UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

JOHN THUMANN,	:	Case No. 1:20-cv-125
Plaintiff,	:	Judge Timothy S. Black
vs.	:	
NORRIS COCHRAN,[1] in his capacity as the Secretary of the United States Department of Health and Human Services,	:	
Defendant.	:	

ORDER RESOLVING THE PARTIES' PENDING MOTIONS (Docs. 9, 11)

This case is before the Court on: (1) Plaintiff's Motion for Summary Judgment (Doc. 9); and (2) Defendant's Combined Motion to Dismiss and Cross-Motion for Summary Judgment (Doc. 11). Also before the Court are the parties' responsive memoranda. (*See generally* Docs. 14, 15, 16, 17, 18, 19, 20, 21).

I. BACKGROUND

Plaintiff John Thumann ("Plaintiff" or "Mr. Thumann"), a natural person residing in the State of Ohio, has brought this action against Defendant Norris Cochran ("Defendant" or the "Secretary"), the Secretary of Health and Human Services, to challenge the denial of certain claims for Medicare coverage, pursuant to 42 U.S.C. § 405(g) and 5 U.S.C. §§ 706(1). (Doc. 1 at ¶¶ 7–8, 26–37).

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

Plaintiff suffers from glioblastoma multiforme ("GBM"), a particularly lethal form of brain cancer. (Doc. 6-2 at 11, 53). Since 2018, Plaintiff has used tumor treatment field therapy ("TTFT") to manage his condition. (*Id.*) TTFT is an FDA-approved treatment for GBM, which uses alternating electric fields to interfere with the replication of tumor cells. (*Id.* at 17; *see also* Doc. 1 at ¶ 14). While TTFT does not cure GBM, it greatly increases patients' survival rates. (Doc. 1 at ¶¶ 15–17; Doc. 5 at ¶¶ 15–17).

The durable medical equipment ("DME") that provides TTFT is called the "Optune system." (Doc. 1 at ¶ 17; Doc. 5 at ¶ 17). The sole supplier of the Optune system is a company called Novocure, Inc. ("Novocure"). (Doc. 1 at ¶ 17; Doc. 5 at ¶ 17). Novocure rents the Optune system to GBM patients on a monthly basis. (Doc. 1 at ¶ 17; Doc. 5 at ¶ 17). As such, any Medicare beneficiary who uses the Optune system must submit monthly claims for its coverage. (Doc. 1 at ¶ 17; Doc. 5 at ¶ 17).

A. The Medicare claims process

Medicare is a federally funded health insurance program that serves elderly and disabled persons. *See* 42 U.S.C. §§ 1395, *et seq.* Part B of the Medicare statute allows qualified beneficiaries to submit claims for the use of DME—such as the Optune system. *Id.* §§ 1395k(a), 1395x(s)(6). DME is covered by Part B of the Medicare statute if it is "reasonable and necessary for the diagnosis or treatment of illness or injury . . . ." *Id.* § 1395y(a)(1)(A). DME is reasonable and necessary if it is safe, effective, and not experimental. Medicare Program Integrity Manual § 13.5.4 (Feb. 12, 2019).[2]

[2] Available at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pim83c13.pdf.

To obtain Medicare coverage, a beneficiary must first submit a claim to a "MAC"—a contractor hired to administer Medicare's day-to-day functions. 42 U.S.C. § 1395kk-1; 42 C.F.R. § 405.920. The MAC reviews the beneficiary's claim and determines whether the DME sought is reasonable and necessary. 42 U.S.C. § 1395kk-1; 42 C.F.R. § 405.920. In making its decision, the MAC is bound by any local coverage determinations ("LCDs") applicable to the DME. 42 U.S.C. § 1395ff(c)(3)(B). LCDs are written policy decisions issued by MACs regarding whether particular items/services are covered by Medicare. *Id.* § 1395ff(f)(2)(B).

If the MAC determines that coverage is appropriate, the beneficiary is generally entitled to payment through Medicare. *See* 42 C.F.R. § 405.928. If, however, the MAC determines that coverage is not appropriate, the beneficiary may seek review of the MAC's decision. *See generally* 42 U.S.C. § 1395ff. A five-part appeals process governs the review of Medicare denials. *See generally id.*; *see also Porzecanski v. Azar*, 943 F.3d 472, 476 (D.C. Cir. 2019) (summarizing the five-part Medicare appeals process); *Maxmed Healthcare, Inc. v. Price*, 860 F.3d 335, 338 (5th Cir. 2017) (summarizing the same).

First, the beneficiary must ask the MAC for a "redetermination" of its initial decision. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940. In making the redetermination, the MAC is, again, bound by any LCDs applicable to the DME. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. § 405.968(b). Second, if the MAC denies coverage on redetermination, the beneficiary may ask a qualified independent contractor (a "QIC") for a "reconsideration" of the MAC's denial of coverage. 42 U.S.C. § 1395ff(c)(1)–(2);

42 C.F.R. § 405.960. Unlike the MAC, the QIC is not bound by any applicable LCDs during reconsideration. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. § 405.1062(a).

Third, if the QIC denies coverage on reconsideration, the beneficiary may appeal the QIC's reconsideration to an Administrative Law Judge ("ALJ"). 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 405.1000. When reviewing the QIC's reconsideration, the ALJ is not bound by any applicable LCDs. 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. § 405.1062(a). But, that said, the ALJ must pay substantial deference to such LCDs. 42 C.F.R. § 405.968(b)(2); *see also id.* § 405.1062(a). If the ALJ departs from an applicable LCD, it must "explain the reasons why the policy was not followed." *Id.* § 405.1062(b); *see also id.* § 405.968(b)(3).

Fourth, if the ALJ denies coverage, the beneficiary may appeal the ALJ's decision to the Medicare Appellate Panel (the "Council"). 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 405.1100. And fifth, if the Council does not issue a decision in 90 days, the beneficiary may seek review in federal court. 42 C.F.R. § 405.1132. Again, during these last two steps of the review process, any applicable LCDs are entitled to substantial deference—but are not binding. *See* 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. § 405.1062(a); *see also U.S. ex rel. Lynch v. Univ. of Cincinnati Med. Ctr., LLC*, No. 1:18-CV-587, 2020 WL 1322790, at *18 (S.D. Ohio Mar. 20, 2020).

B. Facts specific to Plaintiff

Between August 2018 and August 2019, Plaintiff submitted monthly claims for the Optune system's use. (Doc. 6-2 at 10, 25, 52; Doc. 9-1 at 6). However, each of Plaintiff's claims was initially denied by the assigned MAC. (Doc. 6-2 at 10, 25, 52;

Doc. 9-1 at 6). This is because, at the time of the claims' submission, there was an unfavorable LCD in place. (*See, e.g.*, Doc. 6-2 at 15–16). That LCD (the "Original LCD") did not provide any circumstances under which TTFT would be covered. (*Id.* at 17). Instead, it simply stated as follows: "Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary." (*Id.* at 16).

Plaintiff challenged the initial denials through the redetermination and reconsideration processes, but neither the MAC nor the QIC awarded coverage—so, Plaintiff filed four ALJ appeals. (Doc. 6-2 at 10, 25, 52; Doc. 9-1 at 6). ALJ MacDougall considered whether Plaintiff's claims were covered from August–October 2019; ALJ Gates considered whether Plaintiff's claims were covered from November 2018–January 2019; ALJ Bartlett considered whether Plaintiff's claims were covered from February–May 2019; and ALJ Bruch considered whether Plaintiff's claims were covered from June–August 2019.[3] (Doc. 6-2 at 10, 25, 52; Doc. 9-1 at 6).

Although the facts underlying the four appeals were the same, Plaintiff received two different results. ALJs Gates, Bartlett, and Bruch each decided to depart from the Original LCD and award coverage. (Doc. 6-2 at 10, 25; Doc. 9-1 at 6). ALJ MacDougall, however, reached the opposite conclusion. (Doc. 6-2 at 52). ALJ MacDougall concluded that, while Plaintiff's arguments in support of coverage were "outstanding," ALJ MacDougall could not depart from the Original LCD on the record

[3] While ALJ Bruch's decision is not part of the certified administrative record, the Court finds it proper to take judicial notice of ALJ Bruch's decision. *Accord Opoka v. INS*, 94 F.3d 392, 394–95 (7th Cir. 1996) (taking judicial notice of administrative proceedings post-dating those described in an administrative record).

presented. (*Id.* at 57–58). As such, ALJ MacDougall denied Plaintiff Medicare coverage from August–October 2018.[4] (*Id.* at 58).

Importantly however, even though ALJ MacDougall technically denied Plaintiff Medicare coverage, ***ALJ MacDougall did not impose any treatment-related costs on Plaintiff***. (*Id.*) Instead, ALJ MacDougall determined that Novocure was required to pay for Plaintiff's treatment during the period of noncoverage. (*Id.*) Thus, to be clear, on the record presented, **Plaintiff has received all the TTFT prescribed by his physicians, and Plaintiff has never had to pay for his medical care.** (Doc. 6-2 at 10, 25, 52; Doc. 9-1 at 6). Novocure paid for Plaintiff's August–October 2018 treatment; and Medicare paid for the rest. (Doc. 6-2 at 10, 25, 52; Doc. 9-1 at 6).

Claim period	*Payment status*
August 2018 to October 2018	TTFT treatment paid by Novocure
November 2018 to January 2019	TTFT treatment paid by Medicare
February 2019 to May 2019	TTFT treatment paid by Medicare
June 2019 to August 2019	TTFT treatment paid by Medicare

[4] Notably, ALJ MacDougall did not dispute that TTFT is a medically accepted treatment. (Doc. 6-2 at 57–58). Instead, ALJ MacDougall denied coverage on the basis of a procedural concern. (*Id.*) ALJ MacDougall noted that all of Plaintiff's arguments in support of coverage challenged the *validity* of the Original LCD. (*Id.*) And ALJ MacDougall concluded such a challenge (*i.e.*, to the Original LCD's *validity*) was inappropriate in the context of Plaintiff claims appeal. (*See id.* (stating that, while 42 C.F.R. § 405.1062 allows an ALJ to *depart* from an LCD in the context of a claims appeal, 42 C.F.R. § 405.1062 does not allow an ALJ to invalidate an LCD in the context of a claims appeal)). On this basis, ALJ MacDougall concluded that he was without an acceptable basis to depart from the Original LCD on the record presented. (*Id.*)

(Doc. 6-2 at 10, 25, 52; Doc. 9-1 at 6).

Since August 2019, Plaintiff has continued to submit monthly claims for TTFT. (*See* Doc. 1 at ¶ 17; Doc. 9 at 8–9). However, on the record presented, there is no indication that any of Plaintiff's post-August 2019 claims have been denied. (*Cf.* Doc. 15 at 2). This would appear to be because, on September 1, 2019, ***the Original LCD was amended to cover TTFT for patients with GBM***. (Doc. 6-2 at 115–24). The new LCD (the "Current LCD") provides that TTFT is permitted for: (1) patients with newly diagnosed GBM under appropriate circumstances, and (2) continued coverage where the "beneficiary is continuing to use and is benefiting from TTFT."[5] (*Id.* at 119).

C. The procedural history of this case

On September 10, 2020, Plaintiff appealed ALJ MacDougall's decision to the Council. (Doc. 6-2 at 38–44). And then, when the Council did not issue a decision within 90 days, Plaintiff filed a Complaint in this Court. (*Id.* at 1–5; *see also* Doc. 1). In his Complaint, Plaintiff brings several claims against Defendant under 42 U.S.C. § 405(g) and 5 U.S.C. §§ 706(1). (Doc. 1 at ¶¶ 26–37). As to relief, Plaintiff asks the Court the reverse ALJ MacDougall's coverage denial as arbitrary and capricious. (*See generally* Doc. 1). Plaintiff also asks the Court to hold that Defendant is collaterally estopped from

[5] The TTFT LCD was revised again on January 1, 2020. *See* https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?lcdid=34823 (last accessed Mar. 31, 2021). On the Court's review, the Current LCD is substantially similar to the Sept. 1, 2019 revision. *See id.* As such, for sake of simplicity, the Court refers to the 2019 and 2020 LCDs collectively as the "Current LCD."

relitigating whether TTFT is a covered benefit moving forward. (*See generally id.*).

On August 24, 2020, Plaintiff filed a Motion for Summary Judgment on the issue of collateral estoppel. (Doc. 9). Then, on October 8, 2020, Defendant filed a Combined Motion to Dismiss and Cross-Motion for Summary Judgment. (Doc. 11). Defendant's motion: (1) responds to Plaintiff's arguments regarding collateral estoppel; and (2) argues that this case should be dismissed under Rule 12(b)(1) for lack of standing. (*Id.*) As the existence of standing presents a threshold issue, the Court must address the Rule 12(b)(1) argument first. And, as the Court concludes that the Rule 12(b)(1) argument has merit, the Court does not reach the issue of collateral estoppel in this Order.

II. STANDARD OF REVIEW

Where a defendant raises the issue of lack of subject-matter jurisdiction under Rule 12(b)(1), the plaintiff has the burden of proving jurisdiction in order to survive the motion to dismiss. *Moir v. Greater Cleveland Reg'l Transit Auth.*, 895 F.2d 266, 269 (6th Cir. 1990). "A court lacking jurisdiction cannot render judgment but must dismiss the cause at any stage of the proceedings in which it becomes apparent that jurisdiction is lacking." *Basso v. Utah Power & Light Co.*, 495 F.2d 906, 909 (10th Cir. 1974).

Motions to dismiss for lack of subject-matter jurisdiction fall into two general categories: facial attacks and factual attacks. *United States v. Ritchie*, 15 F.3d 592, 598 (6th Cir. 1994). A facial attack on subject-matter jurisdiction goes to whether the plaintiff has properly alleged a basis for subject-matter jurisdiction, and the trial court takes the allegations of the complaint as true. *Ohio Nat'l Life Ins. Co. v. United States*, 922 F.2d 320, 325 (6th Cir. 1990). In a factual attack, the Court must weigh the

"evidence [before it] to arrive at the factual predicate that subject matter jurisdiction exists or does not exist." *Id.*

III. ANALYSIS

Defendant moves to dismiss Plaintiff's complaint, pursuant to Federal Rule of Civil Procedure 12(b)(1) for lack of Article III standing. (Doc. 11); *see Primus Grp., LLC v. Smith & Wesson Corp.*, No. 19-3992, 2021 WL 423741, at *2 (6th Cir. Feb. 8, 2021). Specifically, Defendant brings a factual attack and, as such, the Court must weigh the evidence before it to arrive at the factual predicate that subject matter jurisdiction exists or does not exist. *See Ohio Nat'l Life Ins. Co.*, 922 F.2d at 325.

A Court does not have the subject matter jurisdiction to hear a case, unless the Plaintiff has standing under Article III of the U.S. Constriction. *Memphis A. Philip Randolph Inst. v. Hargett*, 978 F.3d 378, 385 (6th Cir. 2020). The standing doctrine ensures that a plaintiff in federal court has "such a ***personal stake*** in the outcome of the controversy as to warrant his invocation of federal-court jurisdiction . . . ." *Warth v. Seldin*, 422 U.S. 490, 498 (1975) (quoting *Baker v. Carr*, 369 U.S. 186, 204 (1962)) (quotation marks omitted and emphasis added); *see also O'Shea v. Littleton*, 414 U.S. 488, 494 (1974). To establish standing, a plaintiff:

> (1) must have suffered some ***actual or threatened injury*** due to the alleged illegal conduct (the "injury in fact element"); (2) the injury must be fairly traceable to the challenged action (the "causation element"); and (3) there must be a substantial likelihood that the relief requested will redress or prevent [plaintiff]'s injury (the "redressability element").

In re Cannon, 277 F.3d 838, 852 (6th Cir. 2002) (quoting *Grendell v. Ohio Supreme Court*, 252 F.3d 828, 832 (6th Cir.2001), *cert. denied*, 534 U.S. 955 (2001)) (emphasis added).

In this case, the parties debate only the first of the three standing elements. Defendant argues that Plaintiff has failed to establish an injury in fact; Plaintiff disagrees. (Docs. 11, 15). The Court has carefully reviewed the facts of this case. On the record presented, Plaintiff has not suffered the type of actual or threatened injury needed to establish an injury in fact. And, absent an injury in fact, Plaintiff lacks the type of personal stake necessary to invoke this Court's judication. As such, dismissal is proper under Rule 12(b)(1) for lack of standing.

A. Actual injury

Plaintiff has not suffered an actual injury as a result of Defendant's conduct. To establish an actual injury, a plaintiff must show that he has suffered "concrete" harm.[6] *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548 (2016). "A 'concrete' injury must be '*de facto*'; that is, it must actually exist," and therefore must be "'real,' and not 'abstract.'" *Id.* (citations omitted). "A statutory violation in and of itself is insufficient to establish standing." *Lyshe v. Levy*, 854 F.3d 855, 859 (6th Cir. 2017). As stated by the United States Supreme Court, "**Article III standing requires a concrete injury even in the context of a statutory violation**." *Spokeo*, 136 S. Ct. at 1549 (emphasis added); *see also*

[6] A plaintiff must also show that he has suffered a harm that is particularized—*i.e.*, a harm that affects the plaintiff in an individual way. *Spokeo*, 136 S. Ct. at 1548. However, as neither party disputes that the Plaintiff's alleged harm is particularized, the Court will focus its analysis on the concrete prong. (*See* Docs. 11, 15).

Muransky v. Godiva Chocolatier, Inc., 979 F.3d 917, 930 (11th Cir. 2020); *Bassett v. ABM Parking Servs., Inc.*, 883 F.3d 776, 782 (9th Cir. 2018); *Meyers v. Nicolet Rest. of De Pere, LLC*, 843 F.3d 724, 727 n.2 (7th Cir. 2016).

This is not to say that a concrete injury must be tangible—indeed, "intangible injuries can nevertheless be concrete." *Spokeo*, 136 S. Ct. at 1549. And under certain circumstances, the deprivation of a statutory right may give rise to a concrete injury. *Id.* In such cases, "standing is satisfied when the injury asserted by a plaintiff 'arguably [falls] within the zone of interests to be protected or regulated by the statute ... in question …, [such that the] injury of which [plaintiff] complain[s] … is injury of a kind that [the statute] seeks to address." *Fed. Election Comm'n v. Akins*, 524 U.S. 11, 20 (1998). Thus, "[i]n determining whether an intangible harm constitutes injury in fact, both history and the judgment of Congress play important roles." *Spokeo*, 136 S. Ct. at 1549.

However, here, Plaintiff cannot demonstrate either a tangible or intangible harm sufficient to establish Article III standing.

As to a tangible injury, there is no indication that Plaintiff has suffered any physical or financial harm. On the record presented, Plaintiff has received all the TTFT prescribed by his physicians, and Plaintiff has never had to pay for his medical care. (Doc. 6-2 at 10, 25, 52; Doc. 9-1 at 6).

Nevertheless, Plaintiff argues that he has experienced an actual, intangible harm, "because he has been denied his substantive statutory right to Medicare benefits." (Doc. 15 at 3). However, the Court finds that Plaintiff's mere invocation of a statutory right

does not render his harm "concrete." Nor does Plaintiff's alleged injury fall "within the zone of interests to be protected or regulated by the statute…." *See Akins*, 524 U.S. at 20.

Here, Plaintiff has a right to ***seek*** Medicare benefits, to receive all reasonable and necessary treatment at minimal cost, to appeal any denial of coverage through the statutorily authorized process. In his complaint, Plaintiff does not allege that he was denied any of these rights. (*See* Doc. 1). Rather, he argues that the denial of **Medicare's** coverage for his first claim was erroneous, and further argues that the process for seeking coverage was faulty because it resulted in inconsistent determinations of eligibility. But neither of these arguments asserts any concrete harm. Moreover, Congressional intent in creating a robust appeals process was logically intended to ensure eligible applicants are not denied treatment and benefits to which they are entitled. But here, whether the ALJ's decision was erroneous, or whether the procedure for seeking coverage is faulty, Plaintiff received the treatment he sought, at no cost to him. Thus, his alleged injury presents, at best, a technical, procedural violation. But Plaintiff "cannot satisfy the demands of Article III by alleging a bare procedural violation." *Spokeo*, 136 S. Ct. at 1549-50 ("Robins could not, for example, allege a bare procedural violation, divorced from any concrete harm, and satisfy the injury-in-fact requirement of Article III").[7]

[7] Plaintiff argues that other district courts have found that denial of a Medicare entitlement creates a "concrete injury," even when there is no financial harm. (*See* Doc. 15 at 5–6 (collecting cases)). But, on the Court's review, the cases cited by Plaintiff "are inconsistent with modern standing precedent of the Supreme Court because they rely on a notion that standing may be founded on no more than an abstract 'entitlement' right created by statute without focus on whether a plaintiff has sustained a practical, concrete injury from the claimed violation of the statutory right." *Hull v. Burwell*, 66 F. Supp. 3d 278, 284 (D. Conn. 2014).

In light of the foregoing, Plaintiff cannot establish that an actual injury has occurred merely by alleging that he has suffered a "substantive" statutory violation. Plaintiff must nonetheless show that some concrete harm has resulted from that violation. And, on the record presented, Plaintiff has simply not met that standard.[8] *Accord Buchholz v. Meyer Njus Tanick, PA*, 946 F.3d 855, 867 (6th Cir. 2020) ("No matter what Congress provides by statute, the plaintiff must still satisfy Article III's standing prerequisites, including the injury-in-fact requirement." (emphasis added)).

B. Threatened injury

Moreover, Plaintiff has not suffered a threatened injury as a result of Defendant's conduct. It is well established that a "material risk of harm . . . may establish standing." *Huff v. TeleCheck Servs., Inc.*, 923 F.3d 458, 463 (6th Cir. 2019) (quoting *Spokeo*, 136 S.Ct. at 1549). "But the 'threatened injury must be *certainly impending* to constitute injury in fact.'" *Id.* (quoting *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013))

[8] Notably, Plaintiff argues that certain of the language in a recent Supreme Court decision—*Uzuegbunam v. Preczewski*, 141 S. Ct. 792 (2021)—confirms that an injury in fact has resulted from "the denial of [his] substantive statutory right to Medicare coverage." (*See* Doc. 18 at 1 (citing various statements from *Uzuegbunam* such as "the common law inferred damages whenever a legal right was violated")). However, this Court does not read *Uzuegbunam* as displacing *Spokeo*'s unequivocal statement that "Article III standing requires a concrete injury even in the context of a statutory violation." *Spokeo*, 136 S. Ct. at 1549. Instead, *Uzuegbunam* focused on the sole issue of whether nominal damages were sufficient to satisfy the redressability component of the standing analysis, and the statements Plaintiff cites from *Uzuegbunam* were made in the context of that analysis. 141 S. Ct. at 792. Indeed, *Uzuegbunam* concluded with the following caveat: "Our holding concerns only redressability. It remains for the plaintiff to establish the other elements of standing (such as a particularized injury); plead a cognizable cause of action, *Planck v. Anderson*, 5 T. R. 37, 41, 101 Eng. Rep. 21, 23 (K. B. 1792) ("if no [actual] damage be sustained, the creditor has no cause of action" for some claims); and meet all other relevant requirements. We hold only that, for the purpose of Article III standing, nominal damages provide the necessary redress for a completed violation of a legal right." *Id.* *Uzuegbunam* is consistent with the analysis here.

(emphasis in original); *see also Whitmore v. Arkansas*, 495 U.S. 149, 150 (1990). Put differently, future harm cannot establish standing if its occurrence rests upon an attenuated chain of events. *See Clapper*, 568 U.S. at 409; *see also Ohio v. Raimondo*, No. 3:21-CV-064, 2021 WL 1118049, at *7 (S.D. Ohio Mar. 24, 2021).

Here, there is no indication that Novocure has ever threatened to deny Plaintiff his medical treatment. And Plaintiff does not argue otherwise. (*See* Doc. 15 at 2–3). Instead, Plaintiff claims that a material risk of financial harm exists. (*Id.*) Plaintiff contends that Novocure may try to shift the costs associated with any future claims denials to Plaintiff. (*Id.*) The Court finds this argument unavailing for several reasons.

Initially, Plaintiff's concern that Novocure will impose financial liability on him is speculative. A supplier (like Novocure) cannot, of its own accord, simply "shift" the costs associated with any future claims denials to a beneficiary (like Plaintiff). 42 C.F.R. § 411.404. Instead, the supplier must get the beneficiary to sign a cost-shifting agreement—called an "ABN." *Id.*; *California Clinical Lab'y Ass'n v. Sec'y of Health & Hum. Servs.*, 104 F. Supp. 3d 66, 72 (D.D.C. 2015) (explaining that, in the absence of an ABN, the "[supplier] bear[s] the financial risk of coverage denials"). On the record presented, there is no indication that Novocure has asked Plaintiff to sign an ABN; nor is there any indication that Novocure intends to do so. (*Accord* Doc. 11-1 at 12).

Moreover, even if Novocure *did* occasion Plaintiff to sign an ABN, another factor renders Plaintiff's financial liability unlikely. On the record presented, ALJ MacDougall denied Plaintiff's Medicare coverage because the LCD in effect at the time (the Original LCD) did not provide any circumstances under which TTFT would be covered. (Doc. 6-

2 at 57–58). However, since ALJ MacDougall's decision, the Original LCD has been revised. (*Id.* at 115–24). Plaintiff's current and future claims are governed by the Current LCD which specifically permits coverage. (*Id.* at 119). And there is no reason to believe that Plaintiff's current of future claims will be denied under the Current LCD. In fact, on the record presented, there is no indication that any denials have occurred since the Current LCD went into effect.[9] (*Cf.* Doc. 15 at 2).

Finally, even if Novocure *did* occasion Plaintiff to sign an ABN, and even if Plaintiff's TTFT *was* denied, yet another safeguard stands between Plaintiff and any financial harm. Under the Medicare statute, the Secretary can only impose the costs associated with a claims denial on a beneficiary, if the beneficiary either knew or had reason "to know[] that payment would not be made." 42 U.S.C. § 1395pp(a). Here, as the Current LCD governing TTFT specifically ***permits*** coverage, it seems highly unlikely that Plaintiff would be deemed to have actual/constructive knowledge of a claims denial. (Doc. 6-2 at 119). And notably, even Defendant (the Secretary himself) agrees. (Doc. 17 at 3 (confirming that, in light of the TTFT LCD's revision, Plaintiff's previous claims denials could not "reasonably . . . put Plaintiff on notice of a future claim denial")).

[9] In his briefing, Plaintiff asserts that,"[o]ther than the case at issue, each of Mr. Thumann's claims has eventually been paid." (Doc. 15 at 2). It is not clear to the Court whether Plaintiff is referring to both: (1) the claims he had submitted under the Original LCD; ***and*** (2) the claims he has submitted under the Current LCD. But regardless, Plaintiff has not asserted that he has experienced any denials since the Current LCD went into effect. Nor is there any indication on the record presented that such denials have occurred. As such, the Court assumes that all of the claims Plaintiff has submitted under the Current LCD have been approved.

In sum, for Plaintiff to face future harm, several things would need to happen. First, Plaintiff would need to sign an ABN assuming liability for future claims denials (which Novocure has not asked Plaintiff to do). Second, Plaintiff would need to be denied coverage for TTFT (even though the Current LCD permits coverage). Third, the claims denial would have to be upheld at *all* stages of the Medicare appeals process (*i.e.*, redetermination, reconsideration, ALJ review, Council Appeal, *and* court review). And after all that, it would still need to be determined that Plaintiff had actual/constructive knowledge that his claim would be denied (which even the Secretary deems unlikely). Such an attenuated chain of events does not constitute a threatened harm.

C. Personal stake

As Plaintiff has not suffered an actual or threatened injury, Plaintiff lacks the type of personal stake necessary to maintain this lawsuit. *See Warth*, 422 U.S. at 498; *see also O'Shea*, 414 U.S. at 494. Perhaps the best way to illustrate this point is by way of analogy to *Thole*—a recent United States Supreme Court case. *Thole v. U. S. Bank N.A*, 140 S. Ct. 1615 (2020). In *Thole*, the plaintiffs brought a claim against the fiduciaries of their retirement plan alleging mismanagement. *Id.* at 1618–19. But the plan only provided fixed monthly benefits, no matter the fiduciaries' performance. *Id.* Because of this, the Supreme Court concluded that the plaintiffs had no actual "stake" in the outcome of the litigation. *Id.* at 1619.

As stated in the decision:

> [The plaintiffs] have received all of their monthly benefit payments so far, and the outcome of this suit would not affect their future benefit payments. If [the plaintiffs] 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. If [the plaintiffs] were to win this lawsuit, they would still receive the exact same monthly benefits that they are already slated to receive, not a penny more. The plaintiffs therefore have no concrete stake in this lawsuit.

Id.

Here, as in *Thole*, Plaintiff would be in the same situation—regardless of the outcome of this case. If Plaintiff were to lose this lawsuit, Novocure would bear the sole responsibility for his treatment costs, and if Plaintiff were to win this lawsuit, Medicare would bear the full responsibility for his treatment costs. No matter the outcome, Plaintiff's medical treatment will be covered at no cost to him. Thus, here, as in *Thole*, Plaintiff lacks the type of concrete stake in the outcome of the case necessary to establish standing. Accordingly, this case must be dismissed under Rule 12(b)(1) for lack of standing.[10] *Accord Huff*, 923 F.3d at 465 (noting that, "[i]f a claimant has not suffered a

[10] As a final point, the Court would note that it is not alone in reaching this conclusion. To date, at least six other district courts have considered whether Medicare beneficiaries with GBM have standing to pursue TTFT coverage in analogous circumstances. And all but one of those district courts have concluded that dismissal of the Medicare beneficiaries' cases was appropriate for lack of standing. *See Wilmoth v. Azar*, No. 3:20-CV-120, 2021 WL 681118 (N.D. Miss. Feb. 22, 2021) (dismissing case for lack of standing); *Oxenberg v. Cochran*, No. 2:20-CV-738, 2021 WL 462731 (E.D. Pa. Feb. 9, 2021) (same); *Prosser v. Azar*, No. 1:20-CV-194, 2020 WL 6266040 (E.D. Wis. Oct. 21, 2020) (same); *Anne Komatsu v. Alex Azar*, No. 8:20-CV-280, 2020 WL 5814116 (C.D. Cal. Sept. 24, 2020) (same); *Pehoviack v. Azar*, No. 8:20-CV-661, 2020 WL 4810961 (C.D. Cal. July 22, 2020) (same); *but see Robert Townsend, Plaintiff, v. Norris Cochran, in his official capacity as Sec'y of the United States Dep't of Health & Hum. Servs., Defendant*, No. 1:20-CV-1210, 2021 WL 1165142 (S.D.N.Y. Mar. 25, 2021) (concluding that standing existed). *Townsend*, the one exception, concluded that the plaintiff had standing because the plaintiff had alleged a "substantive" statutory violation. 2021 WL 1165142, at *8. This Court respectfully disagrees with that decision for the reasons set forth in Section III.A.

genuine harm or risk of harm, a federal court has no business entertaining his lawsuit"—even if a statutory violation has occurred).

IV. CONCLUSION

Based upon the foregoing:

1. Defendant's Combined Motion to Dismiss and Cross-Motion for Summary Judgment (Doc. 11) is **GRANTED** insofar as it seeks the dismissal of this case for lack of standing and **DENIED** in all other respects **as moot**.

2. Plaintiff's Motion for Summary Judgment (Doc. 9) is **DENIED as moot**.

3. This case is **DISMISSED without prejudice**.

4. The Clerk shall enter judgment accordingly, whereupon this case is **TERMINATED** upon the docket of this Court.

IT IS SO ORDERED.

Date: 3/31/2021

s/ Timothy S. Black
Timothy S. Black
United States District Judge