[PUBLISH]

In the

United States Court of Appeals

For the Eleventh Circuit

No. 22-10072

EDWIN R. BANKS,

Plaintiff-Appellant,

versus

SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Defendant-Appellee.

Appeal from the United States District Court
for the Northern District of Alabama
D.C. Docket No. 5:20-cv-00565-LCB

Before NEWSOM, MARCUS, Circuit Judges, and MIDDLEBROOKS,* District Judge.

NEWSOM, Circuit Judge:

In this appeal, we must decide whether Edwin Banks has standing to challenge a denial of Medicare coverage where the costs of his treatment were imposed not on him, but rather on a third-party supplier. The district court determined that Banks hadn't suffered an injury in fact and accordingly dismissed his case for want of jurisdiction. We agree and affirm.

I

A

Banks is a 77-year-old Medicare beneficiary from Madison, Alabama. In 2009, he was diagnosed with glioblastoma multiforme (GBM), an aggressive form of brain cancer. Without treatment, GBM patients typically don't survive longer than three months. And even with traditional forms of treatment, the five-year survival rate is only 5%.

Banks, however, has defied the odds. Shortly after his diagnosis, he underwent surgery and chemotherapy. That helped for a time, but unfortunately, Banks's cancer progressed. In 2013, Banks's doctors prescribed him Optune, a groundbreaking medical

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* Honorable Donald M. Middlebrooks, United States District Judge for the Southern District of Florida, sitting by designation.

technology that had recently received FDA approval for treating recurrent GBM. Optune is a portable, wearable device that delivers tumor treating field therapy (TTFT) to inhibit cancer-cell replication. A company called Novocure is the sole supplier of the Optune device, which is rented by patients on a monthly basis.

TTFT seems to have worked wonders for Banks. Despite the grim prospects, his condition stabilized, and he has not experienced a further tumor recurrence since beginning the treatment. Banks relied on TTFT through 2019, at which point he "elected to take a break" from the therapy because he had developed an allergy to an adhesive gel used to secure the Optune device. He intends to resume TTFT "if his condition changes" in the future—that is, if his tumor progresses. Happily, that hasn't happened in the three years since Banks stopped the treatment.

B

Because Banks is a Medicare Part B beneficiary, he and Novocure asked Medicare to cover his TTFT from January 2018 through January 2019. As we will explain, some of Banks's claims were approved, and others were denied. But importantly, Banks wasn't held liable for any of the claims—Novocure was. Before we get ahead of ourselves, though, some legal background is in order.

Medicare Part B is a supplemental insurance program "for aged and disabled individuals who elect to enroll" in it. 42 U.S.C. § 1395j. The voluntary program is administered by the Secretary

of Health and Human Services through the Centers for Medicare and Medicaid Services (CMS). *Id.* § 1395kk.

Part B enrollees pay monthly premiums in exchange for certain types of healthcare coverage. *Id.* §§ 1395k(a), 1395q(b)(2), (d). Although Part B typically covers "durable medical equipment" like Optune, *see id.* §§ 1395k(a)(1), 1395x(n), (s)(6), it excludes coverage for services that "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).

There is no hard-and-fast rule for determining whether a particular medical service is "reasonable and necessary." Congress has instead delegated that decision to the Secretary's discretion. *See Heckler v. Ringer*, 466 U.S. 602, 617 (1984). For his part, the Secretary has defined "reasonable and necessary" to mean (1) "[s]afe and effective," (2) "[n]ot experimental or investigational," and (3) "[a]ppropriate" in light of the prevailing "standards of medical practice" and "the patient's medical needs and condition." Medicare Program Integrity Manual, CMS Pub. 100-08, ch. 13, § 13.5.4. Applying that standard often entails case-by-case adjudication. *See Almy v. Sebelius*, 679 F.3d 297, 300 (4th Cir. 2012). But the Medicare Act establishes certain ways for the Secretary "to extend coverage determinations to specific courses of treatment." *Prosser v. Becerra*, 2 F.4th 708, 711 (7th Cir. 2021). "These so-called local coverage determinations (often shorthanded as LCDs) and national coverage determinations guide the individual claims decisions made by CMS." *Id.*; *see also* 42 U.S.C. § 1395ff(f)(1)–(2).

Whether or not an LCD is in place, the Medicare claims-review process proceeds in six steps. *First*, the beneficiary submits his claim to a local contractor for an "initial determination." *See* 42 U.S.C. § 1395ff(a); 42 C.F.R. § 405.920. *Second*, if the beneficiary is dissatisfied with the initial determination, he may request a "redetermination" by the contractor. *See* 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940. *Third*, the beneficiary can appeal his claim to a "qualified independent contractor" for further review—known as a "reconsideration." *See* 42 U.S.C. § 1395ff(c); 42 C.F.R. § 405.960. From this stage forward, an LCD is no longer binding, even if it remains persuasive. *See* 42 U.S.C. § 1395ff(c)(3)(B)(ii)(II); 42 C.F.R. §§ 405.976(b)(3), 405.1062. In addition, when the propriety of the claim turns on "whether an item or service is reasonable and necessary for the . . . treatment of illness," the qualified independent contractor's review "shall include consideration of the facts and circumstances . . . by a panel of physicians or other appropriate health care professionals." 42 U.S.C. § 1395ff(c)(3)(B)(i). *Fourth*, the Medicare beneficiary may request a hearing regarding a denied claim from an administrative law judge (ALJ), who must issue a decision within 90 days. *See id.* § 1395ff(b)(1)(A), (d)(1); 42 C.F.R. § 405.1000(a). *Fifth*, the beneficiary can appeal an unfavorable ALJ decision to the Medicare Appeals Council (MAC). *See* 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. § 405.1100(a). And *sixth*, if the beneficiary is still unsatisfied with the result—or if the MAC doesn't act in a timely manner—he can seek judicial review in federal court. *See* 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A), (d)(3)(B).

Taking stock: A multi-level review process helps to ensure that Medicare beneficiaries receive coverage for medically reasonable and necessary treatment. But "[e]ven when a benefits claim is denied at any level of the appeals process, the beneficiary is not necessarily stuck paying a medical bill." *Prosser*, 2 F.4th at 711. The Medicare Act contains a handful of measures that serve to protect patients from liability. The most important for our purposes is the one contained in 42 U.S.C. § 1395pp—a provision that the parties have called the "Medicare mulligan."[1]

Here's how § 1395pp works. Recall that Medicare normally won't pay for "items and services" that "are not reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). Nevertheless, if "both" the Medicare beneficiary and the supplier "did not know, and could not reasonably have been expected to know, that payment would not be made for such items or services," then Medicare will foot the bill. *Id.* § 1395pp(a). Alternatively, if the supplier knew that coverage would be denied but the beneficiary didn't, then the Secretary will indemnify the beneficiary and impose the costs on the supplier. *Id.* § 1395pp(b); *see also* 42 C.F.R. § 411.402. Either way, § 1395pp provides a one-time allowance—a "mulligan" if you will. Following the mulligan, the Secretary "shall notify" the beneficiary explaining

[1] For those who have never had the misfortune of shanking a drive into the woods, a "mulligan" is a golf term that refers to a player being permitted to replay a stroke without penalty. It's a freebie of sorts—traditionally permitted only on the first tee.

why payment or indemnification was made, "and in the case of comparable situations arising thereafter," the beneficiary "shall, by reason of such notice . . . be deemed to have knowledge that payment cannot be made for such items or services or reasonably comparable items or services." 42 U.S.C. § 1395pp(a), (b).

C

With the legal landscape in view, we return to Banks's case. As already explained, Banks and Novocure submitted 13 claims to Medicare, corresponding to 13 months of TTFT. In accordance with the LCD then in effect, those claims were denied at the initial stages of review and by a qualified independent contractor as not medically reasonable and necessary. In each case, Novocure—not Banks—was required to bear the costs. This was because Novocure presumably knew that coverage would be denied based on the LCD, but the record didn't show that Banks had received advance notice that Medicare would likely deny payment. Accordingly, he was relieved of any liability for those claims.

Banks further appealed the denials, at which point his claims were, for reasons unexplained, split between two different ALJs. On June 3, 2019, ALJ Bruce Kelton ruled that the TTFT provided in January, March, and April 2018 wasn't medically reasonable and necessary to treat Banks's condition. Even so, Banks didn't have to pay; Novocure was held solely liable for the denied charges. Three days later, Banks and Novocure received a favorable decision from another ALJ, Jeffrey Gulin, for the remaining 10 claims. Unlike ALJ Kelton, ALJ Gulin found that TTFT "was medically reasonable and

necessary" for treating Banks's recurrent GBM—at least for the months of service before him. As a result, ALJ Gulin ordered that Medicare pay for the treatment.

Banks and Novocure appealed ALJ Kelton's unfavorable decision to the MAC. And when the MAC didn't issue a decision within 90 days, Banks sought judicial review.

In the district court, Banks argued that ALJ Gulin's decision collaterally estopped the Secretary from denying the claims for TTFT coverage that were adjudicated by ALJ Kelton. But the district court saw things differently and granted the Secretary's cross-motion for summary judgment. In doing so, the court concluded that the "Medicare scheme is incompatible with the doctrine of collateral estoppel."

Banks then appealed for the first of two times to this Court. In the previous appeal, "the Secretary argue[d] for the first time that Banks lack[ed] Article III standing and that [he] 'submitted no evidence' showing he was injured by the claims denial." *Banks v. Sec'y of Health & Hum. Servs.* (*Banks I*), ___ F. App'x ___, 2021 WL 3138562, at *2 (11th Cir. 2021) (per curiam). Banks responded with two theories of standing. We made "quick work of Banks's first argument"—that "the violation of his statutory right to Medicare coverage alone is sufficient to establish standing." *Id.* at *2–3. But because Banks's "Medicare mulligan" theory could have "require[d] resolving factual disputes," we vacated the district court's ruling and remanded "for additional jurisdictional factfinding." *Id.* at *3–4.

On remand, the district court held that Banks lacked standing because he hadn't suffered an injury in fact. It thus dismissed the case without prejudice, and Banks timely appealed.[2]

II

A plaintiff has Article III standing only if he can demonstrate (1) an injury in fact that is both (2) fairly traceable to the defendant's conduct and (3) likely redressable by a favorable decision. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992). "To establish an injury in fact at step one, the plaintiff must demonstrate that [he] suffered an invasion of a legally protected interest which is (a) concrete and particularized; and (b) actual or imminent, not conjectural or hypothetical." *Laufer v. Arpan LLC*, 29 F.4th 1268, 1272 (11th Cir. 2022) (cleaned up). This can be done in either of two ways. First, the plaintiff can "point[] to a direct harm," which can be either "tangible or intangible." *Muransky v. Godiva Chocolatier, Inc.*, 979 F.3d 917, 926 (11th Cir. 2020) (en banc). Second, he can show that the defendant's actions "created a 'risk of real harm'" that is "'sufficient to meet the concreteness requirement.'" *Id.* at 927 (quoting *Spokeo, Inc. v. Robins*, 578 U.S. 330, 341, 343 (2016)).

Here, the Secretary argues—and the district court agreed—that "Banks suffered no injury because he is not financially liable for the denied claims." Br. of Appellee at 16. Banks doesn't dispute

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[2] "We review de novo a district court's dismissal of a case for lack of standing." *Sierra v. City of Hallandale Beach*, 996 F.3d 1110, 1112 (11th Cir. 2021).

that Novocure was stuck with the bill. But he presents three other theories of standing. First, he contends that he suffered an "economic injury" because he paid premiums for coverage that Medicare didn't provide. Second, he asserts that the agency's adverse decision deprives him of a "Medicare mulligan" that might enable him to receive one free TTFT treatment in the future. And third, he insists that he has standing due to the government's denial of a "substantive statutory right." We hold that none of Banks's theories is availing.

A

We begin with Banks's economic-injury argument. And at the outset, it's important to clarify precisely what relief Banks seeks: an order "directing the Secretary to cover the claims at issue in this case."[3] Doc. 1 at 14. Banks "bears the burden of showing that he has standing" to pursue this "type of relief." *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009).

The problem for Banks is that *he* hasn't suffered a cognizable injury at the hands of the Secretary that "would be redressed by a

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[3] Banks also seeks attorney's fees and a declaration that the Secretary acted unlawfully. But an "interest in attorney's fees is . . . insufficient to create an Article III case or controversy where none exists on the merits of the underlying claim." *Lewis v. Cont'l Bank Corp.*, 494 U.S. 472, 480 (1990). And a request for declaratory relief "cannot alone supply jurisdiction otherwise absent." *California v. Texas*, 141 S. Ct. 2104, 2116 (2021); *see also Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 107 (1998) ("Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court . . . .").

decision in [his] favor." *Support Working Animals, Inc. v. Governor of Fla.*, 8 F.4th 1198, 1206 (11th Cir. 2021). It is undisputed that Banks "received the therapy and owes nothing for it even though Medicare denied [some] of [his] coverage claims." *Prosser*, 2 F.4th at 716. And "[w]inning or losing this suit would not change" that. *Thole v. U.S. Bank N.A.*, 140 S. Ct. 1615, 1622 (2020); *see Prosser*, 2 F.4th at 714.

To be sure, Banks's requested relief would require the Secretary to pay *Novocure* for the cost of treatment that *it* had to absorb. But "[t]o invoke federal jurisdiction, a plaintiff must show a 'personal stake' in the outcome of the action." *United States v. Sanchez-Gomez*, 138 S. Ct. 1532, 1537 (2018) (quotation omitted). Because Novocure—not Banks—is the only one "on the hook," Banks does not himself "have a concrete stake in this suit." *Thole*, 140 S. Ct. at 1620; *see Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 106–07 (1998).

Banks nevertheless insists that, because he paid his insurance premiums,[4] he has standing on the ground that he is statutorily entitled "to have qualifying claims paid by Medicare." Br. of

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[4] Banks disavows any request for a "return of his insurance premiums (*i.e.*, recission)," seeking only "an order requiring the Secretary to cover [his] claims." Reply Br. of Appellant at 8 n.3. That comes as no surprise. It is precisely because he paid his Medicare premiums that the Secretary was able to relieve Banks of liability and hold Novocure responsible. *See* 42 U.S.C. §§ 1395pp(a)–(b); 1395q(b)(2), (d). Were Banks to obtain recission, he'd be on the hook to Novocure for the cost of treatment.

Appellant at 24. We're unconvinced. "Congress, in enacting Medicare, did not endow an individual with a substantive right to payment by Medicare each and every time [he] submit[s] a claim." *Prosser*, 2 F.4th at 714. After all, "Medicare payments most often go to the supplier or provider, not the recipient of care." *Id.*; *see also* 42 U.S.C. § 1395k(a)(1) (providing that a beneficiary is "entitle[d] to have payment made to him *or on his behalf* (subject to the provisions of [Medicare Part B]) for medical and other health services" (emphasis added)). And so it would be here if Banks were to prevail. That unique feature of this case matters in our assessment of standing. The Secretary's refusal to pay Novocure on Banks's behalf didn't cause him to personally suffer a concrete harm because, importantly, the Secretary simultaneously held that Banks isn't liable for any of the treatment costs.

Banks fails to explain why ordering the Secretary to cover the claims at issue—and thereby pay Novocure—would "redress a cognizable Article III injury" that is personal to him. *Steel Co.*, 523 U.S. at 107. His only response is the "collateral source rule," a feature of tort law under which "a plaintiff is entitled to recover the full value *of the damages caused by a tortfeasor*, without offset for any amounts received in compensation for the injury *from a third party*." *Higgs v. Costa Crociere S.P.A. Co.*, 969 F.3d 1295, 1310 (11th Cir. 2020) (emphases added). But as our italicization might suggest, that rule is inapposite here. Banks didn't receive any compensation through Novocure's good graces; it was *the Secretary* who ordered Novocure to absorb the cost—in the very same ruling

in which he determined that Banks wasn't liable. As a result, the challenged administrative action didn't cause Banks to suffer an injury in fact.

In the end, Banks's first theory of standing falls short. He "is not out of pocket anything for the therapy and does not contend that Novocure (or any other supplier) has a claim against [him]." *Prosser*, 2 F.4th at 714. Accordingly, he has "failed to plausibly and clearly allege," *Thole*, 140 S. Ct. at 1621, that he "personally suffered a concrete and particularized injury in connection with the conduct about which he complains," *Trump v. Hawaii*, 138 S. Ct. 2392, 2416 (2018) (cleaned up).

B

Next, Banks says that he "separately has standing based on the loss of his right to the Medicare 'mulligan.'" Br. of Appellant at 28. He doesn't meaningfully contend that the abstract loss of a potential mulligan is *by itself* sufficient to confer standing. Nor could he do so without identifying a resultant concrete harm. *See, e.g.*, *ASARCO Inc. v. Kadish*, 490 U.S. 605, 616 (1989) ("[C]laims of injury that are purely abstract . . . do not provide the kind of particular, direct, and concrete injury that is necessary to confer standing to sue in the federal courts."); *see also TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2210–11 (2021). Still, Banks argues that, without the prospect of the mulligan, he "faces the risk of being held financially liable for future treatments." Br. of Appellant at 31.

Such an allegation of future injury "may suffice" for standing purposes "if the threatened injury is certainly impending, or there is a substantial risk that the harm will occur." *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2565 (2019) (quotation omitted). That, we have stressed, is a "high standard," which demands "a robust judicial role in assessing [the] risk" of harm. *Muransky*, 979 F.3d at 927. Here, even after drawing all reasonable inferences in Banks's favor, we conclude that "[t]here is at most a 'perhaps' or 'maybe' chance" that his claimed harm will transpire. *Bowen v. First Fam. Fin. Servs.*, 233 F.3d 1331, 1340 (11th Cir. 2000) (quotation omitted). For reasons we will explain, whether the Secretary's denial of coverage in this particular case will result in Banks having to shoulder a TTFT bill in the future "involves a significant degree of guesswork." *Trump v. New York*, 141 S. Ct. 530, 536 (2020) (per curiam). And because Banks's theory of standing requires us to accept a "speculative chain of possibilities," his claimed future injury is—at least under the Court's current standing framework—insufficiently "concrete" and "imminent" to invoke the judicial power. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409, 414 (2013).

For starters, Banks admits that in 2019, he "elected to take a break" from TTFT—and he doesn't contend that he has any immediate plans to resume the therapy. Rather, he says that he "intends to resume use *if* his condition changes." Though not dispositive, "[s]uch 'some day' intentions—without any description of concrete plans, or indeed even any specification of *when* the some day will be"—usually "do not support a finding of the 'actual or

imminent' injury that [the Supreme Court's] cases require." *Lujan*, 504 U.S. at 564.

This case is no exception. Banks has apparently remained stable for three years. *See* Oral Arg. at 04:45–07:00. And even if his condition does worsen at "some indefinite future time," *Lujan*, 504 U.S. at 564 n.2—which, thankfully, isn't necessarily a guarantee—his claimed injury resulting from the Secretary's decision *in this case* still depends on several contingencies. For instance, at that unknown point in the future, Banks will still have to be enrolled in Medicare Part B and to have paid his premiums, such that he would otherwise qualify for Medicare coverage. *See* 42 U.S.C. § 1395q(b)(2), (d). So too will Banks have to follow through with his intention to use TTFT, even though we don't—and he doesn't—know what the range of treatment options will be at that unspecified time.

Then there are the contingencies that depend on the conduct of others. The Supreme Court has consistently expressed "reluctance to endorse standing theories that rest on speculation about the decisions of independent actors." *Clapper*, 568 U.S. at 414; *see also California v. Texas*, 141 S. Ct. 2104, 2117 (2021); *Lujan*, 504 U.S. at 562 (collecting cases). And the possibility of Banks's claimed injury coming to fruition requires the coalescence of several decisions by at least three independent actors.

First, Banks's doctors will have to prescribe him TTFT. That might seem likely, given that Banks has received such a prescription in the past. *Cf. Dep't of Commerce*, 139 S. Ct. at 2566

(reasoning that a plaintiff can help his case for standing if he can "show[] that third parties will likely react in predictable ways"). But because we don't know *when* Banks will seek treatment, it's more speculative than at first it may appear. As Banks's prescribing doctor explained, TTFT was, in his opinion, "the best FDA approved option *at th[at] time* for treating [Banks's] gliobastoma." But that was several years ago. We don't know what the medical landscape will look like in the future, as "the practice of medicine is an ever-evolving and advancing field." *Cospito v. Heckler*, 742 F.2d 72, 87 n.24 (3d Cir. 1984). We can only speculate. TTFT may no longer be the preferred method of treatment when, if ever, Banks's condition worsens. And even if future scientific developments serve to demonstrate the efficacy or superiority of TTFT, that would only increase the chance that Banks would receive coverage—because TTFT would be deemed medically reasonable and necessary—and thereby diminish the odds that his claimed injury will materialize.

Second, even if Banks eventually resumes TTFT, his claimed injury can occur only if—at that unknown point in the future—both (1) his claim is ultimately denied as not reasonable and necessary, and (2) the adjudicator determines that the case presents a "comparable situation[]." 42 U.S.C. § 1395pp(a), (b). As the Supreme Court has warned, however, "[i]t is just not possible for a litigant to prove in advance that the judicial system will lead to any particular result in his case." *Clapper*, 568 U.S. at 413–14 (alteration in original) (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 159–60

(1990)). And this case is a perfect illustration of that principle. After all, Banks *has* received favorable coverage decisions for 10 of his 13 claims.[5] Because the agency could very well rule the same way with respect to future claims, "the risk of financial liability is speculative at best." *Prosser*, 2 F.4th at 715.[6]

Third, even if all the above-described dominoes fall into place, Banks's claimed injury will still likely depend on the independent actions of Novocure. When medical-device suppliers have reason to believe that Medicare will deny coverage, they can and often do shift the financial risk of non-coverage to "a beneficiary by providing [him] with advance written notice that a device will probably not be covered by Medicare." *Almy*, 679 F.3d at 311 n.4; *see also* Medicare Claims Processing Manual (MCPM), CMS Pub. 100-04, ch. 30, §§ 20, 40. This is known as an advance beneficiary notice, or ABN. A "valid ABN" generally establishes knowledge on the beneficiary's part that his claim won't be covered. MCPM ch. 30, §§ 30, 30.1, 50; *see also* 42 C.F.R. § 411.404; *Int'l Rehab. Scis., Inc. v. Sebelius*, 688 F.3d 994, 998 (9th Cir. 2012).

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[5] In this unusual situation, it isn't entirely clear whether Banks will be charged with knowledge "that payment would not be made" for a future TTFT claim based on ALJ Kelton's decision. 42 U.S.C. § 1395pp(a)(2). ALJ Gulin's decision three days later, which ordered full coverage of the treatment, suggests that payment *will* be made for such a claim.

[6] Banks will also be able to present his collateral-estoppel theory to the agency as an additional reason for Medicare to cover his TTFT. Though we express no view on the merits of that theory, it presents an open question that, to our knowledge, hasn't been addressed by any court of appeals.

And in that case, the Medicare mulligan is unavailable—no matter whether the beneficiary had a previous coverage denial. *See* 42 U.S.C. § 1395pp(a); 42 C.F.R. § 411.406(d); MCPM ch. 30, § 50.9.

At least as things stand, it seems reasonably likely that Novocure will provide an ABN to Banks before he resumes TTFT (if he ever does). Indeed, the Seventh Circuit has held that Novocure, as a medical-device supplier, "must" obtain an ABN "from the beneficiary[] acknowledging that the recipient will be personally liable if Medicare denies coverage for the treatment." *Prosser*, 2 F.4th at 715 (citing 42 U.S.C. § 1395m(j)(4)). Otherwise, that court said, the supplier alone bears the financial risk if Medicare denies a claim as not reasonable and necessary. *See id.* at 711–12, 715; *accord Cal. Clinical Lab. Ass'n v. Sec'y of HHS*, 104 F. Supp. 3d 66, 80 (D.D.C. 2015) (Jackson, J.). The parties here dispute whether that's true. But we needn't decide. For even if an ABN isn't *required* to shift liability to Banks, we still think it fairly likely that Novocure will provide one. After all, the company presumably knows that TTFT has been denied with some frequency. *See, e.g.*, *Prosser*, 2 F.4th at 712; *Oxenberg v. Sec'y U.S. Dep't of Health & Hum. Servs.*, ___ F. App'x ___, 2022 WL 336996, at *2 (3d Cir. 2022). And the only circuit court to have addressed this issue has held that failure to provide an ABN "prevent[s] suppliers from charging beneficiaries the costs incurred after a denial of coverage." *Prosser*, 2 F.4th at 715. As a profit-driven corporation, Novocure will presumably act to minimize that risk.

And if Banks does receive an ABN before future treatment, that creates a potential traceability problem. The notice would probably provide an independent reason—aside from the Secretary's refusal of coverage in this case—for denying Banks a mulligan. *See Bennett v. Spear*, 520 U.S. 154, 167 (1997) (explaining that an injury cannot be "the result of the independent action of some third party not before the court"). That is, armed with a valid ABN from Novocure, Banks would likely be held to "know," or "reasonably have been expected to know, that payment would not be made." 42 U.S.C. § 1395pp(a)(2); *see also* 42 C.F.R. § 411.404; MCPM ch. 30, § 30.1. That makes it even more speculative that Banks's claimed injury—if it were to ever occur—would be fairly traceable to the present denial. *See Simon v. E. Ky. Welfare Rts. Org.*, 426 U.S. 26, 42–43 (1976).[7]

[7] The Secretary appears to make one last "speculation"-based argument grounded in a recent update to the applicable LCD. *See Oxenberg*, 2022 WL 336996, at *2 (noting that the relevant LCD "was revised [in 2019] to cover TTFT for newly diagnosed GBM patients"). But as Banks rightly argues, the updated LCD doesn't purport to cover "recurrent" GBM patients like him. Accordingly, we agree with Banks that the new LCD doesn't affect the likelihood of his claimed injury materializing. There are, however, a couple of LCD-related things to note. First, we know that ALJ Gulin departed from the LCD, citing (1) "FDA findings and recent studies," (2) "general acceptance in the medical community," and (3) the fact that Banks had survived six years with the device despite a life expectancy of six months as evidence that TTFT was "medically reasonable and necessary" for treating his condition. It is thus speculative to think that the agency would rule differently in the future, even though the LCD doesn't yet cover recurrent GBM. *See Clapper*, 568 U.S. at 413–14. Second, the updated LCD reinforces the point made above—that the

In sum, "[f]ar too many steps lay between the instant coverage denial and any future liability." *Prosser*, 2 F.4th at 715. Banks's alleged harm will only come to pass due to the challenged action if, at some indefinite point in the future: (1) his condition worsens, (2) he has paid his premiums and stayed on Medicare Part B, (3) he elects to resume TTFT, (4) his doctor prescribes the therapy, even though we can't know what the range of potential treatment options in the future will be, (5) Banks receives the treatment, (6) he files a claim, (7) which, contrary to 10 of the 13 claims he has submitted, is denied at every level of the Medicare appeals process, (8) the adjudicators determine that Banks's hypothetical future case presents a "comparable situation," and (9) they further find that the instant coverage denial and no other source (such as an ABN) put Banks on notice that he could be held liable. That "theory of standing, which relies on a highly attenuated chain of possibilities," doesn't present the type of concrete and imminent injury that Banks needs to show to invoke our jurisdiction. *Clapper*, 568 U.S. at 410.

To be clear, we don't foreclose the possibility that if Banks's situation were to change, then he might be able to show a sufficiently concrete and imminent harm. But at this point, based on

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science on (and medical acceptance of) TTFT is evolving. By the time Banks resumes treatment, the LCD may be updated again to direct coverage for his condition. We have no way of knowing.

the alleged facts before us, Banks "has not demonstrated the requisite injury to establish Article III standing." *Prosser*, 2 F.4th at 714.

C

Finally, Banks asserts that the denial of his "substantive statutory right" to have Medicare pay for his treatment gives him standing. Br. of Appellant at 33. There are two problems with his argument.

First, it is barred by the law of the case. That doctrine provides that, notwithstanding some inapplicable exceptions, "conclusions of law by an appellate court are . . . binding in all subsequent proceedings in the same case." *Lebron v. Sec'y of the Fla. Dep't of Child. & Fams.*, 772 F.3d 1352, 1360 (11th Cir. 2014) (quotation omitted). In *Banks I*, we made "quick work" of Banks's "argument that the statutory violation itself is sufficient to confer standing." 2021 WL 3138562, at *3. Instead, we held that because "Novocure, and not Banks, is liable for the cost of the January, March, and April 2018 claims," Banks had "not shown how the statutory violation caused a direct harm." *Id.* There's no reason to "revisit[] [that] issue[] that [was] already decided." *Cambridge Univ. Press v. Albert*, 906 F.3d 1290, 1299 (11th Cir. 2018) (alteration adopted) (quotation omitted).

Second, even assuming that Banks's substantive-statutory-violation theory isn't barred by the law of the case, it fails as a matter of law. In fact, this Court rejected almost the exact same argument in *Muransky*. There, the plaintiff argued that the "violation

of a substantive right, unlike a procedural right, automatically" confers standing. 979 F.3d at 929. We disagreed, explaining that "arguments grounded in a distinction between substantive and procedural rights miss the point and are 'unconvincing' because they depend 'entirely on the framing of the right.'" *Id.* at 930 (quotation omitted). We then clarified that "[t]he question, always, is whether an injury in fact accompanies a statutory violation." *Id.*; *accord TransUnion*, 141 S. Ct. at 2205.

For reasons already explained, Banks hasn't alleged such an injury. He hasn't shown "that the statutory violation itself caused" him—as opposed to Novocure—a concrete and particularized harm. *Id.* at 926; *see also Banks I*, 2021 WL 3138562, at *3 ("Because he does not have to pay these claims, Banks has not shown how the statutory violation caused a direct harm."). Nor has he shown a sufficiently substantial risk of future harm. *See Clapper*, 568 U.S. at 410–14. He therefore lacks standing.

* * *

Edwin Banks is, by all accounts, a very sympathetic plaintiff. He has waged—and is continuing to wage—a heroic battle against a dreadful disease. And as we have said, circumstances could well change such that one of the Medicare-related injuries he alleges materializes in a way that satisfies current standing doctrine. As matters currently stand, though, he has not alleged an injury in fact sufficient to satisfy Article III. Accordingly, we must **AFFIRM**.