In the

United States Court of Appeals

For the Seventh Circuit

No. 20-3070

ANNIKEN PROSSER,

Plaintiff-Appellant,

v.

XAVIER BECERRA, Secretary of the United States Department of Health and Human Services,

Defendant-Appellee.

Appeal from the United States District Court for the
Eastern District of Wisconsin.
No. 1:20-cv-00194 — **William C. Griesbach**, *Judge.*

ARGUED JANUARY 13, 2021 — DECIDED JUNE 25, 2021

Before FLAUM, BRENNAN, and SCUDDER, *Circuit Judges*.

SCUDDER, *Circuit Judge*. Anniken Prosser suffers from an aggressive brain cancer called glioblastoma multiforme. To treat her disease, Prosser uses a promising electric field treatment called tumor treating fields therapy. She will receive this therapy for the rest of her life. To pay for the therapy, Prosser enrolled in the supplemental insurance program within Medicare Part B. She files a benefits claim with Medicare for each

period she receives TTF therapy. Medicare denied coverage for the treatment period January to April 2018. Though Prosser received the therapy and owed nothing out of pocket, the denial left the supplier of the treatment, Novocure, Inc., with the bill. Prosser challenged this denial by availing herself of Medicare's multilayer appeals process, losing at each level and eventually reaching federal court.

The district court dismissed Prosser's claim for Medicare Part B coverage, holding that she has suffered no injury-in-fact sufficient to satisfy Article III's standing requirement. We agree. Prosser received—and continues to receive—the TTF therapy. She faces no financial liability for the treatment period Medicare denied coverage. And any future financial risk is too attenuated from the denial of the past coverage at issue here and far too speculative to establish standing. We therefore lack authority to hear Prosser's claim and affirm the dismissal of her complaint.

I

A

Anniken Prosser is a 37-year-old Medicare recipient who suffers from glioblastoma. The disease, which causes a tumor to grow and spread in the brain, is aggressive and deadly—the five-year survival rate hovers around just 5%. As a reference point, this was the disease that took the lives of Senator John McCain and Beau Biden, the eldest son of the President of the United States.

Though not curative, Prosser benefits from tumor treating fields therapy, commonly referred to as TTF therapy. The therapy, approved by the FDA in 2011, works by slowing the growth of brain tumors. For most of the day patients use a

device that attaches to the head via four adhesive patches that connect to a mobile power supply. The device emits electrical fields to the tumor, which disrupt the division of cancer cells, thereby slowing tumor growth. Early studies show that the device holds promise in prolonging life.

TTF therapy is available through a single supplier—a company called Novocure, which markets the device under the commercial name Optune. Patients rent the Optune device on a monthly basis. The therapy is expensive, and Prosser must file a benefits claim with Medicare for each period she uses the device for TTF therapy.

B

Prosser receives coverage from Medicare Part B, a supplementary medical insurance program administered by the Secretary of Health and Human Services through the Centers for Medicare and Medicaid Services, or CMS. Recipients pay a monthly premium in exchange for certain types of coverage, including for durable medical equipment like Novocure's Optune system. See 42 U.S.C. § 1395k. Part B does not cover 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). The Secretary has interpreted "reasonable and necessary" to mean that an item or service must be safe and effective, medically necessary and appropriate, and not experimental in order to qualify for reimbursement. See Medicare Program Integrity Manual § 13.5.4.

CMS makes individual coverage decisions by determining whether a medical service is reasonable and necessary. While this determination often applies to each treatment decision,

there are ways to extend coverage determinations to specific courses of treatment. These so-called local coverage determinations (often shorthanded as LCDs) and national coverage determinations guide the individual claims decisions made by CMS.

When individuals first submit claims for coverage to Medicare Part B, they do so to local contractors who determine if the services or devices are covered or otherwise reimbursable under Medicare. See 42 C.F.R. § 405.920(a). Contractors may issue a local coverage determination that categorically decides whether a treatment is covered, a determination that becomes binding on the issuing contractor for future claims. See 42 U.S.C. § 1395ff(f)(2)(B).

A beneficiary disagreeing with the initial determination of coverage can appeal. Appeals proceed in four stages within the Medicare system. First, the beneficiary may request a redetermination from the Medicare contractor. See 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. § 405.940. At the second level, the beneficiary may seek reconsideration by a qualified independent contractor. See 42 U.S.C. § 1395ff(b)(1)(A). A local coverage determination is not binding once a beneficiary reaches this stage of review. Claimants still unsatisfied with a coverage determination may proceed to step three by requesting a hearing through the Office of Medicare Hearings and Appeals, at which point the dispute is assigned to an administrative law judge for decision. See 42 U.S.C. § 1395ff(b)(1)(A), (d). A claimant may appeal an unfavorable decision by an ALJ to the Medicare Appeals Council, which represents the final decision of the Secretary. If the Council either affirms the coverage denial or does not render a decision within a 90-day timeframe, a beneficiary may bring a claim in federal district

court. See *id.* § 1395ff(b)(1)(A) (incorporating 42 U.S.C. § 405(g)'s judicial review provisions).

Even when a benefits claim is denied at any level of the appeals process, the beneficiary is not necessarily stuck paying a medical bill. If neither the supplier nor the beneficiary knew or could reasonably have been expected to know that the claim would not be covered, Medicare will nevertheless pay for the service. See *id.* § 1395pp; 42 C.F.R. § 411.400(a). This provision limits liability only once—after that, both the beneficiary and supplier are on notice that coverage is likely to be denied. In that way, § 1395pp provides suppliers and beneficiaries alike the benefit of the doubt and shields them both from financial liability the first time Medicare denies coverage. It seems that providers and participants call this one-time liability limitation the Medicare "mulligan."

But coverage denials are not always a risk-free proposition for a beneficiary. Suppliers may shift the risk of non-coverage solely to the beneficiary when they give advance written notice, often referred to as an Advance Beneficiary Notice, informing the beneficiary that Medicare is unlikely to cover the claim. See 42 C.F.R. § 411.404(a), (b). Medical device suppliers—as opposed to healthcare providers in general—bear an additional burden should they wish to shift the risk that coverage may be denied: they must obtain a written agreement by the patient that she will individually bear the cost of coverage denial. See 42 U.S.C. § 1395m(j)(4) (incorporating 42 U.S.C. § 1395m(a)(18)(A)(ii)); Medicare Claims Processing Manual ch. 30, § 30.1. In these ways, suppliers like Novocure are able to limit their financial risk while still providing innovative healthcare solutions like TTF therapy.

C

Prosser was prescribed the TTF therapy in June 2016. The therapy generated monthly Medicare claims. TTF therapy is often covered by private insurers. Medicare, however, had a local coverage determination in place—LCD L34823—that denied coverage for TTF therapy performed on or after October 1, 2015 as not reasonable and necessary for the treatment of glioblastoma. After requests for reconsideration of the LCD by patients and suppliers alike through a separate administrative review process, Medicare revised LCD L34823 to cover TTF therapy as reasonable and necessary as of September 1, 2019. This revision of LCD L34823 did not come until after the ALJ decision denying coverage to Prosser.

Prosser submits coverage claims to Medicare for every three-to-four-month period she receives the TTF therapy. She exhausted the administrative review process within the Medicare program each time. Along the way, Prosser received two favorable coverage decisions, including one in May 2019.

But Prosser received an unfavorable coverage decision too. The decision came from a different ALJ in June 2019, just a month after a favorable decision granting coverage. The denial of coverage applied to TTF therapy provided by Novocure to Prosser from January through April 2018. Given the LCD in place at the time, the ALJ concluded, Novocure should have known that the therapy was not covered by Medicare. Although Medicare would not pay the claim, it was Novocure, not Prosser, that the ALJ left with the bill, as Prosser did not sign an advance beneficiary notice acknowledging her liability. This presents the only unfavorable decision Prosser received through the Medicare appeals process.

Having exhausted her administrative remedies for the coverage denial for the period January through April 2018, Prosser filed a complaint against the Secretary in the Eastern District of Wisconsin in February 2020. Recall that Prosser had received a favorable ALJ decision a month before the subsequent ALJ decision denying coverage. This is the thrust of why Prosser escalated this appeal to federal court—she wants steady and consistent Medicare Part B coverage for TTF therapy on a going-forward basis. To Prosser's mind, the initial favorable ALJ determinations should bind future coverage determinations, and she should not have to go through the Medicare claims review process every time she gets the TTF therapy.

Two months after filing in federal court, Prosser moved for partial summary judgment, seeking to prevent the Secretary from denying the TTF therapy for her glioblastoma because a previous ALJ decision had concluded it was medically reasonable and necessary. The Secretary moved for partial summary judgment too, insisting that ALJ-level decisions are case-by-case, nonprecedential decisions.

In July 2020 the district court entered partial summary judgment for the Secretary, concluding that administrative Medicare coverage decisions made by ALJs did not bind future coverage decisions. Put another way, the doctrine of collateral estoppel does not apply to these administrative coverage decisions.

In October 2020 the Secretary moved for full summary judgment, this time arguing that Prosser lacked Article III standing. The Secretary contended that Prosser had no interest in the case, since all along she received the TTF therapy yet paid nothing. The district court granted the Secretary's

motion, concluding that Prosser lacked standing. Since suppliers are prohibited from charging beneficiaries the costs of denied claims without them signing in advance an acknowledgement of personal liability and there is no evidence that Prosser signed such a notice, it was the supplier Novocure—not Prosser—who bore the costs of having provided the TTF therapy to Prosser. Nor, the district court added, did anything in the record suggest that Prosser has been unable to receive the therapy. In other words, because Prosser was receiving the therapy and faced no financial liability for the denial of coverage relating to past treatment, the district court concluded that she lacked an injury and therefore had no standing to sue.

Prosser now appeals.

II

A

We begin, as we must, with subject matter jurisdiction. Only if Prosser has standing can we proceed to the merits of her argument that ALJ coverage determinations bind future coverage determinations for the same type of treatment.

The Constitution's Case or Controversy requirement limits federal courts to resolving concrete disputes between adverse parties. See *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992). Article III, in short, "prevents federal courts from answering legal questions, however important, before those questions have ripened into actual controversies between someone who has experienced (or imminently faces) an injury and another whose action or inaction caused (or risks causing) that injury." *Sweeney v. Raoul*, 990 F.3d 555, 559 (7th Cir. 2021).

The justiciability doctrines, including the doctrine of standing, give effect to this limitation. Standing "limits the category of litigants empowered to maintain a lawsuit in federal court to seek redress for a legal wrong," and in that way, "confines the federal courts to a properly judicial role." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016). To meet "the irreducible constitutional minimum of standing," a plaintiff must have suffered an injury in fact traceable to the defendant that is capable of being redressed through a favorable judicial ruling. *Lujan*, 504 U.S. at 560–61.

To establish injury in fact, Prosser must show that she suffered "an invasion of a legally protected interest" that is "concrete and particularized" and "actual or imminent, not conjectural or hypothetical." *Id.* at 560 (cleaned up). Concreteness demands that an injury "actually exist," but it need not be tangible or financial. *Spokeo*, 136 S. Ct. at 1548–49. A plaintiff may have standing to enforce an intangible injury, so long as it is concrete. See *id.* When considering an allegation of intangible harm, the Supreme Court instructs us to look to the history of the common law and the judgment of Congress. See *id.* at 1549. Though Congress has "the power to define intangible harms as legal injuries for which a plaintiff can seek relief," *Casillas v. Madison Ave. Assoc., Inc.*, 926 F.3d 329, 333 (7th Cir. 2019), a plaintiff does not "automatically satisf[y] 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. Even in the context of an alleged statutory violation, then, a plaintiff must identify a concrete injury. See *id.*

In the absence of an actual injury, standing may still exist in the face of a threatened injury if that future injury is

certainly impending—in a word, imminent. See *Lujan*, 504 U.S. at 564 n.2 ("Although 'imminence' is concededly a somewhat elastic concept, it cannot be stretched beyond its purpose, which is to ensure that the alleged injury is not too speculative for Article III purposes—that the injury is '*certainly* impending.'" (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990))); *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2565 (2019) (explaining that imminence requires a showing that "there is a substantial risk that the harm will occur"). The Supreme Court has "repeatedly reiterated that threatened injury must be certainly impending to constitute injury in fact, and that allegations of possible future injury are not sufficient." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (cleaned up).

B

Our inquiry begins and ends with Article III standing's injury-in-fact requirement. Prosser received TTF therapy for the relevant period of January through April 2018 at no cost to herself. She is not out of pocket anything for the therapy and does not contend that Novocure (or any other supplier) has a claim against her. Nor has she alleged facts suggesting that any personal liability for past TTF therapy is imminent. To the contrary, the supplier Novocure has shouldered the treatment costs. Even more, the ALJ found that the cost of the TTF therapy would be borne solely by Novocure, as the company never presented Prosser with an advanced beneficiary notice.

On these facts, Prosser has not demonstrated the requisite injury to establish Article III standing. While this dooms Prosser's present appeal, should her situation change—say, for example, if she signs an advanced beneficiary notice and Medicare denies coverage for a treatment in the future—so,

too, may a future court's analysis of her standing to sue change. Here, however, we can do nothing but dismiss Prosser's claim for want of jurisdiction.

Prosser responds by contending that she receives supplemental insurance coverage from Medicare. With that coverage, she claims, comes a substantive statutory right to payment by Medicare. The denial of coverage for the treatment period January to March 2018, in her view, infringes that substantive right and therefore amounts to an injury for Article III standing purposes.

Not so. Congress, in enacting Medicare, did not endow an individual with a substantive right to payment by Medicare each and every time they submit a claim. After all—and as the facts here show—Medicare payments most often go to the supplier or provider, not the recipient of care.

Congress may create and elevate rights by statute while also providing a cause of action to sue in federal court to enforce these rights. But that alone is not enough to establish constitutional standing under Article III. See *Spokeo*, 136 S. Ct. at 1549. Beneficiaries like Prosser can obtain review of a coverage denial in federal court after exhausting the Medicare appeals process. But mere use of that process cannot, in and of itself, create an injury in fact.

Our reasoning parallels the Supreme Court's standing analysis in *Thole v. U.S. Bank N.A.*, 140 S. Ct. 1615 (2020). In *Thole*, the Court concluded that a pair of retirees lacked Article III standing to bring an ERISA claim against a bank for mismanaging a retirement plan, despite the statute providing a cause of action, because the plaintiffs' monthly payouts from the defined benefit plan would be unaffected by a ruling, win

or lose. See *id.* at 1619. The Court underscored that it has repeatedly "rejected the argument 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.'" *Id.* at 1620 (quoting *Spokeo*, 136 S. Ct. at 1549).

What this means here is that Prosser must still identify a concrete injury, notwithstanding the statutory right Congress supplied her to appeal a Medicare coverage decision. See *id.* at 1620–21; *Spokeo*, 136 S. Ct. at 1549. She has not done so.

Nor does Prosser's alleged loss of the one-time limitation of liability under 42 U.S.C. § 1395pp amount to a concrete injury. Section 1395pp states that Medicare will pay a claim if neither the supplier nor the beneficiary knew or could reasonably have been expected to know that the particular treatment would not be covered. This provision alone does not show that Prosser suffered a concrete injury. For one, the prior version of LCD L34823 may have already triggered the one-time liability limitation—that protection is gone regardless of the ALJ's June 2019 decision denying coverage. And recall that the ALJ concluded that the previous version of LCD L34823 denying coverage for TTF therapy put Novocure on notice that the therapy it chose to provide Prosser was not covered under Medicare Part B. Novocure itself would be financially liable in the event of coverage denial, not Prosser. Remember, too, that Prosser is protected by another layer of insulation from financial liability. Medicare regulations prevent suppliers from charging beneficiaries the costs incurred after a denial of coverage except in cases where they provide the beneficiary with advance notice that Medicare is likely to deny coverage for the treatment. See 42 C.F.R. § 411.404.

In addition to the advance notice requirement, there is yet a further layer of protection for recipients of medical equipment and devices. Medical device suppliers must also obtain a written agreement from the beneficiary, acknowledging that the recipient will be personally liable if Medicare denies coverage for the treatment. See 42 U.S.C. § 1395m(j)(4) (incorporating 42 U.S.C. § 1395m(a)(18)(A)(ii)); Medicare Claims Processing Manual ch. 30, § 30.1. Here, Novocure never obtained that agreement from Prosser, which means Prosser owes the company nothing.

Prosser makes one final go at establishing an injury in fact, positing that she may incur financial liability in future coverage determinations for TTF therapy. But that suggestion is far too attenuated from the instant appeal and far too speculative at this juncture to suffice for an imminent injury. True, Prosser suffers from an incurable condition and will likely need TTF therapy for the remainder of her life. But the many favorable ALJ decisions—and even the unfavorable decision on appeal—show that the risk of financial liability is speculative at best.

Far too many steps lay between the instant coverage denial and any future liability. Novocure would need to require Prosser to sign an advanced beneficiary notice, acknowledging her own financial liability should Medicare deny coverage for the therapy. The company has not done so, and there is nothing in the record to suggest it might do so in the future.

Most fatal to Prosser's imminent injury argument, however, is the Medicare program's own recent activity. The recently revised LCD L34823, effective as of September 2019, provides that TTF therapy is presumed reasonable and necessary for the treatment of glioblastoma. At this point, then, we

have no facts before us suggesting that Prosser is at imminent risk of being denied coverage.

* * *

By all accounts, TTF therapy has shown great promise in fighting glioblastoma. The record before us shows that, during the period at issue, Prosser received the therapy and owes nothing for it even though Medicare denied one of her coverage claims. If for some reason she does not receive coverage in the future and as a result is denied the therapy or faces financial liability, Prosser will be able to avail herself of the appeals process, and if necessary, seek judicial review from there.

For these reasons, we AFFIRM.