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MARIE FORTIER,
on behalf of herself and all others
similarly situated

UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

MARIE FORTIER, on behalf of herself and all others similarly situated, Plaintiff, v. ANTHEM, INC.; ANTHEM UM SERVICES, INC., Defendants.	Case No.: 2:20-cv-4952 **CLASS ACTION** **COMPLAINT FOR BENEFITS, DETERMINATION OF RIGHTS AND BREACH OF FIDUCIARY DUTY UNDER ERISA**

Plaintiff, Marie Fortier, on behalf of herself and all others similarly situated, herein sets forth the allegations of her Complaint against Defendants Anthem, Inc. and Anthem UM Services, Inc. ("Anthem UM").

INTRODUCTION

1. Defendant Anthem, Inc. states that "[w]e are one of the largest health benefits companies in the United States in terms of medical membership, serving approximately 40 million medical members through our affiliated health plans as of December 31, 2018."[1] Anthem, Inc. owns "Blue" organizations in California and many other states, as well as other subsidiaries.[2] Through its wholly-owned subsidiaries, including Anthem UM, Anthem, Inc. acts as a fully integrated company that is in the business of insuring and/or administering group health plans within the meaning of 29 Code of Federal Regulations § 2560.503-1(m) (both fully insured and self-insured), most of which are employer-sponsored and governed by the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001, *et seq*. Those ERISA-governed group health plans are hereinafter referred to as "Anthem plans."

2. With respect to all Anthem plans, Anthem UM serves as the claims administrator, responsible for determining whether claims are covered and effectuating any resulting benefit payment. Anthem, Inc. aids Anthem UM in its administrative duties by, among other things, participating with Anthem UM in the development of coverage guidelines, collaborating with Anthem UM on decisions regarding the types of claims that will be approved or denied, including the denial of the claims alleged herein, and assisting Anthem UM in carrying out its various other administrative

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[1] Anthem Inc.'s 2019 Securities and Exchange Commission Form 10-K.

[2] Anthem, Inc. and its subsidiaries operate under the "Blue" moniker in California, Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, Nevada, New Hampshire, New York, Ohio, Virginia and Wisconsin. Anthem also conducts business through subsidiaries such as Amerigroup, Simply Healthcare Holdings, HealthLink, UniCare, and CareMore Health Group, Inc.

duties. As such, Defendants Anthem, Inc. and Anthem UM (jointly "Anthem") have acted as ERISA fiduciaries with respect to all Anthem plans, including Plaintiff's plan.

3. Plaintiff brings this action to address Anthem's practice of improperly denying claims for percutaneous neuromodulation therapy devices made by members under Anthem plans.

JURISDICTION AND VENUE

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

5. The Court has personal jurisdiction over Defendants because ERISA provides for nationwide service of process, and each Defendant has minimum contacts with the United States. 29 U.S.C. § 1132(e)(2).

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

THE PARTIES

7. Plaintiff was at all relevant times covered under an employer-sponsored benefit plan regulated by ERISA and pursuant to which Plaintiff is entitled to health care benefits. Plaintiff resides in San Diego County.

8. Anthem, Inc. and Anthem UM are corporations with their principal place of business in Indianapolis, Indiana. They administer and make benefit determinations related to ERISA group health care plans around the country. Anthem UM denied Plaintiff's claim from its Los Angeles County office within this District.

9. Anthem, Inc. and Anthem UM do not operate independently and in their own interests, but serve solely to fulfill the purpose, goals and policies of each other.

SUBSTANTIVE ALLEGATIONS

A. Percutaneous neuromodulation therapy (PNT) devices.

10. Following orthopedic trauma and/or surgery, pain is a primary source of disability that inhibits rehabilitation and limits a patient's return to the activities of daily living. One of the primary treatments for trauma and postoperative pain is opioids, which can result in misuse, addiction, and debilitating side effects that often interfere with function, activities of daily living, and physical rehabilitation. In addition, patients who undergo the most painful orthopedic surgeries often use opioids for several weeks following surgery. Such long-term use of opioids increases the risks of addiction, dependence, use of illicit substances (e.g., heroin), overdose, and death. Opioids kill nearly 42,000 people each year,

11. PNT is a nondrug therapy that treats pain through a form of electrical nerve stimulation. The treatment is accomplished through use of a PNT device that consists of fine needles with electrodes temporarily implanted percutaneously to target nerves that innervate the region of pain. The lead is connected to an external stimulator, and the therapy is designed to deliver selective stimulation of pain-relieving fibers to avoid the induction of unwanted muscle contractions, muscle weakness, and reduced proprioception.

12. PNT with an FDA-approved device has been shown to be a safe and effective treatment for intractable pain. The PNT devices referenced herein have received United States Food and Drug Administration (FDA) approval for the treatment of chronic pain and acute pain, including postoperative and post-traumatic pain. Clinical evidence that supports effectiveness and safety of PNT devices is strong. There are at least 20 randomized controlled trials demonstrating that PNT treatments for musculoskeletal pain are safe and effective. PNT devices are currently in use as a standard clinical practice in treating chronic pain.

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B. Anthem's wrongful denial of FDA-approved PNT devices.

13. Anthem plans cover surgical and hospital services on both an inpatient and outpatient basis to treat illness and injury. They provide for payment for the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body. As part of these benefits, Anthem plans cover the treatment of pain resulting from illness or injury.

14. In reviewing and deciding claims under Anthem plans, Anthem utilizes internal coverage guidelines called "Medical Policies."

15. Anthem plans exclude from coverage those medical services that Anthem considers "investigational." A Medical Policy entitled "Investigational Criteria ADMIN.00005" sets forth criteria Anthem uses in deciding whether a particular claim for medical services is investigational. It provides in pertinent part:

> "Investigational" means that the procedure, treatment, supply, device, equipment, facility or drug (all services) does not meet the Company Technology Evaluation Criteria because it does not meet one or more of the following criteria:
>
> - have final approval from the appropriate government regulatory body; or
> - have the credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community which permits reasonable conclusions concerning the effect of the procedure, treatment, supply, device, equipment, facility or drug (all services) on health outcomes; or
> - be proven materially to improve the net health outcome; or
> - be as beneficial as any established alternative; or
> - show improvement outside the investigational settings.
>
> In addition to the above criteria, the Medical Policy & Technology Assessment Committee (MPTAC) will consider recommendations of national physician specialty societies, nationally recognized professional healthcare organizations and public health agencies, and in its sole discretion, may consider other relevant factors, including information from the practicing community.

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16. Anthem has developed Medical Policies with respect to certain types of medical treatments. Many of the Medical Policies identify treatments that Anthem has decided are investigational. Anthem follows these Medical Policies when deciding claims made under Anthem plans.

17. One such Medical Policy is Anthem's Medical Policy for Electrical Stimulation as a Treatment for Pain and Related Conditions: Surface and Percutaneous Devices, DME.00011 ("DME.00011"). It provides in pertinent part:

> Investigational and Not Medically Necessary:
> …
> VI. Percutaneous neuromodulation therapy is considered investigational and not medically necessary for all indications.

18. Relying on DME.00011, Anthem has followed a consistent practice of denying claims for FDA-approved PNT devices as investigational.

19. Contrary to Anthem's coverage directive, PNT with an FDA-approved device is not investigational. These devices have been shown to be a safe and effective treatment for pain and eliminate the need for the long-term use of harmful drugs. The PNT devices referenced herein have received FDA approval for the treatment of chronic pain and acute pain, including postoperative and post-traumatic pain. Clinical evidence that supports effectiveness and safety of PNT devices is strong. There are at least 20 randomized controlled trials demonstrating that PNT treatments for musculoskeletal pain are safe and effective. PNT devices are currently in use as a standard clinical practice in treating chronic pain.

C. Anthem's denial of Marie Fortier's claim.

20. At all relevant times, Plaintiff was covered under an ERISA group health plan that was arranged by her husband's employer, Granite Construction, Inc. ("Plaintiff's Anthem plan"). This ERISA group health plan was at all relevant times administered by Anthem.

21. Like all Anthem plans, Plaintiff's Anthem plan covers health services to treat illnesses and injuries. It is an ERISA group health plan because it is arranged by

her husband's employer for the benefit of its employees and their dependents. It provides payment for the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body.

22. Among other services, Plaintiff's Anthem plan covers physician services, medical supplies, and equipment, including services for:

> 8. Pharmaceuticals, medical equipment, and supplies necessary for the management of your condition. Oxygen and related respiratory therapy supplies.
> …
> 10. Palliative care (care which controls pain and relieves symptoms, but does not cure) which is appropriate for the illness.
> …
> Durable Medical Equipment. Rental or purchase of dialysis equipment; dialysis supplies. Rental or purchase of other medical equipment and supplies which are:
>
> 1. Of no further use when medical needs end;
> 2. For the exclusive use of the patient;
> 3. Not primarily for comfort or hygiene;
> 4. Not for environmental control or for exercise; and
> 5. Manufactured specifically for medical use.

23. Plaintiff's Anthem plan excludes from coverage treatment for services that are investigational.

24. Plaintiff has a history of right knee osteoarthritis and has undergone surgeries for this problem starting with a knee replacement and reconstruction in 2014, a revision in 2015, then another in 2016.

25. As a result of these conditions, Plaintiff has experienced chronic right knee pain for which she has received treatment at the USC Chronic Pain Center at the Keck USC Medical Center. Physicians at the USC Chronic Paid Center have provided various forms of treatment to allow Plaintiff to function, including the prescription of opioids.

26. The physicians at the USC Chronic Pain Center recommended that Plaintiff undergo a seven-day trial of the FDA-approved Stimwave PNT device to address her chronic right knee pain.

27. Plaintiff underwent the seven-day trial with the device and experienced relief that allowed her to discontinue the use of opioids during that time. A request was then made of Anthem to approve the use of the Stimwave device for Plaintiff on a permanent basis.

28. On January 22, 2020, Anthem UM sent a letter to Plaintiff's physician denying coverage for the Stimwave device on the basis it was "investigational" under DME:00011.

> This isn't the news you want to hear, but we can't approve your request. Here's why. The review showed that what you've requested is Investigational. Your plan doesn't cover that kind of care. …
>
> The request tells us your doctor ordered an electrical treatment (stimwave) for your pain. This treatment is not approvable under the plan clinical criteria because there is not enough proof it health (*sic*). It is not covered under the medical policy. For this reason, this request is denied as investigational and not medically necessary. It may help your doctor to know we reviewed this request using the plan medical policy called Electrical Stimulation as a Treatment for Pain and Related Conditions: Surface and Percutaneous Devices (DME.00011).

29. Plaintiff appealed this decision. In connection with her appeal, Plaintiff's physicians at the USC Chronic Pain Center, who are experts in pain management, advised Anthem that Plaintiff had, in fact, experienced substantial pain relief with the Stimwave device that allowed her to stop the use of opioids. The physicians further advised Anthem of clinical studies that had found such devices to be safe and effective.

30. On February 24, 2020, Anthem UM denied the appeal from its Los Angeles address, again relying on DME:00011.

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> We cannot approve your request for 64555 I-Percutaneous Implantation Of Neurostimulator Electrodes; Per ** Exception And 64590-Insertion/Rplcmt Peripher Al/Gastric NPGR at this time. Based on the approval criteria for your plan (Anthem Medical Policy Subject: Electrical Stimulation as a Treatment for Pain and Related Conditions: Surface and Percutaneous Devices, Document #:DME.00011), this service is considered an experimental/investigational treatment for your condition (knee pain). This service has not yet been proven to be safe and effective for the treatment of your symptoms in comparison to standard therapy in accord with the medical studies reviewed in the approval criteria for your plan. This decision is based on the health plan's Clinical Guideline/Medical Policy for DME.00011) Electrical Stimulation as a Treatment for Pain and Related Conditions: Surface and Percutaneous Devices.

31. Plaintiff has been unable to afford the treatment so she lives in constant pain while requiring the use of drugs for temporary relief.

CLASS ACTION ALLEGATIONS

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

> All persons covered under ERISA health plans, self-funded or fully insured, that are administered by Anthem and whose claims for an FDA-approved percutaneous neuromodulation therapy device were denied on the basis the treatment is investigational.

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

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

A. Numerosity.

35. The potential members of the proposed class as defined are so numerous

that joinder of all the members of the proposed class is impracticable. While the precise number of proposed class members has not been determined at this time, Plaintiff is informed and believes that there are a substantial number of individuals covered under Anthem plans who have been similarly affected.

B. Commonality.

36. Common questions of law and fact exist as to all members of the proposed class.

C. Typicality.

37. The claims of the named Plaintiff are typical of the claims of the proposed class. Plaintiff and all members of the class are similarly affected by Anthem's wrongful conduct.

D. Adequacy of representation.

38. Plaintiff will fairly and adequately represent and protect the interests of the members of the proposed class. Counsel who represent Plaintiff are competent and experienced in litigating large and complex class actions, including class actions against health plans such as Anthem.

E. Superiority of class action.

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

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

F. Rule 23(b) requirements.

41. Inconsistent or varying adjudications with respect to individual members

of the class would establish incompatible standards of conduct for Anthem.

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

43. Anthem has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole.

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)]

44. Plaintiff and the class members repeat and re-allege each and every allegation set forth in all of the foregoing paragraphs as if fully set forth herein.

45. 29 U.S.C. § 1132(a)(1)(B) entitles Plaintiff to recover benefits due and to enforce and clarify her rights to the benefits at issue.

46. As alleged herein, Plaintiff's Anthem plan provides surgical and hospital services on both an inpatient and outpatient basis to treat illness and injury, including coverage for medical equipment, palliative care, and durable medical equipment.

47. As alleged herein, Plaintiff requested that Anthem authorize coverage for a Stimwave device to treat her chronic right knee pain that was recommended by her physicians at the USC Chronic Pain Center.

48. As alleged herein, Anthem has followed a practice of denying claims for FDA-approved PNT devices on the basis the treatment is investigational pursuant to Anthem's coverage guideline, DME.00011.

49. Pursuant to its practice, Anthem denied Plaintiff's request for an FDA-approved PNT device on the basis the treatment is investigational. The treatment is not investigational. The Stimwave device has been approved by the FDA for the treatment of chronic pain and acute pain, including postoperative and post-traumatic pain. PNT with an FDA-approved device has been shown to be a safe and effective treatment for

pain. Clinical evidence that supports effectiveness and safety of PNT devices is strong. There are at least 20 randomized controlled trials demonstrating that PNT treatments for musculoskeletal pain are safe and effective. PNT devices are currently in use as a standard clinical practice in treating chronic pain.

50. Plaintiff has exhausted her administrative remedies, as alleged above.

51. Based on the foregoing, Plaintiff and the class members seek the payment of medical expenses, interest thereon, a clarification of rights, and attorney fees.

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

52. Plaintiff and the class members repeat and re-allege each and every allegation set forth in all of the foregoing paragraphs as if fully set forth herein.

53. As alleged herein, Anthem has acted as an ERISA fiduciary with respect to the administration and claims decisions under Anthem plans and, in particular, has acted as an ERISA fiduciary in denying claims for PNT devices, as alleged herein.

54. As alleged herein, Plaintiff's Anthem plan provides surgical and hospital services on both an inpatient and outpatient basis to treat illness and injury, including coverage for medical equipment, palliative care, and durable medical equipment.

55. As alleged herein, Plaintiff requested that Anthem authorize coverage for an FDA-approved PNT device to treatment her chronic right knee pain that was recommended by her physicians at the USC Chronic Pain Center.

56. As alleged herein, Anthem has followed a practice of denying claims for FDA-approved PNT devices on the basis the treatment is investigational pursuant to Anthem's coverage directive in DME.00011.

57. Pursuant to its practice, Anthem denied Plaintiff's claim for an FDA-approved PNT device on the basis the treatment is investigational. The treatment is not investigational. The Stimwave device has been approved by the FDA for the treatment of chronic pain and acute pain, including postoperative and post-traumatic pain. PNT with an FDA-approved device has been shown to be a safe and effective treatment for

pain. Clinical evidence that supports effectiveness and safety of PNT devices is strong. There are at least 20 randomized controlled trials demonstrating that PNT treatments for musculoskeletal pain are safe and effective. PNT devices are currently in use as a standard clinical practice in treating chronic pain.

58. Pursuant to 29 U.S.C. § 1104(a), Anthem was required to discharge its fiduciary duties with respect to Anthem plans solely in the interest of the participants and beneficiaries and--

(A) for the exclusive purpose of:

(i) providing benefits to participants and their beneficiaries; and

(ii) defraying reasonable expenses of administering the plan;

(B) with the care, skill, prudence, and diligence under the circumstances then prevailing that a prudent man acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims;

... and

(D) in accordance with the documents and instruments governing the plan insofar as such documents and instruments are consistent with the provisions of this subchapter and subchapter III.

59. Anthem violated its duty of loyalty under 29 U.S.C. § 1104(a)(1)(A) by: (a) creating DME.00011 that erroneously classifies FDA-approved PNT devices as investigational and excluded under all Anthem plans, as alleged herein; (b) instructing claims personnel to implement DME.00011 for claims for FDA-approved PNT devices and to deny those claims on the basis they are investigational; and (c) violating 29 Code of Federal Regulations § 2560.503-1(g)(1)(i) because DME.00011 provides no rationale as to how PNT with an FDA-approved device could be investigational based on actual clinical studies and the widespread acceptance of the devices by the medical community. These actions by Anthem cause the deprivation of benefits under Anthem plans for participants and their beneficiaries and increase the reasonable expenses of

administering the plan because they cause a systematic denial of claims for FDA-approved PNT devices resulting in loss of benefits, needless appeals, and other expenses.

60. Anthem violated its duty of due care under 29 U.S.C. § 1104(a)(1)(B) by: (a) creating DME.00011 that erroneously classifies FDA-approved PNT devices as investigational and excluded under all Anthem plans, as alleged herein; (b) instructing claims personnel to implement DME.00011 for claims for FDA-approved PNT devices and to deny those claims on the basis they are investigational; and (c) violating 29 Code of Federal Regulations § 2560.503-1(g)(1)(i) because DME.00011 provides no rationale as to how PNT with an FDA-approved device could be investigational based on actual clinical studies and the widespread acceptance of the devices by the medical community.

61. Anthem violated its duty to comply with plan terms under 29 U.S.C. § 1104(a)(1)(D) by: (a) creating DME.00011 that erroneously classifies FDA-approved PNT devices as investigational and excluded under all Anthem plans, as alleged herein; (b) instructing claims personnel to implement DME.00011 for claims for FDA-approved PNT devices and to deny those claims on the basis they are investigational; and (c) violating 29 Code of Federal Regulations § 2560.503-1(g)(1)(i) because DME.00011 provides no rationale as to how PNT with an FDA-approved device could be investigational based on actual clinical studies and the widespread acceptance of the devices by the medical community.

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

a. An order declaring that Anthem's denials of claims for FDA-approved PNT devices as investigational were wrong and improper;

b. A class-wide injunction requiring Anthem to retract Medical Policy DME.00011 that erroneously classifies claims for FDA-approved PNT devices as investigational;

c. A class-wide injunction requiring Anthem to reform its claims adjudication process so as to adjudicate future claims without the erroneous "investigational" denial basis under appropriate and valid medical criteria and to reevaluate and reprocess prior denials without the erroneous "investigational" denial basis under appropriate and valid medical criteria;

d. A class-wide injunction requiring Anthem to provide notice of the reformation of its claims adjudication process for such claims in the form and manner required by ERISA to all class members;

e. Surcharge, i.e., an accounting of any profits made by Anthem from the monies representing the improperly denied claims and disgorgement of any profits;

f. Such other equitable and remedial relief as the Court may deem appropriate; and

g. Attorneys' fees in an amount to be proven.

REQUEST FOR RELIEF

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

1. Benefits denied Plaintiff in an amount to be proven at trial, including interest;

2. A clarification of rights to future benefits under the plan for all class members;

3. Injunctive and declaratory relief, as described above;

4. An accounting of any profits made and retained through the improper denial of claims and disgorgement of any profits (surcharge);

5. Attorneys' fees; and

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6. Such other equitable and remedial relief as the Court may deem just and proper.

DATED: June 4, 2020

GIANELLI & MORRIS

By: /s/ Adrian J. Barrio
ROBERT S. GIANELLI
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ClassAction.org

This complaint is part of ClassAction.org's searchable class action lawsuit database and can be found in this post: Class Action Claims Anthem Wrongfully Denied Coverage for FDA-Approved, Pain-Treating Electrical Nerve Stimulation Device