IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WISCONSIN

JILL CRISTA, TORIN HIGNELL,
and KAELAN HIGNELL,

Plaintiffs,

v.

WISCONSIN PHYSICIANS SERVICE
INSURANCE CORPORATION,

Defendant.

OPINION AND ORDER

18-cv-365-wmc

Defendant Wisconsin Physicians Service Insurance Corporation ("WPS") is being sued under the Employee Retirement Income Security Act, 29 U.S.C. § 1132(a) ("ERISA") after it denied prior authorization requests for administration of intravenous immunoglobulin ("IVIG") to plaintiffs Kaelan and Torin Hignell, the twin sons of plaintiff Jill Crista. Before the court are the parties' cross-motions for summary judgment. Plaintiffs contend that WPS's denial was arbitrary and capricious and constituted a breach of fiduciary duties, while WPS counters that the denials were appropriate following a review of the twins' complete medical records. For the reasons that follow, the court concludes that the undisputed facts and binding case law require entry of judgment for WPS.

UNDISPUTED FACTS[1]

A. Background

The plaintiffs all live in Rock County, Wisconsin. Crista is a participant in an employee welfare benefit plan administered by defendant WPS, while Torin and Kaelan

[1] The following facts are material and undisputed for purposes of summary judgment except where

are beneficiaries under that plan. WPS is a Wisconsin service insurance corporation. WPS issued the original policy, an individual preferred provider organization policy, to Crista on January 1, 2015, in which Torin and Kaelan were listed as covered dependents. The policy renewed on January 1, 2016. On September 23, 2016, WPS informed Crista that it would no longer offer individual Affordable Care Act coverage because of changes in the health insurance market. As a result, WPS advised that her policy would end on December 31, 2016.

On January 16, 2017, Crista completed an application seeking small group insurance coverage for her business, Center for Natural Medicine, LLC, to be effective February 1, 2017. WPS issued a Group Master Policy, Group No. 10011017 to Center for Natural Medicine, with a 2017 WPS PPO Certificate of Coverage effective February 1, 2017 (the "Plan").[2] This Plan qualifies as an employee welfare benefit plan under ERISA

noted below. The facts are drawn from the administrative record compiled by WPS in considering plaintiffs' claims. *See Holmstrom v. Metro. Life Ins. Co.*, 615 F.3d 758, 761 (7th Cir. 2010). Throughout this opinion, therefore, the court cites to portions of the administrative record (dkts. #15, 15-1, 15-2, 15-3) as "WPS __." Also before the court is plaintiffs' motion to strike audio files produced by WPS. (Dkt. #28.) The files were provided via USB port on November 13, 2018 -- slightly more than two months after the September 7, 2018, deadline imposed by this court for WPS to produce the entire administrative record and almost a month *after* plaintiffs had already filed their summary judgment motion. (*See* dkts. #24, 11, 16.) Defendant has provided no explanation for the belated disclosure, and so the delay is not justified, nor was the delay harmless as it came after plaintiffs had already filed their own summary judgment motion. The court notes, however, that the recordings were largely immaterial and would not have altered the opinion either way. Regardless, for the purposes of this opinion and order, the court neither considered the audio recordings nor the proposed findings of fact supported only by those recordings, and plaintiffs' motion to strike is GRANTED.

[2] On July 1, 2017, the employer's name on the policy changed to "Crista Corporation" when the company became an S-corporation.

with Crista a plan participant and her sons as beneficiaries. WPS serves as a fiduciary in interpreting and applying the Plan terms.

The Plan vests "the sole and exclusive right to interpret and apply the Policy's provisions and to make factual determinations" in WPS, including determining "whether *benefits* are payable for a particular *health care service*." (WPS 1908.)[3] The Plan "only provides *benefits* for certain *health care services*," and expressly notes that the policy does *not* automatically cover services (1) "performed or prescribed" by a health care provider or (2) that are "the only available *health care service[s]* for your *illness* or *injury*." (*Id.*) The Plan further lists a number of exclusions, including for: (1) "*Health care services* that we determine are not medically necessary"; and (2) "*Health care services* that we determine are *experimental/investigational/unproven*." (WPS 1946.)

The Plan defines "medically necessary" as:

> a *health care service* or facility that we determine to be:
> 1. Consistent with and appropriate for the diagnosis or *treatment* of your *illness* or *injury*;
> 2. Commonly and customarily recognized and generally accepted by the medical profession in the United States as appropriate and standard of care for the condition being evaluated or treated;
> 3. Substantiated by the clinical documentation;
> 4. The most appropriate and cost effective level of care that can safely be provided to you. Appropriate and cost effective does not necessarily mean least expensive;
> 5. Proven to be useful or likely to be successful, yield additional information, or improve clinical outcome; and
> 6. Not primarily for the convenience or preference of the *covered person*, his/her family, or any *health care provider*.

[3] As quoted here, and throughout the Plan documents, a wide-range of terms are italicized and defined elsewhere. Unless otherwise noted, any italics or other emphases appearing in the quotes above are in the original.

(WPS 1976.) Similarly, the Plan expressly states that something "may not be considered *medically necessary* even if the *health care provider* has performed, prescribed, recommended, ordered, or approved the service, or if the service is the only available procedure or treatment for your condition." (*Id.*)

The Plan defines "Experimental/Investigational/Unproven" as "any *health care service* or facility," which is "determined by our Corporate Medical Director" to "meet[] at least one of the following criteria:" (1) "It is not currently recognized as accepted medical practice"; (2) "It is being used in a way that is not approved by the FDA or listed in the FDA-approved labeling (*i.e.* off-label use), except for off-label uses that are accepted medical practice"; (3) "Prevailing peer-reviewed medical literature in the United States has failed to demonstrate that it is safe and effective for your condition"; and (4) insufficient "evidence to . . . make a convincing argument that (a) it can measure or alter the sought after changes . . .; or support conclusions concerning the effect of the drug, device, procedure, service or *treatment* on health outcomes."[4] (WPS 1973.) Similarly, the Plan states that "[a] *health care service* or facility may be considered *experimental/investigational/unproven* even if . . . it is the only available procedure or *treatment* for the condition." (*Id.*)

Finally, under the Plan terms, WPS reserved "full discretionary authority to determine whether a *health care service* is *experimental/investigational/unproven*" and states its "determination will be upheld if it is based on any credible evidence." (WPS 1974.) If

[4] The definition of "Experimental/Investigational/Unproven" also listed other criteria not relevant here. Moreover, the Plan explains that the list provided was "not all-inclusive." (WPS 1973.)

WPS's determination were reversed, the policy beneficiary "will not be entitled to receive any compensatory damages, punitive damages, or attorney's fees, or any other costs," but rather would be limited to the "provision of *benefits* in accordance with the Policy." (*Id.*)

B. Prior Authorization Requests

Section 11 of the Plan outlines the process for submitting prior authorization requests and benefits determinations. (WPS 1960-63.) The Plan explains that any "denial notice will state the specific reason or reasons for the *adverse benefit determination*, the specific Policy provision on which the determination is based, and a description of the internal and external review procedures and associated timelines," as well as "a description of any additional material or information necessary for you to perfect the claim and an explanation of why such material or information is necessary." (WPS 1963.) If the denial "is based on the definition of *medically necessary* or *experimental/investigational/unproven*, the denial notice will include an explanation of the scientific or clinical judgment for the determination" or "a statement that such explanation will be provided, free of charge, upon your request." (*Id.*)

Section 12 outlines the process for appealing an adverse benefits determination. (WPS 1963-68.) A grievance can be filed by submitting to WPS's Grievance/Appeal Department "the concerns, issues, and comments" in writing, with "any supporting documents" within three years following receipt of WPS's "initial notice of denial or partial denial." (WPS 1964.) The policy provides the following example:

> if we denied *benefits* for your claim because we determined that a *health care service* provided to you was not *medically necessary* and/or *experimental/investigative/unproven*, please send us all

> additional medical information (including copies of your *health care provider's* medical records) that shows why the *health care service* was *medically necessary* and/or not *experimental/investigative/unproven* under the Policy.
>
> * * *
>
> For decisions regarding medical judgment, the Committee will consult with a health care professional who has the appropriate training and experience in the field of medicine involved in the medical judgment. Such health care professional will not be the same individual who was consulted regarding the initial adverse benefit determination or a subordinate of such individual.

(*Id.*) If after the completion of the grievance/appeal process, WPS determines that treatment was experimental/investigational/unproven, a beneficiary could request an external review by an independent review organization ("IRO") under Section 13. (WPS 1968.) To invoke that process, the beneficiary must submit in writing a specific request for independent external review. (WPS 1968-69.) Once the request is received, an accredited IRO is then assigned to the case, and will then issue a decision after receiving the request. (WPS 1969.) "Unless your case involves the rescission of the Policy, the IRO's decision is binding for both you and WPS." (*Id.*)

C. Intravenous Immunoglobulin (IVIG) Treatment

There is no dispute that Torin and Kaelan had previously been diagnosed with "hypogammaglobulinemia" by their treating physicians, Drs. Denis Bouboulis and Phillip DeMio, although the parties dispute whether they actually suffer from it. Hypogammaglobulinemia is a serious immune disorder that causes chronic respiratory and gastrointestinal issues and recurring infections, which can lead to the development of autoimmune conditions and premature death. Hypogammaglobulinemia is an FDA-

approved indication for IVIG treatment. There is also no dispute that Torin and Kaelan have received IVIG treatment since 2013, although again the parties dispute its medical necessity.

1. Approval of First Prior Authorization Requests in 2015

The first prior authorization requests for IVIG treatment for Torin and Kaelan were submitted to WPS in late January 2015, listing hypogammaglobulinemia as the necessitating diagnosis. WPS's specialty pharmacy benefits manager, Diplomat, approved these requests, and WPS approved IVIG treatment for each child from January 22, 2015, until January 28, 2016. (WPS 147, 353.)

2. Denial, Appeal, and Ultimate Approval of the 2016 Prior Authorization Requests

Additional prior authorization requests for IVIG treatment were submitted to WPS for Torin and Kaelan in late January 2016, again listing hypogammaglobulinemia as the necessitating diagnosis. These prior authorization requests included some medical records for the Hignells, but the parties dispute whether more documents were requested and subsequently provided. (Def.'s PFOF (dkt. #38) ¶¶ 27, 31.) Specifically, WPS maintains that it requested all office notes and laboratory reports from January 1, 2013, to December 31, 2014, but that plaintiffs did not turn over all of these records. (*Id.*) Plaintiffs dispute that the records were even requested at that time. (*Id.* ¶ 27.) This dispute is addressed further in the opinion that follows.

WPS then referred Kaelan's prior authorization request to Dr. Betty Liu, an outside board-certified pediatric allergist/immunologist at AllMed Healthcare Management

("AllMed"). Dr. Liu determined that the hypogammaglobulinemia diagnosis "is not likely," and she found that IVIG was "experimental / investigational and unproven" and not medically necessary. (WPS 158-59.) Dr. Liu added that "additional testing is necessary to confirm the member's diagnosis as it is not clear if he has a qualified immune deficiency." (*Id.*)

In February 2016, Dr. Michael Ostrov, a WPS physician, next recommended denying both Torin's and Kaelan's prior authorization requests, noting in part that:

> Based upon my review of the submitted documentation, there was not evidence that the diagnosis of hypogammaglobulinemia was supported. The case was sent for external review . . . . A pediatric immunologist performed the review [and] . . . determined that the treatment with IVIG was not medically necessary because the diagnosis was not established. The recommendation was to stop the IVIG and have reevaluation of immunoglobulin levels and antibody response.

(WPS 146, 352.)

On February 9, 2016, WPS formally denied the twins' prior authorization requests via letter. (WPS 116-17, 271-72.) The letters stated that:

> The request for the medication Gammagard (IVIG) is being denied. After review of the documentation submitted it was found that the diagnosis of hypogammaglobulinemia was not supported and for this reason the Gammagard (IVIG) is considered not medically necessary. The recommendation is to stop the medication and have a reevaluation of Immunoglobulin levels and antibody response.

(WPS 116, 271.)

In response, on February 17, 2016, the children's physician, Dr. Bouboulis, submitted letters explaining his reasons for prescribing IVIG. (WPS 115, 345.) Dr. Ostrov

reviewed those letters, but was unpersuaded and his "assessment remain[ed] unchanged." (WPS 146, 352.) On February 22, 2016, WPS contacted Bouboulis's office to inform him of the denial. (*Id.*) On February 25, Bouboulis's office requested a review call with Dr. Liu concerning both Hignells. That same day, Drs. Bouboulis and Liu had a peer-to-peer call, after which Liu revised her original determination and concluded that the IVIG treatment was medically necessary for Kaelan. (WPS 162-65.) "Based on the updated medical information gained via the peer-to-peer call," Dr. Liu explained that "the treating provider has laboratory data that is supportive of an immune deficiency with hypogammaglobulinemia and decreased antibody function (CVID)"; "[a]dditional testing is not medically necessary to further confirm or remove support for this diagnosis"; and "IVIG is medically necessary according to the member's certificate of coverage." (WPS 163.) That same day, plaintiff Jill Crista faxed the lab results apparently discussed on the peer-to-peer call, which WPS apparently forwarded to Dr. Liu. (WPS 145 ("Clinical advisor[] has been reviewing documentation, additional clinical faxed to outside reviewer as requested by Dr. Ostrov."), 351 (same).)

After reviewing those test results, Dr. Liu revised her determinations once again, explaining "the provider [presumably Dr. Bouboulis] gave conflicting information on the peer-to-peer call that was not supported by the written documentation." (WPS 168.) In particular, Liu ultimately concluded that Kaelan "does not have laboratory data that is supportive of immune deficiency"; "[h]e should have repeat immune evaluation done 6 months after being off of IVIG"; "IVIG is not medically necessary"; and "[t]he request is

experimental / investigational per the certificate of coverage."[5] (WPS 168-69.) On March 2, WPS sent Dr. Bouboulis renewed denials of the prior authorization requests, again based on a lack of medical necessity. (WPS 57-58, 279-80.)

After receiving the denials, Crista filed an appeal for both her sons on April 6, 2016. (WPS 27.) In her appeal letter, she stated "[t]he only rationale I can imagine for your company's refusal is that we became too expensive for your company to meet the bottom line." (WPS 28.) She attached 2016 lab results and office visit notes. WPS acknowledged her appeal on April 12, 2016. Around this time, Crista also faxed a letter dated April 4, 2016, seeking "the written clinical rationale used to make the decision to deny the authorization." (WPS 64.) In response, WPS sent a letter to Dr. Bouboulis, copying in Crista, explaining the denial.

In April of 2016, another WPS physician, Dr. Kevin Rak, reviewed the medical records for both Kaelan and Torin, ultimately agreeing that "if this truly were hypogammaglobulinemia, one would expect the immunoglobulin levels to be much lower, and in fact, many of the levels are actually normal," so that "[t]he new lab values and data do not conflict with the prior determination made by the AllMed specialty review." (WPS 172, 362.) Rak added that "although the twins' values of the immunoglobulins tested are not exact, in both cases there are mild depressions in the levels of a few immunoglobulins,

[5] The parties seem to disagree about which of the February 25, 2016, letters from Dr. Liu came first. (*See* Def.'s PFOF (dkt. #38) ¶ 48.) However, the administrative record shows the letters were faxed at different times, with the letter again concluding that the treatment was not medically necessary sent later. (*Cf.* WPS 161 (fax cover sheet dated February 26, 2016); WPS 166 (fax cover sheet dated March 2, 2016).)

but no severe deficiencies, and several of the values are within the range of normal." (WPS 362.)

In late April and early May of 2016, WPS next mailed Crista several letters, including a notification that the "appeal meeting" was scheduled for June 2, 2016. This letter explained that "[y]our provider, at your option, may participate" in the meeting. (WPS 78.) On May 19, 2016, WPS referred the children's prior authorization requests to Dr. Joshua Davidson, a board-certified allergist and immunologist with expertise in pediatric allergy and immunology, also affiliated with AllMed. Dr. Davidson concluded that "the existence of hypogammaglobulinemia diagnosis at this time cannot be supported." (WPS 371, 198.) Davidson also explained that a hypogammaglobulinemia diagnosis

> is dependent upon findings of quantitative and qualitative deficit. The former is supported by low total IgG levels, as IVIG largely consists of pooled IgG intended to replace what is low and/or absent in a given patient. A low level is typically defined as two standard deviations below the lower normal limit. In this case, there are numerous total IgG values, including data obtained prior to IVIG initiation in 2015. These data show either normal or very mildly depressed values that never f[e]ll two standard deviations below the lower normal limit. The latter concern, a qualitative deficit, would be supported by demonstrated failure to respond to a vaccination, such as a specific immune stimulus; this is not present in the documentation provided for review. Thus, with this failure to demonstrate quantitative and qualitative deficit, IVIG therapy is not supported at this time.

(WPS 371-72, 198-99.) WPS provided Dr. Davidson's analyses to Crista before the appeal meeting.

Crista submitted additional letters from Dr. DeMio, one of the twins' other treating physicians, who "st[oo]d by the diagnosis of hypogammaglobulinemia" for both boys. (WPS 6, 238.) DeMio opined that the boys had "low gammaglobulins," as well as "poor immune function with repeatedly failed full-course antimicrobial treatment for multiple infections, and . . . autoimmunity including neuroautoimmunity with resultant brain dysfunction such as tics and OCD." (WPS 6, 238.) He likewise opined that IVIG was medically necessary.

The appeal meeting took place on June 2, 2016, as scheduled, with Dr. Bouboulis in attendance. On June 7, 2016, WPS sent Crista letters approving the prior authorization requests for IVIG treatment for both boys from June 7, 2016, until June 7, 2017. Those letters emphasized that future treatment requests would also require prior authorization.

3. Denial of the 2017 Prior Authorization Requests

On April 26, 2017, obviously still unsatisfied with the state of the medical record and any definitive diagnosis, WPS sent letters to Dr. Bouboulis asking for updated medical documentation for the Hignell boys in advance of the expiration of the IVIG prior authorizations on June 7, 2017. The letters asked for medical records from the past four years and additional testing, stating that these records were necessary so that "an appropriate clinical determination can be rendered." (WPS 785, 1201.) On June 5, 2017, Dr. DeMio submitted the boys' February 2017 lab results as well as prior authorization requests for IVIG therapy along with prescriptions for the therapy. Two days later, PA Navigator Pharmacy Services explained in a letter on behalf of WPS that "[c]overage of GAMMAGARD INJ 5GM/50ML requires review of progress notes detailing diagnosis,

previous therapeutic history, concurrent medications, and treatment and monitoring plan," and further asserting that "[w]e did not receive the above mentioned information." (WPS 788-89, 1402-03.)

On June 13, 2017, WPS initially denied the prior authorization requests as "not medically necessary because [Torin and Kaelan] do not meet the criteria as outlined in the resources used to make coverage determinations." (WPS 789, 1403.) The denial letter added that "[c]ontinued coverage of IVIG requires review of progress notes detailing diagnosis, previous therapeutic history, concurrent medications, and treatment and monitoring plan," which were "requested from [their] provider, but not received." (WPS 789, 1403.) In response, on June 15 and 19, 2017, Dr. DeMio faxed to WPS various 2016 and 2017 lab results for both boys, as well as a letter summarizing the results. In this letter, DeMio explained that "during the period with no IVIG treatment (12/15/16-02/16/17), both children suffered for not having IVIG. Both reported viral infections, headache, and increased school absences during the four to five-week period past the treatment due date." (WPS 840, 1450.) Notably, although WPS had asked on April 26, 2017, for the medical records from the past four years, Dr. DeMio did not include any pre-2016 records in his June 2017 faxes.

On June 15, 2017, the prior authorization requests were again referred to outside health care professionals at Advanced Medical Reviews ("AMR") completed between June 20 and June 23, 2017. (WPS 1006, 1668.) Specifically, Dr. Wayne Imber, a board certified allergist/immunologist, concluded that IVIG treatment was medically necessary

for Kaelan, while an unidentified neurologist concluded likewise for Torin.[6] As to Kaelan, Dr. Imber concluded that "[t]he diagnosis of primary immune deficiency is clear in this patient, as is the need for IVIG treatment." (WPS 1006.) His June 2017 report further noted: (1) "infusions should not be interrupted to learn about a patient's tolerance for frequency of infusion as this will place the patient in harm's way unnecessarily and also would be consistent with medical malpractice"; (2) "[f]uture lapses in therapy should be scrupulously avoided, as they could be a cause of probable morbidity and possible mortality in this patient"; and (3) "it is not reasonable to anticipate that the IVIG/SCIG dose and/or frequency may be tapered and ultimately discontinued according to relevant evidence-based medical literature." (WPS 1007-08.)

As to Torin, the unidentified neurologist concluded that "IVIG would be considered medically necessary and the treatment of choice for this patient with primary immunodeficiency." (WPS 1668.) The reviewer explained that "[c]ontinuation of IVIG/SCIG is considered medically necessary for the diagnosis of hypogammaglobulinemia as his laboratory values have improved," Torin "is noted to be clinically unstable without treatment," and "IVIG/SCIG should be continued indefinitely for the treatment of hypogammaglobulinemia without interruption." (WPS 1669-70.) Further, the reviewer noted that continued IVIG/SCIG was "essential to prevent permanent bodily harm from infectious disease, and/or premature death." (WPS 1669.)

Obviously still unsatisfied, WPS extended its approval of IVIG therapy for both Torin and Kaelan based on these reports, but only for a one-month period from June 28

[6] Plaintiffs refer to both known and unknown reviewers jointly as the "First Reviewer."

through July 28, 2017, adding that their treating physician would need to seek reauthorization to continue the treatment beyond that period, and "future authorizations are not necessarily guaranteed and will be based on your physician submitting appropriate clinical information along with the request." (WPS 794, 1408.) On July 14, 2017, WPS also expressly asked for "all medical records from 2012 through the current date" in order "to make an informed, fair, and accurate determination as to the medical necessity of IVIG." (WPS 840.) Plaintiffs contend that this was the first time that WPS claimed pre-2015 records were necessary to review authorization requests. Defendant disputes this, maintaining that it had previously requested pre-2015 medical history records. (*See* Def.'s Resp. to Pls.' PFOF (dkt. #27) ¶ 66.) Again, this dispute is addressed further in the opinion that follows.

Regardless, on July 19, 2017, Dr. DeMio responded with several additional faxes containing the Hignells' medical records, although the parties also dispute whether these documents had been previously produced to WPS. (Def.'s Reply to Pls.' Resp. to Def.'s PFOF (dkt. #38) ¶ 85.) Those records indicate that a diagnosis of pediatric autoimmune neuropsychiatric disorders associated with streptococcal infections ("PANDAS") had been originally discussed as a possible cause of Torin's symptoms as early as 2012; and in 2013, PANDAS specialist, Dr. Kovacevic, diagnosed Torin with PANDAS and recommended IVIG therapy. (WPS 1578.) As a result, Torin apparently received IVIG therapy on July 5-6, 2013, and January 23-24, 2014. Then, on June 25, 2014, Torin began treatment with Dr. Bouboulis, who recommended continuing IVIG treatment. Torin received IVIG treatment again in February 2015, with his PANDAS symptoms "improve[d] but not

gone," and "[a]fter 5 weeks, all PANDAS [symptoms] return." (WPS 1578-79.) Again, following IVIG treatment on April 23-24, 2015, all Torin's "PANDAS s[ymptoms] disappear[ed] but return[ed] slowly at wk 6." (WPS 1579.) In another record from UW Health from 2011, Dr. James Conway of the Pediatrics Infectious Disease Department noted, "Please let mother know that all infectious serologies negative . . . . Also GI serology for infectious cause of [abdominal] pain negative." (WPS 1627.)

As to Kaelan, the records included treatment notes from Dr. DeMio, who wrote that he was "getting worse of[f] IVIG . . . 'extremely fatigued,' apathetic/mood & lose interest w school . . . tics . . ." (WPS 966.) Another note from Dr. DeMio stated, "tics ~gone . . . IVIG had been (now) resumed. . . . he remains w/more fatigue, malaise." (WPS 974.)

On July 27, 2017, WPS responded by approving another month of IVIG for both Hignells to avoid disruption while it continued its review of the prior authorization requests. (WPS 797, 1411.) On August 4, Dr. DeMio faxed a letter similar to the letters he sent in June summarizing Kaelan and Torin's lab results from February 2017 and March 2016.

After receiving these July 19, 2017, records from Dr. DeMio, WPS also sought yet another review from an outside health care professional. This time, WPS referred the prior authorizations requests to Dr. Maureen Peterson, Board Certified in Allergy and Immunology and in Pediatrics at the Medical Review Institute of America, Inc. ("MRIOA").[7] While plaintiffs contend that the Plan did not authorize WPS to seek a second opinion, defendant responds that it had the discretion to do so. (*See* Def.'s Resp.

[7] Plaintiffs refer to Dr. Peterson as the "Second Reviewer."

to Pls.' PFOF (dkt. #27) ¶ 72.) Dr. Peterson attempted to reach Dr. DeMio before rendering her opinion, as her report indicates that she called his office six times to schedule a conversation, but she was apparently unsuccessful. Nevertheless, upon reviewing the medical records of Torin Hignell, Dr. Petersen issued her report on August 17, 2017, opining that: (1) the medical record "does not support the stated diagnosis, of either hypogammaglobulinemia or of common variable immune deficiency, or of immunoglobulin G (IgG) subclass deficiency" as to Torin; (2) no further testing would clarify his diagnosis given his previous "extensive laboratory evaluation"; (3) Torin "more likely" had "preservation of IgG antibody production," making him "less likely to benefit from Ig therapy"; (4) the "patient has no clinical symptoms of an immunodeficiency"; (5) IVIG was "experimental/investigative/unproven" for Torin, who was "being treated for [PANDAS], not hypogammaglobulinemia" as "[a]utomimmune features is not an indication for supplemental IVIG"; (6) "[t]he evidence supporting the use of IVIG in the treatment of PANDAS is as strong as the evidence refuting [it]"; (7) "no objective criteria . . . demonstrated a clinically significant beneficial response during prior IVIG/SCIG therapy"; (8) continuation of IVIG was not medically necessary; (9) Torin had received "three times the usual replacement dose of immunoglobulins for treatment of immunodeficiency," so that "the total IgG count would take months before [the patient would be] at significant risk for infections"; and (10) "[t]he patient should immediately stop IVIG." (WPS 1673-76.) Dr. Petersen came to the same basic conclusions regarding Kaelan for the same reasons. (WPS 1012-17.)

After summarizing their files and the contradictory opinions therein, WPS's internal reviewer, Dr. Kevin Rak, also concluded that the prior authorization requests for both Hignells should be denied on August 18, 2017. (WPS 998-1001, 1660-63.) Rak noted that "if a serious underlying immune deficiency was truly present, than a greater need for medical services or antiinfectious agents (other than those routinely taken) would have arisen during the [gaps in IVIG treatment], but this is not borne out from the medical records." (WPS 1000-01, 1662-63.) As to Kaelan Hignell, Dr. Rak noted that the records indicated "IVIG may be prescribed for alternative diagnoses other than hypogammaglobulinemia," as notes about how Kaelan felt off the IVIG -- instead of infectious diseases -- and how his tics responded to the IVIG "raise concerns that immune deficiency is not the primary focus of IVIG therapy" in light of alternate diagnoses of OCD and tics. (WPS 998.) Rak reached a similar conclusion about Torin Hignell's condition.[8] (WPS 1660-62.)

Armed once more with supportive opinions supporting a denial of benefits by both an outside and internal physician, WPS again denied the prior authorization requests for IVIG on August 18, 2017, explaining that "the provided documentation does not support the stated diagnosis" and IVIG "[wa]s considered experimental/investigative/unproven for the treatment of the member's signs and symptoms." (WPS 801, 1415.) Plaintiffs and

[8] One difference between the twins was that Dr. Rak noted Torin did not see a doctor during the gap in IVIG treatment, as opposed to Kaelan's one medical visit. However, as plaintiffs point out, that distinction is mistaken as Torin did in fact see a doctor during an IVIG hiatus. (*See* WPS 251-52.)

the boys' treating physicians disagree with this conclusion, and Crista appealed the denial on September 7, 2017.

Five days later, WPS acknowledged receipt of her request for an appeal and scheduled a review for late September. On September 15, WPS provided the clinical rationale for its denial, explaining its concern that immune deficiency was not the primary focus of the IVIG therapy. In particular, WPS noted that additional medical records had been submitted on July 19, 2017 -- after the June 2017 external reviews by Dr. Imber and the unidentified neurologist had been completed -- and that this prompted a subsequent review "with the inclusion of these additional medical records." (WPS 511-12, 1105-06.) Moreover, WPS wrote that "it would be anticipated that if a serious underlying immune deficiency was truly present, then there would have been a greater need for medical services or anti-infectious agents (other than those routinely taken) during these gaps of IVIG treatment, but this is not borne out from the medical records." (WPS 512, 1106).

On September 18, 2017, WPS sent letters and provided appeals packet information to be reviewed by the grievance and appeals committee. Dr. Michael Halwig of MRIOA, specializing in allergy pediatrics, also was retained to review and issue opinions on the prior authorization requests based on the medical records and a peer-to-peer call with the boys' treating physician, Dr. DeMio. Although Dr. Halwig never treated either boy and only spoke to Dr. DeMio for four minutes, he issued opinions as to both boys on September 22, 2017, concluding that: (1) while the documentation supported the hypogammaglobulinemia diagnosis, there was no clinical evidence of a primary immunodeficiency requiring IVIG; (2) IVIG was experimental/investigative/unproven for

treatment of this IgG subclass deficiency because it was not the current immunology practice; (3) no alternative treatments should have been employed because there was no evidence of recurrent bacterial infections; (4) the prescribed dose of IVIG would not be the standard of care for a 17 year old with this diagnosis as the initial recommended dose would be 400 mg/kg, adjusted by IgG levels; (5) a vaccine challenge would not assist in diagnosing; and (6) IVIG was not medically necessary. In addition, for Torin, Dr. Halwig added that "[t]he laboratory findings are consistent with an IgG subclass deficiency with a possible IgA deficiency," and "IVIG replacement would be considered if there was an impaired response to antigenic stimulus and recurrent bacterial infections unresponsive to aggressive medical management and the failure of prophylactic antibiotics to prevent recurrent infections." (WPS 1221.)

The grievance and appeal committee upheld WPS's denials in letters dated September 29, 2017, for each boy. The letters explained that the committee had considered "all of the available information," including the full medical records, and cited to treatment records from Dr. Bouboulis and Dr. DeMio. (WPS 422, 1065.) Ultimately, WPS's committee offered two related reasons for the denial of plaintiffs' appeal. First, it determined that IVIG "is considered experimental/investigative/unproven for treatment" because "its use does not meet current immunology practice standards." (WPS 423, 1066.) The committee noted that "the provided documentation does support the laboratory finding of IgG subclass hypogammaglobulinemia, but there is no evidence of a clinically significant primary immunodeficiency." (WPS 423, 1066.) According to WPS, "current immunology practice standards require that the clinical history, physical exam, and

laboratory findings be consistent with a diagnosis of primary immunodeficiency," while the "[r]ecords that were provided did not demonstrate a clinical picture consistent with a diagnosis of primary immunodeficiency." (WPS 423-24, 1067.) As to Torin, the WPS committee further wrote "it appears that IVIG is being prescribed for the alternative diagnosis of PANDAS" and that "Dr. DeMio's clinical records from the past year seem to focus more on IVIG's impact on symptoms of tics, obsessive compulsive disorder (OCD), mood swings, irritability, anxiety, and fatigue," rather than broader immunodeficiency concerns. (WPS 1067.) Similarly, as to Kaelan, the committee noted that it appeared from treatment notes that IVIG "is being prescribed primarily for other symptoms . . . versus for the purpose of a primary immunodeficiency," such as tics. (WPS 424.) Finally, the committee explained that the use of IVIG to treat tics or PANDAS symptoms is not currently recognized as accepted medical practice and, therefore, is considered experimental/investigative/unproven. (WPS 424, 1067.) Plaintiffs do not dispute that IVIG treatment for PANDAS symptoms or tics would be experimental/investigative/unproven.

The second reason offered by the WPS appeal committee for its denial was that "IVIG is not considered medically necessary because the diagnosis of primary immunodeficiency is not established." (WPS 424, 1067.) The committee again noted that "the diagnosis requires . . . the patient's documented history within his medical records be consistent with a clinically significant immunodeficiency." (WPS 425, 1068.) The committee observed that "the medical records provided did not substantiate any recurrent bacterial infections" or "indicate any assessment of or treatment for bacterial infections."

(WPS 425, 1068.) Instead, "the provided medical documentation only referenced symptoms of headache, sore throat, muscle aches, fatigue, tics, obsessive compulsive disorder (OCD), and anxiety," but "[t]he presence of these symptoms do not warrant IVIG treatment because they are not bacterial in nature." (WPS 425, 1068.)

Disagreeing with the conclusions that IVIG was no covered by the Plan, plaintiffs filed this lawsuit to challenge WPS's final denial of their claims.

OPINION

Specifically, plaintiffs claim that WPS wrongfully denied them benefits owed under the Plan and breached its fiduciary duties, all in violation of ERISA. To remedy these claimed violations, plaintiffs seek: (1) reinstatement of benefits; (2) an injunction providing that both boys' treatment be continued without interruption; (3) removal of WPS as a fiduciary making decisions on whether IVIG treatment is medically necessary; and (4) a surcharge to prevent WPS's unjust enrichment. Defendant does not dispute the applicability of ERISA, contending instead that its actions were in line with the Act's requirements. Both parties have moved for summary judgment.

Summary judgment is appropriate if the moving party "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). Generally, the court must view all facts and draw all inferences in the light most favorable to the non-moving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Where, as here, a court is faced with cross-motions for summary judgment, it must take care to apply the proper standard to each motion. *See Hotel 71 Mezz Lender LLC v. Nat'l Ret. Fund*, 778 F.3d 593, 603 (7th Cir. 2015). Here, the

court will begin with defendant's motion, construing the evidence in the light most favorable to plaintiffs. Even under this unfavorable standard, however, defendant prevails. Necessarily, this means the court must also deny plaintiffs' motion. *Id.* ("Only if the court can say, on that sympathetic reading of the record, that no finder of fact could reasonably rule in the unsuccessful movant's favor may the court properly enter summary judgment against that movant.").

I. Standard of Review

Before turning to plaintiffs' substantive claims under ERISA, the court must first address the deferential standard of review it must apply in reviewing the decision-making by an administrator of an ERISA plan. Where an ERISA plan grants the plan administrator discretionary authority to determine eligibility for benefits, the court must review the decision under an "arbitrary and capricious" standard. *Holmstrom v. Metro. Life Ins. Co.,* 615 F.3d 758, 766 (7th Cir. 2010) (citing *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115 (1989); *Metropolitan Life Ins. Co. v. Glenn*, 554 U.S. 105, 111 (2008); *Jenkins v. Price Waterhouse Long Term Disability Plan*, 564 F.3d 856, 860-61 (7th Cir. 2009)).[9] Under this standard, the court "is not to decide whether it would reach the same decision as the administrator"; rather, the administrator's decision will be upheld as long as specific reasons for the denial are communicated to the claimant and supported by record evidence." *Raybourne v. Cigna Life Ins. Co. of New York*, 576 F.3d 444, 449 (7th Cir. 2009)

[9] This standard is also used interchangeably by the parties and the court as an "abuse of discretion" standard. *See Raybourne*, 576 F.3d at 449 (the "arbitrary-and-capricious standard . . . is synonymous with abuse of discretion" in ERISA cases).

(citing *Davis v. Unum Life Ins. Co. of Am.*, 444 F.3d 569, 576 (7th Cir. 2006); *Leger v. Tribune Co. Long Term Disability Ben. Plan*, 557 F.3d 823, 831 (7th Cir. 2009)). Even so, "[r]eview under this deferential standard is not a rubber stamp," and a court will not uphold a plan administrator's decision "when there is an absence of reasoning in the record to support it." *Holmstrom*, 615 F.3d at 766 (quoting *Hackett v. Xerox Corp. Long-Term Disability Income Plan*, 315 F.3d 771, 774-75 (7th Cir. 2003)).

Moreover, "[a]n administrator's conflict of interest is a key consideration under this deferential standard." *Id.* Such a conflict exists where an administrator "both determines whether an employee is eligible for benefits *and* pays benefits out of its own pocket." *Glenn*, 554 U.S. at 108 (emphasis added). In such a case, "a reviewing court should consider that conflict as a factor in determining whether the plan administrator has abused its discretion in denying benefits." *Id.*; *see also Jenkins*, 564 F.3d at 861-62 ("When the case is borderline . . . the inherent conflict of interest . . . can push it over the edge -- towards a finding of capriciousness.").

Here, the parties agree that the Plan granted WPS discretionary authority to determine benefits allocations, meaning an arbitrary and capricious standard applies. (*See* Pls.' Br. (dkt. #17) 14; Def.'s Br. (dkt. #22) 14; WPS 1974.) What's more, both parties acknowledge that WPS had a conflict of interest insofar as it bore the responsibility to determine the Hignells' eligibility for the requested benefits fairly *and* the obligation to pay for any approved benefits. (*See* Def.'s Resp. to Pls.' PFOF (dkt. #27) ¶ 96.) Accordingly, the court will review WPS's decision to deny plaintiffs' prior authorization requests under

the arbitrary and capricious standard, while considering its obvious conflict of interest as a factor.

II. Wrongful Denial of Benefits

ERISA § 502(a)(1)(B) authorizes a participant or beneficiary to bring a civil action "to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan." ERISA § 502(a)(1)(B) (codified at 29 U.S.C. § 1102(a)(1)(B)). According to plaintiffs, WPS's determination that IVIG treatment for the Hignell twins fell outside a covered benefit under the Plan was arbitrary and capricious. Generally, WPS contends that it "completed a thorough, carefully documented, and fully articulated decision that was in no way influenced by the cost of IVIG treatment." (Def.'s Opp'n (dkt. #26) 5-11.) According to WPS, its decision rested on its findings that the IVIG treatment was "experimental/investigative/unproven" and not medically necessary because it was prescribed primarily to treat PANDAS or other symptoms, not to treat hypogammaglobulinemia as was its intended use.

As noted above, while hypogammaglobulinemia is an FDA-approved indication for IVIG treatment, there is no dispute that IVIG treatment for PANDAS symptoms or tics would be experimental/investigative/unproven, and as such, not covered under the Plan. Plaintiffs, however, contend that: (1) a diagnosis of hypogammaglobulinemia *had* been established; (2) IVIG was medically necessary and not experimental/investigative/unproven for this diagnosis; and (3) PANDAS is nothing more than "a red herring." (Pls.' Br. (dkt. #17) 20.)

At the outset, the court acknowledges that the medical record in this case is a mixed bag. Certainly, there is evidence that supports plaintiffs' position, including the opinions of the boys' two treating physicians, as well as those of Dr. Imber, an internist with specialties in allergy and immunology, and the unidentified neurologist, both of whom were outside experts with AMR retained by WPS. However, there is also evidence supporting WPS's decision, including the opinions from Drs. Liu, Ostrov, Rak, and Davidson in 2016, and Drs. Peterson, Rak, and Halwig in 2017, with Drs. Liu and Davison outside specialists in outside specialists in immunology pediatrics at AllMed and Drs. Peterson and Halwig outside specialists in immunology pediatrics at MRIOA. Moreover, Drs. Peterson, Rak, and Halwig were the only medical reviewers who had the benefit of the boys' full, pre-2015 medical records, something Dr. Imber and the neurologist did not have available in forming their opinions. In the discussion that follows, this court considers plaintiffs' various arguments regarding the alleged capriciousness of WPS's denial. As discussed below, the court is troubled by some of WPS's actions during its multi-year review process, but concludes that even factoring in WPS's profit motive under the deferential standard of review, WPS's decision must be upheld because of the ultimate review of all available medical records by MRIOA's two, outside specialists, and particularly the detailed findings in Dr. Peterson's reports.

A. Pre-2015 Medical Records

To begin, the parties' dispute regarding the boys' earliest medical records must be addressed as it affects the court's consideration of the rest of the evidence. As indicated in the summary of facts above, the parties dispute when WPS requested what records, as well

as the timing of the actual production of those records. Specifically, WPS asserts that as early as January 14, 2016, it requested all office notes and laboratory reports from January 1, 2013, to December 31, 2014. To support this assertion, WPS points to records summarizing two phone calls from its consultant. The first note refers to a call with "Jill (mbr. mom)," during which the consultant "let her know that MD office was contacted for request for documentation." (WPS 147, 352.) The second note concerns a call to Superior Associates, which appears to be the boys' doctors' office, during which the WPS consultant left a voicemail requesting "all documentation for 2 years be sent including all office notes and laboratory reports for the past 2 years ending Jan 2015&to include pretreatment assessment." (WPS 147, 352.) In turn, plaintiffs object that these records do "not establish or substantiate any requests actually communicated to either Plaintiff Crista or Dr. Bouboulis," and they further aver that the "lack of any physical or paper communication to either Plaintiffs or their treatment physicians is noteworthy and calls the veracity of these notes into question." (Pls.' Resp. to Def.'s PFOF (dkt. #38) ¶ 27.)

While plaintiffs' purported dispute regarding this request for older records is rather weak, viewing the evidence in the light most favorable to them, the court will assume for purposes of summary judgment that WPS did not request the boys' pre-2015 medical records in 2016. However, there is no dispute that WPS requested these records in 2017, including: (1) on April 26, 2017, when WPS sent letters to Dr. Bouboulis asking in part for medical records from the past four years, and explaining that the records were necessary to render an appropriate clinical determination; (2) on June 7, 2017, when PA Navigator Pharmacy Services requested (among other things) on behalf of WPS, the boys' previous

therapeutic history; and (3) on July 14, 2017, when WPS asked for all medical records beginning in 2012, explaining that the records were required to make a determination as to the medical necessity of IVIG.

There is also no reasonable dispute that on July 19, 2017, Dr. DeMio sent several faxes to WPS containing a number of previously unproduced medical records for the Hignell twins. While plaintiffs purport to dispute this fact -- pointing out that *some* of the records produced by Dr. DeMio had been previously provided -- WPS maintains that many, *other* records were newly produced. In particular, WPS notes that the records produced in July of 2017 included: (1) records indicating a possible diagnosis of PANDAS for both boys and related symptoms, including OCD and tics; (2) a note from PANDAS specialist Dr. Kovacevic diagnosing Torin with PANDAS and recommending IVIG therapy; and (3) notes indicating that after Torin received IVIG treatment his PANDAS symptoms improved but were not gone, and those symptoms returned after 5-6 weeks. Since plaintiffs fail to identify *any* portion of the administrative record suggesting that these records in particular *were* provided earlier, the court will accept WPS's evidence as establishing that records related to the boys' PANDAS symptoms were produced for the first time in July of 2017.

In fairness, plaintiffs also dispute the relevance of these older records, suggesting that WPS's request for and consideration of these records was unreasonable. Specifically, plaintiffs argue that "[n]othing in [Dr. Imber's or the neurologist's] independent review indicated that more documentation was necessary or that [their] report suggested it was anything other than 'final.'" (Pls.' Br. (dkt. #17) 21.) Instead, plaintiffs characterize

WPS's request for the historical medical records as a search for "any justification to deny the claim." (Pls.' Br. (dkt. #17) 17-18.) On the other hand, defendants contend that these records were "quite material," since "they showed that the IVIG therapy was being used to treat PANDAS, not hypogammaglobulinemia, as was stated in the prior authorization requests for IVIG." (Def.'s Opp'n (dkt. #26) 5.) Additionally, it must be noted that WPS's request for historical records was made *prior* to Dr. Imber and the neurologist's review -- there is no dispute that in April of 2017, WPS requested the past four years of the boys' medical records.

Certainly, a claimant's medical history has been found to be relevant in considering denials of ERISA benefits. *See Holmstrom*, 615 F.3d at 773 ("Holmstrom's overall objective medical history is also highly relevant."); *Diaz v. Prudential Ins. Co. of Am.*, 499 F.3d 640, 646 (7th Cir. 2007) (finding claimant's history of treatment relevant to his claim for benefits). Moreover, the undisputed evidence suggests that contemporaneous immunology practice standards required a patient's *clinical history*, as well as his laboratory findings, to be consistent with a diagnosis of primary immunodeficiency to support IVIG treatment. Thus, given the specific facts of this case, the boys' historical medical records were plainly relevant to WPS's determination, whatever its underlying motives may have been.

That said, the court, like plaintiffs, is somewhat suspicious of the fact that WPS apparently felt it had sufficient information in 2015 and 2016 to render a decision, but in 2017 determined that additional historical information was required. Moreover, neither Dr. Imber nor the neurologist suggested in their opinions that any additional records would be required to arrive at an appropriate diagnosis. Still, the Seventh Circuit has cautioned

that a plan administrator is "entitled to seek and consider new information and, in appropriate cases, to change its mind." *Geiger v. Aetna Life Ins. Co.*, 845 F.3d 357, 363-64 (7th Cir. 2017) (quoting *Holmstrom*, 615 F.3d at 767). And WPS, perhaps fairly, insists that its leniency towards plaintiffs in 2015 and 2016 should not be held against it. Thus, while the court looks at WPS's middle-of-the-game request with a skeptical eye, that WPS asked for older medical records (or considered them once they were produced) does not, standing alone, render WPS's decision unreasonable, particularly given the conflicting views of medical experts from the very beginning of plaintiffs' prior authorization requests in 2016.

B. Competing Opinions and Cherry-Picking Evidence

The Seventh Circuit has said that one "hallmark of an arbitrary and capricious decision" is the rejection of evidence "based on selective readings that are not reasonably consistent with the entire picture." *Holmstrom*, 615 F.3d at 777. In other words, a plan administrator cannot cherry-pick evidence that supports its decision while ignoring contrary evidence. *See Leger*, 557 F.3d at 832-33. Still, where there is a "contest of competing medical opinions," a court cannot second-guess the plan administrator's choice between opinions so long as that choice is rationally supported by record evidence. *See Black v. Long Term Disability Ins.*, 582 F.3d 738, 745-46 (7th Cir. 2009) (in "a contest of competing medical opinions, . . . under our deferential standard of review, we must defer to [the plan administrator's] choice between competing medical opinions so long as it is rationally supported by record evidence"); *Davis*, 444 F.3d at 578 ("[R]eaching a decision amid . . . conflicting medical evidence is a question of judgment that should be left to [the

plan administrator] under the arbitrary-and-capricious standard."); *Semien v. Life Ins. Co. of N. Am.*, 436 F.3d 805, 812 (7th Cir. 2006) (while plaintiff's treating physicians reached different conclusions as to her abilities than the physicians hired by plan administrator, "under an arbitrary and capricious review, neither this Court, nor the district court, will attempt to make a determination between competing expert opinions").

Plaintiffs argue that WPS "impermissibly ignored the conclusions of the [twins'] treating physicians and of the two independent reviewers from AMR that treatment was medically necessary" -- "cherry-picking" which reviewers' conclusions to adopt, while ignoring the rest. (Pls.' Br. (dkt. #17) 18, 23.) As plaintiffs point out, the Hignells' treating physicians -- Drs. Bouboulis and DeMio -- both consistently stood by their conclusions that the boys suffered from hypogammaglobulinemia and that IVIG treatment was medically necessary. In 2017, WPS's designated reviewer, Dr. Imber, himself an internist with relevant specialization in allergy and immunology with AMR, also found that Kaelan's diagnosis of a primary immune deficiency was "clear" (WPS 1006), and its other MRIOA reviewer, an unidentified neurologist, arrived at a similar finding for Torin (WPS 1668). As a result, both Dr. Imber and the neurologist concluded that continuation of IVIG treatment was medically necessary as well.

At the same time, other physicians had come to contrary conclusions both before and after the MRIOA reviewers. Specifically, in 2016, Dr. Liu -- also an outside reviewer hired by WPS -- determined as to Kaelan that a hypogammaglobulinemia diagnosis was "not likely" and found that IVIG was "experimental / investigational and unproven." While Dr. Liu revised her opinion after a phone call with Dr. Bouboulis, she changed her

opinion *back* after receiving the actual historic lab results for both boys, explaining in her final opinion that: (1) information provided by Dr. Bouboulis was not supported by the written documentation; (2) Kaelan's laboratory data did not support a diagnosis of immune deficiency; and (3) IVIG was experimental/investigational and not medically necessary. Also in 2016, WPS physicians, Drs. Ostrov and Rak, concluded that a diagnosis of hypogammaglobulinemia was not supported -- in part because the lab values were not entirely consistent with such a diagnosis -- and both recommended denying the IVIG requests. Another outside reviewer, Dr. Davidson, likewise concluded in 2016 that: (1) hypogammaglobulinemia diagnoses were not supported, finding neither quantitative nor qualitative deficits in the boys' lab values; and (2) IVIG therapy was "not supported at this time." (WPS 371-72.)

Additionally, in 2017, Dr. Peterson, a specialist in immunology pediatrics at MRIOA, opined that the medical record did not support hypogammaglobulinemia diagnoses or other common, variable immune deficiencies, making IVIG treatment both experimental/investigative/unproven and not medically necessary. After WPS physician Dr. Rak affirmed Dr. Peterson's conclusions, a final opinion was rendered by another MRIOA allergy pediatric specialist, external reviewer Dr. Halwig, acknowledged that the documentation supported a *laboratory* finding of hypogammaglobulinemia, but that there was no *clinical* evidence of a primary immunodeficiency, and thus that IVIG was experimental/investigative/unproven and not medically necessary. (WPS 422-25, 1065-68.)

Thus, the record contains mixed opinions from a variety of qualified physicians from the beginning of WPS's review of plaintiffs' authorization requests. Ideally, WPS should have at least sought further input from Dr. Imber and the neurologist as to whether the newly-produced information from Dr. DeMio in July of 2017 would have changed their opinions, instead of immediately seeking another outside expert's opinion. Moreover, WPS's own monetary incentive to deny treatment makes its actions smell of "opinion shopping." Nevertheless, the court cannot ignore the fact that WPS sought out two eminently qualified experts in the relevant field of allergy pediatrics to take a fresh look at all the medical records, nor that both doctors, after having the opportunity to examine the full medical record concluded that IVIG was *not* medically necessary. Further, arguably the *most* appropriate remedy to resolve such a muddied record as the one before WPS would be to submit the evidence to a qualified, neutral decisionmaker. Were there a basis to question the integrity of Dr. Peterson or her report, the court's deference would be substantially less, but there is not on this record. Far from it, Dr. Peterson appears eminently qualified to undertake this review, and her reports are the most thorough and persuasive of those presented to the court. Plus, even after its initial denial, WPS submitted the question to Dr. Halwig for a final review and determination. Although, again, WPS's flip-flopping and motives raise significant questions, and another course of action could have been taken, WPS's ultimate decision to give greater weight to the outside medical experts from MRIOA who concluded that IVIG was not medically necessary does not support a finding of capriciousness.

C. Treating Physicians

Relatedly, plaintiffs fault WPS for not giving greater credit to the opinions from Drs. Bouboulis and DeMio, the boys two treating physicians. While plan administrators generally "may not arbitrarily refuse to credit a claimant's reliable evidence, including the opinions of a treating physician," the Supreme Court has held that ERISA does not require plan administrators to give special consideration to the opinions of treating physicians. *Black & Decker Disability Plan*, 538 U.S. at 834; *see also Love v. Nat'l City Corp. Welfare Benefits Plan*, 574 F.3d 392, 397-98 (7th Cir. 2009) ("While plan administrators do not owe any special deference to the opinions of treating physicians, they may not simply ignore their medical conclusions or dismiss those conclusions without explanation.") (internal citation omitted).[10]

Here, WPS generally explained that it considered "all of the available information," including references to a number of treatment notes from the two treating physicians in the final denial letter. Additionally, both WPS and its external doctors made efforts to include both treating physicians in the determination. For example, WPS explained that the boys' medical provider could participate at the appeals meetings in 2016 and 2017, although Dr. Bouboulis only attended the 2016 meeting and Dr. DeMio did not attend

[10] Plaintiffs also emphasize that Drs. Bouboulis and DeMio were the only ones who personally examined the boys, pointing to cases where courts have criticized plan administrators for rejecting conclusions reached by every doctor that personally examined the claimant and accepting only opinions based on paper records. *See Love*, 574 F.3d at 397; *Holmstrom*, 615 F.3d at 775; *Clark v. Cuna Mut. Long Term Disability Plan*, 2016 WL 1060344, *28 (W.D. Wis. Mar. 15, 2016). In the cases cited by plaintiffs with respect to the need for a personal exam, however, the issue was the claimant's functional ability to engage in full-time work -- a determination that could be better understood or ascertained via physical examination. *See Love*, 574 F.3d at 397; *Holmstrom*, 615 F.3d at 775; *Clark*, 2016 WL 1060344, *28. Here, by contrast, plaintiffs do not explain how such an examination would provide unique insight into the boys' condition.

either meeting. Additionally, among other things, Dr. Halwig called Dr. DeMio's office and spoke with him (albeit only for four minutes) before rendering his ultimate review, and Dr. Peterson called Dr. DeMio's office six times, although was not able to successfully connect with him. (WPS 1011.)

Still, plaintiffs' general argument has some force as WPS does not appear -- at least expressly -- to have given significant consideration to the opinions of Drs. Bouboulis and DeMio in its final denials. Arguably, WPS did not need to address specifically these opinions as it presented a full explanation as to why it concluded they were *not* adequately supported by the medical record, but the court considers WPS's lack of express consideration of the boys' treating physicians' opinions in its denials as a factor cutting against granting its motion for summary judgment. That said, the court also observes that there are internal inconsistencies within Drs. Bouboulis's and DeMio's own records. Although in 2016 and 2017, both physicians stood by their diagnoses of hypogammaglobulinemia, their *own records* from 2015 suggest that IVIG treatment was being used to treat PANDAS or OCD symptoms, including tics. This inconsistency came up again in 2016, when Dr. Liu noted that Dr. Bouboulis had given her "conflicting information on the peer-to-peer call that was not supported by the written documentation." (WPS 168.)

D. Physician Specializations

Plaintiffs also argue that WPS's consideration of the opinions of Dr. Rak was an abuse of discretion as the Wisconsin licensing website shows that he specialized in radiology, and was not an immunologist, allergist, or other specialist in a field familiar with

autoimmune diagnoses. (*See* Pls.' Reply (dkt. #30) 4. n.4.) Certainly, a reviewer's medical specialty may be relevant to a plan administrator's determination of benefits, but there are a number of problems with plaintiffs' position. First, to establish Dr. Rak's specialty, plaintiffs are inappropriately introducing evidence outside of the administrative record. *See Krolnik v. Prudential Ins. Co. of Am.*, 570 F.3d 841, 843 (7th Cir. 2009) ("When review is deferential -- when the plan's decision must be sustained unless arbitrary and capricious -- then review is limited to the administrative record.") (emphasis omitted). Second, as defendant points out, if external evidence may be submitted to prove specialties, and if only physicians with a specialty in autoimmune disorders are qualified to offer an opinion, then one of plaintiffs' treating physicians, Dr. DeMio, would not be qualified, as he has an emergency medicine specialty. (*See* Def.'s Reply to Pls.' Resp. to Def.'s PFOF (dkt. #38) ¶ 99.) Finally, Drs. Liu, Davidson, Peterson, and Halwig were all board certified in allergy and immunology, with further special expertise in pediatrics, and all rendered opinions consistent with that of Dr. Rak. Overall, it would seem that plaintiffs' argument regarding specializations hurts rather than helps them, certainly does not support a finding that WPS's decision was arbitrary and capricious.

E. Previous Grant of Benefits

Plaintiffs also criticize WPS for its "course-reversal," having granted plaintiffs' prior authorization requests in 2015 and 2016 and for a month in 2017, but ultimately denying them in August of 2017. Under Seventh Circuit case law, the previous payment of benefits has been held to be a circumstance or factor to be considered in the court's review process, but it does not create a presumptive burden for the plan to overcome. *Leger,* 557 F.3d at

832. Rather, a "plan administrator is entitled to seek and consider new information and, in appropriate cases, to change its mind." *Holmstrom*, 615 at 767.

In this case, WPS had conflicting medical evidence and questions from at least 2016. Plus, additional historical medical records from plaintiffs' doctor in July of 2017 provided a legitimate basis for WPS to request further outside reviews by Drs. Peterson and Halwig, both board certified in allergy pediatrics, and both of whom concluded that IVIG treatment was experimental/investigative/unproven and not medically necessary given the boys most likely diagnosis. It should also be noted that the 2017 reversal was not out of the blue, since Drs. Liu, Ostrov, Rak, and Davidson had previously come to similar conclusions in 2016, and WPS had initially denied prior authorization requests, only approving them on appeal. Accordingly, WPS's previous grant of benefits cuts neither for nor against either party.

F. Moving Target

The Seventh Circuit has held that "[a]n ERISA benefit cannot be a moving target where the plan administrator continues to add conditions precedent to the award of benefits." *Dabertin v. HCR Manor Care, Inc.*, 373 F.3d 822, 831 (7th Cir. 2004). In *Dabertin*, a plan administrator's denial of benefits was found to be unlawful because, *inter alia*, the administrator imposed three additional qualifications that did not exist in the plain language of the plan. *Id.* at 831. Similarly, in *Holmstrom*, MetLife (a plan administrator) was held to have acted arbitrarily and capriciously in part because it:

> invited additional evidence to establish disability, but when Holmstrom provided it, MetLife repeatedly found that the new

> evidence was not sufficient under new standards or expectations that had not been communicated to Holmstrom.

Holmstrom, 615 F.3d at 775-76.

According to plaintiffs, "WPS concedes that the [hypogammaglobulinemia] diagnosis is supported, but decided to deny the benefits anyway, because -- referencing a standard for the first time -- that diagnosis may not be a 'clinically significant *primary* immunodeficiency.'" (Pls.' Br. (dkt. #17) 23 (emphasis in original).) It is not clear to this court, nor do plaintiffs explain, how a hypogammaglobulinemia diagnosis differs from a diagnosis of a clinically significant primary immunodeficiency. Regardless, WPS did *not* concede that a hypogammaglobulinemia diagnosis had been established; rather, WPS's final denials noted that, consistent with Drs. Peterson's and Halwig's findings, while "the provided documentation does support the laboratory finding of IgG subclass hypogammaglobulinemia," immunology practice standards require a patient's laboratory findings *and* clinical history to be consistent with a diagnosis of a primary immunodeficiency. (WPS 423, 1066.)

Moreover, WPS's requests for medical records not previously required in 2015 and 2016 were consistent and clearly communicated in advance of the denial. In particular, beginning in early 2017, WPS consistently sought additional documentation:

- On April 26, 2017, letters to Dr. Bouboulis, WPS requested medical records from the past four years.
- In a letter on June 7, 2017, PA Navigator Pharmacy Services (on behalf of WPS) wrote to plaintiffs, explaining that "[c]overage of GAMMAGARD INJ 5GM/50ML requires review of progress notes detailing diagnosis, previous therapeutic history,

concurrent medications, and treatment and monitoring plan. We did not receive the above mentioned information." (WPS 788-89, 1402-03.)

- On June 13, 2017, WPS denied the prior authorizations and stated that "[c]ontinued coverage of IVIG requires review of progress notes detailing diagnosis, previous therapeutic history, concurrent medications, and treatment and monitoring plan" which were "requested from [their] provider, but not received." (WPS 789, 1403.)
- On June 28, 2017, WPS approved IVIG therapy for both boys for one month, but added that "future authorizations are not necessarily guaranteed and will be based on your physician submitting appropriate clinical information along with the request." (WPS 794, 1408.)

Finally, when the records *were* provided, WPS ultimately determined that they were not supportive of a hypogammaglobulinemia diagnosis, explaining in part that "it would be anticipated that if a serious underlying immune deficiency was truly present, then there would have been a greater need for medical services or anti-infectious agents (other than those routinely taken) during these gaps of IVIG treatment, but this is not borne out from the medical records." (WPS 512, 1106). Requesting historical medical documents, then considering those documents in rendering an ultimate result, cannot reasonably be considered "moving the target," and so the court does not find capriciousness on this basis.

G. Conclusion

Overall, although the court looks at WPS's motives in this case with some skepticism, and considering the evidence as a whole, a different decision could have been justified under the circumstances, this court's inquiry is more limited as a matter of law. *See Hess v. Reg-Ellen Mach. Tool Corp.*, 423 F.3d 653, 658 (7th Cir. 2005) ("[W]e will not set aside a denial of benefits based on any reasonable interpretation of the plan . . . . Indeed, whether or not we would have reached the same conclusion is irrelevant.") (internal citations omitted). The inquiry is whether WPS's decision was arbitrary and capricious. Here, the undisputed evidence suggests that it was not. Accordingly, summary judgment will be granted in defendant's favor as to this claim.

III. Breach of Fiduciary Duties

In addition to alleging wrongful denial of benefits, plaintiffs also contend that WPS was a fiduciary to the Plan yet breached its fiduciary duties of loyalty and prudence when it "looked for any reason to deny coverage" and by not following the Plan terms. (Pls.' Br. (dkt. #17) 13-17.) Defendant contends generally that a breach of fiduciary action is not appropriate as a matter of law because it is duplicative of plaintiffs' wrongful denial of benefits claim. (Def.'s Br. (dkt. #22) 21.)

To understand the parties' arguments, a review of the structure of ERISA is helpful. Section 402 (codified at 29 U.S.C. § 1102) requires every ERISA plan to provide for one or more named fiduciaries who have the authority to control and manage the operation and administration of the plan. Here, there is no dispute that WPS is a fiduciary to the Plan at issue. In turn, § 404 (codified at 29 U.S.C. § 1104) defines the duties of those

fiduciaries, and provides that the fiduciary "shall discharge his duties with respect to the plan solely in the interests of the participants and beneficiaries." ERISA § 404(a)(1) (codified at 29 U.S.C. § 1104(a)(1)). It also requires the fiduciary to act "in accordance with the documents and instruments governing the plan insofar as such documents and instruments are consistent with the provisions of this subchapter and subchapter III." ERISA § 404(a)(1)(D) (codified at 29 U.S.C. § 1104(a)(1)(D)).

Finally, ERISA § 502 "identifies who is entitled to bring a civil action to enforce the prescriptions of the statute and what relief may be obtained." *Smith v. Med. Benefit Administrators Grp., Inc.,* 639 F.3d 277, 282 (7th Cir. 2011) (citing ERISA § 502, codified at 29 U.S.C. § 1132). This section provides in relevant part that:

> A civil action may be brought --
> (1) by a participant or beneficiary --
> . . .
> (B) to recover benefits due to him under the terms of his plan, to enforce his rights under the terms of the plan, or to clarify his rights to future benefits under the terms of the plan;
> . . .
> (3) by a participant, beneficiary, or fiduciary (A) to enjoin any act or practice which violates any provision of this subchapter or the terms of the plan, or (B) to obtain other appropriate equitable relief (i) to redress such violations or (ii) to enforce any provisions of this subchapter or the terms of the plan.
> . . .

ERISA § 502(a) (codified at 29 U.S.C. § 1132(a)). In addition to bringing a wrongful denial of benefits claim under § 502(a)(1)(B), plaintiffs here also seek relief under §

502(a)(3) for alleged violations of WPS's fiduciary duties.[11] As the Seventh Circuit has explained, § 502(a)(3) "permits a participant to obtain relief for a breach of fiduciary duty on behalf of himself as opposed to the plan." *Smith*, 639 F.3d at 283.

As noted above, defendant argues that this court should dismiss plaintiffs' breach of fiduciary duty claims as duplicative, but case law does not appear to support the proposition that a wrongful denial of benefits can *never* be brought under both § 502(a)(1)(B) and § 502(a)(3). While not directly on point, the U.S. Supreme Court in *Varity Corp. v. Howe*, 516 U.S. 489 (1996), held that an individual could bring a breach of fiduciary claim on behalf of himself through § 502(a)(3), and in doing so, addressed concerns regarding a beneficiary's potential ability to "repackage his or her 'denial or benefits' claims as a 'breach of fiduciary duty.'" *Id.* at 513. The Court explained that "characterizing a denial of benefits as a breach of fiduciary duty does not necessarily change the standard a court would apply when reviewing the administrator's decision to deny benefits." 516 U.S. at 514. The Court also went on to note that § 502(a)(3) authorizes only "appropriate" equitable relief. *Id.* at 515 ("we should expect that where Congress elsewhere provided adequate relief for a beneficiary's injury, there will likely be no need for further equitable relief, in which case such relief normally would not be 'appropriate'").

[11] The court does not understand plaintiffs to be asserting a claim under § 502(a)(2), as they cite only to §§ 502(a)(1)(B) and 502(a)(3) in their amended complaint and briefing. Regardless, as defendant points out, a § 502(a)(2) claim would not be available as the Supreme Court held in *Massachusetts Mutual Life Insurance Co. v. Russell*, 473 U.S. 134 (1985), that that subsection was available only to seek recovery on behalf of the entire plan, rather than recovery for an individual injury. *Id.* at 144, 154.

Thus, the Court contemplated that a beneficiary could bring concurrent § 502(a)(1)(B) and § 502(a)(3) claims, while still noting the limitations of such a strategy.

This question was more directly examined by the Sixth Circuit in *Rochow v. Life Insurance Co. of North America*, 780 F.3d 364 (6th Cir. 2015), which held that:

> A claimant can pursue a breach-of-fiduciary-duty claim under § 502(a)(3), irrespective of the degree of success obtained on a claim for recovery of benefits under § 502(a)(1)(B), only where the breach of fiduciary duty claim is based on an injury separate and distinct from the denial of benefits or where the remedy afforded by Congress under § 502(a)(1)(B) is otherwise shown to be inadequate.

Id. at 372. While this issue does not appear to have been addressed in detail by the Seventh Circuit, in *Sumpter v. Metro. Life Ins. Co.*, 683 F. App'x 519, 521 (7th Cir. 2017) (unpublished), the court stated that "a denial of benefits, *without more*, does not constitute a breach of fiduciary duty that can be remedied under the equitable-relief provision; that's what section 1132(a)(1)(B) is for." *Id.* at 521 (emphasis added). This appears largely consistent with *Rochow*. Thus, case law suggests that a plaintiff can pursue both a § 502(a)(3) and a § 502(a)(1)(B) if she shows, for example, that the remedy under § 502(a)(1)(B) is inadequate.

Here, plaintiffs seek not only a reinstatement of benefits (a remedy available under § 502(a)(1)(B)) but also (1) an injunction ordering that both boys' IVIG treatment be continued without interruption; (2) removal of WPS as a fiduciary making decisions on whether IVIG treatment is medically necessary; and (3) a surcharge to prevent WPS's unjust enrichment. As such, a legal remedy under § 502(a)(1)(B) would not be adequate to make them whole, and additional relief under § 502(a)(3) may be appropriate. At least

as a matter of law, therefore, plaintiffs' fiduciary duty claims do not appear to be completely duplicative of their wrongful denial of benefits claim and will not be dismissed outright on that ground. However, this is a pyrrhic victory for plaintiffs here, since their fiduciary duty claims fail on the merits.

Plaintiffs allege that WPS violated its fiduciary duties in two ways, but as to both claims plaintiffs fail to show that WPS acted contrary to its duties under ERISA for reasons largely already addressed. *First*, plaintiffs argue that WPS failed to act in accordance with its duties of loyalty and prudence when it denied plaintiffs' 2017 preauthorization requests for IVIG treatment. Specifically, they contend that WPS elevated "its own financial interests above either boy's health to deny coverage that it was obligated to provide under the Plan" and that it actively looked "for any reason to deny coverage." (Pls.' Br. (dkt. #17) 16.) But this argument fails to recognize that a plan administrator's fiduciary duties include "the need to preserve assets to satisfy future, as well as present, claims and requires a trustee to take impartial account of the interests of all beneficiaries." *Varity Corp.*, 516 U.S. at 514. Here, WPS owed fiduciary obligations to *all* beneficiaries under the Plan, not just to plaintiffs. Other than pointing out WPS's obvious financial conflict, plaintiffs' argument is simply that IVIG treatment was a covered benefit under the Plan, but as discussed above, WPS reasonably determined that it was not. Indeed, once arriving at that determination, WPS's fiduciary duties arguably *required* it to deny plaintiffs' coverage given its obligation to preserve the Plan's assets. Considered in this way, plaintiffs' first breach of fiduciary duty claim fails, and the undisputed evidence compels judgment in favor of defendant.

Second, plaintiffs argue that WPS breached its fiduciary duty to follow the terms of the Plan. As noted above, ERISA § 404(a)(1)(D) requires a fiduciary to act "in accordance with the documents and instruments governing the plan insofar as such documents and instruments are consistent with the provisions of this subchapter and subchapter III." ERISA § 404(a)(1)(D) (codified at 29 U.S.C. § 1104(a)(1)(D)). Plaintiffs claim that: (1) under the Plan, an external reviewer's decision on medical necessity is binding on WPS; (2) Dr. Imber's and the neurologist's reviews concluding that IVIG was medically necessary were binding; and (3) contrary to the Plan terms, WPS sought additional and contradictory external reviews from Drs. Peterson and Halwig. To support the proposition that an external reviewer's decision is binding in particular, plaintiffs initially cite to Section 13 of the Plan. However, as defendant points out, that section is only invoked if the beneficiary submits in writing a specific request for independent external review, after which a specific sequence of events is set in motion. Only then is the independent review organization's decision binding on the beneficiary and WPS. Here, plaintiffs have produced no evidence that they invoked Section 13 or that Dr. Imber's or the neurologist's review were provided under that section of the Plan.

Apparently recognizing this, plaintiffs argue in their reply brief that WPS's actions violated a different section of the Plan, Section 11.E, which provides that if a decision to deny coverage is based on medical necessity or because treatment is experimental, investigational, or unproven, then the denial "will include an explanation of the scientific or clinical judgment for the determination applying the terms of the Policy to your medical circumstances." (WPS 1963.) Plaintiffs then go on to argue that "[s]uch explanations

would obviously include why WPS chose to drop the First Reviewers after receiving their adverse clinical judgment that IVIG treatment was medically necessary and sought out a different reviewer at a different company. WPS provides none, however, except to say that the First Reviewers did not have the pre-2014 medical records." (Pls.' Reply (dkt. #30) 8.) But plaintiffs themselves supply the explanation: WPS sought an additional review because new information had been provided after plaintiffs submitted the older medical records. Because WPS continued to question coverage in light of conflicting medical opinions from the outset of plaintiffs' prior authorization requests and this additional information supplied reasonable grounds to seek an additional outside review, the court is persuaded that WPS followed the terms of the Plan. Thus, the undisputed facts establish that plaintiffs' second fiduciary duty claim fails and again compel judgment in favor of defendant.

ORDER

IT IS ORDERED that:

1) Plaintiffs' motion for summary judgment (dkt. #16) is DENIED.
2) Defendant's motion for summary judgment (dkt. #21) is GRANTED.
3) Plaintiffs' motion to strike (dkt. #28) is GRANTED.

Entered this 10th day of August, 2021.

BY THE COURT:

/s/

_____
WILLIAM M. CONLEY
District Judge