STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

Jennings Scott Hucks, Appellant, vs. South Carolina Public Employee Benefit Authority, Employee Insurance Program, Respondent.	Docket No.: 13-ALJ-30-0380-AP **ORDER**

STATEMENT OF THE CASE

The above-captioned matter is before the Administrative Law Court (ALC or Court) on an administrative appeal pursuant to S.C. Code Ann. § 1-11-710(C) (2005) and S.C. Code Ann. § 1-23-600(D) (Supp. 2013). Jennings Scott Hucks (Appellant) seeks review of a decision by South Carolina Public Employee Benefit Authority, Employee Insurance Program (Respondent, PEBA[1] or EIP) denying the preauthorization for Appellant's request for enrollment in a clinical trial studying autologous hematopoietic stem cell transplant (HSCT)[2] for treatment for multiple sclerosis (MS). Specifically, by letter dated June 20, 2013, EIP's Health Appeals Committee (Committee) informed Appellant that the treatment sought is considered investigational in nature under the terms of the Standard Plan, part of the South Carolina Group Health Benefits Plan (Plan). Appellant timely filed this appeal to the ALC on August 5, 2013. Appellant submitted a reply brief on January 2, 2014. Respondent filed a Motion to Strike the Appellant's Reply as being untimely. Since the Court agrees the Appellant's Reply Brief was due 38 days prior to its filing, the Court will not consider any issues raised in Appellant's Reply Brief. Based upon the briefs timely submitted and the complete record, this Court affirms the decision of EIP.

[1] Effective July 1, 2012, the EIP became part of PEBA.

[2] An autologous stem cell transplant takes stem cells from the patient's own bone marrow. The patient is then treated with medications to eradicate cancer cells, or in this case, immunosuppressive medications. These medications cause the patient's bone marrow to degrade. The patient then undergoes a bone marrow transplant from his own bone marrow, and stem cells cause new marrow to regrow. See Nat'l lnsts. of Health, Stem Cell Information, Hematopoietic Stem Cells (2011), http://stemcells.nih.gov/info/scireport/pages/chapter5.aspx.

STANDARD OF REVIEW

This case is before the Court as an appeal from a Final Order of EIP. The Plan provides that EIP has "full and exclusive authority to control and manage the Plan, to administer claims, and to interpret the Plan and resolve all questions arising in the administration, interpretation and application of the Plan." That authority includes the right to determine entitlement to benefits. The Plan further provides:

> Any decision we make in the exercise of our authority is conclusive and binding, subject only to appellate judicial review consistent with the standards provided in Section 1-23-380, Code of Laws of South Carolina.

In addition, the enabling legislation for the Plan provides as follows:

> Notwithstanding Sections 1-23-310 and 1-23-320 or any other provision of law, claims for benefits under any self-insured plan of insurance offered by the State to state and public school district employees and other eligible individuals must be resolved by procedures established by [PEBA], which shall constitute the exclusive remedy for these claims, subject only to judicial review consistent with the standards provided in Section 1-23-380.

S.C. Code Ann. § 1-11-710(C) (2005).

Therefore, the Administrative Law Court's review of this case is in an appellate capacity under the standards of S.C. Code Ann. § 1-23-380 (2005 and Supp. 2013), rather than as an independent finder of fact. Specifically, § 1-23-380(5) sets forth:

> The court may not substitute its judgment for the judgment of the agency as to the weight of the evidence on questions of fact. The court may affirm the decision of the agency or remand the case for further proceedings. The court may reverse or modify the decision [of the agency] if substantial rights of the appellant have been prejudiced because the administrative findings, inferences, conclusions, or decisions are:
>
> (a) in violation of constitutional or statutory provisions;
> (b) in excess of the statutory authority of the agency;
> (c) made upon unlawful procedure;
> (d) affected by other error of law;
> (e) clearly erroneous in view of the reliable, probative, and substantial evidence on the whole record; or
> (f) arbitrary or capricious or characterized by abuse of discretion or clearly unwarranted exercise of discretion.

S.C. Code Ann. § 1-23-380(5) (2005 and Supp. 2013).

A decision is supported by substantial evidence when the record as a whole allows reasonable minds to reach the same conclusion reached by the agency. Bilton v. Best Western Royal Motor Lodge, 282 S.C. 634, 321 S.E.2d 63 (Ct. App. 1984). The well settled case law in

this state has also interpreted the substantial evidence rule to mean that a decision will not be set aside simply because reasonable minds may differ on the judgment. Lark v. Bi-Lo, 276 S.C. 130, 276 S.E.2d 304 (1981). The fact that the record, when considered as a whole, presents the possibility of drawing two inconsistent conclusions from the evidence does not prevent the agency's finding from being supported by substantial evidence. Waters v. S.C. Land. Res. Conservation Comm'n, 321 S.C. 219, 467 S.E.2d 913 (1996).

When applying the substantial evidence rule, the factual findings of the administrative agency are presumed to be correct. Rodney v. Michelin Tire Co., 320 S.C. 515, 466 S.E.2d 357 (1996). Furthermore, the reviewing court is prohibited from substituting its judgment for that of the agency as to the weight of the evidence on questions of fact. Grant v. S.C. Coastal Council, 319 S.C 348, 461 S.E.2d 388 (1995). Finally, the party challenging an agency action has the burden of proving convincingly that the agency's decision is unsupported by substantial evidence. Waters, 467 S.E.2d at 913.

ISSUES ON APPEAL

1. Did PEBA err in determining HSCT is an investigational or experimental treatment for MS where other similarly-worded plans have approved the treatment?

2. Did PEBA err in determining HSCT is not medically necessary for Appellant's treatment?

3. Did PEBA err in determining an investigational treatment is excluded from coverage under the Plan?

PROCEDURAL BACKGROUND

Appellant participates in the Plan. Appellant is appealing the decision of the Committee denying preauthorization for enrollment in a clinical trial studying HSCT as treatment for MS.[3] EIP denied authorization because HSCT was considered investigational/experimental in nature and not medically necessary for treatment of MS under the terms of the Plan.

[3] MS is a nervous system disease that affects the brain and spinal cord. It damages the myelin sheath, the material that surrounds and protects nerve cells, often in the form of lesions. This damage slows down or blocks messages between brain and body, leading to symptoms including visual disturbances, muscle weakness, trouble with coordination and balance, sensations such as numbness, prickling or "pins and needles," and thinking and memory problems. Usually, the disease is mild, but some people lose the ability to write, speak or walk. There is no cure for MS, but medicines and/or physical therapy may slow it down and help control symptoms. See U.S. Nat'l Library of Med. & the Nat'l Insts. of Health, A.D.A.M. Medical Encyclopedia [hereinafter A.D.A.M. Medical Encyclopedia], Multiple Sclerosis (2012), http://www.nlm.nih. gov/medlineplus/multiplesclerosis.html.

MEDICAL EVIDENCE IN THE RECORD

On February 3, 2012, internal medicine specialist Richard K. Burt, M.D., submitted a letter and records to Medi-Call[4] requesting preauthorization to enroll Appellant into a Food and Drug Administration (FDA)-approved clinical trial called "Hematopoietic Stem Cell Therapy for Patients with Inflammatory Multiple Sclerosis Failing Interferon[[5]]: A Randomized Study."[6] Dr. Burt stated Appellant was diagnosed with MS in 2010 and was an ideal patient for Dr. Burt's study protocol.

Appellant's MS diagnosis was specified as relapsing-remitting multiple sclerosis (RRMS).[7] With this type of MS, Dr. Burt noted minimal improvement from traditional therapy, as well as risks of developing progressive multifocal leukoencephalopathy (PML)[8] Dr. Burt stated long-term traditional treatment with Tysabri, an FDA-approved treatment, would increase the risk of developing PML, but once a patient was taken off Tysabri, the patient would experience recurrent acute attacks. Dr. Burt stated Fingolomid was another FDA-approved treatment that carries a risk of arrhythmia. However, Dr. Burt indicated that high-dose cyclophosphamide[9] and HSCT had significant success in treating RRMS. Medi-Call denied preauthorization for this treatment because the Plan does not cover investigational or experimental treatments.

On February 29, 2012, Gregory Dean, the transplant liaison for Northwestern Memorial Hospital, sent a letter to Medi-Call appealing the preauthorization denial. He included Appellant's medical records, instructions on how to find the study protocol, and a letter of medical necessity.

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[4] Medi-Call is the Utilization Review Manager as defined in the Plan; it is a division of Blue Cross Blue Shield of South Carolina (BCBSSC), which is the Third Party Claims Processor for the Plan.

[5] An antiviral medication used to treat MS. See Merriam-Webster's Medical Dictionary (rev. ed. 2009) [hereinafter Merriam-Webster's], www.merriam-webster.com/medical/.

[6] As noted in a description of this clinical trial, a randomized study indicates some participants would be assigned, at random, to the experimental treatment and some to the traditional interventions. See Nat'l Insts. of Health, ClinicalTrials.gov, Stem Cell Therapy for Patients With Multiple Sclerosis Failing Interferon: A Randomized Study, http://clinicaltrials.gov/ct2/show/NCT00273364.

[7] The relapsing-remitting subtype of MS is characterized by unpredictable relapses, followed by periods of months to years of relative quiet (remission) with no new signs of disease activity.

[8] PML is a rare disorder that damages the material (myelin) that covers and protects nerves in the white matter of the brain. See id., Progressive Multifocal Leukoencephalopathy (2013), http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001695/.

[9] An immunosuppressant drug used most often in treating cancer. See Merriam-Webster's.

On April 12, 2012, Appellant's case was sent to BCBSSC Medical Director, Ashby Jordan, M.D. Upon review of the case, Dr. Jordan noted that no Corporate Administrative Medical (CAM)[10] policy existed regarding this type of treatment. Dr. Jordan also found Appellant did not meet the medical community's generally accepted clinical criteria for that type of treatment because Appellant did not carry any of the cancer diagnoses for which the treatment is approved. Dr. Jordan recommended denying coverage because the procedure was investigational as treatment for MS. On April 12, 2012, Medi-Call denied Dr. Burt's request for preauthorization.

On April 20, 2012, Dr. Burt appealed to Medi-Call requesting Appellant be approved for his "FDA approved randomized study for relapsing remitting multiple sclerosis." He asked that a board-certified transplant/hematologist or a neurologist review Appellant's file. In response to the denial letter of April 12, 2012, Dr. Burt stated HSCT was recognized as effective treatment for autoimmune diseases and was currently used worldwide and becoming more accepted as treatment. However, Dr. Burt admitted the treatment has not received final approval to market and randomized trials were the next step. The requested treatment was a randomized study comparing stem cell transplant to FDA-approved standard of care therapies such as Tysabri and Gilenya. Dr. Burt also indicated that medical reviews performed for other insurance plans have found that the procedure was not experimental and the rate of recovery outweighed the risks of approving payment for an investigational treatment.

On April 28, 2012, Todd Samuels, M.D., an independent, board-certified neurologist, completed an external review of Appellant's file. Dr. Samuels stated "Autologous non-myeloablative[11] hematopoietic stem cell transplantation [was] a method to deliver intense immunosuppression to patients with multiple sclerosis (MS)." Dr. Samuels found that this technique was currently the object of several clinical trials and remained experimental or investigational. Dr. Samuels noted the results of larger randomized clinical trials with long term follow-up were required to demonstrate that stem cell transplantation provided health benefits, to

[10] CAMs are medical policies assembled by BCBSSC as part of its duties as the third-party claims processor. CAMs aggregate the most current peer-reviewed medical literature on a given medical procedure or services, and make recommendations regarding criteria for medical necessity and/or the investigational (experimental) nature of services based on the consensus of the medical community.

[11] Non-myeloablative means all the patient's bone marrow is not destroyed before transplant, instead relying on the healthy graft to overtake the remaining unhealthy marrow cells. See Merriam-Webster 's.

define the clinical role of stem cell transplantation, and to establish patient selection criteria. Dr. Samuels concluded, "the requested procedure is experimental/investigational and is therefore not medically necessary."

On May 3, 2012, Dr. Jordan, aided by Dr. Samuel's external review, determined the requested autologous bone marrow transplant was not the standard of care for MS. Dr. Jordan concluded the proposed treatment was investigational under the terms of the Plan, and also therefore not medically necessary. On May 4, 2012, Medi-Call reviewed Appellant's appeal. Medi-Call found that pursuant to Paragraph 9(G) of the Plan, experimental or investigational procedures were not covered under the Plan. Accordingly, Medi-Call denied authorization for payment for the treatment as an investigational service.

On July 31, 2012, Appellant appealed to PEBA. He stated BCBSSC's denial under paragraph 9(G) of the Plan was inappropriate, given that the Plan guarantees coverage for procedures deemed medically necessary. Appellant stated Dr. Burt refuted each reason for denial in his letters, and set forth these reasons in his appeal.

On September 25, 2012, PEBA requested an additional medical review and financial information regarding Appellant's appeal. Specifically, the Committee wished to know whether immunosuppressant therapy was the standard of care for MS; whether the stem-cell procedure itself was in fact FDA approved as an immunosuppressant therapy for other diseases, but was still under study for treating MS; whether the journal articles Appellant included in his appeal file have any bearing on the acceptability and standards of care in this medical specialty field for treating MS with the requested stem cell treatment; and, while not binding on the Plan, whether the other approvals for this type of treatment had a bearing on Appellant's case, and whether differences in the plans who made those approvals were outcome-determinative (i.e. based on differences in the plan's language.) PEBA also asked for a cost-benefit analysis of the differing treatments.

On October 16, 2012, William Harms, M.D. answered these questions. First, he stated immunosuppression with steroids or corticotropin (ACTH)[12] had been used for years to treat exacerbations of MS. He clarified the FDA does not evaluate the use or potential use of stem-cell support for any medical condition. He further stated data surrounding the use of stem-cell

[12] A hormone that regulates cortisol levels in the body. See A.D.A.M. Medical Encyclopedia, ACTH (2011). http://www.nlm.nih.gov/medlineplus/ency/article/003695.htm.

support in cancer treatment showed both a net health benefit and no benefit. Dr. Harms noted stem-cell support currently was being evaluated for many conditions, including MS, but as of the relevant time period, the data was not sufficient to permit conclusions regarding the benefit and effectiveness of stem cell transplants to prevent relapse in MS. Dr. Harms indicated Appellant's articles were either interim reports from ongoing clinical trials, and were therefore investigational by definition, or retrospective reporting of a clinical series. As to the medical reviews and approvals included, Dr. Harms indicated the reviews were opinions and were not based on whether the scientific evidence permitted conclusions regarding health outcomes. Dr. Harms noted the evidence did not discuss net health outcomes, or the effect on the health outcomes. Dr. Harms also opined the evidence did not permit a conclusion that a benefit could be achieved outside of an investigational setting. He further noted one reviewer in another case, among those Appellant and his physicians had submitted, who recommended the denial be overturned did not address the investigational nature of the treatment. Dr. Harms also noted still another reviewer did not recommend the denial be overturned. Dr. Harms stated, "a clinical trial is done because it is not known with scientific certainty that the intervention is more beneficial than other therapies."

With regard to the ongoing cost of care, Dr. Harms stated if the member were to be randomized to the stem-cell support arm of the clinical trial, the costs of care would likely be the same. He concluded that the likely cost of stem-cell support in this trial would exceed the cost of use in conditions where there was clinical trial evidence of benefit.

The Committee reconvened and reviewed Appellant's file considering additional information regarding the nature of clinical trials and the specific course of treatment at issue. The Committee reviewed an opinion and sought clarification from a case-management nurse at Medi-Call. The Medi-Call nurse clarified this treatment would not be curative and was not claimed to be, even in the additional studies provided from Dr. Burt. She further noted in some cases, the progression of MS had slowed. In addition, the nurse observed the clinical trial would not be in lieu of the traditional treatment but rather in addition to his treatment. She also noted Appellant's actual costs for prescriptions under the Plan were approximately $48,000 annually.

On June 20, 2013, PEBA informed Appellant, after its *de novo* review, that it was denying preauthorization for enrollment in a clinical trial studying HSCT as treatment for MS.

RELEVANT PLAN PROVISIONS

The following provisions of the 2011 and 2012 State Health Plan documents[13] are pertinent:

2.53 Medical Necessity; Medically Necessary or Necessary Service and Supply:

A procedure, service or supply that meets all of the following criteria:

A. Is required to identify or treat an existing condition, illness or injury; and
B. Is prescribed or ordered by a Physician; and
C. Is consistent for treatment of the Covered Person's illness, injury, or condition, and is rendered **in accordance with recognized, appropriate medical and surgical practices prevailing in the medical specialty or field of medicine** at the time rendered; and
D. Is required for reasons other than the convenience of the patient; and
E. Results in measurable, identifiable progress in treating the Covered Person's condition, illness, or injury.

The **fact that a procedure, service or supply is prescribed by a Physician**, or that a Physician asserts that a procedure, service or supply is necessary to avoid the potential onset of a condition or abnormality in the future, **does not automatically mean that such procedure, service or supply is Medically Necessary** or meets the definition of Medical Necessity in this Plan.

ARTICLE 9
Exclusions and Limitations
No benefits will be provided under any Article of this Plan for any service, supply or charges for the following:

A. Any service or charge for service which is not Medically Necessary as defined in paragraph 2.53; any service or charge for service which is performed in a more costly setting than that required by a Covered Person's condition, in which case benefits will be limited to the benefits due had the services been performed in the least costly setting required by the Covered Person's condition…

G. **Any surgical or medical procedures determined by the medical staff of the Third Party Claims Processor, with appropriate consultation, to be experimental or investigational or not accepted medical practice**. Experimental or investigational procedures are those medical or surgical procedures, supplies, devices, or drugs, which at the time provided, or sought to be provided:

1. Are not recognized as conforming to accepted medical practice in the relevant medical specialty or field of medicine; or
2. The **procedures, drugs or devices have not received final approval to market from appropriate government bodies**; or
3. Are those about which the peer-reviewed medical literature does not permit conclusions concerning their effect on health outcomes; or
4. Are not demonstrated to be as beneficial as established alternatives; or

[13] The Plan provisions are the same for both Plan years except where indicated.

5. Have not been demonstrated, to a statistically significant level, to improve the net health outcomes; or
6. Are those in which the **improvement claimed is not demonstrated to be obtainable outside the investigational or experimental setting**.

The 2011 Insurance Benefits Guide, which is provided to all participants in the state health and dental insurance plans states:

> Exclusions: Services Not Covered
> There are some medical expenses the State Health Plan does not cover. The Plan of Benefits (available in your benefits office or through EIP) contains a complete list of the exclusions. Some expenses that are not covered are charges for:
> 1. Services or supplies that are not medically necessary
> . . .
> 45. **Experimental or investigational surgery or medical procedures, supplies, devices or drugs**. Any surgical or medical procedures determined by the medical staff of the third-party administrator with appropriate consultation, to be experimental or investigational or not accepted medical practice. Experimental or investigational procedures are those medical or surgical procedures, supplies, devices, or drugs, which at the time provided, or sought to be provided:
> - Are not recognized as conforming to accepted medical practice in the relevant medical specialty or field of medicine; or
> - The procedures, drugs or devices have not received final approval to market from appropriate government bodies; or
> - Are those about which the peer-reviewed medical literature does not permit conclusions concerning their effect on health outcomes; or
> - Are not demonstrated to be as beneficial as established alternatives; or
> - Have not been demonstrated, to a statistically significant level, to improve the net health outcomes; or
> - Are those in which the improvement claimed is not demonstrated to be obtainable outside the investigational or experimental setting.

DISCUSSION

Did PEBA Err in Determining HSCT is an Investigational Treatment?

Appellant argues that the substantial evidence in the record does not support PEBA's conclusion that the HSCT treatment is investigational or experimental. A review of the record reflects that PEBA's decision was based on the opinions of Appellant's own treating physicians; the opinions of an independent, expert peer reviewer; the opinions of BCBSSC's in-house medical reviewers; and the unambiguous language of the Plan.

Courts are not well-skilled at deciding exactly when a treatment that has been considered experimental in the past crosses the line into general acceptance. Smith v. Office of Civilian Health and Med. Program of the Uniformed Servs., 97 F.3d 950 (7th Cir. 1996). Normally such

decisions should be left to medical scientists and health-care professionals. The role of this Court is to review the decision and to intervene only if it is clearly erroneous in view of the reliable, probative, and substantial evidence on the whole record. S.C. Code Ann. § 1-23-380(5) (2005). Where there is conflicting evidence, the agency's findings of fact are deemed conclusive. Sharp v. Case Produce, Inc., 336 S.C. 154, 519 S.E.2d 102 (1999).

Based on the statements of Appellant's own treating physicians, it is undisputed the requested treatment was for Appellant to participate in a randomized clinical trial. In his letter on April 20, 2011, Dr. Burt states, "This study is [a] randomized study comparing stem cell transplant to standard of care therapy." This statement reflects not only that the treatment is experimental, but also that it is not the standard of care. By its very definition, treatment in a clinical study is both experimental and investigational, and specifically excluded under Article 9 of the Plan. The Plan may pay only claims for treatment approved and accepted as the standard of care. As Dr. Harms noted, "a clinical trial is done because it is not known with scientific certainty that the intervention is more beneficial than other therapies." Because the treatment at issue is a clinical trial, comparing two interventions (stem-cell transplant versus immunosuppressant therapy), it is by definition investigational, and investigational services are excluded under the Plan.

Appellant's argument that other insurance plans have approved participation in the randomized study is irrelevant. No evidence in the record indicates the language in those plans was identical to the language of the State Health Plan. More importantly, even if the plan language were identical, PEBA would not be bound by the decision of another insurer interpreting a different plan; PEBA has the duty to interpret and apply the terms in its policy. S.C. Code Ann. § 1-11-710(C) (Supp. 2013).

While there are conflicting views expressed by the medical experts in the file, the substantial evidence supports PEBA's conclusion that the use of HSCT is an investigational or experimental treatment for Appellant's condition.

Did PEBA Err in Determining HSCT is not Medically Necessary?

Appellant argues that even an experimental or investigational treatment is covered by the Plan if it has been deemed by physicians to be "medically necessary."

Pursuant to Article 2.53 of the Plan, for a treatment to be determined medically necessary, it must meet five specific criteria. These criteria are: (A) is the treatment required to

identify or treat an existing condition, illness or injury; and (B) is the treatment prescribed or ordered by a Physician; and (C) is the treatment consistent for treatment of the Covered Person's illness, injury, or condition, and is the procedure rendered in accordance with recognized, appropriate medical and surgical practices prevailing in the medical specialty or field of medicine at the time rendered; and (D) is the treatment required for reasons other than the convenience of the patient; and (E) does the treatment result in measurable, identifiable progress in treating the Covered Person's condition, illness, or injury. The failure of the procedure to meet any one of the five criteria is fatal to Appellant's claim.

Based on the substantial evidence in the record, including but not limited to the opinions of Appellant's own treating physicians; the opinions of an independent, expert peer reviewer; the opinions of BCBSSC's in-house medical reviewers and the unambiguous language of the Plan, the criteria set out in Articles 2.53 (C) and (E) were not met. There is ample evidence to support PEBA's conclusion that HSCT is not recognized as conforming to accepted medical practice. Multiple physician reviewers and Appellant's treating physician confirmed immunosuppressant therapy is standard medical practice. Article 2.53(C) of the Plan indicates a service must be rendered in accordance with recognized, appropriate medical and surgical practices prevailing in the medical specialty or field of medicine at the time rendered in order to be considered medically necessary under the terms of the Plan. Article 9(G) of the Plan provides that no benefits will be provided for any service for "medical procedures determined by the medical staff of the Third Party Claims Processor, with appropriate consultation, to be experimental or investigational or not accepted medical practice." Therefore, under the unambiguous terms of the Plan a treatment that is experimental or investigational cannot meet the definition of "medically necessary."

Appellant's argument that because Appellant's treating physician deemed the procedure medically necessary it should be covered, is incorrect. A physician's opinion is one of the criteria mentioned above for medical necessity, but all criteria must be met for a procedure to be covered. The Plan states, "The fact that a procedure, service or supply is prescribed by a physician, or that a physician asserts that a procedure, service or supply is necessary to avoid the potential onset of a condition or abnormality in the future, does not automatically mean that such procedure, service or supply is medically necessary or meets the definition of "medical necessity" in this Plan." "Medical necessity" is an objective standard to be applied by the trier of

fact and is not determined solely by the opinion of the treating physician; Franks v. La. Health Serv. & Indem. Co., 382 So.2d 1064 (La. Ct. 1980) (insurer has discretion in defining medical necessity and is under an obligation to make a sincere and honest effort to determine medical necessity); Sheppard & Enoch Pratt Hosp., Inc. v. Travelers Ins. Co., 32 F.3d 120, 125 (4th Cir. 1994) (In determining benefits, "the very judgment of the treating doctor as to the medical necessity of the prescribed treatment is being assessed by the Plan administrator and its medical consultants. To require the Plan to give conclusive weight to the opinion of the treating physician would deprive it of its role in determining medical necessity"). Thus, the fact that Appellant's treating physician made statements that the treatment in question was medically necessary is not binding on the Plan.

Did PEBA Err in Excluding the Investigational Treatment?

Appellant argues that Articles 9(G) and 2.53 conflict, and therefore both terms should be construed against the Plan to create coverage. "The cardinal rule of contract interpretation is to ascertain and give effect to the intention of the parties and, in determining that intention, the court looks to the language of the contract. If the language is clear and unambiguous, the language alone determines the contract's force and effect." United Dominion Realty Trust, Inc. v. Wal-Mart Stores, Inc., 307 S.C. 102, 413 S.E.2d 866 (Ct. App. 1992). "When a contract is unambiguous, clear, and explicit, it must be construed according to the terms the parties have used, to be taken and understood in their plain, ordinary, and popular sense." C.A.N. Enters., Inc. v. S.C. Health and Human Servs. Fin. Comm'n, 296 S.C. 373, 373 S.E.2d 584 (1988). "The court is limited to the interpretation of the contract made by the parties, regardless of its wisdom or folly, apparent unreasonableness, or failure of the parties to guard their rights carefully. The court is without authority to alter a contract by construction or to make a new contract for the parties." *Id*. It is not the function of the courts to rewrite insurance contracts or torture the meaning of policy language to extend or defeat coverage. Gambrell v. Travelers Ins. Co., 280 S.C. 69, 310 S.E.2d 814 (1983).

A plain reading of Articles 9(G) and 2.53 show that they do not conflict, nor are they ambiguous. Under Medical Necessity, Article 2.53(C) states a treatment is Medically Necessary if it "is consistent for treatment of the Covered Person's illness, injury, or condition, and is rendered in accordance with recognized, appropriate medical and surgical practices prevailing in the medical specialty or field of medicine at the time rendered." Article 9(G)(1) states treatments

are experimental/investigative if they "are not recognized as conforming to accepted medical practice in the relevant medical specialty or field of medicine…" As the above provisions illustrate, these terms are very similar and do not conflict in that they both require the treatment be accepted in the medical field.

Article 2.53(E) states a treatment is Medically Necessary if it "results in measurable, identifiable progress in treating the Covered Person's condition, illness, or injury." This provision is consistent with the experimental/investigational language contained in Article 9(G) (3), (4), (5), and (6), which states treatments are experimental/investigative if they "[a]re those about which the peer-reviewed medical literature does not permit conclusions concerning their effect on health outcomes; or, [a]re not demonstrated to be as beneficial as established alternatives; or [h]ave not been demonstrated, to a statistically significant level, to improve the net health outcomes; or [a]re those in which the improvement claimed is not demonstrated to be obtainable outside the investigational or experimental setting." These provisions also are very similar in that they require the proposed treatment result in a measurable benefit. Accordingly, Articles 9(G) and 2.53 do not conflict.

Based on the unambiguous language of Article 9(G) of the Plan, PEBA's decision denying Appellant's request for preauthorization because the requested procedure was experimental/investigational was not an abuse of discretion and was supported by substantial evidence. Appellant's pre-authorization request to participate in a clinical trial studying HSCT as treatment for MS was excluded under the unambiguous terms of the State Health Plan in that the requested treatment was experimental or investigational and thus, did not meet the Plan's definition of medically necessary.

ORDER

IT IS HEREBY ORDERED that, for the reasons set forth above, EIP's final agency determination denying preauthorization for Appellant's request for enrollment in a clinical trial studying autologous hematopoietic stem cell transplant for treatment for multiple sclerosis is **AFFIRMED**.

AND IT IS SO ORDERED.

June 4, 2014
Columbia, South Carolina

Deborah Brooks Durden, Judge
S.C. Administrative Law Court

CERTIFICATE OF SERVICE

I, Robin E. Coleman, hereby certify that I have this date served this Order upon all parties to this cause by depositing a copy hereof, in the United States mail, postage paid, in the Interagency Mail Service, or by electronic mail to the address provided by the party(ies) and/or their attorney(s).

Robin E. Coleman

Robin E. Coleman
Judicial Aide to Deborah Brooks Durden

June 4, 2014
Columbia, South Carolina

FILED
June 4, 2014
SC ADMIN. LAW COURT