UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

MICHAEL POTTER and BRETT BOYER, on behalf of themselves and all others similarly situated,

Plaintiffs,

v.

BLUE CROSS BLUE SHIELD OF MICHIGAN,

Defendant.
_____/

Case No. 10-cv-14981

HONORABLE STEPHEN J. MURPHY, III

ORDER GRANTING PLAINTIFFS' MOTION FOR JUDGMENT (docket no. 84)
AND DENYING DEFENDANT'S MOTION FOR JUDGMENT (docket no. 92)

This is an ERISA denial-of-benefits class action, filed by named plaintiffs Michael Potter and Brett Boyer against Blue Cross Blue Shield of Michigan ("BCBS"). The matter before the Court is resolution of the parties' cross-motions for judgment. As set forth below, the Court will deny BCBS's motion for judgment, grant Plaintiffs' motion for judgment, award declaratory and injunctive relief, and remand the claims to BCBS for payment of benefits.

BACKGROUND

Each named plaintiff in the matter is a parent of an autistic child who is a dependent beneficiary of the parent's Blue Cross Blue Shield of Michigan insurance coverage. Each child received Applied Behavioral Analysis ("ABA") therapy for autism, and submitted claims for coverage to BCBS, which BCBS denied on the grounds that ABA therapy is "investigative or experimental." Compl. ¶ 12, ECF No. 27.

Potter's child received ABA therapy through the CARE Program, run by Beaumont Hospital's Center for Human Development, from February 13, 2007 through December 18, 2008. Amend. Compl. ¶¶ 10, 78; Administrative Record ("A.R.") 003409, ECF No. 83-2.

Instead of submitting individual claims after each session of treatment, Potter submitted two aggregate claims seeking reimbursement for all sessions. BCBS denied coverage in numerous Explanations of Benefits ("EOBs"). *See* Potter EOBs, A.R. 002621-002856, ECF Nos. 83-24 - 83-27. BCBS denied coverage for various reasons, including that "[t]he service isn't payable under your contract," and because the claim was not submitted within the filing deadline. *See id.*

On or around October 22, 2010, Potter sent a letter in appeal to BCBS, "follow[ing] up" on the EOBs he had recently received, detailing his efforts to submit claims and to obtain updates on the status of those claims, and asking for "more explanation as to why BCBSM is not going to cover these services." October 22, 2010 Letter, A.R. 003415-003416, ECF No. 83-2. The letter specifically referred to "claims . . . from services during the time period of 2/13/07 to 12/18/08." *Id.* To support his claim for coverage Potter included with his letter a report signed by 59 "world renowned experts in psychiatry, child psychology, medicine, behavioral science, and autism research and practice." *Id.*; Report, A.R. 003175, ECF No. 83-33. In response, BCBS sent Potter a letter on November 30, 2010, stating: "Our medical analyst has reviewed the claim for these services and has determined that ABA therapy is not a payable benefit because it is considered investigational/experimental."[1] November 30, 2010 Letter, A.R. 003409, ECF No. 83-2 (referring to dates of service 2/13/07 to 12/18/08). The letter did not mention any other basis for denial of the claims. *See id.* The letter set forth the procedure to appeal the benefits determination. *Id.* Potter did not pursue any further appeal.

[1] In its brief, BCBS cites to A.R. 0002857 as a March 10, 2010 denial-of-claims letter to Potter. But that page in the administrative record is a March 18, 2010 letter to Boyer, denying his claims.

Boyer's child received ABA therapy through Autism Concepts, Inc. from July 1, 2007 through September 2, 2009. *See* BCBS Mar. 18, 2010 letter, A.R. 003407, ECF No, 83-2. Boyer submitted claims for coverage on January 10, 2010. *See* Master Medical Claim Form, A.R. 003406, ECF No. 83-2. BCBS denied the claims, and Boyer pursued both levels of appeal provided for under his plan of insurance. *See* January 26, 2011 Denial Letter, A.R. 000001-000003, ECF No. 83-3. On January 26, 2011, BCBS issued its final decision to deny coverage, stating, "Applied Behavioral Analysis (ABA) is considered investigational." *Id.*

Plaintiffs filed this action in December 2010 under ERISA, 29 U.S.C. § 1132(a)(1)(B) and 29 U.S.C. § 1132(a)(3), seeking payment of their denied claims for ABA therapy, as well as equitable relief, including a declaratory judgment that BCBS's characterization of ABA therapy as investigative or experimental was arbitrary and capricious, and an injunction prohibiting BCBS from characterizing or excluding ABA therapy as experimental or investigative in the future. Usually, to bring a denial-of-benefits claim under ERISA, a plaintiff must demonstrate that he or she exhausted the administrative remedies available under the insurance plan. *See Miller v. Metro. Life Ins. Co.*, 925 F.2d 979, 986 (6th Cir. 1991) ("The administrative scheme of ERISA requires a participant to exhaust his or her administrative remedies prior to commencing suit in federal court."). The Court waived the requirement here, finding that exhaustion would have been futile because of BCBS's across-the-board policy and practice of denying coverage for ABA therapy on the grounds that it is experimental. *See* Order Granting Class Cert, ECF No. 35 ("BCBS has not identified one instance in which it has voluntarily paid benefits for ABA treatment."); *see also Fallick v. Nationwide Mut. Ins. Co.,* 162 F.3d 410, 419 (6th Cir. 1998) (“The standard

for adjudging the futility of resorting to the administrative remedies provided by a plan is whether a clear and positive indication of futility can be made.").

Plaintiffs sought class certification, arguing that class adjudication is appropriate because BCBS denies claims for ABA therapy without considering the individual circumstances of each claimant, but rather relies solely on its medical policy statements deeming the treatment experimental across the board. The Court granted the motion for class certification, observing, in pertinent part, that individualized questions regarding claimant's qualification for benefits do not prevent certification because "[t]he class includes only BCBS members whose claims were denied on the grounds that such treatment is deemed by Blue Cross Blue Shield of Michigan to be experimental. So to the extent claims were denied for other reasons, persons with such claims are excluded from the class because their claims were denied not because BCBS deems ABA treatment experimental, but for another independent and adequate reason." Order Granting Mot. to Certify 16, ECF No. 35. The class certified includes:

> All individuals who were enrolled in or covered by a health care coverage plan offered or administered by a Blue Cross Blue Shield of Michigan policy of insurance governed by ERISA and who made a claim or make a claim to Blue Cross Blue Shield of Michigan for Applied Behavior Analysis treatment for Autism Spectrum Disorder for the CARE program, or at other programs besides Beaumont's, or at home, where the therapy was provided under the supervision of a licensed professional or a person board certified in ABA therapy, for the treatment of autism, which claim was denied on the grounds that, pursuant to Blue Cross Shield's 2010 Medical Policy Statement regarding ABA therapy, such treatment is deemed by Blue Cross Blue Shield of Michigan to be investigative or experimental. Excluded from the subclass are the members in *Johns v. Blue Cross Blue Shield of Michigan*, No. 08-12272 (E.D. Mich.), as to claims released therein.
>
> Also excluded are officers, directors, agents, servants or employees of Blue Cross Blue Shield of Michigan or any parent, subsidiary, or affiliated company, as well as immediate family members of such persons. Also excluded is any judge who may preside over this case or any person who has settled a claim for either of these therapies wth Blue Cross Blue Shield of Michigan.

Order Granting in Part Mot. to Modify Class 14, ECF No. 124.

On May 29, 2012, BCBS filed the administrative record, comprising the documents that were before BCBS when it denied Potter and Boyer's applications for benefits. *See* Administrative Record, ECF No. 83. These include, inter alia, both Potter and Boyer's claims for coverage, EOB's, and letters of appeal; and BCBS's 2008, 2009, and 2010 medical policy statements regarding ABA therapy, and studies and articles cited in those medical policy statements.

Potter and Boyer's plans of insurance are identical in all relevant respects. Potter is covered under the Flexible Blue Group Benefits plan provided by Blue Cross. *See* A.R. 001351-001567, ECF No. 83-16. Boyer is covered under the Community Blue Group Benefits plan. *See* A.R. 000341-000625, ECF No. 83-12. Both plans provide mental health coverage and contain the same provisions relevant to the experimental/investigative exclusion. *See* Flexible Blue Group Provisions, A.R. 001428-001429, 001441, 001457-001458, ECF NO. 83-16; Community Blue provisions, A.R. 000430, 000446, 000469, ECF No. 83-12. Specifically the plans state that BCBS does "not pay for experimental treatment." A.R. 001457; A.R. 000468. The plans further state that "[t]he BCBSM medical director is responsible for determining whether the use of any service is experimental." *Id.* The Plans then provide a nonexhaustive list of bases upon which the medical director may deem a service experimental. The first two are pertinent here: "[T]he service may be determined to be experimental when:

- Medical literature or clinical experience is inconclusive as to whether the service is safe or effective for treatment of any condition, or
- It has been shown to be safe and effective treatment for some conditions, but there is inadequate medical literature or clinical experience to support its use in treating the patient's condition.

A.R. 001457; A.R. 000468-000469. The plans provide a nonexhaustive list of sources that, when available,"will be considered in evaluating whether a treatment is experimental under the above criteria," including scientific data, such as controlled studies in peer-reviewed journals or medical literature, as well as information provided by the Blue Cross Blue Shield Association, and information from independent nongovernmental, technology assessment and medical review organizations, and from local and national media societies and other appropriate professional societies. *Id.*

Since 2008, BCBS has maintained medical policies regarding the use of Applied Behavioral Analysis to treat Autism Spectrum Disorder. BCBS's 2010 medical policy was in effect at the time that BCBS denied Potter and Boyer's claims, and is the policy applicable to the claims of the class. *See* 2010 Medical Policy, A.R. 002884-002895, ECF No. 83-27. The 2010 medical policy starts with a short description of autism, its diagnosis, and treatment. Introducing ABA therapy, it states that,

> The treatment of autistic children has undergone substantial change in the past 20 years, with behavior modification replacing psychotherapy as the dominant and preferred treatment modality. In behavioral therapy programs, operant conditioning techniques are used to help autistic individuals develop skills with social value aimed at improving cognitive and social functioning of children with autism. These programs are referred to as applied behavioral analysis (ABA), intensive behavioral intervention (IBI), early intensive behavioral intervention (EIBI) or Lovaas therapy.

A.R. 002884. The medical policy describes ABA therapy as follows:

> [ABA] therapy involves highly structured teaching techniques that are administered on a one-to-one basis by a trained therapist or paraprofessional 25 to 40 hours per week for two to three years. In classic ABA therapy, the first year of treatment focuses on reducing self-stimulatory and aggressive behaviors, teaching imitation responses, promoting appropriate toy play and extending treatment into the family. In the second year, expressive and abstract language is taught, as well as appropriate social interactions with peers. Treatment in the third year emphasizes development of appropriate emotional expression, preacademic tasks, and observational learning from peers involved in academic tasks. In an ABA therapy session, the child is

> directed to perform an action. Successful performance of the task is rewarded with a positive reinforcer, while noncompliance or no response receives a neutral reaction from the therapist. Food is usually most effective as a positive reinforcer for autistic children, although food rewards are gradually replaced with "social" rewards, such as praise, tickles, hugs or smiles. Parental involvement is considered essential to long-term treatment success; parents are taught to continue behavioral modification training when the child is at home, and may sometimes act as the primary therapist.

A.R. 002885. The medical policy then offers the following "Medical Policy Statement" regarding ABA therapy:

> The effectiveness of applied behavioral analysis in the treatment of certain types of autism spectrum disorders has not been established. While it may be considered safe, there are not enough long-term studies to determine its clinical utility. Therefore, it is considered experimental/investigational.

Id. The medical policy sets forth the following "Rationale" for the Medical Policy Statement.

> The available studies include the original work by Lovaas and a subsequent long-term follow-up study that compared outcomes in young autistic children who underwent intensive therapy with outcomes in children who received minimal treatment. In addition, there were two small nonrandomized studies comparing intensive therapy with minimal or school-based interventions and three randomized or quasi-randomized trials. The latter three trials included one early study that compared residential, outpatient, and home-based interventions, and two studies that compared Lovaas-based therapy with minimal or eclectic therapy. Several studies provided relatively long follow-up data, in some cases up to 10 years following enrollment in the study. All of the available studies involved small numbers of children with autism, who were mostly between the ages of three and seven years, although two studies included younger children as well.
>
> Lovaas reported that almost half of the children receiving intensive therapy passed normal first grade and had an IQ that was at least average. In contrast, none of the children in the minimal treatment group passed normal first grade or had an IQ score in the normal range. This study has been criticized for its small size and failure to randomize subjects to treatment groups. These methodological flaws appear to have had a significant impact on study outcomes since subsequent studies of intensive behavioral therapy have found that it provides limited positive results that are not comparable with those obtained by Lovaas. The Lovaas and subsequent studies excluded low-functioning autistic subjects, and this may have contributed to the high degree of success they obtained. However, the most recent randomized and quasi-randomized trials of intensive behavioral therapy,

> using more stringent exclusion criteria than those applied by Lovaas, failed to duplicate these early results.

A.R. 002886. Finally, the medical policy concludes with a list of fourteen references, largely consisting of scientific studies and articles. *See* A.R. 002887. BCBS included eleven of these references in the administrative record.

LEGAL STANDARD

ERISA provides that insurance companies "shall discharge [their] duties with respect to a plan solely in the interest of the participants and beneficiaries and . . . for the exclusive purpose of . . . providing benefits to participants and their beneficiaries . . . in accordance with the documents and instruments governing the plan insofar as such documents and instruments are consistent with the provisions of this subchapter . . . ." 29 U.S.C. § 1104(a)(1). Claimants may bring a civil action to recover benefits and to enforce or clarify their rights under the plan. *See* 29 U.S.C. § 1132(a)(1)(B). Where, as here, the benefit plan "gives the administrator or fiduciary discretionary authority to determine eligibility for benefits or to construe the terms of the plan," the benefits determination is subject to arbitrary-and-capricious review. *Miller v. Metropolitan Life Ins. Co.*, 925 F.2d 979, 983 (6th Cir. 1991). A coverage decision is not arbitrary and capricious "when it is possible to offer a reasoned explanation, based on the evidence, for a particular outcome." *Williams v. Int'l Paper Co.*, 227 F.3d706, 712 (6th Cir. 2000) (citation omitted). Stated otherwise, to survive arbitrary-and-capricious review, a coverage decision must be "rational in light of the plan's provisions." *Miller*, 925 F.2d at 984 (citation omitted)."[I]ndications of arbitrary and capricious decisions include a lack of substantial evidence, a mistake of law, bad faith and a conflict of interest by the decision-maker." *Wagner v. Ciba Corp.*, 743 F. Supp. 2d 701,

712 (S.D. Ohio 2010) (citing *Caldwell v. Life Insurance Co. of North America*, 287 F.3d 1276, 1282 (10th Cir. 2002)).

The Court's review is limited to the record before BCBS at the time it made the coverage decisions. *Wilkins v. Baptist Healthcare System, Inc.*, 150 F.3d 609, 619 (6th Cir. 1998); *Killian v. Health Source Provident Adm'r, Inc.*, 152 F.3d 514, 522 (6th Cir.1998).

BCBS has the burden to show that the experimental/investigative exclusion applies to claims for coverage of ABA therapy. *Caffey v. Unum Life Ins. Co. of Am.*, No. 95-6373, 1997 WL 49128, at *3 (6th Cir. Feb. 3, 1997) (citing *Farley v. Benefit Trust Life Ins. Co.*, 979 F.2d 653, 658 (8th Cir.1992)) ("[A]ccording to common law trust principles, the administrator of an ERISA-regulated plan has the burden to prove exclusions from coverage."); *cf. Klein v. Cent. States, Se. & Sw. Areas Health & Welfare Plan*, 346 F. App'x 1, 6 (6th Cir. 2009) (acknowledging that the common-law rule applies unless "the Plan Document explicitly place[s] the burden of proof on the claimant").

DISCUSSION

I. Liability

Plaintiffs argue that BCBS's denial of coverage for ABA therapy is arbitrary and capricious because (1) the sources cited and relied upon by BCBS in its medical policy statements support the efficacy of ABA therapy; (2) BCBS selectively reviewed the evidence to come to a contrary conclusion; and (3) BCBS modified its 2010 medical policy statement to eliminate favorable evidence.[2]

[2] Plaintiffs make arguments in reliance on articles cited in BCBS's 2008 and 2009 medical policies, as well as those cited in BCBS's 2010 medical policy. Because the 2010 policy is the one applicable to the decision to deny benefits, the Court will review it to assess whether the denial of benefits was arbitrary and capricious. The articles cited in BCBS's 2008 and 2009 medical policies are relevant to Plaintiffs' argument, discussed below, that BCBS acted arbitrarily and capriciously when it denied benefits after modifying

ERISA's civil enforcement provision provides that a plan beneficiary may bring an ERISA claim "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*." 29 U.S.C. § 1132(a)(1)(B)) (emphasis added). As noted above, a benefits determination survives arbitrary-and-capricious review if it is "rational *in light of the plan's provisions*." *Miller*, 925 F.2d at 984 (emphasis added). Looking to the language of the plans, BCBS's 2010 medical policy, and the articles cited by BCBS to support its policy, the Court finds that BCBS's denial-of-benefits for ABA therapy on the grounds that such therapy is experimental or investigative was arbitrary and capricious.

As set forth above, BCBS's 2010 medical policy states that

> The effectiveness of applied behavioral analysis in the treatment of certain types of autism spectrum disorders has not been established. While it may be considered safe, there are not enough long-term studies completed to determine its clinical utility. Therefore, it is considered experimental/ investigational.

A.R. 002885, ECF No. 83-27. The term "experimental" is not defined in the plans, but to illustrate the meaning of the term, the plans state that a treatment may be deemed experimental when, e.g., "[m]edical literature or clinical experience is inconclusive as to whether the service is safe or effective for treatment of any condition, or [the service] has been shown to be safe and effective treatment for some conditions, but there is *inadequate medical literature or clinical experience* to support its use in treating the patient's condition." A.R. 001457; A.R. 000468-00069 (emphasis added).

Relying on the italicized language, BCBS argues that the 2010 medical policy's findings that (1) ABA's effectiveness for certain autism spectrum disorders has not been

---

its medical policy to eliminate evidence favoring ABA therapy.

established; and (2) there are not enough long-term studies to establish its clinical utility, support application of the experimental exclusion on the grounds that there is "inadequate medical literature or clinical experience" to show that it is safe and effective to treat the plaintiffs' conditions.

As an initial matter, the Court notes that the 2010 medical policy concedes that ABA is "safe." *See* 2010 Medical Policy, A.R. 002885. In addition, although the policy does not define the term, the clinical studies cited in BCBS's policy statement overwhelmingly conclude that ABA is "effective." *See* Svein Eikeseth, et al., *Outcomes for Children with Autism Who Began Intensive Behavioral Treatment Between Ages 4 and 7*, 31 Behavior Modification 264-277 (2009), A.R. 003013-003026 (following up on an earlier study [also in the Administrative Record] and concluding "[r]esults suggest that [ABA therapy] was effective for children with autism in the study"); Esther Ben-Itzchak, et al., *The Effects of Intellectual Functioning and Autism Severity on Outcome of Early Behavioral Intervention for Children with Autism*, 28 Research in Developmental Disabilities 297-303 (2007), A.R. 002965-002974 (observing, e.g., that "children with a range of autistic symptom severity and cognitive impairments before the start of treatment significantly progress with intervention"); Bob Remington, et al., *Early Intensive Behavioral Intervention: Outcomes for Children with Autism and their Parents After Two Years*, 112 Am. J. on Mental Retardation 418-435 (2007), A.R. 003111-003128 ("[A]fter 2 years, robust differences favoring intensive behavorial intervention were observed on measures of intelligence, language, daily living skills, positive social behavior, and a statistical measure of best outcome for individual children."); Howard Cohen, et al., *Early Intensive Behavioral Treatment: Replication of the UCLA Model in a Community Setting*, 27 Developmental and Behavioral Pediatrics S145-154 (2006), A.R. 002982-002991 (showing at year 3 that 17

of 21 children receiving ABA therapy achieved placement in a regular classroom, compared to 1 of 21 children in the comparison group); Tristram Smith, et al., *Randomized Trial of Intensive Early Intervention for Children with Pervasive Developmental Disorder*, 105 Am. J. on Mental Retardation 269-285 (2000), A.R. 003132-003139 (finding that intensively treated children outperformed the control group at follow-up "on measures of intelligence, visual-spatial ability, language, and academic achievement"); O. Ivar Lovaas, *Behavioral Treatment and Normal Educational and Intellectual Functioning in Young Autistic Children*, 55 Journal of Consulting and Clinical Psychology 3-9 (1987), A.R. 003081-003087 (showing that 47% of students receiving ABA therapy achieved normal intellectual functioning and successful first-grade performance compared to 2% of control group children).

The articles in the administrative record — with one exception discussed below — corroborate the results of the clinical studies. *See* Corinna F. Grindle, et al., *Parents' Experiences of Home-Based Applied Behavior Analysis Programs for Young Children with Autism*, J. Autism Development Disorders 42-56 (2008), A.R. 003040-003053 (summarizing a study of parents' experience with ABA, and noting, "Over three quarters of parents reported that . . . [ABA] was *unequivocally* the right choice for all the family, particularly because of the child's progress and its subsequent positive impact on the family") (emphasis in original); Scott M. Meyers, et al., *Management of Children with Autism Spectrum Disorders*, 120 Pediatrics 1162-1182 (2007), A.R. 003088-003102 (discussing ABA as an intervention and noting, "[t]he effectiveness of ABA-based intervention in ASDs has been well-documented through 5 decades of research.").

As stated, BCBS relies on the medical policy's findings that (1) ABA therapy's effectiveness for certain autism spectrum disorders is not established; and (2) there are not

enough long-term studies completed to determine its clinical utility. But those findings are not supported in the record.

First, the articles and studies cited do not provide any support for the claim that ABA therapy is effective for the treatment of some autism spectrum disorders but not others. The medical policy states that it applies to the following list of autism spectrum disorders: Autistic disorder, Asperger's syndrome, pervasive developmental disorders, childhood disintegrative disorder, Rett's syndrome, and "unspecified" and "other specified" pervasive developmental disorders. *See* 2010 Medical Policy, A.R. 002885. For the most part, the studies do not distinguish between specific diagnoses within the autism spectrum, and appear to use the term "autism" as shorthand to refer to "autism spectrum disorder." *See, e.g.*, Ben-Itzchak, *supra* at 288 (using both terms in a single paragraph to refer to "autism spectrum disorder"). When a distinction between diagnoses is noted, it is between diagnoses of "autism," and pervasive developmental disorder not otherwise specified ("PDD-NOS"). *See* Smith, *supra*. The Smith study was the only study cited to distinguish its results for children with PDD-NOS from its results for autistic children more generally, but Smith's results do not support the conclusion that ABA therapy is less effective for some disorders than others. *See id.*, A.R. 003137 (finding that "children with [PDD-NOS] obtained outcomes at least as positive as those obtained by children with autism").

Given that the studies in the record almost uniformly conclude that ABA is effective, and make almost no distinction between types of autism spectrum disorder, the Court finds that the 2010 medical policy's statement that ABA's effectiveness "in the treatment of certain types of autism spectrum disorders has not been established" is not supported by the record. BCBS's reliance on the statement to support a decision to deny benefits, would be arbitrary and capricious. *See Williams*, 227 F.3d at 712 (to survive arbitrary-and-

capricious review, administrator must be able to "offer a reasoned explanation, *based on the evidence*, for a particular outcome") (emphasis added).

Second, the 2010 medical policy states that there are "not enough long-term studies completed" to determine the clinical utility of ABA therapy. BCBS's basis for determining that there are "not enough long-term studies" is unclear. The medical policy states that "[s]everal studies provided relatively long follow-up data, in some cases up to 10 years following enrollment in the study," but it does not name the studies specifically or otherwise define what it means to provide "relatively long follow-up data." *See* 2010 Medical Policy A.R. 002886. The medical policy also does not describe why "several studies" providing relatively long follow-up data does not constitute "enough long-term studies." To the extent BCBS relies on the numerical insufficiency of the long-term studies of ABA therapy, its policy is internally inconsistent and unsupported; reliance on it to determine benefits would be arbitrary and capricious.

It is possible, however, that, although it does not say so, the policy language means to suggest that there are not enough *reliable* long-term studies completed to determine the clinical utility of ABA therapy. With respect to the "several" studies that provide "relatively long follow-up data," this claim is impossible to assess because BCBS did not identify the studies. To the extent the studies referred to are the references in the medical policy, it suggests a relatively broad definition of "long-term" studies, encompassing studies with one-year, two-year, and three-year follow-up data. *See* Smith*, supra* (one-year study); Cohen, *supra* (testing after one, two, and three years); Remington, *supra* (two-year study); Eikeseth*, supra* (following up on prior study after three years). This would further undermine BCBS's claim that there are "not enough" long-term studies.

The medical policy *does* identify and discuss one long-term follow-up study. *See* 2010 Medical Policy ("The available studies include the original work by Lovaas and a subsequent long-term follow-up study."). The Lovaas study is the seminal work on ABA therapy. Children in the Lovaas study received 40 weekly hours of home-based ABA therapy, in comparison with "control groups receiving either a less intensive intervention or the standard treatment offered by educational services." Remington, *supra* 418 (discussing Lovaas). As BCBS's medical policy notes, "Lovaas reported that almost half of the children receiving intensive therapy passed normal first grade and had an IQ that was at least average. In contrast, none of the children in the minimal treatment group passed normal first grade or had an IQ score in the normal range." 2010 Medical Policy, A.R. 002886. The "subsequent long-term follow-up study" referred to in the medical policy appears to be a study conducted by McEachin, Smith and Lovaas, published six years after the original Lovaas study, assessing the same children.[3] McEachin found that "the gains were maintained at age 11.5 years and that 8 of 9 children previously identified as having achieved 'best outcome' status' could not be distinguished from typically developing peers by assessors blind to their treatment." Remington*, supra*, 418 (discussing McEachin).

The medical policy dismisses Lovaas's results — and by implication, McEachin's — due to the Lovaas study's "small size and failure to randomize subjects to treatment groups," and states — without citation — that "the most recent randomized and quasi-randomized trials of intensive behavioral therapy, using more stringent exclusion criteria, than those applied by Lovaas, have failed to reproduce its results." 2010 Medical Policy, A.R. 002886. The statements appear to be based largely on a report on ABA therapy from

[3] The McEachin study is not cited in BCBS's medical policy or included in the record.

the Hayes Medical Technology Directory, which also criticizes the Lovaas study for its small size, failure to randomize, and because certain follow-up studies failed to reproduce its results. *See* Hayes Report, A.R. 003055-3063.[4] The Hayes Report gives ABA therapy a "Hayes Rating" of C, signifying a "potential but unproven" technology. *See* BCBS's Mot. for J. 11, ECF No. 92.

The Hayes Report's criticisms, when examined in light of the evidence in the record, provide little support for BCBS's medical policy. As to study size, the Lovaas study contained a sample size of 59. This is not an unusually small sample size relative to the universe of studies assessing ABA therapy. *See* Hayes Report at 784, A.R. 003057 (noting that its "search of the peer-reviewed literature published between 1966 and March 2008" yielded studies with sample sizes "ranging from 15 to 61 children"). Moreover, the medical policy's references included a meta-analysis, which created a sample size of several hundred children by collecting, normalizing, and evaluating the results of nine prior studies.[5] *See* Sigmund Eldevik, *Meta-Analysis of Early Intensive Behavioral intervention for Children with Autism*, 38 J. of Clinical Child & Adolescent Psychology 439-450 (2009). Even with the larger sample size, Eldevik found that ABA is effective. *Id.* ("Our results support the clinical implication that at present . . . Early Intensive Behavioral Intervention should be the intervention of choice for children with autism.").

With respect to Lovaas' failure to randomize, the references cited in the 2010 medical policy, almost uniformly, conclude that randomization poses ethical difficulties in

[4] The Hayes Report was issued by Hayes, Inc., a company that provides research assistance and general information regarding health technologies to insurance companies. *See* Hayes Report at 782, A.R. 003055.

[5] A "meta-analysis" is "a quantitative statistical analysis of several separate but similar experiments or studies in order to test the pooled data for statistical significance." Merriam Webster Dictionary (2013).

this context. *See* Itzchak, *supra*, at 299, A.R. 002977 ("In our study, a control group of children not included in intervention is not available because of ethical reasons, since all the children diagnosed with autism are referred to early intervention."); Remington, *supra*, at 419 ("[A]s knowledge accumulates and early intervention is accepted as the treatment of choice for autism . . . researchers face ethical difficulties with random assignment."); Cohen, *supra*, at S147, ("[L]egal and ethical considerations precluded random assignment of children to groups."); Lovaas, *supra*, at 4 ("Strict random assignment . . . could not be used due to parent protest and ethical considerations."). Even if randomized studies of ABA therapy may be undertaken ethically, Remington notes, they are difficult to carry out. *See* Remington, *supra*, at 419 (noting that as awareness of ABA's efficacy grows, parents in the control group are likely to abandon the study).

In any event, BCBS included a randomized study of ABA therapy in its references. That study did not reproduce the dramatic results achieved by Lovaas, but it nonetheless confirmed that ABA is effective. *See* Smith, *supra* ("Consistent with previous studies based on the treatment manual we used . . . intensively treated children outperformed children in a parent training group at follow-up on measures of intelligence, visual-spatial ability, language, and academic achievement."). Twenty-eight of the intensively treated children in the Smith study achieved placement in regular classrooms, with and without support, while only three children in the comparison group achieved that placement, all of whom required support.[6]

---

[6] The Hayes Report and the medical policy also suggest that Lovaas's results may result from a selection bias because Lovaas excluded low-functioning autistic children from participation in his study. *See* 2010 Medical Policy, A.R. 002886; Hayes Report at 7, A.R. 003061. But Smith's study purposely corrected for this design element, and, as discussed above, nonetheless demonstrated ABA's efficacy. *See* Smith, *supra*, A.R. 003137 (noting that the study had a mean intake IQ of 50, compared to 63 in Lovaas).

In sum, a review of the administrative record shows an array of studies with different methodological approaches. Each methodological approach introduces a variable that may affect that study's results. Those differences notwithstanding, however, what the studies and commentary in the record have in common is the conclusion that ABA therapy produces clinically proven and statistically significant positive results for children with autism spectrum disorder. In light of the consistency of the scientific evidence in the record on this point, the relatively conclusory criticisms of the Lovaas study in the medical policy and the Hayes Report do not warrant much weight. The medical policy's focus on Lovaas does not support its claim that there are "not enough long-term studies" completed to determine ABA's efficacy; and, even absent Lovaas, the other studies cited in the medical policy *do* support ABA's efficacy.

Accordingly, for all of the reasons stated above, the Court finds that BCBS's medical policy is internally inconsistent, ambiguous, and, most fatally, not supported by the evidence in the record. To review, in its medical policy, BCBS claims that ABA's effectiveness has not been established for different types of autism spectrum disorder, but none of the articles and studies BCBS cites in its medical policy support that claim. The medical policy also states that there are "not enough" long-term studies completed to determine ABA's effectiveness in treating autism. The phrase is ambiguous and, in any event, the policy itself contradicts that claim, and states that "several studies provide relatively long-term follow up data." The medical policy identifies, at most, one of those studies, and dismisses it because of the investigators' failure to randomize and the study's small sample size. But, with respect to randomization, the studies cited in the medical policy state that randomized studies of ABA therapy are unavailable for ethical and practical reasons, and the single randomized study cited in the policy confirmed ABA's efficacy. With

respect to sample size, the sources cited in the medical policy show that clinical trials of ABA therapy uniformly involve relatively small sample sizes, and that, even with a statistical sample size of several hundred children, ABA is clinically effective. Most importantly, as a rule, the studies cited in the medical policy— although they may not each reproduce Lovaas' results in full — all show statistically significant positive results from the treatment. Accordingly, in light of the medical policy's ambiguity, inconsistency, and lack of record support, the Court finds that BCBS's benefits determinations denying coverage on the basis of that policy were arbitrary and capricious.

The class approved includes both self-funded plans and plans administered and funded by BCBS. For that latter group, the Court notes, BCBS's obligation to pay approved claims is another factor that weighs in favor of finding its decision to deny coverage arbitrary and capricious. *See Univ. Hospitals of Cleveland v. Emerson Elec. Co.*, 202 F.3d 839, 846 (6th Cir. 2000) (holding that when an insurer administers a plan and pays the benefits itself, it is subject to a conflict of interest that must be weighted in the arbitrary-and-capricious review).

As noted above, Plaintiffs also argue that BCBS's denial of benefits by reference to the policy is arbitrary and capricious because BCBS modified its 2010 medical policy statement to eliminate articles and statements that favor ABA therapy. Having already determined that the coverage decisions were arbitrary and capricious, the Court need not reach this argument. In any event, it is unsupported. BCBS is entitled to modify its medical policies, and Plaintiffs have not pointed to any evidence that suggests that BCBS did so in bad faith in this instance. The Court declines to find that BCBS's modification of the policy is evidence of bias, or was a factor that rendered its coverage decisions arbitrary and capricious.

II. Remedy

Plaintiffs seek the following class relief:

- A declaratory judgment that [BCBS's] characterization and exclusion of ABA therapy as experimental or investigative was, and is, arbitrary and capricious;
- A permanent injunction prohibiting [BCBS] from characterizing or excluding ABA therapy as experimental or investigative in the future;
- Notice to the class, paid for by [BCBS], that BCBS's characterization and exclusion of ABA therapy as experimental or investigative was improper;
- All class members who made a claim for ABA therapy that was denied by [BCBS] on the grounds that ABA therapy is deemed experimental or investigative shall have their denials overturned and their claims paid, with interest;
- Reimbursement by [BCBS] of Plaintiffs' attorneys' fees and costs.

Mot. for J. 20, ECF No. 84.

The Court will limit the relief granted to that which is appropriate to the question resolved. This order determines that BCBS's denial of benefits for ABA therapy pursuant to BCBS's 2010 medical policy was arbitrary and capricious. The Court will grant Plaintiffs a declaratory judgment to that effect, and will overturn denials of benefits on that basis. The Court will deny Plaintiffs' request for a permanent injunction because this record is insufficient to determine whether future denials of claims, pursuant to plan language, medical policies, and scientific research that are not before the Court, will be arbitrary and capricious.[7]

[7] This determination also disposes of BCBS's argument in its motion to decertify or modify the class, that Plaintiffs' claim for injunctive relief is moot in light of Michigan's recently enacted Public Laws requiring insurers to provide coverage for ABA therapy. *See* Mot. to Decertify 13, ECF No. 106.

Having found that Plaintiffs' claims were improperly denied, the Court has discretion to either enter an award of benefits or remand claims to the administrator for determination. *See Kovach v. Zurich Am. Ins. Co.*, 587 F.3d 323, 339 (6th Cir. 2009) ("[C]ourts have the power either to send the matter back to the plan administrator for further consideration or to make a final decision on the merits."). Remand is appropriate here for the reason illustrated by the posture of Potter's claims. BCBS denied a subset of them as time-barred, and then issued a final determination of benefits denying all his claims by reference to the experimental exclusion. The time-barred claims may not be paid because they were excluded by BCBS for a valid reason below, but the remainder of Potter's claims for coverage are payable. *See* Order Granting in Part Mot. to Decertify 8 (stating that, in the event Plaintiffs are successful, relief will be limited to "class members whose claims were denied by reference to [the experimental exclusion], and for no other valid reason"). Because similar sifting of claims denied for specific and valid reasons may apply to other members of the class, the Court will remand the claims for readministration by BCBS.

It is important to note, however, that remand is not an opportunity for BCBS to invent new bases for denial of claims that were not previously asserted. *See Univ. Hospitals of Cleveland*, 202 F.3d at 849 ("[I]t strikes us as problematic to . . . recognize an administrator's discretion to interpret a plan by applying a deferential 'arbitrary and capricious' standard of review, yet, . . . allow the administrator to 'shore up a decision after-the-fact by testifying as to the 'true' basis for the decision after the matter is in litigation."). Vague language denying a claim such as, "the service isn't payable under your contract," shall be construed as a denial based solely on the experimental/investigative exclusion, and the claim will therefore merit reimbursement. But BCBS is not required to

pay claims that it denied in its initial response for specific valid reasons, plainly having nothing to do with the experimental/investigative exclusion.

ORDER

WHEREFORE it is hereby **ORDERED** that Plaintiffs' Motion for Judgment (docket no. 84) is **GRANTED**.

IT IS FURTHER ORDERED that Defendant's characterization and exclusion of ABA therapy as experimental or investigative, as applied to the claims of the class members, was, and is, arbitrary and capricious.

IT IS FURTHER ORDERED that the class members' claims for coverage of ABA therapy are **REMANDED** to BCBS for readministration as set forth above.

IT IS FURTHER ORDERED that Defendant's Motion for Judgment (docket no. 92) is **DENIED.**

IT IS FURTHER ORDERED that Defendant shall provide notice to the class of this Court's order, at its expense.

SO ORDERED.

s/Stephen J. Murphy, III
STEPHEN J. MURPHY, III
United States District Judge

Dated: March 30, 2013

I hereby certify that a copy of the foregoing document was served upon the parties and/or counsel of record on March 30, 2013, by electronic and/or ordinary mail.

Carol Cohron
Case Manager