UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ROBERT TOWNSEND,	:	
Plaintiff,	:	**20-cv-01210 (ALC)**
-against-	:	**OPINION & ORDER**
NORRIS COCHRAN, *in his official capacity as Secretary of the United States Department of Health and Human Services,*	:	
Defendant.	:	

ANDREW L. CARTER, JR., District Judge:

Plaintiff Robert Townsend (hereinafter, "Plaintiff" or "Mr. Townsend") brings this action against Norris Cochran,[1] in his official capacity as Secretary of the United States Department of Health and Human Services (hereinafter, "Defendant" or the "Secretary"), challenging the Secretary's decision denying coverage of Plaintiff's Medicare claims pursuant to 42 U.S.C. § 405(g), and the Administrative Procedures Act (APA), specifically, 5 U.S.C. §§ 706(1) and (2). Before the Court are the Plaintiff's and Secretary's cross-motions for summary judgment. For the reasons discussed below, both parties' motions for summary judgment are **DENIED** and the Medicare Appeals' Council's unfavorable administrative decision is **REVERSED** and **REMANDED** for further proceedings consistent with this opinion.

PROCEDURAL HISTORY

Plaintiff commenced this action on February 11, 2020. ECF No. 1 ("Compl."). Defendant filed an answer on April 20, 2020. ECF No. 11. On April 28, 2020 and May 1, 2020, the parties filed pre-motion conference letters in connection with motions for summary judgment. ECF Nos.

[1] Under Fed. R. Civ. P. 25(d), Norris Cochran is substituted as Defendant for former Secretary of the Department of Health and Human Services, Alex Azar.

14-15. On June 4, 2020, the Court denied the parties' requests for pre-motion conferences, but granted leave for the parties to file cross-motions for summary judgment. ECF No. 16. The parties filed their opening briefs on June 26, 2020, ECF Nos. 18, 21 (hereinafter, "Pl. Mot." and "Def. Mot.," respectively), their opposition briefs on July 17 and July 20, 2020, ECF Nos. 25, 27 (hereinafter, "Pl. Opp." and "Def. Opp.," respectively), and their reply briefs on August 3, 2020, ECF Nos. 30, 32 (hereinafter, "Pl. Reply" and "Def. Reply," respectively). On December 2, 2020, Plaintiff filed a brief with supplemental authority and on December 9, 2020, Defendant responded. ECF Nos. 40-41. On March 5, 2021 Defendant filed a notice of supplemental authority. ECF No. 42. On March 9, 2021, Plaintiff filed a letter motion for leave to file supplemental authority (including the supplemental authority as an exhibit to the letter motion), which this Court granted. ECF Nos. 43-44. On March 15, 2021, Defendant responded to Plaintiff's supplemental authority. ECF No. 45. The parties' motions are deemed fully briefed.

BACKGROUND[2]

Plaintiff suffers from glioblastoma multiforme ("GBM"), a type of brain cancer, and is seeking Medicare coverage for treatment, specifically, tumor treatment field therapy ("TTFT").[3] Compl. ¶¶ 4, 20. For Medicare to cover a particular medical service, including TTFT, it must fit

[2] This recitation of facts is based on the pleadings and the certified administrative record ("CAR"). *See* 42 U.S.C. § 405(g) ("The court shall have power to enter, upon the pleadings and transcript of the record, a judgment affirming, modifying, or reversing the decision of the [Secretary]."). Plaintiff has submitted a Statement of Undisputed Material Facts pursuant to Fed. R. Civ. P. 56 and Local Rule 56.1. ECF No. 20. Because this case "presents a purely legal challenge to the Secretary's policy, it does not require factual determinations with respect to individual plaintiffs that would require resort to evidence outside the administrative record," and thus the Court declines to consider Plaintiff's Statement of Undisputed Material Facts. *Estate of Landers v. Leavitt*, 545 F.3d 98, 113-14 (2d Cir. 2008) (internal citations and quotation marks omitted) (affirming district court's decision to strike statement of material facts submitted in support of motion for summary judgment), *cert. denied*, 557 U.S. 937 (2009). Accordingly, the Secretary's failure to submit a statement of undisputed material facts with their motion for summary judgment pursuant to Local Rule 56.1 is not grounds for denial of their motion and "Mr. Townsend's facts regarding the elements of collateral estoppel" will not be "deemed admitted" on this ground. *See, e.g.*, Pl. Opp. at 1.

[3] The sole supplier of the equipment that delivers TTFT is Novocure, Inc., which manufactures the Optune system. Compl. ¶ 17. This system is rented on a monthly basis, and thus, once a patient is prescribed TTFT, the patient will continue to have monthly claims for Medicare coverage. *Id.*

within a benefit category established by the Medicare statute. *See* 42 U.S.C. § 1395 *et seq.* This case concerns Medicare Part B, which covers certain types of durable medical equipment ("DME") for qualified recipients. 42 U.S.C. §§ 1395k(a), 1395x(s)(6). Excluded from coverage are "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 . . . ." 42 U.S.C. § 1395y(a)(1)(A).

A. Statutory Framework

The Secretary of the Department of Health and Human Services has delegated to the Center for Medicare & Medicaid Services ("CMS") broad authority to determine whether Medicare covers particular medical services. CMS has interpreted "reasonable and necessary" to mean that an item or service must be "safe and effective," "not experimental or investigational," and "appropriate" in order to qualify for reimbursement. *See* CMS, CHAPTER 13 – LOCAL COVERAGE DETERMINATIONS, MEDICARE PROGRAM INTEGRITY MANUAL § 13.5.4 (Feb. 12, 2019) ("MPIM").[4]

CMS contracts with Medicare Administrative Contractors ("MACs") to administer certain day-to-day functions of the Medicare program. 42 U.S.C. § 1395kk-1. MACs make coverage determinations, issue payments, and develop Local Coverage Determinations ("LCDs") for the geographic area it serves, consistent with controlling regulations and applicable National Coverage Determinations ("NCDs") issued by the Secretary. *Id.*; OFFICE OF THE INSPECTOR GENERAL, HHS, LOCAL COVERAGE DETERMINATIONS CREATE INCONSISTENCY IN MEDICARE COVERAGE 1 (Jan. 2014). NCDs and LCDs are determinations by the Secretary and MACs, respectively, as to whether a particular item or service is covered by Medicare. MPIM § 13.1.1;

[4] The current MPIM is available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf.

42 U.S.C. §§ 1395ff(f)(1)(B), 1395ff(f)(2)(B). These actions are taken in accordance with the reasonable and necessary provisions in 42 U.S.C. § 1395y(a)(1)(A). See 42 U.S.C. §§ 1395kk-1(a)(4), 1395ff(f)(2)(B).

An LCD is binding only on the contractor that issued it and is not binding at later stages of the Medicare claim review process, including on Administrative Law Judges ("ALJs") who review appeals of MAC determinations. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. § 405.1062(a). However, ALJs must give LCDs "substantial deference" if they are applicable, 42 C.F.R. § 405.1062(a), and if it declines to follow an LCD in a particular case, it "must explain the reasons why the policy was not followed." 42 C.F.R. § 405.1062(b). An ALJ's decision not to follow an LCD "applies only to the specific claim being considered and does not have precedential effect." *Id.*

B. LCDs for Tumor Treatment Field Therapy

After the United States Food and Drug Administration ("FDA") approved the commercial distribution of a TTFT device manufactured by Novocure, Inc., (later rebranded Optune) for treatment of newly diagnosed GBM, DME MACs issued an LCD for TTFT indicating that TTFT was not covered for beneficiaries with GBM. Certified Admin. Record ("CAR") at 149.[5] This meant that a beneficiary would have to go through the claims and administrative appeals process to get a claim for TTFT approved.

[5] The original LCD was issued in October 2015. CAR at 149. A substantively unchanged LCD went into effect on January 1, 2017 which stated that "[t]umor treatment field therapy (E0766) will be denied as not reasonable and necessary." CAR at 14-15. On September 1, 2019, a revised LCD was issued permitting coverage for newly diagnosed GBM and continued coverage for newly diagnosed GBM beyond the first three months of therapy in certain circumstances. *See* CMS, LOCAL COVERAGE DETERMINATION (LCD): TUMOR TREATMENT FIELD THERAPY (TTFT) (L34823). The most recent LCD issued on January 1, 2020 (substantively unchanged from the LCD issued a few months prior) states that TTFT "will be denied as not reasonable and necessary for the treatment of recurrent GBM." *Id.*

C. Claims and Administrative Appeals Process

A beneficiary can challenge the denial of a claim under the Medicare statute by submitting a claim for payment to the Medicare contractor. 42 C.F.R. § 405.904(a)(2). If the claim is denied, the beneficiary must generally exhaust the following four levels of administrative review before filing suit in federal court:

- (1) Redetermination: The beneficiary may seek a redetermination from the Medicare contractor, which must be performed by a person who did not make the initial decision. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940. An LCD is only binding at this level. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. § 405.968(b)(2).
- (2) Reconsideration: A beneficiary may then seek reconsideration by a qualified independent contractor ("QIC") whose members must have "sufficient medical, legal, and other expertise, including knowledge of the Medicare program." 42 U.S.C. §§ 1395ff(b)(1)(A), 1395ff(c); 42 C.F.R. §§ 405.960, 405.968(c)(1).
- (3) Hearing before an ALJ: A beneficiary can then request a hearing before an ALJ, who issues a decision based on the evidence presented at the hearing or otherwise admitted into the administrative record by the ALJ. 42 U.S.C. §§ 1395ff(b)(1)(A), 1395ff(d); 42 C.F.R. §§ 405.1000, 405.1042, 405.1046. CMS or MACs may participate or become a party in ALJ hearings involving beneficiaries represented by counsel. 42 C.F.R. §§ 405.1010(a), 405.1012(a).
- (4) Review by Medicare Appeals Council: Finally, a beneficiary can also request review of an ALJ's decision by the Medicare Appeals Council ("the Council"), a division of the Departmental Appeals Board of the Department of Health and Human Services. 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. §§ 405.902, 405.1100, 405.1122. If the Council does not render a decision within 90 days, a beneficiary may request elevation to district court. 42 C.F.R. § 405.1132.

D. Facts Specific to Plaintiff

Mr. Townsend sought coverage of TTFT for dates of service on August 7, 2018, September 7, 2018, and October 7, 2018. CAR at 67. On August 13, 2018, September 13, 2018 and October 13, 2018, MAC Noridian Healthcare Solutions denied payment of the claims. *Id.* On January 3, 2019, Noridian issued a redetermination affirming the initial denial of the claims. *Id.* Plaintiff then requested reconsideration, and on March 19, 2019, the QIC determined the device

was not covered under Medicare. *Id.* However, the QIC found the supplier liable, rather than Plaintiff. *Id.*

On April 1, 2019, Plaintiff filed a request for an ALJ hearing. CAR at 67. ALJ Brian Butler conducted a hearing on May 29, 2019. *Id.* On June 25, 2019, ALJ Butler issued a decision denying Plaintiff's claims for Medicare coverage of the Optune system for the period at issue. Compl. ¶ 22; CAR at 67-73. ALJ Butler held that even though he was not bound by the LCD "categorically den[ying] coverage for TTFT," he was required to give it "substantial deference . . . unless there [was] a reason particular to the specific case that justifie[d] deviation from [it]." CAR at 71-72. ALJ Butler concluded that deviating from the LCD was not warranted, including because Plaintiff had not been using the TTFT device at the recommended usage rate. CAR at 72-73. Additionally, ALJ Butler found it significant that the new LCD (which had then been proposed and which later went into effect) would provide coverage for newly diagnosed GBM, and thus would not provide coverage for Plaintiff who had been initially diagnosed in 2011. CAR at 68, 73. ALJ Butler found that there was no evidence to suggest that Plaintiff "knew, or should have been expected to know, [that] the device would not be covered," and thus would not be held responsible for payment. CAR at 73.[6]

Following ALJ Butler's decision, Plaintiff appealed that decision to the Medicare Appeals Council. CAR at 19-23. The Medicare Appeals Council did not issue a decision within 90 days, and Plaintiff elected to proceed in district court. CAR at 1; Compl. ¶ 23. On January 22, 2020, the Medicare Appeals Council responded indicating that judicial review was authorized

[6] If Medicare coverage is denied to a beneficiary, Medicare will still cover the claim if neither the supplier nor the beneficiary knew or could reasonably have been expected to know that the item or service would not be covered. 42 U.S.C. § 1395pp; 42 C.F.R. § 411.400(a)(2). The supplier can shift the risk of non-coverage to the beneficiary by providing him with advance written notice (called an "Advance Beneficiary Notice") of the specific reason why the item or service will probably not be covered. 42 C.F.R. § 411.404(b). Here, there was no evidence that Plaintiff had received an Advance Beneficiary Notice. CAR at 73.

within 60 days. Compl. ¶ 24. On February 11, 2020, Plaintiff filed an appeal from ALJ Butler's decision before this Court which has jurisdiction pursuant to 42 U.S.C. §§ 405(g) and 1395ff(b). Compl. ¶ 5.

Prior to and subsequent to receiving ALJ Butler's decision denying coverage of TTFT, Plaintiff received favorable decisions from three different ALJs:

- On November 8, 2018 by ALJ David Krane for treatment provided from August through October 2017 (ALJ Appeal No. 1-7737575148), CAR at 1411-1425;
- On February 4, 2019 by ALJ Thomas Tyler for treatment provided from February through April 2018 (ALJ Appeal No. 1-8116629727), Compl. ¶ 21, CAR at 51-57; and
- On August 15, 2019 by ALJ Timothy Gates for treatment provided from November 2018 through January 2019 (ALJ Appeal No. 1-8637672132), CAR at 10-17.[7]

The issue considered in each of these hearings was whether TTFT is "medically reasonable and necessary" for Plaintiff and a Medicare covered benefit for him. CAR at 10-11, 51, 1419-1424. All ALJ's held that TTFT was medically reasonable and necessary for Plaintiff and a Medicare covered benefit for him. CAR at 17, 57, 1425. None of these decisions were appealed by the

[7] These decisions are all part of the administrative record since they were submitted by Plaintiff to the Medical Appeals Council as part of his appeal from ALJ Butler's decision. Def. Mot. at 9, n.3; Pl. Opp. at 6; CAR at 5-17, 19-57. The parties dispute whether these decisions are properly considered by this Court given the Secretary's assertion that the decisions were not before ALJ Butler. Def. Opp. at 5. According to Plaintiff, at least one of the "prior favorable ALJ decision[s]" was before ALJ Butler. Pl. Opp. at 6; CAR at 2124-2177. While the Second Circuit has held in the *social security* context that "new evidence submitted to the Appeals Council following the ALJ's decision becomes part of the administrative record for judicial review when the Appeals Council denies review of the ALJ's decision," *Perez v. Chater*, 77 F.3d 41, 45 (2d Cir. 1996), it has not had occasion to decide this question in the Medicare context. This question need not be decided, however, because the Court reviews the ALJ's legal conclusions *de novo, see infra.* p. 8, and has authority to take judicial notice of these decisions. *See Opoka v. I.N.S.*, 94 F.3d 392, 394-95 (7th Cir. 1996) (recognizing that it was limited "to reviewing the evidence that was before the BIA at the time it made its decision," but taking judicial notice of "the relevant decisions of courts and administrative agencies, whether made before or after the decision under review . . . Indeed, it is a well-settled principle that the decision of another court or agency, including the decision of an administrative law judge, is a proper subject of judicial notice"); *see also Estate of Landers*, 545 F.3d at 113 (stating that the district court "ordinarily must base its judgment upon the pleadings and transcript of the record," but "[n]evertheless, the district court has adequate authority to resolve any statutory or constitutional contention that the agency [did] not, or cannot decide, a power that includes, where necessary, the authority to develop an evidentiary record" (internal citations and quotation marks omitted)); *Liberty Mut. Ins. Co. v. Rotches Pork Packers, Inc.*, 969 F.2d 1384, 1388 (2d Cir. 1992) ("A court may take judicial notice of a document filed in another court not for the truth of the matters asserted . . . but rather to establish the fact of such litigation and related filings." (internal citations and quotation marks omitted)).

Secretary and are thus final for the purposes of administrative exhaustion. CAR at 5; 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. §§ 405.1048, 405.1136.[8]

STANDARD OF REVIEW

Under Fed. R. Civ. P. 56, summary judgment is proper where admissible evidence in the form of affidavits, deposition transcripts, or other documentation demonstrates the absence of a genuine issue of material fact and one party's entitlement to judgment as a matter of law. *See Viola v. Philips Med. Sys. of N. Am.*, 42 F.3d 712, 716 (2d Cir. 1994) (citing Fed. R. Civ. P. 56(c)). Neither party has identified any disputed material fact. Accordingly, the only question before the Court is whether either party is entitled to judgment as a matter of law.

"A district court's review of the Secretary's determination is limited to 'whether the [Secretary] applied the proper legal standards, whether its factual findings were supported by substantial evidence, and whether [the Secretary] provided a full and fair hearing.'" *Glick ex rel. Glick v. Johnson*, No. 09-cv-0666, 2011 WL 6140523, at *4 (E.D.N.Y. Dec. 9, 2011) (quoting *Kaplan ex rel. Estate of Kaplan v. Leavitt*, 503 F. Supp. 2d 718, 722 (S.D.N.Y. 2007)). The Secretary is correct that the Secretary's findings of fact in a final decision are to be upheld if they are supported by substantial evidence. *See* 42 U.S.C. § 405(g); *Keefe ex rel. Keefe v. Shalala*, 71 F.3d 1060, 1062 (2d Cir. 1995). However, the Secretary's (or in this case, ALJ's) conclusions of law are reviewed *de novo*, *Keefe*, 71 F.3d at 1062, and "[f]ailure to apply the correct legal standards is grounds for reversal," *Pollard v. Halter*, 377 F.3d 183, 189 (2d Cir. 2004) (quoting *Townley v. Heckler*, 748 F.2d 109, 112 (2d Cir. 1984)) (internal quotation marks omitted).

[8] On May 4, 2020, ALJ Carolyn Cohn-Morros issued a favorable decision for Plaintiff regarding Medicare coverage for TTFT provided from May through August 2019 (ALJ Appeal No. 3-9212587609). Young Decl., Ex. G. However, this decision was appealed by the Secretary on July 8, 2020 and is not final. Pl. Opp. at 5, n. 1. It is also not a part of the administrative record. However, the Court will take judicial notice of this decision for the reasons discussed above.

Plaintiff appears to suggest that the Administrative Procedures Act ("APA"), 5 U.S.C. § 551 *et seq.*, and its standard of review applies here. Pl. Reply at 8. "Under the APA, a court may overturn an agency decision if it is arbitrary, capricious, or an abuse of discretion." *Diapulse Corp. of Am. v. Sebelius*, No. 06-cv-2226, 2010 WL 1037250, at *6 (E.D.N.Y. Jan. 21, 2010) (citing 5 U.S.C. § 706(2)(A)), *report and recommendation adopted by* 2010 WL 1752571 (E.D.N.Y. Mar. 17, 2010). However, the APA standard does not apply in Medicare appeals pursuant to 42 U.S.C. § 1395ff, and thus does not apply in this case. *See id.*; *see also Estate of Morris v. Shalala*, 207 F.3d 744, 745 (5th Cir. 2000) (rejecting plaintiff's argument for application of APA standard in an appeal pursuant to § 1395ff); *but cf. Willowood of Great Barrington, Inc. v. Sebelius*, 638 F. Supp. 2d 98, 102 (D. Mass. 2009) (applying APA standard to appeal pursuant to § 1395ff). Plaintiff's citation to *Friedman v. Sebelius*, 686 F.3d 813, 826-27 (D.C. Cir. 2012) is unavailing since that case involved an appeal pursuant to 42 U.S.C. § 1320a-7(f).

DISCUSSION

I. PLAINTIFF HAS STANDING TO BRING HIS CLAIM PURSUANT TO 42 U.S.C. § 405(g)

The Court must first consider the threshold question of whether Plaintiff has standing to bring this suit. "[T]o have standing to bring suit, a plaintiff is constitutionally required to have suffered (1) a concrete, particularized, and actual or imminent injury-in-fact (2) that is traceable to defendant's conduct and (3) [that is] likely to be redressed by a favorable decision." *Woods v. Empire Health Choice, Inc.*, 574 F.3d 92, 96 (2d. Cir. 2009) (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992); *Port Wash. Teachers' Ass'n v. Bd. of Educ.*, 478 F.3d 494, 498 (2d Cir. 2007)). "If plaintiffs lack Article III standing, a court has no subject matter jurisdiction to hear their claim." *Mahon v. Ticor Title Ins. Co.*, 683 F.3d 59, 62 (2d Cir. 2012) (quoting *Cent.*

States Se. & Sw. Areas Health & Welfare Fund v. Merck-Medco Managed Care, L.L.C., 433 F.3d 181, 198 (2d Cir. 2005)).

The Secretary argues that Plaintiff lacks standing because ALJ Butler did not hold Plaintiff responsible for the amount owed, and instead held the device manufacturer liable for the costs. *See, e.g.*, Def. Mot. at 10. According to the Secretary, because Mr. Townsend "does not have to pay anything, he has not suffered an injury in fact that is 'actual or imminent.'" *Id.* In making this argument, the Secretary relies heavily on *Spokeo, Inc. v. Robins*, and in particular on the Supreme Court's statement that a plaintiff cannot "allege a bare procedural violation, divorced from any concrete harm, and satisfy the injury-in-fact requirement of Article III." --- U.S. ---, 136 S. Ct. 1540, 1549 (2016).

The Court disagrees with the Secretary and finds that Mr. Townsend has standing to bring this suit even though he did not suffer any monetary harm. As a threshold matter, it is worth noting that it "has long been clear that economic injury is not the only kind of injury that can support a plaintiff's standing." *Vill. of Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 262-63 (1977) (internal citations omitted); *Gambles v. Sterling Infosystems, Inc.*, 234 F. Supp. 3d 510, 517 (S.D.N.Y. 2018) ("A claimed injury, however, need not be tangible to be concrete. Although tangible injuries like monetary loss are perhaps easier to recognize, in a variety of contexts, intangible injuries have been held sufficiently concrete to be cognizable." (internal citations and quotation marks omitted)). Furthermore, as the Supreme Court has recognized in its prior precedent and reiterated in *Spokeo*, "Congress may create a statutory right or entitlement the alleged deprivation of which can confer standing to sue even where the plaintiff would have suffered no judicially cognizable injury in the absence of statute." *Warth v. Seldin*, 422 U.S. 490, 514 (1975) (citing *Linda R.S. v. Richard D.*, 410 U.S. 614, 617 n.3 (1973));

see also Lujan, 504 U.S. at 578; *Spokeo*, 136 S.Ct. at 1549. *Spokeo* concerned a "bare procedural violation" of the Fair Credit Reporting Act and did not overturn this prior precedent. *See Spokeo*, 136 S. Ct. at 1550; *see also id.* at 1553 (Thomas, J., concurring) ("Congress can create new private rights and authorize private plaintiffs to sue based simply on the violation of those private rights . . . A plaintiff seeking to vindicate a statutorily created private right need not allege actual harm beyond the invasion of that private right." (internal citations omitted)); *Bautz v. ARS Nat'l Servs., Inc.*, 226 F. Supp. 3d 131, 141 (E.D.N.Y. 2016). Instead, *Spokeo* clarified that just because Congress elevated certain "intangible harms," that did "not mean that a plaintiff automatically satisfies the injury-in-fact requirement whenever a statute grants a person a statutory right and purports to authorize that person to sue to vindicate that right." *Spokeo*, 136 S. Ct. at 1549. More specifically, "Article III standing requires a concrete injury even in the context of a statutory violation" and a plaintiff cannot "allege a bare procedural violation, divorced from any concrete harm, and satisfy the injury-in-fact requirement of Article III." *Id.* (citing *Summers v. Earth Island Inst.*, 555 U.S. 488, 496 (2009)).

The holding in *Spokeo* requiring showing "actual harm" beyond violation of the statute does not extend to substantive rights created by statute. The interpretation and application of *Spokeo* by the Second Circuit, and multiple district courts in this Circuit support this conclusion. According to the Second Circuit, *Spokeo* did not "categorically . . . preclude[] violations of statutorily mandated procedures from qualifying as concrete injuries supporting standing" and instead "instruct[ed] that an alleged procedural violation can by itself manifest concrete injury where Congress conferred the procedural right to protect a plaintiff's concrete interests and where the procedural violation presents a 'risk of real harm' to that concrete interest." *Strubel v. Comenity Bank*, 842 F.3d 181, 189-90 (2d Cir. 2016) (plaintiff had standing to sue for certain

violations of TILA) (internal citations omitted). That interpretation of *Spokeo* seems to suggest that violations of statutes creating substantive rights also "manifest concrete injury" and are sufficient to support standing. In fact, many district courts in this Circuit have applied that reasoning in concluding that plaintiffs had standing to sue for violations of statutes creating substantive rights. *See, e.g.*, *Melito v. Am. Eagle Outfitters, Inc.*, 14-cv-2440, 2017 WL 3995619, at *4 (S.D.N.Y. Sept. 11, 2017) ("It follows that if a bare procedural violation can cause concrete injury, then a violation of substantive rights created by Congress must surely cause a concrete injury.") (violation of TCPA sufficient to confer Article III standing), *aff'd in part, dismissing appeal in part sub nom. Melito v. Experian Mktg. Sols., Inc.*, 923 F.3d 85 (2d Cir. 2019), *cert. denied*, 140 S. Ct. 677; *see also Grosz v. LSF9 Master Participation Tr.*, 16-cv-4035, 2017 WL 6383912, at *9 (E.D.N.Y. Aug. 7, 2017) ("Since the Supreme Court's decision in *Spokeo*, district courts in this Circuit have consistently held that . . . [violations] of the FDCPA satisf[y] the concrete injury requirement for Article III standing.") (listing cases); *Boelter v. Hearst Commc'ns, Inc.*, 269 F. Supp. 3d 172, 185-86 (S.D.N.Y. 2017) ("Plaintiff's alleged injury is not a 'bare procedural violation,' but a substantive violation . . ." causing a concrete injury) (listing cases); *Bautz*, 226 F. Supp. 3d at 141 ("[I]n cases where a plaintiff sues to enforce a substantive legal right conferred by statute . . . the infringement of that right constitutes, in and of itself, a concrete injury," and thus Plaintiff has standing to pursue that claim. "Put differently, there is a meaningful distinction between the direct violation of a specific statutory interest that Congress has recognized . . . and an ancillary procedural infraction that may or may not materially harm that interest.").

Contrary to the Secretary's assertions, the Supreme Court's decision in *Thole v. U.S. Bank N.A.*, does not compel the conclusion that Plaintiff has no standing to sue. --- U.S. ---, 140

S. Ct. 1615 (2020). *Thole* involved two participants in U.S. Bank's "defined-benefit" retirement plan who alleged that Defendants had mismanaged their plan and had thus violated ERISA's duties of loyalty and prudence. *Thole*, 140 S. Ct. at 1618. The Supreme Court held that they had no standing to sue because they had "no concrete stake in the lawsuit" since they had "received all of their monthly benefit payments so far, and the outcome of this suit would not affect their future benefit payments." *Id.* at 1619. In fact, "[i]f [petitioners] were to *lose* this lawsuit, they would still receive the exact same monthly benefits that they are already slated to receive, not a penny less. *Id.* (emphasis in original). "If [petitioners] were to *win* this lawsuit, they would still receive the monthly benefits that they are already slated to receive, not a penny more." *Id.* (emphasis in original). However, *Thole* is distinguishable from the facts in this case. As Justice Thomas explained, "[i]n a suit for the violation of a private right, courts historically presumed that the plaintiff suffered a *de facto* injury [if] his personal, legal rights [were] invaded." *Id.* at 1623 (Thomas, J., concurring) (quoting *Spokeo*, 136 S. Ct. at 1551) (internal quotation marks omitted). "In [*Thole*], however, none of the rights identified by petitioners belong to them. The fiduciary duties created by ERISA are owed to the plan, not petitioners." *Id.* (citing 29 U.S.C. §§ 1104(a)(1), 1105(a), 1106(a)(1), 1106(b), 1109(a)). Here, there is no question that the substantive legal rights conferred by the Medicare statute belong to Plaintiff.

At least one court in this Circuit has found that wrongful denial of benefits is sufficient to confer Article III standing post-*Spokeo*. *See Fishman by Fishman v. Daines*, 247 F. Supp. 3d 238, 248 (E.D.N.Y. 2017) ("[P]laintiffs had standing at the outset of this litigation to challenge the denial of Medicaid benefits. . . [because] this Court and the Second Circuit found that plaintiffs faced an 'actual or imminent' injury that was 'not conjectural or hypothetical,' based on the violation of a 'substantive legal right conferred by statute. . . .'" (internal citations

omitted)). As Plaintiff points out, some district courts in this Circuit have previously held that the denial of Medicare benefits was sufficient to confer plaintiff Article III standing to sue even where the Plaintiff did not bear costs. *See, e.g.*, *Ryan v. Burwell*, No. 5:14-cv-00269, 2015 WL 4545806, at *5-7 (D. Vt. July 27, 2015) ("[P]laintiffs' statutory right to receive Medicare benefits and to file suit under 42 U.S.C. § 405(g) when these are denied is beyond question;" thus, Plaintiff had standing to sue for denial of Medicare benefits even where Medicaid was "also willing to cover the charges in question."); *Anderson v. Sebelius*, No. 5:09-cv-16, 2010 WL 4273238, at * 3 (D. Vt. Oct. 25, 2010) (beneficiary "retains his or her 'injured' status when the Secretary refuses to pay providers for Medicare benefits the beneficiary has received" even though ALJ "waived Plaintiff's financial responsibility for the services in question"); *Longobardi v. Bowen*, No. H-87-628, 1988 WL 235576, at *2 (D. Conn. Oct. 25, 1988) ("An injury sufficient to satisfy [A]rticle III can be established merely by virtue of the alleged denial of statutorily-created rights or entitlements.") (citing *Warth*, 422 U.S. at 500).[9]

Because Plaintiff is challenging the denial of Medicare benefits, i.e., a violation of a "substantive legal right conferred by statute," this Court is satisfied that Plaintiff has Article III standing to sue.[10]

[9] *Cf. Hull v. Burwell*, 66 F. Supp. 3d 278, 281 (D. Conn. 2014) ("A plaintiff has no constitutional injury-in-fact that would allow her to complain in federal court when her 'injury' consists solely of a financial liability that has been paid for in full by a third party . . . absent a showing of some residual or collateral harm to the plaintiff."). The Court respectfully disagrees with the conclusion that "some residual or collateral harm" is necessary for the reasons explained above. The Court also respectfully disagrees with the decisions of courts outside this Circuit holding that plaintiffs in similar circumstances have no standing to sue. *See Wilmoth v. Azar*, No. 3:20-cv-120, 2021 WL 681118 (N.D. Miss. Feb. 22, 2021); *Oxenberg v. Cochran*, No. 20-cv-738, 2021 WL 462731 (E.D. Pa. Feb. 9, 2021); *Prosser v. Azar*, No. 20-cv-194, 2020 WL 6266040 (E.D. Wis. Oct. 21, 2020), *appeal docketed*, No. 20-3070 (7th Cir. Oct. 22, 2020); *Komatsu v. Azar*, No. 20-cv-00280, 2020 WL 5814116 (C.D. Cal. Sept. 24, 2020), *appeal dismissed*, No. 20-56001, 2020 WL 7865597 (9th Cir. Oct. 2, 2020); *Pehoviack v. Azar*, No. 20-cv-00661, 2020 WL 4810961 (C.D. Cal. July 22, 2020).

[10] The Court need not reach the question whether the other alleged harms identified by Plaintiff are sufficient to establish standing.

II. THE MATTER SHOULD BE REMANDED FOR FURTHER REVIEW

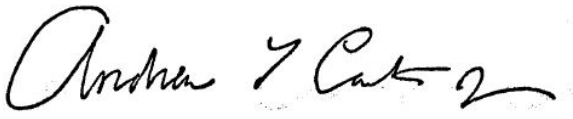
While Plaintiff does have standing to bring this suit, we think it appropriate that this matter be remanded for further review and thus need not reach the issue of whether the principles of collateral estoppel apply in the Medicare context.[11] We find that ALJ Butler's failure to address ALJ Krane's previous decision regarding claims for reimbursement for the same services, to the same beneficiary, for the same diagnosis, undermines ALJ Butler's subsequently issued ruling, and supports a finding that his decision was not supported by substantial evidence. *See Reg'l Human Servs., Inc. v. Sebelius*, No. 4:08-cv-1130, 2011 WL 6148589, at *3 (M.D. Pa. Dec. 8, 2011). Thus, the Medicare Appeals Council's unfavorable administrative decision is REVERSED and REMANDED for further consideration, including consideration of ALJ Krane's previous decision, as well as the decisions of other ALJs that have been issued in favor of Mr. Townsend.

CONCLUSION

For the reasons herein, both parties' summary judgment motions are **DENIED**. The Court hereby **REMANDS** this matter for further proceedings consistent with this opinion. The Clerk of Court is hereby directed to close this case.

SO ORDERED.

Dated: March 25, 2021
New York, New York



ANDREW L. CARTER, JR.
United States District Judge

[11] This issue appears to be one of first impression in this District and in this Circuit.