UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

HENKEL OF AMERICA, INC.,
Plaintiff,

v.

RELIASTAR LIFE INS. CO. *et al*,
Defendants.

No. 3:18-cv-00965 (JAM)

ORDER DENYING DEFENDANT EXPRESS SCRIPTS, INC.'S MOTION FOR SUMMARY JUDGMENT

Plaintiff Henkel of America, Inc. ("Henkel") has paid about $50 million in prescription drug costs for two of its employee health plan participants ("the participants") who suffer from a rare medical condition known as Hereditary Angiodema ("HAE"). Henkel filed a lawsuit to recoup most of these costs from its stop-loss insurer, defendant ReliaStar Life Insurance Company ("ReliaStar"), or in the alternative from defendant Express Scripts, Inc. ("Express Scripts" or "ESI"), the claims administrator retained by Henkel who approved the prescription drug claims.[1]

Express Scripts has now moved for summary judgment, seeking to dismiss Henkel's claims of breach of fiduciary duty and breach of contract. Because there are numerous disputed issues of material fact concerning whether Express Scripts properly approved the claims, I will deny the motion for summary judgment.

BACKGROUND

The following facts are drawn from the parties' Local Rule 56 statements and supporting documents and presented in the light most favorable to Henkel as the nonmoving party.[2]

[1] *See generally Henkel of Am. Inc. v. ReliaStar Life Ins. Co*., 2020 WL 1430008 (D. Conn. 2020); *Henkel of Am. v. ReliaStar Life Ins. Co.*, 2019 WL 2462605 (D. Conn. 2019).

[2] *See* Docs. #185-2, #188 (Express Scripts' sealed and unsealed but redacted statements of material facts); Docs. #196, #197 (ReliaStar's sealed and unsealed but redacted statements of material facts); Docs. #202, #204 (Henkel's

Contracts between Henkel and Express Scripts

At all relevant times, Henkel provided health benefits to its employees and their dependents through a self-funded group health benefit plan ("the Plan"). Pursuant to the Plan, Henkel was the plan administrator and named fiduciary with the "sole authority and responsibility to control and manage the operation and administration of the Plan."[3] The Plan named Henkel as the fiduciary but authorized Henkel to "delegate to any person or entity all or any of the powers or duties" to administer the Plan.[4] The Plan provided that once Henkel delegated the powers or duties in administering the Plan, "the delegate shall become the named fiduciary responsible for administration of the Plan (if the delegate is a fiduciary by reason of the delegation), and references to the Plan Administrator shall apply instead to the delegate."[5]

Henkel hired Mercer Health & Benefits LLC ("Mercer"), a benefits consultant, to aid in administering the Plan.[6] Pursuant to its authority under the Plan, Henkel designated Express Scripts as the claims administrator for prescription drug benefits.[7] The relationship between Henkel and Express Scripts was principally governed by two successive contracts during the time period relevant to this action.[8]

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sealed and unsealed but redacted statements of material facts); Docs. #215-2, #216-1, #217-2, #219-1 (Express Scripts' sealed and unsealed responses to additional statements of material facts by Henkel and ReliaStar). Many of the citations in this ruling are to documents that have been filed under seal; to the extent that this ruling describes selective portions of such sealed documents, the Court concludes that such portions as described do not warrant sealing or redaction in this ruling.

[3] Doc. #188-4 at 40 (§ 12.2) (Henkel Group Benefit Plan).

[4] *Id.* at 39 (§ 12.1).

[5] *Ibid.*

[6] Doc. #152 at 15 (¶ 115); Doc. #185 at 8.

[7] Docs. # 197, #204 at 2 (¶ 1 and response).

[8]Docs. #197, #204 (¶ 2 and response).

The first contract was the Integrated Prescription Drug Program Agreement ("IPDPA"), which was in effect from January 1, 2014 through December 31, 2016.[9] Pursuant to this agreement, Henkel delegated to Express Scripts "the limited authority and discretion solely to undertake the administrative and/or clinical initial determinations, first-level, second-level and urgent appeals of claims eligibility determinations and benefits applications determinations filed by Members with [Henkel's] Program" as well as to "process and determine all filed administrative and/or clinical first-level, second level, and urgent appeals." [10] For this purpose, Express Scripts was the "named fiduciary."[11] The agreement provided that "ESI's decisions will be conclusive and binding and not subject to further review by [Henkel]."[12]

The second contract was the Pharmacy Benefit Management Agreement ("PBMA") which was in effect starting on January 1, 2017.[13] Under the PBMA, Express Scripts performed claims processing for prescription drug benefits.[14] In connection with processing claims, Express Scripts agreed to "perform standard drug utilization review…in order to assist the dispensing pharmacist and prescribing physician in identifying potential drug interactions, incorrect prescriptions or dosages, and certain other circumstances that may be indicative of inappropriate prescription drug usage."[15]

Express Scripts contracted with Accredo Health Group Inc. ("Accredo"), a specialty pharmaceutical and service provider, to perform the drug utilization review that was

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[9] *Ibid.*

[10] Doc. #185-4 at 20 (§ 15.8) (IPDPA).

[11] *Ibid.*

[12] *Ibid.*

[13] Docs. #197, #204 (¶ 2 and response).

[14] Docs. #197, #204 (¶ 8 and response); Doc. #185-5 at 10 (§ 2.3(a)(i)) (PBMA).

[15] Doc. #185-5 at 10 (§ 2.3(a)(ii)) (PBMA).

contemplated under the PBMA.[16] The contract between Express Scripts and Accredo stated that Accredo would provide "cognitive pharmacist review of prescriptions, including interpretation and review for plan compliance, safety and efficacy and clinical appropriateness (drug utilization review)."[17] Both the PBMA and IPDPA provided that Express Scripts could subcontract services, but that Express Scripts would be responsible and liable for any subcontracted services.[18]

The PBMA also specified that in connection with its role as claims administrator, Express Scripts would "provide prior authorization ('PA') services as specified and directed by [Henkel] for drugs designated" by Henkel.[19] Prior authorization determined whether certain drugs were covered by the Plan.[20] The PBMA provided that Express Scripts could approve initial coverage if a member met the criteria outlined in the prior authorization policies or "for an otherwise excluded use in the event of co-morbidities, complications and other factors not otherwise set forth" in the prior authorization guidelines.[21] It further provided that Express Scripts "may rely entirely upon information about the Member and the diagnosis of the Member's condition provided to it from the prescriber."[22]

In addition to the IPDPA and PBMA described above, Henkel and Express Scripts also entered into a PBM Agreement Service Addendum ("PBM Addendum").[23] Effective January 1,

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[16] *See* Doc. #217-2 (¶ 66 and response); *see also* Doc. #215-2 at 3 (¶ 63 and response); Doc. #202-11 (Home Delivery Services Agreement).

[17] Doc. #202-11 at 3 (¶ II).

[18] Doc. #185-4 at 19 (¶ 15.2) (IPDPA); Doc. #185-5 at 18 (¶ 7.4) (PBMA).

[19] *See* Doc. #152 at 21 (¶¶ 101, 194) (Second Amended Complaint); Doc. #185-5 at 11 (§ 2.3(b)) (PBMA).

[20] *See* Doc. #204 at 5-6 (¶¶ 11, 12 and responses); Doc. #185-5 at 11 (§ 2.3(b)) (PBMA).

[21] Doc. #185-5 at 11 (§ 2.3(b)) (PBMA).

[22] *Ibid.*; Doc. #187-1 at 21.

[23] Doc. #204 at 4-5 (¶ 10 and response); Doc. #185-10 (PBM Addendum).

2016, the PBM Addendum clarified that the agreements between Henkel and Express Scripts were "estimated to produce an overall net client savings for [Henkel]."[24] The PBM Addendum specified, among other things, which drugs required prior authorization review.[25] Numerous drugs for the treatment of HAE—including Cinryze, Berinert, Firazyr, Kalbitor, and Ruconest—were among the drugs listed.[26] The PBM Addendum also stated that "[s]tandard guarantees require the implementation of Prior Authorization Reviews *without grandfathering*[.]"[27]

2016 and 2017 prior authorization policies

Express Scripts developed prior authorization policies for the drugs at issue here—Cinryze, Berinert, Firazyr, Kalbitor, Ruconest, and Haegarda ("the subject drugs").[28] The coverage criteria included in the prior authorization policies were drafted and approved by an Express Scripts' committee comprised of clinicians, doctors, and pharmacists.[29]

The criteria in the prior authorization policies for the subject drugs outlined two ways for Express Scripts to approve them as covered by the Plan. The first way allowed for approval if the medication was prescribed by a specialist *and* if the patient had HAE as confirmed by lab results showing low levels of certain a protein and serum:

> The patient has HAE confirmed by the following diagnostic criteria (i and ii): i. Patient has low levels of functional C1-INH protein (<50% of normal) as defined by the laboratory reference values; AND ii. Patient has lower than normal serum C4 levels, as defined by laboratory reference values.[30]

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[24] Doc. #185-10 at 2 (PBM Addendum).

[25] Doc. #204 at 4-5 (¶ 10 and response).

[26] *Id.* at 4-6 (¶¶ 10, 12 and responses); Doc. #185-10 at 7 (PBM Addendum).

[27] Doc. #185-10 at 9 n.7 (PBM Addendum) (emphasis added).

[28] Doc. #204 at 4-6 (¶¶ 10, 12 and responses).

[29]Doc. #152 at 41 (¶ 205); Doc. #215-2 at 4 (¶ 67).

[30] Doc. #186-1 at 3 (Firazyr); Doc. #186-4 at 4 (Cinryze, Berinert, Ruconest); Doc. #186-9 at 3 (Kalbitor); Doc. #186-12 at 3 (Haegarda).

Each policy further provided that there are three different types of HAE—Type I, II, and III—but that only patients with the first two types exhibit *low* levels of C1-INH protein and C4 serum.[31] Because HAE Type III patients have *normal* levels of C1-INH protein and C4 serum, such patients would not be covered under the criteria requiring confirmation of low serum and protein levels.[32]

The second way that a subject drug could meet the criteria under the policies was if the patient had previously been or was currently being treated with the drug. In relevant part:

- Firazyr: "Approve if the patient has been treating previous acute HAE attacks with Firazyr."[33]
- Cinryze, Berinert, and Ruconest: "Approve if patient…is currently receiving Cinryze or Berinert for HAE prophylaxis; OR…has been treating previous acute HAE attacks with Cinryze, Berinert, or Ruconest."[34]
- Kalbitor: "Approve if patient has been treating previous acute HAE attacks with Kalbitor."[35]
- Haegarda: "For patients currently receiving Haegarda Prophylatic Therapy. Approve Haegarda for 3 years if the medication is prescribed by or in consultation with an allergist/immunologist or a physician that specializes in the treatment of HAE or related disorders."[36]

The prior authorization policies provided that after the prior authorization criteria was met, the approval for the drugs would remain in effect for three years.[37]

[31] Doc. #186-1 at 3-4; Doc. #186-4 at 4; Doc. #186-9 at 4; Doc. #186-12 at 4.

[32] *See* Doc. #216-1 at 9-10 (¶ 16 and response); *see also* Doc. #201 at 24.

[33] Doc. #186-1 at 4.

[34] Doc. #186-4 at 4.

[35] Doc. #186-9 at 4.

[36] Doc. #186-12 at 4.

[37] Doc. #186-1 at 3; Doc. #186-4 at 3; Doc. #186-9 at 3; Doc. #186-12 at 3.

Express Scripts approves coverage of the subject drugs

Each time the participants' initial prescription for a subject drug was submitted to a pharmacy, the claims adjudication system flagged the drug as requiring prior authorization.[38] Express Scripts' prior authorization reviews were conducted by an Express Scripts' affiliate known as Express Scripts Utilization Management Co. ("ESI-UM").[39] ESI-UM conducted a prior authorization review for each of the subject drugs prescribed for each participant, as well as the appeal review after coverage was denied for one of the drugs.[40]

When conducting prior authorization reviews, ESI-UM contacted the prescribing physicians' offices and received answers by telephone or fax.[41] ESI-UM instructed its employees to collect and enter only the information required by the criteria in the prior authorization policies.[42]

Express Scripts granted prior authorization for several of the initial drug claims because the prescribers' offices had reported that the participants were using or had previously used the drugs.[43] Express Scripts granted prior authorization for some of the drug claims because the prescribers' offices told ESI-UM that the participant had low levels of the C4 serum and C1-INH protein.[44]

One prior authorization for Haegarda was initially denied because the participant was not currently taking Haegarda for prophylactic therapy and because the physician's office reported

[38] Doc. #186 at 7-8, 10, 13, 15, 16, 18, 19, 21, 23 (¶¶ 21, 26, 34, 41, 48, 53, 61, 66, 74, 79).

[39] *Id.* at 2-3 (¶¶ 1, 4-5).

[40] *Id.* at 3 (¶ 6).

[41] *Id.* at 4 (¶ 9).

[42] *Ibid.* (¶ 7).

[43] *Id.* at 7-8, 11, 15-20 (¶¶ 21-22, 34-35, 48-49, 53-54, 61-62, 66-67).

[44] *Id.* at 8-9, 13-14, 21-22 (¶¶ 26-27, 41-42 74-75)

that the patient's HAE had not been confirmed by low levels of the C1-INH protein.[45] The patient's doctor appealed the denial.[46] Express Scripts subsequently approved the drug on appeal when the doctor sent a fax stating that the patient had low levels of the protein.[47] The fax also stated that the patient did not have lower than normal levels of the C4 serum, but that her "mother also has this diagnosis."[48] ESI-UM accepted what it was told by the physician's office about lab test results; it did not confirm the information in any of the prior authorizations through documentation of lab results or medical records.[49]

Subsequent claims approvals

Because each prior authorization provides that an approved drug will continue to be approved for a period of three years, throughout 2016 and 2017 Express Scripts approved subsequent refills on the basis of the prior authorization.[50] Henkel paid out the claims.[51] The drugs were expensive—by the end of 2017, the claims for the two participants' prescription drug expenses exceeded $50 million.[52]

But even as Express Scripts continued to approve the claims for the drugs in 2016 and 2017, Mercer and Accredo began raising concerns about the participants' use of the drugs, the appropriateness of the dosages, whether the participants in fact had HAE as confirmed by lab results, and whether the claims were covered under the Plan:

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[45] Doc. #186 at 23 (¶¶ 79-80); *see also* Doc. #186-14 at 8.

[46] Doc. #186-14 at 65.

[47] *Id.* at 55, 90.

[48] *Id.* at 55.

[49] Doc. #186 at 7-9, 11, 13-20, 21-24 (¶¶ 21, 26, 34, 41, 48, 53, 61, 66, 74, 82).

[50] *Id.* at 8-12, 14, 16-22, 24 (¶¶ 23, 28, 31, 36, 38, 43, 50, 55, 58, 63, 68, 71, 76, 83).

[51] Doc. #152 at 4 (¶ 15).

[52] Doc. #219-1 at 18 (¶ 32).

- In November 2016, Mercer raised a number of questions by email to Express Scripts regarding the claims, including the quantity of units dispensed, Accredo's role in "active[ly] monitoring" and reaching out to the participants, how the drugs were being used, if the prescriber had adequately indicated the reason for the prescription, and the severity of the HAE attacks.[53]

- In March 2017, Accredo performed Clinical Baseline Assessments on the two participants.[54] The assessments reflected that both had normal C1 inhibitor levels and therefore had HAE Type III.[55] The assessments run by Accredo contradicted information that ESI-UM had recorded for some of the prior authorization reviews and the single appeal.

- In August 2017, when communicating with one of the participants' prescribers to collect information for prior authorization approval, ESI-UM recorded that one of the participants did not have low C1-INH protein levels.[56] This contradicted information that Express Scripts had received for this participant in previous prior authorization approvals, when ESI-UM recorded that the patient had low protein levels.[57] It also contradicted the information that the prescribing physician provided on appeal a few weeks later: that the participant had low C1-INH protein levels.[58]

- In September 2017, the Clinical Program Director for Accredo openly discussed that she did not believe that the drugs met the criteria for the prior authorizations because one of the participants had HAE Type III, writing that "the big problem is that according to [one of the participants'] clinicals she has type III which ESI should not be PAing."[59] In emails between the Clinical Program Director and various managers and executives at Express Scripts, an Express Scripts senior manager of benefit operations wrote that, although the prior authorizations do not categorically deny approval of the subject drugs for HAE Type III, the policies "don't mention approval for Type III only for Type I and II."[60] Express Scripts' Senior Clinical Account Executive wrote that "[w]e need an understanding of how [the Participants' claims] got approved via the PA policy as we currently do not allow for PA Type III."[61]

[53] Doc. #215-2 at 8 (¶ 82); Doc. #202-18.

[54] Doc. #217-2 at 9 (¶ 83 and response).

[55] Doc. #215-2 at 9 (¶ 83); Doc. #202-19; Doc. #202-20; Doc. #216 at 10-11 (¶ 18).

[56] Doc. #186-14 at 8.

[57] Doc. #186 at 9, 13 (¶¶ 26, 41).

[58] Doc. #186-14 at 55.

[59] Doc. #215-2 at 10 (¶ 85); Doc. #202-21.

[60] Doc. #202-30 at 3.

[61] Doc. #215-2 at 11 (¶ 89); Doc. #202-30 at 2.

- As of October 2, 2017, Accredo was aware that one of the participants was using well over the recommended dosage for one of the drugs—66 vials per day (as opposed to the label's recommended five vials per week).[62]

Although Mercer and Accredo raised these concerns and collected evidence indicating that the drugs were potentially not covered by the Plan, Express Scripts continued to approve the drugs. Henkel did not learn of the concerns stated by or known to Mercer and Accredo.[63]

ReliaStar refuses to pay

ReliaStar provided for Henkel what is known as "stop-loss" insurance.[64] Under a stop-loss insurance policy, an insurer for a self-funded health plan takes on the risks of claims that exceed an agreed-upon threshold, thus giving the employer with a self-insured plan a measure of protection against high-dollar claims.[65] After Henkel paid the drug expenses for the subject drugs—which exceeded $50 million—Henkel sought reimbursement from ReliaStar.[66] ReliaStar paid the reimbursement claims for the subject drugs from 2015 but then hired a consultant to perform an independent audit of the most expensive claims that arose in 2016 and 2017.[67] After an investigation, the consultant concluded that the prescription drug claims were not covered by the Plan.[68] ReliaStar declined to pay the participants' claims from 2016 and 2017 on the basis of the consultant's review.

[62] Doc. #215-2 at 10 (¶ 86); Doc. #202-22 at 3.

[63] Doc. #215-2 at 9-11 (¶¶ 84, 85, 87)

[64] *See Henkel of Am.*, 2020 WL 1430008, at *1.

[65] *Ibid.*

[66] *Ibid.*

[67] *Ibid.*

[68] *Ibid.*

Prior proceedings

After ReliaStar refused to reimburse Henkel, Henkel filed this action against ReliaStar, alleging breach of contract and violation of various other state laws. Henkel then moved for judgment on the pleadings, seeking a declaration that ReliaStar did not have a right to make underlying benefit determinations, to overrule the determinations of the fiduciary claims administrators, or to deny coverage on the basis of its own investigation. Judge Eginton denied the motion, ruling that discovery should proceed and that ReliaStar could challenge Henkel's decision to approve the claims under an arbitrary-and-capricious standard of review.[69]

Henkel subsequently filed an amended complaint to join Express Scripts as an additional defendant, alleging claims against Express Scripts as an alternative to its claims against ReliaStar.[70] After I granted Express Scripts' motion to dismiss Henkel's complaint, *see Henkel of Am.*, 2020 WL 1430008, Henkel filed a second amended complaint, alleging breach of fiduciary duty and breach of contract against Express Scripts in addition to its claims against ReliaStar.[71] Express Scripts has now moved for summary judgment against Henkel on the breach of fiduciary duty and breach of contract claims.[72]

DISCUSSION

The principles governing the Court's review of a motion for summary judgment are well established. Summary judgment may be granted only if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The Court must view the facts in the light most favorable to the party

[69] Doc. #47; *Henkel of Am.,* 2019 WL 2462605.

[70] Doc. #56.

[71] Doc. #152.

[72] Doc. #187.

who opposes the motion for summary judgment and then decide if those facts would be enough—if eventually proven at trial—to allow a reasonable jury to decide in favor of the opposing party. The Court's role at summary judgment is not to judge the credibility of witnesses or to resolve closely contested issues but solely to decide if there are enough facts that remain in dispute to warrant a trial. *See generally Tolan v. Cotton*, 572 U.S. 650, 656-57 (2014) (*per curiam*); *Benzemann v. Houslanger & Assocs.*, *PLLC*, 924 F.3d 73, 78 (2d Cir. 2019).[73]

Preliminary issues

Before I turn to the merits of the summary judgment motion, I will first address preliminary issues including (1) whether it is proper for me to consider the opposition papers filed by ReliaStar (in addition to those filed by Henkel); (2) whether I should apply a *de novo* or abuse-of-discretion standard of review; and (3) whether my review should be limited to what Express Scripts claims to be the administrative record.

1. Whether ReliaStar has standing to file objection papers

Although ReliaStar is a co-defendant and has not filed any crossclaims against Express Scripts, ReliaStar has filed an opposition to Express Scripts' summary judgment motion against Henkel.[74] Express Scripts argues that I should not consider ReliaStar's opposition papers because Express Scripts did not move for summary judgment against ReliaStar.[75]

The issue of whether one co-defendant may oppose another co-defendant's motion in the absence of a crossclaim between the two parties has "vexed federal district courts." *Stone v. Marten Transport, LLC*, 2014 WL 1666420, at *4 (M.D. Tenn. 2014). Although some courts

[73] Unless otherwise indicated, this ruling omits internal quotation marks, alterations, citations, and footnotes in text quoted from court decisions.

[74] Doc. #195.

[75] Doc. #219 at 5-7.

hold that a co-defendant may not oppose another co-defendant's motion in the absence of a crossclaim between the two parties, other courts have concluded that a co-party may oppose another party's motion so long as the co-party has a stake in the outcome of the motion. *See ArcelorMittal Plate LLC v. Lapeer Industries, Inc.*, 2021 WL 926276, at *8 (E.D. Mich. 2021) (citing cases for both outcomes).

The better-reasoned view is that any party to litigation may oppose another party's motion for relief if the party can make some showing of likely harm if the relief is granted. As one commentator has observed, "the proper question when analyzing whether a party has standing to oppose a co-party's motion should not be whether the two parties stand opposed to one another in the lawsuit as a whole or whether they are on opposite sides of the 'v.'," but instead "whether parties are adverse on the particular issue, regardless of their position in the overall litigation." *See* Jonathan A. Wolfson, *Warring Teammates: Standing to Oppose a Coparty's Motion for Summary Judgment*, 60 Drake L. Rev. 561, 567 (2012). In other words, the rights of a party in a multi-party lawsuit to oppose relief sought by another party should turn on a functional consideration of the party's true interests rather than formalistic concerns about whether the party is technically adverse to the co-party who has moved for relief.

Here, it is clear that ReliaStar has a stake that justifies its opposition to Express Scripts' motion for summary judgment against Henkel. If I were to grant Express Scripts' motion, this would be detrimental to ReliaStar because then ReliaStar would be the only remaining defendant in the action. Moreover, to the extent that Express Scripts seeks findings that it properly discharged its claims processing functions, then these findings could adversely affect ReliaStar's arguments that it should not be liable to Henkel because the claims were not properly processed and granted. Accordingly, I will consider ReliaStar's arguments.

2. Whether to apply a deferential standard of review

When Henkel first moved for judgment on the pleadings against ReliaStar—then a sole defendant— Judge Eginton ruled that the correct standard of review to apply was whether the grant of benefits to the participants was arbitrary and capricious.[76] ReliaStar, however, now argues for a *de novo* standard of review. By contrast, both Henkel and Express Scripts argue for purposes of this motion for summary judgment that I should apply a deferential standard of review that is akin to the usual arbitrary-and-capricious standard of review applicable to when a health plan claimant seeks to challenge a grant of benefits. *See, e.g., Halo v. Yale Health Plan*, 819 F.3d 42, 51 (2d Cir. 2016). Because I would deny Express Scripts' motion for summary judgment under either standard of review, I need not resolve at this time what is the appropriate standard of review.

3. Whether to consider facts outside the "administrative record"

In a typical ERISA action, the plaintiff has filed a claim against the plan administrator seeking to reverse a denial of health benefits. Courts ordinarily limit themselves in this context to the formal administrative record that was generated in the course of the administrator's processing of the claim. *See Halo*, 819 F.3d at 60. But this is not an ordinary case. It is not the claimant who is the plaintiff or the defendant who is the insurer but instead a plan administrator plaintiff and a stop-loss insurance company defendant that had no opportunity in the first place to take part in the generation of the administrative record that led to the granting of benefits.

Moreover, it would be unfair to grant Express Scripts' request to limit the universe of information to be considered only to the information that was before Express Scripts at the time that it initially granted the prior authorizations. Both Henkel and ReliaStar point to evidence

[76] Doc. #47 at 2.

suggesting that Express Scripts later became aware that the participants' claims were potentially not covered by the Plan. In addition, there are substantial material questions about what information Express Scripts should have known from Accredo's drug utilization review and how or if that information should have caused Express Scripts to reevaluate or deny subsequent claims. Accordingly, I will consider the evidence that is in the summary judgment record rather than limit myself solely to the record that existed before Express Scripts at the time it granted the prior authorizations.

Breach of fiduciary duty

Express Scripts moves for summary judgment on Henkel's claim for breach of fiduciary duty. Henkel alleges that Express Scripts breached its fiduciary duty not only by failing to adhere to the coverage criteria in the prior authorization policies but also by approving the subsequent claims. Although Express Scripts does not dispute its fiduciary status for purposes of this motion, it argues that there is no disputed material fact concerning either the initial or subsequent claims approvals. I will first address the prior authorization policies and then the subsequent claims approvals.

1. Prior authorizations

The prior authorization policies for the subject drugs, which Express Scripts drafted and implemented without input from Henkel, allowed for approval through current or prior use. Express Scripts approved the prior authorization of several of the claims on the basis of prior or current use of the subject drugs.

The PBM Addendum contains a chart that lists whether certain drugs require prior authorization.[77] Cinryze, Berinert, Firazyr, Kalbitor, and Ruconest are listed as requiring prior

[77] Doc. #185-10 at 6-8.

authorization approval.[78] The chart also lists certain criteria related to drug coverage, including whether drugs will require "grandfather[ing]".[79] The "grandfather" criteria for the subject drugs is blacked out, indicating that prior or current use was not a criteria that could be included in the prior authorization policies.[80] A list of notes on the last page of the contract titled "Savings Guarantee" explains that "[s]tandard guarantees require the implementation of Prior Authorization without grandfathering[.]"[81]

On the basis of these documents, Henkel argues that the PBM Addendum prohibits approving drug claims through prior or current use because it clearly prohibits grandfathering of the subject drugs.[82] Express Scripts responds that Henkel takes the "grandfathering" endnote out of context.[83] During oral argument, Express Scripts clarified that "savings guarantees" are negotiated by clients to ensure a certain percentage of savings.[84] According to Express Scripts, prohibiting grandfathering in prior authorization policies is a mechanism for guaranteeing cost savings.[85]

A reasonable jury could find that Express Scripts was prohibited from covering the drugs solely on the basis of current or prior use. The opening paragraphs of the PBM Addendum state that the agreement between Express Scripts and Henkel is "estimated to produce an overall net

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[78] *Ibid.*

[79] *Ibid.*

[80] *Id.* at 7; *see also* Doc. #240 at 36.

[81] Doc. #185-10 at 9 n. 7.

[82] Doc. #201 at 27-28; *see also* Doc. #204 at 10 (¶ 25 and response); Doc. #202 at 9-23 (¶¶ 22 and response, 27 and response, 29 and response, 31 and response, 35 and response, 40 and response, 42 and response, 44 and response, 46 and response, 48 and response, 50 and response, 52 and response); Doc. #196 at 13 (¶ 29 and response).

[83] Doc. #217 at 9.

[84] Doc. #242 at 23-24.

[85] *Ibid.*

client savings for [Henkel]."[86] Moreover, the role of PBMs in the health industry is to serve as intermediaries between pharmaceutical manufacturers and health benefit providers like Henkel. *See Pharmaceutical Management Ass'n v. Rowe*, 429 F.3d 294, 298 (1st Cir. 2005) (describing the role of PBMs).

PBMs are hired, as Express Scripts was, to design, manage, and administer drug benefit programs, which includes determining coverage eligibility and performing drug utilization review. *See In re Pharmaceutical Industry Average Wholesale Price Litigation*, 230 F.R.D. 61, 72 (D. Mass. 2005). Health benefit providers often look to and rely on PBMs for cost savings. *See Rowe*, 429 F.3d at 298. It is undisputed that approving the subject drugs was costly. Prohibiting approval through current or prior use would likely have resulted in several of the claims not being approved, and therefore generated cost savings. Taking into account the role of claims administrators in the pharmaceutical industry and viewing the PBM Addendum in the light most favorable to Henkel, a reasonable jury could conclude that Express Scripts was barred from granting prior authorization approval merely on the basis of prior or current use of the subject drugs.

The disputed issue of whether the contracts prohibited Express Scripts from approving the claims through current or prior use is enough to preclude summary judgment. But another genuine issue of material fact also precludes summary judgment: whether Express Scripts as a fiduciary engaged in responsible claims administration when it failed to confirm through lab reports or medical records that the participants actually met the test-based prior authorization

[86] Doc. #185-10 at 2 (PBM Addendum)

criteria.[87] The parties' dispute concerns whether the prior authorization policies required Express Scripts to confirm the participants' HAE diagnosis by reviewing lab results.

Henkel argues that a reasonable factfinder could conclude that the prior authorization policies required ESI-UM to confirm the lab results by collecting or reviewing the patient's lab results. The prior authorization policies authorize approval if "[t]he patient has HAE as *confirmed by*" certain diagnostic criteria and "as *defined by* the laboratory reference values."[88]

Express Scripts' primary argument against this interpretation is that the contracts between Henkel and Express Scripts permit Express Scripts to rely entirely on what the physician states concerning whether the participant satisfies the prior authorization criteria. Express Scripts points to language in the PBMA that permits Express Scripts to "rely entirely upon information about the Member and the diagnosis of the Member's condition provided to it from the prescriber."[89]

But Express Scripts does not account for other details in the contracts. First, the PBMA did not go into effect until January 1, 2017, and only two of the prior authorization reviews were conducted when it was in effect. Express Scripts has pointed to no language in the IPDPA or any other contract that permits or instructs Express Scripts to rely only on the word of the prescriber without any confirmation.

Second, nothing in any of the contracts—including the language Express Scripts cites from the PBMA—bars Express Scripts from requesting documentation from the physician. The PBMA's authorization to rely entirely on information provided to it by the prescriber does not

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[87] Doc. #203 at 28; *see also* Doc. #196 at 10 (¶ 22 and response); Doc. #202 at 9;Doc. #204 at 10-14, 16-17, 19-20, 22-23 (¶¶ 22 and response, 27 and response, 31 and response, 33 and response, 38 and response, 40 and response, 46 and response, 52 and response, 54 and response); Doc. #216-1 at 11 (¶ 19).

[88] *See, e.g.,* Doc. #186-1 at 3 (emphasis added).

[89] *See* Doc. #185-5 at 11 (§ 2.3(b)) (PBMA).

speak to what type of information is provided and is not inconsistent with asking for lab results or medical records from the prescriber. A reasonable factfinder could conclude that, because the criteria of the prior authorization reviews not only requires such specific lab values in order to authorize approval but also describes the diagnostic differences between HAE Types I, II, and III and in light of the extraordinarily high costs involved, ESI-UM had an obligation to confirm the qualifying levels by seeking to review the lab results before approving the claims.

Further, Express Scripts approved some of the initial claims on the basis of low protein and low serum levels.[90] ESI-UM recorded that that prescribing physician's office had reported the low lab results. The evidence collected during discovery from this same prescribing physician, however, reflects that the participants' lab results showed normal serum and protein levels.[91]

Given the discrepancy between the actual lab results and what ESI-UM recorded in the prior authorization reviews, it is far from clear whether ESI-UM accurately recorded the information provided by the physicians' office or whether the physician provided the correct information.[92] If ESI-UM had documented the lab results contemporaneously with conducting the prior authorization reviews, Express Scripts possibly would have concluded that at least some of the claims were not covered under the Plan.[93]

The cases cited by Express Scripts stand for the proposition that, in the absence of a requirement in a policy that a claims administrator actively investigate or gather information, a court cannot impose a duty requiring confirmation of lab results. *See, e.g.*, *Young v. Hartford*

[90] Doc. #186 at 9-10, 13-14, 21-22 (¶¶ 26-27, 41-42, 74-75).

[91] *See* Doc. #216-1 at 11-12 (¶ 20 and response) *see also* Doc. #202-23 at 4 (Dr. Kanarek deposition); Doc. #202-27 at 6 (Dr. Neustrom deposition).

[92] *See* Doc. #215-2 at 9, 13 (¶ 92 and response).

[93] *See id.* at 12 (¶ 91).

Life and Acc. Ins. Co., 2011 WL 4430859, at *11 (S.D.N.Y. 2011) (policy placed burden of providing documentation on the claimant and plaintiff had "not demonstrated that the [insurer] failed to collect readily available, material information"). Here, a reasonable jury could conclude that, in the totality of circumstances presented here, Express Scripts was obliged to review documentation of lab results to justify the payment of tens of millions of dollars in pharmacy benefit claims.

2. Subsequent approvals

Express Scripts argues that there is no disputed material fact concerning the subsequent approvals of the claims because each prior authorization policy for the subject drugs provided that prior authorization approval was valid for three years.[94] Thus, according to Express Scripts, once the subject drug was approved through prior authorization, Express Scripts was not permitted to disturb the prior authorization finding or even question whether any of the subsequent claims were covered under the Plan, regardless of any intervening events. Henkel and ReliaStar, however, argue that there were a number of "red flags" raised by Mercer and Accredo that a reasonable jury could conclude should have caused Express Scripts to deny or evaluate the subsequent claims rather than blindly approve them.[95]

As an initial matter, the parties dispute whether the information and concerns known to Accredo were available to and may be attributed to Express Scripts. I conclude that there is at least a genuine fact issue on this question. Express Scripts delegated the responsibility for drug utilization review to Accredo but, as stipulated in the contracts, maintained liability and responsibility for Accredo's work.[96] The PBMA described that drug utilization review was to

[94] *See* Doc. #217 at 13-16; *see also* Doc. #215 at 13-15.

[95] *See* Doc. #195 at 11-12, 21; Doc. #203 at 34-35; *see also* Doc. #194 at 10-12, 21, 23-24; Doc. #201 at 34-35.

[96] Doc. #185-4 at 19 (§ 15.2) (IPDPA); Doc. #185-5 at 18 (§ 7.4) (PBMA); Doc. #215 at 3-4 (¶¶ 63-66 and

"assist the dispensing pharmacist and prescribing physician in identifying potential drug interactions, incorrect prescriptions or dosages, and certain other circumstances that may be indicative of inappropriate prescription drug usage."[97] On behalf of Express Scripts, Accredo performed the drug utilization reviews for each prescription submitted.[98]

A jury could reasonably conclude that when performing the drug utilization review, Accredo became concerned that the dosages or prescriptions were incorrect or inappropriate for the participants. In March 2017, Accredo conducted baseline clinical assessments of the participants' HAE and documented information about the diagnosis and symptoms, including that they both had normal serum and protein levels, indicating that the two participants had HAE Type III.[99] The information received by Accredo about the normal serum and protein levels contradicted information that Express Scripts had received for three of the prior authorization approvals.[100] In September 2017, the Clinical Program Director for Accredo noted that she did not believe that the subject drugs met the criteria for the prior authorization policies because one of the participants did not have the low protein and serum levels.[101] Then, in December 2017, the Express Scripts Vice President for Formulary Development wrote that he did not believe that the prior authorization policies allowed for authorization of patients with HAE Type III.[102]

responses); Doc. #219-1 at 5 (¶ 6 response); *see also* Doc. #216-1 at 4 (¶¶ 4-5 and responses); Doc. #217-2 at 4 (¶ 66 and response).

[97] *See* Doc. #185-5 at 10 (§ 2.3(a)(ii)) (PBMA); *see also* Doc. #152 at 14-15 (¶ 65).

[98] *See* Doc. #217-2 at 4 (¶ 66 and response); *see also* Doc. #216-1 at 2-3 (¶ 1 and response).

[99] Doc. #202-19; Doc. #202-20.

[100] Doc. #186 at 8-9, 13, 21-22 (¶¶ 26, 41, 74).

[101] Doc. #202-21 at 3.

[102] Doc. #202-30 at 2.

Accredo also expressed concern that one participant was using 66 vials per day, a number well over what was recommended on the label.[103] Altogether, a reasonable factfinder could conclude that Express Scripts should have concluded, in light of its growing knowledge about the participants and their use of the drugs, that the drugs had been improperly approved as covered by the Plan.

Express Scripts responds that, because the prior authorization policies are silent as to whether it could reconsider the initial coverage approval or deny subsequent claims on the basis of information acquired after the initial reviews, a reasonable course of action was for Express Scripts not to consider how the contradictory information impacted the coverage of the subject drugs.[104] Whether that view is reasonable is a decision best left to the factfinder. A reasonable jury could conclude that, in light of information directly contradicting information Express Scripts had relied upon when granting the initial coverage, it was not reasonable for Express Scripts to continue approval for payments for the subject drugs without additional investigation.

Even if Accredo's knowledge was not attributable to Express Scripts, the records suggest that Express Scripts was independently aware of facts that call into question the reasonableness of continuing claim approvals. When ESI-UM communicated with the prescribing physician's office on February 16, 2016, ESI-UM recorded that the patient had low levels of the serum and protein required to diagnose HAE Type I or Type II.[105] In a subsequent communication on April 7, 2016 with the same prescriber's office for a different prior authorization review, the ESI-UM once again recorded that the patient had low levels of the serum and protein.[106] But then during a

[103] Doc. #202-22 at 3.

[104] Doc. #215 at 15.

[105] Doc. #186 at 13 (¶¶ 40-41).

[106] *Id.* at 8-9 (¶¶ 25-26).

prior authorization review on August 18, 2017 for the same patient, a different prescriber's office informed ESI-UM that the patient did *not* have low levels of the protein.[107] Express Scripts denied this initial claim. When the prescribing physician appealed this claim, his office informed ESI-UM that the patient *did* have low levels of the protein but did not have low serum levels.[108] A factfinder could conclude that, in light of the contradictory reports of the laboratory results diagnosing the patient's HAE, Express Scripts improperly approved the subsequent drug claims without taking appropriate steps to investigate the discrepancies.

Breach of contract claim

Henkel alleges that Express Scripts breached its contracts by initially approving the claims as covered under the Plan, continuing to approve the claims, and failing to perform drug utilization review.[109]

I will deny Express Scripts' motion for summary judgment with respect to the first two alleged breaches—initially approving the claims and then continuing to approve them—for the same reasons set forth above. There are material facts as to whether Express Scripts breached its contract by grandfathering in the drugs and by continuing to approve them even when confronted with contradictory information.

As for the alleged breach for failure to conduct drug utilization reviews, Express Scripts was required, "[i]n connection with each prescription…[to perform standard drug utilization]…to identify[] potential drug interaction, incorrect prescriptions or dosages, and certain other circumstances that may be indicative of inappropriate prescription drug usage."[110]

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[107] *Id.* at 23 (¶¶ 78-79).

[108] Doc. #186-14 at 55.

[109] Doc. #152 at 58 (¶ 294).

[110] Doc. #185-5 at 10 (§ 2.3a(ii)) (PBMA); *see also* Doc. #152 at 14 (¶ 65).

Express Scripts in turn contracted with Accredo to perform certain services "to the extent requested by [Express Scripts]," including "clinical management and review of prescriptions," "cognitive pharmacists review of prescriptions, including interpretation and review for plan compliance, safety and efficacy and clinical appropriateness (drug utilization)," and "interaction with prescribing physician or patients as necessary and appropriate."[111]

A reasonable jury could conclude that Express Scripts did not meet its contractual obligations by failing to identify incorrect prescriptions or dosages and other circumstances reflecting inappropriate drug usage. As Express Scripts has explained, the purpose of standard drug utilization review is "to identify potentially dangerous drug interactions … to question pharmacists and physicians about dosages to ensure that the amount entered was input correctly; and to scan for other instances in which the prescription poses a risk to health and safety."[112]

At least by March 2017, Accredo had concerns that the drugs were inappropriate for the participants because Accredo ordered baseline clinical tests for the participants.[113] Some time after the baseline clinical tests showed that the participants had normal serum and protein levels, management-level employees within Accredo and Express Scripts commented that the drugs were not covered by the Plan because the participants did not have HAE Type I or II.[114]

Furthermore, Accredo also expressed concerns that the participants were using drug amounts that were well over the recommended dosage and well over what HAE patients generally take.[115] ReliaStar's expert witnesses have opined that the dosages prescribed to the

[111] Doc. #215-2 at 3-4 (¶ 65 and response); Doc. #216-1 at 5-6 (¶ 8 and response); *see also* Doc. #217-2 at 4 (¶ 66 and response).

[112] Doc. #185 at 44.

[113] Doc. #202-19; Doc. #202-20.

[114] Doc. #202-21 at 3; Doc. #202-30 at 2.

[115] Doc. #202-22 at 3.

participants were well-above FDA-approved dosages.[116] There remains a question of fact as to whether Express Scripts complied with the drug utilization review requirement when it failed to identify or act on the information that the dosages were well above what was standard in the industry and approved by the FDA.

CONCLUSION

For the reasons set forth above, Express Scripts' motion for summary judgment (Doc. #187) is DENIED. I have considered all other arguments raised by Express Scripts even though not expressly discussed in this ruling.

It is so ordered. Dated at New Haven this 8th day of July 2021

/s/ ***Jeffrey Alker Meyer***
Jeffrey Alker Meyer
United States District Judge

[116] Doc. #202-28 at 20; Doc. #215-2 at 14 (¶ 93); Doc. #216-1 at 13-15 (¶¶ 25, 27).