

**NOT PRECEDENTIAL**

UNITED STATES COURT OF APPEALS  
FOR THE THIRD CIRCUIT

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No. 21-1682

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LYNN OXENBERG; RONALD LEWIS,  
Appellants

v.

SECRETARY UNITED STATES DEPARTMENT OF  
HEALTH AND HUMAN SERVICES

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On Appeal from the United States District Court  
for the Eastern District of Pennsylvania  
(D.C. Civil No. 2:20-cv-00738)  
Senior District Judge: Cynthia M. Rufe

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Submitted Pursuant to Third Circuit L.A.R. 34.1(a)  
January 28, 2022

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Before: CHAGARES, Chief Judge, HARDIMAN and MATEY, Circuit Judges

(Filed: February 4, 2022)

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OPINION\*

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\* This disposition is not an opinion of the full Court and, pursuant to I.O.P. 5.7, does not constitute binding precedent.

CHAGARES, Chief Judge.

Appellants Lynn Oxenberg and Ronald Lewis brought this action pursuant to 42 U.S.C. § 405(g) seeking judicial review of the denial of their Medicare claims by the Secretary of Health and Human Services (the “Secretary”). The District Court dismissed the complaint under Federal Rule of Civil Procedure 12(b)(1) for lack of standing under Article III of the United States Constitution. For the reasons that follow, we will affirm the order of the District Court.

I.

We write primarily for the parties and recite only the facts essential to our decision. Oxenberg and Lewis suffer from a rare form of cancer, glioblastoma multiforme (“GBM”). Both receive tumor treatment field therapy (“TTFT”), a therapy proven effective at treating GBM. TTFT is exclusively offered by Novocure, Inc., which distributes TTFT under the brand name “Optune.” Optune is a medical device that is rented to patients on a monthly basis.

Although durable medical equipment like Optune is covered by Medicare Part B, that coverage is not unqualified. See 42 U.S.C. §§ 1395k(a); 1395x(s)(6). Medicare may only pay for items and services that are deemed “reasonable and necessary” to the patient’s treatment. 42 U.S.C. § 1395y(a)(1)(A). Congress has delegated this determination to the Secretary. See 42 U.S.C. § 1395ff(a); Heckler v. Ringer, 466 U.S. 602, 617 (1984). The Secretary has defined “reasonable and necessary” as (1) safe and effective, (2) not experimental, and (3) appropriate in context of the patient’s medical need. See Medicare Program Integrity Manual (“MPIM”) § 13.5.4. If a claim is denied,

the beneficiary may appeal through a multi-level process. We will not set forth the administrative process here, as it is known to the parties. If the beneficiary receives an unfavorable decision after exhausting administrative remedies, the beneficiary may file a complaint in federal district court seeking judicial review of the denial. See 42 U.S.C. §§ 1395ff(b), 405(g); 42 C.F.R. § 405.1132.

Even if coverage is ultimately denied, the beneficiary is not necessarily responsible for the cost of a non-covered treatment. If neither the supplier nor the beneficiary knew or had reason to know that the treatment would not be covered, Medicare will bear the cost. See 42 U.S.C. § 1395pp(a); 42 C.F.R. § 411.400(a). This limitation on liability, which the plaintiffs refer to as the Medicare “mulligan,” applies only once: after the mulligan is used, the beneficiary and the supplier are on notice that coverage will be denied in the future. See 42 U.S.C. § 1395pp(a). The mulligan also does not apply if either the beneficiary or the supplier had reason to know that coverage would be denied, in which case, the supplier bears the cost. See id. § 1395pp(b). To protect against this risk, a supplier may issue 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 are also subject to additional regulation when shifting liability. See 42 U.S.C. § 1395m(j)(4). If both the beneficiary and supplier know or have reason to know a claim will be denied, the beneficiary is personally liable. See id. § 1395pp(c).

When Oxenberg and Lewis were prescribed TTFT, a Local Coverage Determination (“LCD”) in effect — LCD L34823 — provided that coverage for TTFT

would be categorically denied as not reasonable and necessary to the treatment of GBM. Both Oxenberg's and Lewis's monthly claims were initially denied under this LCD. Oxenberg appealed each denial, and although the facts for each claim were largely identical, all but one ALJ approved coverage. Lewis submitted two claims, which were denied, and appealed both denials. One ALJ approved coverage, and the other upheld the denial. ALJs are not bound by LCDs, which are developed by Medicare contractors, but they must give "substantial deference" to the LCD if it is applicable. 42 C.F.R. § 405.1062(a). If they depart from the LCD, ALJs "must explain the reasons why the policy was not followed." 42 C.F.R. § 405.1062(b).

The ALJs who denied Oxenberg's and Lewis's claims reasoned that, although the LCD may be outdated, they could only depart from the LCD on a case-specific basis but lacked authority to disregard an LCD as medically unsupported. These unfavorable decisions concluded that Novocure knew, or should have known, that Medicare would not cover TTFT and therefore held Novocure responsible for the cost.

In September 2019, LCD L34823 was revised to cover TTFT for newly diagnosed GBM patients. The new LCD provides for continued coverage for newly diagnosed<sup>1</sup> GBM patients as long as the patient receives a timely reevaluation from the patient's doctor and uses the device for an average of eighteen hours per day.

After exhausting the administrative appeals process, Oxenberg and Lewis filed this action seeking judicial review of their denied TTFT claims. Although the Secretary

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<sup>1</sup> The revised LCD L34823 does not cover treatment for recurrent GBM.

did not initially contest jurisdiction, on November 13, 2020, the Secretary filed a motion to dismiss for lack of jurisdiction. The District Court dismissed the Complaint for lack of jurisdiction under Rule 12(b)(1), reasoning that the plaintiffs had neither suffered a concrete injury nor faced an imminent risk of future injury. Oxenberg and Lewis timely appealed.

## II.<sup>2</sup>

The plaintiffs invoked the District Court’s jurisdiction under 42 U.S.C. §§ 405(g) and 1395ff(b)(1)(A), but the District Court held that it lacked jurisdiction because Oxenberg and Lewis had not alleged that they suffered a cognizable injury sufficient for standing under Article III of the Constitution.

Article III limits the federal courts to adjudication of “Cases” and “Controversies.” U.S. Const. art. III, § 2, cl. 1. “Courts enforce the case-or-controversy requirement through . . . several justiciability doctrines[,]” one of which is standing. Toll Bros. v. Twp. of Readington, 555 F.3d 131, 137 (3d Cir. 2009). Standing has three irreducible elements: “[t]he plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.” Spokeo, Inc. v. Robins, 578 U.S. 330, 338 (2016). The plaintiff bears the burden of establishing each of these elements. Id.

To establish the first element — that the plaintiff has suffered an injury in fact —

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<sup>2</sup> We have appellate jurisdiction over the District Court’s dismissal of the complaint under 28 U.S.C. § 1291. Our review of a district court’s order granting a motion to dismiss for lack of standing is plenary. See Toll Bros. v. Twp. of Readington, 555 F.3d 131, 137 (3d Cir. 2009).

the plaintiff must allege an “invasion of a concrete and particularized legally protected interest” resulting in harm that is “actual or imminent,” not “conjectural or hypothetical.” Blunt v. Lower Merion Sch. Dist., 767 F.3d 247, 278 (3d Cir. 2014) (quoting Lujan v. Defenders of Wildlife, 504 U.S. 555, 560 (1992)). Concrete injuries must be “‘real[]’ and not ‘abstract.’” Spokeo, 578 U.S. at 340 (quoting Webster’s Third International Dictionary 472 (1971)).

The plaintiffs have suffered no tangible, economic injury as a result of their denied claims. Both Oxenberg and Lewis still received TTFT, the cost of which was borne by Novocure. However, the plaintiffs argue that they have sustained statutory injuries — a violation of their entitlement to have Medicare pay for their treatment and the loss of their Medicare “mulligan” — and face an imminent risk of future denials for which they will be personally liable. We address each in turn.

A.

The plaintiffs first contend that they have a statutory right to have Medicare, as opposed to Novocure, pay for their treatment. The District Court recognized that the plaintiffs had indeed alleged an intangible injury — that Novocure and not Medicare was held financially responsible — but concluded that this injury could not satisfy the requirements of Article III because it was not concrete. To be sure, so long as they are concrete, intangible injuries can suffice for Article III purposes. See Spokeo, 578 U.S. at 340. The Supreme Court has explained that “because Congress is well positioned to identify intangible harms that meet minimum Article III requirements, its judgment is also instructive and important.” Id. at 341. But although Congress may “‘elevate to the

status of legally cognizable injuries concrete, de facto injuries that were previously inadequate in law,’ . . . Congress’s creation of a statutory prohibition or obligation and a cause of action does not relieve courts of their responsibility to independently decide” whether the plaintiff has Article III standing. TransUnion LLC v. Ramirez, 141 S. Ct. 2190, 2205 (2021) (quoting Spokeo, 578 U.S. at 341).

In a factually similar case involving a patient whose TTFT claim was denied under the old version of LCD L34823, the Court of Appeals for the Seventh Circuit concluded that “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.” Prosser v. Becerra, 2 F.4th 708, 714 (7th Cir. 2021). In Prosser, the court explained that although Congress created a cause of action for beneficiaries to seek judicial review of denials, “mere use of that process cannot, in and of itself, create an injury in fact.” Id.

The Supreme Court recently addressed a similar issue in Thole v. U. S. Bank N.A., 140 S. Ct. 1615 (2020), in which the plaintiffs had alleged an intangible but not concrete injury. The plaintiffs, who were retirees, lacked standing to bring an ERISA claim against the fiduciaries managing their retirement plan because they lacked a “concrete stake” in the outcome of the litigation. Id. at 1620. Regardless of whether the plaintiffs won or lost their case, they would be entitled to the same pension benefits. See id. at 1619. So too in this case. Regardless of whether the plaintiffs’ claims under the old version of LCD L34823 were denied in error, Oxenberg and Lewis were entitled to and received TTFT at no cost to them and have not identified a concrete injury.

Oxenberg and Lewis relatedly argue that the loss of their Medicare “mulligan,” the

one-time limitation of liability under § 1395pp, constitutes an actual, concrete injury. Section 1395pp provides that, after issuing a claim denial, the Secretary will notify the beneficiary and the provider that “in the case of comparable situations arising thereafter with respect to such individual or such provider . . . , each 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) (emphasis added); see also id. § 1395(b). In denying Oxenberg’s and Lewis’s claims, both ALJs attributed the denials to their lack of authority to disregard the old version of LCD L34823, which they conceded was outdated and did not reflect the latest research. There is nothing in the complaint or the coverage denials at issue in this case to suggest that either Oxenberg or Lewis has reason to believe that, on the basis of the prior denial, they know or should reasonably know that future claims under the new LCD will be denied. To say that the plaintiffs have lost their “mulligan” on the basis that they received a rejection under an LCD that has since been significantly amended amounts to speculation.<sup>3</sup>

B.

The plaintiffs further argue that they face an imminent risk of future injury because they may now be held personally liable for future denials. An imminent risk of future injury can satisfy Article III standing requirements. See Lujan, 504 U.S. at 564

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<sup>3</sup> The plaintiffs note that knowledge “can come from any source,” including the denial itself. Pl. Br. 32. But the plaintiffs do not explain how past denials based on the prior version of LCD L34823 would charge them with knowledge that future claims could be denied under the revised LCD.

n.2. The District Court concluded, however, that the plaintiffs' risk of future injury was too speculative to satisfy the requirements of Article III. We agree.

This argument suffers from the same problem as the plaintiffs' argument that they have standing based on their lost "mulligan." "[F]atal" to this argument is Medicare's revision of LCD L34823. Prosser, 2 F.4th at 715–16. The plaintiffs' claims were denied under the prior version of LCD L34823, which categorically denied coverage for TTFT as not reasonable and necessary. The new LCD "provides that [TTFT] is presumed reasonable and necessary for the treatment of glioblastoma." Id. at 716. That is a very significant policy change, and neither the complaint nor the underlying coverage denials suggest that Oxenberg or Lewis would not have future TTFT claims covered.<sup>4</sup> To be held personally liable for future claims, Oxenberg and Lewis would need to first be denied coverage under the new LCD. The Secretary would then need to find that, as a result of their prior denial under the old LCD, they were on notice future claims under the new LCD would likely be denied. That is too speculative and attenuated to constitute an injury in fact.<sup>5</sup>

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<sup>4</sup> In denying Lewis's claim, the ALJ noted that Lewis may not qualify for coverage under the new LCD L34823. But at that time the new LCD was not finalized; documentation was missing from the administrative record, and the ALJ's denial did not analyze whether Lewis would be entitled to coverage for continuing treatment.

<sup>5</sup> The plaintiffs have also moved this Court to take judicial notice of an ALJ decision in another TTFT case, in which the ALJ held a beneficiary personally liable notwithstanding the lack of written notice. Because our decision does not depend on whether Oxenberg and Lewis could potentially be held liable for future denied claims without written notice from Novocure, we need not take notice of that decision, and the motion is denied.

III.

For the foregoing reasons, we will affirm the order of the District Court.