

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Civil No.: 19-1363(DSD/HB)

Patrick Little,

Plaintiff,

v.

ORDER

PreferredOne Insurance Company,

Defendant.

Denise Yegge Tataryn, Esq. and Nolan, Thompson, Leighton & Tataryn, PLC, 5001 American Blvd. West, Suite 595, Bloomington, MN 55437, counsel for plaintiff.

Ryan M. Sugden, Esq., Kadee Jo Anderson, Esq., and Stinson Leonard Street LLP, 50 South 6th Street, Suite 2600, Minneapolis, MN 55402, counsel for defendant.

This matter is before the court upon the motion for a preliminary injunction by plaintiff Patrick Little. Based on a review of the file, record, and proceedings herein, and for the following reasons, the motion is denied.

BACKGROUND

I. The Parties

This Employee Retirement Income Security Act (ERISA) dispute arises out of Defendant PreferredOne Insurance Company's (PIC) denial of coverage for plaintiff Patrick Little's liver transplant surgery.

Little is a fifty-six year old Minnesota resident. Compl.

¶ 1. Little was employed by L&K Tree & Shrub (L&K), a landscaping

business. Id. ¶ 2. L&K maintains an employee benefit plan providing long-term health care benefits (the Plan). Id. ¶ 3. PIC insures the Plan under a group insurance policy. Id. ¶ 4.

II. The Plan

PIC is both the Plan administrator and insurer. Id. ¶ 9. The Plan gives PIC "discretionary authority to determine eligibility for benefits and to interpret and construe terms, conditions, limitations, and exclusions." Cox. Aff. Ex. A § V(a).

Under the Plan, PIC covers eligible organ transplant procedures. Id. § X(L). PIC determines whether an organ transplant procedure is medically necessary. Id. PIC does not cover "investigative" organ transplant procedures. Id. The Plan defines "investigative" as any drug, device, or medical treatment that "reliable evidence does not permit conclusions regarding safety, effectiveness, or effect on health outcomes." Id. § XXII.

PIC considers the following evidence in determining whether an organ transplant procedure is investigative:

1. Whether there is a final approval from the appropriate government regulatory agency, if required. This includes whether a drug or device can be lawfully marketed for its proposed use by the FDA; or if the drug, device or medical treatment or procedure is under study or if further studies are needed to determine its maximum tolerated dose, toxicity, safety or efficacy as compared to standard means of treatment or diagnosis; and
2. Whether there are consensus opinions or recommendations in relevant scientific and medical literature, peer-reviewed journals, or reports of clinical trial committees and other technology assessment bodies.....; and

3. Whether there are consensus opinions of national and local health care providers in the applicable specialty as determined by a sampling of providers, including whether there are protocols used by the treating facility or another facility, studying the same drug, device, medical treatment or procedure.

III. Diagnoses and Treatment

In September 2017, Little was diagnosed with stage IV colorectal cancer. Compl. ¶ 10. In late 2017, Little had surgery to remove the cancer. Id. Shortly after the surgery, Little's surgeon discovered that his cancer metastasized to his liver. Id. Little's liver cancer is unresectable, which means that it cannot be surgically removed. Id. Little is currently undergoing chemotherapy at the Cleveland Clinic. Id. ¶ 11.

In February 2019, the Cleveland Clinic reevaluated Little's treatment options, and found that he is a suitable candidate for a liver transplant. Id. ¶ 12. On March 6, 2019, the Cleveland Clinic put Little on a liver transplant waitlist and sought prior authorization from PIC to cover the proposed liver transplant procedure. Tataryn Aff. Ex. 1 at 4. On March 8, 2019, PIC denied the request for prior authorization because the proposed liver transplant procedure was investigative. Id. PIC stated that its determination was based on the lack of peer-reviewed medical literature demonstrating the safety and effectiveness of the proposed transplant procedure. Id. PIC's determination was made by a doctor certified in family medicine and addiction. Id.

On March 13, 2019, the Cleveland Clinic again requested prior authorization from PIC. Id. Ex. 2 at 1. Dr. Federico Aucejo, the Liver Cancer Program Director, stated that liver transplantation would prolong Little's life, and that "no other alternative [treatment] could match [that] outcome." Id. Dr. Aucejo cited a 2010 Norwegian study, which suggested that the proposed liver transplant procedure had produced favorable patient outcomes and was more effective at arresting the spread of liver tumors than standard chemotherapy. Id. at 2. In addition, Dr. Aucejo explained the Cleveland Clinic's liver transplant protocol and cited several peer-reviewed medical studies analyzing liver transplantation for patients suffering from unresectable liver cancer. Id. at 7-9.

On March 15, 2019, PIC referred Little's request for prior authorization to AllMed Health Care Management (AllMed) for an independent medical review. Cox. Aff. Ex C. Dr. Gary Barone, who is board certified in surgery, surgery critical care, and vascular surgery specializing in abdominal organ transplants, conducted the review. Id. Dr. Barone concluded that: (1) the proposed liver transplant procedure was investigative under the Plan; and (2) that there was a substantial likelihood that Little's cancer would recur. Id. Dr. Barone specifically stated that the studies provided by the Cleveland Clinic were mainly observational and lacked adequate statistical and sample power. Id.

On March 18, 2019, based on Dr. Barone's findings, PIC again denied Little's request for prior authorization. Tataryn Aff. Ex. 3. PIC explained that there "is insufficient peer reviewed medical literature available to demonstrate the safety and effectiveness of this procedure for the specific therapeutic purpose," and that Little suffers from "local or systemic disease likely to limit survival and has inadequately treated malignancy with substantial likelihood of recurrence." Id.

On April 5, 2019, the Cleveland Clinic agreed to provide Dr. Barone with an updated explanation of its transplant protocol, support for its protocol, how it believed Little met the protocol, and a summary of its experience performing the proposed liver transplant procedure. Cox. Aff. Ex. D. On April 11, 2019, Dr. Barone acknowledged that he had reviewed the updated information, but stated that his determination was unchanged: that the reliable evidence does not permit conclusions concerning the proposed liver transplant's safety, effectiveness, or effect on health outcomes and there is a substantial likelihood Little's cancer would recur. Id. Ex. E. Dr. Barone also found that the Cleveland Clinic did not provide clear, specific documentation that Little met its protocol, and that Little "would be transplanted using a[n] ... investigational protocol." Id.

On April 24, 2019, MAXIMUS Federal Services (MAXIMUS) reviewed

PIC's determination.¹ Id. Ex. F. MAXIMUS's review was conducted by a licensed attorney and a practicing physician certified in general surgery and trained in surgical oncology. Id. MAXIMUS reviewed Little's medical file and a number of peer-reviewed studies. Id. MAXIMUS determined that PIC's decision to deny prior authorization should be upheld. Id.

On May 9, 2019, Dr. Aucejo again told PIC that Little met the Cleveland Clinic's liver transplant criteria. Tataryn Aff. Ex. 4. Dr. Aucejo also provided the 2010 Norwegian data demonstrating five year post-liver transplant survival in 50-60% of patients "compared to [chemotherapy] which is associated with 10-15% 5 years overall survival." Id. Dr. Aucejo recommended that Little undergo the proposed liver transplant procedure "to increase his chances of survival." Id. Dr. Aucejo also stated that the Cleveland Clinic had performed three liver transplants in similar liver cancer cases.² Id.

Dr. Aucejo also cited a 2017 article authored Dr. Dimitrios Moris analyzing liver transplant procedures in cases of unresectable liver cancer. Id. Dr. Moris concluded that liver

¹ Under Minn. Stat. § 62Q.73, a health plan enrollee may request that the Minnesota Department of Commerce (DOC) review a plan administrator's adverse determination. The DOC randomly selected MAXIMUS to conduct an independent medical review in this case. Id.

² One of the three patients experienced a cancer recurrence within a year; the other two patients remain cancer free. Id.

transplant procedures have the "potential to become an alternative to current standards of practice," in unresectable liver cancer cases, but "it is premature to support the broader application of [liver transplant procedures] in patients with unresectable" colorectal liver metastases. Id. at 29. Dr. Moris also found that a significant number of patients develop recurrent cancer twenty-eight months after the liver transplant procedure and the patient five-year survival rate was 34.6%. Id. at 25.

Notwithstanding the additional information provided by Dr. Aucejo, PIC did not change its determination.

IV. This Suit

On May 23, 2019, Little commenced this ERISA action pursuant to § 502(a)(1)(B) and 29 U.S.C. § 1132(a)(1)(B). On June 4, 2019, Dr. Aucejo stated that the Cleveland Clinic could not proceed with Little's transplant procedure without advanced insurance coverage approval. Tataryn Aff. Ex. 6. Little now moves for a preliminary injunction under Federal Rule of Civil Procedure 65(a).³

DISCUSSION

I. Standard

A preliminary injunction is an extraordinary remedy, and the

³ Little is asking the court to enjoin PIC from denying him coverage for the proposed liver transplant procedure. On June 17, 2019, the court remanded the matter to PIC for reconsideration, and on June 21, 2019, PIC notified the court that the matter was again ripe for judicial determination.

movant bears the burden of establishing its propriety. Watkins Inc. v. Lewis, 346 F.3d 841, 844 (8th Cir. 2003). The court considers four factors in determining whether a preliminary injunction is appropriate: (1) the likelihood of the movant's ultimate success on the merits; (2) the threat of irreparable harm to the movant in the absence of relief; (3) the balance between the harm alleged and the harm that the relief may cause the non-moving party; and (4) the public interest. Dataphase Sys., Inc. v. C.L. Sys., Inc., 640 F.2d 109, 114 (8th Cir. 1981) (en banc). The party seeking the preliminary injunction "must carry the burden on all four elements." Jensen v. Dole, 677 F.2d 678, 680 (8th Cir. 1982). No single factor is determinative. Dataphase, 640 F.2d at 113. However, "the probability of success factor is the most significant." Home Instead, Inc. v. Florance, 721 F.3d 494, 497 (8th Cir. 2013).

To establish the likelihood of success on the merits, Little must show that he has a "fair chance of prevailing." Planned Parenthood Minn., N.D., S.D. v. Rounds, 530 F.3d 724, 732 (8th Cir. 2008). The question "is ... whether any of [the] claims provide a fair ground for litigation." Watkins, 346 F.3d at 844.

II. Merits

PIC argues that even assuming Little prevails on the second through fourth Dataphase factors, he is nonetheless not entitled to a preliminary injunction because he is unlikely to succeed on the

merits of his ERISA claim. The court agrees.

A. ERISA Standard

"[A] denial of benefits challenged under [ERISA] is to be reviewed under a de novo standard unless the benefit plan gives the administrator or fiduciary discretionary authority to determine eligibility for benefits or to construe the terms of the plan." Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 115 (1989). If the plan vests the administrator or fiduciary with the authority to determine eligibility for benefits or to construe the terms of the plan, a court applies a deferential, abuse of discretion standard of review to the administrator's determinations. Id.; see also Cox v. Mid-American Dairymen, Inc., 965 F.2d 569, 571 (8th Cir. 1992).

When a health plan administrator has the responsibility of "both determining eligibility for benefits and also paying those benefits," the court must "consider that conflict as a factor in determining whether the plan administrator has abused its discretion in denying benefits." Silva v. Metro. Life Ins. Co., 762 F.3d 711, 717 (8th Cir. 2014); see also Manning v. Am. Republic Ins. Co., 604 F.3d 1030, 1038-39 (8th Cir. 2010); Tillery v. Hoffman Enclosures, Inc., 280 F.3d 1192, 1197 (8th Cir. 2002). "[I]n order to properly apply the deferential standard of review, a reviewing court must be provided the rationale underlying the trustee's discretionary decision." Cox, 965 F.2d at 574. However, "[n]othing in [ERISA] itself ... suggests that plan administrators

must accord special deference to the opinions of treating physicians. Nor does [ERISA] impose a heightened burden of explanation on administrators when they reject a treating physician's opinion." Black & Decker Disability Plan v. Nord, 538 U.S. 822, 831 (2003).

Here, the Plan unambiguously gives PIC discretionary authority to determine eligibility for benefits and to interpret and construe the Plan terms. As a result, the court will apply an abuse of discretion standard.⁴ The court must also assess, however, PIC's potential conflict in its dual role as the Plan administrator and insurer in determining whether it abused its discretion.

B. Likelihood of Success on the Merits

Applying this standard, the court concludes that PIC did not abuse its discretion in denying Little's request for prior authorization. PIC's March 13 and 18 denials cited the lack of peer-reviewed medical literature demonstrating the safety and effectiveness of the proposed liver transplant procedure, consistent with the investigative criteria established under the Plan. PIC also sufficiently mitigated any conflict by asking AllMed to conduct an independent medical review of Little's claim. Dr. Barone permitted the Cleveland Clinic to submit updated information regarding its transplant protocol and additional

⁴ The court rejects Little's argument that Minn. Stat. § 62Q.107 precludes the application of an abuse of discretion standard.

medical research after PIC's March 18 denial. The record shows that Dr. Barone engaged in multiple reviews of Little's request in light of the updated materials, only to reach the same conclusion that the proposed liver transplant procedure was investigative, and consequently, not covered under the Plan.

Furthermore, although the 2010 Norwegian data and burgeoning medical literature cited by Little appears promising for future liver transplant procedures in patients like Little suffering from metastatic, unresectable liver cancer, that evidence does not undermine PIC's determination that the proposed liver transplant procedure is presently investigative under the Plan. Indeed, Dr. Moris's article concludes that liver transplant procedures have the potential to improve patient outcomes and could become an important adjunct to chemotherapy, but further study was needed within a larger patient population to confirm the procedure's efficacy. To that point, the Cleveland Clinic has only performed three of the proposed liver transplant procedures. Although those results may appear promising, they do not establish the medical consensus needed under the Plan to overcome PIC's investigative finding.

Finally, although the Cleveland Clinic and Dr. Aucejo opine that the proposed liver transplant procedure increases Little's chances of survival, they are not specific as to how long they predict Little could be expected to survive post-surgery. Conversely, Dr. Barone's determination that Little has a

substantial likelihood of cancer recurrence is bolstered by Dr. Moris's article showing a significant post-surgery cancer recurrence rate after twenty-eight months. Furthermore, under ERISA, PIC is not required to credit Dr. Aucejo's opinions over Dr. Barone's or the MAXIMUS surgeon that found that the proposed liver transplant procedure was investigative, and therefore, excludable under the Plan.

Because PIC has not abused its discretion under ERISA in denying Little's request for prior authorization, Little has not shown a likelihood of success on the merits. As a result, Little is not entitled to a preliminary injunction.

CONCLUSION

Accordingly, **IT IS HEREBY ORDERED** that the motion for a preliminary injunction [ECF No. 2] is denied.

Dated: June 25, 2019

s/David S. Doty
David S. Doty, Judge
United States District Court