI,

Plaintiff,

v.

ALEX M. AZAR, Secretary,
U.S. Department of Health and Human Services,[1]

Defendant.

Civil Action No. 16-2064 (DLF)

MEMORANDUM OPINION

Before the Court are Arturo Porzecanski's Motion for Summary Judgment, Dkt. 15, and the U.S. Department of Health and Human Services' Cross-Motion for Summary Judgment, Dkt. 17. For the reasons that follow, the Court will grant in part and deny in part Porzecanski's motion, and the Court will grant in part and deny in part HHS's motion.

I. BACKGROUND

In 2005, Porzecanski was diagnosed with systemic capillary leak syndrome (SCLS), also known as Clarkson's disease. Administrative Record (AR) 29, 124, Dkt. 22. SCLS is an "exceedingly rare" and life-threatening disorder, characterized by debilitating episodes in which blood and proteins shift from blood vessels into nearby body cavities and muscles. *See* AR 59, 73, 124, 342–45. SCLS can be treated with intravenous immune globulin (IVIG). AR 33, 137. Porzecanski received IVIG treatment on December 16, 2014, but when he submitted a Medicare

[1] When this suit began, Sylvia M. Burwell was the Secretary of the U.S. Department of Health and Human Services. When Alex M. Azar became the Secretary, he was automatically substituted as the defendant. *See* Fed. R. Civ. P. 25(d).

claim for the treatment, an administrative law judge denied the claim. AR 28–33. Porzecanski now challenges that denial, and he seeks declaratory and injunctive relief to prevent HHS from continuing to deny similar claims.

A. Medicare Part B and the Claims Process

Medicare is a federal health insurance program that serves elderly or disabled Americans. *See* 42 U.S.C. § 1395 *et seq.* Medicare Part B covers "medical and other health services," *id.* § 1395k(a)(2)(B), including "services and supplies (including *drugs and biologicals* which are not usually self-administered by the patient) furnished as an incident to a physician's professional service," *id.* § 1395x(s)(2)(A) (emphasis added). The Medicare statute, with a few exceptions not relevant here, defines covered drugs and biologicals based on whether they are approved by certain hospital committees or listed in authoritative sources known as compendia:

> The term "drugs" and the term "biologicals" . . . include only such drugs (including contrast agents) and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital.

Id. § 1395x(t)(1).

In addition, covered services must be reasonable and necessary. "Notwithstanding any other provision of [the Medicare statute], no payment may be made under . . . part B . . . for any expenses incurred or items or services—which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." *Id.* § 1395y(a)(1)(A); *see also* Medicare Benefits Policy Manual, Chapter 15, § 50 (drugs and biologicals must be "reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical

practice"). Drugs approved by the Food and Drug Administration (FDA) are considered reasonable and necessary when used for indications specified on their FDA-approved labeling. Medicare Benefits Policy Manual, Chapter 15, § 50.4.1. And even when used for indications *not* specified on the labeling, *i.e.* "off-label" uses, a drug is considered reasonable and necessary if the use is "medically accepted":

> An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the [Medicare administrative contractor] determines the use to be medically accepted, taking into consideration the major drug compendia, authoritative medical literature and/or accepted standards of medical practice. . . . These decisions are made by the [contractor] on a case-by-case basis.

Id. § 50.4.2.

To submit a Medicare Part B claim, a beneficiary must first file with an administrative contractor hired by HHS to make initial coverage determinations. 42 C.F.R. §§ 405.920, 405.924(b). The initial contractor may review the claim individually, or the contractor may deny the claim automatically by relying on a "local coverage determination," which is a decision promulgated by the contractor "to provide guidance to the public and the medical community within their jurisdictions" as to the clinical circumstances under which a "service is considered to be reasonable and necessary." Medicare Program Integrity Manual, Chapter 13, § 13.1.3; *see* 42 U.S.C. § 1395ff(f)(2)(B); 42 C.F.R. § 400.202. A local coverage determination binds only the contractor that issued it, and only at the initial stages of the Medicare claim review process. *See* 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II).

If the beneficiary disagrees with the contractor's initial determination, the beneficiary may request a "redetermination" by the same contractor. 42 C.F.R. § 405.940. Assuming the contractor does not reverse itself and the beneficiary remains dissatisfied, the beneficiary may

request "reconsideration" by another Medicare program contractor called a "qualified independent contractor." *Id.* § 405.960. After an adverse reconsideration, the beneficiary may appeal to an HHS administrative law judge. *Id.* § 405.1000. The administrative law judge's decision binds the parties unless the Medicare Appeals Council reviews the decision on its own motion or the beneficiary appeals to the Council. *See id.* §§ 405.1048, 405.1110, 405.1102. When evaluating a claim, administrative law judges and the Medicare Appeals Council are not bound by contractors' local coverage determinations or by Medicare program guidance such as manual instructions, but according to HHS regulations, HHS "will give substantial deference to these policies if they are applicable to a particular case." *Id.* § 405.1062. If the Medicare Appeals Council does not issue a decision, dismissal, or remand within 90 days of the beneficiary's request for review, the beneficiary may escalate the appeal to a federal district court. *Id.* §§ 405.1132, 405.1100(c). And if the Medicare Appeals Council does issue a decision, the beneficiary has 60 days to seek review by a federal district court. *Id.* § 405.1130. Decisions by administrative law judges and the Council generally lack precedential effect and bind the parties only. *Id.* § 405.1048, 405.1130; *see also* 82 Fed. Reg. 4974, 5105–06 (Jan. 17, 2017) (authorizing HHS to designate certain Council decisions as precedential).

B. Porzecanski's Claims

Beginning in 2005, Porzecanski experienced numerous life-threatening SCLS episodes that required prolonged stays at intensive care units. AR 21. Despite a preventive regimen of theophylline and terbutaline, the episodes began occurring more frequently. *Id.* In 2009, Porzecanski began treatment with IVIG injections for two consecutive days every four weeks. *Id.* Since receiving IVIG, he has been symptom-free. *Id.*; *see also* Dkt. 23-1 at 4.

This case involves an IVIG treatment that Porzecanski received on December 16, 2014 at Georgetown University Medical Center, for which the Medical Center billed $29,860.95. AR 21. Porzecanski submitted a Medicare claim for the IVIG treatment, but the initial contractor—Novitas Solutions—denied coverage. AR 333. Porzecanski requested a redetermination, and Novitas Solutions again denied coverage. *Id.* Porzecanski then sought reconsideration by a qualified independent contractor, Maximus Federal Services, which also rejected his claim. *Id.* Maximus's decision, although not entirely clear, appeared to rely on a local coverage determination promulgated by Novitas Solutions and the decision stated that Porzecanski's documentation did not justify coverage for his IVIG treatment. *See* AR 333–34; *see also* AR 32; Def.'s Mem. at 8–9, 24, Dkt. 17.

Porzecanski then appealed to an administrative law judge, who held a brief hearing at which Porzecanski testified. AR 53 (appeal); AR 478–91 (hearing transcript). The administrative law judge denied coverage on April 28, 2016. AR 28–33 (opinion). Porzecanski sought review by the Medicare Appeals Council, *see* AR 7, but the Council did not act within 90 days. Porzecanski requested escalation to federal district court, *see* AR 2–4, and filed his complaint on October 17, 2016, asserting that the administrative law judge's decision violated the Administrative Procedure Act. *See* Compl. ¶¶ 9, 44–51, Dkt. 1; *see also* Pl.'s Mem. at 13–14, Dkt. 15-1. The parties cross-moved for summary judgment in summer 2017, and the case was reassigned to the undersigned judge on December 5, 2017. *See* Dkt. 15; Dkt. 17.

Since Porzecanski received the IVIG treatment at issue in this case, initial contractors have continued to deny his claims for other monthly treatments, but he has fared better with at least one qualified independent contractor and *all* other administrative law judges who have heard his appeals. Relying on a local coverage determination, the initial contractor Novitas

Solutions and the qualified independent contractor Maximus Federal Services rejected Porzecanski's claims for IVIG treatments received in November 2015, December 2015, and January 2016. Administrative law judges, however, reversed the contractors in early 2017. *See* Dkt. 15-2; Dkt. 15-3; Dkt. 15-4. In addition, Novitas Solutions denied Porzecanski's claim for IVIG treatment received in April 2016, but the qualified independent contractor Maximus Federal Services reversed in early 2017. *See* Dkt. 15-5. Also, Novitas Solutions and qualified independent contractor C2C Innovative Solutions rejected Porzecanski's claim for IVIG treatment received in April 2017, but an administrative law judge again reversed the contractors in early 2018. *See* Dkt. 23-1. The administrative law judges' decisions highlight the alternating—and oftentimes unclear—reasons given by contractors for denying Porzecanski's monthly claims: (a) Porzecanski lacked documentation to support his diagnosis and treatment; (b) IVIG was not medically necessary; or (c) local coverage determinations did not cover SCLS.[2]

[2] For example, contractors gave the following reasons:

"Maximus Federal Services . . . issued an unfavorable decision, holding that the requirements of the pertinent [local coverage determination] were not met." Dkt. 15-3 at 2; *see also* Dkt. 15-2 at 2 (same).

"Novitas Solutions . . . denied coverage [because] the service was . . . not reasonable and necessary. [At redetermination], Novitas denied coverage [because] the documentation . . . did not support the indications outlined within [the local coverage determination]." Dkt. 15-4 at 2–3.

"C2C characterized the [contractor's] unfavorable redetermination decision as being upon a lack of documentation. Another decision denied coverage on the basis that SCLS was not a covered indication. C2C denied reconsideration based on the lack of documentation, but was more forthcoming it its recitation of what it believed were the deficiencies. C2C indicated that, while there was sufficient information to support the use of the off-label treatment, it did not believe that there was sufficient medical documentation, 'including clinical notes and pertain [sic] testing' to support the diagnosis and treatment for the drug at issue.

The [contractor's] decision in [a companion appeal found that] SCLS is 'not an appropriate diagnosis for treatment per the [local coverage determination].' C2C's reconsideration denial presented a somewhat lengthier list of deficiencies than the recitation in the companion appeal, but ultimately, its conclusions were the same. C2C considered that the journals were approved

Notwithstanding the contractors' purported justifications, the administrative law judges deemed Porzecanski entitled to Medicare coverage. *See* Dkt. 15-2 at 12; Dkt. 15-3 at 12; Dkt. 15-4 at 15; Dkt. 23-1 at 8. Thus, this case presents the only decision by an administrative law judge to reach the opposite conclusion. *See* Dkt. 23-1 at 2–3.

II. LEGAL STANDARDS

A court grants summary judgment if the moving party "shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247–48 (1986). A "material" fact is one with potential to change the substantive outcome of the litigation. *See Liberty Lobby*, 477 U.S. at 248; *Holcomb v. Powell*, 433 F.3d 889, 895 (D.C. Cir. 2006). A dispute is "genuine" if a reasonable jury could determine that the evidence warrants a verdict for the nonmoving party. *See Liberty Lobby*, 477 U.S. at 248; *Holcomb*, 433 F.3d at 895.

In a Medicare action, the court reviews the agency's decision under the Administrative Procedure Act. 42 U.S.C. § 1395oo(f)(1); *see Marymount Hosp., Inc. v. Shalala*, 19 F.3d 658, 661 (D.C. Cir. 1994). Thus summary judgment "serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006). The Court will "hold unlawful and set aside" agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law," 5 U.S.C.

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medical literature, and seemed to indicate that off-label treatment was justified for the condition. However, again, C2C indicated that the progress notes that indicated the diagnosis of SCLS and treatment plan were insufficient to support medical necessity because the laboratory studies, history of bleeding, infection, disease progression, prior medical/surgical therapies, and any other essential information was not provided." Dkt. 23-1 at 7 (citations omitted).

§ 706(2)(A), "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C), or "unsupported by substantial evidence," *id.* § 706(2)(E).

In an arbitrary and capricious challenge, the core question is whether the agency's decision was "the product of reasoned decisionmaking." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 52 (1983); *see also Nat'l Telephone Co-op. Ass'n v. FCC*, 563 F.3d 536, 540 ("The APA's arbitrary-and-capricious standard requires that agency rules be reasonable and reasonably explained."). The court's review is "fundamentally deferential—especially with respect to matters relating to an agency's areas of technical expertise." *Fox v. Clinton*, 684 F.3d 67, 75 (D.C. Cir. 2012) (quotation marks and alteration omitted). The court "is not to substitute its judgment for that of the agency." *State Farm*, 463 U.S. at 43. "Nevertheless, the agency must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Id.* (internal quotation marks omitted). When reviewing that explanation, the court "must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id.* (internal quotation mark omitted). For example, an agency action is arbitrary and capricious if the agency "entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before [it], or [the explanation] is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.* The party challenging an agency's action as arbitrary and capricious bears the burden of proof. *Pierce v. SEC*, 786 F.3d 1027, 1035 (D.C. Cir. 2015).[3]

[3] The arbitrary and capricious standard of § 706(2)(A) is a "catchall" that generally subsumes the "substantial evidence" standard of § 706(2)(E). *See Ass'n of Data Processing Serv. Organizations, Inc. v. Bd. of Governors of Fed. Reserve Sys.*, 745 F.2d 677, 683–84 (D.C. Cir.

To the extent that an agency action is based on the agency's interpretation of a statute it administers, the court's review is governed by the two-step *Chevron* doctrine. At Step One, a court must determine "whether Congress has directly spoken to the precise question at issue" or instead has delegated to an agency the legislative authority to "elucidate a specific provision of the statute by regulation." *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842, 843–44 (1984). If the latter, a court must reach Step Two, which asks whether the agency action "is based on a permissible construction of the statute" or instead is "manifestly contrary to the statute." *Id.* at 843, 844. In addition, "courts will normally give controlling weight to an agency's interpretation of its own regulations," *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (internal quotation marks omitted), but "deference is unmerited where the interpretation is plainly erroneous or inconsistent with the regulation," *Kaiser Found. Hosps. v. Sebelius*, 708 F.3d 226, 230–31 (D.C. Cir. 2013).

III. ANALYSIS

The statutory framework governing Medicare claims like Porzecanski's is clear. Medicare Part B covers "medical and other health services," 42 U.S.C. § 1395k(a)(2)(B), including "services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service," *id.* § 1395x(s)(2)(A), and that are "reasonable and necessary," *id.* § 1395y(a)(1)(A). Porzecanski's IVIG treatment on December 16, 2014 satisfied all requirements for coverage. IVIG is a drug or

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1984) ("When the arbitrary or capricious standard is performing that function of assuring factual support, there is no *substantive* difference between what it requires and what would be required by the substantial evidence test, since it is impossible to conceive of a 'nonarbitrary' factual judgment supported only by evidence that is not substantial in the APA sense . . . ."); *accord Safe Extensions, Inc. v. FAA*, 509 F.3d 593, 604 (D.C. Cir. 2007).

biological within the meaning of the statute because IVIG is listed in the appropriate compendia. *See id.* § 1395x(t)(1) (defining "drugs and biologicals" to include those in the United State Pharmacopoeia); Dkt. 19-1 at 2–3 (listing for immune globulin in the United States Pharmacopoeia). Also, Porzecanski received the IVIG treatment incident to a physician's services as an outpatient at Georgetown University Medical Center. AR 28–29, 383–86, 389–92. And finally, the administrative law judge determined—in a finding that is conclusive on this Court, *see* 42 U.S.C. § 405(g)—that Porzecanski's IVIG treatment was reasonable and necessary. *See* AR 32 ("The record shows persuasively that IVIG is medically reasonable and necessary for the treatment of the Beneficiary's condition"); AR 33 ("The evidence of medical necessity for the use of IVIG for the Beneficiary's condition was compelling and supported by the primary institute for the study and treatment of the condition—an institute of the Department of Health and Human Services."); *see also* AR 33 ("[T]he denial is *not* on the ground that the services were not reasonable and necessary . . . ." (emphasis added)).[4] Yet even though

[4] Even if the administrative law judge's finding was not conclusive on the Court, the record establishes that Porzecanski's IVIG treatment was "reasonable and necessary," 42 U.S.C. § 1395y(a)(1)(A), because it is "medically accepted," Medicare Benefits Policy Manual, Chapter 15, § 50.4.2. The National Institute of Health—itself part of HHS—is "the primary referral center for SCLS in the United States and ha[s] the largest cohort of patients with SCLS in the world." AR 135. In a longitudinal study completed in 2014 and published in the double-blind peer-reviewed American Journal of Medicine in 2015, the National Institute "found that an overwhelming majority of our patients who experienced one or more severe SCLS attacks prior to starting IVIG (and many while on theophylline) have become essentially episode-free after starting monthly IVIG, some for as long as 8 years." AR 135, 137; *see also* AR 139–43 (study); AR 32–33 (administrative law judge relying on the study). Other medical literature in the record also supports that IVIG is medically accepted for treating SCLS. *See* Dkt. 22 at 79–93.

Based on the National Institute's "unique and extensive experience with SCLS," it believes that "IVIG is the best available treatment for this rare and enigmatic condition, and therefore should be considered the current standard of care for SCLS patients." AR 137. Furthermore, the National Institute "strongly recommend[s] that Dr. Porzecanski *continue with his monthly IVIG infusions . . . and do so indefinitely*." *Id.* (emphasis in original). In this litigation, HHS attempts to poke holes in the medical literature and studies because they are not final, *i.e.*, they "concluded by recommending more investigation is warranted." Def.'s Mem. at 15; *see also id.*

Porzecanski's IVIG treatment met all requirements for coverage, the administrative law judge denied Porzecanski's claim. That was clear error.

The administrative law judge's reasoning—and the HHS arguments in this litigation—do not redeem the decision, which goes astray in four ways. First, the administrative law judge's decision relies on the wrong law. The decision imports the *Medicaid* statute's definition of a "covered outpatient drug" as one used for a "medically accepted indication," 42 U.S.C. § 1396r-8(k)(3), meaning "a use that is approved by the FDA or the use of which is supported by one or more of the statutorily approved drug compendia," AR 30. Relying on the Medicaid definition, the decision denies coverage for Porzecanski's IVIG treatment because such a *use* is not listed in the approved compendia. *See* AR 32. Needless to say, the Medicaid statute does not govern coverage under Medicare Part B, which defines coverage as discussed above. *Cf. Caring Hearts Pers. Home Servs., Inc. v. Burwell*, 824 F.3d 968, 970 (10th Cir. 2016) ("For surely one thing no agency can do is apply the wrong law to citizens who come before it, especially when the right law would appear to support the citizen and not the agency.").

Second, when the administrative law judge's decision turns to the Medicare statute, the decision points out that Medicare Part B defines anticancer drugs to include drugs used for a "medically accepted indication," but does not define *non*-anticancer drugs in the same way. AR 30 (quoting 42 U.S.C. § 1395x(t)(2)(A)). From that fact, the decision infers that non-anticancer

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at 11–15, 18; Def.'s Reply at 5–6. But that is how the scientific method works, and HHS does not point to any countervailing literature or studies. Therefore, the overwhelming brunt of the evidence in the record supports that Porzecanski's IVIG treatment was reasonable and necessary, as all other administrative law judges—including the one whose decision is at issue here—have found. *See* AR 32–33; Dkt. 15-2 at 12 ("[T]he IVIG infusions at issue were medically reasonable and necessary."); Dkt. 15-3 at 12 (same); Dkt. 15-4 at 14–15 (IVIG treatment "is medically accepted"); Dkt. 23-1 at 7 ("The record is replete with authoritative information that use of IVIG therapy is appropriate to treat SCLS.").

drugs or biologicals (like IVIG treatment) "must be prescribed for an FDA-approved *use* or the *use* must be supported [by] a listing in one of the specified drug compendia." *Id.* (emphasis added). The definition of non-anticancer drugs, however, imposes no such requirement. *See* 42 U.S.C. § 1395x(t)(1). Rather, the definition requires only that the drug or biological be listed in the appropriate compendia or approved by certain hospital committees. *Id.*

Third, the decision relies on an inapposite statutory provision to suggest that Medicare limits IVIG coverage to patients who, unlike Porzecanski, have an immune deficiency disease and receive treatment in their homes. *See* AR 31 (citing 42 U.S.C. § 1395x(s)(2)(Z), 1395x(zz)); AR 33 ("The statute specifically covers IVIG only for the treatment of primary immune deficiency diseases."). But the provision cited by the administrative law judge—although it expands coverage to include in-home IVIG treatment—does not apply here. As explained above, different provisions makes clear that certain drugs or biologicals furnished in a hospital incident to a physician's professional service, such as Porzecanski's IVIG treatment at issue here, are covered when they are reasonable and necessary. *See* 42 U.S.C. §§ 1395x(s)(2)(A), 1395x(t)(1), 1395y(a)(1)(A).

Fourth, the decision appears to lean on a local coverage determination promulgated by Novitas Solutions. *See* AR 32 ("[SCLS] is not one of the listed codes. The LCD instructs that all [such] codes not listed under the codes that support medical necessity will be denied."); AR 33 ("[The local coverage determination] lists the only ICD-9 diagnoses codes that describe a covered primary immune deficiency disease."). A local coverage determination, however, is not binding on administrative law judges. *See* 42 C.F.R. § 405.1062. And although a local coverage determination may direct how contractors process certain billing codes, it cannot obviate the duty of administrative law judges and this Court to determine what the Medicare statute requires.

Faced with these missteps, HHS now argues that any errors were harmless or non-prejudicial because the administrative law judge ultimately reached the correct result. *See* Def.'s Mem. at 19–21; Def.'s Reply at 1–4, Dkt. 21; *see also* 5 U.S.C. § 706 ("[D]ue account shall be taken of the rule of prejudicial error."). In particular, HHS argues that Porzecanski's IVIG treatment was not a drug or biological within the meaning of the Medicare statute because the statutory definition of "drug or biological" does not include IVIG when used for treating SCLS. Def.'s Reply at 2–4. The statute, however, defines a covered drug or biological based on whether the product itself is listed in various compendia, *not* whether certain *uses* of the product are listed in the compendia. *See* 42 U.S.C. § 1395x(t)(1) ("The term 'drugs' and the term 'biologicals' . . . include only such drugs . . . and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia . . . ."). That is, a plain reading of the statute reveals that the definition encompasses listed drugs, not simply listed uses of drugs, which forecloses HHS's argument and HHS's request for *Chevron* deference on this point. Furthermore, this reading does not—as HHS laments—"lead to the absurd result that any drug listed in a compendium or approved by the hospital committee must be covered by Medicare for *any use whatsoever, even when where it has no utility*." Def.'s Reply at 2 n.1 (emphasis added). The distinct "reasonable and necessary" requirement prevents such absurdity by ensuring that Medicare does not cover pointless drugs or biologicals. *See* 42 U.S.C. § 1395y(a)(1)(A). And finally, the reading offered by HHS conflicts with HHS's own instructions. The instructions clearly permit Medicare Part B to cover off-label uses of certain drugs, *see* Medicare Benefits Policy Manual, Chapter 15, § 50.4.2, and the instructions distinguish as separate requirements the definition of drugs or biologicals from the determination of medically necessary uses, *see id.* § 50 ("[D]rugs and biologicals are covered only if all of the following requirements are met:"

(1) "They meet the definition of drugs or biologicals"; . . . (4) "They are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice . . . .").

Due to its errors, the administrative law judge's decision is arbitrary, capricious, and otherwise not in accordance with law. In particular, the decision ignores the Medicare statute and HHS's own rules, the decision is not the product of reasoned decisionmaking, and the decision does not "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43 (internal quotation marks omitted). Therefore, the Court will reverse the decision and direct HHS to take all steps necessary to reflect Medicare coverage for Porzecanski's IVIG treatment of December 16, 2014. *See* 42 U.S.C. § 405(g); 5 U.S.C. § 706(2).[5]

In addition to seeking reversal of the adverse decision, Porzecanski seeks further declaratory and injunctive relief. In particular, Porzecanski asks the Court "to make certain that the Secretary and his various contractors, [administrative law judges] and administrative tribunals will make appropriate coverage determination for *future* rounds of the Beneficiary's IVIG treatment." Pl.'s Mem. at 27 (emphasis added); *see also* Dkt. 15-6 at 2 (Porzecanski's proposed order directing HHS to "take all timely and appropriate actions" needed to ensure that

[5] In lieu of reversal, HHS asks the Court to "remand the matter to the agency for additional evidence development." Def.'s Mem. at 24; *see also* 42 U.S.C. § 405(g) (permitting a reviewing court to reverse an HHS decision, "with or without remanding the cause for a rehearing"). HHS grants that the Court "is not obliged" to remand, Def.'s Reply at 13, but urges remand "where the administrative law judge fails diligently to explore all relevant facts," *id.* (quoting *Walker v. Harris*, 642 F.2d 712, 714 (4th Cir. 1981)). This case, however, has a complete record. The administrative law judge examined the most critical factual question—whether Porzecanski's IVIG treatment was reasonable and necessary—and adamantly concluded that it was, but then failed to apply the appropriate rules to that conclusion. *See* AR 32–33. Because further evidence development is not needed to supplement the record, this case is ill-suited for remand.

HHS and its contractors "will not deny Medicare Part B coverage for past, present, or future IVIG treatments"). Porzecanski's request is understandable. On a monthly basis, he must navigate a warren of contractors who appear to deny his claims summarily. And then Porzecanski must appeal similar legal and medical issues, over and over again.

Although this process is burdensome, the Medicare statute precludes the further relief Porzecanski seeks here. 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). This channeling requirement admittedly "comes at a price, namely, occasional individual, delay-related hardship." *Id.* The price, however, "may seem justified" in "the context of a massive, complex health and safety program such as Medicare." *Id.* "In any event, such was the judgment of Congress . . . ." *Id.* As a result, 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. Therefore, the Court will not grant declaratory and injunctive relief.

Even so, the Court's decision does not leave Porzecanski without recourse. He may challenge the local coverage determination under which contractors have summarily denied his claims. *See* 42. C.F.R. § 426.400. Also, he may request that HHS issue a *national* coverage determination on IVIG treatment for SCLS, *see* 42 U.S.C. § 1395ff(f)(4)(A); 78 Fed. Reg. 48,164, 48,167, which might help bring coherence to the conflicting medical and legal views

advanced by HHS's own contractors, administrative law judges, National Institute for Health, and litigation counsel, *see, e.g.*, *supra* Part I.B & n.4. And if Porzecanski continues to receive adverse determinations by initial contractors, he may seek review by qualified independent contractors, administrative law judges, and ultimately federal courts, as he has done successfully at least six times now. *See* Dkt. 15-2; Dkt. 15-3; Dkt. 15-4; Dkt. 15-5; Dkt. 23-1; Dkt. 24.

CONCLUSION

For the foregoing reasons, the Court grants in part and denies in part Porzecanski's motion, Dkt. 15, and the Court grants in part and denies in part HHS's cross-motion, Dkt. 17. A separate order consistent with this decision accompanies this memorandum opinion.

Dabney L. Friedrich

DABNEY L. FRIEDRICH
United States District Judge

Date: May 30, 2018