UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AGENDIA, INC., **Plaintiff,** **v.** **XAVIER BECERRA, Secretary, United States Department of Health and Human Services,** **Defendant.**	**Civil Action No. 22-3242 (JDB)**

MEMORANDUM OPINION

Agendia, Inc. ("Agendia") is a clinical laboratory that provides molecular tests used in the diagnosis and treatment of breast cancer. From 2012 through 2015, Agendia was denied insurance coverage when it provided two of those tests—BluePrint and TargetPrint—to Medicare beneficiaries. Agendia appealed those denials within the U.S. Department of Health and Human Services ("HHS") but was foiled repeatedly by an HHS regulation requiring agency adjudicators to give "substantial deference" to a coverage determination developed by private Medicare contractors.

In 2019, Agendia sought judicial review in federal court in California, challenging the "substantial deference" scheme as unconstitutional and contrary to the Medicare statute. While Agendia prevailed in the district court, that decision was reversed by the Ninth Circuit. Agendia subsequently filed this lawsuit against HHS Secretary Xavier Becerra (the "Secretary") seeking judicial review of five further administrative decisions denying coverage for BluePrint and TargetPrint tests, again raising statutory and constitutional challenges to the substantial deference scheme. The Secretary argues that Agendia's lawsuit is barred by claim preclusion and issue preclusion, and alternatively fails on the merits.

The Court concludes that Agendia's legal challenges to the substantial deference scheme are barred by the earlier litigation, but that its claims concerning the basis for the administrative decisions are not. However, because those decisions are supported by substantial evidence, the Court will enter judgment for the Secretary.

Background

I. Statutory Background

Medicare is a federal health insurance program for people sixty-five or older and younger people with qualifying disabilities. 42 U.S.C. §§ 1395 et seq. While Medicare Part A pays for inpatient hospital services and other institutional care, id. § 1395c–i6, Medicare Part B covers outpatient services and diagnostic tests, id. §§ 1395j–1395w-6. Under both Parts, Medicare only reimburses medical services and items "reasonable and necessary" for the treatment of beneficiaries. Id. § 1395y(a)(1)(A).

After providing service to a Medicare beneficiary, a medical provider submits a claim for reimbursement to a private entity administering Medicare under contract with HHS. The Medicare administrative contractor makes an initial determination as to whether the service is covered. 42 C.F.R. § 405.920; see also 42 U.S.C. § 1395kk-1(a)(4)(A). If the contractor denies the claim, the provider can appeal. 42 C.F.R. § 405.904; see generally 42 U.S.C. § 1395ff.

The Medicare administrative appeals process has four levels: (1) redetermination by the contractor that originally denied the claim; (2) review by a different contractor (known as a "qualified independent contractor"); (3) a hearing before an administrative law judge ("ALJ"); and (4) review by the Medicare Appeals Council ("the Council"). 42 C.F.R. § 405.904(a)(2). If a provider exhausts its administrative appeals, or the appeals are not decided within statutory time limits, the provider can seek judicial review in a federal district court. 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A).

To maintain consistency among administrative determinations, Congress has authorized the issuance of binding regulations and non-binding guidance. As relevant here, the Secretary may, after a unique notice-and-comment process, issue national coverage determinations, which are legally binding "with respect to whether or not a particular item or service is covered nationally." Id. § 1395ff(f)(1)(B); see also 42 C.F.R. §§ 400.202. These determinations bind all levels of the administrative review process. See 42 C.F.R. § 405.1060(a)(4).

Absent such a policy, a Medicare administrative contractor may issue local coverage determinations ("LCD") governing its front-line adjudication. 42 U.S.C. §§ 1395kk-1(a)(4), 1395ff(f)(2)(B). An LCD states the contractor's policy as to whether a specific service is "reasonable and necessary" under Medicare and, therefore, whether the contractor will reimburse the service. Id. Unlike national coverage determinations, LCDs are not binding on any subsequent administrative review. However, under HHS regulations, qualified independent contractors, ALJs, and the Council must give "substantial deference" to applicable LCDs. 42 C.F.R. §§ 405.968(b)(2)–(3), 405.1062(a)–(b). "If an ALJ or attorney adjudicator or Council declines to follow a policy in a particular case, the ALJ or attorney adjudicator or Council decision must explain the reasons why the policy was not followed." Id. § 405.1062(b).

Local and national coverage determinations can be challenged facially before an ALJ. See 42 U.S.C. § 1395ff(f). But only Medicare beneficiaries "who are in need of the items or services that are the subject of the coverage determination" have standing to raise such challenges. Id. § 1395ff(f)(5). Providers may only appeal coverage denials on a claim-by-claim basis. In such appeals, the agency adjudicators "will give substantial deference to [LCDs] if they are applicable to a particular case." 42 C.F.R. § 405.1062(a). Any decision to "disregard such policy applies only to the specific claim being considered and does not have precedential effect." Id. § 405.1062(b).

II. Factual Background

Agendia is a clinical laboratory that provides molecular diagnostic testing to patients with breast cancer. Compl. for Judicial Review [ECF No. 1] ("Compl.") ¶ 1. The laboratory's tests identify the genetic and molecular profile of a breast cancer tumor, providing information relevant to the patient's prognosis and the physician's assessment of treatment options. Id. Principally at issue here are two of Agendia's tests: BluePrint and TargetPrint. From 2012 to 2015, Agendia provided hundreds of these tests to Medicare beneficiaries and submitted claims for reimbursement to its assigned contractor—first Palmetto GBA ("Palmetto"), then Noridian Healthcare Solutions, LLC ("Noridian"). See id. ¶¶ 2–3.

Both contractors relied on the Molecular Diagnostic Services ("MolDX") Program, developed by Palmetto, to "identify and establish coverage and reimbursement for molecular diagnostic tests." See Admin. R. ("A.R.") 1:362 (J.A. 88) (Noridian Position Paper); A.R. 5:538–39 (J.A. 857–58).[1] The MolDX program deploys subject matter experts to perform technical assessments of published data regarding the tests. See A.R. 1:362–63 (J.A. 88–89). If a test does not "demonstrate analytical and clinical validity" and "clinical utility," MolDX considers it "investigational" and not "reasonable and necessary" to support Medicare coverage. See A.R. 1:363 (J.A. 89). In August 2012, MolDX issued a policy article concluding, after a technical assessment, that "there is insufficient evidence to support reasonable and necessary criteria for Medicare reimbursement" for BluePrint. Mem. of P. & A. in Supp. of Def.'s Cross-Mot. for Summ. J. & Opp'n to Pl.'s Mot. for Summ. J., ("Def.'s Cross-Mot. & Opp'n"), Ex. C [ECF No. 22-4] at *3. MolDX did not publish an evaluation of the TargetPrint test. See Def.'s Cross-Mot. & Opp'n [ECF No. 22-1] at 8. Another breast cancer typing test offered by Agendia—

[1] The Court has provided dual citations to the Administrative Record, which is cited by volume and page number, and to the Joint Appendix submitted pursuant to Local Civil Rule 7(n).

MammaPrint—is specifically covered under an LCD. See Def.'s Cross-Mot. & Opp'n, Ex. D [ECF No. 22-5] at *5.

During the relevant periods, Palmetto and Noridian issued LCDs indicating they would not cover molecular diagnostic tests that were not authorized by a national coverage determination or by MolDX. See Def.'s Cross-Mot. & Opp'n, Ex. A [ECF No. 22-2] (Palmetto LCD 32288); id., Ex. D (Noridian LCD L33541). Because neither BluePrint nor TargetPrint was approved by MolDX or a national coverage determination, the contractors denied Agendia's claims for reimbursement. See A.R. 1:622 (J.A. 328).

As noted above, a provider can only challenge coverage denials on a claim-by-claim basis. However, providers can bundle appeals together into tranches comprising dozens of claims for the same service or services. Here, Agendia filed "multiple, separate, bundled appeals" for denials of coverage for BluePrint and TargetPrint tests. Pl.'s Opp'n to Def.'s Cross-Mot. & Reply in Supp. of Mot. for Summ. J. [ECF No. 24] ("Pl.'s Reply & Opp'n") at 5. Those tranches were reviewed first on reconsideration by the Medicare administrative contractor, then on review by the qualified independent contractor, and finally at hearing before different ALJs—a process that took several years. At hearings before ALJ Fuller, ALJ Conway, and ALJ Smibert, Agendia presented testimony from a medical oncologist who described how the BluePrint and TargetPrint tests were used to diagnose and develop treatment plans for a sample set of beneficiaries whose claims were, nonetheless, denied. See, e.g., A.R. 1:181–83 (J.A. 63–65). Agendia also submitted in some cases medical articles that it claimed supported the use of its tests. See id. at 4:8436–50 (J.A. 768–82). ALJ Fuller, ALJ Conway, and ALJ Smibert considered the evidence but also gave "substantial deference" to the relevant LCD and ultimately decided that the BluePrint and TargetPrint tests at issue were not reasonable or necessary for the beneficiaries. See A.R. 1:180 (J.A. 62) (ALJ Fuller I); A.R. 2:180 (J.A. 495) (ALJ Fuller II); A.R. 3:79 (J.A. 614) (ALJ Conway); A.R. 4:54 (J.A.

667) (ALJ Smibert). Agendia sought review of those decisions from the Council, but the administrative body never took up their claims. See A.R. 1:1 (J.A. 1); A.R. 2:1 (J.A. 441); A.R. 3:1 (J.A. 556); A.R. 4:1 (J.A. 625). ALJ Amendola issued a decision in Agendia's favor without giving substantial deference to the applicable LCDs. See A.R. 5:101 (J.A. 845). The Council, on its own motion, reviewed and overturned the favorable decision because ALJ Amendola failed to give "substantial deference to the applicable LCD or explain[] the reasons for not doing so." A.R. 5:4 (J.A. 810).

III. Procedural History

A. Agendia I

Before describing the procedural history of this litigation, the Court will first recount the procedural history of Agendia's litigation in the Ninth Circuit, as the outcome of that litigation bears directly on the claims before this Court. On January 14, 2019, Agendia filed a complaint in the Central District of California seeking judicial review of a Council decision denying Medicare coverage for a tranche of BluePrint and TargetPrint tests. Agendia, Inc. v. Azar, 420 F. Supp. 3d 985, 990 (C.D. Cal. 2019). At issue in that case were tests provided to 86 Medicare beneficiaries from 2012 to 2013. Id. at 989. Agendia's claims for reimbursement were initially denied by its assigned contractor—Palmetto—and upon reconsideration by the qualified independent contractor, who relied on a MolDX determination that "there [was] insufficient evidence to support the required clinical utility" of the tests. Id. After a hearing, an ALJ reversed, concluding that the testing was reasonable and necessary. Id. at 989–90. But the Council reversed the ALJ's decision because "the ALJ erred as a matter of law by departing from the LCD, the relevant policies, and MolDX, and the Council found no reason 'not to apply substantial deference to the LCD or to question the MolDX program's findings.'" Id. at 990 (quoting the administrative record).

In federal court, Agendia raised three challenges to the Council's decision: (1) "that the administrative process at issue is an unconstitutional delegation of lawmaking authority to private contractors in violation of the Fifth Amendment Due Process Clause"; (2) "that the administrative process depended on an LCD, policy article, and MolDX program that were adopted without complying with the rulemaking requirements in the Medicare Act"; and (3) "that the decision in this matter is arbitrary and capricious and not in accordance with the law or supported by substantial evidence." Id. The district court rejected Agendia's constitutional nondelegation challenge because the agency retained "authority and surveillance" over the private contractors. Id. at 994. But the court sustained Agendia's rulemaking challenge, holding that LCDs must be promulgated by notice-and-comment rulemaking because they establish "substantive legal standard[s]" through the requirement that agency adjudicators give them "substantial deference." Id. at 997–98. Having reached this conclusion, the district court did not consider whether the agency's decision was arbitrary and capricious or otherwise unsupported by the evidence. Id. at 998.

The Secretary sought review in the Ninth Circuit. The appellate court agreed with the district court that private contractors' ability to issue LCDs was not an unconstitutional delegation. Agendia, Inc. v. Becerra ("Agendia I"), 4 F.4th 896, 902–03 (9th Cir. 2021). However, the court reversed on the rulemaking question, holding that the Medicare Act does not require LCDs to go through notice-and-comment. Id. at 901–02. The Supreme Court denied Agendia's petition for a writ of certiorari on January 24, 2022. Agendia, Inc. v. Becerra, 142 S. Ct. 898 (2022).

B. Present Litigation

Nine months later, on October 24, 2022, Agendia filed the present complaint for judicial review. This complaint seeks review of five HHS administrative decisions (issued after the Ninth Circuit litigation began) denying coverage for BluePrint and TargetPrint tests and raises

constitutional and statutory challenges to Medicare's policy of giving substantial deference to LCDs. See Compl. ¶¶ 20–21. On May 11, 2023, Agendia filed a motion for summary judgment, which makes four arguments: (1) Medicare's substantial deference to LCDs issued by private entities is an unconstitutional delegation; (2) the regulation requiring substantial deference to LCDs is arbitrary and capricious and contrary to the Medicare statute; (3) the LCDs should have been issued pursuant to notice-and-comment; and (4) each of the five administrative decisions is not supported by substantial evidence. See Pl.'s Mem. of P. & A. in Supp. of Pl.'s Mot. for Summ. J. [ECF No. 20-1] ("Pl.'s Mot.").

The Secretary filed an opposition and cross-motion for summary judgment asserting that the entire lawsuit, or at minimum two of Agendia's arguments, are precluded by prior litigation between the parties in Agendia I. See Def.'s Cross-Mot. & Opp'n. Alternatively, the Secretary argues that there is no constitutional or statutory violation, and that each administrative decision is supported by substantial evidence. The parties submitted a joint appendix of the administrative record, as required by Local Civil Rule 7(n). The motions are now fully briefed and ripe for resolution.

Legal Standard

"Although styled [as] Motions for Summary Judgment, the pleadings in this case more accurately seek the Court's review of an administrative decision." Gentiva Healthcare Corp. v. Sebelius, 857 F. Supp. 2d 1, 6 (D.D.C. 2012), aff'd, 723 F.3d 292 (D.C. Cir. 2013). The function of the Court in such cases is to determine whether the administrative record supports the agency's action. Id. "Summary judgment thus serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the [relevant] standard of review." Id.

"Federal jurisdiction is extremely limited for claims arising under the Medicare Act." Porzecanski v. Azar, 943 F.3d 472, 480 (D.C. Cir. 2019). A provider must first present its claims to the agency and exhaust its administrative remedies, id.; see 42 U.S.C. § 1395ff(b)(1)(A), "regardless of whether the matter involves a direct constitutional, statutory, or regulatory challenge," Three Lower Ctys. Cmty. Health Servs., Inc. v. U.S. Dep't of Health & Hum. Servs., 317 Fed. App'x 1, 2 (D.C. Cir. 2009) (per curiam).

The scope of judicial review of Medicare adjudications is also limited. As to matters of fact, a court must uphold the Secretary's determinations if they are "supported by substantial evidence" in the administrative record. 42 U.S.C. § 405(g). Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support [the Secretary's] conclusion." Saunders v. Kijakazi, 6 F.4th 1, 4 (D.C. Cir. 2021) (quoting Butler v. Barnhart, 353 F.3d 992, 997 (D.C. Cir. 2004)); accord Richardson v. Perales, 402 U.S. 389, 401 (1971)). While it "requires more than a scintilla, [it] can be satisfied by something less than a preponderance of the evidence." Id. (quoting Butler, 353 F.3d at 999). Apart from matters of fact, the Secretary's decisions are reviewable under the Administrative Procedure Act standard, which requires courts to determine if the agency's action was "arbitrary, capricious, an abuse of discretion, . . . otherwise not in accordance with law, . . . [or] without observance of procedure required by law." 5 U.S.C. § 706(2); see Almy v. Sebelius, 679 F.3d 297, 302 (4th Cir. 2012).

Analysis

The Court begins with the Secretary's argument that this litigation is precluded by Agendia I and then proceeds to the merits of the remaining, non-precluded claims.[2]

[2] This Court has subject matter jurisdiction to hear Agendia's claims because Agendia presented its claims to the agency, and the Council issued a final decision with respect to one tranche of claims, 42 U.S.C. § 1395ff(b)(1)(A), and the Council did not issue a decision before the statutory deadline with respect to the other four tranches of claims, id. § 1395ff(d)(2)(A). Agendia also exhausted its arguments concerning the constitutionality of giving substantial deference to LCDs and the need for notice-and-comment rulemaking on LCDs. See J.A. 824–27. It does not appear that Agendia previously raised its argument that the substantial deference rule is contrary to the

I. Preclusion

The Secretary argues that Agendia's lawsuit, or at least two issues raised in it, are precluded by the prior litigation in Agendia I.

A. Claim Preclusion

Under the doctrine of claim preclusion, "a final judgment on the merits of an action precludes the parties or their privies from relitigating issues that were or could have been raised in that action." Cal. Cmtys. Against Toxics v. EPA, 928 F.3d 1041, 1051 (D.C. Cir. 2019) (quoting Allen v. McCurry, 449 U.S. 90, 94 (1980)). A subsequent lawsuit is barred by claim preclusion "if there has been prior litigation (1) involving the same claims or cause of action, (2) between the same parties or their privies, and (3) there has been a final, valid judgment on the merits, (4) by a court of competent jurisdiction." Nat. Res. Def. Council v. EPA ("NRDC"), 513 F.3d 257, 260 (D.C. Cir. 2008) (quoting Smalls v. United States, 471 F.3d 186, 192 (D.C. Cir. 2006)).

Here, it is undisputed that the latter three requirements are met. See Def.'s Cross-Mot. & Opp'n at 12; Pl.'s Reply & Opp'n at 5. Agendia I involved the same parties (Agendia and the Secretary) and resulted in a final judgment on the merits (Agendia I, 4 F.4th at 903) by a court of competent jurisdiction (the Ninth Circuit). The disputed issue is whether Agendia seeks to litigate the same "claim or cause of action" that it previously litigated in Agendia I.

In the D.C. Circuit, "[w]hether two cases implicate the same cause of action turns on whether they share the same 'nucleus of facts.'" Apotex, Inc. v. FDA., 393 F.3d 210, 217 (D.C. Cir. 2004) (quoting Drake v. Fed. Aviation Admin., 291 F.3d 59, 66 (D.C. Cir. 2002)). "In pursuing this inquiry, the court will consider 'whether the facts are related in time, space, origin, or motivation, whether they form a convenient trial unit, and whether their treatment as a unit

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substantive statute. See id. However, because the Secretary does not challenge any failure to exhaust this argument, he has forfeited it, and the Court has jurisdiction to hear it. See Am. Hosp. Ass'n v. Hargan, 289 F. Supp. 3d 45, 51 (D.D.C. 2017), aff'd sub nom. Am. Hosp. Ass'n v. Azar, 895 F.3d 822 (D.C. Cir. 2018).

conforms to the parties' expectations or business understanding or usage.'" Id. (quoting I.A.M. Nat'l Pension Fund v. Indus. Gear Mfg. Co., 723 F.2d 944, 949 n.5 (D.C. Cir. 1983)).

The Secretary argues that this case and Agendia I are materially the same because they concern coverage denials of the same tests, during the same time periods, pursuant to the same legal principles:

> In both cases, [Agendia] challenges coverage denials of the same molecular diagnostic tests, TargetPrint and BluePrint, based on the same LCDs, Policy Article A51931, and the Molecular Diagnostic Services program. There are overlapping service dates for the claims at issue. The final decision applied 42 C.F.R. § 405.1062 (the "substantial deference rule") by deferring to the specific LCDs at issue both in the disputed final agency decision in Agendia I and in each of the final decisions at issue here.

Def.'s Reply in Supp. of Def.'s Cross-Mot. [ECF No. 26] ("Def.'s Reply") at 2 (citations omitted). Agendia contends that this case is materially different from Agendia I because it concerns five different administrative decisions that were not challenged in the prior litigation. "Among other differences, the doctors who ordered the testing and the beneficiaries who received the testing are different from those in Agendia I, and thus the facts regarding the medical necessity and reasonableness of the testing are not the same." Pl.'s Mot. at 17.

The D.C. Circuit's analysis in NRDC guides this Court's application of the "common nucleus" test to legal challenges to agency action. NRDC involved an advocacy group's successive challenges to EPA's regulation of methyl bromide. In its first suit, NRDC challenged EPA's framework rule for determining critical uses of chemicals that deplete the ozone and this framework rule's 2005 application to methyl bromide. 513 F.3d at 258. After losing that challenge, NRDC brought another lawsuit, once again challenging the framework rule, now applied to the 2007 regulation of methyl bromide. Id. Although NRDC had presented slightly different arguments as to why the 2004 rule was unlawful, the second suit was barred because "NRDC's claim has not changed: in the first case it argued that the 2004 framework was invalid

as adopted and applied to determine the 2005 exemption, and now it challenges the 2004 framework—which EPA left unchanged—as applied to determine the 2007 exemption." Id. at 258. Ultimately, NRDC's lawsuits both boiled down to the same claim: "that . . . the Framework Rule [is] unlawful." Id. at 261.

Under NRDC, Agendia's statutory and constitutional claims are precluded by the earlier litigation in Agendia I. Agendia's first argument is that allowing private contractors to issue LCDs, which get "substantial deference" on administrative appeal, is an impermissible, unconstitutional delegation. Agendia's second argument is that the regulation requiring agency adjudicators to give "substantial deference" to LCDs is arbitrary and capricious and contrary to the Medicare statute. Agendia's third argument is that LCDs must go through notice-and-comment because they are given "substantial deference" and, therefore, create substantive legal standards. All three of these arguments go to the same claim: that substantial deference to LCDs is unlawful. Like the plaintiff in NRDC, Agendia is merely offering "different legal theories to support the same claim." 513 F.3d at 261.[3]

This conclusion draws further support from University of Colorado Health v. Azar, 486 F. Supp. 3d 185 (D.D.C. 2020), where the court held that a hospital system was barred from bringing another challenge to the same reimbursement rule after that rule was reapplied to the next year's reimbursement. Id. at 202–03. The court concluded that the claim was defined by a challenge to the rule, not its application to a specific reimbursement. The subsequent enforcement of the same rule did not create a new claim. Id. at 203. Likewise, here, the reapplication of substantial

[3] Indeed, Agendia relied on the first and third of these legal theories in the prior action. And there can be no question that Agendia was able to raise the second. A court's resolution of the argument that the substantial deference rule is arbitrary, capricious, and contrary to the Medicare statute is based on purely legal considerations that have not changed since the prior litigation and that are not specific to any adjudication. That argument is closely related to Agendia's constitutional challenge to the same rule and its rulemaking challenge to a related provision. This challenge could and should have been made in the earlier litigation.

deference to LCDs denying reimbursement for Agendia's genetic tests does not give Agendia license to rechallenge the same rule.

Plaintiff's reliance on Galen Hospital Alaska, Inc. v. Azar, 474 F. Supp. 3d 214 (D.D.C. 2020), is unavailing. That case involved the claims of 158 hospitals that were party to an earlier action challenging certain Medicare reimbursement rules for fiscal years 2004 to 2006. See id. at 219. At the time of the earlier litigation, the hospital plaintiffs in the new case were statutorily precluded from seeking judicial review of the 2005 and 2006 rules. The court held that, because "claim preclusion does not bar a claim which could not have been brought in the earlier action," those plaintiffs were not precluded from challenging the 2005 and 2006 rules in a second proceeding. Id. at 225–26. The case would only support challenge to a new rule that could not have been challenged during the earlier litigation. Here, Agendia challenges the same rule it challenged previously. Hence, Agendia is barred from raising its arguments that LCDs should have been promulgated by rulemaking and that giving substantial deference to an LCD is unconstitutional and contrary to the Medicare statute.

That leaves Agendia's argument that the five administrative decisions at issue in this case were not supported by substantial evidence. This argument does not turn on the legal validity of the overarching coverage determination framework, and Agendia is not precluded from advancing it. It is axiomatic that claim preclusion "does not bar a litigant from doing in the present what he had no opportunity to do in the past." Drake, 291 F.3d at 67. Hence, claim preclusion "does not bar parties from bringing claims based on material facts that were not in existence when they brought the original suit." Apotex, Inc., 393 F.3d at 218 (citing Drake, 291 F.3d at 66). Thus, in Drake, the D.C. Circuit held that a plaintiff who previously challenged a regulatory scheme was not precluded from challenging "the agency's subsequent determination that [a party] did not violate those regulations." Id. at 66. Similarly, here, the five administrative decisions did not issue

until after the earlier litigation concluded, and Agendia did not have an opportunity to argue in Agendia I that the Secretary's determination that BluePrint and TargetPrint tests were not "reasonable and necessary" for the specific beneficiaries was unsupported by substantial evidence. Unlike Agendia's purely legal claims, these "substantial evidence" challenges turn on the specific facts presented in those adjudications. See Compl. ¶ 20.

It is true, as the Secretary points out, that the tests at issue were performed before Agendia I was filed and many of the material facts are the same between the sets of adjudications. Def.'s Cross-Mot. & Opp'n at 15–16. However, the challenged administrative decisions had not issued before Agendia I was filed. Moreover, the Secretary does not suggest that Agendia presented exactly the same evidence each time, or that each of the patients had materially the same condition. It undermines the Secretary's arguments elsewhere that LCDs are not binding, see Def.'s Cross-Mot. & Opp'n at 21, 27–28, to suggest that applying substantial deference to the same LCDs obviates any differences among beneficiaries' claims. See Cal. Cmtys. Against Toxics, 928 F.3d at 1051 (noting that "[n]o matter how similar the defendant's conduct," a plaintiff is allowed to maintain a challenge based on a "completely different event" (cleaned up) (quoting Russian Media Grp. v. Cable Am., Inc., 598 F.3d 302, 311 (7th Cir. 2010)).

If Agendia's argument were only that the Secretary legally erred by applying the substantial deference rule in later adjudications, that claim would merge into the others discussed above. Indeed, Agendia's argument sometimes seems to boil down to this. Agendia argues that the adjudicator's decision in each case was faulty because the adjudicator relied on the LCD in the face of the factual evidence proffered by Agendia. See Compl. ¶ 21 ("[I]n each of the five decisions, the ultimate government adjudicator was required by regulation, 42 C.F.R. § 405.1062, to defer substantially, and did, in fact, defer substantially to the coverage policies established by a private contractor, a [Medicare administrative contractor's] LCD."). Agendia further argues that

there is no evidence in support of the agency's decision because the decisionmaker "relied solely on [the LCD], which is not 'evidence.'" Pl.'s Mot. at 26; see id. at 31–34. However, Agendia also seems to be challenging the basis for each decision, which varied slightly from adjudication to adjudication. Construing Agendia's claims in this manner, Agendia's challenge to whether the LCD should have prevailed despite the evidence presented in each case is not precluded by earlier litigation. See Univ. of Colo. Health, 486 F. Supp. 3d at 204 (recognizing distinction between repetitive facial challenges and "an as-applied challenge—for example, that the Secretary had made 'a unique calculational error' in applying an already-upheld rule to a new cost report").

In sum, claim preclusion bars Agendia from arguing that (1) Medicare's substantial deference to LCDs issued by private entities is an unconstitutional delegation; (2) the regulation requiring substantial deference to LCDs is arbitrary and capricious and contrary to the Medicare statute; and (3) the LCDs should have been issued pursuant to notice-and-comment rulemaking. However, claim preclusion does not bar Agendia from arguing that each of the five administrative decisions is not supported by substantial evidence.

B. Issue Preclusion

Issue preclusion also bars relitigation of Agendia's arguments that Medicare's substantial deference to LCDs issued by private entities is an unconstitutional delegation and that the LCDs should have been issued pursuant to notice-and-comment, because those issues were actually and necessarily decided by the Ninth Circuit and there is no valid reason for this Court to revisit them. Under the doctrine of issue preclusion, "once a court has decided an issue of fact or law necessary to its judgment, that decision may preclude relitigation of the issue in a suit on a different cause of action involving a party to the first case." Cal. Cmtys. Against Toxics, 928 F.3d at 1051 (quoting Allen, 449 U.S. at 94). A prior holding has preclusive effect if three requirements are met: (1) "the same issue now being raised must have been contested by the parties and submitted for judicial

determination in the prior case"; (2) "the issue must have been actually and necessarily determined by a court of competent jurisdiction in that prior case"; and (3) "preclusion in the second case must not work a basic unfairness to the party bound by the first determination." Id. at 1051–52 (quoting Yamaha Corp. of Am. v. United States, 961 F.2d 245, 254 (D.C. Cir. 1992)).

Agendia does not dispute that its nondelegation and rulemaking challenges were actually and necessarily decided in Agendia I. Pl.'s Reply & Opp'n at 6; see Agendia I, 4 F.4th at 902. Agendia argues, however, that this Court should nonetheless consider them for two reasons. First, Agendia urges the Court to reconsider the constitutional nondelegation issue due to "intervening changes in the controlling legal principles since Agendia I." Pl.'s Reply & Opp'n at 6–7. But while preclusion is "inappropriate when the issue is one of law and there has been a change in the legal context after the first decision," Pharm. Care Mgmt. Ass'n v. District of Columbia, 522 F.3d 443, 447 (D.C. Cir. 2008), Agendia has not identified any change in law that would warrant reconsideration. Agendia cites a case from the Fifth Circuit holding a private delegation unconstitutional in an entirely unrelated statutory scheme, Nat'l Horsemen's Benevolent & Protective Ass'n v. Black, 53 F.4th 869 (5th Cir. 2022), and a decision of another judge in this District rejecting a plaintiff's nondelegation argument, Scottsdale Cap. Advisors Corp. v. Fin. Indus. Regul. Auth., Civ. A. No. 23-1506 (BAH), 2023 WL 3864557, at *10 (D.D.C. June 7, 2023). Those cases do not change controlling legal principles.

Second, Agendia asks the Court to disregard the issue-preclusive effect of Agendia I because the issues are "important" and involve "'questions of national law' in litigation involving the federal government as opposed to purely private party litigants." Pl.'s Mot. at 17. On this point, Agendia misstates the legal principle on which it relies. The Supreme Court has recognized a limited exception to nonmutual issue preclusion when the federal government seeks to relitigate a legal question decided in a dispute with a different party. See United States v. Mendoza, 464

U.S. 154, 159 (1984). Preclusion is inappropriate under such circumstances because binding the government to a single judgment would foreclose national, circuit-by-circuit litigation of issues of law with different parties. Id. at 159–60. Those same concerns are not raised, however, when the government asserts issue preclusion in litigation with the same party. "[I]n the instant case, where the government and the private entity are litigating the same issue, application of the issue preclusion doctrine is appropriate without running the risk of 'petrifying the law' because other regulated entities not a party to [this case] are still free to litigate this issue." Canonsburg Gen. Hosp. v. Sebelius, 989 F. Supp. 2d 8, 22–23 (D.D.C. 2013), aff'd sub nom. Canonsburg Gen. Hosp. v. Burwell, 807 F.3d 295 (D.C. Cir. 2015)). Agendia had its "bite at the apple" with respect to the nondelegation and rulemaking issues in the Ninth Circuit, and there is no basis for this Court to revisit them.

II. Substantial Deference Regulation

As discussed above, the Court concludes that Agendia's challenge to the coherence of the "substantial deference" rule with the Medicare statute is barred by claim preclusion. But because the Ninth Circuit did not directly consider the question, it is not as clearly barred by issue preclusion. Out of an abundance of caution, the Court will also briefly address the merits of this challenge and the extent to which it is issue precluded by the Ninth Circuit's decision.

Agendia's argument that the regulation requiring ALJs and the Council to give "substantial deference" to LCDs, 42 C.F.R. § 405.1062(a), is inconsistent with the Medicare statute has two parts. Although Agendia's arguments on this point are not clearly presented, the Court will undertake to deal with them fairly. First, Agendia seems to argue that the substantial deference rule is arbitrary and capricious because it delegates authority to private contractors without statutory authorization. See Pl.'s Mot. at 22–24. Agendia relies primarily on U.S. Telecom Ass'n v. FCC, 359 F.3d 554 (D.C. Cir. 2004), which held that a federal agency "may not subdelegate

['decision-making authority'] to outside entities—private or sovereign—absent affirmative evidence of authority to do so." Id. at 566. Although framed as a new challenge to the Secretary's authority to delegate under the statute, this challenge is strikingly similar to Agendia's unconstitutional delegation argument and the determinations already reached by the Ninth Circuit on that challenge resolve this one too. Cf. Yamaha, 961 F.2d at 256 (concluding that plaintiff's later allegation was precluded by decisive holding in prior litigation); McLaughlin v. Bradlee, 803 F.2d 1197, 1203 (D.C. Cir. 1986) (barring successive presentation of "overlapping issues").

In Agendia I, the Ninth Circuit held that giving "substantial deference" to LCDs does not unconstitutionally delegate final decision-making authority to private contractors because LCDs are not binding on ALJs or the Council, and the Secretary retains authority to review them (upon a challenge by a beneficiary) or to supersede them with national coverage determinations. 4 F.4th at 902–03. The Agendia I court also held that LCDs do not establish any substantive legal standards but only "help adjudicators apply the reasonable and necessary standard to the facts of a claim." Id. at 902. From these holdings, it follows that the Secretary has not delegated decision-making authority to private contractors.

Second, Agendia contends that the "substantial deference" rule conflicts with the language of the Medicare statute. See Pl.'s Mot. at 22; Pl.'s Reply & Opp'n at 12–13. Agendia points out that the statute does not specifically authorize ALJs or the Secretary to give substantial deference to LCDs. Pl.'s Mot. at 22. Agendia further argues that statutory language instructing qualified independent contractors to "consider" LCDs suggests that Congress did not intend higher-level reviewers "to even consider," much less give substantial deference to, those determinations. Id. The Secretary acknowledges that the statute does not address the level of deference ALJs or the Council should give LCDs but responds that the Secretary's regulation is reasonable and warrants

deference under Chevron U.S.A. Inc. v. Natural Resources Defense Council, 467 U.S. 837 (1984). Def.'s Cross-Mot. & Opp'n at 30.

The D.C. Circuit has instructed courts to give Chevron deference to the Secretary when the challenged agency regulation is "based on the text of the Medicare Act itself." Gentiva Health Servs., Inc. v. Becerra, 31 F.4th 766, 775 (D.C. Cir. 2022) (cleaned up) (quoting Marymount Hosp., Inc. v. Shalala, 19 F.3d 658, 661 (D.C. Cir. 1994)). "Under Chevron, the court considers two questions: first, whether Congress 'directly addressed' the issue in dispute, and second, if 'the statute is silent or ambiguous with respect to the specific issue,' whether 'the agency's answer is based on a permissible construction of the statute.'" Gentiva Health Servs., Inc., 31 F.4th at 775 (citations omitted). The Court agrees with the parties that the statute does not "directly address" how ALJs and the Council should weigh LCDs. But the Court concludes that the Secretary's regulation is reasonable in the context of the statutory scheme.

The statutory scheme distinguishes claim appeals, which may be brought by providers or beneficiaries, from facial challenges to local coverage determinations, which can only be brought by beneficiaries. See Medicare Program: Changes to the Medicare Claims Appeal Procedures, 70 Fed. Reg. 11420, 11458 (Mar. 8, 2005). Compare 42 U.S.C. § 1395ff(b) (appeal rights from claim denials), with id. § 1395ff(f) (review of coverage determinations). On facial review of a local coverage determination, the ALJ "shall . . . evaluate the reasonableness of the determination" and "shall defer only to the reasonable findings of fact, reasonable interpretations of law, and reasonable applications of fact to law by the Secretary." 42 U.S.C. § 1395ff(f)(2)(A). This separate process suggests that Congress may not have intended for challenges to the "reasonableness of the determination" to be raised within a claim appeal. Indeed, the statutory provision pertaining to claim appeals does not provide for any review of local coverage determinations and does not set forth the level of deference that should (or could) be given to them.

Therefore, the Secretary's view that the claim appeal process gives providers and beneficiaries an opportunity to challenge "whether and how the policy in question applies to the specific claim for benefits," 70 Fed. Reg. at 11458, is a reasonable interpretation of the bifurcated statutory appeals process. Giving "substantial deference" to LCDs is consistent with this interpretation.

The statutory provision requiring qualified independent contractors to "consider" LCDs does not suggest that ALJs and the Council are prohibited from giving "substantial deference" to the same. Read in context, that command appears to reflect an effort to clarify that LCDs warrant continued consideration, even when "independent" review is conducted. See 42 U.S.C. § 1395ff(c)(3)(ii)(II) (noting that while LCDs "shall not be binding . . . the qualified independent contractor shall consider the [LCD] in making [its] decision"). The provision does not suggest a particular ceiling on the level of consideration that can be given by an ALJ or the Council.

Agendia asks the Court to reject Chevron deference considering the Supreme Court's pending review of the doctrine. Pl.'s Reply & Opp'n at 13. Even if this Court were not still bound by Chevron (it is), there would be good reasons to defer to the Secretary's regulation. Cf. Kisor v. Wilkie, 139 S. Ct. 2400, 2414 (2019) (suggesting courts should consider an interpretation's "power to persuade" when Chevron deference is not warranted); Skidmore v. Swift & Co., 323 U.S. 134, 140 (1944). The Secretary has authority to "make rules and regulations and to establish procedures" governing the administrative appeals process. 42 U.S.C. § 405(a). The challenged rule was promulgated after notice-and-comment where the Secretary expressly considered the question of ALJ and Council independence and revised the regulation to provide for deviation in particular cases. See 70 Fed. Reg. at 11458. Further, the regulation has endured for nineteen years, despite subsequent changes to related portions of the Medicare statute, suggesting Congress's implicit approval. See Def.'s Cross-Mot. & Opp'n at 32; see Zuni Pub. Sch. Dist. No. 89 v. Dep't of Educ., 550 U.S. 81, 90–91 (2007) (applying congressional acquiescence canon).

Finally, the regulation is reasonable in light of Congress's and the Secretary's efforts to maintain consistency among adjudications in the administrative appeals regime. See 42 U.S.C. 1395ff(e)(4)(A); Medicare Program: Changes to the Medicare Claims Appeal Procedures, 67 Fed. Reg. 69312, 69328 (Nov. 15, 2002) (preamble to proposed rule). Hence, even if Agendia's statutory challenges to the "substantial deference" rule were not barred by claim preclusion, they would fail.

III. Substantial Evidence

The Court has concluded that Agendia's challenges to each of the five administrative decisions are not barred to the extent Agendia's argument is that each decision is unsupported by substantial evidence—a question that was not and could not have been raised in Agendia I. Before proceeding to the merits of those challenges, the Court makes two preliminary points.

First, as noted above, Agendia's challenges to the decisions at times seem to collapse into the argument that agency adjudicators should not have given "substantial deference" to LCDs at all. See, e.g., Pl.'s Mot. at 26 ("[T]he Council relied solely on LCD L33541."); id. at 32 ("Such deference . . . is not warranted."); id. at 34 ("LCDs divin[ed] the outcome notwithstanding the lack of substantial evidence in the record to support it."). The claim that the Secretary's decisions were not supported by substantial evidence because the adjudicator applied the "substantial deference" rule is precluded by the earlier Ninth Circuit litigation because it is inseparable from the argument that the substantial deference scheme is unlawful.

Second, Agendia's arguments and evidence presented before the agency adjudicators—although channeled through a claims appeal process—were generalized and seemed to apply equally to any breast cancer patient. Indeed, Agendia's patient-specific evidence was given on a representative basis. The Court's review of prior agency decisions supplied by the Secretary, see ECF Nos. 26-2 through 26-5, as well as the explanation given in the agency's analysis of the

"substantial deference" rule in the Federal Register, see 70 Fed. Reg. at 11458, suggest that claim appeals succeed, notwithstanding an applicable LCD, when the appellant raises and makes an individualized argument; indeed, the statute prohibits providers and beneficiaries from facially challenging LCDs within a claim appeal (instead of the separate process limited to beneficiaries). See Council Decision M-22-3814 [ECF No. 26-5] at 4 (suggesting that facts specific to a beneficiary are a basis for departing from an LCD but that "in the claims appeals process, ALJs and the Council may not decline to follow [an LCD] because its evidentiary support may be outdated or contradicted by the medical community or peer-reviewed literature"). Agendia's arguments do not seem individualized in a way that would result in deviation from an applicable LCD.

Turning to the merits, each of the five administrative decisions concerns claims for reimbursement of BluePrint and/or TargetPrint tests provided to patients with breast cancer. In each case, Agendia received an unfavorable decision from the contractor, which was upheld on reconsideration by the qualified independent contractor. During the relevant time periods, an LCD, premised on the MolDX program, denied coverage for BluePrint and TargetPrint. (Agendia concedes this point. See Compl. ¶ 3.) Hence, in the administrative decisions before the Court, the adjudicator was required to give "substantial deference" to the LCD or "explain the reasons why the policy was not followed." See 42 C.F.R. § 405.1062(a). Because the provider "has the burden of proving entitlement to Medicare benefits," I & R Med., P.C. v. Cochran, 520 F. Supp. 3d 274, 282 (E.D.N.Y. 2021) (quoting Friedman v. Sec'y of Dep't of Health & Hum. Servs., 819 F.2d 42, 45 (2d Cir. 1987)); see Def.'s Reply at 20, the ultimate question for the adjudicators was whether Agendia provided evidence supporting deviation. On judicial review, the question is even more limited: whether the ALJ or the Council's refusals to disregard the applicable LCD were supported by substantial evidence. The Court concludes that they were.

The Court addresses the decisions together before turning briefly to each individual decision. To begin, in each case, the adjudicators considered the LCDs and how they were supported by the MolDX program. The ALJs and the Council all recognized that MolDX conducts technical assessments of new molecular diagnostic tests. See, e.g., A.R. 5:7 (J.A. 812). During this process, MolDX employs subject matter experts from "academia and industry" to "assess the scientific literature" and review the clinical utility, analytical validity, and clinical validity of molecular diagnostic tests. Id. Indeed, as the Council pointed out, this is "the specific purpose of the MolDX program." A.R. 5:8 (J.A. 813). As the adjudicators noted, neither BluePrint nor TargetPrint was approved for coverage by MolDX, and MolDX issued a specific policy article announcing that the evidence was insufficient to support coverage of BluePrint. A.R. 5:8–9 (J.A. 813–14). It appears that in each decision, the agency adjudicator deferred to the applicable LCD in light of the MolDX process.

Against the LCDs, Agendia presented two types of evidence. First, Agendia's medical director, a breast cancer oncologist, testified about a representative sample of patients whose doctors used BluePrint or TargetPrint to inform their treatment and prognosis. The doctor described "how the BluePrint and TargetPrint tests were utilized, how the tests identified the type of cancer the beneficiary had, how the tests yielded different and/or more accurate results than the standard pathology tests, and how the tests were used in directing the patient's course of treatment." A.R. 1:182 (J.A. 64). While this testimony led ALJs to find that the test was "promising," A.R. 4:59 (J.A. 672), or even that the test "benefited" the patients, A.R. 3:79 (J.A. 620), the ALJs did not find the evidence sufficient to disregard the LCD.

Second, Agendia relied on certain publications, including some that were peer reviewed. The extent to which the ALJs and the Council considered those publications is not always clear—in one case, Agendia apparently did not submit them, A.R. 3:82–83, 83 n.5 (J.A. 617–18, 618 n.5),

and in another, the ALJ limited his review to those specifically offered by the company, A.R. 4:59 (J.A. 672). In the one decision where the publications were specifically considered, the ALJ concluded that the studies Agendia submitted warranted little weight. ALJ Smibert disregarded two of the articles because they were published after the dates of service. Id. As to a third article, ALJ Smibert pointed out that two of its authors were employees of Agendia and two received honoraria from Agendia. Id. He further noted that while this article "found that 18% of patients with a conventional assessment of the biopsy were reclassified with another form of breast cancer," it "focused on both MammaPrint and BluePrint subtyping." Id.

Agendia offers three principal reasons why the adjudicators' decisions are not supported by substantial evidence. First, Agendia argues that the adjudicators should not have relied on the LCDs and conclusions of the MolDX program because the record contained "no 'evidence' to support these policies and conclusion[s]." Pl.'s Mot. at 28. The Court does not find this argument persuasive considering the agency's regulation requiring deference in the absence of reasons to depart. Further, the relevant LCDs were supported by evidence (or lack thereof) concerning the validity and utility of Agendia's tests.

Second, Agendia asserts that the adjudicators erred by relying on the LCD over the evidence supplied by its medical director. Pl.'s Mot. at 29–30. The Court disagrees. As the Secretary argues, the physician testimony related to how the test was used, but did not establish "the accuracy, safety, clinical validity, analytic validity, or clinical utility of the two lab tests." Def.'s Cross-Mot. & Opp'n at 43; cf. Int'l Rehab. Scis. Inc. v. Sebelius, 688 F.3d 994, 1004 (9th Cir. 2012) (concluding that other insurers' coverage of a certain service did not establish general acceptance). As one ALJ noted, because the company "does not receive follow-up clinical results of patients," "they do not know the ultimate clinical results for each patient." A.R. 4:58 (J.A. 671).

The Court cannot conclude that the adjudicators erred by refusing to depart from the LCD on this basis.

Finally, Agendia argues that the agency did not adequately consider the articles submitted. As noted above, there is inconsistency with respect to how the articles were treated. However, ALJ Smibert's decision articulated a reasonable basis why the articles did not deserve significant weight. Agendia contends that ALJ Smibert's "reasons for ignor[ing] the important peer-reviewed articles" were "not valid" because each author was "highly credentialed and extremely well qualified," the relationships were "fully disclosed" and "[o]bviously, the companies that are expanding the precision of medicine have an interest in conducting studies that prove those outcomes." Pl.'s Mot.at 32–33. However, the Fourth Circuit found these same considerations supportable in a similar case. That court held that it was reasonable for an adjudicator to discount studies where the author had a financial interest in the outcome, since "[i]t is a maxim of evidence that a party's interest in a potential outcome can affect his objectivity." Almy, 679 F.3d at 306. The court also concluded it was rational to discredit a study that "failed to isolate the effect" of the contested service at issue. Id. Because the articles submitted here had these same defects, this Court cannot conclude that the failure to address them by the Council or the ALJs warrants vacatur and remand.

The Court will now briefly address the individual decisions.

A. ALJ Fuller's Decisions (Nos. 1-2899285920, 1-2806373709)

Two tranches of Agendia's reimbursement claims, for BluePrint and TargetPrint tests provided from January through December 2013, came before ALJ Fuller for a combined hearing. See A.R. 1:180–89, 2:180–89 (J.A. 62–71, 495–504). At the hearing, Agendia offered testimony from Bastian van der Baan, the company's chief clinical and business development officer, and Dr. William Audeh, its medical director, who testified to the use of BluePrint and TargetPrint to

diagnose and treat six representative beneficiaries. See A.R. 1:180, 1:5224, 1:5235 (J.A. 62, 410, 421). Noridian, the private contractor who denied Agendia's claim, submitted a position paper and accompanying exhibits explaining its reasons for denying coverage. The paper, from which ALJ Fuller quotes at length, explains the technical assessment process and includes a statement from Noridian's medical director asserting that neither the College of American Pathologists/American Society of Clinical Oncology nor the National Comprehensive Cancer Network supported use of the BluePrint tests and that the evidence does not support a conclusion that additional information provided by BluePrint "adds . . . to care and a better outcome." A.R. 1:363 (J.A. 89). The Noridian official further noted that the TargetPrint test is "more expensive than . . . standardized methods" and "has not shown superior utility." Id. The Court concludes that ALJ Fuller reasonably decided that Dr. Audeh's testimony did not provide a "reason not to apply substantial deference to the LCD or to question the MolDX program's findings." A.R. 1:187 (J.A. 69).

B. ALJ Conway's Decision (No. 3-2912323743)

Another tranche of Agendia's reimbursement claims, for BluePrint and TargetPrint tests provided from July 2012 through May 2014, came before ALJ Conway for a hearing. See A.R. 3:79–86 (J.A. 614–21). Agendia provided testimony from van der Baan and Dr. Audeh, who similarly described six beneficiaries (found as representative of the tranche) and the "clinical utility of the testing in the medical management and treatment of the beneficiary's cancer." A.R. 3:83 (J.A. 618). While ALJ Conway found that "the record sufficiently demonstrated that the [tests] . . . benefited the course of cancer treatment for the 150 beneficiaries in this appeal," he concluded that Agendia "failed to provide sufficient evidence outside of their hearing testimony . . . to deviate from well-established CMS Policy." A.R. 3:85 (J.A. 620). Indeed, ALJ Conway stated that the record did not include the "numerous peer-reviewed publications" Agendia cited. A.R. 3:82 (J.A.

617). This Court concludes that it was reasonable for ALJ Conway to rely on the record submitted and to find that hearing testimony was an insufficient basis to deviate from the LCD. ALJ Conway's decision, like that of ALJ Fuller, shows that he took account of the technical assessment performed by the MolDX program and reasonably concluded that hearing evidence supporting the usefulness for certain patients was insufficient to warrant deviation from the LCD.

C. ALJ Smibert's Decision (No. 3-3935618441)

A fourth tranche of Agendia's reimbursement claims, for BluePrint tests provided from late 2014 through early 2015, came before ALJ Smibert for a hearing. See A.R. 4:54–61 (J.A. 667–73).[4] Agendia submitted exhibits and presented testimony from van der Baan and Dr. Audeh. A.R. 4:54 (J.A. 667). Dr. Audeh testified about a representative sample of beneficiaries "where the Blueprint test provided a more refined diagnosis of the type of cancer cell, which then provided a likely treatment option for the physician." A.R. 4:58 (J.A. 671). ALJ Smibert specifically asked Agendia to submit articles on which it relied for the proposition that BluePrint was "more accurate at determining a better course of action during that narrow window of diagnosis," A.R. 4:9132 (J.A. 798), but for the reasons discussed above, he rejected the studies provided. A.R. 4:59 (J.A. 672). The Court does not fault ALJ Smibert for deferring to the LCD over Agendia's testimony. Indeed, ALJ Smibert noted that Agendia acknowledged in response to his question that because the company "does not receive follow-up clinical results of patients," "they do not know the ultimate clinical results for each patient." Id. at 671. Further, for the reasons discussed above, the Court does not fault ALJ Smibert for rejecting the studies submitted as a basis for diverging from the applicable LCD.

[4] Agendia withdrew its claims for TargetPrint tests at this hearing. See A.R. 4:60 (J.A. 673).

D. Council Decision (No. M-22-4685)

The fifth tranche of Agendia's reimbursement claims, for BluePrint and TargetPrint tests provided from 2013 through 2015, came before ALJ Amendola for review. See A.R. 5:99–102 (J.A. 843–46). ALJ Amendola concluded, without holding a hearing, that the tests were covered by Medicare. A.R. 5:101 (J.A. 845).[5] The Council, on its own motion, reviewed the decision and reversed because ALJ Amendola "materially erred as a matter of law by not giving substantial deference to the applicable LCD or explaining the reasons for not doing so." A.R. 5:4–5 (J.A. 809–10). Further, because Agendia "identified no facts particular to this case for departing from the LCD," the Council found "no basis for departing" and denied coverage without remand. A.R. 5:9 (J.A. 814).[6]

Agendia argues that the Council ignored relevant evidence, including a nineteen-page letter authored by Dr. Jia-Perng Jennifer Wei and submitted as part of Agendia's reconsideration petition to the qualified independent contractor "discussing the peer-reviewed articles attesting to 'the clinical validity of molecular subtyping . . . and the clinical utility these distinct molecular subtypes have in clinical decision making,'" Pl.'s Mot. at 28 (alteration in original) (quoting A.R. 5:4095–96), and "opin[ing] that BluePrint and TargetPrint testing were medically necessary in this case." Id. Agendia also points to a 2012 study that found "TargetPrint, BluePrint and MammaPrint may improve the clinical management of breast cancer patients." Pl.'s Reply & Opp'n at 15. It appears to the Court that Agendia had an opportunity to highlight this evidence for the Council but chose instead to focus on its legal arguments. See A.R. 5:21–22 (J.A. 825–26) (primarily arguing that LCDs and "substantial deference" are unlawful); Def.'s Reply at 20–21.

[5] ALJ Amendola denied coverage for nine appeals not timely filed. A.R. 5:101 (J.A. 845).

[6] The Council also concluded that it lacked jurisdiction to consider the legal issues presented in Agendia I and in this case. A.R. 5:9 (J.A. 814).

To the extent plaintiff's subsequent reliance on these documents is not forfeited, remand on this basis is not warranted. The letter is extremely difficult to parse, see A.R. 5:4095–4114 (A.R. 869–88), and the study cited appears to suffer from the same potential bias issues identified by ALJ Smibert, see A.R. 5:4153 (J.A. 923); Pl.'s Reply & Opp'n at 15 (conceding three of twelve authors were affiliated with Agendia). Moreover, the study appears at most weakly supportive of the utility of such tests and, specifically, the utility of BluePrint and TargetPrint over the approved MammaPrint test. See A.R. 5:4153 (J.A. 923) ("The implementation of multigene assays such as TargetPrint, BluePrint, and MammaPrint may improve the clinical management of breast cancer patients."). Ultimately, it is neither appropriate nor prudent for this Court to attempt to reweigh the evidence considered by the agency. After all,

> [t]he Supreme Court has warned time and again that a "technical factual dispute simply underscores the appropriateness of deferring" to agency decisions. Talk America, Inc. v. Mich. Bell Tel. Co., [564 U.S. 50, 67] n.7 (2011). . . . For "we as a court are confronted with a problem in administrative law, not in chemistry, biology, medicine, or ecology. It is the administrative agency which has been called upon to hear and evaluate testimony . . . relevant to its ultimate question." Envt'l Def. Fund v. EPA, 489 F.2d 1247, 1252 (D.C. Cir. 1973). The [Council] "has greater expertise and stands in a better position than this Court to make the technical and policy judgments necessary to administer the complex regulatory program at issue." Talk America, [564 U.S. at 67 n.7]. The court's role is to perform the "narrowly defined duty of holding agencies to certain minimal standards of rationality." Ethyl Corp. v. EPA, 541 F.2d 1, 36 (D.C. Cir. 1976). There can be little doubt that the Secretary's decisions surpass that threshold and are supported by "substantial evidence."

Almy, 679 F.3d at 306–07.

* * *

Conclusion

For the reasons stated above, the Court will deny Agendia's motion for summary judgment and grant the Secretary's motion for summary judgment. An Order consistent with this opinion will issue.

/s/
JOHN D. BATES
United States District Judge

Dated: March 29, 2024