UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION at LEXINGTON

CIVIL ACTION NO. 13-cv-241-KKC

JOHN EVERETT WILLIAMS and
MICHELLE JOSIE WILLIAMS PLAINTIFFS

v. **OPINION & ORDER**

AETNA LIFE INSURANCE COMPANY DEFENDANT

* * * * * * * * * * * *

In this civil action, the plaintiffs, John Everett Williams and Michelle Josie Williams (collectively "the Plaintiffs"), appeal the refusal of the defendant, Aetna Life Insurance Company ("Aetna"), to pay medical benefits allegedly due under an employee benefits plan governed by the Employee Retirement Income System Act of 1974 ("ERISA"), 29 U.S.C. §1001 *et seq*. In compliance with the Court's Scheduling Orders [DE #23, 29, 31, 48], the parties have submitted their Joint Report regarding the appropriate standard of review [DE #27], their cross motions for judgment [DE #50, 52], and their responses [DE #53, 54]. Also pending before the Court is Aetna's unopposed motion to supplement the administrative record [DE #49].

I. FACTUAL BACKGROUND AND THE ADMINISTRATIVE PROCESS

After a premature birth, the plaintiff Michelle Williams ("Williams") spent over nine months in the neonatal intensive care unit. Once released, she remained on a ventilator until about 20 months of age. She subsequently developed problems from the respiratory syncytial virus, or RSV, at age two. Currently, Williams is twenty-four years old and continues to suffer from a variety of

medical conditions, including selective antibody deficiency, also know as selective immunodeficiency [AR 354, 368, 965, 1352, 1412]. This condition prevents her immune system from making antibodies appropriately [AR 305]. As a result, she has been treated with intravenous immunoglobulin or "IVIG" therapy [AR 262-63, 357-58, 969, 1046-47, 1647]. IVIG therapy is given intravenously every 3 to 4 weeks, takes about 3 hours, and costs over $5,000 per infusion [AR 968, 1557]. Williams has a central veinous access device which her physicians use to infuse the IVIG into her body [AR 968]. Without IVIG therapy, the Plaintiffs allege that Williams will suffer chronic respiratory infections, including pneumococcus or bronchiectasis, the former of which can kill a person within 6 hours, the latter of which leads to continued lung deterioration and death generally 20 years or so younger than the anticipated life span of the individual [AR 312, 355].

In March 2009, the Plaintiffs made a claim for Williams' IVIG treatment with the National Rural Electric Cooperative Association ("NRECA")[AR 354, 368, 1302]. At that time, the Plaintiffs had medical coverage under the NRECA through its self-funded Group Benefits Program based on John Williams' employment [AR 1360]. That claim was denied on July 23, 2009 and again on December 16, 2009[AR 1362]. According to the Plaintiffs, this denial was based on the fact that the NRECA had mis-diagnosed Williams with common variable immune deficiency instead of selective antibody deficiency. [*See* AR 357-58, 965-66, 1046-47, 1646-47]. A lawsuit challenging this denial was ultimately resolved through settlement [AR 1358-65]. The Plaintiffs allege that this settlement was the result of the conclusion of the NRECA's medical consultant that it was possible that Williams had selective antibody deficiency, for which IVIG therapy is an covered treatment [AR 1647].

Shortly after this settlement, John Williams' employer switched from a self-funded plan to

one insured by Aetna, effective January 1, 2011. There is no dispute that this Plan is an "employee welfare benefit plan" as defined by ERISA. Based on the Plan, Aetna is the party obligated to pay benefits and determine eligibility for benefits. This action arises out of Aetna's refusal to pay for Williams' IVIG treatments beginning in January 2011 and continuing through December 31, 2013, when John Williams' employer switched back to a self-funded plan.

Pursuant to the Court's Scheduling Orders, Aetna filed the administrative record under seal on February 7, 2014 [DE #37]. On June 27, 2014, Aetna filed its motion to supplement the administrative record with several documents inadvertently omitted from the earlier filing [DE #49]. As the Plaintiffs have not opposed this motion, the Court will grant the motion to supplement.

II. EXHAUSTION OF REMEDIES

A. EXHAUSTION REQUIREMENTS UNDER ERISA AND THE PLAN

Before turning to the merits of this action, the Court must first decide if the Plaintiffs have exhausted their administrative remedies with respect to any or all of the Plaintiffs' claims for Williams' IVIG treatments during the relevant time frame. Although ERISA is silent as to whether exhaustion of administrative remedies is a prerequisite to bringing a civil action, it does require that every employee benefit plan give "a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim." 29 U.S.C. § 1133. The Sixth Circuit has read this requirement to mean that "the administrative scheme of ERISA requires a participant to exhaust his or her administrative remedies prior to commencing suit in federal court." *Coomer v. Bethesda Hosp., Inc.*, 370 F.3d 499, 504 (6th Cir. 2004)(citing *Miller v. Metro. Life Ins. Co.*, 925 F.2d 979, 986 (6th Cir. 1991)). However, "a court is obliged to exercise its discretion to excuse nonexhaustion where resorting to the plan's

administrative procedure would simply be futile or the remedy inadequate." *Fallick v. Nationwide Mut. Ins. Co.*, 162 F.3d 410, 419 (6th Cir. 1998).

In accordance with section 1133 of ERISA, the Plan at issue provides a tiered administrative review process. *See* 29 U.S.C. § 1133. Within 30 days after a participant submits a claim for non-emergency services, Aetna must make a "claim determination" [AR 946]. If Aetna determines that the service is covered, it will process and pay the claim pursuant to the terms, conditions and limitations of the Plan. However, if Aetna determines that a medical service or supply is not covered by the Plan, it will issue an "adverse benefit determination" instead [AR 945]. An adverse benefit determination may be based on, among other things, a person's "eligibility for coverage;" a "determination that the service or supply is experimental or investigational;" or a "determination that the service or supply is not medically necessary" [*Id.*]. In addition to stating the reason for the denial, the Plan requires the adverse benefit determination to provide information on how to appeal the decision through the two-leveled appeal process [AR 946].

To pursue a "level one" appeal, Plan participants "have 180 calendar days following the receipt of notice of an adverse benefit determination to request [a] level one appeal" [AR 947 (emphasis omitted)]. The appeal will be conducted "by Aetna personnel not involved in making the adverse benefit determination." If the decision is upheld at the level one phase, "and the reason for the adverse determination was based on medical necessity or experimental or investigational reasons," a Plan participant may "file a level two appeal . . . within 60 calendar days following the receipt of notice of a level one appeal." The "level two" appeal will be conducted "by Aetna personnel not involved in making an adverse benefit determination." A decision will be issued within 30 days of receipt of the request for level two appeal [*Id.*].

Once these two levels of appeal have been exhausted, and if the denial was based on a determination that "a service or treatment is experimental or investigational," a Plan participant may request external review by "an independent physician, selected by an External Review Organization, who has expertise in the problem or question involved" [AR 948 (emphasis omitted)]. Finally, the Plan provides that if a party wishes to initiate litigation on a contested claim, exhaustion of this process is mandatory. Specifically, the Plan provides:

> You must exhaust the applicable Level one and Level two processes of the Appeal Procedure before you:
> - contact the Georgia Department of Insurance to request an investigation of a complaint or appeal; or
> - file a complaint or appeal with the Georgia Department of Insurance; or
> - establish any:
>
> -litigation; or
> -administrative proceeding.

[*Id*.].

B. THE PLAINTIFFS' CLAIMS FOR WILLIAMS' IVIG TREATMENTS

Williams received IVIG treatments every 3 to 4 weeks during the time period that Aetna administered the Plan (January 1, 2011 thru December 31, 2013). Aetna has denied coverage for all Williams' IVIG claims. Aetna, however, argues that the Plaintiffs only contested three of its adverse benefit determinations - for IVIG treatments in January 2011, March 2011, and January 2012. Additionally, Aetna contends that only one of those claims - January 2012 - was fully exhausted. On the other hand, the Plaintiffs argue that all Williams' claims for IVIG treatment in 2011 should be deemed exhausted due to Aetna's failure to provide material information in accordance with its fiduciary duties and ERISA laws and regulations. Because they fully exhausted the January 2012 claim, and because all remaining claims in 2012 and 2013 are identical in nature, the Plaintiffs argue

that it would be futile to require exhaustion of those claims.

1. THE JANUARY 2011 CLAIM

The Plaintiffs' first claim under the Plan for Williams' IVIG treatment was made by Williams' physician, Lawrence T. McKean, M.D, on January 4, 2011 [AR 003]. In a January 22, 2011 adverse benefits determination mailed to Plaintiff John Williams, Aetna denied the claim because it considered the treatment to be "experimental or investigational" [AR 011, 1644-45]. Dr. McKean's office filed a level one appeal of this adverse benefit determination on February 4, 2011 [AR 003], and followed up with a phone call, noted in the record as a "misdirected verbal appeal," on February 10, 2011 [AR 011]. On March 15, 2011, Aetna denied coverage in a level one decision addressed to "Health Care Professional" and mailed only to Dr. McKean's office, stating:

> The basis for this decision is that Ms. Williams has been given a diagnosis of [OTHER SELECTIVE IMMUNOGLOBULIN DEFICIENCIES (279.03)] which is not listed as a covered diagnosis on the CPB . . . Aetna considers the use of IVIG experimental and investigational for all other clinical conditions . . . The previous denial remains upheld as experimental and investigational. This decision was made utilizing the Aetna CPB referenced above. You may obtain a copy of this CPB through the Internet at: www.aetna.com.

[AR 001]. The denial also provided that "[i]f you disagree with this decision, you may request a Level 2 appeal" by forwarding any relevant information "no later than 60 days from the receipt date of this letter" [AR 001]. Under the terms of the Plan, an appeal of this decision would have been due on May 16, 2011. As no appeal was filed by that date, Aetna argues that the Plaintiffs failed to exhaust their remedies as to this claim.

The Plaintiffs, however, contend that they were not provided with or made aware of Aetna's March 15, 2011 denial until Aetna produced the administrative record to this Court and to their counsel on February 7, 2014. While the original adverse benefit determination of January 22, 2011

was addressed and mailed to John Williams, the March 15, 2011 level one denial was addressed to "Health Care Professional" and mailed to Dr. McKean's office.

Counsel for the Plaintiffs first entered the claims process on March 31, 2011, and sent an initial letter to Aetna [AR 1649-52]. This letter indicates that he was taking over representation of the Plaintiffs for the January 4, 2011 claim for IVIG treatment, requests a copy of the claim file, and asks for status on the claim. No response was received. On May 9, 2011, the Plaintiffs' counsel sent Aetna a second letter requesting the identical information [AR 1653-56]. No response was received. A third letter was sent to Aetna on June 6, 2011 requesting the same information [AR 1657-60]. No response was received. On July 13, 2011, an appeal was filed by counsel for the Plaintiffs[1] [AR 955-957]. This appeal was within the 180 days provided by the January 22, 2011 denial letter that had been addressed and mailed to John Williams, but outside of the 60 days provided by the March 15, 2011 denial addressed to "Health Care Professional" and mailed to Dr. McKean's office.

2. MARCH 24, 2011 CLAIM

On March 24, 2011, Williams received another IVIG treatment from Dr. McKean [AR 124]. This claim was denied by Aetna on April 1, 2011 [AR 15], again by providing notice to Dr. McKean's office and not to the Plaintiffs. Although the April 1, 2011 adverse benefits determination was appealed by Dr. McKean on November 17, 2011 [AR 16-17], it was beyond the 180 day

[1]This appeal included two important medical opinions: (1) a July 6, 2011 sworn statement from Dr. McKean setting forth his opinion that Williams suffered from selective antibody deficiency and that although another diagnosis of common variable immune deficiency was reported in the record, it was a clerical error [AR 968-969]; and (2) an opinion from Terry O. Harville, M.D., Ph.D., a recognized expert in immune deficiencies, who also stated that Williams suffers from selective antibody deficiency and that IVIG treatment is medically necessary [AR 1046-47]. Additionally, attached to this appeal were medical records from many providers all operating under the selective antibody deficiency diagnosis.

deadline for filing a level one appeal, and only sought $11.02 related to Aetna's alleged failure to pay a contracted rate for a different service performed on the same day. No request for a level two appeal was filed by Dr. McKean or the Plaintiffs.

3. JANUARY 12, 2012 INJECTION

Williams received an IVIG treatment on January 12, 2012, and consistent with its prior adverse benefit determinations, Aetna denied this claim on February 17, 2012 [AR 25]. Dr. McKean apparently appealed this denial. In an April 3, 2012, letter to the Plaintiffs' counsel, Aetna requested an additional fifteen days to resolve the appeal [AR 281]. On April 18, 2012, Aetna informed the Plaintiffs' counsel that it was denying the level one appeal on the grounds that IVIG therapy is "experimental and investigational" and stated that any level two appeal must be filed within 60 days [AR 25-26].

On June 13, 2012, within the 60 day time frame, the Plaintiffs' counsel sent Aetna a letter appealing the adverse benefits determination, and requested an additional 60 days "in order to obtain additional evidence to support this claim" [AR 422]. On July 24, 2012, the Plaintiffs submitted the May 30, 2012 sworn statement of Terry Harville, M.D., stating that Williams suffers from selective antibody deficiency, that IVIG is not only medically necessary but is in accordance with generally accepted standards, is clinically appropriate and not primarily for the convenience of the patient [AR 262-63]. Furthermore, Dr. Harville's statement explains the difference between selective antibody deficiency (which Williams suffers from) and selective isolated IgA immunodeficiency (which the Plaintiffs allege Aetna believed she had) and that IVIG is indicated for the former by not the later. Finally, he opined that if IVIG therapy is withheld from Williams, she could develop bronchiectasis, which is not curable and which would cause continued deterioration of her lungs at a relatively rapid

rate such that she would die by the age of 50 or so [AR 269-70].

On September 3, 2012, Aetna mistakenly informed the Plaintiffs that it did not receive a timely appeal and denied the level two request as late [AR 024]. The Plaintiffs' counsel sent multiple letters to Aetna explaining that the June 13, 2012 appeal of the April 18, 2012 decision was timely, but received no response [AR390, 387, 388]. On January 13, 2013, Aetna finally responded, incorrectly stating that it received an appeal on June 26, 2012, outside of the 180 day appeal window [AR 288]. By letter dated February 11, 2013, the Plaintiffs' counsel explained again that they had timely appealed the April 18, 2012 denial on June 13, 2012 [DE #52-3].

Aetna ultimately conceded that the Plaintiffs had timely appealed and reconsidered the January 12, 2012 claim on the merits [AR 333]. On April 10, 2013, Aetna issued a new level one appeal determination. This time, the adverse decision was based on its determination that the IVIG services were experimental or investigation, and also, for the first time, on the requirement that "IVIG should be discontinued and the medical necessity of IVIG should be reevaluated one year after initiating therapy and every two years thereafter by reassessing the immune response to vaccines, as not all persons with selective IgG subclass deficiencies benefit from IVIG" [AR 333-37].

On June 5, 2013, the Plaintiffs requested a level two appeal [AR 339]. In response, on June 18, 2013, Aetna scheduled a review panel to meet on July 3, 2013, and offered an opportunity for the Plaintiffs' counsel to make a presentation [AR 709]. The panel convened on July 3, 2013, and consisted of Dr. Richard Fornadel, an Aetna medical director; Donna Fortun, RN, an Appeal Nurse Consultant; and Dr. Richard F. Lavi, an independent physician board certified in allergy and immunology [AR 750]. Counsel for the Plaintiffs addressed the review panel and asked them to consider Dr. Harville's sworn statement that Williams suffers from selective antibody deficiency,

not selective IgG deficiencies, and that IVIG is medically necessary and in accordance with generally accepted medical standard [AR 750]. According to the panel's notes, Dr. Fornadel stated that he did not see any information regarding antibody levels necessary to confirm the selective antibody deficiency diagnosis; however, counsel for the Plaintiffs replied that this information had been previously submitted in conjunction with earlier appeals. Counsel was then excused for the panel deliberations [AR 751].

The panel determined that it did not have necessary records needed to make a determination as to the proper diagnosis and requested Plaintiffs' counsel to provide the panel with certain information [AR 752]. The requested information, even though previously provided to Aetna on July 13, 2011, was then faxed to the panel the same day [AR 752, 652-698]. Shortly thereafter, the panel determined that Williams has selective antibody deficiency and "meets the criteria" for coverage [AR 753-54].

Nevertheless, the panel issued a decision denying coverage on July 8, 2013 [AR 326]. Although the panel agreed that Williams suffers from selective antibody deficiency, a covered condition, they held that she should have had a trial off the IVIG before being retested pursuant to their policy. Specifically, the decision states:

> Per the criteria referenced above for persons with normal total IgG levels and severe polysaccharide non-responsiveness, IVIG should be discontinued and the medical necessity of IVIG should be re-evaluated 1 year after initiating therapy and every 2 years thereafter by reassessing immune response to protein and polysaccharide antigens. Immune response should be re-evaluated at least 3 months after discontinuation of IVIG. IVIG should also be discontinued at that time if the number and/or severity of infections have not been reduced, as not all persons with polysaccharide non-responsiveness benefit from IVIG. Therefore, based on our review of the above information, we are upholding the previous decision to deny coverage for the immune globulin injection . . . The basis for this determination is there is no documentation indicating IVIG therapy was discontinued for Ms.

Williams and the medical necessity of IVIG re-evaluated.

[AR 326].

C. ANALYSIS

There is no dispute that the Plaintiffs failed to timely appeal the March 15, 2011 level one adverse benefit determination within the 60 days provided. However, the Plaintiffs' failure to fully exhaust the administrative process as to this claim is due solely to Aetna's failure to provide notice of its denial directly to the Plaintiffs in violation of the procedural protections of section 1133 of ERISA. Section 1133 provides:

> In accordance with regulations of the Secretary, every employee benefits plan shall -
>
> (1) provide adequate notice in writing to any **participant or beneficiary** whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant, and
>
> (2) afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim.

29 U.S.C. § 1133(1), (2) (emphasis added). Furthermore, the regulations promulgated under section 1133 provide:

> *Content of notice*. A plan administrator . . . shall provide to every **claimant** who is denied a claim for benefits written notice setting forth in a manner calculated to be understood by the claimant:
>
> (1) The specific reasons for the denial;
> (2) Specific reference to pertinent plan provisions on which the denial is based;
> (3) A description of any additional material or information necessary for the claimant to perfect the claim and an explanation of why such material or information is necessary; and
> (4) Appropriate information as to the steps to be taken if the participant or beneficiary wishes to submit his or her claim for review.

29 C.F.R. § 2560.503-1(f)(emphasis added). Here, Aetna never provided the "participant" or the

"claimant" - the Plaintiffs - with timely written notice of the March 15, 2011 denial of benefits as required, but instead sent the notice of denial to the provider, Dr. McKean. Nothing in the record suggests that the Plaintiffs or their counsel ever received the March 15, 2011 denial until after the filing of this lawsuit. Additionally, since Plaintiffs' counsel entered this process on March 31, 2011, good faith efforts have been exerted on behalf of the Plaintiffs to comply with the terms of the Plan's administrative process, only to be frustrated by Aetna's failure to respond to numerous requests for the status of their claims. *See* 29 U.S.C. § 1132(c).

As the party obligated to pay benefits and given the discretion in construing and applying the provisions of its group health plan and assessing a participant's entitlement to benefits, Aetna is an ERISA fiduciary. *See* 29 U.S.C. § 1002(21)(A)(i) and (iii); *Aetna Health Inc. v. Davila*, 542 U.S. 200, 220 (2004). A fiduciary is required to carry out its duties with respect to the Plan "solely in the interest of the participants and beneficiaries and - (A) for the exclusive purpose of: (i) providing benefits to participants and their beneficiaries; . . . and (B), with the care, skill prudence, and diligence under the circumstances then prevailing that a prudent man acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character and with like aims. . . . " 29 U.S.C. § 1104(a)(1). Certainly this duty includes responding to counsel's repeated requests for information about the Plaintiffs' claim. *See Krohn v. Huron Memorial* Hosp., 173 F.3d 542, 548 (6th Cir. 1999)(once an ERISA [beneficiary] has requested information from an ERISA fiduciary who is aware of the beneficiary's status and situation, the fiduciary has an obligation to convey complete and accurate information material to the beneficiary's circumstance, even if that requires conveying information about which the beneficiary did not specifically inquire"); *Gregg v. Transp. Workers of Am. Int'l*, 343 F.3d 833, 845-46 (6th Cir. 2003)(same). By failing to respond in

any manner to counsel's repeated requests for information, Aetna violated its fiduciary duty to the Plaintiffs. As a result, equity demands that the Plaintiffs be excused from the exhaustion requirement for all claims made in 2011.

Aetna concedes that the Plaintiffs fully exhausted the January 2012 claim, but argues that no subsequent claims were exhausted. The Plaintiffs contend that exhaustion of any claims subsequent to the January 2012 claim would be futile. The Sixth Circuit has "repeatedly held that exhaustion may be excused if the claimant establishes futility." *Welsh v. Wachovia Corp.*, 191 Fed. Appx. 345, 357 (6th Cir. 2006)(citing e.g., *Hill v. Blue Cross Blue Shield of Mich.*, 409 F.3d 710, 718-19 (6th Cir. 2005); *Weiner v. Klais & Co.*, 108 F.3d 86, 90-91 (6th Cir. 1997)). In assessing futility, the Court must decide "whether a clear and positive indication of futility can be made." *Fallick*, 162 F.3d at 419. In order to meet this standard, the Plaintiffs "must show that it is certain that [their] claim will be denied on appeal, not merely that [they] doubt[] that an appeal will result in a different decision." *Id*.(quoting *Lindemann v. Mobile Oil Corp.*, 79 F.3d 647, 650 (7th Cir. 1996)).

Here, there is no dispute that the Plaintiffs' claim for Williams' IVIG treatment on January 12, 2012 was identical to each and every other claim they made to Aetna. Aetna's continued reliance on a mis-diagnosis and subsequent denials of the IVIG treatment under its "experimental or investigational" rationale, precluded any different administrative result. Even after correcting its mis-diagnosis of Williams' condition and changing its denial rationale to "failure to discontinue IVIG treatment" in in July 2013, there is simply nothing to suggest that a remand would result in any different outcome. Even this litigation, Aetna continues to argue that the Plaintiffs are not entitled to medical benefits for Williams' IVIG treatments. As a result, the Court will excuse the Plaintiffs' failure to exhaust each and every claim on futility grounds for all claims after January

2012 until Aetna's coverage expired on December 31, 2013.

III. STANDARD OF REVIEW

Turning to the merits of this action, the Court must first determine the standard of review applicable to Aetna's refusal to pay for Williams' IVIG treatments. Generally, a *de novo* standard of review applies to decisions of plan administrators "unless the benefit plan gives the administrator or fiduciary discretionary authority to determine eligibility for benefits or to construe the terms of the plan." *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115 (1989); *see also Perez v. Aetna Life Ins. Co.*, 150 F.3d 550, 555 (6th Cir. 1998). When an ERISA plan confers discretion upon an administrator, the administrator's determinations must be reviewed under the "arbitrary and capricious" standard. *Perez*, 150 F.3d at 555; *Wendy's Int'l, Inc. v. Karsko*, 94 F.3d 1010, 1012 (6th Cir. 1996).

Here, the parties agree that based on the discretion afforded Aetna under the Plan at issue, the arbitrary and capricious standard of review applies [DE #27]. While this is a very deferential standard, "[i]t is not, however, without some teeth." *McDonald v. Western-Southern Life Ins. Co*, 347 F.3d 161, 172 (6th Cir. 2003)(citing *Cozzie v. Metropolitan Life Ins. Co.*, 140 F.3d 1104, 1107-08 (7th Cir. 1998)(internal citation omitted)). "Deferential review is not no review," and "deference need not be abject." *Id*.(citing *Hess v. Hartford Life & Accident Ins. Co.*, 274 F.3d 456, 461 (7th Cir. 2001). In making this review, the Court must review both the quality and quantity of the medical evidence and the opinions on both sides of the issues." *Id.* at 172. The Court should not rubber stamp a determination when there is an absence of reasoning in the record to support it. Finally, less deference is given to the decision of a plan administrator if it fails to gather or examine relevant evidence. *Caldwell v. Life Ins. Co. of North America*, 287 F.3d 1276, 1282 (10th Cir. 2002).

Also relevant to this Court's review is the fact that Aetna is a conflicted administrator, due to its dual role as an ERISA plan administrator and payer of plan benefits. *See Firestone Tire & Rubber Co.,* 489 U.S. at 115; *Metropolitan Life Ins. Co. v. Glenn*, 554 U.S. 105, 112 (2008). The Sixth Circuit has held that in these situations, "the potential for self-interested decision-making is evident." *University Hosps. of Cleveland v. Emerson Elec. Co.*, 202 F.3d 839, 846 n.4 (6th Cir. 2000). This conflict, however, does not displace the arbitrary and capricious standard of review, but rather becomes a factor to consider when determining whether the administrator's decision to deny benefits was arbitrary and capricious. *Kalish v. Liberty Mut./Liberty Life Assurance Co. of Boston*, 419 F.3d 501, 506 (6th Cir. 2005).

IV. ANALYSIS

A. AETNA'S CHANGE IN RATIONALE FOR DENYING COVERAGE FROM "EXPERIMENTAL OR INVESTIGATIONAL" TO "FAILURE TO CONDUCT A TRIAL DISCONTINUATION OF TREATMENT" WAS ARBITRARY AND CAPRICIOUS.

In four denial of coverage determinations from January 22, 2011 to April 10, 2013, Aetna denied coverage for Williams' IVIG therapy because it was "experimental and investigational" for her condition [AR 1, 25-26, 24, 333]. Only in its last denial of July 8, 2013, did Aetna indicate it was denying her benefits because her physicians failed to put her through trial discontinuation of IVIG treatment, as articulated in Aetna's Clinical Policy Bulletin 206 [AR 326]. The Plaintiffs contend that Aetna's change in rationale so late in the process violates ERISA and was arbitrary and capricious.

Under ERISA, Aetna is required to provide notice of the "specific reasons for such denial, written in a manner calculated to be understood by the participant. . . ." 29 U.S.C. § 1133. The

regulations further provide that the notice provide the following: "(1) The specific reason or reasons for the denial; (2) Specific reference to the pertinent plan provisions on which the denial is based; (3) A description of any additional material or information necessary for the claimant to perfect the claim and an explanation of why such material or information is necessary; and (4) Appropriate information as to the steps to be taken if the participant or beneficiary wishes to submit his or her claim for review. 29 C.F.R. § 2560-503-1(f). By changing its rationale from its initial denials of coverage notices until its final denial of coverage notice of July 8, 2013, Aetna failed to comply with these requirements.

Aetna's Clinical Policy Bulletins ("CPBs") are available online at www.aetna.com. Relevant to this case is CPB 206: Parenteral Immunoglobulins [AR 755-799]. This forty-four page CPB sets forth the criteria, or clinical indications, to be used in evaluating claims for IVIG treatments. According to CPB 206, IVIG treatments can be a medical necessity in some circumstances "for persons with normal total IgG levels and severe polysaccharide nonresponsiveness" However, it goes on to state that "IVIG should be discontinued and the medical necessity of IVIG should be re-evaluated 1 year after initiating therapy and every 2 years thereafter by reassessing immune response to protein and polysaccharide antigens." The CPB states that this protocol is based on scientific research showing that "not all persons with polysaccharide nonresponsiveness benefit from IVIG" [AR 775].

From Aetna's initial adverse benefit determination on March 15, 2011 until its final denial on July 8, 2013, the Plaintiffs were told that coverage was being denied because IVIG therapy was experimental or investigational. Counsel for the Plaintiffs took considerable strides to correct the mis-characterization of Williams' diagnosis and other errors on the part of Aetna during the

administrative process, but other than reference a 44-page document on the internet, Aetna did nothing to communicate the fact that periodic discontinuation of IVIG therapy was required.

Additionally, Aetna's reliance on the CPB alone does not satisfy its duty under Section 1133 and the regulations to provide the claimant with specific reasons for a denial. The periodic discontinuation requirement in CPB 206 appears only on pages 4 and 18 of the online document [AR 757-58, 775]. This does not amount to "specific reference to the plan provisions on which the denial is based," particularly in light of the fact that another very specific reason for the denial has been cited. Moreover, even if the mere citation to CPB 206 was sufficient, the language of the document itself is not specific due to the fact that it repeatedly uses the word "should" when requiring periodic discontinuation of IVIG treatment. The term "should" could be understood in this context as "precatory" rather than "mandatory," such that it did not amount to adequate notice to the Plaintiffs that if Williams' physicians did not conduct a trial discontinuation of IVIG therapy, she would be denied benefits. *See Burke v. Kodak Retirement Income Plan*, 336 F.3d 103, 109 (2nd Cir. 2003)(the use of the word "should" in the handbook was grossly uninformative because it could be understood as precatory rather than mandatory and did not amount to adequate warning to the claimant). Aetna could have easily used unambiguous mandatory language in its CPB, but did not. Accordingly, the Court finds that Aetna's change in rationale for denying coverage was arbitrary and capricious and requires reversal of the administrative decision.

B. AETNA'S FAILURE TO MEANINGFULLY INVESTIGATE THE PLAINTIFFS' CLAIMS WAS ARBITRARY AND CAPRICIOUS.

Even if citing CPB 206 in its earlier denials was sufficient, and the term "should" is construed as mandatory, the record reveals that Aetna failed to make any meaningful investigation

into the Plaintiffs' claims. Although the Plaintiffs provided Aetna with laboratory data and other medical evidence sufficient to justify her diagnosis of selective antibody deficiency on July 13, 2011, Aetna continued to operate under the wrong diagnosis [AR 955, 957]. It was almost two years later, after the Plaintiffs resubmitted the laboratory data on July 3, 2013, that Aetna acknowledged that it based its "experimental or investigational" denial rationale on the wrong diagnosis. In addition to the laboratory data, Aetna also had on hand Dr. Harville and Dr. McKean's opinions that Williams suffers from selective antibody deficiency and that an attempt to decrease or stop the IVIG therapy would cause Williams' lung function to deteriorate, she could die within six hours of an overwhelming pneumococcal infection or she could develop bronchiectasis, which is not curable, and would cause continued deterioration of her lungs at a relatively rapid rate such that she would die by the age of 50 or so [AR 269-70, 355, 968-69].

Under ERISA, Aetna had "the responsibility to fully investigate" the claim before denying it. *Capone v. Aetna Life Ins. Co.*, 592 F.3d 1189, 1199-1200 (11th Cir. 2010). Any termination of benefits must be based on "a reasoned explanation," resulting from "a deliberate, principled reasoning process." *Davis v. Kentucky Fin. Cos. Ret. Plan*, 887 F.2d 689, 693 (6th Cir. 1989); *Killian v. Healthsource Provident Administrators, Inc.*, 152 F.3d 514, 520 (6th Cir. 1998). The Plaintiffs repeatedly attempted to correct Aetna's mis-diagnosis of Williams' condition to no avail. There is no evidence that Aetna ever reviewed Dr. McKean's or Harville's sworn statements. From the record, it appears that Aetna failed to consider any part of the record until the review panel met on July 3, 2013. As a result, the Court cannot find that any "full investigation" or "reasoned explanation" took place.

Had Aetna ever looked at the data provided to it early in the administrative process, then it

would never have denied coverage for "experimental or investigational" reasons. Continuing to deny coverage based on this later-abandoned theory, prejudiced the Plaintiffs both in treatment time and for money spent by counsel to correct Aetna's misunderstanding of her condition. Aetna's failure to conduct a deliberate, reasonable investigation into the Plaintiffs' claims, in violation of ERISA law and regulations, clearly amounts to arbitrary and capricious conduct sufficient to reverse the administrative decision.

C. THE PLAINTIFFS ARE ENTITLED TO AN AWARD OF PAST DUE BENEFITS, AND THE PARTIES SHALL BRIEF WHETHER THE COURT SHOULD AWARD INTEREST, ATTORNEYS' FEES AND COSTS.

After considering the quality and the quantity of the medical evidence and the opinions on both sides of the issues, the Court concludes that Aetna acted arbitrarily and capriciously in denying coverage for Williams' IVIG treatments when it ignored medical evidence related to her diagnosis and need for IVIG treatment, by changing its rationale between its initial and final decisions, and by failing to fully investigate her claim for over two years. Accordingly, the Court will reverse the administrative decision and award the Plaintiffs the past due benefits for all of Williams' IVIG treatments during the relevant time period (January 2011 through December 31, 2013). Since the total amount of past due benefits is not clear from the record, the Court will order the Plaintiffs to file a motion for entry of judgment, setting forth the amount of past due benefits, and a proposed judgment. Any response and reply may be filed in accordance with the Local Rules.

The Plaintiffs have also requested an award of interest, attorneys' fees, and costs. Section § 1132(a)(1)(B) of ERISA provides that "[a] civil action may be brought . . . by a participant or beneficiary . . . to recover benefits due to him under the terms of the plan." The Sixth Circuit has held that this includes prejudgment interest, which is awarded to "compensate a beneficiary for the

lost interest value of money wrongly withheld from him or her." *Ford v. Uniroyal Pension Plan*, 154 F.3d 613, 618 (6th Cir. 1998). Additionally, post judgment interest may be awarded pursuant to 28 U.S.C. § 1961. Finally, under ERISA, "the court in its discretion may allow a reasonable attorney's fee and costs of action to either party." 29 U.S.C. § 1132(g)(1). With these principles in mind, the Plaintiffs may file a motion for interest, attorneys' fees and costs within 30 days of entry of this Opinion & Order; any response and reply may be filed in accordance with the Local Rules.

V. CONCLUSION

For the reasons set forth above, the Court hereby **ORDERS** as follows:

(1) Aetna's motion to supplement [DE #49] is **GRANTED**, and the supplement shall be considered part of the administrative record herein;

(2) Aetna's motion for judgment [DE #50] is **DENIED**;

(3) the Williams' motion for judgment [DE # 51] is **GRANTED**, and the administrative decision is **REVERSED**;

(4) **WITHIN THIRTY DAYS OF ENTRY OF THIS OPINION & ORDER**, Plaintiffs shall file their motion for entry of judgment. Any response or reply shall be filed in accordance with the Local Rules; and

(5) **WITHIN THIRTY DAYS OF ENTRY OF THIS OPINION & ORDER**, the Plaintiffs may file a motion for interest, attorneys' fees and costs. Any response or reply shall be filed in accordance with the Local Rules.

Dated this 8th day of October, 2014.

Karen K. Caldwell

KAREN K. CALDWELL, CHIEF JUDGE
UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY