STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

ABOLGHASEM ZOLFAGHARI,

Petitioner

and

MIAMI CANCER INSTITUTE AT BAPTIST HEALTH, INC.,

Intervenor,

vs. Case No. 20-0146

DEPARTMENT OF MANAGEMENT SERVICES, DIVISION OF STATE GROUP INSURANCE,

Respondent.
_____/

RECOMMENDED ORDER

Pursuant to notice, a formal administrative hearing was conducted before Administrative Law Judge Robert S. Cohen of the Division of Administrative Hearings ("DOAH") on March 9, 2020, by video teleconference at sites located in Miami and Tallahassee, Florida.

APPEARANCES

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For Respondent: Erica D. Moore, Esquire
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## STATEMENT OF THE ISSUE

Whether Petitioner's request for coverage of proton beam radiation therapy ("proton beam therapy" or "PBRT") is a covered benefit pursuant to the State Employees' Health Maintenance Organization ("HMO") Plan ("Plan"), administered by AvMed.

## PRELIMINARY STATEMENT

Petitioner is a member of the Plan, administered by AvMed, as a retiree of the State of Florida. Petitioner was diagnosed with prostate cancer and sought preservice authorization of PBRT at the Miami Cancer Institute at Baptist Health, Inc. ("Miami Cancer Institute"), in July 2019. On November 21, 2019, Respondent issued a Level II Appeal Determination letter, denying coverage because PBRT "is not an approved treatment option for prostate cancer and is not a covered benefit under the member's plan." On December 19, 2019, Petitioner appealed and filed a petition for administrative hearing. On February 26, 2020, the Miami Cancer Institute moved to intervene as the Provider. The Motion was granted on February 27, 2020.

On March 9, 2020, the final hearing was held. Petitioner testified on his own behalf, and Intervenor presented the testimony of Petitioner's wife, Michelle Zolfaghari, and Maria-Amelia Rodrigues, M.D., Petitioner's treating radiation oncologist at Miami Cancer Institute. Respondent presented the testimony of Sri Gorty, M.D., radiation oncologist for Magellan Healthcare, an independent reviewer for AvMed; Edwin Rodriguez, M.D., senior medical director at AvMed; Carol Cardoba, claims analyst at AvMed; and

Dearline Thomas-Brown, R.N., legal nurse coordinator for Respondent, Department of Management Services, Division of State Group Insurance. Petitioner's Exhibits A through BB were admitted into evidence without objection. Respondent's Exhibits 1 through 16 were admitted into evidence without objection. Respondent's Motion for Official Recognition was granted, recognizing sections 110.123 and 110.161, Florida Statutes (2019), and the IRS Cafeteria Plan under 26 U.S.C. § 125.

A two-volume transcript was filed with DOAH on April 2, 2020. The parties (Petitioner joined in Intervenor's post-hearing submission) thereafter timely filed proposed recommended orders on April 13, 2020. Both proposed orders have been duly considered in the preparation of this Recommended Order.

All references to the Florida Statutes are to the 2019 version, unless otherwise specified.

## FINDINGS OF FACT

1. Respondent is the state agency charged with administering the state employee health insurance program pursuant to section 110.123.

2. At all times material hereto, Petitioner was a member of the Plan. AvMed is the third-party administrator for the Plan at issue in this cause. As the third-party administrator, AvMed provides claims processing, utilization, and benefit management services. The applicable benefit document is the State Employees' HMO Plan, Group Health Insurance Plan Booklet and Benefits Document ("Plan Document"), effective January 1, 2019.

3. Petitioner is a 66-year-old male who was diagnosed with prostate cancer in November 2017 and underwent a prostatectomy to remove his prostate on April 12, 2018. Subsequent to his initial surgery and treatment,

Petitioner experienced increasing prostate specific antigen ("PSA") in three follow-up tests. His prostate cancer had returned.

4. Petitioner's physician sought to treat his condition with PBRT, a form of external beam radiation utilizing protons, rather than traditional intensity modulated radiation therapy ("IMRT"), which is, without question, covered under the Plan. Medicare, a federal healthcare insurance program, agreed to pay 80 percent of Intervenor's charges for PBRT, leaving Petitioner responsible for the remaining 20 percent being sought to be paid by Petitioner's Plan.

5. On July 3, 2019, Petitioner, through his healthcare provider, Maria-Amelia Rodrigues, M.D., and Intervenor, Miami Cancer Institute, submitted a request for coverage of PBRT to AvMed.

6. On July 10, 2019, AvMed denied the preservice request for coverage on the basis that the therapy was experimental/investigational and, therefore, not medically necessary treatment for the member's condition. The request was reviewed by Sri Gorty, M.D., a consultant radiation oncologist at Magellan Healthcare, which is under contract with AvMed.

7. On July 23, 2019, Petitioner submitted a request for a Level I appeal to AvMed. The appeal was reviewed by Dr. Gregg Goldin, M.D., a consultant radiology oncologist at Dane Street, which is under contract with AvMed. He filed a report dated August 19, 2019.

8. On August 20, 2019, AvMed denied the request for Level I appeal on the basis that the therapy was experimental/investigational and, therefore, not a medically necessary treatment.

9. On November 19, 2019, Petitioner submitted a request for an "Expedited" Level II appeal to Respondent. The Level II appeal was reviewed by Dearline Thomas-Brown, a registered nurse and Level II appeal coordinator for Respondent.

10. On November 21, 2019, Respondent denied Petitioner's Level II appeal on the basis that the therapy is experimental/investigational and, therefore, not medically necessary for treatment of the member's condition.

11. Pursuant to the Plan Document, the Plan pays its share of the cost of covered services, if the services are:

> a. Ordered by a Network Provider (a provider who is in AvMed's network);
> b. Considered Medically Necessary for the covered person's treatment because of accident, illness, condition or mental health or nervous disorder;
> c. Not specifically limited or excluded under this Plan; and
> d. Rendered while this Plan is in effect.

12. Pursuant to the Plan Document, Section I. Introduction:

> The Plan is not intended to and does not cover or provide any Medical Services or benefits that are not Medically Necessary for the diagnosis and treatment of the Health Plan Member. AvMed determines whether the services are Medically Necessary on the basis of terms, conditions, and criteria established by the Plan as interpreted by the state, and as set forth in medical guidelines.

13. This chart provides a description of services and supplies covered under the Plan. Coverage Access Rules are specified under the Plan as follows:

> Cancer Services
>
> Diagnosis and Treatment
>
> Includes both inpatient and outpatient diagnostic tests and treatment (including anti-cancer medications administered by Network providers), including cancer clinical trials as set forth in the Florida Clinical Trial Compact. Does not include Experimental or Investigational Treatment.

14. In order to be a covered benefit, the treatment must be "medically necessary," not "experimental or investigational," and it must not be specifically excluded by the Plan.

15. "Medically Necessary" is defined as follows:

> The use of any appropriate medical treatment, service, equipment and/or supply as provided by a Hospital, skilled nursing facility, physician or other provider which is necessary for the diagnosis, care and/or treatment of a Health Plan Member's Illness or injury, and which is:
>
> • Consistent with the symptom, diagnosis and treatment of the Health Plan Member's condition;
> • The most appropriate level of supply and/or service for the diagnosis and treatment of the Health Plan Member's condition;
> • In accordance with standards of acceptable medical practice;
> • Not primarily intended for the personal comfort or convenience of the Health Plan Member, the Health Plan Member's family, the physician or other health care providers;
> • Approved by the appropriate medical body or health care specialty involved as effective, appropriate and essential for the care and treatment of the Health Plan Member's condition; and
> • Not experimental or investigational.

16. The service must meet all of the above-referenced criteria in order to be medically necessary. Given the above definition, if a service is experimental or investigational, then it cannot be medically necessary.

17. Section VI. Limitations and Exclusions in the Plan Document specifically exclude services that are "experimental/investigational or not medically necessary treatment with the exception of routine care in connection with a clinical trial in cancer, pursuant to the Florida Clinical Trial Compact and the Patient Protection and Affordable Care Act."

18. "Experimental and/or Investigational" is defined as follows:

> For the purposes of this Plan a medication, treatment, device, surgery or procedure may initially be determined by AvMed to be experimental and/or investigational if any of the following applies:
>
> • The FDA has not granted the approval for general use; or
> • There are insufficient outcomes data available from controlled clinical trials published in peer-reviewed literature to substantiate its effectiveness for the disease or injury involved; or
> • There is no consensus among practicing physicians that the medication, treatment, therapy, procedure or device is safe or effective for the treatment in question or such medication, treatment, therapy, procedure or device is not the standard treatment, therapy procedure or device utilized by practicing physicians in treating other patients with the same or similar condition; or
> • Such medication, treatment procedure, or device is the subject of an ongoing Phase I or Phase II clinical investigation, or Experimental or research arm of a Phase III clinical investigation, or under study to determine: maximum tolerated dosage(s), toxicity, safety, efficacy, or efficacy as comparted with the standard for treatment or diagnosis of the condition in question.

19. If any one or more of the above-cited criteria are met, then the treatment is experimental and/or investigational and is not a covered service.

20. In making an adverse determination as to coverage in both the Level I and Level II appeals, Edwin Rodriguez, M.D. (note the slightly different spelling of Petitioner's expert Dr. Maria-Amelia Rodrigue*s* versus Dr. Edwin Rodrigue*z*), and Nurse Thomas-Brown utilized AvMed's Medical Coverage Guideline on PBRT. This coverage guideline regarding PBRT provides AvMed's "Exclusion Criteria" explaining "PBRT is not covered, and is considered investigational, as to all other tumors not listed" in the guideline.

PBRT is not an approved treatment option for localized prostate cancer under the NIA Magellan criteria.

21. The Medical Technology Assessment Committee at AvMed drafts clinical policy guidelines and is responsible for maintaining or changing them as technology advances.

22. AvMed's policy on use of PBRT for the treatment of prostate cancer states that it is not medically necessary because studies have not shown clinical outcomes to be superior to conventional radiation therapy (i.e., IMRT).

23. This policy was developed following extensive review of studies in peer-reviewed medical literature, available guidelines, technology assessments, and opinions from experts. The policy is updated on a yearly basis in order to take into consideration any new evidence. A recent review of the policy on PBRT resulted in no change in AvMed's position on coverage for treatment of prostate cancer.

24. The medical coverage guidelines are meant to be used in conjunction with the Plan Document to determine whether services are medically necessary and a covered benefit.

25. Dr. Gorty, AvMed's external reviewer from Magellan Healthcare, who was accepted as an expert in the field of radiation oncology, testified that his recommended denial of coverage of PBRT was informed by Petitioner's medical records, Intervenor's Letter of Medical Necessity, clinical trials, the model policy from the American Society of Therapeutic Radiation and Oncology ("ASTRO"), and the National Comprehensive Cancer Network ("NCCN") guidelines.

PBRT

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

27. As stated earlier, Petitioner's prostate was removed in April 2018. Thereafter, rising PSA levels indicated that he needed further treatment, and Dr. Rodrigues, a board-certified radiation oncologist at Miami Cancer Institute, became his treating physician.

28. Dr. Rodrigues has been treating patients for 23 years, including prostate cancer patients. She was accepted as an expert in her field for these proceedings.

29. Dr. Rodrigues determined PBRT to be the appropriate radiation treatment for Mr. Zolfaghari given his type of prostate cancer—recurrent prostate cancer. Dr. Rodrigues testified that recurrent prostate cancer occurs when a cancer has been treated and then reoccurs.

30. In addition to PBRT, Dr. Rodrigues recommended, and Petitioner received, androgen deprivation therapy, generally referred to as hormone therapy, to be used in conjunction with PBRT. Dr. Rodrigues testified that the androgen deprivation therapy blocks the production of testosterone. She testified that patients with recurrent prostate cancer or certain high-risk patients have better overall survival when the two treatments are used in conjunction.

31. As an additional aggravating factor to Petitioner's cancer treatment, Petitioner was diagnosed with colon cancer leading to surgery in January 2020. Dr. Rodrigues testified that Petitioner's colon cancer made his need for PBRT even more necessary, because now Petitioner is at a higher risk for adverse effects from the unwanted spread of toxicity common with IMRT.

32. Dr. Rodrigues, as a Miami Cancer Institute physician, wrote letters requesting treatment and appealing denials of treatment as set forth above, and testified at the March 9, 2020, administrative hearing in support of Petitioner's efforts to obtain coverage through AvMed for PBRT, which she considers to be a medically necessary treatment modality.

33. Dr. Rodrigues was asked why she had not gone forward and provided Petitioner IMRT in order to prevent any further delay due to the passage of time from unsuccessful appeals of the denial by AvMed for the PBRT treatment of his recurring prostate cancer. She replied that she was attempting to secure a less toxic treatment modality, PBRT, for her patient who was already approved by Medicare for coverage of 80 percent of the cost of the treatment.

MEDICAL NECESSITY OF PBRT VERSUS IMRT

34. There is no dispute that IMRT is an accepted treatment modality for Petitioner's recurrent prostate cancer, even bearing in mind his complicating factor of colon cancer surgery and treatment endured following his 2018 prostatectomy. The remaining dispute here is whether PBRT is both medically necessary and not an experimental and/or investigative form of radiation treatment.

35. IMRT is a recognized form of treatment for Petitioner's recurrent prostate cancer. Dr. Rodrigues testified that Miami Cancer Institute considered only candidates for PBRT as those who would qualify for IMRT, such as Petitioner. Given the availability of another treatment option, IMRT, which is the most widely recognized standard of care within the medical establishment for the treatment of Petitioner's condition, Respondent's experts conclude that PBRT is not medically necessary because it is not the most appropriate level of service in this case.

36. While PBRT has been accepted by AvMed, according to its Plan, for certain types of cancer, the insurer has not yet authorized it for the treatment of prostate cancer. This is where the semantics of the contract come into play. Petitioner and Intervenor argued that Respondent mistakenly based its denial upon a diagnosis of "localized prostate cancer" (Dr. Rodrigues' reading of the proscription of the use of PBRT for Petitioner) rather than "recurrent prostate cancer" (not specifically proscribed by the Plan according to her reading), combined with the fact that Petitioner's

unique medical condition requires lower toxicity in the specific type of radiation used. PBRT, she testified, offers lower radiation toxicity, which will have less of a harmful effect on Petitioner's colon and rectum as a survivor of colon cancer surgery.

37. Dr. Rodriguez, the AvMed senior medical director, testified that studies comparing PBRT to 3-D confirming radiation or IMRT are limited. Overall studies have not shown clinical outcomes to be superior to conventional radiation therapy.

38. In addition to the preservice and Level I appeal reviews by AvMed, and Respondent's Level II appeal review, an Independent Organization Review ("IRO") was conducted by a licensed radiation oncologist employed by Independent Medical Expert Consulting Services. As a result of this independent review, the Plan's denial was upheld.

39. Dr. Rodrigues presented studies in her testimony and a letter of medical necessity which cited the potential for favorable outcomes with PBRT. Dr. Gorty, Respondent's expert in radiation oncology, contradicted her testimony in that many of the studies she cited noted a need for further study regarding the safety and efficacy of PBRT for treatment, and all of these studies were based upon "localized prostate cancer," rather than "recurrent prostate cancer." Dr. Gorty also testified that Petitioner's records indicated that his cancer was localized, although it could also be "recurrent." Dr. Gorty testified that clinical studies show no significant difference in the toxicity between IMRT and PBRT. Further, Dr. Rodriguez explained that localized cancer can be recurrent. "Localized" refers to where the cancer may be found, while "recurrent" refers to a repeat or re-occurrence of a cancer, which might return to the same location or reappear in a different location.

40. Paragraph 15 lists the criteria to determine whether a treatment or procedure is "medically necessary" under the AvMed policy. PBRT does not meet the third criterion of the definition of "medically necessary," as PBRT treatment of prostate cancer is not in accordance with standards of

acceptable community practice. Dr. Gorty testified that AvMed medical guidelines utilize IMRT as the "next generation" treatment, rather than PBRT. Further, Dr. Gorty testified that he was aware of several recent clinical trials concerning PBRT and IMRT, and these studies do not reach a conclusion that PBRT is preferable to IMRT.

41. PBRT does not meet the fifth criterion of the definition of "medically necessary," as PBRT has not been approved by the appropriate medical body or healthcare specialty involved as effective, appropriate, and essential for the care and treatment of prostate cancer. PBRT is not essential for the treatment of prostate cancer. There are several treatment modalities that are generally available for the treatment of prostate cancer and, as discussed above, several of those treatment options were reasonable treatment options for Petitioner. While Dr. Rodrigues believes PBRT to be preferable for Petitioner in this case due to, in her opinion, fewer adverse side effects of the treatment, she admitted that Petitioner is a suitable candidate for IMRT.

42. Therefore, PBRT does not meet the sixth criterion of the definition of "medically necessary," as it meets the definition of "experimental and/or investigational." Specifically, criteria 2, 3, and 4 of the definition of "experimental and/or investigational" are met, which lead to the ultimate conclusion that PBRT is not medically necessary in this case.

EXPERIMENTAL AND/OR INVESTIGATIONAL TREATMENT

43. Paragraph 18 sets forth the criteria for determining whether a treatment or procedure is "experimental and/or investigational." The second criterion from the definition of experimental and/or investigational treatment is met in this case. Insufficient outcomes data are not available from controlled clinical trials published in peer-reviewed literature to substantiate PBRT's safety and effectiveness for treatment of prostate cancer. Dr. Rodriguez testified that there is a lack of peer-reviewed, published, randomized studies regarding proton beam therapy.

44. Further, PBRT treatment is not the generally accepted standard of care. Dr. Rodrigues testified that only a handful of medical centers in the United States are using PBRT to treat cancer malignancies. Only two such programs are located in Florida—the University of Florida and Intervenor. Outside of Florida, only Massachusetts General and Loma Linda offer the treatment. Prior to Intervenor offering the treatment, Dr. Rodrigues referred her patients to one of these other facilities for PBRT when she deemed it appropriate to do so.

45. Current randomized trials are on-going and being published in peer-reviewed medical literature. PBRT treatment for prostate cancer is considered investigational and not a standard of care option and, therefore, not medically necessary. Nurse Thomas-Brown testified that a treatment considered experimental or investigational is, automatically, not medically necessary.

46. NIA Magellan Clinical Guideline Number NIA_CG_124, which was developed in July 2018 for implementation in January 2019 to assist physicians in the application of treatment, states that both surgery and radiation therapy should be used to treat organ confined prostate cancer, as well as prostate cancers extended into adjacent tissues. This guideline finds that PBRT is not an approved treatment option for localized prostate cancer as studies comparing it to 3-D conformal radiation or IMRT are limited.

47. Leading organizations, such as NCCN and ASTRO, have noted insufficient data outcomes and a need for more study of proton beam therapy, which these organizations have not yet accepted as the standard of care.

48. PBRT also meets the third criterion of the definition of "experimental and/or investigational." There is no consensus among practicing physicians that PBRT is safe or effective for the treatment of prostate cancer or that PBRT is the standard treatment utilized by practicing physicians in treating other patients with the same or similar conditions. Both Dr. Gorty and Dr. Rodriguez testified that proton beam therapy is experimental and

investigational and, therefore, not medically necessary for all forms of prostate cancer; two additional radiation oncologists reviewed the appeal and reached the conclusion that PBRT is not medically necessary.

49. Additionally, there was uncontroverted evidence that IMRT, not PBRT, is the standard form of treatment utilized by practicing physicians for treatment of prostate cancer.

50. Dr. Gorty testified that AvMed approved the NIA Magellan clinical guidelines for prostate cancer, which are based on the peer-reviewed studies; and he explained three such studies. His testimony noted that the second study from the University of Pennsylvania at Baltimore, Maryland, specifically matched Petitioner's medical condition. This study compared 307 men and their comparative toxicity outcomes of PBRT verses IMRT for post-operative sites. It concluded that future prospective investigation and ongoing follow-up will determine whether dosimetric differences between treatment with IMRT and proton beam therapy convert to meaningful differences in long-term outcomes.

51. As part of the appeal process on behalf of Petitioner, Intervenor also requested a review by an IRO. The review was completed by a board-certified radiation oncologist, and a report was generated on January 9, 2020. The "List of Materials Reviewed" is extensive and includes Petitioner's medical records and Intervenor's supporting documentation. The independent reviewer upheld the denial and noted that medical necessity has not been established. The IRO states that "until the current randomized trials ongoing are published in peer reviewed medical literature, proton beam treatment for prostate cancer is considered investigational and not a standard of care treatment option."

## CONCLUSIONS OF LAW

52. DOAH has jurisdiction over the parties to and the subject matter of this proceeding. §§ 120.569 and 120.57, Fla. Stat.

53. Respondent is the state agency charged by the Legislature with oversight of the administration of the state group insurance program. § 110.123(3)(c), Fla. Stat.

54. The Plan is a health insurance benefit enacted by the Florida Legislature and offered by Respondent. § 110.123, Fla. Stat.

55. In administrative proceedings, the party asserting the affirmative of an issue is required to prove that he or she is entitled to the relief sought. *Young v. Dep't of Cmty. Aff.*, 625 So. 2d 831, 833-34 (Fla. 1993); *Dep't of Transp. v. J.W.C. Co.*, 396 So. 2d 778, 788 (Fla. 1st DCA 1981). The burden of proof that applies is a preponderance of the evidence. § 120.57(1)(j), Fla. Stat. In this proceeding, Petitioner bears the burden of proving by a preponderance of the evidence that PBRT is a benefit covered under the Plan. If Petitioner meets this requirement, then the burden shifts to Respondent to prove that the claims were not covered due to the application of a policy exclusion. *Herrera v. C.A. Seguros Catatumbo*, 844 So. 2d 664 (Fla. 3d DCA 2003); *State Comprehensive Health Ass'n v. Carmichael*, 706 So. 2d 319, 320 (Fla. 4th DCA 1997).

56. In this case, one criterion in the definition of "medically necessary" is that the treatment at issue cannot be "experimental and/or investigational." Therefore, in proving that the treatment was medically necessary, Petitioner also had to prove that the treatment was not "experimental and/or investigational" as defined in the Plan Document. A treatment that is experimental and/or investigational is excluded by the Plan.

57. Petitioner and Intervenor failed to meet their burden of proving that PBRT was medically necessary. They failed to present competent substantial evidence that each of the criteria in the definition of "medically necessary"

was met. The greater weight of the evidence presented was that criteria 2, 3, 4, and 5 were not met.

58. Additionally, a preponderance of the evidence supports a finding that PBRT for treatment of prostate cancer is experimental and/or investigational as criteria 2, 3, and 4 of that definition are met. Petitioner and Intervenor failed to present sufficient evidence to rebut Respondent's witness testimony and documentary evidence on this issue. The independent reviewer's report, introduced by Petitioner, also confirms that PBRT for prostate cancer is considered investigational and not a standard of care treatment option. Since the treatment is excluded as an experimental and/or investigational service, it also fails to meet the definition of medically necessary treatment.

59. The therapy fails to meet the definition of medically necessary and, while recent clinical trials on the efficacy of its use for prostate cancer are underway, it currently continues to satisfy the criteria that render PBRT experimental and/or investigational. None of these clinical trials have acknowledged PBRT as preferable treatment for Petitioner's recurrent prostate cancer.

60. Petitioner's frustration regarding this coverage decision is not surprising, especially where, as here, the treatment proposed was approved for Medicare coverage. Acceptance by one insurer, but not another, is, understandably, difficult for him to accept when his physician, in good faith, has convinced him of the necessity for PBRT versus IMRT. However, the issue for determination here is not whether Medicare has elected to cover the therapy, but whether PBRT is a medically necessary treatment as defined in the Plan, which covers services offered to state workers and their dependents. By virtue of the Plan's definition of medical necessity, which controls the benefit determination for its insureds, proton beam therapy for the treatment of localized or recurrent prostate cancer is not a covered benefit at this time.

61. The conclusion reached by the undersigned in this case is not intended to declare that prescribing or administering PBRT is below the standard of

care. A qualified physician's (such as Dr. Rodrigues) consideration of a particular therapy as best for her patient does not always mean that the treatment will translate into a covered service. The definitions for a medically necessary service are for the purpose of benefit decisions and not necessarily clinical treatment decisions.

62. In the Proposed Recommended Order submitted by Petitioner and Intervenor, they declare that "[b]asic contract principles of insurance law apply here":

> Florida law provides that insurance contracts are construed in accordance with the plain language of the policies as bargained for by the parties. *See* [*Prudential Prop. & Cas. Ins. Co. v.*] *Swindal*, 622 So. 2d at 470. If the relevant policy language is susceptible to more than one reasonable interpretation, one providing coverage and the another limiting coverage, the insurance policy is considered ambiguous. *See Weldon v. All Am. Life Ins. Co.*, 605 So. 2d 911, 914–15 (Fla. 2d DCA 1992); *see also Container Corp. of Am. v. Maryland Cas. Co.*, 707 So. 2d 733, 736 (Fla. 1998) (where policy language is susceptible to differing interpretations, it should be construed in favor of the insured). Ambiguous policy provisions are interpreted liberally in favor of the insured and strictly against the drafter who prepared the policy. *See CTC Dev. Corp.*, 720 So. 2d at 1076; *Swindal*, 622 So. 2d at 470. Likewise, ambiguous insurance policy exclusions are construed against the drafter and in favor of the insured. *See Deni Assocs. of Fla., Inc. v. State Farm Fire & Cas. Ins. Co.*, 711 So. 2d 1135, 1138 (Fla. 1998). In fact, exclusionary clauses are construed even more strictly against the insurer than coverage clauses. *See State Comprehensive Health Ass'n v. Carmichael*, 706 So. 2d 319, 320 (Fla. 4th DCA 1997).

*Auto-Owners Ins. Co. v. Anderson*, 756 So. 2d 29, 34 (Fla. 2000).

63. This accurate statement of the principles for reading the plain language of an insurance policy and construing any ambiguities in the

language of the policy in favor of the insured and against the insurer set forth long-established principles of construction concerning insurance contracts. These principles apply to the reading of the Plan language related to whether PBRT is a covered expense for Petitioner's recurrent prostate cancer in this case. AvMed's senior medical director, Dr. Rodriguez, an expert in internal medicine, testified about the Plan language regarding the use of PBRT as "not approved for the treatment of localized prostate cancer." He further testified, and the undersigned credits his testimony (also supported by Dr. Gorty, Respondent's expert radiation oncologist) that the use of the term "recurrent" does not change his opinion, nor does it negate the findings of Dr. Rodrigues's cited clinical trials in support of her advocacy on behalf of Petitioner. "Recurrence," or a return, of cancer to an affected area is not the antonym of "localized." A recurrence of cancer can be localized or not, and the inclusion of the term "localized" in the Plan and NIA Magellan guidelines does not transform "recurrent" into a different type of prostate cancer that should be read into the plain language of the coverage. The fact that the Plan does not cover PBRT for "localized prostate cancer," does not translate into coverage for "recurrent prostate cancer," nor does it support, based upon the clinical trials to date and the guidelines of accepted organizations, such as NIA Magellan and NCCN, the use of PBRT rather than IMRT as the preferred treatment for Petitioner's condition.

64. Recurrence of prostate cancer after a prostatectomy can still be treated as localized, although, as testified to in this case, the locality of the cancer (it could not have recurred in the prostate gland itself since that was removed in 2018) has recurred in the prostate bed, seminal vesicles, and adjacent lymph nodes, all areas in close proximity or "localized" to the prostate. Each of these areas is reachable by radiation therapy. Dr. Rodrigues's preference for treating the recurrence with PBRT rather than IMRT is, in her opinion, to achieve a result with fewer adverse side effects. She did not testify that IMRT would not attack the cancer and provide the patient with a favorable result.

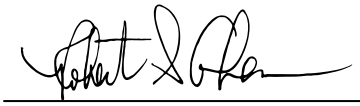
Dr. Rodrigues's personal preference for PBRT here, based upon her dedicated care and concern for the best outcomes for her patient and the fact that she works in one of the few facilities in the country offering proton beam therapy, does not override the only radiological treatment authorized by the Plan for prostate cancer, IMRT. Her care for Petitioner and, presumably, for all her patients is admirable, but without the clinical trials and nationally recognized support for the treatment modality she has selected, PBRT cannot be authorized for reimbursement in this case under the Plan.

65. The only remaining concern here that was not fully addressed at hearing is the delay in Petitioner receiving treatment of his cancer by IMRT, due to the several levels of appeal of the denial of authorization for PBRT by AvMed. The undersigned has no doubt in the sincerity of Dr. Rodrigues in seeking what she believes to be the best treatment for her patient. Hopefully, the passage of time will have had no measurable bearing on the efficacy of whatever radiation treatment is ultimately employed for Petitioner. One thing is clear, there is no absolute right to the best treatment for a medical condition according to your physician's opinion. An insured is entitled to an appropriate treatment modality that is designed to fully treat and, hopefully, resolve the medical issue. The preponderance of the evidence supports IMRT as an approved, tested, and efficacious treatment modality for Petitioner's recurrent prostate cancer. He should continue his treatment as expeditiously as possible.

## RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that the Department of Management Services, Division of State Group Insurance, enter a final order denying Petitioner's request for coverage for proton beam therapy.

DONE AND ENTERED this 4th day of May, 2020, in Tallahassee, Leon County, Florida.



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Filed with the Clerk of the
Division of Administrative Hearings
this 4th day of May, 2020.

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## NOTICE OF RIGHT TO SUBMIT EXCEPTIONS

All parties have the right to submit written exceptions within 15 days from the date of this Recommended Order. Any exceptions to this Recommended Order should be filed with the agency that will issue the Final Order in this case.