UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT KNOXVILLE

DONALD K. TURNER, Plaintiff, v. ALCOA INC., and HIGHMARK INC., d/b/a/, HIGHMARK BLUE CROSS BLUE SHIELD, Defendants.	)	No. 3:15-cv-270-TAV-HBG

REPORT AND RECOMMENDATION

This case is before the undersigned pursuant to 28 U.S.C. § 636, the Rules of this Court, and the referral Order [Doc. 16] of the Chief District Judge.

For the reasons stated herein, the undersigned will **RECOMMEND** that the Plaintiff's Motion for Judgment on the Record **[Doc. 12]** be **DENIED** and that the Defendants' Joint Motion for Judgment on the Administrative Record **[Doc. 14]** be **GRANTED**.

Plaintiff Donald K. Turner brought this action against Defendants Alcoa Inc., and Highmark Inc., d/b/a Highmark Blue Cross Blue Shield ("Defendants"), alleging that the Defendants' adverse claims determination with respect to coverage for the Plaintiff's proton beam therapy was an arbitrary and capricious decision. Plaintiff brings this action pursuant to the Employment Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1132, and requests that the decision denying coverage be reversed.

I. BACKGROUND

The facts relevant to the parties' Motions for Judgment are as follows.

A. The History of Plaintiff's Claim

The Plaintiff is a participant in the Employees' Group Benefits Plan of Alcoa Inc., Plan I for Retirees ("Plan"). Defendant Alcoa Inc. ("Alcoa") is the plan sponsor and administrator, and Defendant Highmark Blue Cross Blue Shield ("Highmark") is the designated claims administrator. [R. 10-1 at 52-53]. The Plan reimburses "medically necessary services and supplies, as determined by the claims administrator, that are provided by an eligible provider." [R. 10-1 at 10]. However, "services or supplies that are experimental or investigational . . . as determined by the claims administrator" are not covered. [R. 10-1 at 25]. Pursuant to the terms of the Plan, "Experimental or Investigational Services" is defined as follows:

> Medical, surgical, diagnostic, psychiatric, substance abuse, or other health care services, technologies, supplies, treatments, procedures, drug therapies, or devices that, at the time the claims administrator makes a determination regarding coverage in a particular case, are determined to be:
>
> - Not approved by the U.S. Food & Drug Administration (FDA) to be lawfully marked 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 used;
>
> - Subject to review and approval by an institutional review board for the proposed use;
>
> - The subject of an ongoing clinical trial that meets the definition of a phase 1, 2, or 3 clinical trial set forth in the FDA regulations, regardless of whether the trial actually is subjected to FDA oversight; or
>
> - Not demonstrated through authoritative medical or scientific literature published in the U.S. to be safe and effective for treating or diagnosing the condition or illness for which its use is proposed.

[R. 10-1 at 48-49]. Further, the Plan provides the plan administrator with discretionary authority as follows:

> [T]he plan administrator has the discretionary authority to determine eligibility under all provisions of the plans; correct defects, supply omissions, and reconcile inconsistencies in the plans; ensure that all benefits are paid according to the plans; interpret plan provisions for all participants and beneficiaries; and decide issues of credibility necessary to carry out and operate the plans. Benefits under the plans will be paid only if the plan administrator decides in its decision that the applicant is entitled to them.
>
> The plan administrator has designated the Benefits Management Committee to oversee the operation of the plans and the Benefits Management Committee has all the foregoing discretionary authority. All actions, decisions, or interpretations of the Benefits Management Committee are conclusive, final and binding.

[R. 10-1 at 52]. Finally, Defendant Highmark has an internal guideline, the Medical Policy Bulletin R-18 ("Bulletin"), that provides:

> Proton beam therapy is considered eligible when performed for the following indications:
>
> - Chordomas and chondrosarcomas of the base of the skull or spine;
> - Melanoma of the uveal tract (iris, ciliary body, and choroid). There must be no evidence of extrascleral extension. The diameter of the tremor must not exceed 24 mm and the height must not exceed 14 mm;
> - Hepatocellular carcinoma;
> - Pediatric brain tumors such as posterior fossa tumors, optic pathway tumors, and brainstem lesions (from the report of ASTRO's emerging technology committee);
> - Pediatric CNS tumors;
> - Pediatric Spinal tumors.

[R. 10-3 at 5]. The Bulletin further provides, "All other applications or uses of proton beam radiation therapy are considered experimental/investigational and ineligible for payment. Currently published medical literature does not provide sufficient documentation to permit conclusions concerning the effect on health outcomes. This modality remains an area of research." [R. 10-3 at 5]. Finally, the Bulletin states, "This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition.

Each person's unique clinical circumstances may warrant individual consideration, based on review of applicable medical records." [R. 10-3 at 5].

The Plaintiff was diagnosed with prostate cancer in 2014. [Doc. 13 at 3 and Doc. 15 at 3]. The Plaintiff's family physician discussed with the Plaintiff several treatment options, including proton beam therapy, and ultimately scheduled a consultation with Provision Center for Proton Therapy ("Provision"). [R. 10-7 at 3]. Subsequently, on May 22, 2014, Deborah Schleicher, a representative of Defendant Highmark, noted that proton beam therapy was not covered for prostate cancer because it was considered experimental or investigational pursuant to the Bulletin. [R. 10-6 at 151]. She also noted that if the provider wanted an expedited review, the provider should fax the information to her attention or to a supervisor. [R. 10-6 at 151].

In a letter entitled, "Letter of Medical Necessity," and dated May 23, 2014, the Plaintiff's physician with Provision, Dr. Fagundes, wrote that proton beam therapy was the recommended course of treatment. [R. 10-7 at 26-30]. Dr. Fagundes summarized the clinical findings, described in detail how proton beam therapy treats prostate cancer, and described the efficacy and advantages of proton beam therapy. [R. 10-7 at 26-30]. In addition, Dr. Fagundes explained that the Plaintiff was "electing to pursue treatment with proton therapy given the potential benefits in terms of disease control and function preservation[,] such as urinary control and erectile function." [R. 10-3 at 26].

Later, on June 10, 2014, Defendant Highmark denied preauthorization because the treatment was considered experimental/investigative in nature. [R. at 10-6 at 31 and 247].

B. Procedural History

On June 18, 2014, Provision requested an expedited appeal of the denial. [R. 10-6 at 31]. Provision enclosed comparative treatment plans to show the difference between proton beam

therapy and image modulated radiation therapy ("IMRT"). [R. 10-6 at 31]. Provision enclosed studies and reports with respect to proton beam therapy. [R. 10-6 at 31]. Two days later, on June 20, 2014, Defendant Highmark denied coverage stating that proton beam therapy was "determined not to be medically effective for the condition being treated and therefore is considered experimental/investigative in nature." [R. 10-7 at 8]. Defendant Highmark included the definition of experimental/investigative and noted that it considered the facts and circumstances of the Plaintiff's case in light of the Bulletin [R. 10-7 at 8]. Defendant Highmark also noted that there were no "unique clinical features of this case that would make it appropriate to approve on individual consideration" and that the Plaintiff had "not tried and failed other prostate therapies, including image modulated radiation therapy ("IMRT"), brachytherapy, and radical prostatectomy." [R. 10-7 at 8-9].

Provision appealed the decision, which was received by Defendant Highmark on June 23, 2014. [R. 10-6 at 96]. Defendant Highmark arranged for three radiation oncologists to review Plaintiff's file and determine whether there were unique clinical features that would make it appropriate to approve the treatment on an individual consideration based on the fact that the Bulletin excluded coverage. [R. 10-6 at 111-16]. Each physician answered, "No." [R. 10-6 at 111-16].

On July 21, 2014, the Appeals Committee upheld the decision to deny coverage. [R. 10-6 at 99-100]. The July 21 letter stated that the Appeals Committee was comprised of a Board Certified physician, who specialized in radiation oncology and had no involvement with the previous adverse decision and was not a subordinate of anyone involved in the previous adverse decision. [R. 10-6 at 99]. The letter stated that the Appeals Committee gave no deference to the prior decision maker and considered all available information. [R. 10-6 at 99]. The letter explained

that the Appeals Committee considered the facts and circumstances of the Plaintiff's case in addition to the Bulletin. Further, the letter explained that pursuant to the Bulletin, proton beam therapy is eligible for coverage with respect to certain types of tumors and/or cancers. [R. 10-6 at 99].[1] The letter noted that all other applications or uses of proton beam therapy are considered experimental/investigative and ineligible for payment. [R. 10-6 at 100]. The letter continued that "published medical literature does not provide sufficient documentation to permit conclusions concerning the effect on health outcomes. This modality remains an area of research." [R. 10-6 at 100]. The letter explained that IMRT, surgery, and brachytherapy are all reasonable options and that "[m]any studies have shown that protons do not necessarily have an improved side effect profile when compared to IMRT." [R. 10-6 at 100]. The letter concluded that Provision or the Plaintiff may file a voluntary level of appeal or an external review to an Independent Review Organization. [R. 10-6 at 100].

On August 6, 2014, Provision sought review on behalf of the Plaintiff by the Alcoa Benefits Appeals Committee. [R. 10-7 at 3]. Provision's letter explained that after the Plaintiff was diagnosed, he was told that due to the size of his prostate, he was not a candidate for brachytherapy seed implant and that his other options would include surgery to remove his prostate or external beam radiotherapy. [R. 10-7 at 3]. The letter continued that the Plaintiff's physician did not recommend surgery because the Plaintiff's cancer had been found early and was treatable with other methods. [R. 10-7 at 3]. The letter stated that the Plaintiff's family physician scheduled a consultation for the Plaintiff at Provision. [R. 10-7 at 3]. Further, the letter noted that Provision would accept $75,000.00 as payment in full, noting that with IMRT, an insurance company would pay in excess of $70,000.00. [R. 10-7 at 3]. The letter stated that proton beam therapy is covered

[1] As noted above, prostate cancer is not included in the list.

by Medicare, multiple Blue Cross Blue Shield plans, United Healthcare, and other carriers. [R. 10-7 at 3-4]. The letter also enclosed studies regarding patients who have been treated with proton beam therapy. [R. 10-7 at 4]. In addition, the letter noted that Dr. Fagundes had previously prepared a Letter of Medical Necessity, which was enclosed, along with a consult note and medical records. [R. 10-7 at 4].

In a letter dated October 15, 2014, the Alcoa Benefits Appeals Committee denied coverage, noting that it served as a final internal adverse benefit determination. [R. 10-7 at 5-7]. The letter explained that proton beam therapy "was determined to be experimental/investigational in nature." [R. 10-7 at 5]. The letter explained that the Committee relied upon the following:

> Highmark denial to authorize services lettered dated 6.20.2014
> Highmark medical policy R-18 dated 1.06.14
> Highmark member appeal denial letter dated 7.21.2014
> Independent Medical Review dated 8.27.14.

[R. 10-7 at 6]. With respect to the independent medical review dated August 27, 2014, a reviewing physician determined that proton beam therapy did not meet the definition as provided in the Plan. [R. 10-7 at 16]. [2] The reviewing physician noted that he/she spoke with Dr. Fagundes on August 26, 2014. [R. 10-7 at 16]. Dr. Fagundes told the reviewing physician that protons have been used for prostate cancer for several decades and are associated with reduced toxicity compared with photons. [R. 10-7 at 16]. Dr. Fagundes also told the reviewing physician that additional research was not necessary and that the American Society for Therapeutic Radiology and Oncology's Choosing Wisely campaign would deprive patients of a superior and less costly treatment option. [R. 10-7 at 17]. In addition, Dr. Fagundes told the reviewing physician that the cost of protons would be less if given in a hypogractionated fashion as opposed to standard fractionation with

[2] The report states, "It is the policy of Medical Review Institute of America to keep the names of its reviewing physicians confidential." [Doc. 10-7 at 20].

photons. [R. 10-7 at 17]. Dr. Fagundes also clarified that the Plaintiff was treated on a Registry trial. [R. 10-7 at 17].

In the reviewing physician's report, he/she noted the definition of "experimental/investigational" pursuant to the terms of the Plan. [R. 10-17 at 17]. The reviewing physician determined that proton radiation therapy was considered experimental/investigational pursuant to the terms of the Plan. [R. 10-7 at 17]. The reviewing physician explained as follows:

> Proton radiation therapy is considered experimental/investigational per Alcoa's plan provisions. There has been significant interest in the use of protons for the treatment of prostate cancer over the last four decades with several studies published in the peer-reviewed medical literature describing the safety and efficacy of this technology for selected patients with localized prostate cancer. However, there are no comparative trials evaluating the safety and efficacy of protons as compared with standard modern radiation therapy techniques utilizing photons. The only randomized trial compared a boost dose using photons or protons after the majority of treatment had been delivered with photons and found no differences in outcomes . . . Consequently, most investigators recommend additional study of the long-term safety and efficacy of protons as compared with modern radiation therapy techniques utilizing photons before recommending that protons be routinely used for patients with localized prostate cancer . . . Therefore, the use of protons for the treatment of prostate cancer is the subject of several ongoing NCI (National Cancer Institute)—approved clinical trials . . . . In addition, current evidence-based treatment guidelines state that "the outcome is similar to IMRT (intensity-modulated rational therapy) therapy, however, with no clear advantage from clinical data for either technique in disease control or preservation of late toxicity (NCCN [National Comprehensive Cancer Network] . . . Finally, ASTRO (American Society for Therapeutic Radiology and Oncology), as part of its Choosing Wisely Campaign, does not recommend the treatment of low risk prostate cancer patients with protons outside of a clinical trial setting. Therefore, the use of protons in this particular patient is defined as experimental/investigational according to the Plan language definitions.

[R. 10-7 at 18]. The reviewing physician concluded:

> There are few data in the recent-peer reviewed medical literature demonstrating improved outcomes with the use of protons as compared with standard radiation therapy techniques with photons and the use of this technology in this clinical setting remains under active clinical investigation. Therefore, the use of protons in this specific patient is defined as experimental/investigational according to the plan language definitions.

[R. 10-7 at 18].

Accordingly, the Alcoa Benefits Appeals Committee concluded, "Based upon plan provisions, Highmark documentation and information and the Independent third party review, the Alcoa Benefits Appeal Committee denied the request for coverage of proton radiotherapy treatment." [R. 10-7 at 6].

On November 19, 2014, per Provision's request, Defendant Highmark arranged an independent external review by Permedian. [R. 10-9 at 1]. Provision provided Permedian with a letter from Dr. Fagundes. [R. 10-9 at 7-10]. Dr. Fagundes's letter stated that per the Plan language, a treatment is considered experimental if it is the subject of an ongoing clinical trial that meets the definition of a phase 1, 2, or 3 clinical trial as set forth in the FDA regulations. [R. 10-9 at 8]. Dr. Fagundes cited a number of clinical trials involving x-ray radiotherapy and noted that proton beam therapy was widely considered to be the best option for pediatric patients and patients with base skull tumors because it spared healthy tissue. [R. 10-9 at 8-9]. Dr. Fagundes stated that "it is a non-sequitur to state that proton therapy works exceptionally well in the treatment a base of skull tumor or a pediatric tumor but to state it is unknown if it works for prostate cancer and thus it is experimental." [R. 10-9 at 9]. Dr. Fagundes's letter then explained several studies regarding proton therapy and requested that the decision denying coverage be reversed. [R. 10-9 at 9-10].

Subsequently, on December 29, 2014, Permedion upheld the denial. [R. 10-9 at 14]. Permedion noted that the reviewing panel assigned to the case had many credentials.[3] Further, Permedion explained that the Plaintiff had an early stage of prostate carcinoma and that treatment options that are considered the standard of care include prostatectomy, IMRT with photons, and a low dose rate or high dose rate of brachytherapy. [R. 10-9 at 15]. Permedion noted that proton beam radiation therapy had been approved by the FDA, but the medical and scientific evidence did not demonstrate that the expected benefits of the requested health care service are more likely to be beneficial to the Plaintiff than any available standard heath care service. [R. 10-9 at 15]. Permedion continued, "Proton beam radiation therapy is not considered a standard of care treatment option for prostate carcinoma." [R. 10-9 at 15]. Permedion explained, "There is no adequate medical literature published in peer reviewed journals supporting its use as equivalent nor better or safer than standard photon radiation therapy such as 3D conformal or IMRT." [R. 10-9 at 15]. Permedion noted that the National Comprehensive Cancer Network guidelines state the investigational nature of proton beam radiation therapy for prostate carcinoma. Finally, Permedion suggested that more randomized studies were needed to support its use as safe and effective for early stage prostate carcinoma. [R. 10-9 at 15]. Permedion cited ten references in support of its decision. [R. 10-9 at 16-17].

The Plaintiff filed suit on June 26, 2015.

II. POSITIONS OF THE PARTIES

In his Motion for Judgment on the Record [Doc. 12], the Plaintiff asserts that the Defendants' denial with respect to the proton beam therapy was arbitrary and capricious. In support

[3] Specifically, Permedion noted that the physician was certified by The American Board of Radiology in Radiation Oncology; a Member of the American Society for Therapeutic Radiology and Oncology, the American College of Radiation Oncology, the American College of Radiology, the American Brachytherapy Society, the American Radium Society; and was licensed in the State of Washington with an active clinical practice. [R. at 10-9 at 9].

of his argument, the Plaintiff asserts that Defendant Highmark had a conflict of interest when it denied coverage because it served dual roles. In addition, the Plaintiff asserts that Defendants' Bulletin would have covered proton beam therapy for prostate cancer in 2012, but it was amended in 2014 to exclude proton beam therapy without a medical basis for doing so. Further, the Plaintiff states that proton beam therapy is not experimental or investigational pursuant to the terms of the Plan. The Plaintiff also argues that the Defendants had no reason to favor any other treatment option over proton therapy in his case. Finally, the Plaintiff states that his action was timely filed.

The Defendants respond that the Plaintiff has failed to properly apply the arbitrary and capricious standard of review. The Defendants assert that they relied upon several independent oncologists with respect to whether the Plaintiff's form of cancer warranted an exception to the Bulletin. In addition, the Defendants argue that the Alcoa Benefits Appeals Committee consulted another oncologist who concluded that proton beam therapy constituted an experimental or investigational treatment. Finally, the Defendants assert that Plaintiff's request for coverage was sent to an independent review organization, and the physician reviewing the Plaintiff's file concluded that proton beam therapy constituted an experimental or investigational treatment.

III. STANDARD OF REVIEW

Where a benefit plan gives the plan administrator discretionary authority to determine eligibility for benefits or to construe the terms of the plan, the administrator's benefit determination is reviewed "under the highly deferential arbitrary and capricious standard of review." Goetz v. Greater Georgia Live Ins. Co., 649 F. Supp. 2d 802, 811 (E.D. Tenn. 2009) (quoting McDonald v. Western-Southern Life Ins. Co., 347 F.3d 161, 168 (6th Cir. 2003) (internal quotation marks removed)).

If it is possible to offer a "reasoned explanation" for the decision, based on all the evidence known to the administrator, then the decision is not arbitrary and capricious. Hunter v. Caliber System, Inc., 220 F.3d 702 (6th Cir. 2000); Yeager v. Reliance Standard Life Ins. Co., 88 F.3d 376, 381 (6th Cir. 1996). This standard is not demanding, but neither is it toothless. McDonald v. Western–Southern Life Ins. Co., 347 F.3d 161, 169, 172 (6th Cir. 2003). Courts must scrutinize the decision to determine whether, "substantively or procedurally, [the plan administrator] has abused his discretion." Metro. Life Ins. Co. v. Glenn, 554 U.S. 105, 115 (2008). In other words, the administrator's decision will be upheld only "if it is the result of a deliberate, principled reasoning process and if it is supported by substantial evidence." Glenn v. MetLife, 461 F.3d 660, 667 (6th Cir. 2006).

Moreover, the Court is to limit its review to the administrative record. Perez v. Aetna Life Ins. Co., 150 F.3d 550, 555 (6th Cir. 1998); Wilkins v. Baptist Healthcare Sys., 150 F.3d 609, 613 (6th Cir. 1998).

In the present matter, the parties do not dispute that the arbitrary and capricious standard applies. Moreover, the Court notes that the Plan provides the plan administrator with discretionary authority. [R. 10-1 at 51-52]. Accordingly, the arbitrary and capricious standard applies.

IV. ANALYSIS

The primary issue before the Court is whether the decision to deny coverage for the Plaintiff's proton beam therapy was arbitrary and capricious. For the reasons explained below, the Court finds that the Defendants' denial was not arbitrary and capricious.

(a) Conflict of Interest

The Plaintiff argues that the plan administrator served dual roles in both evaluating and paying benefit claims. In support of his argument that Defendant Highmark had a conflict of

interest, the Plaintiff asserts that it had a fiduciary obligation to act solely in the interest of the Plaintiff as a plan participant, but it acted in an adverse fashion and without a justifiable medical reason. In addition, the Plaintiff submits that the Defendants' own Bulletin describes proton beam therapy's benefits. Finally, the Plaintiff argues that although Provision offered to accept the cost of IMRT, his coverage was still denied.

A conflict of interest will arise when the decision-maker of which claims are covered is also the payor of those claims. Calvert v. Firstar Finance, Inc., 409 F.3d 286, 292-93 (6th Cir. 2005); Marks v. Newcourt Credit Group, 342 F.3d 444, 457 (6th Cir. 2003). It is well-established that the standard of review—that is, arbitrary and capricious—will not change because of a conflict of interest. Calvert, 409 F.3d 286, 292-93; see also Myers v. Prudential Ins. Co. of Am., 581 F. Supp. 2d 904, 909-10 (E.D. Tenn. 2008) (discussing Calvert). However, a conflict of interest is a factor to consider when determining whether the plan administrator's denial of benefits was arbitrary and capricious. Calvert, 409 F.3d at 292-93.

The Defendants assert that the Plan is self-insured, and the Plaintiff has not responded to the Defendants' argument. [R. 10-1 at 53]. Accordingly, the Court finds that a conflict of interest does not exist because the Plan is self-insured. See Ankney v. Metropolitan Life Ins., 438 F. Supp. 2d 566, 575 (D. MD. 2006) (noting that there was no conflict of interest when the disputed portion of the plan was self-insured). Further, the Court finds the Plaintiff's argument that Provision offered to accept the price of IMRT unavailing. The Plaintiff has not cited any authority that declining to accept a cost similar to another approved procedure is arbitrary and capricious. Moreover, it appears to the Court that such evidence would only negate the Plaintiff's argument that the Defendants had a conflict of interest. Finally, with respect to the Plaintiff's argument that the Bulletin describes the benefits of proton beam therapy, the Bulletin also states that the policy

is designed to address medical guidelines for the majority of individuals with a particular disease, illness, or condition. Prostate cancer is not included.

(b) Defendants' Denial

The Plaintiff submits that pursuant to the Plan's terms, proton beam therapy is not experimental. The Plaintiff asserts that proton beam therapy has been approved by the FDA. In addition, the Plaintiff argues that there is no indication in the record that proton beam therapy for prostate cancer is still subject to approval or that proton beam therapy has not been demonstrated through authoritative medical or scientific literature published in the United States to be safe and effective for treating or diagnosing the condition or illness for which its use is prosed. The Plaintiff acknowledges that proton beam therapy is still the subject of clinical trials, but he asserts that IMRT is also.

The Defendants respond that six separate, independent radiation oncologists found that proton beam therapy for Plaintiff's cancer was experimental/investigative per the terms of the Plan. The Defendants also explain that the Plaintiff has overlooked the independent review organization's opinion.

In the Defendants' denials, they consistently state that pursuant to the Bulletin, proton beam therapy is considered experimental or investigative.[4] As mentioned above, the Bulletin provides, "All other applications of uses of proton beam radiation therapy are considered experimental/investigational and ineligible for payment. Currently published medical literature

[4] To be clear, the Defendants acknowledge that the Bulletin is not part of the Plan documents. The Defendants argue, however, that the Bulletin is not inconsistent with the Plan, citing Smith v. Health Services of Coshocton, 314 F. App'x 848, 859 (6th Cir. 2009) (finding that a policy reasonably interpreted the terms of the plan and that the district court did not err in finding defendant's use of the policy arbitrary or capricious). The Plaintiff does not specifically argue that the Plan is inconsistent with the Bulletin.

does not provide sufficient documentation to permit conclusions concerning the health effect on health outcomes." [R. 10-3 at 5].

Defendant Highmark initially rejected coverage by relying upon the definition of "experimental/investigative" as stated in the Plan. In addition, it also acknowledged the Bulletin. In its July 21, 2014 denial, the Appeals Committee relied upon three radiation oncologists' opinions to determine where there were unique clinical features that would make it appropriate to approve the treatment on an individual consideration based on the fact that the Bulletin excluded coverage. All three radiation oncologists opined that proton beam therapy for prostate cancer was inconsistent with the Bulletin and that there were no unique clinical features in this case that would make it appropriate.

More notably, however, was the evidence that the Appeals Committee relied upon. In a report dated August 27, 2014, a reviewing physician determined that proton beam therapy met the definition of experimental/investigational as provided in the Plan. [R. 10-7 at 16]. Specifically, the reviewing physician noted that "while several studies published in the peer-reviewed medical literature describ[e] the safety and efficacy of this technology for selected patients with localized prostate cancer, . . . there are no comparative trials evaluating the safety and efficacy of protons as compared with standard moderation radiation therapy techniques utilizing photons." [R. 10-7 at 17].

Finally, upon request by the Plaintiff, the Defendants sent the Plaintiff's file for an external review with Permedion. Permedion upheld the denial, explaining that "[t]here is no adequate medical literature published in peer reviewed journals supporting its use as equivalent nor better or safer than standard photon radiation therapy such as 3D conformal or IMRT." [R. 10-9 at 15]. In addition, Permedion reasoned that the National Cancer Network guidelines state the

investigational nature of proton beam radiation therapy for prostate cancer and that more randomized studies are needed to support its use as a safe and effective method of early stage prostate cancer.

The Plaintiff acknowledges that proton beam therapy "is the subject of open clinical trials." [Doc. 13 at 13]. It asserts, however, that IMRT is also the subject of clinical trials. The Court has reviewed the administrative record and finds that the Defendants took a careful review of the Plaintiff's request to cover proton beam therapy, including requesting reviews from several different physicians and an external review. Accordingly, the Court finds the Plaintiff's arguments not well-taken.

Further, the Plaintiff submits that Provision provided numerous recent authorities and references showing that proton beam therapy is safe and effective for treating prostate cancer. Specifically, the Plaintiff cites to a reference list included in Dr. Fagundes's Letter of Medical Necessity [Doc. 10-6 at 31][5] and Dr. Fagundes's letter to Promedian. The physicians the Defendants relied upon also cited to studies and reports and provided reasons as to why proton beam therapy is considered experimental/investigative. The Court agrees with the Defendants in that it is not the Court's role to determine which study prevails. Instead, the Court's role is to determine whether the administrator's decision was the "result of a deliberate, principled reasoning process . . . supported by substantial evidence." Glenn, 461 F.3d at 667.

(c) 2012 Bulletin

The Plaintiff also asserts that the Defendants would have covered proton beam therapy two years prior to his diagnosis. Specifically, citing the 2012 version of the Medical Policy Bulletin R-18 ("2012 Bulletin"), the Plaintiff argues that he met the 2012 requirements for receiving proton

[5] The cited page does not include an ECF stamp at the bottom, so the Court has cited to the PDF page.

beam therapy. In addition, he asserts that other policies, such as Blue Cross Blue Shield in other states and Medicare, provide coverage for proton beam therapy.

The 2012 Bulletin was issued on October 15, 2012. [Doc. 10-3 at 9]. The 2012 Bulletin lists several different types of cancers eligible for proton beam therapy but does not include prostate cancer. The 2012 Bulletin states that proton beam therapy also may be covered when:

> (1) The dose volume histogram illustrates at least three (3) critical structures or organs protected by the use of proton beam therapy;
>
> (2) The dose to control or treat the tumor cannot be delivered without exceeding the tolerance of the normal tissue;
>
> (3) There is documented clinical rational that is generally thought to be above the level otherwise attainable with other radiation methods might improve control rates; or
>
> (4) There is documented clinical rational that higher levels of precision associated with proton beam therapy compared to other radiation treatments are clinically necessary.

[R. 10-3 at 9]. The 2012 Bulletin continues, "All other applications or uses of proton beam radiation therapy are considered investigational and ineligible for payment." [R. 10-3 at 9].

On January 6, 2014, Defendant Highmark issued another version of the Medical Policy Bulletin R-18 (hereinafter, "2014 Bulletin"). The 2014 Bulletin added several types of cancers eligible for proton beam therapy coverage, deleted others, and deleted the additional four circumstances in which proton beam therapy may be covered. [R. 10-3 at 5].

In the present matter, the Court finds the Plaintiff's argument not well-taken. Even if the Plaintiff met the additional criteria of the 2012 Bulletin, it was amended several months before the Plaintiff was diagnosed. See Doc. 13 at 3 (noting that the Plaintiff was diagnosed in March 2014); see generally McFarland v. Union Cent. Life Ins. Co., 907 F. Supp. 1153, 1163 (E.D. Tenn. 1995) (noting that the issue of the examiner's consideration was whether the plaintiff's claim was payable

under the terms of the plan as written, making the language used in any previous policies irrelevant). This is not a situation where the Plaintiff was diagnosed and then the Bulletin was amended to deny coverage. Further, the Plaintiff's arguments that other plans cover proton beam therapy are unavailing. The Court declines to issue a recommendation on plans that are not before it. Accordingly, the Court finds the Plaintiff's arguments not well-taken.

The Plaintiff also asserts that Provision cited numerous studies and clinical trials in its Letter of Medical Necessity and that the 2014 Bulletin cites a few outdated studies. Thus, the Plaintiff asserts that the 2014 amendment was arbitrary and capricious.

The Court finds this argument unavailing. As noted above, the Defendants submitted this matter to several physicians, who reviewed the terms of the Plan and the Bulletin. Specifically, the report dated August 27, 2014, explained that most investigators recommend additional study of the long-term safety and efficacy of protons as compared with modern radiation therapy techniques before recommending that protons be routinely used for patients with localized prostate cancer. [R. 10-7 at 18]. In addition, the reviewing physician noted that proton beam therapy was still the subject of several ongoing clinical trials at the National Cancer Institute and that the American Society for Therapeutic Radiology and Oncology did not recommend the treatment of low risk prostate cancers with protons outside the clinical trial setting. [R. 10-7 at 18]. Further, the reviewing physician with Permedion noted that the National Comprehensive Cancer Network guidelines explain the investigational nature of proton beam therapy, and Permedion suggested that more randomized studies were needed. Accordingly, the Court finds the Plaintiff's argument not well-taken.

(d) Miscellaneous Arguments

The Plaintiff also asserts this lawsuit was timely. The Defendants do not dispute that the suit was filed timely. [Doc. 22 at 5] ("Finally, to be clear, the Plan does not seek a decision based on the contractual statute of limitations."). Accordingly, the Court finds that the suit was timely filed.

In addition, the Defendants assert that the Plaintiff alleged bad faith and breach of contract claims in his Complaint. The Defendants argue that ERISA preempts any and all state laws. The Plaintiff does not respond to the Defendants' argument. Accordingly, the Court agrees that ERISA preempts such claims and recommends that they be dismissed. Pilot Life Insurance Co. v. Dedeaux, 4811 U.S. 41, 41 (1987) (breach of contract and bad faith claims arising out of a failure to provide benefits under the insurance contract are preempted by ERISA).

V. CONCLUSION

Accordingly, the undersigned **RECOMMENDS**[6] that the Plaintiff's Motion for Judgment on the Record **[Doc. 12]** be **DENIED** and that the Defendants' Joint Motion for Judgment on the Administrative Record **[Doc. 14]** be **GRANTED**.

Respectfully Submitted,

Bruce Guyton
United States Magistrate Judge

[6] Any objections to this Report and Recommendation must be served and filed within fourteen (14) days after service of a copy of this recommended disposition on the objecting party. Fed. R. Civ. P. 72(b)(2). Such objections must conform to the requirements of Rule 72(b), Federal Rules of Civil Procedure. Failure to file objections within the time specified waives the right to appeal the District Court's order. Thomas v. Arn, 474 U.S. 140, 106 S. Ct. 466 (1985). The district court need not provide de novo review where objections to this report and recommendation are frivolous, conclusive or general. Mira v. Marshall, 806 F.2d 636 (6th Cir. 1986). Only specific objections are reserved for appellate review. Smith v. Detroit Federation of Teachers, 829 F.2d 1370 (6th Cir. 1987).