UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. _____

RICHARD COLE,
on behalf of himself and
all others similarly situated,

Plaintiff,

v.

UNITED HEALTHCARE
INSURANCE COMPANY,

Defendant.
_____/

CLASS ACTION COMPLAINT

Plaintiff Richard Cole ("Plaintiff"), individually and on behalf of all others similarly situated, brings this Class Action Complaint against Defendant United Healthcare Insurance Company ("UHC"), pursuant to Rule 23 of the Federal Rules of Civil Procedure, and alleges as follows:

INTRODUCTION

1. This is a class action on behalf of beneficiaries of ERISA plans administered by UHC who were denied Proton Beam Radiation Therapy ("PBRT") because of UHC's uniform application of an arbitrary medical policy to deny as experimental or investigational such treatment for prostate cancer, despite PBRT being recognized for decades by the medical community as an established, medically appropriate treatment for cancer, including prostate cancer.

2. Instead of acting solely in the interests of the participants and

Colson Hicks Eidson
255 Alhambra Circle, Penthouse, Coral Gables, Florida 33134-5008 Telephone: (305) 476-7400 Fax: (305) 476-7444

beneficiaries of its health insurance plans, upon information and belief, UHC denied coverage for PBRT to treat prostate cancer because, on average, PBRT is significantly more expensive than traditional Intensity Modulated Radiotherapy ("IMRT") or other treatments.

3. Plaintiff is a beneficiary in a health insurance plan issued on behalf of his employer (the "Employer Plan"), which is a group health benefit plan. The Employer Plan is governed by the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1001, *et seq.*, and is administered by UHC.

4. Plaintiff was diagnosed with prostate cancer in April 2018. In May 2018, Plaintiff consulted with physicians at Miami's Cancer Institute ("MCI") at Baptist Health South Florida, including: Dr. Michael Zinner, Chief Executive Officer and Executive Medical Director; Dr. Minesh Mehta, Deputy Director and Chief of Radiation Oncology; and Dr. Marcio Fagundes, Medical Director and Vice Chair of the Radiation Oncology Department. The physicians at MCI recommended that Plaintiff undergo PBRT as an alternative to IMRT because, among other things, the likelihood of achieving a better outcome was greater for PBRT.

5. PBRT has been recognized for decades by the medical community as an established, medically appropriate treatment for cancer, including prostate cancer. The first hospital-based proton-beam center in the United States was at the Loma Linda University Medical Center, which began operation in 1990.

6. MCI is affiliated with Memorial Sloan Kettering Cancer Center ("Sloan") in New York, New York. Physicians from the radiation oncology department

at Sloan agreed with the treatment plan established for Plaintiff by the physicians at MCI.

7. On May 30, 2018, UHC denied Plaintiff's request for pre-authorization of PBRT on the grounds that it fell under an exclusion in the Employer Plan entitled "Experimental or Investigational or Unproven Services" ("E/I Exclusion") and UHC's uniform medical policy that PBRT is experimental or investigational, and therefore not covered for prostate cancer in persons that are 19 years of age or older (the "UHC PBRT Policy").

8. Notwithstanding UHC's denial of coverage, Plaintiff proceeded to have PBRT, with very positive results. Plaintiff paid for the treatment out-of-pocket and sought payment of benefits from UHC. UHC denied coverage. Plaintiff exhausted all internal appeals provided by the Employer Plan. UHC responded by upholding the denial of coverage based solely on the UHC PBRT Policy, and without considering the substantial materials submitted by Plaintiff and his providers supporting coverage for PBRT. Thereafter, Plaintiff filed an external appeal with Medical Review Institute of America ("MRIA"), a so-called Independent Review Organization ("IRO")—which is unilaterally selected by UHC—that upheld the denial based on the E/I Exclusion and the UHC PBRT Policy.

9. In denying coverage, UHC followed the UHC PBRT Policy, which mandates denial of coverage for PBRT to treat prostate cancer on patients over 19 years old for all plans insured or administered by UHC.

10. During the external appeal process, MRIA rubber-stamped UHC's

Colson Hicks Eidson
255 Alhambra Circle, Penthouse, Coral Gables, Florida 33134-5008 Telephone: (305) 476-7400 Fax: (305) 476-7444

denial decision without conducting a truly independent evaluation of whether PBRT is a proven and effective treatment for prostate cancer. Neither UHC nor MRIA properly applied the E/I Exclusion found in the Employer Plan.

11. On January 1, 2019, UHC changed its PBRT policy. The new policy acknowledges that PBRT is not experimental, as PBRT and IMRT are "proven and considered clinically equivalent for treating prostate cancer."

12. Thus, as of January 1, 2019, UHC acknowledged that PBRT is a proven, efficacious treatment for prostate cancer, and is not experimental or investigational by any fair definition of those terms, and certainly not within the meaning of those terms as defined in the Employer Plan.

13. UHC's PBRT Policy and resulting denial of PBRT coverage for Plaintiff and members of the Class he seeks to represent (as defined below) violated the terms of the relevant plans and UHC's fiduciary obligations under ERISA.

14. Under ERISA, Plaintiff and Class members are entitled to equitable and declaratory relief enjoining the application of any UHC PBRT Policy that pre-dates UHC's new January 1, 2019 PBRT policy change, reversing UHC's benefits denials of coverage for PBRT that were based on any UHC PBRT Policy that pre-dates UHC's new January 1, 2019 PBRT policy change, and awarding such other relief the Court finds appropriate.

THE PARTIES

15. Plaintiff Richard Cole is a citizen of Florida who resides in Miami, Florida.

16. Defendant UHC is a Connecticut corporation with its principal place of business in Hartford, Connecticut. UHC is a global health care benefits company, which, along with its wholly owned and controlled subsidiaries, offers, insures, underwrites, and administers health benefits plans, including Plaintiff's health benefits plan, as detailed herein. UHC and its subsidiaries are referred to as "UHC" in this Complaint.

JURISDICTION AND VENUE

17. UHC's actions in administering employer-sponsored health care plans, making coverage and benefit determinations under the terms and conditions of the health care plans, and/or processing appeals of coverage and benefit determinations under the terms and conditions of the health care plans are governed by ERISA. This Court has jurisdiction of this case under 28 U.S.C. § 1331 (federal question jurisdiction) and 29 U.S.C. § 1132(e) (ERISA).

18. This Court has personal jurisdiction over UHC pursuant to § 48.193(1), Florida Statutes, because UHC has operated, conducted, engaged in, and carried on a business in Florida and has an office in Florida. UHC is also subject to personal jurisdiction pursuant to § 48.193(4), Florida Statutes, because it contracted to insure Plaintiff within Florida at the time of contracting.

19. Venue is proper in this judicial district under 28 U.S.C. § 1391(b)(1), because Defendant resides in this judicial district, and under 28 U.S.C. § 1391(b)(2) and 1391(d), because a substantial part of the events or omissions giving rise to Plaintiff's and Class members' claims occurred in this judicial district.

FACTUAL ALLEGATIONS

A. UHC Acts as a Fiduciary for its ERISA Plans.

20. The majority of the health plans underwritten and/or administered by UHC, including the Employer Plan, are employee welfare benefit plans sponsored by private-sector employers governed by ERISA ("ERISA plans").

21. During all relevant times, UHC acted as a fiduciary with respect to its administration of ERISA plans. In particular, UHC interpreted and applied ERISA plan terms, made coverage and benefit decisions under the ERISA plans within its sole discretion, and provided payment under the ERISA plans to participants/beneficiaries and their providers. Accordingly, UHC was required to comply with the requirements ERISA imposes on fiduciaries.

22. The health insurance plans administered by UHC are either fully insured or self-funded. With respect to fully insured plans, UHC both administers the plan by making all benefit determinations and pays the benefits out of its own assets. With respect to self-funded plans, UHC administers the plan, but the underlying plan sponsor or employer through which the insurance is provided is ultimately responsible for reimbursing UHC for the benefit payments.

23. When processing benefits for a self-funded plan, UHC makes all benefit determinations and authorizes benefit checks to be issued out of bank accounts that UHC controls. Periodically, UHC will notify the sponsors of the self-funded plans of the need to replenish their accounts so that benefits can be paid. But UHC nevertheless continues to control these accounts and is fully responsible for processing

the insurance claims and making the determination whether to issue the check from these accounts.

24. Thus, irrespective of whether a particular ERISA plan is fully insured or self-funded, UHC is the proper party for Plaintiff, and the putative Class, to sue because UHC—not the underlying plan sponsor or employer—made all the relevant decisions and wielded the authority to issue benefit checks under the ERISA plans.

B. Proton Beam Radiation Therapy.

25. PBRT is a procedure that uses protons to deliver a curative radiation dose to a tumor, while reducing doses to healthy tissues and organs, which results in fewer complications and side effects than traditional IMRT.

26. With PBRT, protons deposit their energy over a very small area called the "Bragg peak." The Bragg peak can be used to target high doses of proton beams to a tumor, while doing less damage to normal tissues in front of and behind the tumor. Proton beams enable patients to tolerate higher total doses of radiotherapy compared with photons, which are used for traditional IMRT.

27. There is overwhelming evidence that PBRT is safe and effective and is a generally accepted standard of medical practice for the treatment of cancer, including prostate cancer, within the medical community.

28. PBRT has been around and well-accepted for over 30 years. The Food and Drug Administration ("FDA") approved PBRT for treatment of prostate cancer in 1988; the National Association for Proton Therapy, Alliance for Proton Therapy and other nationally-recognized medical organizations, and numerous meticulous peer-reviewed studies have validated the safety and effectiveness of PBRT.

29. Additionally, many respected cancer facilities and providers, including Baptist Hospital's Miami Cancer Institute, MD Anderson Cancer Center, Loma Linda University, University of Florida, Harvard Medical School/Massachusetts General Hospital, University of Maryland, Northwestern University, Mayo Clinic, Emory University, Case Western Reserve University, Washington University in St. Louis, University of Washington, New York Proton Center, and the Texas Center for Proton Therapy recommend and use PBRT on a regular basis.

30. Other insurers, including Medicare, cover PBRT as a safe and effective treatment for prostate cancer that is not "experimental."

C. UHC's Proton Beam Radiation Therapy Medical Policy.

31. Up until January 1, 2019, UHC employed the UHC PBRT Policy, which maintained that PBRT was experimental or investigational, and therefore not covered for prostate cancer in persons that are 19 years of age or older.

32. As evidence of the arbitrary and capricious nature of UHC's denial of PBRT for treatment of prostate cancer, the UHC PBRT Policy maintains that PBRT is experimental or investigational, and therefore not covered, for persons 19 years of age or older, while simultaneously finding PBRT to be non-experimental and non-investigational (i.e., proven safe and effective), and therefore covered, for persons under 19 years of age.

33. There are no medical studies that support a conclusion that PBRT would be a proven, safe and effective treatment for one age group, but not the other.

34. On January 1, 2019, UHC changed its PBRT policy (the "New 2019 Policy"). The new policy acknowledges that PBRT is, in fact, not experimental, as

PBRT and IMRT are "proven and considered clinically equivalent for treating prostate cancer." Under the New 2019 Policy, a person's request for authorization of PBRT to treat prostate cancer will be determined on a case-by-case basis as opposed to a blanket denial based on the UHC PBRT Policy.

35. The driving force behind the advent of the New 2019 Policy on January 1, 2019 appears entirely arbitrary, as there were no significant clinical developments in PBRT from the time UHC denied Plaintiff's request for pre-authorization of PBRT on May 30, 2018, until January 1, 2019, the effective date of the New 2019 Policy.

36. Despite the change in policy, MRIA continued to uphold UHC's decision to deny coverage of PBRT to Plaintiff under the old UHC PBRT Policy, even as of February 4, 2019.

D. Despite its Uniform Policy to Deny the Claims of its Beneficiaries, UHC's Public Initiatives Support PBRT for the Treatment of Prostate Cancer.

37. In 2015, ProHEALTH Proton Center Management, LLC ("ProHealth"), an affiliate of UHC, received approval from the New York Public Health and Health Planning Council to construct and operate the New York Proton Center in Harlem, New York.

38. As part of the agreement with the State of New York, ProHealth pledged $15,359,260 for the New York Proton Center and became a 33% member in the management company that provides equipment and day-to-day administrative/non-clinical support for the project.

39. The New York Proton Center's website acknowledges their partnership with ProHealth to make PBRT more accessible to patients seeking cancer treatment,

including prostate cancer.

40. Thus, during the time that the UHC PBRT Policy was in effect, UHC simultaneously presented to the New York Public Health and Health Planning Council that PBRT was an appropriate treatment for prostate cancer while denying coverage for such treatment to its plan participants and beneficiaries.

INDIVIDUAL ALLEGATIONS

A. The Employer Plan.

41. The Employer Plan is a fully insured plan, meaning that UHC both administers the Employer Plan by making all benefit determinations and pays the benefits out of its own assets. UHC maintains control over the decision-making process and is ultimately responsible for authorizing the issuance of checks for paying benefits.

42. As a beneficiary to the Employer Plan, Plaintiff was issued the Certificate of Coverage for the Health Savings Account ("HSA") Plan AHP3 of Cole, Scott & Kissane, P.A. ("Benefit Handbook"). The Benefit Handbook, which is a plan document governing Plaintiff's insurance that details the terms and conditions of the Employer Plan, defines "Covered Health Care Service(s)" as "health care services . . . which [UHC] determine[s] to be . . . Medically necessary."

43. The Benefit Handbook defines "Medically necessary" as "health care services provided for the purpose of preventing, evaluating, diagnosing or treating a Sickness, Injury, Mental Illness, substance-related and addictive disorders, condition, disease or its symptoms . . . ."

44. In addition, the Benefit Handbook includes a list of "Exclusions," which are deemed to be services that are not covered under the Employer Plan. One such Exclusion is entitled "Experimental or Investigational or Unproven Services" (the "E/I Exclusion"). The E/I Exclusion states as follows:

> [M]edical, surgical, diagnostic, psychiatric, mental health, substance-related and addictive disorders or other health care services, technologies, supplies, treatments, procedures, drug therapies, medications or devices that, at the time [UHC] make[s] a determination regarding coverage in a particular case, are determined to be any of the following:
>
> - Not approved by the *U.S. Food and Drug Administration (FDA)* to be lawfully marketed for the proposed use and not identified in the *American Hospital Formulary Service* or the *United States Pharmacopeia Dispensing Information* as appropriate for the proposed use.
> - Subject to review and approval by any institutional review board for the proposed use. (Devices which are *FDA* approved under the Humanitarian Use Device exemption are not Experimental or Investigational.)
> - The subject of an ongoing clinical trial that meets the definition of a Phase I, II or III clinical trial set forth in the *FDA* regulations, regardless of whether the trial is actually subject to *FDA* oversight.

(Emphasis in original).

45. The first criterion is inapplicable. As UHC acknowledges in its New 2019 Policy, radiation therapy is a procedure, and therefore, is not subject to FDA regulation.

46. The accelerators and other equipment used to generate and deliver PBRT are regulated by the FDA. On February 22, 1988, the FDA approved the Proton Therapy System, and designated it as a Class II Device for radiological treatment. This classification was codified at 21 C.F.R. § 892.5050, and describes the Proton Therapy System as a "device that produces by acceleration high energy charged particles (e.g., electrons and protons) intended for use in radiation therapy." Thus, at

Colson Hicks Eidson
255 Alhambra Circle, Penthouse, Coral Gables, Florida 33134-5008 Telephone: (305) 476-7400 Fax: (305) 476-7444

least as of February 22, 1988, PBRT no longer fit within the E/I Exclusion to the Employer Plan.

47. The last two criteria under the E/I Exclusion would not serve to exclude treatment for prostate cancer. Clinical trials of PBRT may be ongoing but only to refine PBRT's use or to treat other conditions, such as seizures. PBRT has long been recognized by the medical community as an established, medically appropriate treatment for the treatment of cancer, including prostate cancer.

48. UHC has since recognized that PBRT is not experimental, and PBRT and IMRT are "proven and considered clinically equivalent for treating prostate cancer." There were no clinical developments in the field of PBRT from the time UHC denied Plaintiff's request for pre-authorization of PBRT in May 2018 to January 2019, when the New 2019 Policy took effect, and UHC deemed PBRT to be a proven, safe, and effective treatment for prostate cancer in persons 19 years of age or older.

49. The denials at issue in this case relate to UHC's E/I Exclusion and its application of the UHC PBRT Policy prior to the New 2019 Policy taking effect.

B. UHC's Denial of Coverage for PBRT.

50. Plaintiff was diagnosed with prostate cancer in April 2018. In May 2018, Plaintiff's radiation oncologist, Dr. Marcio Fagundes, recommended that Plaintiff undergo PBRT as an alternative to IMRT because, among other things, the likelihood of achieving a better outcome was greater for PBRT.

51. On May 30, 2018, UHC denied Plaintiff's request for pre-authorization of PBRT on the grounds that it fell under the "E/I Exclusion" and was prohibited by the UHC PBRT Policy.

52. On August 13, 2018, Baptist Hospital of Miami ("Baptist") submitted an internal appeal on Plaintiff's behalf, asking that UHC reconsider its decision to deny coverage or payment for PBRT.

53. By letter dated August 28, 2018, UHC upheld its decision to deny coverage. UHC stated:

> It was determined that your benefit plan does not pay for this service(s). This decision is based on the UnitedHealthcare Proton Beam Radiation Therapy Medical Policy and the terms of your plan.

54. UHC's August 28, 2018 letter exhausted Plaintiff's internal remedies available to challenge UHC's benefits denial.

55. On December 27, 2018, Plaintiff formally requested an external review of UHC's decision to deny his request for PBRT to treat his prostate cancer.

56. On January 7, 2019, Plaintiff received a letter from MRIA accepting his external review request and requiring that he submit all pertinent information he wanted considered by the IRO.

57. In compliance with MRIA's January 7th letter, Plaintiff, by and through counsel,[1] wrote to MRIA on January 24, 2019, requesting that UHC's denial of coverage for PBRT be overturned. In the letter, Plaintiff's counsel included evidence—including the New 2019 Policy, an updated report from Dr. Fagundes, and documents evincing UHC's public support for PBRT in the State of New York—supporting Plaintiff's position that PBRT is not experimental or investigational.

58. Dr. Fagundes's updated report concluded that Plaintiff has an

[1] The undersigned submitted this letter with Plaintiff's consent and after Plaintiff signed UHC's Appointment of Authorized Representative Form.

Colson Hicks Eidson
255 Alhambra Circle, Penthouse, Coral Gables, Florida 33134-5008 Telephone: (305) 476-7400 Fax: (305) 476-7444

undetectable amount of prostate-specific antigen, a result consistent with the efficacy of "combined androgen deprivation therapy and PBRT."

59. As part of Plaintiff's external appeal process with MRIA, Dr. Fagundes wrote UHC a letter dated January 18, 2019, to support Plaintiff's request for coverage. In the letter, Dr. Fagundes cited to peer-reviewed studies that demonstrate the efficacy of PBRT. Dr. Fagundes requested that UHC "reconsider approval for proton therapy" and noted that PBRT "significantly reduces radiation dose to normal rectal, bladder, and uninvolved tissue (10)."

60. Dr. Fagundes's letter also asked that UHC overturn its decision because of the FDA's approval of proton therapy on February 22, 1988. He further stated that Plaintiff "meets every criterion as defined by the FDA for appropriateness of use and therefore designating [PBRT] as experimental is fallacious, inaccurate, and contrary to the public record."

61. Despite the substantial support for PBRT provided to MRIA, on February 4, 2019, MRIA rejected Plaintiff's request for reconsideration of its denial and concluded that PBRT was not covered.

62. Notably, in denying coverage, UHC failed to discuss or even acknowledge the information provided by Dr. Fagundes supporting PBRT, including the many studies verifying its safety and efficacy. Thus, UHC provided Plaintiff with no basis for its negative coverage determination aside from its reliance—to the exclusion of all contrary evidence—on UHC's pre-existing policy that PBRT falls under the E/I Exclusion.

Colson Hicks Eidson
255 Alhambra Circle, Penthouse, Coral Gables, Florida 33134-5008 Telephone: (305) 476-7400 Fax: (305) 476-7444

63. UHC's decision finding PBRT to be "experimental and investigational" under the Employer Plan was erroneous, arbitrary, and capricious.

64. Indeed, the Glossary definition of "Unproven Service(s)" in the Benefits Handbook further confirms that UHC's application of its E/I Exclusion to PBRT is improper. The definition states that unproven services are: "services . . . that are determined not to be effective for treatment of the medical condition and/or not to have a beneficial effect on health outcomes due to insufficient and inadequate clinical evidence from well-conducted randomized controlled trials or cohort studies in the prevailing published peer-reviewed medical literature."

65. PBRT is not a "new" technology; it has been around and well-accepted for thirty years. PBRT has been determined to be "effective for treatment" of prostate cancer, and its use is entirely consistent with prevailing medical research, based on numerous "controlled trials or cohort studies in the prevailing published peer reviewed medical literature." UHC persistently ignored such trials and studies when applying its E/I Exclusion to deny coverage for PBRT to Plaintiff and the Class he seeks to represent.

C. UHC's ERISA Violations.

66. As the claims administrator responsible for interpreting and administering the Employer Plan and similar UHC plans issued nationwide, and vested with responsibility for making final benefit determinations, UHC is an ERISA fiduciary.

67. As an ERISA fiduciary, UHC was required to discharge its duties

consistent with 29 U.S.C. § 1104, which requires (among other things) that it do so "solely in the interest of the participants and beneficiaries" and for the "exclusive purpose" of "providing benefits to participants and their beneficiaries" and paying reasonable expenses of administering the plan. It must do so with the "care, skill, prudence, and diligence" and in accordance with the terms of the plans it administers. UHC violated all of these requirements.

68. UHC violated these duties when it prepared and promulgated the UHC PBRT Policy, because UHC relied upon outdated evidence, ignored evidence indicating that PBRT was not experimental, and unreasonably concluded that PBRT was "experimental, investigational or unproven." UHC then compounded that breach of duty by relying upon the UHC PBRT Policy to deny insurance claims submitted by Plaintiff and Class members in contravention of the terms of their UHC plans.

69. In some areas of the United States, the cost to administer PBRT far exceeds the cost for traditional IMRT for the same condition; the cost for PBRT can be double that of traditional IMRT.

70. UHC did not act "solely in the interests of the participants and beneficiaries" when it denied coverage for PBRT. Rather, upon information and belief, UHC denied coverage for PBRT to treat prostate cancer because, on average, PBRT is significantly more expensive than traditional IMRT or other treatments.

71. In violating its fiduciary duties, UHC elevated its own interests above the interests of plan participants and beneficiaries, reflecting its conflict of interest when determining whether to cover PBRT. By promulgating and applying its PBRT

Policy, UHC sacrificed the interests of insureds like Plaintiff and the Class so that it could artificially decrease the number and value of claims it was required to pay from its own assets (i.e., with respect to fully insured plans and self-funded plans with stop-loss provisions requiring UHC to cover benefits above a certain threshold) and the assets of its employer-sponsor customers (i.e., with respect to other self-funded plans); moreover, by prioritizing the assets of its employer-sponsor customers, UHC also advanced its own interests in retaining and expanding its business with such customers.

CLASS ACTION ALLEGATIONS

72. The proposed PBRT Class meets all requirements of Fed. R. Civ. P. 23(a) and 23(b).

A. The Class.

73. Plaintiff brings his claims on his own behalf and on behalf of a nationwide "PBRT Class," defined as:

> All participants or beneficiaries in ERISA Plans underwritten or administered by United Healthcare Insurance Company who, based on the application of a UHC PBRT Policy in effect prior to January 1, 2019, were denied health insurance coverage for Proton Beam Radiation Therapy to treat prostate cancer, on grounds that included the assertion that it was "experimental or investigational." The PBRT Class includes both persons whose post-service claims for reimbursement were denied and persons whose pre-service requests for authorization were denied.

74. The definition of "experimental or investigational" services or treatment in UHC's health insurance policies at all relevant times has been substantially similar to the definition in the Employer Plan.

75. The E/I Exclusion contained in the Employer Plan and relied upon by

UHC in denying coverage for Plaintiff is largely identical to, and is interpreted by UHC as having the same meaning as, comparable exclusions included in the UHC plans applicable to all Class members.

76. The PBRT Class excludes (a) UHC, including any entity or division in which UHC has a controlling interest, as well as its agents, representatives, officers, directors, employees, trustees, and other entities related to, or affiliated with UHC, (b) Class Counsel, and (c) the Judge to whom this case is assigned and any members of the Judge's staff or immediate family.

B. Numerosity.

77. The members of the PBRT Class are so numerous that joinder of all members is impractical.

78. While the precise number of members in this Class is known only to UHC, UHC is the ERISA fiduciary and has issued the policies providing coverage under tens of thousands of employer-sponsored ERISA plans, and PBRT has become so widespread that at a minimum, requests numbering in the hundreds, if not thousands, must have been submitted to and denied by UHC for coverage of this therapy.

79. Upon information and belief, just last year, approximately 5,000 patients with prostate cancer were treated using PBRT nationwide and across all payors.

80. The PBRT Class is ascertainable because its members can be readily identified using UHC's claims data. PBRT therapy is described with a discrete set of procedure codes under the Current Procedural Terminology ("CPT") promulgated by

the American Medical Association. Accordingly, Class members can be readily and objectively ascertained through use of records maintained by UHC.

81. Finally, PBRT Class members are dispersed geographically throughout the United States, such that joiner of all members is impracticable.

C. Predominance of Common Issues.

82. This action satisfies the requirements of Fed. R. Civ. P. 23(a)(2) and 23(b)(3) because questions of law and fact that have common answers predominate over questions affecting only individual Class members. These include, without limitation:

a. Whether PBRT therapy is an "experimental or investigational" service or treatment;

b. Whether UHC acted as an ERISA fiduciary when it created or developed the UHC PBRT Policy;

c. Whether UHC categorically applied the UHC PBRT Policy to deny coverage to PBRT Class members;

d. Whether PBRT Class members' claim denials were based in whole or in part on the UHC PBRT Policy;

e. Whether the creation or development of the UHC PBRT Policy constituted a violation of ERISA;

f. Whether UHC's application of the UHC PBRT Policy constituted a violation of ERISA; and

g. Whether PBRT Class members are entitled to the relief sought if Plaintiff establishes liability.

Colson Hicks Eidson
255 Alhambra Circle, Penthouse, Coral Gables, Florida 33134-5008 Telephone: (305) 476-7400 Fax: (305) 476-7444

D. Typicality.

83. Plaintiff's claims are typical of the claims of PBRT Class members because Plaintiff is a beneficiary of an ERISA Plan administered by UHC, he submitted a claim for coverage of PBRT for treatment of his prostate cancer, and, like other PBRT Class members, UHC denied his claim based on the PBRT Policy and an incomplete research database that it references with respect to all requests for coverage of PBRT for treatment of prostate cancer.

E. Adequacy of Representation.

84. Plaintiff will fairly and adequately protect the interests of the Class. Plaintiff's interests do not conflict with the interests of the members of the Class. Further, Plaintiff has retained counsel who are competent and experienced in complex class action litigation, and Plaintiff and his counsel intend to prosecute this action vigorously on behalf of the Class members and have the financial resources to do so. Neither Plaintiff nor his counsel has any interest adverse to those of the Class members.

F. Superiority.

85. This action satisfies the requirements of Fed. R. Civ. P. 23(b)(1) because the prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudications that could establish incompatible standards of conduct for UHC.

86. This action satisfies the requirements of Fed. R. Civ. P. 23(b)(2) because by applying a uniform policy treating PBRT as "experimental, investigational or

Colson Hicks Eidson
255 Alhambra Circle, Penthouse, Coral Gables, Florida 33134-5008 Telephone: (305) 476-7400 Fax: (305) 476-7444

unproven," UHC has acted and refused to act on grounds that apply generally to the Class, thereby requiring the Court's imposition of uniform relief to ensure compatible standards of conduct towards Class members, and making final injunctive relief or corresponding declaratory relief appropriate respecting the proposed Class as a whole.

87. This action satisfies the requirements of Fed. R. Civ. P. 23(b)(3) because a class action is superior to other available methods for the fair and efficient adjudication of this controversy. Questions of law and fact common to the Class members predominate over any questions affecting only individual members.

88. A class action is superior to other available methods for the fair and efficient adjudication of this controversy because joinder of all Class members is impracticable. Further, because the unpaid benefits denied Class members are small relative to the expense and burden of individual litigation, it would be impossible for the members of the Class to redress individually the harm done to them, such that most or all Class members would have no rational economic interest in individually controlling the prosecution of specific actions, and the burden imposed on the judicial system by individual litigation by even a small fraction of the Class would be enormous, making class adjudication the superior alternative under Fed. R. Civ. P. 23(b)(3)(A).

89. The conduct of this action as a class action presents far fewer management difficulties, far better conserves judicial resources and the parties' resources, and far more effectively protects the rights of each Class member than would piecemeal litigation. Compared to the expense, burdens, inconsistencies, economic infeasibility, and inefficiencies of individualized litigation, the challenges of

Colson Hicks Eidson
255 Alhambra Circle, Penthouse, Coral Gables, Florida 33134-5008 Telephone: (305) 476-7400 Fax: (305) 476-7444

managing this action as a class action are substantially outweighed by the benefits to the legitimate interests of the parties, the court, and the public of class treatment in this court, making class adjudication superior to other alternatives, under Fed. R. Civ. P. 23(b)(3)(D).

COUNT I

VIOLATION OF FIDUCIARY OBLIGATIONS ON BEHALF OF PLAINTIFF AND THE CLASS

90. Plaintiff incorporates by reference paragraphs 1 through 89 as if fully stated herein.

91. This count is brought pursuant to 29 U.S.C. § 1132(a)(1)(B).

92. As the entity responsible for making medical benefit determinations under the Employer Plan and the PBRT Class members' similar plans, and responsible for developing internal practices and policies to facilitate such determinations, UHC is an ERISA fiduciary.

93. As an ERISA fiduciary, and pursuant to 29 U.S.C. § 1104(a), UHC is required to discharge its duties "solely in the interests of the participants and beneficiaries" and for the "exclusive purpose of providing benefits to participants and their beneficiaries" and paying "reasonable expenses of administering the plan." UHC must do so with reasonable "care, skill, prudence, and diligence" and in accordance with the terms of the plans it administers. UHC must conform its conduct to a fiduciary duty of loyalty and may not make misrepresentations to its insureds.

94. UHC violated these duties by adopting and implementing a policy to

Colson Hicks Eidson
255 Alhambra Circle, Penthouse, Coral Gables, Florida 33134-5008 Telephone: (305) 476-7400 Fax: (305) 476-7444

deny coverage for PBRT based on the experimental and investigational exclusions under its plans, when such a finding was contrary to generally accepted practices and to the terms of the plans. In particular, prior to the New 2019 Policy taking effect, UHC ignored current evidence, and widespread acceptance of PBRT as a safe and effective treatment for prostate cancer in improperly applying the E/I Exclusion to PBRT.

95. In doing so, UHC did not act "solely in the interests of the participants and beneficiaries" for the "exclusive purpose" of "providing benefits." UHC did not utilize the "care, skill, prudence, and diligence" of a "prudent man" acting in a similar capacity. UHC did not act in accordance with the terms of the Employer Plan and other UHC plans, all of which contain E/I Exclusions.

96. Instead, UHC elevated its own interests and those of its corporate affiliates above the interests of plan participants and beneficiaries. By adhering to an incorrect and outdated policy with regard to PBRT, UHC artificially decreased the number and value of covered claims thereby benefiting its corporate affiliates at the expense of insureds.

97. In some areas of the United States, the cost to administer PBRT far exceeds the cost for traditional IMRT for the same condition; the cost for PBRT can be double that of traditional IMRT.

98. UHC did not act "solely in the interests of the participants and beneficiaries" when it denied coverage for PBRT. Rather, upon information and belief, UHC denied coverage for PBRT to treat prostate cancer due to its average higher cost

Colson Hicks Eidson
255 Alhambra Circle, Penthouse, Coral Gables, Florida 33134-5008 Telephone: (305) 476-7400 Fax: (305) 476-7444

throughout the nation.

99. UHC's decision to implement the New 2019 Policy—without any recent clinical developments—and acknowledge that PBRT is no longer experimental or investigational, demonstrates that UHC arbitrarily applied the UHC PBRT Policy prior to January 1, 2019.

100. Plaintiff and Class members have been harmed by breaches of fiduciary duty of UHC because their claims have been subjected improperly to the E/I Exclusion, leading to denials of coverage for PBRT, when PBRT is actually a Covered Health Care Service within the definition of the UHC plans.

101. Plaintiffs and Class members seek the relief identified below to remedy this claim.

COUNT II

IMPROPER DENIAL OF BENEFITS ON BEHALF OF PLAINTIFF AND THE CLASS

102. Plaintiff incorporates by reference paragraphs 1 through 89 as if fully stated herein.

103. This count is brought pursuant to 29 U.S.C. § 1132(a)(1)(B).

104. UHC denied the insurance claims for PBRT submitted by Plaintiff and other Class members in violation of the terms of the Employer Plan and the other UHC plans that insure members of the Class. UHC denied these claims based on its E/I Exclusion, which does not properly apply to PBRT.

105. Plaintiff and Class members have been harmed by UHC's improper benefit denials because they were deprived of insurance benefits they were owed.

Colson Hicks Eidson
255 Alhambra Circle, Penthouse, Coral Gables, Florida 33134-5008 Telephone: (305) 476-7400 Fax: (305) 476-7444

106. Plaintiff and Class members seek the relief identified below to remedy this claim.

COUNT III

CLAIM FOR INJUNCTIVE RELIEF ON BEHALF OF PLAINTIFF AND THE CLASS

107. Plaintiff incorporates by reference paragraphs 1 through 89 as if fully stated herein.

108. This count is brought pursuant to 29 U.S.C. § 1132(a)(3)(A) only to the extent that the Court finds that the injunctive relief sought to remedy Counts I and/or II are unavailable pursuant to 29 U.S.C. § 1132(a)(1)(B). Plaintiff and the Class have been harmed by UHC's breaches of fiduciary duty described above.

109. In order to remedy these harms, Plaintiff and the Class are entitled to enjoin these acts and practices pursuant to 29 U.S.C. § 1132(a)(3)(A).

COUNT IV

CLAIM FOR OTHER APPROPRIATE EQUITABLE RELIEF ON BEHALF OF PLAINTIFF AND THE CLASS

110. Plaintiff incorporates by reference paragraphs 1 through 89 as if fully stated herein.

111. This count is brought pursuant to 29 U.S.C. § 1132(a)(3)(B) only to the extent that the Court finds that the equitable relief sought to remedy Counts I and II are unavailable pursuant to 29 U.S.C. § 1132(a)(1)(B).

112. Plaintiff and the Class have been harmed by UHC's breaches of fiduciary duty described above.

Colson Hicks Eidson
255 Alhambra Circle, Penthouse, Coral Gables, Florida 33134-5008 Telephone: (305) 476-7400 Fax: (305) 476-7444

113. Additionally, by engaging in this misconduct, UHC was unjustly enriched in two ways: first, with regard to fully-insured plans or plans that include a stop-loss provision requiring UHC to pay all benefits above a certain threshold, it avoided paying benefits out of its own funds and/or the funds of its corporate affiliates; second, with regard to self-funded plans, UHC charged its corporate customers fees for serving as claims administrator while improperly denying PBRT benefits based on the inapplicable E/I Exclusion and also lowered costs for its corporate customers, allowing UHC to retain current customers and expand its business to new customers.

114. In order to remedy these harms, Plaintiff and the Class are entitled to appropriate equitable relief, including an appropriate monetary award based on restitution, disgorgement or surcharge, pursuant to 29 U.S.C. § 1132(a)(3)(B).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment in his favor and against Defendant UHC as follows:

A. Certifying the Class, as set forth in this Complaint, and appointing Plaintiff as Class Representative and undersigned counsel as Class Counsel;

B. Declaring that UHC violated the Employer Plan, and the similar ERISA Plans of the other members of the Class, and that UHC violated its fiduciary duties under ERISA, and awarding appropriate equitable relief including disgorgement and surcharges;

C. Ordering UHC to reprocess Plaintiff's and PBRT Class members' claims under the New 2019 Policy, which reflects the state of the science and medical

Colson Hicks Eidson
255 Alhambra Circle, Penthouse, Coral Gables, Florida 33134-5008 Telephone: (305) 476-7400 Fax: (305) 476-7444

community's acceptance of PBRT as a proven, safe and effective treatment for prostate cancer;

D. Ordering UHC to create a common fund out of which it will make payment, with interest, of any unpaid benefits to Plaintiff and PBRT Class members;

E. Awarding Plaintiff disbursements and expenses of this action, including reasonable attorneys' fees pursuant to 29 U.S.C. § 1132(g)(1), in amounts to be determined by the Court; and

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

Colson Hicks Eidson
255 Alhambra Circle, Penthouse, Coral Gables, Florida 33134-5008 Telephone: (305) 476-7400 Fax: (305) 476-7444

DATED: April 3, 2019.

Respectfully submitted,

COLSON HICKS EIDSON
255 Alhambra Circle, Penthouse
Coral Gables, Florida 33134
Telephone: (305) 476-7400
Facsimile: (305) 476-7444
E-mail: eservice@colson.com

/s/ Dean Colson
Dean Colson, Esq.
Florida Bar No. 228702
dean@colson.com
Stephanie A. Casey, Esq.
Florida Bar No. 97483
scasey@colson.com
Lazaro Fields, Esq.
Florida Bar No. 1004725
laz@colson.com

Counsel for Plaintiff and the Putative Class