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11
12 UNITED STATES DISTRICT COURT
13 CENTRAL DISTRICT OF CALIFORNIA
14

15 SPERO KOULOURAS, on behalf of
himself and all others similarly situated;

16 Plaintiff,

17 vs.

18 UNITED HEALTHCARE SERVICES,
19 INC.; UNITEDHEALTH GROUP, INC.;
20 UNITEDHEALTHCARE INSURANCE
COMPANY;

21 Defendants.
22

Case No.: 2:24-cv-06460

CLASS ACTION

**COMPLAINT FOR BENEFITS,
DETERMINATION OF RIGHTS,
AND BREACH OF FIDUCIARY
DUTY UNDER ERISA**

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24
25 Plaintiff Spero Koulouras, on behalf of himself and others similarly situated, herein
26 sets forth the allegations of his Complaint against Defendant UnitedHealth Group, Inc.
27 (“UnitedHealth Group”) and its subsidiaries, Defendants United HealthCare Services, Inc.
28 (“United HealthCare Services”) and UnitedHealthcare Insurance Company

1 (“UnitedHealthcare”).

2 INTRODUCTION

3 1. Defendant UnitedHealth Group, Inc. owns UnitedHealthcare organizations in
4 California and many other states, as well as other subsidiaries. Through its wholly owned
5 subsidiaries, including Defendants United HealthCare Services and UnitedHealthcare Insurance
6 Company, UnitedHealth Group, Inc. acts as a fully integrated company that is in the business of
7 insuring and/or administering group health plans within the meaning of 29 Code of Federal
8 Regulations § 2560.503-1(m) (both fully insured and self-insured), most of which are employer-
9 sponsored and governed by the Employee Retirement Income Security Act of 1974 (“ERISA”),
10 29 U.S.C. § 1001, *et seq.* Those ERISA-governed health plans are hereinafter referred to as
11 “UnitedHealth plans”.

12 2. With respect to all UnitedHealth plans, UnitedHealthcare serves as the claim
13 administrator, responsible for determining whether claims are covered and effectuating
14 any resulting benefit payment. United HealthCare Services provides administrative
15 services to UnitedHealthcare as the claim administrator. UnitedHealth Group aids
16 UnitedHealthcare and United HealthCare Services in their duties by, among other things,
17 participating with UnitedHealthcare and United HealthCare Services in the development
18 of coverage guidelines, collaborating with UnitedHealthcare and United HealthCare
19 Services on decisions regarding the types of claims that will be approved or denied,
20 including the denials of the claims alleged herein, and assisting UnitedHealthcare and
21 United HealthCare Services in carrying out their various other duties. As such, Defendants
22 UnitedHealth Group, Inc., United HealthCare Services, Inc., and UnitedHealthcare
23 Insurance Company (jointly “UnitedHealth”) have acted as ERISA fiduciaries with respect
24 to all UnitedHealth plans, including Plaintiff’s plan.

25 3. Plaintiff brings this action to address UnitedHealth’s practice of improperly
26 denying claims for non-invasive ventilators (“NIV”) for the care of patients with
27 Amyotrophic lateral sclerosis (“ALS”) under UnitedHealth plans.

28 //

JURISDICTION AND VENUE

1
2 4. This action is brought under 29 U.S.C. §§1132(a), (e), (f), and (g) as it
3 involves claims by Plaintiff for employee benefits under employee benefit plans regulated
4 and governed by ERISA. Subject matter jurisdiction is predicated under these code
5 sections as well as 28 U.S.C. § 1331 as this action involves a federal question.

6 5. The court has personal jurisdiction over Defendants because ERISA
7 provides for nationwide service of process, and each Defendant has minimum contacts
8 with the United States. 29 U.S.C. § 11322(e)(2).

9 6. Plaintiff’s health plan that is the subject of this lawsuit was administered in
10 Orange County, the denial letters to plaintiff were issued in Orange County, and
11 Defendants regularly conduct business in Orange County. Therefore, the claims of
12 Plaintiff and the putative class arise out of policies Defendants issued, administered,
13 and/or implemented in this District, and a substantial part of the events giving rise to the
14 claims asserted herein occurred in this District. Thus, venue is proper in this judicial
15 district pursuant to 28 U.S.C. § 1391 and 29 U.S.C. § 1132(e)(2) (setting forth special
16 venue rules applicable to ERISA actions).

THE PARTIES

17
18 7. Plaintiff was at all relevant times covered under an employer-sponsored
19 benefit plan regulated by ERISA and pursuant to which Plaintiff is entitled to health
20 benefits. Plaintiff resides in Yuba City, California. Plaintiff’s employer, CrossFire Group
21 LLC, is a corporation with its principal place of business in Oakland County, Michigan.

22 8. UnitedHealth Group, Inc. and United HealthCare Services, Inc. are
23 corporations with their principal place of business in Minnetonka, Minnesota.
24 UnitedHealthcare Insurance Company is a corporation with its principal place of business
25 in Hartford, Connecticut. UnitedHealth Group, Inc., United HealthCare Services, Inc., and
26 UnitedHealthcare Insurance Company administer and make benefit determinations related
27 to ERISA group health care plans around the country. As alleged below, Plaintiff’s claim
28 was denied in a letter that stated the claims decision was made in UnitedHealth’s Cypress

1 office in Orange County, California within this District and Plaintiff's appeal was denied
2 in a letter that said the appeal decision was made in the same office within this District.
3 Thus, Plaintiff's claim was administered within this District.

4 9. UnitedHealth Group, Inc., United HealthCare Services, Inc., and
5 UnitedHealthcare Insurance Company do not operate independently and in their own
6 interests, but serve solely to fulfill the purpose, goals, and policies of each other.

7 **FACTUAL BACKGROUND**

8 **A. Noninvasive ventilation ("NIV") devices.**

9 10. Amyotrophic lateral sclerosis ("ALS") is a progressive neurodegenerative
10 disease that causes a loss of muscle control. ALS affects the nerve cells that control
11 voluntary muscle movements, known as motor neurons, causing them to deteriorate and
12 eventually die. Once these neurons are damaged, the brain can no longer send messages to
13 the muscles. ALS symptoms can start with small muscle twitching or weakness, but as the
14 disease progresses, the muscles are eventually unable to function. Patients begin to lose
15 control of the muscles needed for moving, speaking, eating, and breathing. Most people
16 with ALS ultimately pass away from respiratory failure, as their body can no longer
17 control the muscles needed to breathe.

18 11. Because of the effect of ALS on breathing, one of the most important
19 aspects of prolonging the life of ALS patients is addressing their ability to breathe. To
20 combat the loss of breathing muscle control, many ALS patients use ventilators. There are
21 different types of ventilation that can be used with ALS patients. For the more advanced
22 cases, in which a patient's muscles are nearly unable to control breathing, the patient may
23 require invasive ventilation through a tracheostomy. The patient undergoes a procedure to
24 reroute their trachea through the skin of their throat, forming a permanent opening. Air is
25 then forced into the central airways via a tracheostomy tube, and the ventilator breathes for
26 the patient.

27 12. However, many ALS patients do not need the full support of invasive
28 ventilation. Patients may require support for, but not replacement of, their breathing. Also,

1 patients may need support but not continuous 24/7 support. Invasive ventilation keeps
2 patients tied to their ventilators, greatly limiting their mobility and ability to leave their
3 homes. There are also complications related to permanent tracheostomies—surgical
4 complications, potential infections, required stoma hygiene practices, etc. Invasive
5 ventilation is typically reserved for the more advanced cases of ALS, in cases where there
6 are no more conservative options available. For those patients who do not require as much
7 support as invasive ventilation offers, noninvasive ventilation is a great option. They can
8 receive the breathing support they need without the limitations and complications that
9 invasive ventilation brings.

10 13. Noninvasive ventilation has been scientifically proven to prolong the life of
11 ALS patients, and it significantly improves their quality of life as well. ALS patients can
12 get the appropriate level of breathing support at all stages between the weakening of their
13 breathing muscles and the point where they would require invasive ventilation to replace
14 their breathing. Access to noninvasive ventilation is essential for ALS patients, preventing
15 unnecessary complications and restriction of the patient’s activities until absolutely
16 necessary.

17 **B. UnitedHealth’s categorical denial of non-invasive ventilation as not**
18 **medically necessary.**

19 14. UnitedHealth plans cover medical services on an inpatient, outpatient, and
20 in-home basis to treat illness and injury. They provide payment for the diagnosis, cure,
21 mitigation, treatment, or prevention of disease. As part of these benefits, UnitedHealth
22 plans cover the cost of life-sustaining durable medical equipment for those suffering from
23 chronic or terminal illnesses.

24 15. In reviewing and deciding claims under UnitedHealth plans, UnitedHealth
25 utilizes internal coverage guidelines called “Medical Policies”. The Medical Policies are
26 not themselves part of UnitedHealth’s plans, but rather are interpretive guidelines used by
27 UnitedHealth to assist it in making fact-based determinations regarding whether certain
28 medical services fall within a particular contractual term or exclusion that precludes or

1 limits coverage.

2 16. UnitedHealth plans exclude from coverage those medical services that
3 UnitedHealth considers “not medically necessary”. Plaintiff’s UnitedHealthcare Certificate
4 of Coverage provides the following definition of “medically necessary”—

5 Health care services provided for the purpose of preventing, evaluating, diagnosing
6 or treating a Sickness, Injury, Mental Illness, substance use disorder, condition,
7 disease or its symptoms, that are all of the following as determined solely by us or
8 our designee.

- 9 - In accordance with *Generally Accepted Standards of Medical Practice*.
- 10 - Clinically appropriate, in terms of type, frequency, extent, site and duration,
11 and considered effective for your Sickness, Injury, Mental Illness, substance
12 use disorder, disease or its symptoms.
- 13 - No more costly than an alternative drug, service(s) or supply that is at least as
14 likely to produce equivalent therapeutic or diagnostic results as to the
15 diagnosis or treatment of your Sickness, Injury, disease or symptoms.

16 *Generally Accepted Standards of Medical Practice* are standards that are based on
17 credible scientific evidence published in peer-reviewed medical literature generally
18 recognized by the relevant medical community, relying primarily on controlled
19 clinical trials, or if not available, observational studies from more than one institution
20 that suggest a causal relationship between the service or treatment and health
21 outcomes.

22 17. UnitedHealth’s Medical Policy, “Durable Medical Equipment, Orthotics,
23 Medical Supplies, and Repairs/Replacements” MP.009.29 and earlier versions of this
24 policy (collectively referred to hereinafter as “Medical Policy MP.009.29” or
25 “MP.009.29”) upon which Plaintiff’s claim was denied, states, “Ventilators are covered to
26 treat neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure
27 consequent to chronic obstructive pulmonary disease.” Despite ALS being a relevant
28 neuromuscular disease, the following criteria are specific to sleep apnea and COPD,
neglecting the specific needs of ALS patients. MP.009.29 goes on to state that ventilators
are not medically necessary when used for the treatment of a condition wherein
interruption of respiratory support would not immediately lead to serious harm or death.
UnitedHealth has developed Medical Policies with respect to certain types of medical
treatment for certain types of medical conditions, while failing to consider the different
needs of different medical conditions, such as ALS. ALS patients utilizing noninvasive
ventilation may not face immediate life-threatening consequences from the interruption of
respiratory support, however the long-term lack of ventilation can lead to an increased rate

1 of muscle deterioration, lower quality of life, and higher likelihood of needing invasive
2 ventilation via tracheostomy.

3 18. As a result, UnitedHealth has categorically deemed noninvasive ventilation
4 Not Medically Necessary for ALS patients who are trying to prevent deterioration of
5 breathing related muscles and prolong their lives. Relying on MP.009.29, and as
6 demonstrated by UnitedHealth's denial of Plaintiff's claim, UnitedHealth has categorically
7 denied claims for noninvasive ventilators as not medically necessary without regard to a
8 member's medical condition, need, or qualification for the device.

9 19. Contrary to UnitedHealth's factual conclusion in MP.009.29, the use of
10 noninvasive ventilators for ALS patients who do not require 24/7 breathing assistance is
11 medically necessary, to prevent deterioration and to prolong life. Noninvasive ventilation
12 has been shown to be effective in prolonging life through peer reviewed literature on
13 clinically demonstrated benefits of the device. Noninvasive ventilation has been used
14 widely by ALS experts across the nation and has received positive coverage
15 recommendations by ALS and other neuromuscular disease specialty organizations such
16 as the ALS Association, the Muscular Dystrophy Association, and ALS Worldwide.

17 **C. UnitedHealth's denial of Spero Koulouras' claim.**

18 20. At all relevant times, Plaintiff was covered under an ERISA group health
19 plan that was arranged by his employer, CrossFire Group LLC ("Plaintiff's UnitedHealth
20 plan"). Plaintiff's UnitedHealth plan was purchased by his employer from UnitedHealth
21 subsidiary UnitedHealthcare Insurance Company, a healthcare service plan regulated by
22 the California Department of Managed Health Care. This ERISA group health plan was at
23 all relevant times administered by UnitedHealth.

24 21. Like all UnitedHealth plans, Plaintiff's UnitedHealth plan covers health
25 services to treat illnesses and injuries. It is an ERISA group health plan because it is
26 arranged by his employer for the benefit of its employees and their dependents. It provides
27 payment for the diagnosis, mitigation, treatment, or prevention of disease, or amounts paid
28 for the purpose of affecting any structure or function of the body.

1 22. Plaintiff’s UnitedHealth plan excludes from coverage treatment for services
2 that are “determined to be Not Medically Necessary”. This term is defined in Plaintiff’s
3 UnitedHealth plan as:

4 Health care services provided for the purpose of preventing, evaluating, diagnosing
5 or treating a Sickness, Injury, Mental Illness, substance use disorder, condition,
6 disease or its symptoms, that are all of the following as determined solely by us or
7 our designee.

- 8 - In accordance with *Generally Accepted Standards of Medical Practice*.
- 9 - Clinically appropriate, in terms of type, frequency, extent, site and duration,
10 and considered effective for your Sickness, Injury, Mental Illness, substance
11 use disorder, disease or its symptoms.
- 12 - No more costly than an alternative drug, service(s) or supply that is at least as
13 likely to produce equivalent therapeutic or diagnostic results as to the
14 diagnosis or treatment of your Sickness, Injury, disease or symptoms.

15 *Generally Accepted Standards of Medical Practice* are standards that are based on
16 credible scientific evidence published in peer-reviewed medical literature generally
17 recognized by the relevant medical community, relying primarily on controlled
18 clinical trials, or if not available, observational studies from more than one institution
19 that suggest a causal relationship between the service or treatment and health
20 outcomes.

21 23. Plaintiff has a diagnosis of Amyotrophic lateral sclerosis (ALS) and has
22 received many different treatments to manage the progression of his disease. As a result of
23 Plaintiff’s disease, he experiences progressive degeneration of muscle control, most
24 recently impacting his ability to breathe. While not yet requiring 24/7 respiratory support,
25 his shortness of breath affects his speech and impairs his ability to clear his throat.
26 Spirometry tests revealed restrictive lung disease with confirmed diaphragm weakness and
27 severe obstructive sleep apnea. Previously only requiring respiratory support at night,
28 Plaintiff’s need for breathing care has progressed to daytime use and, due to the nature of
degenerative disease, will eventually progress to 24/7 use.

29 24. In May 2023, Plaintiff’s doctors submitted a coverage request for procedure
30 code E0466 – “Home ventilator, any type, used with noninvasive interface, (e.g., mask,
31 chest shell)”. On May 24, 2023, UnitedHealth sent a letter to Plaintiff stating that the
32 ventilator was not a Covered Service. According to the Durable Medical Equipment
33 section of Plaintiff’s plan, “Benefits are available only for the equipment that meets the
34 minimum specifications for your needs”. UnitedHealth’s May 24 denial letter states, “This
35 home breathing machine request does not meet your health plan criteria because it exceeds

1 what is needed for your care”. UnitedHealth determined, based on its own criteria, that
2 Plaintiff did not need the level of respiratory support that his doctors prescribed for him
3 based on their medical expertise and knowledge of his health needs. This letter
4 acknowledged that UnitedHealth was in possession of Plaintiff’s medical records
5 regarding this coverage request.

6 25. After Plaintiff’s doctors submitted an appeal, UnitedHealth issued a second
7 denial on November 21, 2023. This time, UnitedHealth claimed that the request was not
8 medically necessary due to lack of medical records proving why Plaintiff needed this
9 ventilator. The letter states the request may be reviewed again once medical records are
10 received. Plaintiff and his medical team did indeed submit all required medical records as
11 listed in this denial letter. On November 27, 2023, Plaintiff submitted a second appeal
12 along with all medical records, related journal articles about NIV, and his doctors’
13 explanation of medical necessity. On or about December 11 and December 13, 2023,
14 United Health again rejected Plaintiff’s appeals.

15 **CLASS ACTION ALLEGATIONS**

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

- 19 a. All individuals covered under ERISA health plans, self-funded or fully
20 insured, that are administered by UnitedHealth and who were diagnosed
21 with ALS and whose request for a non-invasive home ventilator was denied
22 under UnitedHealth’s Medical Policy “Durable Medical Equipment,
23 Orthotics, Medical Supplies, and Repairs/Replacements” as not meeting the
24 health plan criteria because it exceeded what was needed for the individual’s
25 care.
- 26 b. All individuals covered under ERISA health plans, self-funded or fully
27 insured, that are administered by UnitedHealth and who were diagnosed
28 with ALS and whose request for a non-invasive home ventilator was denied

1 because it did not show “medical necessity” under the criteria of
2 UnitedHealth’s Medical Policy “Durable Medical Equipment, Orthotics,
3 Medical Supplies, and Repairs/Replacements”.

4 27. Plaintiff and the class members reserve the right under Federal Rule of Civil
5 Procedure Rule 23(c)(1)(C) to amend or modify the class to include greater specificity, by
6 further division into subclasses, or by limitation to particular issues.

7 28. This action has been brought and may be properly maintained as a class
8 action under the provisions of the Federal Rules of Civil Procedure Rule 23 because it
9 meets the requirements of Rule 23(a) and Rule 23(b)(1) and (b)(2).

10 **A. Numerosity.**

11 29. The potential members of the proposed class as defined as so numerous that
12 joinder of all the members of the proposed class is impracticable. While the precise
13 number of proposed class members has not been determined at this time, Plaintiff is
14 informed and believes that there are a substantial number of individuals covered under
15 UnitedHealth plans who have been similarly affected.

16 **B. Commonality.**

17 30. Common questions of law and fact that pertain to all class members, which
18 predominate over other questions that affect only individual class members, include,
19 without limitation:

20 a. Whether United Health’s application under MP.009.29 of criteria that are
21 specific to sleep apnea and COPD to ALS patients’ requests for coverage for
22 non-invasive home ventilators violates its fiduciary duties under 29 U.S.C. §
23 1104(a);

24 b. Whether United Health’s application under MP.009.29 of criteria that
25 provide that ventilators are not medically necessary when used for the
26 treatment of a condition wherein interruption of respiratory support would
27 not immediately lead to serious harm or death to ALS patients’ requests for
28 coverage for non-invasive home ventilators violates its fiduciary duties

- 1 under 29 U.S.C. § 1104(a);
- 2 c. Whether United Health’s failure to apply medical policies with criteria that
- 3 are relevant and appropriate to ALS patients’ requests for non-invasive
- 4 home ventilators when making coverage decisions violates its fiduciary
- 5 duties under 29 U.S.C. § 1104(a);
- 6 d. Whether UnitedHealth violated its duty of loyalty under 29 U.S.C. §
- 7 1104(a)(1)(A) by creating MP.009.29 which erroneously classifies the use of
- 8 non-invasive home ventilators by ALS patients as not medically necessary,
- 9 thereby categorically excluding coverage under all UnitedHealth plans;
- 10 e. Whether UnitedHealth violated its duty of loyalty under 29 U.S.C. §
- 11 1104(a)(1)(A) by instructing claims personnel to implement MP.009.29 for
- 12 non-invasive home ventilators claims by ALS patients and to deny those
- 13 claims on the basis they are not medically necessary, thereby categorically
- 14 excluding coverage under all UnitedHealth plans;
- 15 f. Whether UnitedHealth violated its duty of loyalty under 29 U.S.C. §
- 16 1104(a)(1)(A) by violating 29 Code of Federal Regulations § 2560.503-
- 17 1(g)(1)(i) because MP.009.29 provides no rationale as to how treatment with
- 18 non-invasive home ventilators could be medically necessary based on actual
- 19 clinical studies and the widespread acceptance of non-invasive home
- 20 ventilators by the ALS medical community;
- 21 g. Whether UnitedHealth violated its duty of due care under 29 U.S.C. §
- 22 1104(a)(1)(B) by creating MP.009.29 which erroneously classifies the use of
- 23 non-invasive home ventilators by ALS patients as not medically necessary,
- 24 thereby categorically excluding coverage under all UnitedHealth plans;
- 25 h. Whether UnitedHealth violated its duty of due care under 29 U.S.C. §
- 26 1104(a)(1)(B) by instructing claims personnel to implement MP.009.29 for
- 27 non-invasive home ventilators claims by ALS patients and to deny those
- 28 claims on the basis they are not medically necessary, thereby categorically

- 1 excluding coverage under all UnitedHealth plans;
- 2 i. Whether UnitedHealth violated its duty of due care under 29 U.S.C. §
- 3 1104(a)(1)(B) by violating 29 Code of Federal Regulations § 2560.503-
- 4 1(g)(1)(i) because MP.009.29 provides no rationale as to how treatment with
- 5 non-invasive home ventilators could be medically necessary based on actual
- 6 clinical studies and the widespread acceptance of non-invasive home
- 7 ventilators by the ALS medical community;
- 8 j. Whether UnitedHealth violated its duty to comply with plan terms under 29
- 9 U.S.C. § 1104(a)(1)(D) by creating MP.009.29 which erroneously classifies
- 10 the use of non-invasive home ventilators by ALS patients as not medically
- 11 necessary, thereby categorically excluding coverage under all UnitedHealth
- 12 plans;
- 13 k. Whether UnitedHealth violated its duty to comply with plan terms under 29
- 14 U.S.C. § 1104(a)(1)(D) by instructing claims personnel to implement
- 15 MP.009.29 for requests for non-invasive home ventilators by ALS patients
- 16 and to deny those claims on the basis they are not medically necessary,
- 17 thereby categorically excluding coverage under all UnitedHealth plans;
- 18 l. Whether UnitedHealth violated its duty to comply with plan terms under 29
- 19 U.S.C. § 1104(a)(1)(D) by violating 29 Code of Federal Regulations §
- 20 2560.503-1(g)(1)(i) because MP.009.29 provides no rationale as to how
- 21 treatment with non-invasive home ventilators could be medically necessary
- 22 based on actual clinical studies and the widespread acceptance of non-
- 23 invasive home ventilators by the ALS medical community.
- 24 m. Whether UnitedHealth’s wrongful actions caused the deprivation of benefits
- 25 under UnitedHealth plans for participants and their beneficiaries and
- 26 increased the reasonable expenses of administering the plan because the
- 27 systemic denials of claims for non-invasive home ventilators made by ALS
- 28 patients has resulted in loss of benefits, needless appeals, and other

1 expenses.

2 **C. Typicality.**

3 31. Plaintiff's claims are typical of the claims of the members of the proposed
4 class because all members of the class had coverage for their requests for non-invasive
5 home ventilators denied as part of United Health's policy and practice of wrongfully
6 applying Medical Policy MP.009.29 to ALS patients' requests for non-invasive home
7 ventilators. Plaintiff and all members of the class are similarly affected by UnitedHealth's
8 wrongful conduct.

9 **D. Adequacy of representation.**

10 32. Plaintiff will fairly and adequately represent and protect the interests of the
11 members of the proposed class. Counsel who represent Plaintiff are competent and
12 experienced in litigating large and complex class actions, including class actions against
13 health plans such as UnitedHealth.

14 **E. Superiority of class action.**

15 33. A class action is superior to all other available means for the fair and
16 efficient adjudication of this controversy. Individual joinder of all members of the
17 proposed class is not practicable, and common questions of law and fact exist as to all
18 class members.

19 34. Class action treatment will allow those similarly situated persons to litigate
20 their claims in the manner that is most efficient and economical for the parties and the
21 judicial system. Plaintiff is unaware of any difficulties that are likely to be encountered in
22 the management of this action that would preclude its maintenance as a class action.

23 **F. Rule 23(b) requirements.**

24 35. Inconsistent or varying adjudications with respect to individual members of
25 the class would establish incompatible standards of conduct for UnitedHealth.

26 36. Adjudications with respect to individual class members would be dispositive
27 of the interests of the other members not parties to the individual adjudications or would
28 substantially impair or impede their ability to protect their interests.

1 37. UnitedHealth has acted or refused to act on grounds generally applicable to
2 the class, thereby making appropriate final injunctive relief or corresponding declaratory
3 relief with respect to the class as a whole.

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FIRST CLAIM FOR RELIEF

**DENIAL OF PLAN BENEFITS AND FOR CLARIFICATION OF RIGHTS
UNDER AN ERISA PLAN [29 U.S.C. § 1132(a)(1)(B)]**

38. Plaintiff and the class members repeat and reallege each and every allegation
set forth in all of the foregoing paragraphs as if fully set forth herein.

39. 29 U.S.C. § 1132(a)(1)(B) entitles Plaintiff to recover benefits due and to
enforce and clarify his rights to the benefits at issue.

40. As alleged herein, Plaintiff’s UnitedHealth plan provides surgical, hospital,
and in-home medical services on both an inpatient and outpatient basis to treat illness and
injury, including coverage for prosthetic devices, durable medical equipment, professional
services, and other medical services.

41. As alleged herein, Plaintiff requested that UnitedHealth authorize coverage
for a non-invasive ventilation device, as recommended by his treatment team, to assist
with breathing as his ALS causes progressive deterioration to his muscles.

42. As alleged herein, UnitedHealth has followed a policy and practice of
denying claims for non-invasive ventilators to ALS patients on the basis the device is not
medically necessary under UnitedHealth’s policy MP.009.29 and, therefore, the request
did not meet the UnitedHealth plan’s criteria.

43. Pursuant to its practice, UnitedHealth denied Plaintiff’s request for a
noninvasive ventilator on the basis that its use is not medically necessary under
MP.009.29. However, the use of noninvasive ventilators for ALS patients is medically
necessary under the pertinent plan provisions. NIV has been shown to be effective at
prolonging lifespan in ALS patients by peer reviewed literature, as well as patient
outcomes over the more than 15 years of NIV being the standard treatment.

1 44. Plaintiff has exhausted his administrative remedies, as alleged above.

2 45. Based on the foregoing, Plaintiff and the class members seek reevaluation
3 and reprocessing of their requests for non-invasive ventilators without the requirement of
4 showing medical necessity under Medical Policy MP.009.29 and instead under appropriate
5 and valid medical criteria; a clarification of future rights; and attorneys' fees.

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7

SECOND CLAIM FOR RELIEF

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BREACH OF FIDUCIARY DUTY AND EQUITABLE RELIEF UNDER AN

9

ERISA PLAN [29 U.S.C. § 1132(a)(3)]

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46. Plaintiff and the class members repeat and reallege each and every allegation set forth in all of the foregoing paragraphs as if fully set forth herein.

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47. As alleged herein, UnitedHealth has acted as an ERISA fiduciary with respect to the administration and claims decisions under UnitedHealth plans and, in particular, has acted as an ERISA fiduciary in denying claims for non-invasive ventilators, as alleged herein.

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48. As alleged herein, Plaintiff's UnitedHealth plan provides surgical, hospital, and in-home medical services on both an inpatient and outpatient basis to treat illness and injury, including coverage for prosthetic devices, durable medical equipment, professional services, and other medical services.

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49. As alleged herein, Plaintiff requested that UnitedHealth authorize coverage for a non-invasive ventilator to help him breathe as his ALS progresses, as recommended by his medical team.

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50. As alleged herein, UnitedHealth has followed a policy and practice of denying claims for non-invasive ventilators to ALS patients on the basis that the use of the device is not medically necessary under UnitedHealth's policy MP.009.29.

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51. Pursuant to its policy and practice, UnitedHealth denied Plaintiff's request for treatment with a non-invasive ventilator on the basis that the use of such ventilators is not medically necessary. However, the use of a non-invasive ventilator for patients

1 suffering from ALS is medically necessary under the pertinent plan provisions. Non-
2 invasive ventilators have been scientifically proven to not only prolong the life of the
3 patient, but to prolong the time the patient can live without the use of invasive ventilation,
4 in the form of tracheostomy.

5 52. Pursuant to the 29 U.S.C. § 1104(a), UnitedHealth was required to discharge
6 its fiduciary duties with respect to UnitedHealth plans solely in the interests of the
7 participants and beneficiaries and—

- 8 a. for the exclusive purpose of:
- 9 i. providing benefits to participants and their beneficiaries; and
 - 10 ii. defraying reasonable expenses of administering the plan;
- 11 b. with the care, skill, prudence, and diligence under the circumstances then
12 prevailing that a prudent man acting in a like capacity and familiar with such
13 matters would use in the conduct of an enterprise of a like character and
14 with like aims; and
- 15 c. in accordance with the documents and instruments governing the plan
16 insofar as such documents and instruments are consistent with provisions of
17 this subchapter and subchapter III.

18 53. UnitedHealth violated its duty of loyalty under 29 U.S.C. § 1104(a)(1)(A)
19 by: (a) creating MP.009.29 that erroneously classifies the use of NIV by ALS patients as
20 not medically necessary and excluded under all UnitedHealth plans, as alleged herein; (b)
21 instructing claims personnel to implement MP.009.29 for NIV claims and to deny those
22 claims on the basis they are not medically necessary and excluded; and (c) violating 29
23 Code of Federal Regulations § 2560.503-1(g)(1)(i) because MP.009.29 provides no
24 rationale as to how treatment with NIV could be not medically necessary based on actual
25 clinical studies and the widespread acceptance of NIV by the ALS medical community.
26 These actions by UnitedHealth cause the deprivation of benefits under UnitedHealth plans
27 for participants and their beneficiaries and increase the reasonable expenses of
28 administering the plan because the cause a systemic denial of NIV claims resulting in loss

1 of benefits, needless appeals, and other expenses.

2 54. UnitedHealth violated its duty of due care under 29 U.S.C. § 1104(a)(1)(B)
3 by: (a) creating MP.009.29 that erroneously classifies the use of NIV by ALS patients as
4 not medically necessary and excluded under all UnitedHealth plans, as alleged herein; (b)
5 instructing claims personnel to implement MP.009.29 for NIV claims and to deny those
6 claims on the basis they are not medically necessary and excluded; and (c) violating 29
7 Code of Federal Regulations § 2560.503-1(g)(1)(i) because MP.009.29 provides no
8 rationale as to how treatment with NIV could be not medically necessary based on actual
9 clinical studies and the widespread acceptance of NIV by the ALS medical community.

10 55. UnitedHealth violated its duty to comply with plan terms under 29 U.S.C. §
11 1104(a)(1)(D) by: (a) creating MP.009.29 that erroneously classifies the use of NIV by
12 ALS patients as not medically necessary and excluded under all UnitedHealth plans, as
13 alleged herein; (b) instructing claims personnel to implement MP.009.29 for NIV claims
14 and to deny those claims on the basis they are not medically necessary and excluded; and
15 (c) violating 29 Code of Federal Regulations § 2560.503-1(g)(1)(i) because MP.009.29
16 provides no rationale as to how treatment with NIV could be not medically necessary
17 based on actual clinical studies and the widespread acceptance of NIV by the ALS medical
18 community.

19 56. Pursuant to 29 U.S.C. § 1132(a)(3), Plaintiff and the class members seek
20 declaratory, equitable and remedial relief as follows:

- 21 a. An order declaring that UnitedHealth's denials of NIV claims for ALS
22 patients as not medically necessary under MP.009.29 were wrong and
23 improper and that UnitedHealth has violated 29 Code of Federal Regulations
24 §§ 2560.503-1(g)(1)(i) and (g)(1)(v)(B);
- 25 b. A class-wide injunction requiring UnitedHealth to retract that portion of
26 MP.009.29 it uses to deny requests for NIV for ALS patients as not
27 medically necessary;
- 28 c. A class-wide injunction requiring UnitedHealth to provide notice to all class

- 1 members, in the form and manner required by ERISA, of the retraction;
- 2 d. A class-wide injunction requiring UnitedHealth to stop violating 29 Code of
- 3 Federal Regulations §§ 2560.503-1(g)(1)(i) and (g)(1)(v)(B);
- 4 e. Plaintiff is not seeking any relief in this Second Claim for Relief under 29
- 5 U.S.C. § 1132(a)(3) that is duplicative of the relief sought in the First Claim
- 6 for Relief under 29 U.S.C. § 1132(a)(1)(B). However, if it is determined that
- 7 the reprocessing relief sought in the First Claim for Relief cannot be
- 8 awarded because such relief is more appropriately sought in the Second
- 9 Claim for Relief, then Plaintiff requests in the claim a reprocessing of the
- 10 denied requests for NIV with appropriate instructions for reprocessing;
- 11 f. Surcharge, i.e., an accounting of any profits made by UnitedHealth from the
- 12 monies representing the improperly denied claims and disgorgement of any
- 13 profits;
- 14 g. Such other equitable and remedial relief as the Court may deem appropriate;
- 15 and
- 16 h. Attorneys' fees in an amount to be proven.

17

18 **REQUEST FOR RELIEF**

19 Wherefore, Plaintiff and the class members pray for judgment against UnitedHealth

20 as follows:

- 21 1. Reevaluation and reprocessing of the class members' requests for non-
- 22 invasive home ventilation with appropriate instructions for reprocessing;
- 23 2. A clarification of rights to future benefits under the plan for all class
- 24 members;
- 25 3. Interest;
- 26 4. Injunctive and declaratory relief, as described above;
- 27 5. An accounting of any profits made and retained through the improper denial
- 28 of claims and disgorgement of any profits (surcharge);

- 1 6. Attorneys' fees; and
- 2 7. Such other equitable and remedial relief as the Court may deem just and
- 3 proper.

4

5 DATED: July 31, 2024

LAW OFFICES OF SCOTT GLOVSKY, APC

6

7 By: *S/ Scott Glovsky*

8 SCOTT C. GLOVSKY

9 JULIA ZALBA SELTZ

 Attorney for Plaintiffs

10

11 DATED: July 31, 2024

LAW OFFICES OF CHRISTIAN GARRIS

12

13 By: *S/ Christian Garris*

14 CHRISTIAN GARRIS

15 Attorney for Plaintiffs