UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES -- GENERAL

Case No. **CV 16-7925-JFW (SKx)** Date: December 12, 2017

Title: Aubrey Cohorst *-v-* Anthem Health Plans of Kentucky, Inc.

PRESENT:
HONORABLE JOHN F. WALTER, UNITED STATES DISTRICT JUDGE

Shannon Reilly	**None Present**
Courtroom Deputy	**Court Reporter**

ATTORNEYS PRESENT FOR PLAINTIFFS:	**ATTORNEYS PRESENT FOR DEFENDANTS:**
None	None

PROCEEDINGS (IN CHAMBERS): FINDINGS OF FACT AND CONCLUSIONS OF LAW

Plaintiff Aubrey Cohorst ("Plaintiff") brings this action under the Employee Retirement Income Security Act ("ERISA") against Anthem Health Plans of Kentucky, Inc. ("Anthem"). This action came before the Court for trial on August 29, 2107. Christian Garris of the Law Offices of Christian J. Garris appeared for Plaintiff. Cynthia Sands of Martin & Martin, LLP appeared for Anthem. After considering the evidence in the administrative record, the parties' trial briefs and supplemental briefs, and argument of counsel, the Court makes the following findings of fact and conclusions of law:

Findings of Fact[1]

Natural Energy Field Services LLC ("Natural Energy") established an employee welfare benefit plan (the "Plan") that provides PPO health insurance to its employees and their dependents. At all times relevant to this action, Plaintiff was a participant in the Plan by virtue of her husband's employment with Natural Energy. The Plan is fully insured and administered by Anthem.

In September of 2015, Plaintiff was experiencing cervical pain radiating into her left arm and some numbness in her left leg. As a result, on September 16, 2015, she met with Dr. Robert S. Bray, Jr. ("Dr. Bray") for treatment. Dr. Bray was advised that in 2008, Plaintiff had surgery on her

[1] The Court has elected to issue its decision in narrative form because a narrative format more fully explains the reasons behind the Court's conclusions, which aids appellate review and provides the parties with more satisfying explanations. Any finding of fact that constitutes a conclusion of law is hereby adopted as a conclusion of law, and any conclusion of law that constitutes a finding of fact is hereby adopted as a finding of fact.

cervical spine due to injuries she suffered in a car accident. During that surgery, doctors inserted a metal plate that fused her C4-C6 vertebrate.

Based on Dr. Bray's examination of Plaintiff and review of prior MRI and CT scans taken of Plaintiff's spine, Dr. Bray determined that Plaintiff had ruptured discs that were compressing her spinal column. Dr. Bray concluded that it was medically necessary to perform an artificial disc replacement ("ADR") surgery on Plaintiff's C3-C4 vertebrate. Due to Plaintiff's prior fusion, Dr. Bray concluded that it would be necessary to use a Mobi-C inter-vertebral device for the ADR surgery.

A. Anthem Provides Prior Authorization for ADR Surgery Using the Pro Disc-C Device (Reference Number 0239572642)

On September 30, 2015, Dr. Bray's office contacted Anthem to obtain prior authorization for the ADR surgery. During the authorization process, Anthem obtained information relating to the medical necessity of the surgery. AR 166. Although Plaintiff claims that Dr. Bray's office requested approval of the surgery using a Mobi-C device, Anthem's notes do not reflect Dr. Bray's request. AR 166. After reviewing the information submitted by Dr. Bray, Anthem approved the surgery using the Pro Disc-C device. AR 168. Anthem's notes indicate that Anthem deemed the procedure "medically necessary" and that the procedure met "criteria guidelines." AR 166. In addition, Anthem's notes indicate that Plaintiff had a bilateral fusion of the C3-C4 vertebrate in 2008. AR 166–68.

The same day, Anthem sent Plaintiff and Dr. Bray a letter confirming it had authorized the ADR surgery (CPT Code 22856) and the medical device (CPT Code 69990). AR 158. The letter did not specifically state what device was approved for the surgery. Anthem assigned reference number 0239572642 to the claim. AR 158.

On October 7, 2015, Dr. Bray's office contacted Anthem to clarify its authorization for Plaintiff's surgery. AR 172. Dr. Bray's office indicated it understood the codes for the ADR surgery and the medical device, but it wanted clarification about the specific device that was approved. AR 172. Anthem's notes from the call indicate that it informed Dr. Bray's office that the Pro Disc-C, not the Mobi-C, was approved. AR 174. Dr. Bray's office questioned why he could not use the Mobi-C instead of the Pro Disc-C, given that the device had been approved by the FDA. AR 174.

On October 14, 2015, Dr. Bray's office called Anthem again regarding its authorization of the medical device to be used in Plaintiff's surgery. AR 179. Specifically, Dr. Bray asked for a peer-to-peer review to discuss use of the Mobi-C device instead of the Pro Disc-C device in connection with Plaintiff's surgery. AR 180. At the time of the call, Plaintiff's surgery was scheduled to occur the following Monday–October 19, 2015. AR 180.

B. Anthem Denies Prior Authorization for ADR Surgery Using the Mobi-C Device

(Reference Number 0239749165)

Following the October 14, 2015 call with Dr. Bray's office, Anthem created a new reference number (0239749165), allegedly in response to Dr. Bray's request for authorization to use a Mobi-C device for Plaintiff's surgery. AR 182.

On October 15, 2015, Dr. Bray wrote a letter to Anthem explaining that it was medically necessary to use the Mobi-C device on Plaintiff because the Pro Disc-C would not fit over her existing two level plate. AR 207. According to Dr. Bray, in order to use the Pro Disc-C he would have to remove the entire plate system, which would require him to perform a complicated three level surgery through scar tissue. AR 207. Dr. Bray cautioned Anthem that a three level surgery would pose significant additional risks to Plaintiff, and he concluded that he could not perform the procedure on Plaintiff under those circumstances. AR 207.

On October 23, 2015, Dr. Bray discussed Plaintiff's condition with Dr. Sanchez, Anthem's Medical Director. AR 206. During their call, they discussed the possibility of using one of three alternative devices. AR 206. On October 23, 2015, Anthem entered notes into its system that indicate that its prior approval of Plaintiff's ADR surgery was "overturned" because the procedure was now "Experimental/Investigative." AR 170.

On October 26, 2015, Dr. Bray sent a follow up letter to Anthem regarding his request to use the Mobi-C device. AR 206. According to Dr. Bray, he thoroughly investigated the possibility of using one of the three alternative devices, but he determined they were not viable options given the construct and/or technique and tools used in placement. AR 206. Dr. Bray requested another conference with one of Anthem's physicians regarding his findings. AR 206.

Dr. Bray sent a follow up letter to Anthem on November 6, 2015 stating that he had not yet received any response to his October 26, 2015 letter. AR 205. He explained that Plaintiff suffered from cord compression and that Anthem's delay in responding to his request was exposing Plaintiff to additional risks. AR 205.

On November 9, 2015, Anthem sent a letter to Plaintiff stating that it had reviewed the appeal and was denying the request for prior authorization of the ADR surgery using the Mobi-C device. AR 183. According to Anthem, it had now determined that the procedure was considered "investigational and not medically necessary as defined in the Exclusion section of [the] Health Care Benefit Booklet." AR 183. Anthem also stated that based on a review by its external physician consultant, and pursuant to its Medical Policy, "cervical disc arthroplasty in an individual with a previous fusion at another cervical level is considered investigational and not medically necessary for all indications." AR 183. The denial letter further stated that Plaintiff "has had a prior C4-6 cervical discectomy and fusion in 2008" and that given her history of prior fusion, "the requested service would not be a medically covered service per policy." AR 183.

C. Dr. Bray Performs ADR Surgery on Plaintiff Using the Mobi-C Device, and Anthem Denies the Claim for Benefits

Notwithstanding Anthem's denial, given Plaintiff's deteriorating condition, she had no choice but to move forward with the ADR surgery using the Mobi-C device. AR 193–194. Dr. Bray

performed the surgery on November 23, 2015. AR 193. In his operative report, Dr. Bray confirmed that due to the existing metal plate, the only commercially available FDA approved device that would fit in the relevant space was the Mobi-C device. AR 194.

The total charge associated with Plaintiff's surgery was approximately $140,434.25. AR 187. Approximately $130,000 was attributed to the ADR surgery and $5,434.25 was attributed to the cost of the Mobi-C device. AR 192. Dr. Bray's office submitted medical records to Anthem on July 25, 2016 in connection with its request for payment of $140,434.25 for the ADR surgery using the Mobi-C device. AR 191.

On September 1, 2016, Anthem denied Dr. Bray's request for payment because of Plaintiff's prior fusion in 2008 and, pursuant to its Medical Policy, a "cervical disc arthroplasty in an individual with a previous fusion at another cervical level is considered investigational and not medically necessary for all indications." AR 223. In its claim notes, Anthem cited a study described in its Medical Policy, conducted by Phillips et al., which evaluated cervical disc replacement in 26 patients who had prior adjacent level fusions and found that revision surgery was required in 2 patients. AR 223. Based on the study, Anthem determined that the use of cervical disc replacement near a prior cervical fusion had not been adequately studied and was therefore considered investigational. AR 223.

On September 6, 2016, Anthem notified Plaintiff in a letter that it was re-affirming its previous denial of benefits for the ADR surgery because she had a prior fusion surgery. AR 227. According to Anthem, "medical studies do not show than an artificial disc placed after fusion surgery works well long term." AR 227. As a result, Anthem deemed the surgery "investigational and not medically necessary in all cases." AR 227.

D. Relevant Plan Provisions

The Plan's health insurance coverage is explained in the Health Certificate of Coverage ("Health Certificate"). The Health Certificate provides that the Group Contract and the Health Certificate and any addendums and endorsements, amendments or riders attached, form the Group Contract under which Covered Services are available health care benefits to Plan participants.

1. The Health Certificate

The Health Certificate defines Covered Services as "services, supplies or treatment" described in the Health Certificate that are "performed, prescribed, directed, or authorized by a Provider." AR 111. To qualify as a Covered Service, "the service, supply, or treatment," must be: (1) Medically Necessary or otherwise specially included as a benefit under the Certificate; (2) within the scope of the license of the Provider performing the service; (3) rendered while coverage is in force under the Health Certificate; (4) not Experimental/Investigative or otherwise excluded or limited by the Health Certificate or by any amendment or rider to it; and (5) authorized in advance by Anthem, if Prior Authorization is required. AR 112.

According to the Health Certificate, "all Covered Services and benefits are subject to the

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conditions, Exclusions, limitations, terms and provisions" of the Certificate, including any attachments, riders and endorsements. AR 24. "The fact that a Provider may prescribe, order, recommend, or approve a service, treatment or supply does not make it Medically Necessary or a Covered Service." The Health Certificate also provides that Anthem "bases [its] decisions about Prior Authorization, Precertification, Medical Necessity, Experimental/Investigative services and new technology" on its "clinical coverage guidelines and medical policy." AR 24. Anthem also considers "published peer-review medical literature, opinions or experts and the recommendations of nationally recognized public and private organizations which review the medical effectiveness of health care services and technology." AR 24.

a. Experimental/Investigative Services Exclusion

The Health Certificate contains a section entitled Non Covered Services/Exclusions that "indicates items which are excluded from benefit consideration, and are not considered covered services." AR 58. In this section, the Plan provides that Anthem "will not provide benefits for procedures, equipment, services, supplies or charges" that are "Experimental/Investigative or related to such, whether incurred prior to, or in connection with, or subsequent to the Experimental/Investigative services or supply," as determined by Anthem. AR 58. The Plan specifically provides that,"the fact that a service is the only treatment available for a condition will not make it eligible for coverage" if Anthem "deems it to be Experimental/Investigative." AR 58.

The term Experimental/Investigative is defined in the Plan, in relevant part, as: any device, service, treatment, or procedure "used in or directly related to the diagnosis, evaluation, or treatment of a disease, injury, illness, or other non health condition which [Anthem] determine[s] to be unproven." AR 114. The Plan directs participants to refer to the "Non-Covered Services/Exclusion" section for details on how Anthem determines whether a device, service, treatment, or procedure is experimental or investigative. AR 114.

The "Experimental/Investigative Services Exclusion" section of the Plan provides, in relevant part, that Anthem will deem any device, procedure, service, or treatment to be Experimental/Investigative if it determines that "one or more of the following criteria apply when the service is rendered with respect to the use for which benefits are sought." AR 63. The device, procedure, service, or treatment:

- Cannot be legally marketed in the United States without final approval of the Food and Drug Administration ("FDA"), or other licensing or regulatory agency, and such final approval has not been granted;
- Has been determined by the FDA to be contraindicated for the specific use;
- Is provided as part of a clinical research protocol or clinical trial or is provided in any other manner that is intended to evaluate the safety, toxicity, or efficacy of the device, procedure, service, or treatment;
- Is subject to review and approval of an Institutional Review Board ("IRB") or other body serving a similar function;
- Is provided pursuant to informed consent documents that describe the device,

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procedure, or treatment as Experimental/Investigative, or otherwise indicate that the safety, toxicity, or efficacy of the device, procedure, service, or treatment is under evaluation.

AR 63–64.

This section also provides, in relevant part, that any "service not deemed Experimental/ Investigative based on the criteria above may still be deemed Experimental/Investigative by" Anthem. AR 64. "In determining whether a Service is Experimental/Investigative," Anthem "will consider the information described below and assess whether":

- The scientific evidence is conclusory concerning the effect of the service on health outcomes;
- The evidence demonstrates the service improves net health outcomes of the total population for whom the service might be proposed by producing beneficial effects that outweigh any harmful effects;
- The evidence demonstrates the service has been shown to be beneficial for the total population for whom the service might be proposed as any established alternatives; and
- The evidence demonstrates the service has been shown to improve the net health outcomes of the total population for whom the service might be proposed under the usual conditions of medical practice outside clinical investigatory settings.

AR 64.

The section further provides, in relevant part, that the "information considered or evaluated" by Anthem "to determine whether" a device, procedure, service, or treatment is Experimental/ Investigative "under the above criteria may include one or more items from the following list which is not all inclusive"

- Published authoritative, peer-reviewed medical or scientific literature, or the absence thereof;
- Evaluations of national medical associations, consensus panels, and other technology evaluation bodies;
- Documents issued by and/or filed with the FDA or other federal, state or local agency with the authority to approve, regulate, or investigate the use of the device, procedure, service, or treatment;
- Documents of an IRB or other similar body performing substantially the same function;
- Consent documents and/or the written protocols used by treating physicians, other

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medical professionals, or facilities or by other treating physicians, other medical professionals or facilities studying substantially the same device, procedure, service, or treatment;

- Medical records;

- The opinions of consulting providers and other experts in the field

AR 64. Anthem will apply its "medical policy to identify and weigh all information and determine all questions pertaining to whether" a device, procedure, service, or treatment is Experimental/ Investigative. AR 64.

b. Prior Authorization Provision

The Health Care Management section of the Health Certificate explains the processes of Precertification, Predetermination, and Post Service Clinical Claims review. AR 90. This section provides that network providers "are required to obtain Prior Authorization" for participants "to receive benefits for certain services." AR 90. The Health Certificate defines Prior Authorization as "the process applied to certain services, supplies, treatment, and certain [d]rugs and/or therapeutic categories to define and/or limit the conditions under which they will be covered." AR 116. According to the Health Certificate, "Prior Authorization criteria will be based on multiple sources, including medical policy, clinical guidelines, and pharmacy and therapeutics guidelines." AR 90.

2. Medical Policy

Anthem maintains a Medical Policy on Cervical Total Disc Arthroplasty ("Medical Policy"). AR 133–145. This policy was reviewed and revised on August 6, 2015, approximately three months before Plaintiff's surgery. AR 133. The document "addresses the use of FDA approved cervical inter[-]vertebral discs in cervical total disc arthroplasty to treat symptomatic cervical disease when conservative treatment options have been unsuccessful." AR 133.

a. Medical Necessity of Pro Disc-C Device

Implantation of a Pro Disc-C cervical artificial inter-vertebral disc is considered medically necessary when all of the following criteria are met:

- The individual is skeletally mature; and

- Replacement of a degenerative cervical disc is limited to a single level from C3-C4 to C6-C7; and

- The individual does not have a previously implanted cervical artificial inter-vertebral disc device at another cervical level; and

- The individual has one or more of the following:
    - A cervical radicular neurologic deficit; or
    - Myelopathy due to a single-level abnormality localized to the disc space; or
    - Intractable cervical radicular pain which has failed at least 6 weeks of conservative, non-operative treatment; and

- An FDA-approved cervical artificial inter-vertebral device is used in accordance with FDA labeling and will be implanted using an anterior approach; and

- Imaging studies confirm one or more of thefollowing at the disc space identified on a neurological exam:
    - Herniated nucleus pulposus; or
    - Osteophyte formation; or
    - Not more than 50 percent loss of disc height as compared to adjacent levels; and

- The individual is free from contraindications to cervical total arthroplasty including, but not limited to those on the FDA label and all of the following:
    - Active systemic infection or infection localized to site of implantation; and
    - Osteoporosis defined as dual energy X-ray absorptiometry bone density measured T-score of negative 2.5 or worse; and
    - Marked cervical instability on neutral resting lateral or flexion/extension radiographs; with greater than 3 mm translation or greater than 11 degrees of angular difference to either adjacent level; and
    - Clinically compromised vertebral bodies at the affected level due to:
        - Current or past trauma; or
        - Anatomical deformity; or
        - Cervical spine malignancy; and
    - Moderate or severe spondylosis at the level to be treated, characterized by any of the following:
        - Bridging osteophytes; or
        - Loss of greater than 50% normal disc height; or
        - Absence of motion less than 2 degrees; and

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- Symptoms of cervical degenerative discdisease at more than one level

AR 133–34.

b. Investigational and Not Medically Necessary

The Medical Policy provides that "[c]ervical total disc arthroplasty is considered investigational and not medically necessary for all other devices including, but not limited to, Mobi-C Cervical Disc Prosthesis [used by Dr. Bray], Secure-C Cervical Artificial Disc and Prestige LP Cervical Disc." AR 134. The Medical Policy also provides that "[c]ervical total disc arthroplasty in an individual with a previous fusion at another cervical level is considered investigational and not medically necessary for all indications." AR 134.

Conclusions of Law

I. Jurisdiction and Venue

This action involves a claim for medical benefits under an employee welfare benefit plan that is subject to ERISA. Accordingly, the Court has original jurisdiction over this matter pursuant to 28 U.S.C. § 1331 and 29 U.S.C. § 1132(e). *See e.g.*, *Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 63 (1987). Venue in the United States District Court for the Central District of California is appropriate under 29 U.S.C. § 1132(e)(2) because the acts that gave rise to this lawsuit took place in this district.

II. Standard of Review

"Section 502 of ERISA entitles a participant or beneficiary of an ERISA-regulated plan to bring a civil action to recover benefits due to [her] under the terms of [the] plan, to enforce [her] rights under the terms of the plan, or to clarify [her] rights to future benefits under the terms of the plan." *Chappel v. Lab. Corp. of Am.*, 232 F.3d 719, 724 (9th Cir. 2000) (quoting 29 U.S.C. § 1132 (a)(1)(B)).

A plan administrator's decision to deny benefits is reviewed *de novo*, unless the Plan provides the administrator with discretionary authority to determine eligibility for benefits or to construe the terms of the Plan. *Firestone Tire & Rubber Co. v. Brunch*, 489 U.S. 101, 115 (1989). The Plan contains a discretionary clause; however, California Insurance Code Section 10110.6 outlaws discretionary clauses in life, health, and disability plans. The Ninth Circuit has specifically recognized that Insurance Code Section 10110.6 applies to group life, disability, and health plans fund by insurance companies that are otherwise governed by ERISA. *See Orzechowski v. The Boeing Co. Non-Union Long-Term Disability Plan*, 856 F.3d 686 (9th Cir. 2017); *see also Williby v. Aetna Life Ins. Co.*, 867 F.3d 1129, 1136 (9th Cir. 2017). Thus, the parties agree that the Court should review Anthem's denial of coverage *de novo*. *See* Joint Rule 26 Report, Docket No. 20; Trial Tr. 2:6–10.

Under a *de novo* standard of review, the Court performs "an independent and thorough inspection" of the Plan administrator's decision to determine whether the Plan administrator correctly or incorrectly denied benefits." *Silver v. Exec. Car Leasing Long-Term Disability Plan*, 466 F.3d 727, 733 (9th Cir. 2006). The Court may "evaluate the persuasiveness of conflicting

testimony and decide which is more likely true." *Kearney v. Standard Ins. Co.*, 175 F.3d 1084, 1095 (9th Cir. 1999) (en banc).

When a district court reviews a plan administrator's decision to deny benefits under the *de novo* standard of review, the claimant bears the burden of proving she is entitled to benefits under the Plan. *See Muniz v. Amec Const. Mgmt., Inc.*, 623 F.3d 1290, 1294 (9th Cir. 2010). If the claimant satisfies this burden, the administrator has the burden of proving that an exclusion applies. *See Intel Corp. v. Hartford Acc. & Indem. Co.*, 952 F.2d 1151, 1157 (9th Cir. 1991).

III. Discussion

According to the Health Certificate, a service, supply, or treatment is a Covered Service if it is: (1) medically necessary; (2) within the scope of the license of the provider performing the service; (3) rendered while the coverage under the Certificate is in place; (4) not experimental or investigative or otherwise excluded or limited by the Certificate or by any amendment or rider; and (5) authorized in advance by Anthem if prior authorization is required under the terms of the Certificate.

Plaintiff presented substantial evidence that the ADR surgery using the Mobi-C device was medically necessary under the terms of the Plan. According to the Plan, a procedure is medically necessary if it is: (1) medically appropriate and consistent with the symptoms and proper diagnosis or treatment of the Member's condition, illness, disease or injury; (2) obtained from a provider; (3) provided in accordance with applicable medical and professional standards; (4) known to be effective, as proven by scientific evidence, in materially improving health outcomes; (5) the most appropriate level of service that can be safely provided to a participant; (6) cost-effective compared to alternative interventions; (7) not experimental/investigative; (8) not primarily for the convenience of the member; and (9) not otherwise subject to an exclusion.

Despite Plaintiff's evidence, Anthem argues that the ADR surgery using the Mobi-C device is investigational, as described in the Medical Policy, and, thus, excluded under the Experimental/Investigative Services Exclusion of the Plan. The parties agree that Anthem bears the burden of proving the exclusion applies. Def.'s Findings of Fact & Conclusions of Law at 15 ¶ 1 [Docket No. 36].

A. Whether the Medical Policy Is Part of the Plan

"Every employee benefit plan shall be established and maintained pursuant to a written instrument." 29 U.S.C. § 1102(a)(1). "The written instrument requirement is intended to ensure that participants are on notice of the benefits to which they are entitled and their own obligations under the plan." *Wilson v. Moog Auto., Inc. Pension Plan & Trust for U.A.W. Emps.*, 193 F.3d 1004, 1008 (8th Cir. 1999) (citations omitted). The parties agree that Health Certificate constitutes the Plan document. However, they disagree as to whether the Medical Policy is also part of the Plan.

"[A]n employee benefit plan under ERISA can be comprised of more than one document." *Gonzales v. Unum Life Ins. Co. of Am.*, 861 F. Supp. 2d 1099, 1107 (S.D. Cal. 2012) (internal citation and quotation marks omitted). Indeed, multiple courts have found that an ERISA plan may

include formal and informal documents where they are incorporated by reference. *Noah U. v. Tribune Co. Med. Plan*, 138 F. Supp. 3d 1134, 1144 (C.D. Cal. 2015); *see e.g., Gonzales*, 861 F. Supp. 2d at 1107 (finding that a Plan document may incorporate other formal or informal documents); *Langlois v. Metro. Life Ins. Co.*, 833 F. Supp. 2d 1182, 1185 (N.D. Cal. 2011) (finding a provision in a SPD enforceable where the SPD expressly provided that the company intended that the terms in the SPD be legally enforceable). Moreover, "there is no requirement that documents claimed to collectively form the employee benefit plan be formally labeled as such." *Horn v. Berdon, Inc. Defined Benefit Pension Plan*, 938 F. 2d 125, 127 (9th Cir. 1991).

Plaintiff contends that Anthem's Medical Policy is not part of the Plan and, therefore, the Court should not consider it when determining whether Anthem properly denied Plaintiff's claim. Although the Medical Policy is contained in a separate document, it is referenced throughout the Health Certificate, including in the Table of Contents, Covered Services section, Non Covered Services/Exclusion section, Experimental/Investigative Exclusion section, and in the portion of the Health Care Management section discussing prior authorizations. In each of these sections, Anthem provides participants with ample notice that the terms of the policy will be applied to "identify and weigh all information and determine all questions" related to whether a procedure, device, treatment, or supply is experimental or investigative. AR 64. In addition, the Health Certificate clearly provides that prior authorization criteria will be based on "multiple sources including medical policy, clinical guidelines, and pharmacy and therapeutics guidelines." AR 90. Accordingly, the Court concludes that the Medical Policy is part of the Plan.

B. Experimental/Investigative Services Exclusion

Anthem argues that the ADR surgery using the Mobi-C device is not covered because it falls within the scope of the Experimental/Investigative Services Exclusion detailed in the Plan. Anthem advances two primary reasons for application of the exclusion: (1) the Mobi-C device is experimental; and (2) ADR surgery is investigational and not covered in patients with prior fusions.

Under the Experimental/Investigative Services Exclusion, a device, treatment, service, or procedure is experimental or investigative if Anthem determines that one or more of the following criteria apply: (1) the device cannot be legally marketed in the United States without final approval of the FDA and final approval has not been granted; (2) the device has been determined by the FDA to be contraindicated for the specific use; (3) the device is provided as part of a clinical research protocol or clinical trial or any other manner that is intended to evaluate the safety or efficacy of the device; (4) the device is subject to review and approval of an institutional review board or other body serving a similar body; (5) the device is provided pursuant to an informed consent document that describes it as experimental or investigative or otherwise indicates that its safety or efficacy is under evaluation.

Moreover, even if these criteria are not satisfied, Anthem may deem a device, treatment, procedure, or service investigative or experimental where scientific evidence is inconclusive regarding the effectiveness of the device, treatment, procedure or service on health outcomes, or fails to demonstrate that the procedure is beneficial for the total population that may receive the service, device, treatment, or procedure. AR 64.

1. Whether the Mobi-C is Experimental

Anthem first argues that the ADR surgery using the Mobi-C device is experimental because it falls within the scope of the exclusion that provides a procedure or device is experimental if it "cannot be legally marketed in the United States without the final approval" of the FDA and "such final approval has not been granted." AR 63. According to Anthem, the Mobi-C had only received two years of pre-market approval by the FDA at the time of Plaintiff's surgery and had not received final approval. The Court finds Anthem's argument borders on the frivolous. The uncontroverted evidence presented clearly demonstrates that the Mobi-C could be legally marketed in the United States at the time of Plaintiff's surgery and that the FDA had approved sales of the device. AR 133, 138–39. Accordingly, the Court concludes that the use of the Mobi-C in ADR surgery does not fall within the scope of the exclusion.

2. Whether the Surgery Is Experimental/Investigative In Patients With Prior Fusions

Anthem also argues that "cervical disc arthroplasty in an individual with a previous fusion at another cervical level is considered investigational and not medically necessary for all indications" under the terms of its Medical Policy. For support, Anthem relies on the study from Phillips et al., cited in the Medical Policy, which suggests that although ADR after a prior fusion may be effective in the short-term, additional studies are needed to determine whether it is effective in the long-term. AR 139.

The Court agrees with Anthem that ADR surgery in individuals with a prior fusion at another cervical level may be properly deemed an investigative procedure within the meaning of the Experimental/Investigative exclusion. First, the exclusion clearly provides that Anthem may deem any service experimental or investigative even if the service does not meet the criteria outlined in the exclusion. The exclusion also plainly provides that in doing so, Anthem will consider: whether scientific evidence conclusively establishes the effect of the service on health outcomes; whether evidence demonstrates the service improves net health outcomes of the total population for whom the service might be proposed by producing beneficial effects that outweigh any harmful effects; whether the evidence demonstrates the service has been shown to be as beneficial for the total population for whom the service might be proposed as any established alternatives; and whether the evidence demonstrates the service has been shown to improve the net health outcomes of the total population for whom the service might be proposed under the usual conditions of medical practice outside clinical investigatory settings. As previously discussed, Anthem has cited to scientific literature that arguably suggests that ADR surgery in patients with prior fusion does not conclusively establish that the treatment is effective or that all populations who receive the service will benefit from it.

Despite the plain language in the Health Certificate, Plaintiff argues that under the reasonable expectations doctrine, this exclusion is not enforceable. Under this doctrine, where a "plan's attempted exclusion [is] not clear, plain, and conspicuous enough to negate the claimant's objectively reasonable expectations of coverage, it . . . is unenforceable." *Winters v. Costco Wholesale Corp.*, 49 F.3d 550, 554 (9th Cir. 1995). The Court disagrees. As explained in more detail above, the exclusion clearly provides that Anthem may deem a procedure experimental or investigative where the scientific literature does not conclusively establish that it will improve health

outcomes or benefit all patients who receive the treatment. As a result, a claimant under the Plan could reasonably expect that a device, procedure, treatment, or service would not be covered when the scientific literature does not conclusively establish that it improves health benefits. Accordingly, the Court concludes that an ADR surgery in a patient with a prior fusion falls within the scope of the Investigative/Experimental exclusion.

C. Waiver

Despite the fact that Plaintiff's ADR surgery falls within the scope of the exclusion because of Plaintiff's prior fusion, Plaintiff argues that Anthem waived its right to deny her claim under this exclusion because it initially approved her ADR surgery, albeit with a Pro Disc-C device. The Court agrees. Waiver occurs when "a party intentionally relinquishes a right" or "when that party's acts are so inconsistent with an intent to enforce the right as to induce a reasonable belief that such right has been relinquished." *Salyers v. Metro. Life Ins. Co.*, 871 F.3d 934, 938 (9th Cir. 2017). The doctrine of waiver "looks to the act, or the consequences of the act, of one side only." *Intel Corp. v. Hartford Accident & Indem. Co.*, 952 F.2d 1551, 1559 (9th Cir. 1991) (internal citations and question marks omitted). Several courts have applied the doctrine of waiver in ERISA cases. *See id.*

It was not until November 9, 2015 that Anthem decided to "overturn" its previous approval of Plaintiff's surgery relying on its existing Medical Policy, which deems "cervical disc arthroplasty in an individual with a previous fusion at another cervical level . . . investigational and not medically necessary for all indications" even though Anthem was fully aware of Plaintiff's prior fusion and its own Medical Policy at the time of its initial approval. The Administrative Record conclusively establishes that Anthem was fully advised that Plaintiff had a prior fusion when it initially approved her ADR surgery (Reference No. 0239572642). Specifically, Anthem's notes, dated September 30, 2015, clearly indicate that Plaintiff had a prior fusion at the C4-C6 vertebrate. In addition, Anthem's Medical Director was fully aware of Plaintiff's prior fusion when he agreed that the ADR surgery was medically necessary during a peer-to-peer review with Dr. Bray. AR 183. Indeed, it was only after Dr. Bray appealed Anthem's decision regarding the type of device to be used in the surgery that Anthem suddenly decided to completely reverse its prior authorization and deny Plaintiff's entire claim. Because there was no new information regarding Plaintiff's prior condition or any change in its Medical Policy, the Court concludes that Anthem waived its right to rely on the exclusion that was available to it when it provided its initial approval.[2]

[2] Anthem argues that it properly denied the claim because Dr. Bray performed the ADR surgery using a Mobi-C device instead of a Pro Disc-C device. However, the type of device is irrelevant to the prior fusion exclusion ultimately relied on by Anthem. The fact that Anthem did not invoke this exclusion until well after Dr. Bray appealed Anthem's refusal to approve use of the Mobi-C device further demonstrates that Anthem waived this exclusion.

IV. Conclusion

In light of the foregoing, the Court concludes that Anthem improperly denied Plaintiff's claim for benefits for the ADR surgery using the Mobi-C device and enters judgment in favor of Plaintiff. Counsel for the parties are ordered to meet and confer and prepare a joint proposed Judgment which is consistent with this Order. The parties shall lodge the joint proposed Judgment with the Court by December 18, 2017.

IT IS SO ORDERED.