# IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

DENNIS LARKIN and DANIELLE GOSLINE, individually and on behalf of all others similarly situated,

Plaintiffs,

Case No.

v.

JURY TRIAL DEMANDED

CAREMARK RX, L.L.C. (d/b/a CVS CAREMARK),

Defendant.

### **CLASS ACTION COMPLAINT**

Plaintiffs Dennis Larkin and Danielle Gosline ("Plaintiffs"), individually and on behalf of all others similarly situated, allege as follows against Defendant Caremark RX, L.L.C. (d/b/a CVS Caremark) ("CVS Caremark" or "Defendant").

### **INTRODUCTION**

- 1. This case is brought as a class action lawsuit under the Employee Retirement Income Security Act of 1974, 29 U.S.C. § 1001, et seq. ("ERISA"), on behalf of Plaintiffs and a class consisting of members of an employer-sponsored health benefit plan for whom Defendant acts as a pharmacy benefit manager ("PBM"), whose requests for coverage of Zepbound (tirzepatide) were denied by Defendant due to alleged lack of medical necessity and not being covered under the plan, in violation of ERISA and the terms of the applicable plan documents.
- 2. In a fully insured plan, the employer pays a fixed premium to an insurance carrier, who assumes the financial risk and administrative burden of paying claims. In a self-funded plan,

the employer pays for employee claims directly from their own funds, including contributions made by employees, and often hire third-party administrators ("TPAs") to help administer the plan.

- 3. One type of TPA hired by both self-funded plans and insurance carriers that issue fully insured plans is a PBM. PBMs are engaged to oversee and administer prescription drug coverage for plan participants. Among other things, PBMs manage formularies, maintain pharmacy networks, negotiate rebates with drug manufacturers, process prescription drug claims and appeals, provide mail order services, and manage drug use. PBMs are used by virtually all employer sponsored health plans to manage prescription drug benefits.
- 4. In 2024, CVS Caremark administered approximately 27% of all pharmacy benefit claims for the more than 154 million people covered under employer-sponsored health plans.
- 5. While PBMs can sometimes reduce prescription drug costs for employers who offer health plans, PBMs in some cases reduce access to prescribed medication and increase the price of drugs for beneficiaries of employer-sponsored plans.
- 6. PBMs negotiate prescription drug rebates with brand name drug manufacturers that are expressly conditioned on PBMs reducing access to generic alternatives and/or similar drugs from competing manufacturers. As part of these rebate agreements between the PBMs and drug manufacturers, PBMs sometimes refuse to fill prescriptions for generic alternatives and biosimilars from competing formularies.
- 7. Defendant (either itself or through its parent company, CVS Health Corporation ("CVS Health")) entered into a prescription drug rebate agreement with Novo Nordisk for the weight management drug Wegovy (semaglutide). As part of that rebate agreement, beginning on July 1, 2025, CVS Caremark stopped covering Zepbound (tirzepatide). Zepbound is an FDA approved drug for the treatment of obesity and weight management, and on December 20, 2024,

Zepbound became the first and only FDA-approved drug to treat moderate-to-severe obstructive sleep apnea for adults with obesity. We govy is *not* FDA approved for the treatment of moderate-to-severe obstructive sleep apnea in adults with obesity.

- 8. Plaintiff Dennis Larkin ("Larkin") participates in his employer's self-funded health plan. Mr. Larkin's plan uses CVS Caremark to manage pharmacy benefits for its covered employees and participants.
- 9. Mr. Larkin received a prescription for Zepbound from his physician in December of 2023, for the purpose of weight management. At the time of Mr. Larkin's initial prescription for Zepbound, his employer did not use CVS Caremark as its PBM.
- 10. Shortly thereafter, on or about April 22, 2024, after beginning treatment with Zepbound, Mr. Larkin was also diagnosed with severe obstructive sleep apnea.
- 11. Mr. Larkin relies on Zepbound to treat his severe obstructive sleep apnea and for weight management.
- 12. Mr. Larkin's employer began using CVS Caremark as its PBM and, effective January 1, 2025, Mr. Larkin's prescription benefits were managed by CVS Caremark.
- 13. CVS Caremark approved Mr. Larkin's physician's request for coverage for Zepbound in January 2025, and Mr. Larkin continuously refilled his prescription until June 19, 2025, when Defendant denied Mr. Larkin's request for coverage of his Zepbound prescription, stating that Mr. Larkin's plan no longer covered Zepbound.
- 14. Mr. Larkin submitted a first-level member appeal to Defendant on July 14, 2025, appealing Defendant's decision to deny coverage for Zepbound.
- 15. On July 14, 2025, Defendant denied Mr. Larkin's first-level member appeal. Defendant stated that "[p]er physician review, current plan approved criteria and current medical

literature do not support the use of Zepbound over the available formulary alternatives" and stated that "[t]he primary covered drug for [Mr. Larkin's] plan is Wegovy." Defendant also informed Mr. Larkin that "[t]he secondary covered drug for your plan is a tirzepatide product [Brand Mounjaro] that has the same active ingredient at the same strength and dosage as the requested drug."

- 16. Mr. Larkin submitted a second-level member appeal on July 21, 2025, which Defendant denied on July 23, 2025, again stating that Zepbound was not medically necessary.
- 17. Defendant escalated Mr. Larkin's appeal for an independent review on July 23, 2025, with a final external review denial received by Mr. Larkin on July 25, 2025.
- 18. After exhausting all of his appeals, Mr. Larkin's physician prescribed Mr. Larkin with Wegovy, which was approved by CVS Caremark. Mr. Larkin took his first dose on August 9, 2025 and his second dose on August 16, 2025, and experienced a number of side effects, including the return of his Gastroesophageal Reflux Disease, stomach pain, hunger, and, most notably, weight gain.
- 19. Plaintiff Danielle Gosline participates in her employer's self-funded health plan.

  Ms. Gosline's plan uses CVS Caremark to manage pharmacy benefits for its covered employees and participants.
- 20. Ms. Gosline's physician prescribed Zepbound on January 3, 2024, to treat Ms. Gosline's obesity and for the purpose of weight management.
- When Ms. Gosline initially sought coverage for Zepbound, her employer's PBM was Express Scripts, which approved her initial prescription of Zepbound. Ms. Gosline's employer transitioned to using CVS Caremark as its PBM on January 1, 2025, and, at that time, CVS Caremark honored Ms. Gosline's existing prior authorization and continued coverage.

- 22. On April 1, 2025, CVS Caremark approved a new prior authorization for Zepbound, which was supposedly valid through April 1, 2026.
- 23. Ms. Gosline continuously refilled her prescription for Zepbound until July 1, 2025, when Defendant denied Ms. Gosline's request for coverage for her Zepbound prescription, stating that Ms. Gosline's plan no longer covered Zepbound.
- 24. On July 7, 2025, Ms. Gosline appealed Defendant's decision to deny coverage for Zepbound, pointing out, among other things, that she requires Zepbound to treat her obesity, and that Zepbound is not clinically interchangeable with other medications.
- 25. On July 8, 2025, Defendant denied Ms. Gosline's appeal on the basis that Zepbound is "not medically necessary." In its denial letter sent to Ms. Gosline, Defendant explained that "[p]er physician review, current plan approved criteria and current medical literature do not support the use of Zepbound over the available formulary alternatives," and stated that "[t]he primary covered drug for [Ms. Gosline's] plan is Wegovy." Defendant also informed Ms. Gosline that "[t]he secondary covered drug for your plan is a tirzepatide product [Brand Mounjaro] that has the same active ingredient at the same strength and dosage as the requested drug."
- 26. By denying Zepbound as not being covered under the applicable plans and as not "medically necessary" for both Plaintiffs (and those similarly situated), CVS Caremark is exercising delegated authority to interpret plan provisions and make coverage determinations. When a PBM/TPA is delegated the authority to handle claims and appeals under the plan, they are acting as a fiduciary under ERISA. CVS Caremark, which interprets the terms of the applicable plans and is delegated the authority to handle claims and appeals under the plans, is acting at all times as a fiduciary under ERISA.

- 27. Both Plaintiffs' plans contain language under which Zepbound should be covered as a medically necessary service. As an FDA-approved drug, with credible scientific evidence published in recognized peer-reviewed medical literature, Zepbound falls within "Generally Accepted Standards of Medical Practice" as defined in the plans and it has been proven to be "clinically appropriate" to treat patients diagnosed with obesity and sleep apnea. It is not prescribed mainly for the "convenience" of the patient or clinician, and it is "not more costly" than any alternative drug that is "at least as likely to produce equivalent therapeutic or diagnostic results."
- 28. The medical necessity of Zepbound is evidenced by the fact that CVS Caremark did indeed find the drug to be medically necessary for Plaintiffs, and continued to do so every month until the terms of its rebate agreement with Novo Nordisk required it to stop filling prescriptions for Zepbound in favor of Wegovy beginning July 1, 2025.
- 29. Plaintiffs' claims for coverage for their Zepbound prescriptions were improperly denied, and the arbitrary and capricious denials issued by CVS Caremark ignored the language of the underlying plans, the reasons why Zepbound is medically necessary for each Plaintiff, and overruled the recommendations of Plaintiffs' skilled and knowledgeable medical providers.
- 30. CVS Caremark breached its fiduciary duties to Plaintiffs and Class members by removing Zepbound from formularies and adding Wegovy pursuant to a rebate agreement with Novo Nordisk, placing its own financial interests ahead of plan participants and violating its duty of loyalty.
- 31. This type of fiduciary self-dealing is also a prohibited transaction under ERISA. CVS Caremark engaged in fiduciary self-dealing by denying Zepbound prescriptions and substituting Wegovy, thereby causing the plans to engage in prohibited transactions from which it profits through rebate agreements with Novo Nordisk.

- 32. The improper denials of coverage caused Plaintiffs and Class members to delay and/or forego medically necessary care, to pay out-of-pocket for health and medical services that were in fact covered under their health plans, and to incur additional costs and economic losses related to the delay in receiving care. Plaintiffs or Class members who stopped taking Zepbound also likely lost some of the gains in managing their health conditions that were realized while taking Zepbound.
- 33. Accordingly, Plaintiffs bring this action on behalf of themselves and all similarly-situated members of employer sponsored health plans whose coverage for Zepbound was improperly denied by CVS Caremark based on an arbitrary and capricious determination that it was not medically necessary.

### **JURISDICTION AND VENUE**

- 34. Subject matter jurisdiction exists pursuant to 28 U.S.C. § 1331.
- 35. This Court has personal jurisdiction over Defendant, who operates and makes benefit determinations in New York and in this District, and processes claims that originate in New York, including Plaintiffs' claims.
- 36. Venue is proper in this District as one of the Plaintiffs resides in this District. Under 29 U.S.C. § 1132(e)(2), venue is proper in an ERISA lawsuit in the District where the plan is administered, where the breach took place, or where a defendant resides or may be found. Here, suit is brought in the Southern District of New York where Plaintiff Larkin's plan is administered and where the breach took place.

### **PARTIES**

37. Plaintiff Dennis Larkin is a resident of Mahopac, NY. Mr. Larkin is a beneficiary of a self-funded health plan sponsored by his employer, Publicis, Inc. Medical ("Publicis"),

which contracts with CVS Caremark to manage pharmacy benefits for its plan participants, including Mr. Larkin.

- 38. Plaintiff Danielle Gosline is a resident of Auburn, NY. Ms. Gosline is a beneficiary of a self-funded health plan sponsored by Ms. Gosline's employer, Hillside Children's Center, which contracts with CVS Caremark to manage pharmacy benefits for its participants, including Ms. Gosline.
- 39. Defendant Caremark RX, L.L.C. (d/b/a CVS Caremark) ("CVS Caremark") is a wholly owned subsidiary of CVS Health and is organized and existing under the laws of Delaware with a principal place of business in Rhode Island, at the same location as CVS Health, its parent company. Defendant is referred to herein as "CVS Caremark," which is the name Defendant does business under and how Defendant refers to itself in public communications and in communications with Plaintiffs and other similarly situated health plan members.

#### **FACTUAL ALLEGATIONS**

### A. Zepbound Pharmacology and Differences from Mounjaro and Wegovy

- 40. Zepbound is a brand name formulary of tirzepatide, which was developed by Eli Lilly and Company and FDA-approved in May 2022 for weight management in adults with obesity or overweight adults with at least one weight-related comorbidity.
- 41. In December 2024, the FDA also approved Zepbound for the treatment of moderate-to-severe obstructive sleep apnea in adults with obesity, making Zepbound the only FDA-approved medication to treat obstructive sleep apnea in adults with obesity.
- 42. Eli Lilly and Company also developed and sells Mounjaro, a tirzepatide that is FDA-approved exclusively for the treatment of type 2 diabetes in adults. Mounjaro is not FDA-

approved for weight management in adults with obesity, for overweight adults with at least one weight-related comorbidity, nor for treating sleep apnea.

- 43. Zepbound, like all tirzepatides, is a dual agonist for two naturally-occurring hormones that help regulate appetite, digestion, and blood glucose (sugar): glucose-dependent insulinotropic polypeptide ("GIP") and glucagon-like peptide-1 ("GLP-1").1
- 44. By targeting both GIP and GLP-1, Zepbound leads to significantly improved glycemic control and reductions in weight.<sup>2</sup>
- 45. Zepbound's dual-agonist method of action differs markedly from semaglutides such as Wegovy, which are single-agonists for GLP-1 alone.
- 46. Studies have found that patients receiving tirzepatides are significantly more likely to achieve weight loss than patients receiving semaglutides.
- 47. In 2024, researchers compared a cohort of 41,222 adults, 32,029 of whom were receiving semaglutide and 9,193 of whom were receiving tirzepatide, and found that "individuals with overweight or obesity treated with tirzepatide (Zepbound) were significantly more likely to achieve clinically meaningful weight loss and larger reductions in body weight compared with those treated with semaglutide" (Wegovy).<sup>3</sup>
- In 2025, a similar study published in the New England Journal of Medicine 48. comparing treatment of adult patients with obesity found that tirzepatide (Zepbound) led to greater

<sup>&</sup>lt;sup>1</sup> Khashayar Farzam & Preeti Patel, "Tirzepatide," StatPearls, https://www.ncbi.nlm.nih. gov/books/NBK585056/ (last updated: February 20, 2024).

<sup>&</sup>lt;sup>3</sup> Patricia J. Rodriguez, et al., Semaglutide vs Tirzepatide for Weight Loss in Adults With Overweight or Obesity, JAMA Internal Medicine, 2024; 184(9): 1056-1064.

reductions in weight, improved weight circumference, and a higher percentage of patients achieving meaningful weight loss relative to patients receiving semaglutide (Wegovy).<sup>4</sup>

- 49. Further, patients often respond differently to semaglutides and tirzepatides, meaning a patient may find one medication easier to tolerate than another. Both semaglutides and tirzepatides share a number of side effects, including gastrointestinal issues, and patients may be able to remedy or reduce side effects by switching to one medication or another.<sup>5</sup>
- 50. According to physicians, individuals who experienced intense side effects with semaglutide sometimes experienced reduced side effects when switching to tirzepatides.<sup>6</sup> The reverse is also true, with patients often needing to try out both medications to determine which is more tolerable.
- 51. Because of their different methods of action, different clinical outcomes, and different side effects for individual patients, Zepbound and Wegovy are not clinically interchangeable. And as studies have proven, Zepbound is more effective than Wegovy in achieving weight loss, and only Zepbound is has been proven effective and approved by the FDA for treating sleep apnea in patients with obesity.
- 52. Furthermore, while Zepbound and Mounjaro may be clinically interchangeable, only Zepbound is FDA approved for treating obesity and for treating moderate to severe sleep apnea. Both plans only provide coverage for FDA approved drugs, which means drugs must be prescribed only for the purpose(s) for which they have received FDA approval.

<sup>&</sup>lt;sup>4</sup> *Id*.

<sup>&</sup>lt;sup>5</sup> Julia Ries Rexler, "Why You Might Tolerate One Weight Loss Drug Better Than Another, According to Experts," *Health* (May 13, 2025), https://www.health.com/tirzepatide-vs-semaglutide-side-effects-11713296.

# B. Plaintiff Dennis Larkin's Experiences with Zepbound

- 53. Mr. Larkin receives medical treatment for his obesity, a condition which has severely affected his physical health and wellbeing.
- 54. Prior to beginning his prescribed treatment with Zepbound, Mr. Larkin had a BMI in excess of 42, which severely compromised his quality of life, including relentless fatigue, daytime drowsiness, severe sleep disturbances, back and joint pain, and emotional distress, including anxiety, depression, extremely low self-esteem, and overwhelming isolation.
- 55. For years, Mr. Larkin tried to lose weight via other weight loss medications, rigorous diet and exercise programs, and healthy eating regimens. None worked. Instead, Mr. Larkin found it impossible to maintain any weight loss achieved and ultimately would gain more weight than he had initially lost.
- 56. Along with obesity, Mr. Larkin has gastroesophageal reflux disease ("GERD"), a weight-related comorbidity of obesity, which Mr. Larkin manages daily with Pantoprazole.
- 57. In December 2023, Mr. Larkin's physician prescribed Zepbound to treat his obesity.
- 58. Since being prescribed Zepbound in December 2023, Mr. Larkin has injected Zepbound once per week to treat his obesity.
- 59. On April 22, 2024, four months after beginning treatment with Zepbound, Mr. Larkin was also diagnosed with severe obstructive sleep apnea.
- 60. On December 20, 2024, Zepbound became FDA-approved to treat moderate-to-severe obstructive sleep apnea. Consequently, Mr. Larkin is now prescribed Zepbound as both a weight management drug and to treat his severe obstructive sleep apnea.

- 61. We govy is not FDA-approved to treat obstructive sleep apnea. Mounjaro is not FDA-approved to treat obesity or obstructive sleep apnea.
- 62. In the nineteen months that he has been using Zepbound, Mr. Larkin has lost 104.2 pounds, reducing his BMI to well within the normal range.
- 63. Mr. Larkin's energy levels and physical health have improved significantly since beginning Zepbound.
- 64. Currently, Mr. Larkin exercises for several hours per week, including visits to the gym, hikes, walks, and engages in resistance training with a personal trainer.
- 65. Mr. Larkin's comorbidities make it difficult and ill-advised to switch to another weight loss drug. Other weight loss drugs, including Wegovy, may lead to intolerable side effects and/or exacerbate his existing conditions, or just not perform as well as Zepbound performs for his conditions. There is no compelling medical reason for Mr. Larkin to stop taking the drug that is working so well and arbitrarily switch to taking another drug.
- 66. Further, Zepbound is the *only* medication that is FDA-approved to treat Mr. Larkin's obstructive sleep apnea. Being denied coverage for Zepbound means Mr. Larkin would lose access to the *only* FDA-approved medication that exists to treat his condition.

### C. Plaintiff Danielle Gosline's Experiences with Zepbound

- 67. Ms. Gosline sought medical treatment for her obesity, a condition that has deeply affected her physical, emotional, and mental health.
- 68. Prior to beginning her treatment with Zepbound, Ms. Gosline struggled with daily tasks due to her obesity, including walking up a flight of stairs, carrying groceries, or even tying her shoes. Ms. Gosline also experienced constant joint pain, particularly in her knees and lower

back, and dealt with sleep issues caused by her weight. Emotionally, Ms. Gosline experienced weight-related anxiety, low self-esteem, and episodes of depression.

- 69. Ms. Gosline was prescribed various other medications to regulate her weight prior to beginning her prescribed treatment with Zepbound.
- 70. These other medications imposed intolerable side effects for Ms. Gosline. For example, Metformin caused Ms. Gosline to experience intense nausea, dehydration, dizziness, and severe stomach upset. The side effects were so intolerable that Ms. Gosline could not function at home or work, requiring discontinuation.
- 71. Ms. Gosline also tried taking Orlistat, another commonly prescribed anti-obesity medication, but this resulted in negative side effects including severe gastrointestinal symptoms, intense nausea, and dizziness, that forced her to discontinue that medication as well.
- 72. In January 2024, Ms. Gosline's physician prescribed Zepbound to treat her obesity, beginning with a 2.5 mg dose, titrating to 15 mg, before ultimately finding a maintenance dose of 10 mg per week.
- 73. Ms. Gosline has been taking Zepbound injections once a week since she was prescribed the medication in January 2024.
- 74. Over the approximately eighteen months that Ms. Gosline took Zepbound between January 2024 and July 2025, Ms. Gosline lost more than seventy (70) pounds, reducing her body mass index (BMI) from well above 33 (a patient is considered obese if their BMI exceeds 30), to within a healthy, normal range.
- 75. Crucially, Ms. Gosline not only lost weight, but she was also able to maintain her weight loss over time, a notoriously rare outcome in treatment for obesity.

- 76. Ms. Gosline's joint pain and physical discomfort have meaningfully improved, as have her laboratory markers and weight-related comorbidities, such as hyperlipidemia and GERD.
- 77. Ms. Gosline's emotional wellbeing also improved, including that she experienced less anxiety, decreased feelings of shame, and diminished depression.
- 78. Since starting Zepbound, Ms. Gosline also committed to and maintained lifestyle interventions to supplement her treatment. Ms. Gosline uses Weight Watchers meal planning and calorie tracking tools, and adheres to a calorie-restricted diet, and exercises more than five hours per week, with a mixture of walking, running, HIIT, yoga, and strength training.
- 79. Ms. Gosline's gastrointestinal issues and struggles with other weight loss medications as documented above, make it incredibly challenging for her to stop her use of Zepbound, which has significantly benefitted her, and arbitrarily switch to another weight loss medication, including Wegovy.
- 80. Ms. Gosline does not want to stop taking her prescribed medication that is working and has been medically necessary and approved by her physician and is very fearful of experiencing intolerable side effects and exacerbation of her existing gastrointestinal issues.

### D. CVS Caremark Approved Plaintiffs' Requests for Coverage of Zepbound

- 81. Plaintiffs are both participants in their employers' health benefit plans.
- 82. Plaintiffs' employers' both contract with CVS Caremark to manage and administer prescription drug benefits for their respective health plans.
- 83. CVS Caremark requires prior authorization for certain prescriptions, including Zepbound.

- 84. In compliance with Defendant's requirements, Plaintiffs' physicians submitted requests for prior authorization for Zepbound.
- 85. Defendant approved Plaintiffs' physicians' requests for prior authorization, finding Zepbound to be medically necessary for both Plaintiffs and filled their prescriptions month after month for Zepbound, beginning in December 2023 and for approximately nineteen (19) months for Mr. Larkin, and beginning in January 2025 and for approximately seven (7) months for Ms. Gosline, without issue.

# E. <u>CVS Caremark Enters Into a Rebate Agreement with Novo Nordisk to Favor Wegovy</u>

- 86. Like other PBMs, Defendant frequently enters into rebate agreements with drug manufacturers under which Defendant agrees to favor a certain drug manufacturers' brand name medication to the exclusion of other biosimilar medications. In exchange, Defendant is paid rebates from the sale of the drug subject to the agreement.
- While theoretically, rebate agreements in certain circumstances may lead to lower prices for consumers, the reality is that PBMs frequently prioritize negotiating rebate agreements to favor drugs with higher list prices, which result in higher rebates for the PBM.<sup>7</sup>
- 88. This is true here; the U.S. list price for a one-month supply of Wegovy is approximately \$1,350, while the list price for a one-month supply of Zepbound is approximately \$1,086.37 per month.<sup>8</sup>

<sup>&</sup>lt;sup>7</sup> See "FTC Sues Prescription Drug Middlemen for Artificially Inflating Insulin Drug Prices," FTC (September 20, 2024), https://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-sues-prescription-drug-middlemen-artificially-inflating-insulin-drug-prices.

<sup>&</sup>lt;sup>8</sup> See https://www.goodrx.com/wegovy/wegovy-for-weight-loss-cost-coverage?srsltid=AfmBOopEz3HSBsjEsiwkm9rze9oV2XN95cKftsTMUy04lZR8YpQ37w5i (Wegovy price per month) and https://pricinginfo.lilly.com/zepbound (Zepbound price per month).

- 89. Defendant recently entered into one such rebate agreement with the brand manufacturer Novo Nordisk, to favor coverage of its drug, Wegovy, to the exclusion of Zepbound.
- 90. On May 1, 2025, Defendant announced that it would take a formulary action to prefer Wegovy in exchange for which Novo Nordisk would pay an undisclosed percentage of the price of Wegovy to Defendant in the form of rebates.<sup>9</sup>
- 91. Evidence will show that CVS Caremark profits from entering into this type of rebate agreement with drug manufacturers. For the fully insured plans under which CVS Caremark administers pharmacy benefits, particularly those issued by one of its health insurance carrier subsidiaries, it likely keeps 100% of the rebates provided by the manufacturer pursuant to contracts with drug manufacturers. For self-funded plans, even if some portion of the rebate is passed on to the employer sponsoring the self-funded plan, CVS Caremark financially benefits from each transaction as well, as it retains some portion of the rebate.
- 92. As part of Defendant's agreement with Novo Nordisk, Defendant agreed to remove Zepbound from its formulary list effective July 1, 2025, <sup>10</sup> meaning Zepbound is no longer covered for participants in employer-sponsored health plans that use CVS Caremark as their PBM.
- 93. Evidence will show that removing Zepbound from its formulary list effected around 200,000 individuals who had prescriptions for Zepbound and used CVS Caremark for their pharmacy benefits.<sup>11</sup>

<sup>&</sup>lt;sup>9</sup> Annika Kim Constantino, "CVS to boost access to Novo Nordisk's weight loss treatment Wegovy for patients on its drug plans," CNBC (May 1, 2025), https://www.cnbc.com/2025/05/01/cvs-wegovy-caremark-patients.html.

<sup>&</sup>lt;sup>10</sup> "Enabling wider access to effective weight management treatment," CVS Caremark, https://business.caremark.com/employer-solutions/cost-management/formulary/glp-1s.html (last accessed August 19, 2025).

<sup>&</sup>lt;sup>11</sup> Madison Muller, "Zepbound Patients Fear Losing Coverage After CVS Deal for Wegovy," Bloomberg (May 9, 2025), https://www.bloomberg.com/news/articles/2025-05-09/zepbound-patients-fear-switch-to-wegovy-after-cvs-deal?embedded-checkout=true; Rebecca Robbins and Reed Abelson, "Why Patients Are Being Forced to Switch to a 2nd-Choice Obesity Drug," New York Times (May 11, 2025),

https://www.nytimes.com/2025/05/11/health/zepbound-wegovy-weight-loss-drugs.html.

# F. <u>CVS Caremark Has a History of Making Formulary Changes with Serious Consequences for Patients</u>

- 94. Defendant has a long history of making non-medical formulary changes without regard for patient wellbeing.
- 95. For example, in 2021, Defendant sent a letter to 150,000 patients who were prescribed Eliquis (apixaban), a direct oral anticoagulant medicant ("DOAC"), for the treatment of venous thromboembolism ("VTE"), announcing that Defendant would be removing all DOACs from their 2022 formulary list, including apixaban, in favor of Xarelto (rivaroxaban).<sup>12</sup>
- 96. Defendant decided to favor rivaroxaban because it was more profitable for Defendant to favor rivaroxaban.<sup>13</sup>
  - 97. Eliquis and Xarelto, like Zepbound and Wegovy, are not interchangeable.
- 98. Rivaroxaban is associated with a significantly greater risk of major ischemic or hemorrhagic events than apixaban.<sup>14</sup> Further, a national patient survey conducted by the American Society for Preventative Cardiology found that patients who were switched from one blood thinner to another experienced high rates of side effects and resurfacing of symptoms, required additional doctor visits and lab work, and suffered serious emotional side effects from being forced to

<sup>&</sup>lt;sup>12</sup> "ACC, ASH Meet with CVS Caremark on New DOAC Formulary Change," American College of Cardiology (January 13, 2022), https://www.acc.org/Latest-in-Cardiology/Articles/2022/01/13/14/15/ACC-ASH-Meet-With-CVS-Caremark-on-New-DOAC-Formulary-Change.

<sup>&</sup>lt;sup>13</sup> Dr. Seth J. Baum, "Non-medical switching an unmitigated threat to patient care," American Journal Prev. Cardiol. 2023, https://pmc.ncbi.nlm.nih.gov/articles/PMC9947224/.

<sup>&</sup>lt;sup>14</sup> Wayne A. Ray, et al., "Association of Rivaroxaban vs Apixaban With Major Ischemic or Hemorrhagic Events in Patients with Atrial Fibrillation," JAMA, 2021; 326(23): 2395-2404.

switch.<sup>15</sup> Many patients who had been forced to switch simply stopped taking blood thinners, leaving them at a major risk of heart attack and stroke.<sup>16</sup>

99. Due to the serious consequences for patients and objections from patient groups and professional organizations, Defendant ultimately decided to reintroduce apixaban to its formulary list in June 2022.<sup>17</sup>

### G. CVS Caremark Begins Denying Coverage for Zepbound Claims as of July 1, 2025

### 1. CVS Caremark's Denial of Mr. Larkin's Claim for Coverage of Zepbound

- 100. On July 7, 2025, Mr. Larkin received a letter from Defendant informing him that his claim for prescription coverage for Zepbound, after being approved for the previous 19 months, was now suddenly denied.
- 101. Under the section of this letter titled "Why your request was denied," Defendant stated that Mr. Larkin's plan "does not cover this drug" and that "For your plan, you may need to try 1 other covered drug."
- 102. Mr. Larkin submitted a first-level member appeal of the denial on June 30, 2025, which was denied on July 14, 2025. Defendant gave the following as the basis for denying Mr. Larkin's appeal:

After careful consideration, review of nationally accepted medical guidelines and compendia (drug information compiled by clinical experts), your appeal was denied. A qualified health care professional conducted the review and determined that the medication is not medically necessary or is experimental or investigational... Your appeal for Zepbound has been determined as not medically

18

<sup>15 &</sup>quot;Total Stress and Fear: The Impact of Non-Medical Switching on Patients Taking a Blood Thinner," American Society for Preventative Cardiology (August 2022), https://assets.noviams.com/novi-file-uploads/aspc/pdfs\_and\_documents/Advocacy\_Statements/ ASPC-NMSBloodThinner-SurveyReport-August2022-b33dab04.pdf.

 <sup>&</sup>lt;sup>16</sup> Id.
 <sup>17</sup> "CVS Caremark to Reverse Change to DOAC Formulary Classification," American College of Cardiology (June 22, 2022), https://www.acc.org/Latest-in-Cardiology/Articles/2022/06/22/20/ 10/CVS-Caremark-to-Reverse-Change-to-DOAC-Formulary-Classification

- necessary. Per physician review, current plan approved criteria does not allow coverage of Zepbound. The primary covered drug for your plan is Wegovy.
- 103. In the denial, CVS Caremark did not cite to the medical necessity language in Mr. Larkin's health plan, nor did it explain how Zepbound could be medically necessary under the plan as of June 30, 2025 and suddenly not medically necessary as of July 1, 2025.
- 104. As required by his plan, Ms. Larkin submitted a second-level member appeal of Defendant's decision to deny coverage on July 21, 2025, which was denied on July 23, 2025. Defendant reiterated its conclusion that Zepbound is not medically necessary.
- 105. The appeal was then escalated for an independent review on July 23, 2025, and the external review also upheld the denial on July 25, 2025.
- 106. Mr. Larkin has exhausted his administrative remedies, such that he now has the right to pursue his claim in federal court.

### 2. CVS Caremark's Denial of Ms. Gosline's Claim for Coverage of Zepbound

- 107. On July 1, 2025, Ms. Gosline received a letter from Defendant informing her that her claim for prescription coverage for Zepbound, after being approved for the previous 18 months, was suddenly denied.
- 108. Under a section of the letter titled "Why your request was denied," Defendant stated that Ms. Gosline's plan "does not cover this drug" and that "[t]he primary covered drug for your plan is Wegovy." The letter explained that "[i]f you have tried [Wegovy], another option for you is a tirzepatide product that has the same active ingredient at the same strength and dosage as the requested drug," but that "[y]our doctor may need to get approval from your plan for covered drugs."

109. Ms. Gosline appealed CVS Caremark's denial on July 7, 2025 and on July 8, 2025, Defendant denied Ms. Gosline's appeal. Defendant provided a virtually identical basis for denying Ms. Gosline's appeal as was provided to Mr. Larkin:

After careful consideration, review of nationally accepted medical guidelines and compendia (drug information compiled by clinical experts), your appeal was denied. A qualified health care professional conducted the review and determined that the medication is not medically necessary or is experimental or investigational... Your appeal for Zepbound for obesity has been determined as not medically necessary. Per physician review current plan approved criteria and current medical literature do not support the use of Zepbound over the available formulary alternatives. The primary covered drug for your plan is Wegovy.

- 110. In this denial letter, CVS Caremark did not cite to the medical necessity language in Ms. Gosline's health plan, nor did it explain how Zepbound could be medically necessary under the plan as of June 30, 2025 and suddenly not medically necessary as of July 1, 2025.
- While Ms. Gosline's plan mandated two levels of internal appeal for prescription drug benefit decisions, CVS Caremark indicated in writing that Ms. Gosline's appeal satisfied both levels of appeal due to her appeal being deemed "urgent." Thus, Ms. Gosline has exhausted her administrative remedies, such that she now has the right to pursue her claim in federal court.

# H. <u>CVS Caremark's Denial of Coverage for Zepbound Violated The Terms of the Underlying ERISA Plans</u>

112. Defendant's decision denying coverage for Zepbound for Plaintiffs violates the terms of the underlying ERISA plans.

### 1. Zepbound is Covered under the Terms of The Larkin Plan

- 113. Mr. Larkin's health benefits are set forth in the Summary Plan Description ("SPD") issued by his employer, Publicis (the "Larkin Plan").
- 114. On page 112 of the Larkin Plan is a section titled "When Are Benefits Available for Covered Health Care Services," which states: "The health care service, *including supplies of*

**Pharmaceutical Products**, is only a Covered Health Care Service if it is Medically Necessary. (See definitions of Medically Necessary and Covered Health Care Service in *Section 9: Defined Terms*.)" (emphasis added).

- "Medically Necessary" is then defined on p. 183 of the SPD as follows:
  - **Medically Necessary** health care services that are all of the following as determined by the Claims Administrator or its designee, within the Claims Administrator's sole discretion:
  - In accordance with Generally Accepted Standards of Medical Practice.
  - Clinically appropriate, in terms of type, frequency, extent, service site and duration, and considered effective for your Sickness, Injury, Mental Illness, substance-related and addictive disorders, disease or its symptoms.
  - Not mainly for your convenience or that of your doctor or other health care provider.
  - Not more costly than an alternative drug, service(s), service site or supply that is at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of your Sickness, Injury, disease or symptoms.
- 116. The same page of the SPD defines Generally Accepted Standards of Medical Practice as "standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, relying primarily on controlled clinical trials, or, if not available, observational studies from more than one institution that suggest a causal relationship between the service or treatment and health outcomes. . . ."
- 117. Zepbound satisfies each element of a medically necessary prescription drug. As an FDA-approved drug, with credible scientific evidence published in recognized peer-reviewed medical literature, it falls within "Generally Accepted Standards of Medical Practice"; it has been proven to be "clinically appropriate" to treat patients diagnosed with obesity and sleep apnea (and has, in fact, been clinically appropriate treating Mr. Larkin's obesity and sleep apnea over the course of the preceding 19 months); it is not prescribed mainly for the "convenience" of the patient

or clinician; and it is "not more costly" than any alternative drug that is "at least as likely to produce equivalent therapeutic or diagnostic results."

- The last bullet point is particularly significant. Under the Larkin Plan, CVS has the discretion to approve a less costly drug that is "equivalent" in providing therapeutic or diagnostic results; that is a patently inapplicable basis for CVS to require Wegovy over Zepbound since they are *not* equivalent. In particular, Zepbound has been proven to be *more effective* than Wegovy in treating obesity and *only* Zepbound has been proven to be successful and FDA-approved for treating sleep apnea. Additionally, Wegovy is *more costly* than Zepbound.
- 119. Thus, by denying coverage for Zepbound in lieu of Wegovy, CVS has blatantly violated the medical necessity provisions of the Larkin Plan.
- alternative to Zepbound, yet Mounjaro is *not* a covered drug under the plan. The Larkin Plan SPD contains an exclusion at p. 180 for "Experimental or Investigational Services" which includes medications that are "[n]ot approved by the *U.S. Food and Drug Administration (FDA)* to be lawfully marketed for the proposed use..." Mounjaro has *not* been approved by the FDA for treating obesity or sleep apnea. As a result, it is excluded under the Experimental or Investigational Services exclusion.
- 121. We govy is also excluded under the same provision for sleep apnea, as it is not FDA-approved to treat that condition.
- 122. Denying coverage to Mr. Larkin for his continued medically necessary use of Zepbound while suggesting replacement drugs that are excluded as experimental/investigational is contrary to the plan terms, and is an inherently arbitrary and capricious denial of benefits.

# 2. Zepbound is Covered Under the Terms of the Gosline Plan

- 123. Ms. Gosline's health benefits are set forth in the SPD issued by her employer, Hillside Children's Center (the "Gosline Plan").
- 124. The Gosline plan pays for covered services (including prescription drugs) which are "Medically Necessary", defined on p. 79 as follows:
  - (1) They are clinically appropriate in terms of type, frequency, extent, site, and duration, and considered effective for Your illness, injury, or disease;
  - (2) They are required for the direct care and treatment or management of that condition;
  - (3) Your condition would be adversely affected if the services were not provided;
  - (4) They are provided in accordance with generally accepted standards of medical practice;
  - (5) They are not primarily for the convenience of you, your family, or your provider;
  - (6) They are not more costly than an alternative service or sequence of services, that is at least as likely to produce equivalent therapeutic or diagnostic results;
  - (7) When setting or place of service is part of the review, services that can be safely provided to You in a lower cost setting will not be Medically Necessary if they are performed in a higher cost setting. For example, the Plan will not provide coverage for an inpatient admission for surgery if the surgery could have been performed on an outpatient basis or an infusion or injection of a specialty drug provided in the outpatient department of a Hospital if the drug could be provided in a Physician's office or the home setting.
- 125. As with the Larkin Plan, Zepbound falls squarely within this definition. It is "clinically appropriate" for Ms. Gosline's diagnosed condition, as shown by her positive experience to taking Zepbound for her condition; it is required for the "direct care and treatment" of her obesity; her ability to treat her condition will be "adversely affected" without Zepbound (as her experience has demonstrated); it is being provided "in accordance with generally accepted standards of medical practice," given that it is FDA-approved and proven to be effective for her condition based on credible scientific evidence published in peer-reviewed medical literature

generally recognized by the relevant medical community, relying primarily on controlled clinical trials; it is not prescribed primarily for the her "convenience" or that of her clinicians; and, importantly, is "not more costly than an alternative" drug that is "at least as likely to produce equivalent therapeutic or diagnostic results," given that Zepbound has been proven to be more effective in treating obesity than Wegovy and has a lower monthly list price.

126. As in the Larkin Plan, the Gosline Plan similarly includes an exclusion for "experimental or investigational" drugs at pp. 138-139 of the Plan, defined as follows:

"Experimental or investigational" means that the Claims Administrator determines the Service is:

- A. not of proven benefit for a particular diagnosis or for treatment of a particular condition;
- B. not generally recognized by the medical community, as reflected in published, peer-reviewed, medical literature, as effective or appropriate for a particular diagnosis or for treatment of a particular condition; or
- C. not of proven safety for a person with a particular diagnosis or a particular condition, e.g., is currently being evaluated in research studies to ascertain the safety and effectiveness of the treatment on the well-being of a person with the particular diagnosis or in the particular condition.
- 127. Moreover, the Gosline Plan then provides that, "[i]n determining whether a Service is experimental or investigational, the Claims Administrator may require that . . . [a] . . . drug . . . must have received final approval of the United States Food and Drug Administration (FDA) to market for the particular diagnosis or for your particular condition." *Id*.
- 128. Just like under the Larkin Plan, Mounjaro is therefore excluded as experimental and investigational because it has not been FDA-approved to treat obesity.
- 129. Denying coverage to Ms. Gosline for continued medically necessary use of Zepbound while suggesting replacement drugs that are excluded as experimental/investigational is contrary to the Gosline Plan terms and is an inherently arbitrary and capricious denial of benefits.

# I. <u>CVS Caremark's Denials of Plaintiffs' Claims Based on Medical Necessity and Upholding Those Decisions on Appeal Were Improper, Arbitrary and Capricious Denial of Benefits</u>

- 130. In denying Plaintiffs' requests for coverage due to medical necessity, Defendant failed to properly account for the information submitted by Plaintiffs in connection with their appeals.
- Defendant instead issued arbitrary, boilerplate, virtually identical letters to both Plaintiffs with generic statements that a review of the medical literature and medical guidelines indicated Zepbound is not medically necessary for their conditions, and that Plaintiffs would instead be required to take Wegovy or, in the event treatment with Wegovy was intolerable, Mounjaro. Defendant further informed Plaintiffs that their physicians would need to seek prior authorization for approval of Mounjaro if Wegovy was intolerable, and Plaintiffs' plans might not cover Mounjaro, a conclusion that was particularly likely since Mounjaro is not FDA-approved for treating obesity or sleep apnea.
- Zepbound is not medically necessary for Plaintiffs, nor does Defendant purport to rely on any such basis. Plaintiffs were clinically obese when they began treatment with Zepbound with weight-related comorbidities, and as a result of treatment with Zepbound, have been able to lose weight and maintain weight loss over a period of time. Moreover, Mr. Larkin had been diagnosed with severe obstructive sleep apnea, a condition that was also treated effectively by Zepbound, and can *only* be treated by Zepbound, as the only FDA approved drug for obstructive sleep apnea.
- 133. Indeed, Defendant's approval of coverage of Wegovy for Plaintiffs—a drug that is FDA-approved exclusively for weight management—demonstrates CVS Caremark's understanding that weight management drugs are medically necessary for Plaintiffs.

- 134. Defendant's prior approval of Zepbound as medically necessary for Plaintiffs likewise demonstrates that Defendant determined that Zepbound was medically necessary for Plaintiffs.
- 135. Further, in arbitrarily and suddenly deciding that Zepbound is not medically necessary after reaching a rebate agreement with the manufacturer of Wegovy, Defendant ignores the well-studied fact that Wegovy and Zepbound are not clinically interchangeable.
- 136. Zepbound (a tirzepatide) is well-documented to produce greater reductions in weight, improved weight circumference, and a higher percentage of patients achieving meaningful weight loss relative to Wegovy (a semaglutide).
- 137. Defendant did not properly review the relevant medical literature in determining that Zepbound and Wegovy are clinically interchangeable.
- 138. In denying Plaintiffs' appeals, Defendant relied exclusively on surveys from 2022. However, Zepbound was only FDA-approved in November 2023, meaning any large-scale population studies comparing semaglutide and tirzepatide post-date the studies that were relied on by Defendant to justify its decision.
- 139. Those large-scale studies have universally found that tirzepatides produce greater reductions in weight than semaglutides. *See* ¶¶ 42, 43 and n. 3, 4 *supra*.
- 140. Defendant also failed to consider that Zepbound and Wegovy are not interchangeable, as they often come with differing side effects for many patients.
- 141. There is no medical or scientific basis for Defendant's determination that Zepbound is not medically necessary for Plaintiffs.

- 142. Instead, Defendant's determination that Zepbound is not medically necessary for Plaintiffs is motivated solely by its rebate agreement with Novo Nordisk to prefer Wegovy, and not any review of Plaintiffs' medical history, scientific studies, or medical consensus.
- 143. Defendant's decision to deny coverage for Zepbound was plainly made in disregard of detailed information provided in the preauthorization request letters submitted by Plaintiffs' medical providers and was contrary to the information provided to Defendant when requesting pre-authorization.
- 144. Non-medical switching (forcing a patient to switch medications for non-medical reasons) can cause many types of injury. In addition to causing a patient to forego a treatment that works for them or incur out of pocket costs to continue taking a drug that works for them but is no longer covered, it can also expose patients to less effective therapies, leading to disease progression, worsening symptoms, and potentially serious side effects or allergic reactions. Stopping a medication that is working can lead to the reversal of progress that has been made while using the drug, as can switching to a less effective therapy; either way, the patient is worse for the wear due to the non-medical switch. Non-medical switching has been associated with unintended negative consequences on patients' clinical outcomes, healthcare utilization and medication adherence/persistence.<sup>18</sup>

# J. <u>CVS Caremark Was Acting as a Fiduciary Within the Meaning of ERISA When it</u> <u>Denied Coverage for Zepbound on the Basis of Medical Necessity</u>

145. Mr. Larkin's plan states that "[t]he administrator for the pharmacy benefits is [CVS] Caremark." The plan explicitly delegates decision-making authority regarding payment of

https://doi.org/10.1371/journal.pone.0225867https://pmc.ncbi.nlm.nih.gov/articles/PMC6953849/#abstract1

<sup>&</sup>lt;sup>18</sup> Salam, T., Duhig, A., Patel, A. A., Cameron, A., Voelker, J., Bookhart, B., & Coleman, C. I. (2020). Physicians' perspectives regarding non-medical switching of prescription medications: Results of an internet e-survey. *PloS one*, *15*(1), e0225867.

claims to CVS Caremark, stating that "Your physician must send a letter to the Claim Administrator's prescription drug administrator explaining the reason for the prescription. The prescription drug administrator will review the letter and determine whether the reason for the prescription meets the criteria for medically necessary care."

- 146. As a Claims Administrator of the Larkin Plan, Defendant is acting as an ERISA fiduciary when making determinations of claims and appeals under the Larkin Plan.
- 147. Similarly, Ms. Gosline's plan expressly identifies the "Prescription Drug Benefit Manager" as the Plans' "Claims Administrator." The Gosline Plan states that "the Plan Sponsor may delegate fiduciary and other responsibilities to any individual or entity." The Gosline Plan further states that "[t]he Plan Sponsor delegates its responsibility with respect to the payment of claims to the Claims Administrator. The Claims Administrator is the *named fiduciary* with respect to the determination of claims and appeals under the Plan." (Emphasis added).
- 148. As a Claims Administrator of the Gosline Plan, Defendant is acting as a named ERISA fiduciary when making determinations of claims and appeals under the Gosline Plan.
- 149. Switching a patient's medication for financial gain, like CVS Caremark did to Plaintiffs and Class members, is self-dealing that places its own profits above the plan members well-being; this is not only a breach of the duty of loyalty that CVS Caremark owes the members of the health plans to which it acts as a fiduciary for pharmacy claims administration, but is a prohibited transaction under ERISA.

# **CLASS ACTION ALLEGATIONS**

150. Defendant's policies followed with respect to the claims filed by Plaintiffs are the same as those that have been applied by Defendant to thousands of other similarly situated individuals seeking coverage for Zepbound. Consequently, pursuant to Federal Rule of Civil

Procedure 23, Plaintiffs bring each of their causes of action set forth below individually and on behalf of the following class of similarly-situated individuals:

Any member of an ERISA-governed employer-sponsored health benefit plan for whom Defendant acts as a pharmacy benefit manager whose request for coverage of Zepbound (tirzepatide) was denied by Defendant as not covered under the applicable Plan, and which was upheld on appeal due to lack of medical necessity, on or after July 1, 2025 (the "Class").

- 151. The Class members can be easily and objectively ascertained through the use of information contained in Defendant's files because Defendant adjudicated Class members' claims.
- 152. The Class is sufficiently numerous, numbering in the thousands, such that joinder is impracticable. Information concerning the identity of the Class members is readily available and is in the possession and control of Defendant.
- 153. Certification of the Class is desirable and proper as there are questions of law and fact in this case that are common to all members of the Class. Such common questions of law and fact include, but are not limited to:
  - a) whether Zepbound is medically necessary for treatment of certain adults with obesity;
  - b) whether Zepbound is medically necessary for ongoing weight management for certain adults;
  - c) whether Zepbound is medically necessary for treatment of moderate-to-severe obstructive sleep apnea in adults;
  - d) Whether Defendant's rebate agreement with Novo Nordisk played a role in Defendant's formulary change;
  - e) whether Defendant breached its fiduciary duties when it denied coverage on the basis that Zepbound is not medically necessary;
  - f) whether Defendant's denial of coverage for Zepbound violated the terms of the Class member's ERISA plans; and
  - g) what remedies are available to the Class.

- 154. Plaintiffs' claims are typical of the claims of the members of the Class that Plaintiffs seek to represent.
- 155. Plaintiffs will fairly and adequately protect the interests of the Class. There are no conflicts between the interests of Plaintiffs and those of the Class members, and Plaintiffs are cognizant of their duties and responsibilities to the Class. Plaintiffs have selected attorneys that are qualified, experienced, and have the resources to conduct the proposed class action litigation.
- 156. It is desirable to concentrate the litigation of these claims in this forum. The determination of the claims of all Class members in a single forum, and in a single proceeding is a fair and efficient means of resolving the issues in this litigation.
- 157. Class certification is proper pursuant to Rule 23(b)(1) of the Federal Rules of Civil Procedure because prosecuting separate actions by individual Class members would create a risk of inconsistent or varying adjudications with respect to individual Class members that would establish incompatible standards of conduct for Defendant.
- 158. Class certification is proper pursuant to Rule 23(b)(2) of the Federal Rules of Civil Procedure because Defendant have acted or refused to act on grounds that apply generally to the Class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the Class as a whole.
- 159. Class certification is proper pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure because the common questions of law or fact predominate over any questions affecting only individual Class members, and a class action is superior to other available methods for fairly and efficiently adjudicating the claims alleged herein.
- 160. The difficulties likely to be encountered in the management of a class action in this litigation are reasonably manageable, especially when weighed against the virtual

impossibility of affording adequate relief to the members of the Class through thousands of separate actions.

# CAUSES OF ACTION COUNT I

# Breach of Fiduciary Duty (On behalf of Plaintiffs and the Class Against Defendant)

- 161. Plaintiffs incorporate by reference all preceding paragraphs as though such paragraphs were fully stated herein. Plaintiffs bring this count individually and on behalf of the Class pursuant to 29 U.S.C. §§ 1132(a)(1)(B) and (a)(3).
- As explained above, Defendant is responsible for interpreting the terms of the health plans that they administer with respect to coverage for prescription drugs and making final and binding decisions about whether to approve coverage for prescription drugs requested by plan members. As such, Defendant exercises discretionary authority with respect to the administration of the plans and the payment of plan benefits as applicable to prescription drugs. Defendant is therefore an ERISA fiduciary as defined by 29 U.S.C. §§ 1002(21)(A) and 1104(a).
- 163. As an ERISA fiduciary, and pursuant to 29 U.S.C. § 1104(a), Defendant has a duty of loyalty to plan participants and beneficiaries that requires them to discharge their duties "solely in the interests of the participants and beneficiaries" of the plans they administer and for the "exclusive purpose" of providing benefits to participants and beneficiaries and paying reasonable expenses of administering the plans.
- 164. Defendant also owes plan participants and beneficiaries a duty of care, which requires them to act with reasonable "care, skill, prudence, and diligence" and in accordance with the terms of the plans, so long as such terms are consistent with ERISA.
- 165. As set forth herein, Defendant violated these duties by determining that Zepbound is not covered under the applicable ERISA Plans and otherwise was not medically necessary.

Despite the fact that Plaintiffs' and Class members' health plans require medical necessity determinations concerning prescription drugs to be made consistent with generally accepted standards of medical practice, and the fact that generally accepted standards of medical practice are widely available and well-known to Defendant, Defendant failed to review all of the medical and scientific literature and/or failed to make individualized determinations about Plaintiffs' and the Class members' medical needs.

- 166. In doing so, Defendant did not act "solely in the interests of the participants and beneficiaries" for the "exclusive purpose" of "providing benefits." It did not use the "care, skill, prudence, and diligence" that ERISA demands of fiduciaries. It did not act in accordance with the terms of the Plaintiffs' or the Class members' plans.
- 167. Instead, Defendant elevated its own interests above the interests of the plan participants and beneficiaries. By uniformly denying Zepbound as not medically necessary, including based upon a rebate agreement that Defendant reached with the manufacturer of Wegovy, Defendant artificially decreased the scope of coverage available under the plans, thereby transferring risk from themselves and their employer customers to the participants and beneficiaries of the plans and limiting the availability of prescription medication to Plaintiffs and the Class. In so doing, Defendant harmed Plaintiffs and the Class.
  - 168. Plaintiff and the Class seek the relief identified below to remedy this claim.

#### **COUNT II**

# Prohibited Transaction in Violation of ERISA Section 406 (On behalf of Plaintiffs and the Class against Defendant)

169. Plaintiffs incorporate by reference all preceding paragraphs as though such paragraphs were fully stated herein. Plaintiffs bring this count individually and on behalf of the Class pursuant to 29 U.S.C. § 1108.

- 170. CVS Caremark is a "party in interest" and fiduciary within the meaning of ERISA §§ 3(14) and 3(21), 29 U.S.C. §§ 1002(14), 1002(21), because it administers pharmacy benefit claims and exercises discretionary authority and control over plan assets and benefits.
- 171. ERISA § 406, 29 U.S.C. § 1106, prohibits fiduciaries and parties in interest from causing a plan to engage in transactions that constitute self-dealing, conflicts of interest, or that otherwise benefit the fiduciary or party in interest at the expense of participants.
- 172. By removing Zepbound from formularies and substituting Wegovy, CVS Caremark caused the plans for which it administers pharmacy claims to engage in transactions from which CVS Caremark directly benefited through rebate agreements with Novo Nordisk.
- 173. These actions constitute fiduciary self-dealing and prohibited transactions under ERISA § 406(b), 29 U.S.C. § 1106(b), because CVS Caremark acted to advance its own financial interests rather than the exclusive interests of plan participants and beneficiaries.
- 174. As a result, Plaintiffs and the Class have been harmed through the denial of medically necessary prescriptions and the imposition of higher costs and barriers to treatment, while CVS Caremark improperly profited at their expense.
- 175. Plaintiffs and the Class are entitled to equitable relief, including restitution, surcharge, and other remedies under ERISA §§ 409 and 502(a), 29 U.S.C. §§ 1109, 1132(a).

# COUNT III Violation of Plan Terms (On behalf of Plaintiffs and the Class Against Defendant)

176. Plaintiffs incorporate by reference all preceding paragraphs as though such paragraphs were fully stated herein. Plaintiffs bring this count individually and on behalf of the Class pursuant to 29 U.S.C. § 1132(a)(1)(B).

- 177. Defendant denied the requests for coverage of Zepbound submitted by Plaintiffs and Class members in violation of the terms of the applicable plans. Defendant denied benefits to Plaintiff and the Class notwithstanding the fact that Zepbound satisfied the definition of medical necessity under the plans and did not fall within any exclusion in the plan.
- 178. In addition to denying coverage for Zepbound, Defendant required Plaintiffs and Class members to use Wegovy instead and suggested the possibility of using Mounjaro as an alternative. In doing so, Defendant violated the terms of the applicable plans, given that Zebpound has been proven to be more effective than Wegovy for treating obesity and that Wegovy falls within the experimental and investigational exclusion for treating sleep apnea, since it is not FDA-approved for that condition, and that Mounjaro falls within the experimental and investigational exclusion for treating obesity or sleep apnea, because it is not FDA-approved for either condition.
- 179. The denial of Zepbound should therefore be reversed as arbitrary and capricious or pursuant to de novo review.
- 180. Plaintiff and the Class were harmed by Defendant's improper benefit denials because they are not being covered for Zepbound, the FDA-approved drug for their diagnosed medical conditions that their clinicians have prescribed, in violation of Plan terms and ERISA.
  - 181. Plaintiff and the Class seek the relief identified below to remedy this claim.

#### **COUNT IV**

# Claim for Injunctive Relief (On behalf of Plaintiffs and the Class Against Defendant)

- 182. Plaintiffs incorporate by reference all preceding paragraphs as though such paragraphs were fully stated herein.
- 183. Plaintiffs bring this count individually and on behalf of the Class pursuant to 29 U.S.C. § 1132(a)(3)(A) only to the extent that the Court finds that the injunctive relief available

pursuant to 29 U.S.C. § 1132(a)(1)(B) is inadequate to remedy the violations alleged in Counts I or II.

- 184. Plaintiffs and the Class have been harmed, and are likely to be harmed in the future, by Defendant's breaches of fiduciary duty and/or violations of Plan terms and ERISA described above.
- 185. To prevent Defendant's ongoing violations of ERISA and the applicable plans, and the harm those violations cause, Plaintiffs and the Class are entitled to enjoin these acts and practices pursuant to 29 U.S.C. § 1132(a)(3)(A).

#### **COUNT V**

# Claim for Other Appropriate Equitable Relief (On behalf of Plaintiffs and the Class Against all Defendant)

- 186. Plaintiffs incorporate by reference all preceding paragraphs as though such paragraphs were fully stated herein.
- 187. Plaintiffs bring this count on behalf of themselves and the Class pursuant to 29 U.S.C. § 1132(a)(3)(B) only to the extent that the Court finds that the equitable relief available pursuant to 29 U.S.C. § 1132(a)(1)(B) is inadequate to remedy the violations alleged in Count I.
- 188. Plaintiffs and the Class have been harmed, and are likely to be harmed in the future, by Defendant's breaches of fiduciary duty and/or violations of ERISA described above.
- 189. To completely and adequately remedy these harms, Plaintiffs and the Class are entitled to appropriate equitable relief pursuant to 29 U.S.C. § 1132(a)(3)(B).

#### REQUESTED RELIEF

WHEREFORE, Plaintiffs demand judgment in his favor against Defendant as follows:

A. Certifying the Class and their claims, as set forth in this Complaint, for class

treatment;

B. Appointing Plaintiffs as Class Representatives;

C. Designating the undersigned counsel as Class Counsel;

D. Declaring that Zepbound is medically necessary for the treatment in adults with

obesity or overweight with at least one weight-related condition;

D. Declaring that Zepbound is medically necessary for the treatment of moderate-to-

severe obstructive sleep apnea in adults with obesity;

E. Ordering Defendant to reprocess the claims for coverage of Zepbound that it

previously denied and issue appropriate benefits under the Plan;

F. Awarding other appropriate equitable relief, including but not necessarily limited

to additional declaratory and injunctive relief;

H. Awarding Plaintiffs' disbursements and expenses for this action, including

reasonable attorneys' fees, costs, and expert fees, in amounts to be determined by the Court,

pursuant to 29 U.S.C. § 1132(g); and

I. Granting such other and further relief as is just and proper.

Dated: September 3, 2025

Respectfully,

/s/ D. Brian Hufford

D. Brian Hufford, Esq.

THE HUFFORD LAW FIRM PLLC

76 Midland Ave.

Rye, NY 10580

Tel. (614) 371-3657

Tel. (014) 3/1-303/

Email: dbhufford@huffordlawfirm.org

Shanon J. Carson

Natalie Lesser

Amey J. Park

**BERGER MONTAGUE PC** 

36

1818 Market Street, Suite 3600 Philadelphia, PA 19103 Telephone: (215) 875-4656 scarson@bergermontague.com nlesser@bergermontague.com apark@bergermontague.com

Alexandra K. Piazza

BERGER MONTAGUE PC
8241 La Mesa Blvd., Suite A
La Mesa, CA 91942
Telephone: (215) 875-03063
apiazza@bergermontague.com

Julie Selesnick **BERGER MONTAGUE PC**Berger Montague
1001 G Street, NW, Suite 400 East
Washington, D.C. 20001
Telephone: (202) 559-9740
jselesnick@bergermontague.com

Zoe Seaman-Grant
BERGER MONTAGUE PC
110 N. Wacker Drive, Suite 2500
Chicago, IL 60606
Telephone: (773) 257-0255
zseamangrant@ bergermontague.com

Attorneys for Plaintiffs