STATE OF SOUTH CAROLINA
ADMINISTRATIVE LAW COURT

Kathleen Mayer-Solosy, Appellant, vs. South Carolina Public Employee Benefit Authority, Employee Insurance Program, Respondent.	Docket No. 18-ALJ-30-0424-AP **ORDER**

STATEMENT OF THE CASE

This matter is before the Administrative Law Court (ALC or Court) pursuant to a Notice of Appeal filed by Kathleen Mayer-Solosy (Appellant). Appellant seeks review of a final decision issued by the Appeals Committee of the South Carolina Public Employee Benefit Authority, Employee Insurance Program's Appeals Committee (PEBA Insurance Benefits or Committee) denying Appellant's claim for preauthorization of benefits for the implantation of a hypoglossal neurostimulator. Upon consideration of the arguments raised in the parties' briefs, and a review of the record, the pertinent policy provisions, and the law, the Court affirms PEBA Insurance Benefits' Final Decision.

BACKGROUND

Appellant has been enrolled in the South Carolina Group Health Benefits Plan (Plan) since September 1, 2008. On December 8, 2017, Appellant's provider, John Foster, M.D., sent a preauthorization request and letter of medical necessity to Medi-Call,[1] the Third-Party Claims Processor for the Plan, requesting approval for the implantation of a hypoglossal neurostimulator. Hypoglossal neurostimulator implants are used to treat obstructive sleep apnea (OSA) through a pulse generator implanted in the upper part of the chest. The implant is used to stimulate the activity of the hypoglossal nerve which supports the activity of the tongue. Dr. Foster's letter stated that Appellant was intolerant of continuous positive airway pressure (CPAP) therapy, was not a good candidate for oral appliance therapy, and that no other appropriate or beneficial treatment was available to her. Dr. Foster continued by stating that the implantation of a hypoglossal

[1] Medi-Call is a division of BlueCross BlueShield of South Carolina (BCBSSC). Medi-Call is the Plan's review agency and is responsible for pre-certifications, utilization management, and case management for various procedures and conditions.

neurostimulator was the best clinical option available to Appellant. A review of Dr. Foster's medical records that accompanied the request evidence that his request was not supported by his contemporaneous medical records.

Dr. Foster's office notes from Appellant's visit on October 23, 2017 state as follows:

> PRESENT ILLNESS INFORMATION
> **Chief Complaint: I want to know more about Inspire.**[2]
> HPI:
> SI: Evaluation of a sleep-related disorder.
> Diagnosis: obstructive sleep apnea syndrome (OSA).
> Diagnosis was made by a medical provider.
> Symptoms or signs: problems when sleeping: snoring with apnea - had sleep study in 2015 and PAP study in 2016.
> Severity of the sleep problem: unspecified.
> Timing: the sleep problem has been present for a few years.
> Setting in which it first occurred: Patient had a sleep study a few years ago and had another 6/20/17. **She states she started using the CPAP 8/2017 and has been sleeping great. She states that it seems to be aging her face and is interested in other forms of sleep therapy. She wants to discuss Inspire.**
> **Aggravating factors: none identified.**
> Relieving factors: none identified.
> Predisposing factors: none identified.
> Associated manifestations: dry mouth in the mornings.
> - Pertinent negatives: nasal congestion.
>
> Previous tests and diagnostic procedures:
> - Other polysomnogram: Apnea analysis from SNAP diagnostics 6/20/17 - patient brought copy of report with her.
>
> **Previous treatment: CPAP. Compliance – uses the CPAP every night 6 hours per night with full face mask. Tolerance – good.**

(Emphasis added). Dr. Foster's request included a Food and Drug Administration (FDA) approval letter dated March 29, 2017, approving the use of the Inspire Upper Airway Stimulation (UAS) System as well as other materials. The FDA approval letter stated in relevant part:

> Inspire UAS is used in adult patients 22 years of age and older who have been confirmed to fail or cannot tolerate positive airway pressure (PAP) treatments (such as continuous positive airway pressure [CPAP] or bi-level positive airway pressure [BPAP] machines) and who do not have a complete concentric collapse at the soft palate level.
>
> PAP failure is defined as an inability to eliminate OSA (AHI of greater than 15 despite PAP usage), and PAP intolerance is defined as:

[2] Inspire is the brand name of a hypoglossal neurostimulator.

(1) Inability to use PAP (greater than 5 nights per week of usage; usage defined as greater than 4 hours of use per night), or
(2) Unwillingness to use PAP (for example, a patient returns the PAP system after attempting to use it).

Based upon the information submitted, the PMA supplement is approved. You may begin commercial distribution of the device as modified by your PMA supplement in accordance with the conditions described below…

The articles submitted by Dr. Foster along with his request included a summary of peer-reviewed literature on the use of hypoglossal nerve stimulation using the Inspire system for the treatment of OSA, Inspire product information, an article by the American Academy of Otolaryngology - Head and Neck Surgery and New England Journal of Medicine, and others. These articles collectively indicated that a hypoglossal neurostimulator was a second-line treatment of moderate to severe OSA to be utilized in patients who were intolerant of, or had difficulty accepting or adhering to, CPAP treatment.

On December 15, 2017, Medi-Call wrote Appellant advising that it would not authorize the service request for the hypoglossal nerve stimulator on the basis that the BlueCross BlueShield Medical Policy pursuant to the Plan denied it as investigational for the treatment of OSA. On January 2, 2018, Appellant submitted an appeal to Medi-Call stating that the CPAP device did not work for her, and that her provider believed that she met the clinical criteria for the device. The appeal was received by Medi-Call on January 12, 2018. In her appeal, Appellant represented that when using the CPAP, she must lie on her left side so as not to disturb her husband's sleep, and that the prolonged position has presented a host of challenges to her otherwise good health, including back, shoulder and wrist pain. Appellant advised that the use of the CPAP machine had also caused inflammation of the skin on her face, lack of balance, swollen eyes and cheeks, and the development of wrinkles on her face, which cause her to look much older than her actual age. Appellant also stated that she had become more restless since she started using the CPAP machine.

On February 20, 2018, Leonard Sonne, MD, FACP, FCCP, MAAC, a board-certified internist and pulmonologist, independently reviewed Appellant's file and upheld the denial of preauthorization. Dr. Sonne reported in part as follows:

QUESTION(S) UNDER REVIEW

QUESTION #1: Is there sufficient published peer reviewed data from well-constructed clinical trials to establish the durable benefit to health outcomes from hypoglossal nerve stimulation for obstructive sleep apnea or would it be considered investigational and/or unproven?

> ANSWER: It would be investigational/unproven, especially in a patient who is tolerating CPAP six hours a night and has been sleeping great. There is insufficient documentation to substantiate that the requested hypoglossal nerve stimulator is superior to CPAP. The patient has not failed CPAP. The requested hypoglossal nerve stimulator is experimental/investigational; it is not medically necessary for this patient …
>
> **RATIONALE FOR DETERMINATION**
> The patient has a listed diagnosis of obstructive sleep apnea, was started on CPAP and has been sleeping great and has been markedly improved on CPAP. Since 1981, CPAP has been the standard of care for patients with clinically significant obstructive sleep apnea. The patient has improved on CPAP and has been compliant with CPAP. The question is that she perceives that the CPAP is aging her face, and she has various complaints of her shoulder and wrist. There is no documentation that the patient has been managed with a sleep medicine specialist for at least three months and has changed the mask or pillars or anything else that could be adjusted in this patient. The alternative requested hypoglossal nerve stimulator is experimental/investigational and is certainly not medically necessary in this patient who has had clinical improvement on CPAP and has been tolerating CPAP and has been compliant with CPAP.

On February 21, 2018, a BCBSSC medical director who is a board-certified emergency medicine specialist, concurred with Dr. Sonne's independent review concluding that the hypoglossal neurostimulator was "experimental/investigational" and not medically necessary given Appellant's clinical improvement on CPAP. A denial letter was sent to Appellant by letter dated February 21, 2018, including references to BCBSSC's Corporate Administrative Medical (CAM) Policy[3] 701101 captioned, "Surgical Treatment of Snoring and Obstructive Sleep Apnea Syndrome," and Article 9, Paragraph G of the Plan which disallows authorization for experimental or investigational procedures.

On March 12, 2018, Appellant submitted an appeal to PEBA Insurance Benefits' Authority that was nearly identical to her appeal letter to Medi-Call dated January 12, 2018. On October 2, 2018, the Committee wrote Appellant advising that it was upholding the denial of the request for the implantation of a hypoglossal neurostimulator because the requested procedure was investigational and not medically necessary pursuant to Paragraphs 9.A, 9.G and 2.49 of the Plan. The Committee enclosed a copy of its detailed Final Decision. This appeal followed.

[3] CAM policies 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. Hucks v. S.C. Pub. Employee Benefit Auth, ALC Docket No.: 13-ALJ-30-0380-AP, 2014 WL 2559160, at *9 n. 10 (June 4, 2014).

ISSUE

Whether substantial evidence exists in the record to support PEBA Insurance Benefits' decision denying Appellant preauthorization of benefits for the implantation of a hypoglossal neurostimulator under the terms of the State Health Plan.

STANDARD OF REVIEW

The Board of Directors of PEBA has the authority to establish the procedure by which employee insurance benefits decisions are made. S.C. Code Ann. § 1-11-710(C) (2005). Section 1-11-710(C) establishes PEBA Insurance Benefits as the final agency arbiter of disputes under the Plan and states 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 the procedures established by the board, which shall constitute the exclusive remedy for these claims, subject only to appellate judicial review consistent with the standards provided in Section 1-23-380.

S.C. Code Ann. § 1-11-710(C) (2005). Under PEBA Insurance Benefit's procedures, which are set forth in Article 12 of the Plan, a claim for benefits is reviewed by the Third-Party Claims Processor,[4] with final agency appeal to the Plan Administrator in the form of PEBA Insurance Benefits' Appeals Committee.

Pursuant to the Administrative Procedures Act, this Court sits in its appellate capacity in this matter rather than an independent fact finder. S.C. Code Ann. § 1-23-600(E) (Supp. 2018); S.C. Code Ann. § 1-11-710(C) (2005). The Court's review is limited to the record. S.C. Code Ann. § 1-23-380(4) (Supp. 2018). According to Section 1-23-600(E), when acting in an appellate capacity, the Court must apply the criteria of Section 1-23-380(5):

> (5) 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 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

[4] In this case, the Third-Party Claims Processor is Medi-Call.

(f) arbitrary or capricious or characterized by abuse of discretion or clearly unwarranted exercise of discretion.

S.C. Code Ann. § 1-23-380 and -600 (Supp. 2018).

This section requires the Court to apply the "substantial evidence" rule. See e.g., Waters v. S.C. Land Res. Conservation Comm'n, 321 S.C. 219, 467 S.E.2d 913 (1996); Palmetto Alliance, Inc. v. S.C. Pub. Serv. Comm'n, 282 S.C. 430, 319 S.E.2d 695 (1984). Substantial evidence is "'not a mere scintilla of evidence nor the evidence viewed blindly from one side of the case, but is evidence which, considering the record as a whole, would allow reasonable minds to reach the conclusion that the administrative agency reached …'" Lark v. Bi-Lo, Inc., 276 S.C. 130, 135, 276 S.E.2d 304, 306 (1981) (citation omitted). 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 W. Royal Motor Lodge, 282 S.C. 634, 321 S.E.2d 63 (Ct. App. 1984).

The possibility of drawing two inconsistent conclusions from the evidence does not mean that the agency's conclusion was unsupported by substantial evidence. Id. See also, Waters, 321 S.C. at 227, 467 S.E.2d at 917 (citing Palmetto Alliance, Inc. v. South Carolina Pub. Serv. Comm'n, 282 S.C. 430, 432, 319 S.E.2d 695, 696 (1984). The well-settled case law in this State has also interpreted the 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).

In applying the substantial evidence rule, the factual findings of the administrative agency are presumed to be correct and will be set aside only if unsupported by substantial evidence. Rodney v. Michelin Tire Co., 320 S.C. 515, 518, 466 S.E.2d 357, 358 (1996) (citing Kearse v. State Health and Human Serv. Fin. Comm'n, 318 S.C. 198, 456 S.E.2d 892 (1995)). Thus, the party challenging an agency action has the burden of proving convincingly that the agency's decision is unsupported by substantial evidence. Waters, 321 S.C. at 226, 467 S.E.2d at 917 (citing Hamm v. AT & T, 302 S.C. 210, 394 S.E.2d 842 (1994)).

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, 319 S.C. at 353, 461 S.E.2d at 391 (citing Gibson v. Florence Country Club, 282 S.C. 384, 386, 318 S.E.2d 365, 367 (1984)). However, "[d]etermining the proper interpretation of a statute is a question of law, and [an appellate court] reviews questions of law de novo." Palmetto Co. v. McMahon, 395 S.C. 1, 3, 716 S.E.2d 329, 330 (Ct. App. 2011) (citation omitted).

DISCUSSION

Law Governing Construction of Contracts

The Plan is an insurance contract, and the cardinal rule of contract interpretation is to ascertain and give effect to the intention of the parties. Chan v. Thompson, 302 S.C. 285, 289, 395 S.E.2d 731, 734 (Ct. App. 1990). In determining the intentions of the parties, a court first looks to the language of the contract. C.A.N. Enters., Inc. v. S.C. Health & Human Servs. Fin. Comm'n, 296 S.C. 373, 377, 373 S.E.2d 584, 586 (1988). If the language is clear and unambiguous, the language of the contract alone determines the contract's force and effect. Conner v. Alvarez, 285 S.C. 97, 101, 328 S.E.2d 334, 336 (1985).

"Contracts of insurance, like other contracts, should be interpreted according to general rules of construction and the language employed is to be understood in its plain, ordinary and popular sense." Universal Underwriters Ins. Co. v. Metro. Prop. & Life Ins. Co., 298 S.C. 404, 406, 380 S.E.2d 858, 860 (Ct. App. 1989). "The rights of the parties must be measured by the contract which the parties themselves made, regardless of its wisdom, reasonableness, or failure of the parties to guard their rights carefully." Chan, 302 S.C. at 289, 395 S.E.2d at 734. "Parties to a contract of insurance have the right to make their own contract." Sphere Drake Ins. Co. v. Litchfield, 313 S.C. 471, 473, 438 S.E.2d 275, 277 (Ct. App. 1993). "It is not the function of the court to rewrite or torture the meaning of the policy to extend coverage." Id. Simply put, "[c]ourts must enforce, not write, contracts of insurance." Beaufort County Sch. Dist. v. United Nat. Ins. Co., 392 S.C. 506, 516, 709 S.E.2d 85, 90 (Ct. App. 2011).

Relevant Plan Language

Here, the applicable terms of the 2017 Plan are clear and unambiguous. The Plan defines medical necessity as follows:

> 2.49 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.

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 void 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 of the Plan outlines the Plan's exclusions and limitations as follows:

Article 9.

Exclusions And Limitations

No benefits will be provided under any Article of this Plan for any service, supply or charge for the following:

A. Any service or charge for service that is not Medically Necessary; any service or charge for service that 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, investigational, or not accepted medical practice. Experimental or investigational procedures are those medical or surgical procedures, supplies, devices, or drugs that 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;
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.

Substantial Evidence Supports PEBA Insurance Benefits' Decision that a Hypoglossal Neurostimulator is Experimental and Investigational

Paragraph 9.G of the Plan excludes experimental and investigational devices and outlines six criteria that must be met for a device to qualify as neither experimental nor investigational. Meeting any one of the six criteria is sufficient to establish a medical device as investigational and thus, ineligible for pre-authorization under the Plan. PEBA Insurance Benefits denied Appellant's

request for pre-authorization based upon the fourth criterion. Substantial evidence in the record supports this decision.

The Committee's Final Decision noted that an independent medical reviewer, and a BCBSSC medical director agreed that the implantation of a hypoglossal neurostimulator was investigational. The decision stated that the comparative efficacy of implantation of hypoglossal neurostimulator as compared to established OSA treatment options was currently uncertain. In particular, there was insufficient documentation to substantiate that an implantable hypoglossal neurostimulator was as beneficial as, or superior to, CPAP or other treatment options. The Final Decision said further studies comparing the implantation of a hypoglossal neurostimulator to established surgical procedures were needed to permit conclusions on the effect of the treatment on health outcomes.

While Appellant disagrees and argues that the implantation of a hypoglossal neurostimulator is not investigational, there is substantial evidence in the record to support the conclusion that it is. The possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's findings from being supported by substantial evidence. Sharp v. Case Produce, Inc., 336 S.C. 154, 519 S.E.2d 102 (1999). Moreover, "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." Hucks v. S.C. Pub. Employee Benefit Auth, ALC Docket No.: 13-ALJ-30-0380-AP, 2014 WL 2559160, at *7 (June 4, 2014) (citing 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." Id. Courts generally should not interfere with such decisions unless they are clearly erroneous in view of the reliable, probative, and substantial evidence on the whole record. S.C. Code Ann. § 1-23-380(5) (Supp. 2018).

Appellant argues that BCBSSC's medical director and the independent medical reviewer that concluded that the implantation of a hypoglossal neurostimulator was investigational are "doctors who have nothing to do with the study of Sleep Apnea." Their medical opinions are consistent, however, with the 2017 Blue Cross Blue Shield CAM Policy 701101 (also upon which the Final Decision was based), that provides that the implantation of a hypoglossal neurostimulator is considered investigational for treating OSA. Specifically, CAM Policy 701101 states in part that "[T]he role of nerve stimulation for among the surgical procedures for OSA treatment is

uncertain." CAM Policy 701101 continues to provide that hypoglossal neurostimulation including the use of such devices as the Inspire II System for Upper Airway Stimulation (the system about which Appellant inquired), is considered investigational for the treatment of all indications including OSA. CAM Policy 701101 references numerous articles, position statements, and studies, which are specifically related to sleep apnea and the use of the hypoglossal neurostimulator including those from otolaryngologists, like Appellant's physician.

Substantial Evidence Supports PEBA Insurance Benefits' Decision that a Hypoglossal Neurostimulator is Not Medically Necessary

Paragraph 2.49 of the Plan indicates that four criteria must be met for a service to be considered medically necessary, including that 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." As stated by the Committee, an investigational procedure cannot be medically necessary under the Plan's terms as it cannot be considered the prevailing practice within a medical specialty.

Appellant again questions the judgment of BCBSSC's medical director and independent medical reviewer, but even the FDA approval letter dated March 29, 2017, that Appellant's own provider submitted with his request on Appellant's behalf, indicated that a hypoglossal neurostimulator was a second-line treatment of moderate to severe OSA and should be used only in patients who had failed CPAP treatment or were intolerant of it. The notes of Dr. Foster, Appellant's provider, also support the PEBA Insurance Benefits' finding. Dr. Foster's notes indicated that Appellant reported that she had been "sleeping great" with the use of her CPAP machine, was compliant with its utilization six hours per night, and that her tolerance of it was "good." Clinical improvement was achieved with the CPAP machine.

Appellant avers that her physician believes that the hypoglossal neurostimulator is medically necessary. The Plan provides that the fact that a physician prescribes a procedure, service or supply and asserts that it is necessary, does not automatically mean that it is medically necessary under the Plan's definition. 2017 South Carolina Group Health Benefits Plan § 2.49.

Materials Submitted by Appellant that are Outside of the Record Cannot be Considered by This Court

In her original and reply briefs, Appellant included and referenced materials in support of her position that other insurers (and Blue Cross Blue Shield Association) have concluded that there is now sufficient evidence to determine that the implantation of a hypoglossal neurostimulator

results in a meaningful improvement in the net health outcome in patients with moderate to severe OSA who have failed an adequate trial of (or are unable to tolerate) continuous positive airway pressure. She also included a letter of support from her physician which is dated January 10, 2019.

PEBA Insurance Benefits contends that Appellant's initial brief references and includes materials that encompassed in the record on appeal, and that none of the articles included with the brief accompanied Appellant's treating physician's December 5, 2017, request for services. Because these materials were not presented during the course of the administrative review, they should be stricken from the record.

Pursuant to Section 1-23-380(4), this Court's appellate review is limited to the record on appeal. Accordingly, new evidence may not be submitted for consideration on appeal and the Court is required by law to limit its review to the record presented to the agency below. Sheppard v. State, 357 S.C. 646, 594 S.E.2d 462 (2004).

ORDER

Based on the foregoing including that substantial evidence exists in the record to support the Final Decision, it is not based on an error of law, and it is neither arbitrary nor capricious,

IT IS HEREBY ORDERED that the Final Decision of the South Carolina Public Employee Benefit Authority, Employee Insurance Program, is **AFFIRMED**.

AND IT IS SO ORDERED.

Deborah Brooks Durden

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

March 25, 2019
Columbia, South Carolina

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
Judicial Aide to Deborah Brooks Durden

March 25, 2019
Columbia, South Carolina

FILED
March 25, 2019
SC ADMIN. LAW COURT