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

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

16 Plaintiff,

17 vs.

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

21 Defendants.
22

Case No.: **'24CV0936 JLS KSC**

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.

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JURISDICTION AND VENUE

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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. The claims of Plaintiff and the putative class arise out of policies Defendants
10 issued, administered, and/or implemented in this District. Thus, venue is proper in this
11 judicial district pursuant to 29 U.S.C. § 1132(e)(2) (setting forth special venue rules
12 applicable to ERISA actions).

THE PARTIES

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

18 8. UnitedHealth Group, Inc. and United HealthCare Services, Inc. are
19 corporations with their principal place of business in Minnetonka, Minnesota.
20 UnitedHealthcare Insurance Company is a corporation with its principal place of business
21 in Hartford, Connecticut. UnitedHealth Group, Inc., United HealthCare Services, Inc., and
22 UnitedHealthcare Insurance Company administer and make benefit determinations related
23 to ERISA group health care plans around the country. As alleged below, Plaintiff’s claim
24 was denied in a letter that stated the claims decision was made in UnitedHealth’s Cypress
25 office in Orange County, California within this District and Plaintiff’s appeal was denied
26 in a letter that said the appeal decision was made in the same office within this District.
27 Thus, Plaintiff’s claim was administered within this District.

28 9. UnitedHealth Group, Inc., United HealthCare Services, Inc., and

1 UnitedHealthcare Insurance Company do not operate independently and in their own
2 interests, but serve solely to fulfill the purpose, goals, and policies of each other.

3 **FACTUAL BACKGROUND**

4 **A. Noninvasive ventilation (“NIV”) devices.**

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

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

23 12. However, many ALS patients do not need the full support of invasive
24 ventilation. Patients may require support for, but not replacement of, their breathing. Also,
25 patients may need support but not continuous 24/7 support. Invasive ventilation keeps
26 patients tied to their ventilators, greatly limiting their mobility and ability to leave their
27 homes. There are also complications related to permanent tracheostomies—surgical
28 complications, potential infections, required stoma hygiene practices, etc. Invasive

1 ventilation is typically reserved for the more advanced cases of ALS, in cases where there
2 are no more conservative options available. For those patients who do not require as much
3 support as invasive ventilation offers, noninvasive ventilation is a great option. They can
4 receive the breathing support they need without the limitations and complications that
5 invasive ventilation brings.

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

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

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

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

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

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

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

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

18 17. UnitedHealth’s Medical Policy, “Durable Medical Equipment, Orthotics,
19 Medical Supplies, and Repairs/Replacements” MP.009.29 and earlier versions of this
20 policy (collectively referred to hereinafter as “Medical Policy MP.009.29” or
21 “MP.009.29”) upon which Plaintiff’s claim was denied, states, “Ventilators are covered to
22 treat neuromuscular diseases, thoracic restrictive diseases, and chronic respiratory failure
23 consequent to chronic obstructive pulmonary disease.” Despite ALS being a relevant
24 neuromuscular disease, the following criteria are specific to sleep apnea and COPD,
25 neglecting the specific needs of ALS patients. MP.009.29 goes on to state that ventilators
26 are not medically necessary when used for the treatment of a condition wherein
27 interruption of respiratory support would not immediately lead to serious harm or death.
28 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
of muscle deterioration, lower quality of life, and higher likelihood of needing invasive
ventilation via tracheostomy.

18 18. As a result, UnitedHealth has categorically deemed noninvasive ventilation
19 Not Medically Necessary for ALS patients who are trying to prevent deterioration of

1 breathing related muscles and prolong their lives. Relying on MP.009.29, and as
2 demonstrated by UnitedHealth’s denial of Plaintiff’s claim, UnitedHealth has categorically
3 denied claims for noninvasive ventilators as not medically necessary without regard to a
4 member’s medical condition, need, or qualification for the device.

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

13 **C. UnitedHealth’s denial of Spero Koulouras’ claim.**

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

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

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

28 Health care services provided for the purpose of preventing, evaluating, diagnosing
or treating a Sickness, Injury, Mental Illness, substance use disorder, condition,

disease or its symptoms, that are all of the following as determined solely by us or our designee.

- In accordance with *Generally Accepted Standards of Medical Practice*.
- Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for your Sickness, Injury, Mental Illness, substance use disorder, disease or its symptoms.
- No more costly than an alternative drug, service(s) 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.

Generally Accepted Standards of Medical Practice are 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.

23. Plaintiff has a diagnosis of Amyotrophic lateral sclerosis (ALS) and has received many different treatments to manage the progression of his disease. As a result of Plaintiff's disease, he experiences progressive degeneration of muscle control, most recently impacting his ability to breathe. While not yet requiring 24/7 respiratory support, his shortness of breath affects his speech and impairs his ability to clear his throat. Spirometry tests revealed restrictive lung disease with confirmed diaphragm weakness and severe obstructive sleep apnea. Previously only requiring respiratory support at night, 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.

24. In May 2023, Plaintiff's doctors submitted a coverage request for procedure code E0466 – "Home ventilator, any type, used with noninvasive interface, (e.g., mask, chest shell)". On May 24, 2023, UnitedHealth sent a letter to Plaintiff stating that the ventilator was not a Covered Service. According to the Durable Medical Equipment section of Plaintiff's plan, "Benefits are available only for the equipment that meets the minimum specifications for your needs". UnitedHealth's May 24 denial letter states, "This home breathing machine request does not meet your health plan criteria because it exceeds what is needed for your care". UnitedHealth determined, based on its own criteria, that Plaintiff did not need the level of respiratory support that his doctors prescribed for him based on their medical expertise and knowledge of his health needs. This letter acknowledged that UnitedHealth was in possession of Plaintiff's medical records

1 regarding this coverage request.

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

11 **CLASS ACTION ALLEGATIONS**

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

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

28 27. Plaintiff and the class members reserve the right under Federal Rule of Civil

1 Procedure Rule 23(c)(1)(C) to amend or modify the class to include greater specificity, by
2 further division into subclasses, or by limitation to particular issues.

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

6 **A. Numerosity.**

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

12 **B. Commonality.**

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

- 16 a. Whether United Health's application under MP.009.29 of criteria that are
17 specific to sleep apnea and COPD to ALS patients' requests for coverage for
18 non-invasive home ventilators violates its fiduciary duties under 29 U.S.C. §
19 1104(a);
- 20 b. Whether United Health's application under MP.009.29 of criteria that
21 provide that ventilators are not medically necessary when used for the
22 treatment of a condition wherein interruption of respiratory support would
23 not immediately lead to serious harm or death to ALS patients' requests for
24 coverage for non-invasive home ventilators violates its fiduciary duties
25 under 29 U.S.C. § 1104(a);
- 26 c. Whether United Health's failure to apply medical policies with criteria that
27 are relevant and appropriate to ALS patients' requests for non-invasive
28 home ventilators when making coverage decisions violates its fiduciary

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- duties under 29 U.S.C. § 1104(a);
- d. Whether UnitedHealth violated its duty of loyalty under 29 U.S.C. § 1104(a)(1)(A) by creating MP.009.29 which erroneously classifies the use of non-invasive home ventilators by ALS patients as not medically necessary, thereby categorically excluding coverage under all UnitedHealth plans;
 - e. Whether UnitedHealth violated its duty of loyalty under 29 U.S.C. § 1104(a)(1)(A) by instructing claims personnel to implement MP.009.29 for non-invasive home ventilators claims by ALS patients and to deny those claims on the basis they are not medically necessary, thereby categorically excluding coverage under all UnitedHealth plans;
 - f. Whether UnitedHealth violated its duty of loyalty under 29 U.S.C. § 1104(a)(1)(A) by violating 29 Code of Federal Regulations § 2560.503-1(g)(1)(i) because MP.009.29 provides no rationale as to how treatment with non-invasive home ventilators could be medically necessary based on actual clinical studies and the widespread acceptance of non-invasive home ventilators by the ALS medical community;
 - g. Whether UnitedHealth violated its duty of due care under 29 U.S.C. § 1104(a)(1)(B) by creating MP.009.29 which erroneously classifies the use of non-invasive home ventilators by ALS patients as not medically necessary, thereby categorically excluding coverage under all UnitedHealth plans;
 - h. Whether UnitedHealth violated its duty of due care under 29 U.S.C. § 1104(a)(1)(B) by instructing claims personnel to implement MP.009.29 for non-invasive home ventilators claims by ALS patients and to deny those claims on the basis they are not medically necessary, thereby categorically excluding coverage under all UnitedHealth plans;
 - i. Whether UnitedHealth violated its duty of due care under 29 U.S.C. § 1104(a)(1)(B) by violating 29 Code of Federal Regulations § 2560.503-1(g)(1)(i) because MP.009.29 provides no rationale as to how treatment with

1 non-invasive home ventilators could be medically necessary based on actual
2 clinical studies and the widespread acceptance of non-invasive home
3 ventilators by the ALS medical community;

4 j. Whether UnitedHealth violated its duty to comply with plan terms under 29
5 U.S.C. § 1104(a)(1)(D) by creating MP.009.29 which erroneously classifies
6 the use of non-invasive home ventilators by ALS patients as not medically
7 necessary, thereby categorically excluding coverage under all UnitedHealth
8 plans;

9 k. Whether UnitedHealth violated its duty to comply with plan terms under 29
10 U.S.C. § 1104(a)(1)(D) by instructing claims personnel to implement
11 MP.009.29 for requests for non-invasive home ventilators by ALS patients
12 and to deny those claims on the basis they are not medically necessary,
13 thereby categorically excluding coverage under all UnitedHealth plans;

14 l. Whether UnitedHealth violated its duty to comply with plan terms under 29
15 U.S.C. § 1104(a)(1)(D) by violating 29 Code of Federal Regulations §
16 2560.503-1(g)(1)(i) because MP.009.29 provides no rationale as to how
17 treatment with non-invasive home ventilators could be medically necessary
18 based on actual clinical studies and the widespread acceptance of non-
19 invasive home ventilators by the ALS medical community.

20 m. Whether UnitedHealth's wrongful actions caused the deprivation of benefits
21 under UnitedHealth plans for participants and their beneficiaries and
22 increased the reasonable expenses of administering the plan because the
23 systemic denials of claims for non-invasive home ventilators made by ALS
24 patients has resulted in loss of benefits, needless appeals, and other
25 expenses.

26 **C. Typicality.**

27 31. Plaintiff's claims are typical of the claims of the members of the proposed
28 class because all members of the class had coverage for their requests for non-invasive

1 home ventilators denied as part of United Health’s policy and practice of wrongfully
2 applying Medical Policy MP.009.29 to ALS patients’ requests for non-invasive home
3 ventilators. Plaintiff and all members of the class are similarly affected by UnitedHealth’s
4 wrongful conduct.

5 **D. Adequacy of representation.**

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

10 **E. Superiority of class action.**

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

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

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

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

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

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

28 //

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)]

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

6 39. 29 U.S.C. § 1132(a)(1)(B) entitles Plaintiff to recover benefits due and to
7 enforce and clarify his rights to the benefits at issue.

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

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

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

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

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

26 45. Based on the foregoing, Plaintiff and the class members seek reevaluation
27 and reprocessing of their requests for non-invasive ventilators without the requirement of
28 showing medical necessity under Medical Policy MP.009.29 and instead under appropriate

1 and valid medical criteria; a clarification of future rights; and attorneys' fees.

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3 **SECOND CLAIM FOR RELIEF**
4 **BREACH OF FIDUCIARY DUTY AND EQUITABLE RELIEF UNDER AN**
5 **ERISA PLAN [29 U.S.C. § 1132(a)(3)]**

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

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

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

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

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

22 51. Pursuant to its policy and practice, UnitedHealth denied Plaintiff's request
23 for treatment with a non-invasive ventilator on the basis that the use of such ventilators is
24 not medically necessary. However, the use of a non-invasive ventilator for patients
25 suffering from ALS is medically necessary under the pertinent plan provisions. Non-
26 invasive ventilators have been scientifically proven to not only prolong the life of the
27 patient, but to prolong the time the patient can live without the use of invasive ventilation,
28 in the form of tracheostomy.

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

4 a. for the exclusive purpose of:

5 i. providing benefits to participants and their beneficiaries; and

6 ii. defraying reasonable expenses of administering the plan;

7 b. with the care, skill, prudence, and diligence under the circumstances then
8 prevailing that a prudent man acting in a like capacity and familiar with such
9 matters would use in the conduct of an enterprise of a like character and
10 with like aims; and

11 c. in accordance with the documents and instruments governing the plan
12 insofar as such documents and instruments are consistent with provisions of
13 this subchapter and subchapter III.

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

26 54. UnitedHealth violated its duty of due care under 29 U.S.C. § 1104(a)(1)(B)
27 by: (a) creating MP.009.29 that erroneously classifies the use of NIV by ALS patients as
28 not medically necessary and excluded under all UnitedHealth plans, as alleged herein; (b)

1 instructing claims personnel to implement MP.009.29 for NIV claims and to deny those
2 claims on the basis they are not medically necessary and excluded; and (c) violating 29
3 Code of Federal Regulations § 2560.503-1(g)(1)(i) because MP.009.29 provides no
4 rationale as to how treatment with NIV could be not medically necessary based on actual
5 clinical studies and the widespread acceptance of NIV by the ALS medical community.

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

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

- 17 a. An order declaring that UnitedHealth's denials of NIV claims for ALS
18 patients as not medically necessary under MP.009.29 were wrong and
19 improper and that UnitedHealth has violated 29 Code of Federal Regulations
20 §§ 2560.503-1(g)(1)(i) and (g)(1)(v)(B);
- 21 b. A class-wide injunction requiring UnitedHealth to retract that portion of
22 MP.009.29 it uses to deny requests for NIV for ALS patients as not
23 medically necessary;
- 24 c. A class-wide injunction requiring UnitedHealth to provide notice to all class
25 members, in the form and manner required by ERISA, of the retraction;
- 26 d. A class-wide injunction requiring UnitedHealth to stop violating 29 Code of
27 Federal Regulations §§ 2560.503-1(g)(1)(i) and (g)(1)(v)(B);
- 28 e. Plaintiff is not seeking any relief in this Second Claim for Relief under 29

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U.S.C. § 1132(a)(3) that is duplicative of the relief sought in the First Claim for Relief under 29 U.S.C. § 1132(a)(1)(B). However, if it is determined that the reprocessing relief sought in the First Claim for Relief cannot be awarded because such relief is more appropriately sought in the Second Claim for Relief, then Plaintiff requests in the claim a reprocessing of the denied requests for NIV with appropriate instructions for reprocessing;

- f. Surcharge, i.e., an accounting of any profits made by UnitedHealth from the monies representing the improperly denied claims and disgorgement of any profits;
- g. Such other equitable and remedial relief as the Court may deem appropriate; and
- h. Attorneys’ fees in an amount to be proven.

REQUEST FOR RELIEF

Wherefore, Plaintiff and the class members pray for judgment against UnitedHealth as follows:

- 1. Reevaluation and reprocessing of the class members’ requests for non-invasive home ventilation with appropriate instructions for reprocessing;
- 2. A clarification of rights to future benefits under the plan for all class members;
- 3. Interest;
- 4. Injunctive and declaratory relief, as described above;
- 5. An accounting of any profits made and retained through the improper denial of claims and disgorgement of any profits (surcharge);
- 6. Attorneys’ fees; and
- 7. Such other equitable and remedial relief as the Court may deem just and proper.

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DATED: May 29, 2024

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DATED: May 29, 2024

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