UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

Cheryl Kort, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Civil No. 1:14-cv-01519 (APM)**
	)	
Sylvia M. Burwell, Secretary of the U.S. Department of Health and Human Services, *et al.*,	)	
	)	
Defendants.	)	

MEMORANDUM OPINION

I. INTRODUCTION

Plaintiffs Cheryl Kort, Lorraine Kovnat, and George Hepburn all have exhibited symptoms of cognitive impairment. None, however, have a firm diagnosis for their respective illnesses. Diseases associated with cognitive impairment—such as Alzheimer's Disease, frontotemporal dementia, and Parkinson's Disease—are notoriously difficult to diagnose because they share common symptoms. Doctors attempt to diagnose such diseases by eliminating potential causes, a process known as "differential diagnosis." Plaintiffs believe that a recently developed imaging procedure—a beta-amyloid positron emission tomography scan ("BA Scan")—can assist their physicians in eliminating a potential cause of their symptoms and thereby identifying the precise condition from which each suffers.

The Food and Drug Administration has approved the use of BA Scans for adults with cognitive impairment who are being evaluated for Alzheimer's Disease. A negative BA Scan is inconsistent with a diagnosis of Alzheimer's and thus potentially could be used to *exclude*

Alzheimer's as the cause of a patient's cognitive impairment. Stated differently, while a BA Scan cannot be used to definitively diagnose a patient with Alzheimer's, a negative scan potentially could rule it out as a cause.

The Medicare program, however, does not cover the costs of BA Scans, except for limited use in certain clinical studies. That is because, in September 2012, the Centers for Medicare and Medicaid Services, or CMS, which administers the Medicare program, determined that the then-existing medical and scientific evidence did not support a finding that BA Scans are reasonable and necessary for the diagnosis of an illness. Key to CMS' decision was its finding that the evidence did not show that BA Scans improved health outcomes of patients exhibiting cognitive impairment or informed the management of such patients' diseases.

Plaintiffs filed this suit against CMS, the Department of Health and Human Services, and the Department's Secretary Sylvia M. Burwell, arguing that the factors Defendants considered in evaluating BA Scans and their ultimate denial of Medicare coverage for such scans violated the Administrative Procedure Act. Specifically, Plaintiffs claim that Defendants' consideration of health outcomes and disease management in determining whether to cover BA Scans is contrary to the plain language of the Medicare Act and inconsistent with similarly-situated coverage determinations. Further, Plaintiffs argue that even if the "coverage standard" Defendants applied was proper, the denial of coverage for BA Scans cannot be reconciled with Defendants' statements indicating that the procedure has diagnostic value. Defendants counter that the coverage standard they employed fell well within the broad authority granted to them by Congress and that their coverage decision was supported by then-existing scientific evidence (or the lack thereof). They also assert that their coverage decision is congruent with their past actions.

Plaintiffs and Defendants have cross-moved for summary judgment. Their Motions are now before this court. Upon consideration of the parties' filings and the Administrative Record, the court finds that Defendants' denial of Medicare coverage to BA Scans did not violate the Administrative Procedure Act, except in one respect: the failure to adequately explain why Medicare covers a different test that relies on similar technology—known as FDG PET scans—but not BA Scans, for patients who have exhibited symptoms of cognitive decline but whose diagnosis remains uncertain. The court therefore grants in part and denies in part both Plaintiffs' and Defendants' Cross-Motions for Summary Judgment. Further, it remands the Decision Memo for further proceedings consistent with this Memorandum Opinion.

II. BACKGROUND

A. Regulatory Framework

Medicare is a federally funded health insurance program for the elderly and disabled. Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*—commonly known as the Medicare Act—tasks the Secretary of the Department of Health and Human Services (the "Secretary") with administering Medicare. The Secretary does so through the Centers for Medicare and Medicaid Services ("CMS"). *See* 46 Fed. Reg. 56,911, 56,911-34 (Nov. 19, 1981) (establishing the Health Care Financing Administration, which was later renamed CMS). CMS, in turn, contracts with private entities to which healthcare providers and suppliers submit their claims for reimbursement. *See* 42 U.S.C. § 1395kk-1; *id.* § 1395u; 42 C.F.R. § 421.200.

Medicare Part B is one of the program's four segments. It provides insurance coverage for outpatient services, including "diagnostic services which are—(i) furnished to an individual as an outpatient by a hospital or by others under arrangements with them made by a hospital, and (ii) ordinarily furnished by such hospital (or by others under such arrangements) to its outpatients

for the purpose of diagnostic study." 42 U.S.C. § 1395x(s)(2)(C); *see also* 42 C.F.R. § 410.28 ("Medicare Part B pays for hospital or [other] diagnostic services furnished to outpatients, including drugs and biologicals required in the performance of the services[.]"). Part B does not guarantee coverage for *all* diagnostic services, however. Section 1395y(a)(1)(A) of the Medicare Act establishes that "no payment may be made under . . . part B . . . for any expenses incurred for items or 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." 42 U.S.C. § 1395y(a)(1)(A) (emphasis added). That provision lies at the center of this dispute.

Among the ways that the Secretary, through CMS, informs Medicare contractors and providers of the items and services that she has deemed "reasonable and necessary for the diagnosis or treatment of illness and injury," *id.*, are National Coverage Determinations ("NCDs"). An NCD is a decision "with respect to whether or not a particular item or service is covered nationally." *See* 42 U.S.C. § 1395ff(f)(1)(B); *see also* 68 Fed. Reg. 55,634, 55,635 (Sept. 26, 2003) ("In general, an NCD is a national policy statement granting, limiting, or excluding Medicare coverage for a specific medical item or service."); 42 C.F.R. § 405.1060(a)(1) ("An NCD is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare."). If an NCD concludes that a particular use of an item or service shall not be covered under Medicare, such decision is binding on all entities and persons that implement the Medicare program. *See* 42 C.F.R. § 405.1060(a)(4) ("An NCD is binding on fiscal intermediaries, carriers, . . . [administrative law judges], and the [Medicare Appeals Council]," among others); *see also* 42 U.S.C. § 1395ff(c)(3)(B)(ii)(I) ("If the Secretary has made a[n NCD] . . . such determination shall be binding on the qualified independent contractor in making a decision with respect to a reconsideration [of an initial coverage determination]."). Plaintiffs here ask the court to overturn

an NCD that barred Medicare reimbursement for all BA Scans, except for those provided to patients participating in certain clinical studies.

B. Factual Background

1. PET Scans

BA Scans are within a family of imaging procedures known as Positron Emission Tomography ("PET") scans. In scientific terms, a PET scan "is a minimally invasive diagnostic imaging procedure used to evaluate normal tissues as well as diseased tissues in conditions such as cancer, ischemic heart disease, and some neurologic disorders," in which a "radiopharmaceutical (or 'tracer') [that] emits positrons when it decays" is "injected" into a patient and "a positron camera (tomograph) [is used] to measure the decay of [the radiopharmaceutical] within human tissue." *See* J.A. of Administrative Record, ECF Nos. 36 & 36-1 [hereinafter AR], at 4719. In terms understandable to the rest of us, a patient receiving the procedure has a substance—the "radiopharmaceutical" or "tracer"—injected into his or her body, which the PET scan allows a physician to view. What that substance does in the patient's body—principally, the rate at which it decays—may assist a physician in identifying the medical condition from which the patient is suffering.

PET scans first were developed in the 1970s, but Medicare did not cover any form of the procedure until 1995. *See* Defs.' Cross-Mot. for Summ. J., ECF No. 13 [hereinafter Defs.' Mot.], at 13.[1] In the two decades since, CMS has expanded Medicare coverage of PET scans to include a range of scans that employ several different radiopharmaceuticals, which are used to diagnose

[1] Citing CMS, Decision Memo for PET (FDG) (CAG-0065N) (Dec. 15, 2000) *available at* https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=85&fromdb=true [hereinafter 2000 FDG PET Decision], at 4.

many different conditions. *See id.* at 13-14.[2] But Medicare does not provide blanket-coverage for all PET scans. Rather, the NCD Manual, which "lists all Medicare-covered uses of PET scans," makes clear that "a particular use of PET scans is not covered *unless th[e] manual specifically provides that such use is covered*." NCD Manual § 220.6 (emphasis added).

2. Alzheimer's Disease and Beta-Amyloid Plaques

"Dementia is a syndrome involving cognitive and behavioral impairment in an otherwise alert patient." AR at 4715. Alzheimer's Disease, one of several conditions that cause the syndrome, "is an irreversible dementia characterized by progressive, relentless cognitive and functional decline." *Id.* at 4716. Although Alzheimer's "is the number one cause of dementia in older Americans (age 65 and over), contributing to 60-80% of cases," *id.*, frontotemporal dementia, cerebrovascular dementia, dementia with Lewey bodies, Parkinson's Disease, and Creutzfeldt-Jakob disease, among others, also cause dementia *and* share many of Alzheimer's symptoms. *Id.* at 4718. It is precisely "because several other neurological diseases can mimic the dementia seen in" Alzheimer's that the accuracy of "clinical diagnosis" of the disease is "poor." *Id.; see also id.* at 4717 ("[D]espite being the 'cornerstone' of diagnosis, clinical assessment of [Alzheimer's] remains poor."). And it is in large part because clinical diagnosis is poor that Plaintiffs believe they will benefit from BA Scans. *See, e.g.*, Pls.' Mot. for Summ. J., ECF No. 10-1 [hereinafter Pls.' Mot.], at 18 ("Plaintiffs suffer from symptoms of cognitive impairment that preclude a reliable diagnosis based solely on a clinical assessment. Therefore, each Plaintiff would benefit from a [BA Scan]." (citations omitted)).

The build-up of beta-amyloid plaques in the brain is a physiological "hallmark[]" of Alzheimer's. AR at 4718. Such build-up, however, is "seen in other diseases" as well, including

[2] Citing Medicare NCD Manual [NCD Manual], § 220.6, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_part4.pdf.

several of the dementia-causing conditions with symptoms similar to Alzheimer's. *Id.* It also can "be detected in cognitively normal older adults." *Id.* Indeed, "[a]utopsy studies demonstrate that approximately 33% of older individuals . . . who are cognitively normal have amyloid accumulation at levels consistent with" Alzheimer's. *Id.* Thus, as noted by CMS' "Decision Memo for [BA Scans] in Dementia and Neurogenerative Disease" (the "Decision Memo")—which accompanies and explains the NCD at issue in this case—while it "is widely accepted that the presence of amyloid plaques in the human brain is virtually necessary for the diagnosis of" Alzheimer's, "there are competing views" as to what exactly that means. *Id.* The National Institute on Aging's Alzheimer's Association has "conclude[d] that at this point, it remains unclear whether it is meaningful or feasible to make the distinction between [beta-amyloid plaques] as a risk factor for developing the clinical syndrome of [Alzheimer's] versus [beta-amyloid plaque] accumulation as an early detectable stage of [Alzheimer's] because current evidence suggests that both concepts are plausible." *Id.* at 4719 (citation and quotation marks omitted).

3. BA Scans

a. FDA Approval of Amyvid

Historically, beta-amyloid plaques "could only be identified upon autopsy." Pls.' Mot. at 3. That has changed in recent years with the development of BA Scans, PET scans that allow physician's to view beta-amyloid plaques in the body. *See* AR at 20-21. BA Scans "became clinically available for the first time in April 2012," when the Food and Drug Administration ("FDA") approved a radiopharmaceutical to be used in connection with such scans. Pls.' Mot. at 12. That radiopharmaceutical—Amyvid—is manufactured by Lilly USA, LLC ("Lilly") and was approved specifically for use with a PET Scan "of the brain to estimate [beta]-amyloid . . . plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's . . .

and other causes of cognitive decline." AR at 29. In approving Amyvid, the FDA noted that while a "negative Amyvid scan indicates sparse to no amyloid plaques and is inconsistent with a . . . diagnosis of [Alzheimer's]" and a "positive Amyvid scan indicates moderate to frequent amyloid . . . plaques" which "is present in patients with [Alzheimer's]," "Amyvid is an adjunct to other diagnostic evaluations" and "does not establish a diagnosis of [Alzheimer's] or other cognitive disorder." AR at 13.

b. Request for Medicare Coverage of BA Scans

FDA approval of a drug does not automatically entitle it to coverage under Medicare. Although "[b]oth CMS and the FDA review scientific evidence, and may review the same evidence," the agencies operate "under different statutory standards and different delegated authority." 68 Fed. Reg. at 55,636. "Whereas the FDA must determine that a product is safe and effective as a condition of approval, CMS must determine that the product is reasonable and necessary as a condition of [Medicare] coverage." *Id.* Thus, on June 29, 2012, after receiving FDA approval, Lilly submitted a letter to CMS seeking Medicare coverage for BA Scans that would use Amyvid. AR at 10-28.

Lilly's letter to CMS formally requested that the agency "reopen and revise Section 220.6 of the" NCD Manual—which denies Medicare coverage to all PET Scans not specifically listed in that Section, *see* NCD Manual § 220.6—to guarantee coverage for BA Scans. *Id.* at 10. Lilly argued that BA Scans would "provide physicians with accurate and reliable diagnostic information with which to evaluate patients within the Medicare population suffering from cognitive impairment and being evaluated for Alzheimer's disease and other causes of cognitive decline." *Id*. Lilly urged CMS to grant nationwide coverage for the procedure through the issuance of an NCD. *Id.*

c. CMS' Scientific Review of BA Scans

Lilly's letter prompted CMS to initiate a substantial scientific review process, which included several public comment periods, the convening of an expert panel, the release of a proposed NCD, and ultimately, the issuance of an NCD. The process commenced with a public comment period that began on October 9, 2012, and concluded on November 8, 2012. *See* AR at 4736. During that period, CMS received 27 comments, 26 of which "supported Medicare coverage of [BA S]cans in the diagnostic context of suspected dementia." *Id.*

Thereafter, on January 30, 2013, the Medicare Evidence Development and Coverage Advisory Committee ("MEDCAC")—which was "established to provide independent guidance and expert advice to CMS on specific clinical topics" and to assist CMS "in making decisions based upon the reasoned application of scientific evidence,"[3]—assembled a panel of 16 M.D.- or Ph.D.-holding experts. *See* AR at 1000, 1003-04. The panel's task was "to review available evidence and hear public testimony on the use of [BA Scans] for the management of dementia and neurogenerative disease." *Id.* at 999, 1003-04. The panel received a presentation from CMS; heard testimony from five "guest speakers" and public comments from 13 others; participated in a question-and-answer session with those who presented; and engaged in a discussion of the evidence before it. *See id.* at 1000-01, 1004-05; *see generally id.* at 1464-1906 (MEDCAC Meeting Transcript).

At the meeting's conclusion, the panel was asked to vote, using a 5-point scale "with a score of 1 being low or no confidence, and 5 representing high confidence," on two questions relevant to the case at hand:

> 1. How confident are you that there is adequate evidence to determine whether or not PET imaging of brain beta[-]amyloid changes health outcomes

[3] CMS, Factors CMS Considers in Referring Topics to MEDCAC, at 1 (Dec. 12, 2006), *available at* https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=10.

(improved, equivalent or worsened) in patients who display early symptoms or signs of cognitive dysfunction?," and

2. How confident are you that these conclusions are generalizable to the Medicare beneficiary population?"

Id. at 1002. The average vote for Question 1 was 2.17, meaning the panel had "medium-low confidence" that then-existing evidence was sufficient to evaluate the effects of BA Scans on health outcomes. *Id.* at 4741; *see also id*. at 1853. The average vote for Question 2 was 4.25, meaning that the panel had "high confidence" that its finding as to Question 1 was generalizable across all Medicare beneficiaries. *Id.* at 1875.

d. CMS' Decision

On July 3, 2013, CMS issued the Proposed Decision Memo for Lilly's requested coverage of BA Scans. *See generally id.* at 1908-74. While an NCD itself may be relatively succinct, *see, e.g.*, *id.* at 1-6, such a determination is generally accompanied by a thorough memorandum that explains CMS' conclusion, *see, e.g.*, *id.* at 4709-92. In this case, a 68-page Proposed Decision Memo—the final version of which would accompany the NCD for BA Scans—provided background information on PET scans, BA Scans, Alzheimer's, and other cognitive conditions, *see id.* at 1912-18; "summarized the published literature [and scientific studies] on whether [BA Scans are] beneficial to patients with symptoms of [Alzheimer's]," *id.* at 1919; *see also id.* at 1920-29, 1934-37; discussed the MEDCAC panel, *id.* at 1930; and presented CMS' lengthy analysis of the information before it, *id.* at 1933-56.

CMS expressly centered its analysis on two "Key Questions," similar to those posed to the MEDCAC panel:

1. Is the evidence adequate to conclude that [BA Scans] improve[] meaningful health outcomes in beneficiaries who display signs and symptoms of [Alzheimer's]?

> 2. Is the evidence adequate to conclude that [BA Scan] results inform the treating physician's management of the beneficiary to improve meaningful health outcomes? Those outcomes may include reasonably considered beneficial therapeutic management or the avoidance of unnecessary, burdensome interventions.

Id. at 1939.

CMS answered "'No' to both questions." *Id.* The Proposed Decision Memo found "that the evidence is insufficient to conclude that the use of [BA Scans] improves health outcomes for Medicare beneficiaries with dementia or neurogenerative disease, and thus [BA Scans are] not reasonable and necessary." *Id.* at 1955. CMS did, however, propose reimbursement for "one [BA Scan] per patient through coverage with evidence development . . . in clinical studies that meet [certain] criteria" set forth by the agency. *Id.* In other words, CMS proposed limited coverage of BA Scans for certain clinical trials.

A second public comment period, lasting 30 days, followed the release of the Proposed Decision Memo. *Id.* at 4737. CMS received 202 comments. *Id.* Among the 202 comments was a letter from Lilly that raised many of the challenges to CMS' decision that Plaintiffs have raised here. *See id.* at 4171-79.

Nearly two months after the close of the second public comment period, on September 27, 2013, CMS released its final "[NCD] for [BA Scans] in Dementia and Neurogenerative Disease," *id.* at 1-3, and the accompanying Decision Memo, *id.* at 4709-92. Both the NCD and the Decision Memo mirrored the findings of the MEDCAC panel and the conclusions contained in the Proposed Decision Memo. Over 84 pages, the Decision Memo explained how and why CMS reached its final determination. *See id.* The NCD stated: "[CMS] has determined that the evidence is insufficient to conclude that the use of [BA Scans] is reasonable and necessary for the diagnosis or treatment of illness or injury . . . for Medicare beneficiaries with dementia or neurodegenerative

diseases, and thus [BA Scans are] not covered under [the Medicare Act]." *Id.* at 1. It did, however, provide for limited coverage of BA Scans in certain clinical studies. *See id.*

III. LEGAL STANDARD

A. Cross-Motions For Summary Judgment on Administrative Procedure Act Claims

Plaintiffs and Defendants have filed Cross-Motions for Summary Judgment as to Plaintiffs' claims brought under the Administrative Procedure Act (the "APA"), 5 U.S.C. § 701 *et seq.* Cross-motions for summary judgment ordinarily are reviewed under the standard set forth in Federal Rule of Civil Procedure 56, which requires a court to grant summary judgment when the pleadings and the evidence demonstrate that "there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). However, in cases such as this one that involve the review of a final agency action, the Rule 56 standard does not apply. *See Stuttering Found. of Amer. v. Springer*, 498 F. Supp. 2d 203, 207 (D.D.C. 2007). Instead, "the district judge sits as an appellate tribunal" and "[t]he 'entire case' on review is a question of law." *Am. Biosci. Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001) (citing cases). "[T]he court's review is limited to the administrative record," *Fund for Animals v. Babbitt*, 903 F. Supp. 96, 105 (D.D.C. 1995) (citing *Camp v. Pitts*, 411 U.S. 138, 142 (1973)), and its role is limited to "determin[ing] whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did," *see Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006) (citation and internal quotation marks omitted).

B. *Chevron* Review

As will be discussed below, Plaintiffs' primary contention is that Defendants' reliance on a coverage standard that considers health outcomes and disease management is inconsistent with Section 1395y(a)(1)(A) of the Medicare Act. This argument implicates the two-step formula set

forth in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-44 (1984). Where, as here, "Congress gives an agency authority to interpret a statue, [courts] review the agency's interpretation" using the *Chevron* framework. *Council for Urological Interests v. Burwell*, 790 F.3d 212, 219 (D.C. Cir. 2015). Under *Chevron*'s first step, courts must determine whether Congress has "directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842. "If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. This inquiry "begins with the text" of the statute, *W. Minnesota Mun. Power Agency v. Fed. Energy Regulatory Comm'n*, 806 F.3d 588, 591 (D.C. Cir. 2015) (citing *Engine Mfrs. Ass'n v. S. Coast Air Quality Mgmt. Dist.*, 541 U.S. 246, 252 (2004)), but may also involve consideration of "the specific context in which th[e] language [at issue] is used, and the broader context of the statute as a whole." *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997). "Because the judiciary functions as the final authority on issues of statutory construction, [a]n agency is given no deference at all on the question whether a statute is ambiguous." *Wells Fargo Bank, N.A., v. Fed. Deposit Ins. Co.*, 310 F.3d 202, 205-06 (D.C. Cir. 2002) (citation and internal quotation marks omitted).

Where a court determines that Congress has *not* directly spoken to the precise question at issue, it must move to *Chevron*'s second step, which asks whether the agency's interpretation of the language in controversy is "based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. An interpretation is permissible if it is a "'reasonable' explanation of how an agency's interpretation serves the statute's objectives." *Northpoint Tech., Ltd. v. FCC*, 412 F.3d 145, 151 (D.C. Cir. 2005); *see also D.C. v. Dep't of Labor*, 819 F.3d 444, 449 (D.C. Cir. 2016) ("[U]nder *Chevron* . . . the fundamental question is not whether we think the [agency]'s interpretation is correct, but whether the [agency]'s interpretation of the Act is at least reasonable in light of any

ambiguities in the statute."). "If the agency's construction is reasonable, [courts] defer." *Burwell*, 790 F.3d at 219 (citing *Chevron*, 467 U.S. at 842-43).

When applying *Chevron*'s second step, courts must defer to an agency's interpretations of the statute under which it operates. As the Supreme Court stated in *Chevron*, "[w]e have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations." 467 U.S. at 844. And where, as here, a court is tasked with evaluating the Secretary's interpretation of a provision of the Medicare Act, such deference is heightened. *See, e.g.*, *Cty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1016 (D.C. Cir. 1999) ("In marking off the metes and bounds of our review under the second step of *Chevron*, we accord particular deference to the Secretary's interpretation of [the Medicare Act] 'given the tremendous complexity of the Medicare statute.'" (quoting *Appalachian Reg'l Healthcare, Inc. v. Shalala*, 131 F.3d 1050, 1054 (D.C. Cir. 1997))); *Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1229 (D.C. Cir. 1994)) ("[I[n framing the scope of review, the court takes special note of the tremendous complexity of the Medicare statute. That complexity adds to the deference which is due to the Secretary's decision."); *Appalachian Reg'l Healthcare*, 131 F.3d at 1054 (noting that the "case would be easier had the Board [within the Department of Health and Human Services] provided a more thorough explanation for its decision," but "nevertheless" finding that the Board's "reading [is one] we can accept, especially in light of the particular deference we afford the Secretary given the tremendous complexity of the Medicare statute."). This court must bear that deference in mind in analyzing the action challenged here.

C. The "Arbitrary and Capricious" Standard of Review

Plaintiffs also argue that Defendants' denial of coverage for BA Scans violated the APA as agency action that was "arbitrary [and] capricious." 5 U.S.C. § 706(2)(A). Application of the "arbitrary and capricious" standard and "[t]he analysis of disputed agency action under *Chevron* Step Two . . . is often 'the same, because under *Chevron* step two, [the court asks] whether an agency interpretation is arbitrary or capricious in substance.'" *Agape Church, Inc. v. FCC*, 738 F.3d 397, 410 (D.C. Cir. 2013) (citing *Judulang v. Holder*, 132 S. Ct. 476, 483 n.7 (2011)). Thus, similar to *Chevron*'s second step, the arbitrary and capricious standard of review requires courts to determine whether the action at issue was based on "reasoned analysis." *Motor Vehicle Mfrs. Ass'n of U.S. Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 56-57 (1983).

Generally, an agency has engaged in reasoned analysis when the administrative record indicates it "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Id.* at 43 (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)). Where, however, the administrative record indicates that an agency "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or [made a decision that] is so implausible that it could not be ascribed to a difference in view or the product of agency expertise," it has acted in an arbitrary and capricious manner. *Id.* Although this standard is not "particularly demanding," *Pub. Citizen, Inc. v. FAA*, 988 F.2d 186, 197 (D.C. Cir. 1993), and a reviewing court may "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned," *Bowman Transp., Inc. v. Ark.-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974) (citation omitted), a court is not to "supply a reasoned basis for the agency's action that the agency itself has not

given," *State Farm*, 463 U.S. at 43 (citation and internal quotation marks omitted). And, as with *Chevron* step two, the arbitrary and capricious standard "appropriately encourages courts to defer to the agency's expertise." *Ark Initiative v. Tidwell*, 64 F. Supp. 3d 81, 90 (D.D.C. 2014), *aff'd*,816 F.3d 119 (D.C. Cir. 2016).

IV. DISCUSSION

The court first addresses Plaintiffs' arguments under *Chevron* that the coverage standard applied to BA Scans contravenes the will of Congress and is an impermissible interpretation of the Medicare Act. In evaluating the coverage standard under *Chevron*'s second step, the court simultaneously addresses Plaintiff's assertion that the coverage standard is arbitrary and capricious. The court then turns to Plaintiffs' other claims under the arbitrary and capricious standard, namely that the Decision Memo is inconsistent both with itself and with a CMS regulation.

A. *Chevron* Step One

In applying the first step of *Chevron*, the court "begin[s], as always, with the plain language of the statute in question." *Citizens Coal Council v. Norton*, 330 F.3d 478, 482 (D.C. Cir. 2003). Here, the statutory provision at issue reads as follows:

> [N]o payment may be made under part A or part B of this subchapter for any expenses incurred for items or services—(1)(A) which . . . are not *reasonable and necessary for the diagnosis or treatment* of illness or injury or to improve the functioning of a malformed body member.

42 U.S.C. § 1395y(a)(1)(A) (emphasis added).

Plaintiffs contend that the "statute's use of the disjunctive term 'or' to separate items and services that are reasonable and necessary for 'diagnosis' from those that are reasonable and necessary for 'treatment' is critically important." Pls.' Mot. at 4-5. "[I]t is a commonsense '[c]anon[] of construction,'" Plaintiffs argue, "that when Congress uses the word 'or' to connect

two terms, it intends to 'give[] independent significance' to each." Pls.' Mot. at 25 (quoting *Reiter v. Sonotone Corp.*, 442 U.S. 330, 338-39 (1979)). Relying on definitions contained in dictionaries and a Medicare manual, Plaintiffs assert that "'[d]iagnosis' and 'treatment' ordinarily are understood to have separate meanings," *id.* at 23, and "[b]y using these 'distinct' terms in juxtaposition—separated by the disjunctive 'or'—Congress unambiguously required Defendants to cover diagnostic services based *on their diagnostic value alone*," *id.* at 20 (emphasis added). Thus, Plaintiffs claim, the "coverage standard Defendants have imposed on [BA Scans]"—which considered the effect of the procedure on patients' health outcomes and disease management—"is flatly inconsistent with the plain text of the Medicare Act." Pls.' Mot. at 22; *see also id.* at 23 ("This case can be resolved at *Chevron*'s first step because the Medicare Act expressly requires Defendants to cover a medical service that is reasonable and necessary to obtaining a 'diagnosis,' regardless of its treatment impact[, and] Defendants' contrary coverage standard cannot be reconciled with this statutory mandate."). Stated differently, Plaintiffs argue that a coverage standard that takes into account *treatment*-related factors—such as health outcomes and disease management—to evaluate whether a test is reasonable and necessary for *diagnosis*, is improper.

Defendants counter that "Plaintiffs' singular focus on the word 'or' leads them to ignore the critical words 'reasonable and necessary.'" Defs.' Mot. at 27. They disagree that the canon of construction on which Plaintiffs rely is an "absolute rule," *see* Reply Mem. in Supp. of Defs.' Cross-Mot. for Summ. J., ECF No. 34 [hereinafter Defs.' Reply], at 4 (quoting *Marx v. Gen. Rev. Corp.*, 133 S. Ct. 1166, 1177 (2013)), and argue that "[e]ven if Plaintiffs were correct that 'or' must be read in the disjunctive, the statute would still bar payment for items and services not 'reasonable and necessary for . . . diagnosis' of a disease," Defs.' Mot. at 27 (quoting 42 U.S.C. § 1395y(a)(1)(A) (emphasis added)). Citing the Court of Appeal's decision in *Williams Natural*

Gas Company v. FERC, 943 F.2d 1320 (D.C. Cir. 1991), Defendants assert that the coverage standard they employed was not barred under *Chevron*'s first step. Defs.' Mot. at 28 (citing *Williams Natural Gas Co.*, 943 F.2d at 1331 (stating that where a statute "provides neither an implicit nor an explicit definition of the terms 'reasonable' or 'necessary,' . . . Congress has left the task of defining th[ose] term[s] to" the agency) (citation and internal quotation marks omitted)).

The court agrees with Defendants' reading of the Medicare statute. Plaintiffs have expended much breath attempting to direct the court's attention to Section 1395y(a)(1)(A)'s use of the word "or." But it is the phrase "reasonable and necessary" that merits greatest regard. That phrase undoubtedly has a limiting effect on the scope of Medicare coverage, "preclud[ing] reimbursement for any items or services . . . which are not reasonable and necessary for the diagnosis or treatment of illness or injury." *Heckler v. Ringer*, 466 U.S. 602, 605 (1984) (citation and internal quotation marks omitted); *see also United Seniors Ass'n, Inc. v. Shalala*, 182 F.3d 965, 967 (D.C. Cir. 1999) ("If a service is deemed not to have been reasonable and necessary, Medicare will not make [a] payment[.]"); *Power Mobility Coal. v. Leavitt*, 404 F. Supp. 2d 190, 194 (D.D.C. 2005) ("All Medicare coverage is *limited to* services that are medically 'reasonable and necessary' for the diagnosis or treatment of illness." (emphasis added)). But it also has the effect of vesting substantial authority in the Secretary. "[T]he words 'reasonable' and 'necessary' are among the broadest in the congressional lexicon of delegation." *Williams Nat. Gas*, 943 F.2d at 1331. And, Congress' use of those words means that the "Secretary's decision as to whether a particular medical service is 'reasonable and necessary' . . . [is] *clearly discretionary*." *Heckler*, 466 U.S. at 617 (emphasis added). To accept Plaintiffs' argument that the Secretary, and thus CMS, unlawfully considered health outcomes and disease management here, the court would have to accept the novel principle that diagnosis and treatment occupy mutually-exclusive spheres in

which *nothing* related to one may be contemplated when assessing the other. The court declines to read the statue to so substantially restrict the Secretary's discretion.

Plaintiffs' reading also suffers from a textual defect. The assertion that "or" creates a hard-and-fast distinction between "treatment" and "diagnosis" is untenable because the same cannot be said of the statute's use of "or" in other contexts. *See Sorenson v. Sec'y of Treasury of U.S.*, 475 U.S. 851, 860 (1986) ("The normal rule of statutory construction assumes that identical words used in different parts of the same act are intended to have the same meaning." (citations and internal quotation marks omitted)). For instance, in the *very same sentence*, the phrase "illness or injury" appears. 42 USC § 1395y(a)(1)(A). Those two words cannot reasonably be said to be mutually-exclusive. Additionally, in the *very same section* are the phrases "palliation or management," *id.* § 1395y(a)(1)(C), and "cutting or removal," *id.* § 1395y(a)(13)(C), among others. *See* Hr'g Tr. at 7:7-8:3, Apr. 21, 2016 (draft). The use of the word "or" in those phrases likewise cannot be said to connote categorically separate and distinct concepts. As these examples demonstrate, Congress plainly did not intend that "or" in Section 1395y(a) would establish concepts that are mutually-exclusive and non-overlapping in every respect.

Plaintiffs cite *Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009), in both their Motion and reply brief for the proposition that "courts have not hesitated to invalidate the Secretary's interpretations of the Medicare Act that conflict with its statutory text, including the Secretary's interpretations of the same Coverage Provision at issue here." Pls.' Mot. at 29; *see also* Pls.' Reply at 12 ("The D.C. Circuit's decision in *Hays v. Sebelius* . . . is a classic example of a similar effort by Defendants to avoid the limits that Congress set in the statute."). Plaintiffs, however, overstate the relevance of *Hays*. Although that case did *involve* Section 1395y(a)(1)(A), it addressed a very different question than the one at issue here: "whether 'reasonable and necessary' modifies

'expenses' . . . or 'items and services.'" *Hays*, 589 F.3d at 1281. The Court of Appeals determined that "reasonable and necessary" modifies the latter. And in so holding, it highlighted the great latitude provided by the phrase "reasonable and necessary." *Id.* ("If the Secretary is correct [that 'reasonable and necessary' modifies 'expenses'], then Medicare may, as it has here, partially cover an item or service, declining to reimburse expenses associated with the marginal difference in price between a prescribed item or service and its least costly and medically appropriate alternative."). In sum, *Hays* does not alter the court's conclusion that, under *Chevron*'s first step, the plain text of the Medicare Act does not preclude Defendants' reliance on health outcomes and patient management to determine what is "reasonable and necessary."

B. *Chevron* Step Two and Arbitrary and Capricious Review

Having rejected Plaintiffs' argument at *Chevron* step one, the court "consider[s] whether the content that the agency has given" the words "reasonable and necessary" "is 'permissible,'" as the Court used that term in *Chevron*. *Williams Nat. Gas*, 943 F.2d at 1331. Plaintiffs do not claim that Defendants violated the APA by failing to "examine the relevant data"; nor do they argue that Defendants failed to "articulate a satisfactory explanation for its" consideration of a BA Scan's effect on health outcomes and disease management[4] *State Farm*, 463 U.S. at 43. Instead, under the combined *Chevron* step two and "arbitrary and capricious" framework, Plaintiffs argue that the "coverage standard Defendants have imposed on [BA Scans] squarely conflicts with the coverage positions they consistently have applied, and continue to apply, to highly similar medical services." Pls.' Mot. at 30.

[4] Nor does not the court read Plaintiffs' Motion as making the more general, and traditional, *Chevron* step two argument that Defendants' interpretation of the Medicare Act is unreasonable. *See D.C. v. Dep't of Labor*, 819 F.3d at 449 (stating that "the fundamental question" under Chevron step two is "whether the [agency]'s interpretation of the Act is at least reasonable in light of any ambiguities in the statute"). Even if Plaintiffs did make that argument, the court would reject it for the reasons discussed in Part IV.B.2. below. Specifically, the substantial scientific and medical literature discussed and/or cited in the Decision Memo supports the consideration of health outcomes and disease management in assessing the utility of a diagnostic test.

1. Treatment of Similar Situations

"[F]oolish consistency" may be the "hobgoblin of little minds,"[5] but consistency—whether foolish or not—is a well-rooted concept in APA jurisprudence. "'A long line of precedent has established that an agency action is arbitrary when the agency offer[s] insufficient reasons for treating similar situations differently.'" *Cty. of Los Angeles*, 192 F.3d at 1022 (quoting *Transactive Corp. v. U.S.*, 91 F.3d 232, 237 (D.C. Cir. 1996)); *see also Petroleum Commc'ns, Inc. v. F.C.C.*, 22 F.3d 1164, 1172 (D.C. Cir. 1994) ("We have long held that an agency must provide adequate explanation before it treats similarly situated parties differently."); *Local 777, Democratic Union Org. Comm., Seafarers Int'l Union of N. Am., AFL-CIO v. N. L. R. B.*, 603 F.2d 862, 872 (D.C. Cir. 1978) (stating that agencies may not "arbitrarily treat similar situations dissimilarly"). To be certain, the actions of "[r]egulatory agencies do not establish rules of conduct to last forever," *Am. Trucking Ass'ns, Inc. v. Atchison, T. & S.F.R. Co.*, 387 U.S. 397, 416 (1967), and "an administrative agency is not disqualified from changing its mind," *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417 (1993) (citation and internal quotation marks omitted). However, "[w]here an agency applies different standards to similarly situated entities and fails to support this disparate treatment with a reasoned explanation and substantial evidence in the record, its action is arbitrary and capricious and cannot be upheld." *Burlington N. & Santa Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 776-77 (D.C. Cir. 2005); *see also Lilliputian Sys., Inc. v. Pipeline & Hazardous Materials Safety Admin.*, 741 F.3d 1309, 1313 (D.C. Cir. 2014) (quoting *Burlington N.*).

[5] Ralph Waldo Emerson, *Essays: Self-Reliance* (1841).

2. The Coverage Standard

Before turning to Plaintiffs' specific allegation that Defendants have applied the "health outcomes" and "patient management" coverage standard inconsistently, the court provides background on the standard itself. The Decision Memo directly addresses why Defendants considered health outcomes and disease management in evaluating BA Scans. Responding to "several" comments "that evidence of 'improved health outcomes' should not be a factor for a coverage determination on [BA Scans]," AR at 4737, the Decision Memo summarized scientific literature that explains why health outcomes and patient management are relevant to determining whether a diagnostic test is reasonable and necessary.

The Decision Memo first quotes a 2003 publication about diagnostic testing in general, identified as "Mol and colleagues (2003)." *Id.* at 4738. It quotes the authors as writing: "Whether or not patients are better off from undergoing a diagnostic test will depend on how test information is used to guide subsequent decisions on starting, stopping, or modifying treatment. Consequently, the practical value of a diagnostic test *can only be assessed by taking into account subsequent health outcomes*." *Id.* (emphasis added).

The Decision Memo then cites a study authored by "Fryback and Thornbury (1991)," which addresses how to assess the value of a diagnostic test. *Id.* In their paper entitled "The Efficacy of Diagnostic Testing," *see* AR at 840-46—which Lilly itself cited in its coverage request letter, *see id.* at 55—the authors conceived of a "hierarchical model of efficiency" "as an organizing structure for appraisal of the literature on efficacy of imaging," *id.* at 840; *see also id.* at 841 ("[A] more global analysis reveals diagnostic radiology to be part of a larger system whose goal is to treat patients effectively and efficiently."). The model, which consists of five "levels," illustrates the relationship between the efficacy of a diagnostic imaging test, on the one hand, and

health outcomes and patient management, on the other. The lowest level of the hierarchy—Level 1—is a diagnostic imaging test that has achieved what the authors describe as "technical efficiency," that is, clarity in image quality. *Id.* One level up, at Level 2, is what the authors describe as "Diagnostic Accuracy Efficacy," that is, effectiveness in measuring the "performance of the image[] for the purpose of making diagnoses[.]" *Id.* Only at higher levels of Fryback and Thornbury's model does a diagnostic imaging test attain "therapeutic" (Level 4) and "patient outcome" (Level 5) efficacy. *Id.* at 843-44. At those levels, such a test "may influence a patient's diagnostic thinking and yet may have no impact on patient treatment" (Level 4) or may advance the "ultimate goal of medical care . . . to improve, or return to normal, the health of the patient" (Level 5). *Id.* Fryback and Thornbury's article provides ample support for Defendants' reliance on health outcomes and patient management in assessing whether a test is "reasonable and necessary."[6]

And, so too, does other literature cited in the Decision Memo and included in the Administrative Record. *See, e.g.*, *id.* at 2914 (study by Laforce et al. which states that "to be widely adopted a diagnostic test needs to have a significant impact on patient management and outcomes"); *id.* at 2630-31 (study by Grundman et al. noting that a "remaining question is whether clinical care that includes [BA Scans] will translate into better outcomes" and that "[a]dditional .

[6] Countering Defendants' reliance on Fryback and Thornbury, Plaintiffs write:

> Although a diagnostic test may offer added special benefits when it leads to a health improvement, Defendants offer no evidence that Congress intended that this was a mandatory requirement of diagnostic coverage. Indeed, since the statutory coverage language was enacted in 1965, nearly three decades before [Fryback and Thornbury] published their [study], it is an historical impossibility that it was a basis for the statute.

Pls.' Reply at 13-14. The court is not persuaded by this argument. Defendants need not offer evidence that Congress mandated that CMS consider whether a "diagnostic test . . . leads to health improvement"; they need only demonstrate that Congress did not foreclose such consideration by speaking directly to the issue, and that such consideration is reasonable. And Defendants certainly need not present evidence that Congress considered Fryback and Thornbury's article when drafting the Medicare Act.

. . studies would be required . . . to explicitly quantify the relationship between [BA Scans] and patient outcomes"); *see also id.* at 4781, 4785 (inclusion of Grundman et al. and Laforce et al. in the Decision Memo's bibliography). In sum, the Decision Memo and Administrative Record explain why Defendants considered health outcomes and patient management, and leave little doubt about either factors' relevancy.

3. "Similarly-Situated" Items and Services

The court now turns to whether, as Plaintiffs have argued, Defendants' denial of Medicare coverage to BA Scans was inconsistent with their approval of coverage for similarly-situated items and services.

a. FDG PET

Plaintiffs focus much of their argument on Defendants' decision to cover a particular type of PET scan known as FDG PET. That diagnostic test uses a different radiopharmaceutical—fluorodeoxyglucose—to differentiate between patients suffering from frontotemporal dementia and Alzheimer's. Like BA Scans, FDG PET's primary utility is assisting in the differentiation between diseases that might cause dementia; it does not affirmatively diagnose any particular disease. Although CMS did not at first grant Medicare coverage for FDG PET, *see generally* 2000 FDG PET Decision, it reversed course in 2004. The decision memo accompanying the NCD that approved FDG PET stated:

> The evidence is adequate to conclude that [FDG PET scans are] reasonable and necessary in patients with documented cognitive decline of at least six months and a recently established diagnosis of dementia who meet diagnostic criteria for both Alzheimer's . . . and frontotemporal dementia . . . who have been evaluated for specific alternate neurodegenerative diseases or causative factors, and for whom the cause of the clinical symptoms remains uncertain.[7]

[7] CMS, Decision Memo for Positron Emission Tomography (FDG) and Other Neuroimaging Devices for Suspected Dementia (CAG-00088R) (Sept. 15, 2004) *available at* https://www.cms.gov/medicare-coverage-database/details/nca-decision-

Critically, for present purposes, CMS approved FDG PET even though "[n]o published studies evaluated whether FDG PET can alter clinical decision-making and improve patient outcomes." *Id.* at 35. "Nonetheless," CMS explained,

> an expert consensus articulated in a report published by the [Alzheimer's Association] and confirmed by a panel convened by [the National Institute of Aging] suggests that the addition of FDG PET may be warranted . . . in patients with documented cognitive decline of at least six months who meet diagnostic criteria for both [Alzheimer's] and [frontotemporal dementia] and for whom the subtype of neurodegenerative disease remains uncertain.

Id. On that basis, CMS found the "evidence adequate to conclude that FDG PET improves net health outcomes" in patients who meet the above-referenced criteria. *Id.*

Plaintiffs contend that "[i]t is arbitrary and capricious for Defendants to refuse to ever cover [BA Scans] on the ground that they cannot 'improve health outcomes' or alter 'disease management' when Defendants have not held FDG PET scans to this standard," Pls.' Mot. at 32, adding that "Defendants fail to provide any plausible justification for the disparity," Pls.' Reply at 24. They argue, essentially, that Defendants' 2004 FDG PET Decision set a precedent that Defendants, without explanation, failed to follow when making the decision at issue here.

Defendants disagree. They point to the Decision Memo itself, in which CMS explained why it approved FDG PET but not BA Scans: "FDG PET is a fundamentally different—not a similar—technology [to a BA Scan]. FDG PET measures the physiological process of metabolism, while [a BA Scan] looks at the anatomical burden of amyloid plaques." AR at 4739. Emphasizing the significance of this distinction, Defendants argue in their Motion that while a BA Scan "uses a radiopharmaceutical that preferentially binds to [beta-amyloid] plaques, and thus measures amyloid density in the brain," "FDG PET uses a different radiopharmaceutical . . . that is

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memo.aspx?NCAId=104&NcaName=Positron+Emission+Tomography+(FDG)+and+Other+Neuroimaging+Devices+for+Suspected+Dementia+(1st+Recon)&bc=AiAAAAAAEAAA& [hereinafter 2004 FDG PET Decision], at 3.

preferentially metabolized by certain tissues." Defs.' Mot. at 36. Defendants argue that this "difference is enough to distinguish the two tests." *Id.* The court disagrees.

The similarities between FDG PET and BA Scans are manifest. Both are diagnostic tests that involve the use of a PET scan and a radiopharmaceutical tracer. Both are indicated for use on overlapping patient populations exhibiting symptoms of cognitive impairment. And, although neither test can affirmatively diagnose a disease, both have diagnostic value as a tool for differentially diagnosing patients who exhibit symptoms associated with several different diseases. *Compare* 2004 FDG PET Decision at 3 (approved for patients with cognitive decline who may have Alzheimer's or frontotemporal dementia but for whom "the cause of the clinical symptoms remains uncertain") *with* AR at 29 (FDA approval of BA Scans for "adult patients with cognitive impairment who are being evaluated for Alzheimer's . . . and other causes of cognitive decline"); *see also id.* at 4740 (stating that it "may or may not be true—the evidence is not clear" "that [a BA Scan] is a better tool than FDG PET for differentiating [frontotemporal dementia] from [Alzheimer's]").

And both are the same in another critical respect—neither test has demonstrated effectiveness in terms of improving health outcomes or altering patient management. Defendants approved FDG PET even when "[n]o published studies evaluated whether FDG PET can alter clinical decision-making and improve patient outcomes." 2004 FDG PET Decision at 35. Yet, the absence of such studies with respect to BA Scans led Defendants to reach the opposite conclusion—denying coverage for the procedure.

The court cannot reconcile these different conclusions on the present record and finds that Defendants' failure to provide a cogent explanation for the disparate outcomes was arbitrary and capricious, in violation of the APA. *See, e.g.*, *Cty. Of Los Angeles*, 192 F.3d at 1022-23 (finding

that the Secretary's "sole justification" for why certain data was "suitable for one significant calculation but unreliable for another" was insufficient and concluding that the "Secretary's proffered distinction is thus not reasonable"). Several commenters challenged Defendants' disparate treatment of FDG PET and BA Scans. *See* AR at 4739. Yet, the only explanation that Defendants offered to distinguish the two was that "FDG PET is a fundamentally different—not a similar—technology." *Id.* That may be so, but that does not explain why Defendants agreed to cover FDG PET despite the complete lack of published studies evaluating the procedure's effect on health outcomes and patient management, 2004 FDG PET Decision at 35, when similarly insufficient clinical evidence was the basis for Defendants' denial of coverage for BA Scans. The "post hoc" explanation Defendants offer in their reply brief—that an "expert consensus" existed as to the benefits of FDG PET that was absent with regard to BA Scans, *see* Defs.' Reply at 15-16—was not offered in the Decision Memo itself and, therefore, cannot cure its deficiency. *See Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 419 (1971), *abrogated on other grounds by Califano v. Sanders*, 430 U.S. 99 (1977) ("'[P]ost hoc' rationalizations . . . have traditionally been found to be an inadequate basis for review.").

Although the court concludes that Defendants' failure to adequately distinguish between its treatment of FDG PET and BA Scans was arbitrary and capricious, it disagrees with Plaintiffs' assertion that "[h]aving conceded coverage for FDG-PET patients, [Defendants] must provide it for appropriate [BA Scan] patients." Pls.' Mot. at 33. Instead, the court is compelled to remand the Decision Memo to CMS so that the agency can evaluate in the first instance whether its coverage decisions can be reconciled. *See PPG Indus., Inc. v. United States*, 52 F.3d 363, 365 (D.C. Cir. 1995) ("Under settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case

must be remanded to the agency for further action consistent with the corrected legal standards."); *see also Cty. Of Los Angeles*, 192 F.3d at 1023. Remand, without vacating the NCD, is the appropriate relief here. *See Allied-Signal, Inc. v. United States Nuclear Regulatory Comm'n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993) ("The decision to vacate depends on the 'the seriousness of the order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed.'" (citation omitted)).

b. Alzheimer's Treatment and Diagnostic Tests

The above conclusion, however, does not end the matter. Plaintiffs advance the additional argument that Defendants' decision not to extend Medicare coverage to BA Scans "cannot be reconciled with their consistent and longstanding practice of providing coverage for a host of Alzheimer's-related treatment services." Pls.' Mot. at 33. Specifically, Plaintiffs assert that "Defendants consistently reimburse Alzheimer's patients for the costs of visits to physicians' offices" and "for the prescription of memantine and cholinesterase inhibitors, two drugs used to mitigate Alzheimer's symptoms," *id.* at 34, as well as "cover counseling services for Alzheimer's patients and their families [and] mental health services for appropriate Alzheimer's patients struggling to cope with the implications of their disease," *id.* Because none of these items and services "prevent, stabilize or reverse" a condition, but are nonetheless covered under Medicare, *id.*, Plaintiffs posit, they "should not, under Defendants' theory, be covered any more than [BA Scans]," *id.* at 33.

Plaintiffs make a similar argument as to Defendants' coverage of diagnostic services for conditions that, like Alzheimer's, are incurable. They assert that Defendants "have covered and continue to cover services that aid in the diagnosis of these conditions, even though those services cannot 'improve health outcomes' or alter 'disease management.'" Pls.' Mot. at 35. Plaintiffs cite

as examples "MRI scans used to diagnose multiple sclerosis," *id.* at 35-36; "diagnostic electromyography/nerve conduction studies for patients with symptoms of amyotrophic lateral sclerosis," also known as ALS, *id.* at 36; "electromyography/nerve conduction testing to aid in the diagnosis of patients experiencing symptoms of muscular dystrophy, a progressive musculoskeletal disease," *id.*; "services that aid in the diagnosis of Cruetzfeldt-Jakob disease, a rapidly progressive and uniformly fatal neurological condition," *id.*; and "genetic testing used in the diagnosis of Huntington's disease, a neurodegenerative genetic disorder that leads to cognitive decline and behavioral problems," *id.* at 37. Plaintiffs contend that these diagnostic services, like the Alzheimer's-related items and services referenced above, do not "prevent, stabilize or reverse" any condition, and thus, it "is arbitrary and capricious for Defendants to cover the[m] on the basis of their diagnostic value while refusing to apply the same standard to [BA Scans]." *Id.*

The court cannot, based on the record before it, find Defendants' coverage of any of the cited Alzheimer's-related items or services or diagnostic tests for incurable conditions to be inconsistent with the denial of coverage for BA Scans or the coverage standard applied thereto. At the outset, the court observes that these items and services are fundamentally different from a BA Scan. None uses PET technology. None is used to determine the cause of dementia symptoms. None counts, as its primary recipients, patients who may have, but have not yet been diagnosed with Alzheimer's. It is thus more challenging for the court to evaluate the consistency of Defendants' decision with respect to BA Scans with Defendants' decisions as to these items and services than it is for the court to do so with regard to FDG PET.

Such evaluation is made even more challenging by the fact that the record before the court does not allow it to compare BA Scans to the allegedly similarly-situated items and services in the same manner that it permits the court to do so with FDG PET. The NCD for FDG PET is included

in the Administrative Record, *see* AR at 4-8; the accompanying decision memo is cited in the parties' pleadings, *see, e.g.*, Defs.' Mot. at 13; Pls.' Reply at 22; and the Decision Memo itself specifically addressed FDG PET, even directly comparing it to BA Scans, *see* AR 4739-40. Contrastingly, the other items and services Plaintiffs raise are not discussed in the Decision Memo. Further, Plaintiffs have not put before the court the actual decision memo or the NCD, to the extent such exist, for *any* of these items or services. Nor have Plaintiffs cited in their briefs the decision memos for any of these items or services, and cite the NCD of only one—MRI scans used to diagnose multiple sclerosis. *See* Pls.' Mot. at 36, n.18. As the party asserting a violation of the APA, it was Plaintiffs' burden to put forward a record from which the court could fully evaluate their arguments. *See San Luis Obispo Mothers for Peace v. U.S. Nuclear Regulatory Comm'n*, 789 F.2d 26, 37 (D.C. Cir. 1986) ("[T]he party challenging an agency's action as arbitrary and capricious bears the burden of proof."). Given that "the court's review is limited to the administrative record," *Fund for Animals*, 903 F. Supp. at 105 (citing *Camp*, 411 U.S. at 142), it is not able, as Plaintiffs urge, to determine that Defendants "treat[ed] similarly situated entities differently," *Lilliputian Sys.*, 741 F.3d at 1313, by granting Medicare coverage for the cited items and services while denying coverage to BA Scans.

Finally, Plaintiffs argue in their reply brief—for the first time—that Defendants' coverage of BA Scans is inconsistent with their coverage of PET scans for the diagnosis of conditions other than Alzheimer's, such as lung cancer, extranodal metastasis, and neck tumors. *See* Pls.' Reply at 27-28 (quoting 2000 FDG PET Decision at 11, 21, 23). Plaintiffs did not, however, raise that argument in their initial Motion. The court will not break with the "well-settled prudential doctrine that courts generally will not entertain new arguments first raised in a reply," *Aleutian Pribilof*

Islands Ass'n, Inc. v. Kempthorne, 537 F.Supp.2d 1, 12 n. 5 (D.D.C. 2008) (citing *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 196 (D.C. Cir. 1992)), by entertaining that argument here.

* * *

In summary, applying the *Chevron* framework, the court concludes that the plain text of the Medicare Act did not preclude Defendants' consideration of health outcomes and disease management in determining whether to afford coverage for BA Scans as "reasonable and necessary for diagnosis." Yet the court also concludes that the NCD did not adequately explain why that standard resulted in different coverage outcomes for BA Scans and FDG PET, even though the two tests are similarly situated and both lacked studies demonstrating an effect on health outcomes or disease management. The agency's failure to offer a sufficient rationale for treating these two tests differently was arbitrary and capricious under the APA.

C. The Decision Memo's Internal Inconsistency

Plaintiffs next argue that the Decision Memo is arbitrary and capricious because it is "internally inconsistent." That is, "Defendants' refusal to cover [BA S]cans on the ground that such scans cannot 'improve health outcomes' or alter 'disease management' is irreconcilable with their own concessions in the administrative record," specifically the concession "that a negative [BA Scan] 'virtually excludes' an Alzheimer's diagnosis." Pls.' Mot. at 40-41 (citing AR at 4758, 4766). "Once this is conceded," Plaintiffs contend, "it is inescapable that such diagnostic information can improve patient health and impact disease management." *Id.* at 41.

Plaintiffs focus on "four harms," Pls.' Reply at 35, which they argue will be avoided if a patient receives a negative scan: "depriv[ation] of the opportunity to be diagnosed with, and treated for, the actual cause of his or her symptoms[], . . . an especially severe injury on the subset of those patients whose symptoms derive from a potentially reversible condition," Pls.' Mot. at 41;

for patients suffering from frontotemporal dementia, the "potentially toxic" effects of "memantine and cholinesterase inhibitors, the two drugs typically prescribed to Alzheimer's patients to mitigate their symptoms," *id.* at 42; for all patients, the "harmful side effects" of "memantine and cholinesterase inhibitors," including "fatigue, dizziness, headache, sleepiness, constipation, vomiting, back pain, coughing, shortness of breath, and hallucination," *id.* at 42-43; and the subjecting of patients to "unnecessary medical procedures and other interventions, such as MRI and CT scans," for which "[t]here is inherent harm," *id.* at 43.

The court does not question the legitimacy of the harms of misdiagnosis that Plaintiffs have identified. Defendants—aside from remarking that the "side effects of [memantine and cholinesterase inhibitors] are 'typically mild and transient,'" Defs.' Mot. at 41 (quoting AR at 3396)—do not either, *see id.* at 39-41. Indeed, Defendants, in the Decision Memo, examined each one of the harms Plaintiffs have set forth here. They determined, however, that then-existing evidence regarding BA Scans did not support a conclusion that the test would improve health outcomes or disease management, *see, e.g.*, AR at 4769-70, and thus, would not allow patients to avoid the harms Plaintiffs have identified, *see id.* at 4760 (addressing the ability for a negative BA Scan to "hasten the work up for other, potentially treatable diseases" and concluding that the "evidence [in favor of] such arguments . . . is of limited persuasiveness, based almost entirely on clinical vignettes and case studies, which carry unmitigated risk of methodological bias and confounding, rather than clinical trials"); *id.* at 4759 (acknowledging that "in differentiating frontotemporal dementia and [Alzheimer's] . . . potential for harm appears to exist," but noting that "CMS covered FDG PET in 2004 for use specifically in the differential of [frontotemporal dementia] and [Alzheimer's]"); *id.* (discussing several studies involving memantine and cholinesterase inhibitors and concluding that "[i]n these particular cases, no additional harm

appears to result from misdiagnosis that places patients on such dementia medications"); *id.* at 4760 (finding that a negative BA Scan would not avoid other interventions because, absent "a convincing clinical picture, work up to exclude other, diagnosable and potentially treatable diseases should proceed anyway (as it would if an amyloid scan were negative)"). The court cannot and will not substitute its judgment for that of Defendants by invalidating those conclusions.

Further, the court is not moved by the statements in the Decision Memo that Plaintiffs characterize as "concessions" "irreconcilable" with Defendants' denial of coverage for BA Scans. Pls.' Mot. at 40-41. Plaintiffs, on several occasions, point to the following statement: "In this case, a negative scan virtually excludes [Alzheimer's]." AR at 4758; *see also* Pls.' Mot. at 3 ("As Defendants concede, a negative [BA S]can '*virtually excludes*' an Alzheimer's diagnosis." (quoting AR at 4758) (emphasis added)); Pls.' Mot. at 6 ("Once Defendants concede that a negative scan 'virtually excludes' Alzheimer's, AR 4758, . . . they cannot avoid the inevitable logical consequences of that admission[.]"); Pls.' Mot. at 22 ("Once Defendants concede that a negative [BA S]can 'virtually excludes' Alzheimer's, AR 4758 (*id.*), it follows unavoidably that this diagnostic information can improve the health or alter the disease management [of certain patients.]"). In quoting this statement, Plaintiffs ignore its context. The "case" that the statement refers to is a hypothetical, used in the Decision Memo "for the sake of illustration . . . although [it] has never been demonstrated." AR at 4757. The statement, which is explicitly based on unproven assumptions, cannot fairly be read as a "concession" or "admission" that negative BA Scans impact outcomes and disease management. Nor can the other two statements Defendants cite to support that proposition, as both are similarly qualified by conditional language. The statement that "a negative [BA S]can *could* virtually exclude [Alzheimer's] in many patients," AR at 4758

(emphasis added), and another noting "the *potential* power of a negative scan to virtually exclude significant brain beta amyloid deposition," do not eclipse the Decision Memo's detailed discussion of the relevant evidence and its thoroughly explained conclusions.

D. Inconsistency with a CMS Regulation

Plaintiffs last argue that Defendants' reliance on CMS regulation 42 C.F.R. § 410.32 to supports its consideration of health outcomes and disease management is arbitrary and capricious. Section 410.32 reads, in relevant part, as follows:

> All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.

42 C.F.R. § 410.32(a). The Decision Memo quotes a portion of Section 410.32 and states that the "expectation that a medical test inform physician management . . . is . . . *consistent with* [the regulation]." AR at 4752 (emphasis added). Plaintiffs contend that "Section 410.32(a) simply identifies the type of health care provider who is authorized to order a diagnostic test; it does not require the test to 'improve health outcomes' or alter 'disease management.'" Pls.' Mot. at 38; *see also* Pls.' Reply at 31 ("In any event, the regulation does *not* require diagnostic services to improve health outcomes or alter disease management, as Defendants contend."). They claim that "Defendants misinterpret their own regulation, once again pressing an interpretation that is inconsistent with the plain text before them." Pls.' Mot. at 38. The court disagrees.

"[Courts] must give substantial deference to an agency's interpretation of its own regulations." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994). Accordingly, such an interpretation merits "controlling weight unless it is plainly erroneous or inconsistent with the regulation." *Id.* (internal quotation and citation omitted); *see also Wyoming Outdoor Council v.*

U.S. Forest Serv., 165 F.3d 43, 52 (D.C. Cir. 1999) ("So long as an agency's interpretation of ambiguous regulatory language is reasonable, it should be given effect."). As the court has concluded above, Defendants' consideration of health outcomes and disease management was permissible under the Medicare Act itself. Therefore, Defendants need not have relied on a regulation such a Section 410.32(a) to justify their consideration of those factors.

In any event, Defendants' interpretation of Section 410.32(a) is not unreasonable, plainly erroneous, or inconsistent with the statute. A regulation that limits Medicare coverage of diagnostic tests to those ordered by a "treating" physician "who uses the results in the management of the beneficiary's specific medical problem," 42 C.F.R. § 410.32(a), can be reasonably read as allowing CMS to consider health outcomes and patient management in deciding whether to cover a diagnostic test.

IV. CONCLUSION

For the foregoing reasons, the court grants in part and denies in part Plaintiffs' and Defendants' Cross-Motions for Summary Judgment. This matter is remanded to the agency for further proceedings consistent with this Memorandum Opinion. A separate Order accompanies this Memorandum Opinion.

Dated: July 19, 2016

Amit P. Mehta
United States District Judge