UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

DANICA DUBAICH,

Plaintiff,

v.

CONNECTICUT GENERAL LIFE INSURANCE COMPANY,

Defendant.

Case No. CV 11-10570 DMG (AJWx)

AMENDED FINDINGS OF FACT AND CONCLUSIONS OF LAW

This matter is before the Court following a bench trial on the administrative record on November 6, 2012. Russell G. Petti of The Law Offices of Russell G. Petti appeared on behalf of Plaintiff, Danica Dubaich. Donald P. Sullivan of Wilson, Elser, Moskowitz, Edelman & Dicker LLP appeared on behalf of Defendant CIGNA.[1] Plaintiff filed a supplemental brief on November 16, 2012. On April 25, 2013, the Court issued

[1] Plaintiff refers to Defendant throughout the briefing as CIGNA, without objection from Defendant. The Court therefore uses the same appellation because CIGNA is the institution responsible for all but the initial claims review, which is performed by Connecticut General Life Insurance Company ("CGLIC") as the Claims Administrator.

Findings of Fact and Conclusions of Law ("FFCL"), finding CIGNA was entitled to judgment under the benefit plan language. [Doc. # 28.] Thereafter, on June 5, 2013, the Court granted Plaintiff's motion to alter judgment after realizing that the language on which the Court previously relied was not contained within the plan document, but rather in a policy document internal to CIGNA. [Doc. # 33.] The Court therefore vacated the prior FFCL.

Having again reviewed the administrative record and the arguments of counsel as presented at the hearing and in their written submissions, the Court makes the following amended findings of fact and conclusions of law pursuant to Rule 52 of the Federal Rules of Civil Procedure.

I. FINDINGS OF FACT

1. Plaintiff Danica Dubaich was a participant in the HCA Health and Welfare Benefit plan ("Plan"), a self-funded employee welfare benefit plan, as that term is defined in section 2(1) of the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1002(1). The Plan is sponsored by HCA for the benefit of its employees. (Administrative Record ("A.R.") at 366-69.)

2. Dubaich was covered under CIGNA Coverage Plan 0104. (A.R. at 9, 91.)

Pertinent Plan Terms

3. The Plan states that it covers medical expenses which are determined to be medically necessary by the Plan Administrator. (A.R. at 217-18.)

4. To be considered "medically necessary" a treatment must:

- Be consistent with the diagnosis
- Meet quality medical practice standards
- Be the most appropriate level of service (for example, in the case of hospital inpatient care, care that could not be appropriately provided on an outpatient basis)
- Be recognized as an accepted medical practice and have received the required federal approval

- Not be primarily for the comfort and convenience of the patient

(A.R. at 217.)

5. The Plan excludes experimental and investigational treatments, listed under "General Medical Expenses Not Covered." (A.R. at 226.) The specific language is as follows:

> Research, experimental, investigational and unproven procedures, supplies, drugs and devices (Federal Drug Administration [FDA] approval does not necessarily mean a procedure or supply has been removed from the experimental list), with the exception of precertified clinical trials.

(*Id.* at 227.)

6. The term "experimental" is defined as follows:

> Experimental Procedures: Any medical procedure, equipment, treatment or course of treatment, or drugs or medicines that are:
>
> - limited to research
> - not proven in an objective manner to have therapeutic value or benefit
> - restricted to use by medical facilities capable of carrying out scientific studies
> - of questionable medical effectiveness or
> - would be considered inappropriate medical treatment
>
> To determine whether a procedure is experimental, HCA will consider, among other things, commissioned studies, opinions and references to or by the American Medical Association, the federal Food and Drug Administration, the Department of Health and Human Services, the national Institutes of Health, the Council of Medical Specialty Societies and any other association or program or agency that has the authority to review or regulate medical testing or treatment.

(A.R. at 371.) The terms "research," "investigational," and "unproven" are not defined in the Plan. (*Id.* at 370-72.)

7. The Plan grants the Plan Administrator discretionary authority to interpret the Plan's terms and make benefit payments. (A.R. at 217, 366.)

8. The Plan defines the "Plan Administrator" as the HCA Plan Administration Committee. "The HCA Plan Administration Committee is the Plan Administrator for the HCA 401(k) Plan and the HCA Health and Welfare Benefits Plan." (A.R. at 366.)

9. "The Plan Administrator may delegate any of its duties and responsibilities to one or more persons or entities. Such delegation of authority must be in writing, and must identify the delegate and the scope of the delegated responsibilities." (A.R. at 366.)

10. The Plan states that "[f]or the self-funded benefits (Medical, Dental, Wellness, HRA and Health Care FSA), HCA has delegated to the Claims Administrator initial claims determinations." (A.R. at 352.)

11. The Plan defines Claims Administrator as "[t]he company responsible for administering and paying claims under a benefit plan." (A.R. at 370.) In this case, the Claims Administrator is CGLIC.

12. Regarding appeals, the Plan states:

> All decisions following a review by the Claims Administrator are final and binding for purposes of the plan's internal claim review procedures. . . . If your claim is denied in whole or in part after all stages of the internal review procedures have been completed (except any voluntary levels of review), you have the right to seek to have your claim paid by filing a request for external review or a civil action in court, but you will not be able to do so unless you have completed all of the levels of the internal review process (except any voluntary levels) required under the plan.

(A.R. at 357.)

13. Under the Plan, external review is an alternative to court review, with the option granted to the beneficiary. If external review is elected, the Claims Administrator would then "complete a preliminary review . . . to determine whether [the] request is eligible for external review," and would subsequently "issue a notification of [] external review eligibility." (A.R. at 357.)

Dubaich's Initial Claim

14. On or about June 15, 2011, Dubaich was seen by her physician and orthopedic surgeon, Dr. Brian D. Rudin, for complaints of bilateral foot pain, low back pain, left arm and hand weakness, right thigh numbness, right hip pain, and headaches. (A.R. at 24.) Dr. Rudin does business at Brian D. Rudin, M.D., Inc. (*Id.* at 33.)

15. Dr. Rudin concluded that Dubaich had degenerative disc disease at disc L5-S1. (A.R. at 31.)

16. On June 29, 2011, Dubaich underwent a discogram, a surgical procedure designed to identify which spinal discs are pain generators. The MRI and Dr. Rudin had already identified the damaged L5-S1 as a pain generator. The discogram was undertaken to determine "whether a pain generator is also attributable to the disc at L4-L5." (A.R. at 35.) The discogram showed "an annular tear of the disc at L4-L5" and identified that disc as a pain generator as well. (*Id.*)

17. Dr. Rudin observed degeneration at L4-L5 in his initial review. (A.R. at 24.)

18. Plaintiff therefore has multi-level degenerative disc disease.

19. According to the CIGNA Medical Coverage Policy, the standard surgical treatment for pain caused by degenerative disc disease is spinal fusion. (A.R. at 151.) This involves immobilizing the unstable disc by fusing it to the stable adjacent discs. "Spinal fusion alters the biomechanics of the spine, reducing motion of the spinal segments, potentially leading to premature disc degeneration at adjacent levels." (*Id.*) "Preservation of motion within the spinal column and avoidance of adjacent segment disease are goals for treatment of patients with degenerative disc disease." (*Id.*) Dr. Rudin concluded that conservative treatment had failed and that Dubaich was a good

candidate for an L5-S1 artificial disc replacement ("ADR"), designed as an alternative to fusion.

20. The CIGNA Medical Coverage Policy states: "CIGNA covers the surgical implantation of the Charité or ProDisc-L . . . as medically necessary" when the required criteria are met. (A.R. at 150.)

21. On June 28, 2011, Dr. Rudin made a claim for a two-level ADR at L4-5 and L5-S1. (A.R. at 13.)

22. Dr. Rudin's notes read as follows:

> [Dubaich] would also be a good candidate for a disc replacement or a standard ACDF at this level in the future. For her lumbar spine we went over the perioperative course in great detail. I showed her the implant and where it would go. She understands the risks, benefits, alternatives of surgery, which include but are not limited to bleeding, infection, scar, nerve injury, dural tear, hardware failure, future surgery, incomplete recovery, adjacent segment disease, transfusion, anesthetic risks including death.

(A.R. at 31.)

23. To date, the U.S. Food and Drug Administration ("FDA") has approved only two lumbar intervertebral disc prostheses: the Charité Artificial Disc and the ProDisc-L Lumbar. (A.R. at 151.) The FDA granted premarket approval to the ProDisc-L in August 2006 for "spinal arthroplasty in skeletally mature patients with [degenerative disc disease ("DDD")] at one level of the lumbar spine from L3-S1." (*Id.* at 155; Pl.'s Request for Judicial Notice, Ex. A [Doc. 21-1]). While Plaintiff disputes that the FDA approved the device only for single-level DDD, the approval letter clearly contemplates single-level use only. (*Id.* ("These DOD patients should have no more than Grade 1 spondylolisthesis at the involved *level*." (emphasis added)).)

24. On July 11, 2011, Kim Jones, a Prior Authorization Nurse assigned to the case, reviewed Dubaich's file. Jones determined that the treatment should be denied as it

was not medically necessary. Specifically, Jones found that "the documentation submitted does not confirm that disc degeneration has been confirmed on complex imaging studies such as magnetic resonance imaging or computerized tomography." (A.R. at 15.) This was an internal finding, and CIGNA did not share this or any other finding regarding medical necessity with Dubaich.

25. Next, Dr. Granato, a urologist, reviewed Dubaich's file on behalf of CIGNA. Dr. Granato opined that the treatment should be denied as experimental. Dr. Granato's notes read as follows:

> Based upon current available information, coverage cannot be approved because there is insufficient scientific evidence to demonstrate the safety and/or effectiveness of any of the following in treating degenerative disc disease:
>
> - Charité or ProDisc-L lumbosacral intervertebral disc prosthesis when any of the following apply :
>   - o the planned procedure includes the combined use of a prosthesis and spinal fusion
>   - o simultaneous multi-level implantation is planned
>   - o the implant will be inserted outside of the L4-S1 region (Charité) or outside of the L3-S 1 region (ProDisc-L-L) [sic]
>   - o the individual has osteopenia or osteoporosis (T-score less than -1.0) –the individual has a history of a prior lumbar fusion
>   - o there is evidence on imaging studies the spine [sic] of any of the following:
>   - ▪ degenerative spondylolisthesis of Grade 2 or greater
>   - ▪ infection
>   - ▪ multi-level degenerative disc disease
>   - ▪ nerve root compression or spinal stenosis

- pars interarticularis defect with either spondylolysis or spondylolisthesis
- scoliosis
- severe facet joint arthrosis
- spinal fracture
- tumor

- a lumbosacral disc prosthesis other than Charité or ProDisc-L

At the present time, each is considered non-standard therapy and falls under the category of experimental/investigational/unproven. Your benefit plan does not cover experimental/investigational/unproven services.

(A.R. at 12.)

26. The above language is not taken from the Plan. Rather, it is a direct quote from the "CIGNA Medical Coverage Policy," an internal document "intended to provide [CIGNA employees] guidance in interpreting certain standard CIGNA HealthCare benefit plans." (A.R. at 150-51.) With the exception of the last paragraph, the above language is quoted virtually verbatim from the Policy, except for two typographical errors – the use of "ProDisc-L-L" instead of "ProDisc-L" and the space between "apply" and the colon in the 7th line – and the omission of the word "isthmic" before "spondylolisthesis." (*Compare id.* at 11-12 *with id.* at 150-51.)

27. Dr. Granato's notes do not indicate which condition renders the treatment recommended by Dr. Rudin "experimental/investigational/unproven," and do not state that the requested treatment is not approved by the FDA or that the requested treatment could be denied as not medically necessary. (A.R. at 12.)

28. On July 11, 2011, CIGNA issued its "Initial Case Resolution Letter" denying Dubaich's requested treatment. The language of the denial letter quotes verbatim from Dr. Granato's notes. (A.R. at 18-19.) Like Dr. Granato's notes, the letter does not

specify the reason for the denial, nor does it mention a lack of FDA approval or absence of medical necessity.

Dubaich's First Appeal of CIGNA's Denial

29. On July 13, 2011, Dr. Rudin filed an appeal on behalf of Dubaich. (A.R. at 43.) In his letter, Dr. Rudin stated that he believed the reason for the denial was "the lack of scientific evidence when the planned procedure involves multilevel implantation." In the letter, Dr. Rubin opined that while there might have been some question in the past regarding the effectiveness of two-level ADR, at this point, "there is plenty of scientific evidence that supports the use of multilevel implantation of the Synthes ProDisc-L." (*Id.* at 43.)

30. In his letter, Dr. Rudin stated that he had personally performed more than 200 disc replacements. While he did not explicitly specify whether this number applied only to multi-level disc replacement, he implied as such by comparing them to multilevel fusion. (A.R. at 43.)

31. Accompanying Dr. Rudin's letter was a 2011 study by Delamarter, *et al.*, published in *The Journal of Bone and Joint Surgery* ("Delamarter Study"). (A.R. at 45-55.) The full title of this study is "Prospective, Randomized, Multicenter Food and Drug Administration Investigational Device Exemption Study of the ProDisc-L Total Disc Replacement Compared with Circumferential Arthrodesis for the Treatment of Two-Level Lumbar Degenerative Disc Disease." (*Id.* at 45.) The study compared the efficacy of ProDisc-L ADR with that of spinal fusion for "the treatment of degenerative disc disease at two contiguous vertebral levels from L3 to S1." (*Id.* at 45.) Using "a composite regulatory FDA-guided end point consisting of ten criteria," the study found that 58.8% of the two-level ADR patients "met all ten criteria and were considered a study success," as compared to 47.8% of the spinal fusion patients. (*Id.* at 47-48.) It found that "the mean improvement [in back pain, as measured by the Oswestry Disability Index (ODI)] from baseline was 52.4% in the [ADR] group compared with 40.9% in the [fusion] group." (*Id.* at 48.) According to the study, its "results suggest that the ProDisc-L total disc

replacement is an appropriate alternate treatment to lumbar arthrodesis in [the two-level degenerative disc disease] patient population." (*Id.* at 54.)

32. The study also noted that it had several limitations. "Despite the positive findings, the present study was limited by its regulatory design. (A.R. at 54.) "The statistical composite end point in the . . . study was designed exclusively for regulatory application purposes and is not a clinically relevant representation of patient outcomes . . . . The twenty-four-month end point of this study was not long enough to adequately evaluate the benefits or disadvantages of" ADR or fusion for patients with two-level degenerative disc disease." (*Id.*)

33. Dr. Rudin's appeal also included an abstract of a 2007 study by Hannibal, *et al.*, published in *Spine* ("Hannibal Study"). (A.R. at 59.) The full title of the study is "ProDisc-L Total Disc Replacement: A Comparison of 1-Level Versus 2-Level Arthroplasty Patients With a Minimum 2-Year Follow Up." (*Id.* at 59.) The Hannibal Study followed patients who had received two-level ADR and compared their outcomes with patients who had received one-level ADR. (*Id.* 59-60.) The study "was unable to identify a statistically significant difference in outcome between 1- and 2-level ProDisc [ADR] patients in a cohort from a single center." (*Id.* at 60.) The study was referenced in the CIGNA Medical Coverage Policy. (*Id.* at 179.)

34. Dr. Rudin included with his appeal letter an abstract from a report presented by Dr. Goldstein and others at Spine Week 2008 ("Goldstein Report"). (A.R. at 61.) The Goldstein Report states that "patients who received the [ADR] at either one or two levels demonstrated a similar degree of overall improvement compared to control group patients who had a fusion." (*Id.*) It found ProDisc-L to be "safe and effective for patients who have one- or two-level degenerative disease between L3 and S1." (*Id.* at 62.)

35. Dr. Rudin also included a summary of an earlier 2005 German study conducted by Dr. Bertagnoli, titled "The Treatment of Disabling Single-Level Lumbar Discogenic Low Back Pain with Total Disc Arthroplasty Utilizing the ProDisc Prosthesis ("Bertagnoli Study"). (A.R. at 63.) The Bertagnoli Study found "the ProDisc prosthesis

to be a safe and effective treatment for patients with debilitating, multilevel low back pain related to fusion surgery or degenerative conditions." (*Id*. at 64.) Of the 93 patients in the study, "[a]lmost 90% of the [ADR] patients were satisfied . . . , [n]one of the patients had severe or extreme low back pain," and "[p]atients' ranges of motion increased and were maintained at follow-up." (*Id*.) The summary also noted that while "[t]he results were encouraging, . . . more studies are still needed to 'provide some indication' of pain relief and sustained movement at long-term follow-up." (*Id.* at 63.) The Bertagnoli Study was referenced in the CIGNA Medical Coverage Policy. (*Id.* at 176.)

36. On August 10, 2011, Dr. Mino, an orthopedic surgeon, conducted CIGNA's review of its earlier decision. (A.R. at 9, 82.) Dr. Mino made the determination to "[u]phold noncertification of Lumbar intervertebral disc replacement 28857x2." (*Id.* at 9.)

37. Dr. Mino reiterated that the procedure was "experimental/ investigational/unproven," and then repeated the list from the Initial Case Resolution Letter and Dr. Granato's notes, with the exception of an "a" added before the first appearance of the word "Charité." As demonstrated by the repeated inclusion of the typographical errors, this rationale was copied verbatim from the earlier decision. (A.R. at 9-10.)

38. On August 10, 2011, Dr. Mino wrote to Dubaich informing her of his decision to uphold the denial. ("First Appeal Letter") (A.R. at 80-82.) Dr. Mino did not individually address or rebut any of the materials referenced by or accompanying Dr. Rudin's appeal, though he did state that he reviewed all the supporting documentation. (A.R. at 81.) Dr. Mino seems to have copied and pasted the Initial Case Resolution Letter, as indicated by the perpetuation of the typos.

39. Dr. Mino's letter also added generally:

> The quality and quantity of data in the current peer-reviewed scientific medical literature is inadequate to establish the clinical utility, safety and efficacy of the use of an intervertebral disk prosthesis in any of these clinical presentations. The requested service is therefore excluded from

> coverage under your medical benefit plan as experimental/investigational/unproven.

(*Id.* at 10, 81.) Dr. Mino cited no studies contradicting the findings in the materials supplied by Dr. Rudin.

40. As with the Initial Case Resolution Letter and Dr. Granato's notes, Dr. Mino's notes do not specify the characteristics making the treatment experimental, nor do they mention a lack of FDA approval or absence of medical necessity as a basis for the denial.

Dubaich's Appeal to the Benefit Appeals Committee

41. On August 26, 2011, Dubaich filed a second-level appeal to the Benefit Appeals Committee. (A.R. at 145.)

42. The Benefit Appeals Committee held a hearing on September 27, 2011, which Dubaich and Dr. Rudin attended telephonically. (A.R. at 145-148.)

43. The question the Benefit Appeals Committee considered was: "Is the requested intervention; lumbar artificial diskectomy (22857) medically necessary as per the medical coverage policy?" (A.R. at 147.) At the hearing, the appeal summary was read aloud to the Committee and the Committee voted to uphold the denial. The notes state that the review was based on "the available documents and specialist recommendation." There is no indication of whether the documents included those provided by Dr. Rudin. (A.R. at 148.)

44. The Benefit Appeals Committee upheld the denial as experimental on the ground that a "[s]imultaneous multilevel implantation is planned." (A.R. at 145.)

45. In its rationale, the Committee stated that "[p]revious denial letters have outlined the lack of sufficient published data in peer reviewed medical literature demonstrating the effectiveness and long term safety of more than one simultaneous disc insertions. . . . There has been no new compelling information submitted which would change this position at this time." (A.R. at 148.)

46. At no point in the record does CIGNA address or mention any of the studies included in Dubaich's appeal other than the Hannibal Study and the Bertagnoli Study which are cited as references in the internal policy.

47. CIGNA appears to have relied solely on a prior internal policy determination that multi-level ADR is experimental or unproven, without explicitly addressing the new information provided by Dr. Rudin.

48. The review by the Benefit Appeals Committee was an internal review. (A.R. at 355.)

49. On September 28, 2011, CIGNA communicated the Benefit Appeals Committee's decision upholding the denial of benefits to Dubaich ("Second Appeal Letter"). This letter repeated the rationale of the Benefit Appeals Committee. The letter also identified the provisions of the Plan that pertain to the denial. (A.R. at 141-143.)

50. Although, according to the internal notes, the question under review was whether the treatment was medically necessary, the final denial letter did not include any reference to medical necessity or FDA approval. (A.R. at 141-143.)

Dubaich Did Not Request an External Review and CIGNA Conducted No Such Review

51. CIGNA's final denial letter states that the appeal was also reviewed by an external reviewer, but no one is named. (A.R. at 141.)

52. The Benefit Appeals Committee meeting minutes list Edward Jordan as the "NAU Reviewer." (A.R. at 145.) While CIGNA has referred to "Dr. Jordan," the record does not at any time identify him as a medical doctor.

53. Dubaich did not request an external review and received no notice of eligibility for such a review. There is no record of an external review having been conducted.

The Plan Administrator Was Not Involved in the Decision

54. The denial of coverage was not issued by the HCA Plan Administration Committee, which is a different entity than the Benefit Appeals Committee.

55. The Benefit Appeals Committee made the final decision denying coverage.

56. There is no evidence in the record that the HCA Plan Administration Committee delegated its discretionary authority to the Benefit Appeals Committee.

II. CONCLUSIONS OF LAW

1. Dubaich's health benefits claims are governed by ERISA, 29 U.S.C. § 1001 *et seq*.

2. This Court has subject matter jurisdiction pursuant to ERISA, 29 U.S.C. § 1132(a), and 28 U.S.C. § 1331.

The Standard Of Review is *De Novo*

3. A district court reviews an administrator's denial of benefits *de novo* "unless the benefit plan gives the administrator or fiduciary discretionary authority to determine eligibility for benefits." *Saffon v. Wells Fargo & Co. Long Term Disability Plan*, 522 F.3d 863, 866 (9th Cir. 2008) (citing *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 115 (1989)). If the benefit plan does grant the administrator discretionary authority, then the district court reviews the administrator's decision for an abuse of discretion. *Id*.

4. A grant or delegation of discretion cannot be inferred or implied. Rather the grant of delegation must be clear and unambiguous. *Feibusch v. Integrated Device Technology, Inc. Employee Ben. Plan*, 463 F.3d 880, 883 (9th Cir. 2006) ("Neither the parties nor the courts should have to divine whether discretion is conferred. It either is, in so many words, or it isn't.").

5. CIGNA bears the burden to prove that the entity which actually denied Dubaich's claim was delegated or granted discretionary authority by the Plan. *Sharkey v. Ultramar Energy Ltd., Lasmo PLC, Lasmo (AUL Ltd.)*, 70 F.3d 226, 229-230 (2d Cir. 1995) ("[T]he party claiming deferential review should prove the predicate that justifies it."). CIGNA has not met this burden. The Benefit Appeals Committee conducted the final review for which there is a record. The Plan grants discretionary authority only to the Plan Administrator, not the Benefit Appeals Committee, and there is no evidence of a delegation of that discretion to the Benefit Appeals Committee in the record.

6. The Court therefore reviews CIGNA's denial of benefits *de novo*.

The Court May Not Consider Arguments Raised for the First Time in Litigation

7. A defendant in an ERISA case may not assert new grounds for denial once litigation in federal court has begun. *Harlick*, 686 F.3d at 720 ("The general rule . . . in this circuit and in others, is that a court will not allow an ERISA plan administrator to assert a reason for denial of benefits that it had not given during the administrative process.").

8. Because CIGNA did not raise either medical necessity or FDA approval as grounds for denial in any of its communications with Dubaich during the administrative proceedings, those grounds for denial are waived, and the Court may not consider them.

CIGNA Bears the Burden of Proof that an Exclusion Applies

9. Dubaich bears the burden of proof that a procedure is covered. If Dubaich can establish that a procedure is covered in the first instance, CIGNA bears the burden of demonstrating that an exclusion applies. *See Intel Corp. v. Hartford Acc. & Indem. Co.*, 952 F.2d 1551, 1557 (9th Cir. 1991) ("In insurance litigation, while the burden is on the insurer to prove a claim covered falls within an exclusion, the burden is on the insured initially to prove that an event is a claim within the scope of the basic coverage." (internal quotation omitted)).

10. The Plan covers expenses which are considered medically necessary. (A.R. at 218.) Moreover, the CIGNA Medical Coverage Policy states that CIGNA covers the surgical implantation of the ProDisc-L as "medically necessary" when the required criteria are met. Plaintiff has put forth evidence of medical necessity, whereas Defendant has waived the defense of lack of medical necessity. Plaintiff has therefore established medical necessity for the requested treatment and has met her burden to demonstrate coverage.

11. According to the CIGNA Medical Coverage Policy, CIGNA excludes coverage of experimental procedures. Because it is an exclusion, CIGNA has the burden of proving that multi-level ADR fits within the Plan's definition of "experimental."

Specifically, CIGNA must show that multi-level ADR is either (1) limited to research; (2) not proven in an objective manner to have therapeutic value or benefit, (3) restricted to use by medical facilities capable of carrying out scientific studies; (4) of questionable medical effectiveness; or (5) would be considered inappropriate medical treatment. (A.R. at 371.)

CIGNA Fails to Prove that the Plan Excludes Multi-Level ADR from Coverage

12. As a general matter, CIGNA has made no showing that multi-level ADR is experimental. The initial denial and first appeal both quoted from CIGNA's internal policy. CIGNA simply relied on its prior conclusions as reflected in its internal policy and did not address the new information provided by Dr. Rudin.

13. CIGNA has not met its burden to show that multi-level ADR is limited to research. Dr. Rudin offered Dubaich the procedure and has personally performed approximately 200 multi-level disc replacements. Nothing in the record establishes that the procedure is limited to research. Therefore, on this record, it does not appear that multi-level ADR is limited to research.

14. CIGNA has not met its burden to show that multi-level ADR lacks therapeutic benefit. In addition to recommending the procedure as therapeutic for Dubaich (and 200 other patients for whom he has performed the procedure), Dr. Rudin submitted several studies demonstrating therapeutic benefit. The Delamarter Study found two-level ADR to have better reduced back pain than spinal fusion, and the Bertagnoli Study found that two-level ADR eliminated instances of severe back pain and improved ranges of motion. While the CIGNA Medical Coverage Policy references the Bertagnoli Study, CIGNA has not rebutted this evidence.

15. CIGNA has not met its burden to show that multi-level ADR is restricted to use by medical facilities capable of carrying out scientific studies. Dr. Rudin is an orthopedic surgeon and has performed over 200 disc replacements. CIGNA has not shown that the offices of "Brian D. Rudin, M.D., Inc." performed these procedures as a part of any "scientific studies."

16. CIGNA has not met its burden to show that multi-level ADR is of questionable medical effectiveness. All the studies Dr. Rudin submitted found equal or better success in two-level ADR as single-level ADR. CIGNA does not dispute that single-level ADR is medically effective. CIGNA has not demonstrated that two-level ADR is not similarly effective.

17. CIGNA has not met its burden to show that multi-level ADR would be considered inappropriate medical treatment. Dr. Rudin is a credentialed orthopedic surgeon and has recommended the procedure. Dr. Rudin stated that Dubaich specifically is a good candidate for multi-level ADR. CIGNA has not rebutted Dr. Rudin's assessment.

18. Based upon a *de novo* review of the claim decision, the Court concludes that CIGNA has failed to prove that two-level ADR is an experimental procedure excluded from the Plan's coverage. CIGNA does not put forth any evidence that multi-level ADR is currently an experimental procedure. When confronted with Dr. Rudin's evidence that two-level ADR is not experimental, CIGNA merely stated that the quality and quantity of such evidence is inadequate. This conclusory statement, without supporting evidence or rationales as to why the medical literature is inadequate, does not satisfy CIGNA's burden of proof.

III. CONCLUSION

1. Dubaich is entitled to coverage for multi-level ADR under the Plan.
2. Judgment shall be entered in favor of Dubaich.

DATED: July 31, 2013

DOLLY M. GEE
UNITED STATES DISTRICT JUDGE