UNITED STATES DISTRICT COURT
DISTRICT OF COLUMBIA

Martin Hamburger, on his own behalf, and on behalf of all similarly situated individuals, Plaintiff, v. CVS Caremark and Group Hospitalization and Medical Services, Inc., d/b/a CareFirst BlueCross BlueShield, Defendants.	Case No. **COMPLAINT** **CLASS ACTION**

INTRODUCTION

1. This is a class action brought by Plaintiff Martin Hamburger on behalf of participants and beneficiaries of health benefit plans administered by Defendants CVS Caremark and Group Hospitalization and Medical Services, Inc., doing business as CareFirst BlueCross BlueShield ("CareFirst"). Mr. Hamburger challenges Defendants' standard practice of categorically excluding all coverage for ZEPBOUND® ("Zepbound") to treat obstructive sleep apnea in violation of the Employee Retirement Income Security Act of 1974 (ERISA) and the plain terms of the plans Defendants jointly administer.

2. Defendants' health plans promise to cover prescription medications that are prescribed for the treatment of a condition for which benefits are provided under their health plans. Obstructive sleep apnea is one such covered condition.

3. Zepbound is the only prescription medication approved by the FDA to treat obstructive sleep apnea. Zepbound has been shown to achieve a significant and clinically meaningful reduction in apnea or hypopnea events in two randomized, double blind, placebo-

controlled studies.

4. Mr. Hamburger has been diagnosed with moderate obstructive sleep apnea since 2015. Mr. Hamburger requires Zepbound to treat his obstructive sleep apnea. However, as discussed in detail below, Mr. Hamburger has been wrongfully denied coverage for this medically necessary prescription drug by Defendants.

5. The sole basis of Defendants' denials is that the CareFirst Plan categorically "does not cover Zepbound."

6. The problem for Defendants is simple: Under the plain terms of the CareFirst Plan, Zepbound to treat obstructive sleep apnea is covered. Defendants' actions violate both the terms of the CareFirst Plan(s) and the requirements of ERISA.

7. In addition, Defendants' categorical denial of Zepbound evinces a claims procedure operating outside well-established ERISA requirements. Specifically, Mr. Hamburger's experience reveals at least the following violations:

a. Defendants fail to ensure that decisions are made "in accordance with governing plan documents." 29 CFR § 2560.503-1(b)(5).

b. Defendants do not consider all information submitted with claims or appeals, as Defendants ignored requests to consider the medical necessity of Zepbound to treat obstructive sleep apnea through the federally mandated Non-Formulary Drug Exception Request process. 29 CFR § 2560.503-1(b)(1); 29 CFR § 2560.503-1(h)(2)(iv).

c. Defendants failed to provide legally adequate notice under ERISA including "the specific plan provisions on which the determination is based. 29 CFR § 2560.503-1(b)(1); 29 CFR § 2560.503-1(g)(1)(ii).

8. Plaintiff Martin Hamburger, on behalf of the proposed Class, seeks an injunctive order ensuring that Defendants will review claims for coverage of Zepbound in a fully ERISA compliant claims process, going forward.

JURISDICTION AND VENUE

9. Plaintiff Martin Hamburger brings this action pursuant to 29 U.S.C. § 1132(a)(1) and (3), which provide that participants in an employee retirement plan may pursue a civil action to remedy breaches of fiduciary duties and other unlawful conduct in violation of ERISA, and to obtain appropriate equitable relief as set forth in 29 U.S.C. § 1109, including but not limited to surcharge (make-whole) and prospective and retrospective injunctive relief. *See CIGNA Corp. v. Amara,* 563 U.S. 421, 444 (2011).

10. This case presents a federal question, and this Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 and 29 U.S.C. § 1132(e)(1).

11. Venue is proper pursuant to 29 U.S.C. § 1132(e)(2) and 28 U.S.C. § 1391(b) because this is the District where the Plan is administered, where the actions giving rise to this lawsuit occurred, and where Defendants may be found. In addition, Mr. Hamburger also resides in this District.

12. In conformity with 29 U.S.C. § 1132(h), Mr. Hamburger has served this Complaint by certified mail on the Secretary of Labor and the Secretary of Treasury.

THE PARTIES

PLAINTIFF

13. Plaintiff Martin Hamburger resides in Washington, DC, and has been a member of the BluePreferred Health Reimbursement Account (BLUEFUND) ("the Plan") since at least July 2024.

14. The Plan is a self-funded employee welfare benefit plan within the meaning of 29 C.F.R. § 1002(1) because the Plan "was established or is maintained for the purpose of providing for its participants or their beneficiaries, through the purchase of insurance or otherwise... medical, surgical, or hospital care or benefits." The Plan is also a "group health plan" within the meaning of 29 U.S.C. § 1191b(a) because it provides medical care (or items and services paid for as medical care) to employees and their dependents, including payments for "the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body."

15. As a member of the Plan, Mr. Hamburger has the right to benefits under the Plan.

16. Mr. Hamburger has been diagnosed with moderate obstructive sleep apnea since on or about 2015 by Michael Siegel, M.D., in Rockville, Maryland.

17. Mr. Hamburger has tried various surgical procedures to resolve his obstructive sleep apnea, none of which have fully resolved his condition. These procedures have included uvulectomy, nasal turbinate reduction surgery, and a Pillar procedure.

18. In 2016, Mr. Hamburger started to use a continuous positive airway pressure (CPAP) machine which provided some relief but was not fully satisfactory. The CPAP machine requires Mr. Hamburger to sleep with a mask over his mouth and nose connected by tubes to a machine to ensure proper airflow.

19. The CPAP machine does not fully resolve Mr. Hamburger's obstructive sleep apnea. He still experiences interrupted and inadequate sleep, which impacts his productivity at work and his alertness in other situations. Mr. Hamburger's lack of sleep affects other health conditions, including his essential tremor and risk of high blood pressure.

20. As discussed in detail below, Mr. Hamburger's doctor prescribed Zepbound to treat

his obstructive sleep apnea after the FDA authorized Zepbound for such a purpose.

21. Because of Defendants' misconduct, Mr. Hamburger has been wrongfully denied benefits covered under the Plan and has been unable to begin his prescribed pharmaceutical treatment for obstructive sleep apnea.

22. Because Defendants have denied his prior authorization request for Zepbound, Mr. Hamburger has purchased, out-of-pocket, a less expensive GLP-1 medication that is not Zepbound to treat his sleep apnea. He nonetheless seeks coverage of Zepbound, the only FDA-approved medication to remedy Defendants' ERISA violations.

DEFENDANTS

Group Hospitalization and Medical Services, Inc ("CareFirst")

23. Group Hospitalization and Medical Services, Inc., doing business as CareFirst is an independent licensee of the Blue Cross and Blue Shield Association.[1]

24. CareFirst is the largest not-for-profit healthcare insurer in the Mid-Atlantic region, with more than 3.5 million members across Maryland, Washington, D.C., and Northern Virginia.[2]

25. CareFirst maintains corporate headquarters at 840 First Street NE, Washington, DC 20065.[3]

26. CareFirst is the "administrator" of the Plan within the meaning of 29 U.S.C. § 1002(16)(B), and is a "named fiduciary" within the Plan documents, making CareFirst a fiduciary pursuant to 29 U.S.C. § 1002(a)(2).

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[1] CareFirst BlueCross BlueShield is the shared business name of CareFirst of Maryland, Inc. and Defendant Group Hospitalization and Medical Services, Inc. *See, e.g.*, Exhibit A (Member Contract), at 2. (In this citation and the citations that follow, pincites are to the ECF-generated page numbers, not to any internal pagination within the document).

[2] *See* Company Overview, CAREFIRST, https://individual.carefirst.com/individuals-families/about-us/company-overview.page (last accessed August 27, 2025).

[3] *See* Our History, CAREFIRST, https://individual.carefirst.com/individuals-families/about-us/corporate-offices-and-affiliates.page (last accessed August 27, 2025).

27. As the Plan administrator and as a named fiduciary, CareFirst exercises discretionary authority or discretionary control with respect to the administration of the Plan. CareFirst is therefore also a fiduciary under 29 U.S.C. § 1002(21)(A).

28. Interpreting Plan documents and making discretionary benefit eligibility determinations are fiduciary actions. "[A] benefit determination is part and parcel of the ordinary fiduciary responsibilities connected to the administration of a plan" *Aetna Health Inc. v. Davila*, 542 U.S. 200, 219 (2004). "When administering employee benefit plans, [plan administrators] must make discretionary decisions regarding eligibility for plan benefits, and, in this regard, must be treated as plan fiduciaries." *Id.* at 220. "Classifying any entity with discretionary authority over benefits determinations as anything but a plan fiduciary would thus conflict with ERISA's statutory and regulatory scheme." *Id*.

29. CareFirst delegated its fiduciary responsibility for administering the Plan's pharmacy benefit management program, including its fiduciary responsibility and discretionary authority to determine a participant's eligibility for pharmacy and drug benefits, to CVS Caremark.[4] CareFirst also delegated its fiduciary responsibility and discretionary authority to review internal appeals for pharmacy and drug benefits to CVS Caremark.[5]

30. Pursuant to CareFirst's delegation of these fiduciary responsibilities, CareFirst's discretionary appointment of CVS Caremark to administer the Plan's pharmacy benefit management program, and CareFirst's discretionary authority to remove or replace CVS Caremark as the Plan's pharmacy benefit manager, CareFirst has a duty to monitor the performance of CVS Caremark and is jointly liable for any ERISA violations incurred by CVS while administering the

[4] *See* Exhibit B (Initial Notice of Adverse Coverage Determination, dated February 25, 2025 ("Initial Adverse Determination Notice")), at 2.
[5] *See* Exhibit D (Notice of Final Adverse Coverage Determination, dated April 3, 2025 ("Final Adverse Determination Notice")), at 2.

CareFirst health plans.[6]

CVS Caremark

31. CVS Caremark is the pharmacy benefit manager responsible for administering the prescription drug benefits on behalf of the health plan or plan sponsor.[7] In its role as the pharmacy benefit manager for the Plan, CVS Caremark is "responsible for reviewing requests for prior authorization of pharmacy and drugs to ensure coverage is available and the request is appropriate for payment purposes."[8]

32. In its role as the pharmacy benefit manager for the Plan, CVS Caremark has fiduciary discretion to grant or deny a member's claim for benefits.[9] Because CVS Caremark exercised discretion in interpreting the Plan document and denied Mr. Hamburger's claim for benefits, CVS Caremark is a functional fiduciary within the meaning of 29 U.S.C. § 1002(21)(A).

33. CVS Caremark is also responsible for reviewing internal appeals concerning a denied request for pharmacy or drugs, and has fiduciary discretion to grant or deny a member's claim for benefits on appeal.[10] Because CVS Caremark exercised discretion in denying Mr. Hamburger's internal appeal, CVS Caremark is a functional fiduciary within the meaning of 29 U.S.C. § 1002(21)(A).

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[6] *See Understanding Your Fiduciary Responsibilities Under a Group Health Plan*, U.S. Department of Labor, Employee Benefits Security Administration (EBSA) at 3, 6 (Sept. 2023) (noting a delegating fiduciary "must monitor [a] service provider periodically to assure that it is handling the plan's administration prudently" and discussing the minimum basic standards for monitoring service providers), available at https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/publications/group-health-plan-fiduciary-responsibilities.pdf.
[7] Exhibit B (Initial Adverse Determination Notice), at 2.
[8] *See* Exhibit B (Initial Adverse Determination Notice), at 2.
[9] *See* Exhibit B (Initial Adverse Determination Notice), at 2.
[10] *See* Exhibit D (Final Adverse Determination Notice), at 2.

FACTUAL ALLEGATIONS

I. CareFirst Plan and Formulary Covers Medically Necessary Pharmaceutical Treatment of Obstructive Sleep Apnea

34. Obstructive sleep apnea is a serious sleep disorder in which an individual's upper airway becomes blocked while asleep, which can reduce or completely stop airflow.[11] Obstructive sleep apnea is "a highly prevalent syndrome that is associated with substantial morbidity and increased mortality."[12]

35. Obstructive sleep apnea is a covered medical condition under the Plan.

36. The Plan's Prescription Drug Rider states, in relevant part, "benefits will be provided for a Prescription Drug dispended by a Pharmacist for self-administered-use on an outpatient basis for the treatment of a condition for which benefits are provided under the terms of the [Plan]."[13]

37. Zepbound is "an injectable prescription medicine that may help adults with... moderate to severe obstructive sleep apnea (OSA) and obesity to improve their OSA."[14] As such, Zepbound meets the Plan's definition of "Prescription Drug."[15]

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[11] *See generally* Giannicola Iannella et al., *The Global Burden of Obstructive Sleep Apnea*, 15 DIAGNOSTICS 1088 (2025); Sleep-Related Breathing Disorders, Wellness, Sleep and Circadian Network (WSCN), available at https://www.sleephealth.org/sleep-related-breathing-disorders/; *Sleep Apnea*, Johns Hopkins Medicine, available at https://www.hopkinsmedicine.org/health/conditions-and-diseases/sleep-apnea

[12] Sigrid C. Veasey, M.D., et al., *Medical Therapy for Obstructive Sleep Apnea: A Review by the Medical Therapy for Obstructive Sleep Apnea Task Force of the Standards of Practice Committee of the American Academy of Sleep Medicine*, 29 SLEEP 1036, 1036 (2006), available at https://aasm.org/wp-content/uploads/2017/07/Review_MedicalTherapyOSA.pdf; Atul Malhotra, M.D., et al., *Tirzepatide for the Treatment of Obstructive Sleep Apnea and Obesity*, 391 NEW ENG. J. MED. 1193, 1194 (2024) ("The disease is common and has major medical and economic effects; more than 900 million persons are affected worldwide, approximately 40% of whom have moderate-to-severe disease.").

[13] Exhibit A (Member Contract), at 155 (Prescription Drug Benefits Rider at H(1)).

[14] Zepbound Medication Guide, https://pi.lilly.com/us/zepbound-us-mg.pdf; *see generally* Zepbound, ELI LILLY https://zepbound.lilly.com.

[15] *See* Exhibit A (Member Contract) at 11–12 (Section 1 - Definitions) ("Prescription Drug means... [a] drug, biological or compounded prescription intended for outpatient use that carries

38. The Plan utilizes the CareFirst Formulary 3, which is the formulary used by CareFirst plans governed by ERISA for employees of large businesses (*i.e.*, businesses with 50+ employees).

39. From at least December 1, 2024, through June 30, 2024, Zepbound was included on the CareFirst Formulary 3.

40. Zepbound was removed from the CareFirst Formulary 3 on July 1, 2025, with the qualification that excluded medications would be covered if medically necessary.[16] In its news update and summary of changes, CareFirst stated that Orlistat, Qsymia, Saxenda, Wegovy would remain as "alternative options" to Zepbound. None of these "alternative options" are FDA-approved treatments for obstructive sleep apnea.

41. Pursuant to CareFirst's Prescription Guidelines, Zepbound remains a "non-specialty product[] requiring prior authorization," whose coverage is "subject to a member's plan benefit."[17]

42. Zepbound for the treatment of obstructive sleep apnea is not expressly excluded in the CareFirst Plan.

II. Plaintiff is Wrongfully Denied Zepbound to Treat Obstructive Sleep Apnea.

43. Following the FDA's approval of Zepbound to treat obstructive sleep apnea, Mr. Hamburger's treating physician, Shalini Sitzmann, M.D., recommended that Mr. Hamburger

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the FDA legend 'may not be dispensed without a prescription[.]'"); *see also* Exhibit A (Member Contract) at 154 (Prescription Drug Benefits Rider, Section 1 - Definitions) (same).

[16] July 1, 2025 CareFirst Formulary Updates, at 1, CAREFIRST, https://provider.carefirst.com/carefirst-resources/pdf/2025-july-formulary-changes.pdf; *see also* Upcoming CareFirst Formulary Updates Effective July 1, 2025, CareFirst (updated on June 3, 2025 at 22:44:32), https://provider.carefirst.com/providers/news/2025/06/carefirst-formulary-updates-effective-jul-1-2025/ (last accessed August 27, 2025).

[17] Prescription Guidelines for Formularies 1, 2, 3 and 3 Choice (eff. July 1, 2025), at 11, 13, CAREFIRST, https://member.carefirst.com/carefirst-resources/pdf/prescription-guidelines-2025.pdf (last accessed August 27, 2025)

take Zepbound in addition to using the CPAP machine to treat his obstructive sleep apnea.

44. Dr. Sitzmann subsequently prescribed Zepbound for Mr. Hamburger and submitted a request for coverage of Zepbound for the purpose of treating obstructive sleep apnea.

45. Dr. Sitzmann's request for coverage listed the associated diagnosis as "Obstructive sleep apnea," and included the International Classification of Diseases (ICD) diagnosis code of G47.33, which is the diagnosis code for obstructive sleep apnea.[18]

46. Mr. Hamburger's pre-authorization request for Zepbound to treat his sleep apnea was denied on February 25, 2025, by CVS Caremark on behalf of CareFirst. The sole reason for the denial was "Drug Not Covered/Plan Exclusion – Your request for coverage was denied because your prescription benefit plan does not cover the requested medication."[19] The denial notice further stated, "This decision relates specifically to coverage provided under your prescription benefit plan and does not involve any determination of medical judgment."[20]

47. Conclusory statements denying benefits do not constitute the "meaningful dialogue" that is required under ERISA. *See Lukas v. United Behav. Health*, 504 F. App'x 628, 629 (9th Cir. 2013); *Booton v. Lockheed Med. Benefit Plan*, 110 F.3d 1461, 1463 (9th Cir.1997); *see also, e.g.*, *Dwyer v. United Healthcare Ins. Co.*, 115 F.4th 640, 649–50 (5th Cir. 2024); *Ian C. v. UnitedHealthcare Ins. Co.*, 87 F.4th 1207, 1223–24 (10th Cir. 2023).

48. Because the denial did "not involve any determination of medical judgment," CVS Caremark failed to consider the ICD diagnosis code (G47.33) and the associated diagnosis (obstructive sleep apnea) that Mr. Hamburger's doctor included with the initial prior approval request for Zepbound and whether it was diagnosed to treat a covered medical condition under the

[18] *See* Exhibit B (Initial Adverse Determination Notice), at 4.
[19] Exhibit B (Initial Adverse Determination Notice), at 2.
[20] Exhibit B (Initial Adverse Determination Notice), at 2.

Plan when CVS Caremark determined that Zepbound was not a covered medication.

49. CVS Caremark's mechanical denial of Zepbound and failure to process requests for Zepbound to treat a covered medical condition evinces a claims procedure that fails to contain "administrative processes and safeguards designed to ensure and to verify that benefit claim determinations are made in accordance with governing plan documents." 29 CFR § 2560.503-1(b)(5).

50. CVS Caremark's perfunctory notice failed to provide "adequate notice" to Mr. Hamburger because it failed to set forth "the specific reasons for such denial, written in a manner calculated to be understood by the participant," 29 U.S.C. § 1133; 29 C.F.R. § 2560.503-1(g)(1), and failed to reference "the specific plan provisions on which the determination is based," 29 C.F.R. § 2560.503-1(g)(1).

III. Defendants Failed to Appropriately Evaluate Plaintiff's Internal Appeal for Zepbound to Treat Obstructive Sleep Apnea

51. On April 2, 2025, Mr. Hamburger, through counsel, submitted an internal appeal to CVS Caremark.[21] Among other things, Mr. Hamburger reminded CVS Caremark that he is entitled to certain protections under ERISA, including a full, fair, and thorough review conducted by an appropriately qualified reviewer which takes into account all of the information he provides, and gives a meaningful response to the arguments and evidence he presents, and which provides him with the specific reason(s) for the adverse determination, references the specific plan provisions on which the denial was based, and gives him any information necessary to perfect his claim.

52. Mr. Hamburger's internal appeal plainly asserted that because obstructive sleep apnea is a medical condition that is covered by the Plan, Zepbound for the purpose of treating sleep

[21] Exhibit C (Internal Appeal Letter dated April 2, 2025 ("Internal Appeal")).

apnea is a covered prescription benefit.[22]

53. Mr. Hamburger reminded CVS Caremark that Zepbound is the only prescription medication that the FDA has approved to treat obstructive sleep apnea.[23] To the extent that his prior-authorization request was denied because of a formulary exception, Mr. Hamburger asked CVS Caremark to process his request for Zepbound as a Non-Formulary Drug Request.[24]

54. Finally, in connection with his internal appeal, Mr. Hamburger requested all documents considered or relied upon in any way by CareFirst or CVS Caremark related to the denial of his pre-authorization request for Zepbound.

55. One day later (April 3, 2025), CVS Caremark issued a Notice of Final Adverse Coverage Determination (the "Final Adverse Determination Notice").[25] The Final Adverse Determination Notice stated, "CVS Caremark has reviewed your appeal for the denial of your request for Zepbound 5MG/0.5ML SC SOAJ. Your request for this benefit was denied because it does not meet the coverage terms of your prescription benefit plan."[26]

56. The Final Adverse Determination Notice further stated:

> The reason for denial was:
>
> Your request for coverage of Zepbound is denied. Your pharmacy benefit plan does not cover Zepbound. You may refer to the prescription benefit drug section in your Explanation of Coverage document for guidelines used in making this decision....
>
> This decision relates specifically to coverage provided under your prescription benefit plan and does not involve any determination of medical judgment. [27]

57. The Final Adverse Determination Notice confirmed that Mr. Hamburger had

[22] Exhibit C (Internal Appeal), at 3.
[23] Exhibit C (Internal Appeal), at 3.
[24] Exhibit C (Internal Appeal), at 2 (citing Prescription Drug Coverage Pharmacy Exception Requests, CareFirst, available at https://member.carefirst.com/members/drug-pharmacy-information/pharmacy-exception-requests.page).
[25] Exhibit D (Final Adverse Determination Notice).
[26] Exhibit D (Final Adverse Determination Notice), at 2.
[27] Exhibit D (Final Adverse Determination Notice), at 2.

exhausted CVS Caremark's internal appeal process.[28]

58. The Final Adverse Determination Notice did not identify the "guidelines" in the prescription benefit drug section of the Plan's Explanation of Coverage document that were "used in making this decision."[29]

59. The Final Adverse Determination Notice stated that Mr. Hamburger's appeal was "[r]eviewed by NS, CPhT."[30] However, the Final Adverse Determination Notice failed to provide Mr. Hamburger with sufficient information to determine whether his internal appeal was "conducted by an appropriate named fiduciary of the plan who is neither the individual who made the adverse benefit determination that is the subject of the appeal, nor the subordinate of such individual," in accordance with 29 CFR § 2560.503-1(h)(3)(ii).

60. The Final Adverse Determination Notice's regurgitation of the phrase that the denial of benefits did "not involve any determination of medical judgment," confirms that CVS Caremark *again* failed to consider whether Zepbound was prescribed to treat a covered condition under the Plan.[31] *E.g.*, *Benjamin v. Oxford Health Ins., Inc.*, 2018 WL 3489588, at *7–8 (D. Conn. July 19, 2018).

61. CVS Caremark failed to "take into account" that obstructive sleep apnea is a covered medical condition under the Plan and that Zepbound is the only approved medication for obstructive sleep apnea.[32] This failure deprived Mr. Hamburger of his rights under ERISA to a full

[28] Exhibit D (Final Adverse Determination Notice), at 2.
[29] *See* Exhibit D (Final Adverse Determination Notice), at 2–4.
[30] Exhibit D (Final Adverse Determination Notice), at 2. "CPhT" stands for Certified Pharmacy Technician.
[31] The ICD diagnosis code (G47.33), the associated diagnosis (obstructive sleep apnea) that Mr. Hamburger's doctor included with the initial prior approval request for Zepbound were printed on Page 3 of the Final Adverse Determination Notice but never addressed by CVS Caremark. Exhibit D (Final Adverse Determination Notice), at 4.
[32] 29 CFR § 2560.503-1(b)(1); 29 CFR § 2560.503-1(h)(2)(iv); *see* Exhibit D (Final Adverse Determination Notice), at 2–4.

and fair review that "takes into account all comments, documents, records, and other information submitted by the claimant relating to the claim, without regard to whether such information was submitted or considered in the initial benefit determination" under 29 CFR § 2560.503-1(b)(1) and 29 CFR § 2560.503-1(h)(2)(iv). *See Ian C.*, 87 F.4th at 1223–24; *Dwyer v. United Healthcare Ins. Co.*, 115 F.4th 640, 651 (5th Cir. 2024); *D. K. v. United Behav. Health*, 67 F.4th 1224, 1241 (10th Cir. 2023), cert. denied, 144 S. Ct. 808 (2024); *Raymond M.*, 463 F. Supp. 3d at 1274 (holding there was "no indication that [the fiduciary] provide[d] for a review that takes into account the Plaintiffs' submitted information on appeal" as required under § 2560.503-1(h)(2)(iv) based on the a "dearth of analysis" in the claim denial letters, which fell "far short of the 'meaningful dialogue'" that ERISA envisions"); *Kansas v. Titus*, 452 F. Supp. 2d 1136, 1148–49 (D. Kan. 2006).

IV. Defendants Failed to Appropriately Evaluate Plaintiff's Request for a Non-Formulary Exception Request for Zepbound for Purposes of Treating Sleep Apnea

62. Mr. Hamburger specifically invoked his right to a Non-Formulary Exception Request in his internal appeal.

63. CVS Caremark failed to consider the Plan's procedure for Non-Formulary Exception Requests when reviewing Mr. Hamburger's internal appeal: the Final Adverse Determination Notice neither responded to Mr. Hamburger's request to process his claim for Zepbound as a Non-Formulary Drug Request, nor indicated whether any additional information was necessary in order to perfect a Non-Formulary Drug Request, as required under 29 C.F.R. § 2560.503-1(g)(1).[33]

64. CVS Caremark's failure to process Mr. Hamburger's Non-Formulary Drug Exception Request deprived Mr. Hamburger of his rights under ERISA to a full and fair review that "takes into account all comments, documents, records, and other information submitted by the

[33] *See* Exhibit D (Final Adverse Determination Notice), at 2–4.

claimant relating to the claim, without regard to whether such information was submitted or considered in the initial benefit determination" under 29 CFR § 2560.503-1(b)(1) and 29 CFR § 2560.503-1(h)(2)(iv). *E.g.*, *Raymond M.,* 463 F. Supp. 3d at 1274.

65. CVS Caremark's failure to respond to Mr. Hamburger's invocation of his right under the Plan to submit a Non-Formulary Drug Exception Request evinces a fundamentally flawed claims procedure that does not contain "administrative processes and safeguards designed to ensure and to verify that benefit claim determinations are made in accordance with governing plan documents." 29 CFR § 2560.503-1(b)(5).

V. CareFirst Enabled and Failed to Remedy CVS Caremark's Misconduct

66. CareFirst knew or should have known of CVS Caremark's deficient process for making eligibility determinations, including the process for reviewing initial claims for benefits, internal appeals, and Non-Formulary Drug Exception Requests.

67. CareFirst knew or should have known of CVS Caremark's practice of sending inadequate Notices to Plan participants.

68. CareFirst knew or should have known of CVS Caremark's deficient process for responding to requests for documents.

69. CareFirst has stood idly by while CVS Caremark has deprived Mr. Hamburger of his rights under ERISA and the terms of the Plan.

CLASS ACTION ALLEGATIONS

70. Plaintiff brings this action on behalf of himself and all others similarly situated as a Class pursuant to Federal Rules of Civil Procedure 23. Pursuant to Rule 23(b)(1) and (b)(2), Plaintiff seeks certification of the following Class:

All individuals who:

(a) have been, are, or will be participants or beneficiaries covered under ERISA welfare benefit plans administered by CareFirst BlueCross BlueShield with pharmacy benefit management programs administered by CVS Caremark; and

(b) required or will require Zepbound for the purpose of treating obstructive sleep apnea from December 20, 2024, to the present.

71. Plaintiff and the Class Members reserve the right under Rule 23(c)(1)(C) to amend or modify the Class, including, *inter alia*, to include greater specificity, by further division into subclasses, or by limitation to particular issues.

72. Numerosity: the potential members of the proposed Class are so numerous that joinder of all Class Members is impracticable. While the precise number of proposed Class Members has not been determined at this time, based on the prevalence of sleep apnea in the general population, a substantial number of individuals with obstructive sleep apnea have been similarly affected by Defendants' failure to cover Zepbound to treat obstructive sleep apnea. *E.g., Paul v. Blue Cross Blue Shield of N. Carolina*, 725 F. Supp. 3d 505, 519 (E.D.N.C. 2024) (numerosity is the subject of class certification discovery).

73. Typicality: Plaintiff's claims are typical of the Class Members' claims. Like other Class Members, Plaintiff has been denied a covered benefit and denied a full and fair review as a result of Defendants' misconduct. Defendants' imprudent decisions and blanket denial of coverage of Zepbound to treat obstructive sleep apnea has affected all Class Members similarly.

74. Adequacy: Plaintiff will fairly and adequately protect the interests of the Class. Plaintiff's interests are aligned with the Class that he seeks to represent, and he has retained counsel experienced in complex class action litigation, including ERISA litigation. Plaintiff does not have any conflicts of interest with any Class Members that would impair or impede his ability to

represent such Class Members.

75. Commonality: Common questions of law and fact exist as to all Class Members and predominate over any questions solely affecting individual Class Members. The overarching common question is whether Defendants breached the plan terms and relevant ERISA and other federal law by categorically excluding all coverage of Zepbound when sought to treat obstructive sleep apnea. Additional common questions, include but not are limited to:

a. Whether Defendants are fiduciaries with respect to the Plan;

b. Whether Defendants breached their fiduciary duties by engaging in the conduct described herein; and

c. The proper form of equitable and injunctive relief.

76. Class certification is appropriate under Fed. R. Civ. P. 23(b)(1) because, *inter alia*, prosecuting separate actions against Defendants would create a risk of inconsistent or varying adjudications with respect to individual Class Members that would establish incompatible standards of conduct for Defendants.

77. Class certification is also appropriate under Fed. R. Civ. P. 23(b)(2) because, *inter alia*, by categorically denying Zepbound without regard for whether it is medically necessary to treat obstructive sleep apnea and by failing to appropriately process non-formulary exception requests for the only FDA-approved prescription medication to treat obstructive sleep apnea, Defendants have acted on grounds generally applicable to the Class, rendering declaratory relief appropriate respecting the entire Class.

COUNT I
Claim for Recovery of Benefits Under 29 U.S.C. § 1132(a)(1)(B) as to both Defendants

78. Plaintiff alleges and incorporates by reference the allegations in the preceding paragraphs.

79. 29 U.S.C. § 1132(a)(1)(B) provides that a participant or beneficiary may bring an

action to "recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan."

80. Mr. Hamburger and the Class are entitled to recover benefits due to them under the terms of their plans. They are also entitled to a clarification and declaration of present and future rights to coverage of Zepbound to treat obstructive sleep apnea, including corrective notice.

81. Mr. Hamburger and the Class also seek equitable relief to recover benefits due them in the form of retrospective injunction requiring Defendants to reprocess Mr. Hamburger's and Class Members' claims for Zepbound to treat obstructive sleep apnea, and to process claims for such services incurred by Class Members during the Class Period (even if not submitted), as well as equitable tolling of claim and appeal deadlines for requesting authorization or coverage of such services and appealing denials of such authorizations or coverage requests, and any applicable statute of limitations.

COUNT II
Claim to Enjoin Acts and Practices in Violation of the Terms of the Plans, to Obtain Other Equitable Relief and to Enforce the Terms of the Plans Under 29 U.S.C. § 1132(a)(3) as to both Defendants

82. Plaintiff alleges and incorporates by reference the allegations in the preceding paragraphs.

83. As set forth herein, Mr. Hamburger and the Class Members are participants in, or beneficiaries of, health benefit plans jointly administered by Defendants and governed by ERISA.

84. Defendants are functional ERISA fiduciaries that must discharge their duties with respect to the plan "solely in the interest of the participants and beneficiaries and … in accordance with the documents and instruments governing the plan insofar as such documents and instruments are consistent with the provisions of this title and Title IV." 29 U.S.C. § 1104(a)(1)(C).

85. Defendants have discretionary authority, and actually exercise the authority, to

administer self-funded plans (like the Plan), and make decisions on claims for benefits and appeals thereof.

86. As fiduciaries, Defendants must act with the utmost prudence and loyalty in communicating to plan participants and beneficiaries and in administering their claims under the Plan, and must comply with other requirements of ERISA, including complying with terms and conditions of ERISA plans themselves when making benefit determinations.

87. CVS Caremark repeatedly violated its obligations and duties to Mr. Hamburger and the Class during the Class Period, including *inter alia*:

a. Drafting and implementing policies and procedures for prior authorization review that provide for an inadequate review of clinical records by their medical directors prior to rendering a determination of coverage for Zepbound to treat obstructive sleep apnea;

b. Drafting and implementing policies and procedures for the review of Non-Formulary Exception Requests that provide for an inadequate review of clinical records by their medical directors prior to rendering a determination of coverage for Zepbound to treat obstructive sleep apnea;

c. Drafting and implementing policies and procedures for the adjudication of internal appeals that provide for an inadequate review of clinical records by an independent medical director prior to rendering a determination of coverage for Zepbound to treat obstructive sleep apnea;

d. Failing to provide adequate notice to Plan participants in response to claims for Zepbound to treat obstructive sleep apnea.

88. CareFirst likely knew of these fiduciary duty violations by CVS Caremark and joined in them.

89. Defendants' categorical denial of Zepbound and failure to process requests for Zepbound to treat a covered medical condition evinces a claims procedure that fails to contain "administrative processes and safeguards designed to ensure and to verify that benefit claim determinations are made in accordance with governing plan documents." 29 CFR § 2560.503-

1(b)(5).

90. Defendants' failure to respond to Mr. Hamburger's specific references in his internal appeal to the medical necessity of Zepbound to treat obstructive sleep apnea and CVS Caremark's failure to process Mr. Hamburger's internal appeal as a non-formulary drug exception request deprived Mr. Hamburger of his rights under ERISA to a full and fair review that "takes into account all comments, documents, records, and other information submitted by the claimant relating to the claim, without regard to whether such information was submitted or considered in the initial benefit determination" under 29 CFR § 2560.503-1(b)(1) and 29 CFR § 2560.503-1(h)(2)(iv).

91. Defendants' failure to reference to "the specific plan provisions on which the determination is based" deprived Mr. Hamburger of his right to a reasonable claims procedure pursuant to 29 CFR § 2560.503-1(b)(1) and 29 CFR § 2560.503-1(g)(1)(ii).

92. Pursuant to 29 U.S.C. § 1132(a)(3), Plaintiff and the Class seek equitable and remedial relief as the Court may deem appropriate, including, *inter alia*, an injunction compelling Defendants to:

a. Retract their categorical denials for Zepbound;

b. Provide corrective notice of said determination in the form and manner required by ERISA to all Class Members who have had prior authorization requests or claims for Zepbound denied;

c. Reprocess and process all claims for Zepbound to treat obstructive sleep apnea incurred by Mr. Hamburger and the Class Members during the Class Period under an ERISA-compliant procedure and, where warranted, pay Class Members for amounts incurred to treat obstructive sleep apnea as a result of Zepbound coverage denials in violation of ERISA; and

d. Provide equitable "surcharge" relief to compensate Mr. Hamburger and Class Members who purchased less expensive GLP-1 medications, out-of-pocket, due to Defendants' wrongful denial and misrepresentation of coverage for Zepbound to treat obstructive sleep apnea.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of the Class, requests the following relief:

A. An Order certifying the proposed Class, appointing Mr. Hamburger to represent the proposed Class, and designating Mr. Hamburger's counsel as Class Counsel;

B. An Order declaring that Defendants' practices described herein violate ERISA and its ERISA-based fiduciary duties;

C. Injunctive and other equitable relief as described and requested above;

D. An Order awarding disbursements and expenses for this action, including reasonable attorneys' fees and costs, in amounts to be determined by the Court, pursuant to 29 U.S.C. §1132(g);

E. Payment of pre-judgment and post-judgment interest as allowed under ERISA; and

F. For such other and further relief as this Court may deem just and proper.

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