

1 Plaintiff Andrew Howard on behalf of himself and all others similarly situated,
2 set forth herein the allegations of his Complaint against Defendant Aetna Life
3 Insurance Company.

4 **INTRODUCTION**

5 1. Defendant Aetna Life Insurance Company (“Aetna”) is in the business of
6 insuring and/or administering group health plans within the meaning of 29 Code of
7 Federal Regulations § 2560.503-1(m) (both fully insured and self-insured), most of
8 which are employer-sponsored and governed by the Employee Retirement Income
9 Security Act of 1974 (“ERISA”), 29 U.S.C. § 1001, *et seq.* Those ERISA-governed
10 group health plans are hereinafter referred to as “Aetna plans.”

11 2. Plaintiff brings this action to address Aetna’s repeated violations of
12 ERISA resulting from its systemic practice of denying services for lumbar artificial
13 disc replacement surgery (L-ADR) on the basis that such services are “experimental
14 and investigational.” Aetna has developed and used a coverage policy, the Clinical
15 Policy Bulletin “Intervertebral Disc Prostheses,” that it uses when deciding claims for
16 L-ADR. That Policy Bulletin provides that lumbar ADR is experimental and
17 investigational and, therefore, excluded in all circumstances. Aetna has systematically
18 denied all requests for L-ADR as experimental and investigational under this Clinical
19 Policy Bulletin. Contrary to Aetna’ position, L-ADR has been approved by The United
20 States Food and Drug Administration (“FDA”) for over fifteen years and is a safe,
21 effective, and often recommended procedure that has successfully treated the
22 symptoms of lumbar disc disease.

23 **JURISDICTION AND VENUE**

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

1 FDA Premarket Approval on August 14, 2006 for use in patients who have single-level
2 degenerative disc disease of the lumbar spine (L3-S1). The activL device received
3 FDA Premarket Approval on June 11, 2015, also for use in patients who have single-
4 level degenerative disc disease of the lumbar spine (L4-L5 or L5-S1).

5 11. The FDA's Premarket Approval process is rigorous and applies to all
6 Class III medical devices such as the PRODISC-L and the activL. Class III medical
7 devices are devices which, by definition, present significant risks to human health.
8 These devices must therefore meet the FDA's most stringent safety standards before
9 they are approved for commercial sale and distribution. These include sufficient
10 controlled clinical trial evidence to ensure that a given device is safe and effective. *See*
11 *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317-318, 322-323 (2008).

12 12. There have been numerous published peer-reviewed articles of controlled
13 clinical trials establishing that L-ADR with an FDA-approved device is safe and
14 effective. L-ADR is widely recognized in the medical community and by providers
15 throughout the nation as a viable, safe and effective treatment for degenerative disc
16 disease. Artificial disc devices have been used in thousands of spinal arthroplasties and
17 have been proven to be safe and effective in the treatment of degenerative disc disease.
18 Medical societies such as the North American Spine Society have endorsed the surgery
19 and it is performed at leading medical centers across the country. All major health
20 insurers other than Aetna (Anthem, United HealthCare, Humana, Cigna) cover the
21 surgery.

22 **B. Aetna's categorical denial of requests for L-ADR**

23 13. Aetna plans are either fully insured (i.e., funded by Aetna) or self-insured
24 (funded by the employer). Regardless of which entity funds the plan, Aetna acts as the
25 claims administrator. If the plan is self-funded, Aetna will enter into an administrative
26 services agreement with the plan's employer-sponsor to perform critical claims
27 handling functions, including the functions of adjudicating claims and utilization
28 management

1 14. Aetna plans cover surgical and hospital services to treat illness and injury,
2 including services for surgery on both an inpatient and outpatient basis.

3 15. Aetna plans exclude from coverage those medical services that Aetna
4 considers “experimental and investigational.”

5 16. Aetna has developed internal Clinical Policy Bulletins ("CPB"), that is,
6 written directives on coverage positions Aetna takes with respect to certain medical
7 treatments.

8 17. Aetna's CPB 0591, “Intervertebral Disc Prostheses,” sets forth Aetna’s
9 coverage position on L-ADR. It provides in pertinent part:

10 Aetna considers lumbar prosthetic intervertebral discs (e.g., the activL
11 Artificial Disc, the Charité Artificial Disc, and the ProDisc-L Total Disc
12 Replacement) experimental and investigational for lumbosacral
degenerative disc disease and for all other indications.

13 18. Pursuant to CPB 0591, Aetna has denied all requests for L-ADR on the
14 basis that L-ADR is “experimental and investigational.” Aetna denies coverage for L-
15 ADR regardless of the member’s medical profile or medical need. Aetna denies
16 coverage for L-ADR upon the initial request for the surgery and on any appeal taken
17 on the identical basis, that L-ADR is experimental and investigational.

18 **C. Aetna’s denial of Plaintiff Andrew Howard’s request for L-ADR**

19 19. At all relevant times, Plaintiff Andrew Howard was covered under an
20 ERISA group health plan, an Aetna Open Access Managed Choice High Deductible
21 Health Plan, offered under ADP Total Source, Inc., a certified professional
22 employer organization, through his employer, Shamrock Capital Advisors (“Howard
23 Aetna Plan”).

24 20. Howard’s ERISA group health plan is a fully-insured plan, i.e., insured
25 and administered at all relevant times by Aetna.

26 21. Like all Aetna plans, the Howard Aetna Plan covers health services to
27 treat illnesses and injuries. It is an ERISA group health plan because it is arranged by
28 his employer for the benefit of its employees and their dependents. It provides payment

1 for the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid
2 for the purpose of affecting any structure or function of the body.

3 22. Among other services, the Howard Aetna Plan covers surgical services
4 performed in a surgical center or hospital.

5 **Outpatient Surgery**

6 **Covered services** include services provided and supplies used in
7 connection with outpatient **surgery** performed in a surgery center or a
8 **hospital's** outpatient department

9 **Physician Services**

10 **Covered services** include services by your **physician** to treat an illness
11 or injury. You can get services:

- 12 • At the **physician's** office
- 13 • In your home
- 14 • In a **hospital**
- 15 • From any other inpatient our outpatient facility
- 16 • By way of **telemedicine**.

17 **Hospital Care**

18 **Covered services** include inpatient and outpatient **hospital** care.

19 23. The Howard Aetna Plan contains an exclusion for services that are
20 "Experimental or Investigational."

21 24. Plaintiff suffered from disc disease at the L5-S1 level of his lumbar
22 spine that caused Plaintiff significant pain and immobility. Conservative measures
23 such as medication and corrective exercises did not help to relieve these symptoms
24 or the further degeneration of Plaintiff's spine condition.

25 25. After confirming Plaintiff's condition on MRI, and conducting a
26 history and physical of Plaintiff, his surgeon, Robert Bray, M.D., recommended that
27 Plaintiff undergo L-ADR. Plaintiff elected to proceed with the procedure.

28 26. Request was made of Aetna to preauthorize L-ADR for Plaintiff.

29 27. On November 10, 2021, Aetna advised Plaintiff that it was denying his
30 request for L-ADR because it was experimental and investigational pursuant to CPB
31 0591. Aetna stated:

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33 ///

1 We reviewed information received about your condition and
2 circumstances. We used the Clinical Policy Bulletin (CPB):
3 Intervertebral Disc Prostheses. Based on CPB criteria and the information
4 we have, we are denying coverage for L5-S1 anterior disk replacement
5 with Active-L. Clinical studies have not proven that this service is
6 effective for treatment of the member's condition.

7 28. Plaintiff and his physician appealed this decision. On December 2, 2021
8 2019, Aetna rejected the appeal and affirmed its initial denial of Plaintiff's request for
9 L-ADR surgery pursuant to CPB 0591 on the basis that L-ADR is experimental and
10 investigational.

11 29. In making its determination on Plaintiff's initial request for L-ADR and its
12 determination of Plaintiff's appeal, the only reason given by Aetna for rejecting the
13 claim was that it deemed L-ADR experimental and investigational under CPB 0591.

14 30. As a result of Aetna's rejection of his claim, Plaintiff paid for L-ADR out
15 of his own pocket.

16 **D. *Hendricks v. Aetna Life Insurance Company***

17 31. In *Hendricks v. Aetna Life Insurance Company*, Case No.: 2:19-cv-
18 06840 CRC (MRWx), a pending federal action venued in the Central District of
19 California, plaintiffs Brian Hendricks and Andrew Sagalongos allege that Aetna
20 violated ERISA by systematically and categorically denying requests for lumbar
21 ADR surgery on the ground it is "experimental and investigational." The *Hendricks*
22 action was filed on August 7, 2019.

23 32. On June 11, 2021, the court certified a class consisting of Aetna
24 members whose claims are governed by the *abuse of discretion* standard of review
25 under ERISA. The court did not include in the class those Aetna members insureds
26 whose plans are subject to a *de novo* standard of the review on the basis that the
27 Hendricks plaintiffs' claims, subject to an abuse of discretion standard, were not
28 typical of their claims.

33. California Insurance Code section 10110.6 voids discretionary clauses
in fully-insured health insurance policies that provide coverage to California

1 residents, regardless where the plan was issued. Aetna takes that position members
2 of fully-insured plan in states that ban discretionary clauses, such as California, are
3 subject to *de novo* review, and hence, claims for lumbar ADR arising under them
4 fall outside of the *Hendricks* class.

5 CLASS ACTION ALLEGATIONS

6 34. Plaintiff brings this action on behalf of himself and all others similarly
7 situated as a Class Action pursuant to Federal Rules of Civil Procedure Rule 23.
8 Pursuant to Rule 23(b)(1) and (b)(2), Plaintiff seeks certification of a class defined as
9 follows:

10 All persons covered under Aetna Plans, governed by ERISA and subject
11 to a *de novo* standard of review, whose requests for lumbar artificial disc
12 replacement surgery were denied at any time within the applicable statute
13 of limitations, or whose requests for that surgery will be denied in the
14 future, on the ground that lumbar artificial disc replacement surgery is
15 experimental or investigational.

16 35. Plaintiff and the Class reserve the right under Federal Rule of Civil
17 Procedure Rule 23(c)(1)(C) to amend or modify the class to include greater specificity,
18 by further division into subclasses, or by limitation to particular issues.

19 36. This action has been brought and may be properly maintained as a class
20 action under the provisions of Federal Rules of Civil Procedure Rule 23 because there
21 is a well-defined community of interest in the litigation and the proposed class is easily
22 ascertainable.

23 A. Numerosity

24 37. The potential members of the proposed class as defined are so numerous
25 that joinder of all the members of the proposed class is impracticable. While the
26 precise number of proposed class members has not been determined at this time,
27 Plaintiff is informed and believes that there are a substantial number of individuals
28 covered under Aetna plans who have been similarly affected.

1 **B. Commonality**

2 38. Common questions of law and fact exist as to all members of the proposed
3 class.

4 **C. Typicality**

5 39. The claims of the named Plaintiff are typical of the claims of the proposed
6 class. Plaintiff and all members of the class are similarly affected by Aetna' wrongful
7 conduct.

8 **D. Adequacy of representation**

9 40. Plaintiff will fairly and adequately represent and protect the interests of
10 the members of the proposed class. Counsel who represent Plaintiff are competent and
11 experienced in litigating large and complex class actions.

12 **E. Superiority of class action**

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

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

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

23 43. Inconsistent or varying adjudications with respect to individual members
24 of the class would establish incompatible standards of conduct for Aetna.

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

1 would have been futile due Aetna’s policy that lumbar ADR is experimental and
2 investigational, as determined by the court in *Hendricks*. (*Hendricks*, Dkt. 94 at 13-14.)

3 52. There is now due and owing to Plaintiff benefits, interest, and attorney
4 fees in an amount to be determined at the time of trial.

5 53. On behalf of the class, Plaintiff seeks a clarification of rights relating to
6 Aetna’s categorical denial of L-ADR as experimental and investigational.

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

9 54. Plaintiff and the Class repeat and re-allege each and every allegation set
10 forth in all of the foregoing paragraphs as is fully set forth herein.

11 55. Aetna acts as ERISA fiduciary with respect to the administration and
12 claims decisions under Aetna plans, such as the plans at issue, within the meaning of
13 29 U.S.C. § 1109(a) and 1002(21)(A). With respect to these plans, Aetna exercises
14 discretionary authority or control respecting management of the plans, and exercises
15 authority and control respecting management or disposition of the plans’ assets. Aetna
16 has the authority, and actually exercise the authority, to make decisions on claims for
17 benefits and appeals thereof, and to write checks for benefits.

18 56. As alleged herein, Plaintiff’s Aetna plan provides surgical and hospital
19 services to treat illness and injury. L-ADR is a form of spinal surgery that is covered
20 under Plaintiff’s Aetna plan. Plaintiff requested that Aetna authorize coverage for L-
21 ADR.

22 57. As alleged herein, Aetna categorically denies all requests for L-ADR
23 based upon the position set forth in CPB 0591 that L-ADR surgery is “experimental
24 and investigational” and excluded under all Aetna plans.

25 58. Aetna improperly denied Plaintiff’s requests for L-ADR because, it said,
26 L-ADR is experimental and investigational pursuant to CPB 059 and therefore
27 excluded under Plaintiff’s Aetna plans. Aetna has applied and continues to apply its
28 internal guideline in a manner which restricts access to L-ADR for individuals with

1 degenerative disc disease, a practice wholly inconsistent with the Aetna plans' promise
2 to provide surgical and hospital services to treat illness and injury. Moreover, L-ADR
3 is not experimental or investigational. As alleged herein, L-ADR is a safe and effective
4 treatment and has been approved by the FDA for over fifteen years.

5 59. Pursuant to 29 U.S.C. § 1104(a), Aetna was required to discharge its
6 fiduciary duties with respect to Aetna plans solely in the interest of the participants and
7 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 with
14 like aims;

15 ... and

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

19 60. Aetna violated its duty of loyalty under 29 U.S.C. § 1104(a)(1)(A) by: (a)
20 creating CPB 0591 that erroneously classifies L-ADR surgery as experimental and
21 investigational and excluded under all Aetna plans, in violation of the plans' promise
22 to provide coverage for surgery to treat illness or injury and the terms of the
23 "experimental and investigational" exclusion; (b) instructing claims personnel to
24 implement CPB 0591 for claims for L-ADR and to deny those claims on the basis they
25 are experimental and investigational; and (c) failing to provide or offer to provide an
26 explanation of the scientific or clinical judgment for its "experimental and
27 investigational" denial reason in violation of 29 Code of Federal Regulations §
28 2560.503-1(g)(1)(v)(B) by providing a knowingly biased and incomplete picture of the

1 safety and effectiveness of L-ADR in CPB 0591. These actions by Aetna cause the
2 deprivation of benefits under Aetna plans for participants and their beneficiaries and
3 increase the reasonable expenses of administering the plan because they cause a
4 systematic denial of claims for L-ADR resulting in loss of benefits, needless appeals,
5 and other expenses.

6 61. Aetna violated its duty of due care under 29 U.S.C. § 1104(a)(1)(B) by:
7 (a) creating CPB 0591 that erroneously classifies L-ADR surgery as experimental and
8 investigational and excluded under all Aetna plans, in violation of the plans' promise
9 to provide coverage for surgery to treat illness or injury and the terms of the
10 "experimental and investigational" exclusion; (b) instructing claims personnel to
11 implement CPB 0591 for claims for L-ADR and to deny those claims on the basis they
12 are experimental and investigational; ; and (c) failing to provide or offer to provide an
13 explanation of the scientific or clinical judgment for its "experimental and
14 investigational" denial reason in violation of 29 Code of Federal Regulations §
15 2560.503-1(g)(1)(v)(B) by providing a knowingly biased and incomplete picture of the
16 safety and effectiveness of L-ADR in CPB 0591.

17 62. Aetna violated its duty to comply with plan terms under 29 U.S.C. §
18 1104(a)(1)(D) by: (a) creating CPB 0591 that erroneously classifies L-ADR surgery as
19 experimental and investigational and excluded under all Aetna plans, in violation of the
20 plans' promise to provide coverage for surgery to treat illness or injury and the terms
21 of the "experimental and investigational" exclusion; (b) instructing claims personnel to
22 implement CPB 0591 for claims for L-ADR and to deny those claims on the basis they
23 are experimental and investigational; and (c) failing to provide or offer to provide an
24 explanation of the scientific or clinical judgment for its "experimental and
25 investigational" denial reason in violation of 29 Code of Federal Regulations §
26 2560.503-1(g)(1)(v)(B) by providing a knowingly biased and incomplete picture of the
27 safety and effectiveness of L-ADR in CPB 0591.

28

1 3. Injunctive and declaratory relief for all class members, as described
2 above;

3 4. Surcharge, including an accounting of any profits made by Aetna from the
4 monies representing the improperly denied claims and disgorgement of any profits;

5 5. Pursuant to 29 U.S.C. § 1132(g), payment of all costs and attorney fees
6 incurred in pursuing this action;

7 6. Payment of prejudgment and post-judgment interest as allowed for under
8 ERISA; and

9 7. For such other and further relief as the Court deems just and proper.

10

11 DATED: March 4, 2022

GIANELLI & MORRIS

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