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)

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. Thereafter, the Court took the matter under submission.

[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.

Having carefully reviewed the administrative record and the arguments of counsel as presented at the hearing and in their written submissions, the Court makes the following 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 by ERISA section 2(1), 29 U.S.C. § 1002(1), 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 Medical Coverage Policy regarding intervertebral disc prosthesis states as follows:

> CIGNA covers the surgical implantation of the Charité or ProDisc-L lumbar intervertebral disc (IVD) prosthesis for chronic, unremitting, discogenic low back pain and disability secondary to single-level degenerative disc disease (DDD) as medically necessary in a skeletally mature individual when ALL of the following criteria are met:
>
> - The unremitting low back pain and disability described has been refractory to at least six consecutive months of standard medical and surgical management (e.g., exercise, analgesics, physical therapy, spinal education).
> - Single-level disc degeneration has been confirmed on complex imaging studies (i.e., computerized tomography [CT] scan, magnetic resonance imaging [MRI]).
> - The planned implant will be used in the L4-S1 region if the Charité or the L3-S1 region if ProDisc-L.

CIGNA does not cover the surgical implantation of any of the following because they are considered experimental, investigational or unproven:

- Charité or ProDisc-L lumbosacral intervertebral disc prosthesis when any of the following apply:
    - the planned procedure includes the combined use of a prosthesis and spinal fusion
    - simultaneous multi-level implantation is planned
    - the implant will be inserted outside of the L4-S 1 region (Charité) or outside of the L3-S 1 region (ProDisc-L)
    - the individual has osteopenia or osteoporosis (T-score less than -1.0) –the individual has a history of a prior lumbar fusion
    - 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

(A.R. at 150-51.)

4. The Plan excludes experimental and investigational treatments. 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.

(A.R. at 227.)

5. 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. (A.R. at 370-72.)

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

7. 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.)

8. "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.)

9. 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.

10. 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.

11. 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.)

12. 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

13. On or about June 15, 2011, Dubaich was seen by her physician, 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.)

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

15. 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*.)

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

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

18. 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.

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

20. To date, the U.S. Food and Drug Administration 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 only approved the device 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)).)

21. On July 11, 2011, Kim Jones, a Prior Authorization Nurse, reviewed the 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 no communication regarding medical necessity was shared with Dubaich.

22. The file was then reviewed by Dr. Granato, a urologist. 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 :
>   - the planned procedure includes the combined use of a prosthesis and spinal fusion
>   - simultaneous multi-level implantation is planned
>   - the implant will be inserted outside of the L4-S1 region (Charité) or outside of the L3-S 1 region (ProDisc-L-L) [sic]
>   - the individual has osteopenia or osteoporosis (T-score less than -1.0) –the individual has a history of a prior lumbar fusion

- 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.)

23. The above language is taken directly from the Plan, which lists all the conditions for which ADR is not covered. (A.R. at 150-51). Prior to the last paragraph, the above language is quoted 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* A.R. at 11-12 *with* A.R. at 150-51.)

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

25. On July 11, 2011, CIGNA issued its "Initial Case Resolution Letter" denying Dubaich's requested treatment. The language of the denial letter was copied 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 medical necessity.

Dubaich's First Appeal of CIGNA's Denial

26. 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." (A.R. at 43.)

27. Accompanying Dr. Rudin's letter was a study published in *The Journal of Bone and Joint Surgery*. (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." (A.R. at 45.) Dr. Rudin's appeal also included an abstract from an article in *Spine*, an abstract from a report presented by Dr. Goldstein and others at Spine Week 2008, and an abstract of a 2005 German study. (A.R. at 59-63).

28. 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." (A.R. at 9.)

29. Dr. Mino's rationale 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 from the earlier decision. (A.R. at 9-10.)

30. The last paragraph of Dr. Mino's review is as follows:

> 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.

31. 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.)

32. Dr. Mino did not individually address or rebut any of the materials referenced by or accompanying Dr. Rudin's appeal.

33. 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 medical necessity as a basis for the denial.

Dubaich's Appeal to the Benefit Appeals Committee

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

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

36. The question the Benefits 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.)

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

38. 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.)

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

40. On September 28, 2011, CIGNA communicated the Benefit Appeals Committee's upholding of the denial 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.)

41. 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 No Record Exists of One

42. The final denial letter states that the appeal was also reviewed by an external reviewer, but none is named. (A.R. at 141.)

43. 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.

44. Dubaich did not request an external review and received no notice of eligibility. There is no record of an external review.

The Plan Administrator Was Not Involved in the Decision

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

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

47. 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 the Employee Retirement Income Security Act of 1974 ("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) ("the party claiming deferential review should prove the predicate that justifies it").

6. CIGNA has not met this burden. The Appeals Committee conducted the final review for which there is a record. The Plan only grants discretionary authority to the Plan Administrator, not the Appeals Committee, and there is no indication of a delegation of that discretion in the record.

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

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

8. 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.").

9. 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.

The Plan Unambiguously Excludes Multi-Level ADR from Coverage

10. Plaintiff bears the burden of proof to demonstrate that a procedure is covered. If Plaintiff can establish that a procedure is covered in the first instance, CIGNA bears the burden to demonstrate that an exclusion applies. *See Jenkins v. Montgomery Indus., Inc.*, 77 F.3d 740, 743 (4th Cir. 1996) ("A basic rule of insurance law provides that the insured must prove that a covered loss has occurred, while the insurer carries the burden of demonstrating that a loss falls within an exclusionary clause of the policy.")

11. The Plan 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.) This language demonstrates that the basis for the coverage is medical necessity. Plaintiff has put forth evidence of medical necessity, and 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.

12. Based upon a *de novo* review of the claim decision, however, the Court concludes that the Plan language ineluctably and unambiguously excludes coverage of multi-level ADR for multi-level degenerative disc disease even where there has been a showing of medical necessity. Unlike cases in which a court must construe terms such as "experimental," "investigational," or "unproven," *see, e.g., Johnson v. Dist. 2 Marine*

Engineers Beneficial Ass'n-Associated Mar. Officers, Med. Plan, 857 F.2d 514, 516 (9th Cir. 1988); *McHenry v. PacificSource Health Plans*, 679 F. Supp. 2d 1226, 1237 (D. Or. 2010), there is no room for interpretation here. The Plan states: "CIGNA does not cover the surgical implantation of any of the following **because they are considered experimental, investigational or unproven**: Charité or ProDisc-L lumbosacral intervertebral disc prosthesis when any of the following apply:

* * *

- **simultaneous multi-level implantation is planned**

* * *

- there is evidence on imaging studies the spine [sic] of any of the following:

* * *

  - **multi-level degenerative disc disease**
  - nerve root compression or spinal stenosis

(A.R. at 150-51 (emphasis added).) Dr. Rudin submitted a claim for multi-level ADR, and the record shows that Dubaich has multi-level degenerative disc disease at the location of the proposed surgery.[2] Although Dubaich has submitted medical literature in support of her position that multi-level ADR should not be considered experimental, investigational or unproven, this Court cannot order CIGNA to rewrite its policy. CIGNA was not only correct to deny the claim in accordance with the Plan language, but required by law to do so as a fiduciary of the Plan participants. *See Firestone Tire*, 489 U.S. at 110-11.

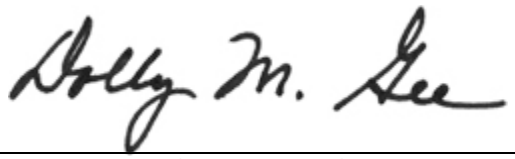
[2] Plaintiff also has spinal stenosis at C5-C6. (A.R. at 31.) The Plan language is ambiguous as to whether spinal stenosis anywhere on the spine or only at the implant location disqualifies Plaintiff from ADR. Under the doctrine of *contra proferentem*, ambiguities in insurance contracts are construed in favor of the insured. *Blankenship v. Liberty Life Assur. Co. of Boston*, 486 F.3d 620, 625 (9th Cir. 2007). Therefore, the Court does not construe Plaintiff's spinal stenosis, which is located away from the proposed implant location, as a factor disqualifying her from coverage.

III. CONCLUSION

1. Dubaich is not entitled to coverage for multi-level ADR under the Plan's policy.

2. Judgment shall be entered in favor of CIGNA.

DATED: April 25, 2013



DOLLY M. GEE
UNITED STATES DISTRICT JUDGE