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**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.

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

5 **I. FINDINGS OF FACT**

6 1. Plaintiff Danica Dubaich was a participant in the HCA Health and Welfare
7 Benefit plan (“Plan”), a self-funded employee welfare benefit plan, as that term is defined
8 by ERISA section 2(1), 29 U.S.C. § 1002(1), sponsored by HCA for the benefit of its
9 employees. (Administrative Record (“A.R.”) at 366-69.)

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

11 **Pertinent Plan Terms**

12 3. The Medical Coverage Policy regarding intervertebral disc prosthesis states
13 as follows:

14 CIGNA covers the surgical implantation of the Charité or ProDisc-L
15 lumbar intervertebral disc (IVD) prosthesis for chronic, unremitting,
16 discogenic low back pain and disability secondary to single-level
17 degenerative disc disease (DDD) as medically necessary in a skeletally
18 mature individual when ALL of the following criteria are met:

- 19 - The unremitting low back pain and disability described has been
20 refractory to at least six consecutive months of standard medical and
21 surgical management (e.g., exercise, analgesics, physical therapy,
22 spinal education).
- 23 - Single-level disc degeneration has been confirmed on complex
24 imaging studies (i.e., computerized tomography [CT] scan, magnetic
25 resonance imaging [MRI]).
- 26 - The planned implant will be used in the L4-S1 region if the Charité or
27 the L3-S1 region if ProDisc-L.
- 28

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

3 - Charité or ProDisc-L lumbosacral intervertebral disc prosthesis when
4 any of the following apply:

5 o the planned procedure includes the combined use of a
6 prosthesis and spinal fusion

7 o simultaneous multi-level implantation is planned

8 o the implant will be inserted outside of the L4-S 1 region
9 (Charité) or outside of the L3-S 1 region (ProDisc-L)

10 o the individual has osteopenia or osteoporosis (T-score less than
11 -1.0) –the individual has a history of a prior lumbar fusion

12 o there is evidence on imaging studies the spine [sic] of any of
13 the following:

14 ▪ degenerative spondylolisthesis of Grade 2 or greater

15 ▪ infection

16 ▪ multi-level degenerative disc disease

17 ▪ nerve root compression or spinal stenosis

18 ▪ pars interarticularis defect with either spondylolysis or
19 spondylolisthesis

20 ▪ scoliosis

21 ▪ severe facet joint arthrosis

22 ▪ spinal fracture

23 ▪ tumor

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

25 (A.R. at 150-51.)

26 4. The Plan excludes experimental and investigational treatments. The specific
27 language is as follows:

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

6 (A.R. at 227.)

7 5. The term “experimental” is defined as follows:

8 Experimental Procedures: Any medical procedure, equipment, treatment
9 or course of treatment, or drugs or medicines that are:

- 10 - limited to research
11 - not proven in an objective manner to have therapeutic value or benefit
12 - restricted to use by medical facilities capable of carrying out scientific
13 studies
14 - of questionable medical effectiveness or
15 - would be considered inappropriate medical treatment

16 To determine whether a procedure is experimental, HCA will consider,
17 among other things, commissioned studies, opinions and references to or
18 by the American Medical Association, the federal Food and Drug
19 Administration, the Department of Health and Human Services, the
20 national Institutes of Health, the Council of Medical Specialty Societies
21 and any other association or program or agency that has the authority to
22 review or regulate medical testing or treatment.

23 (A.R. at 371.) The terms “research,” “investigational,” and “unproven” are not defined in
24 the Plan. (A.R. at 370-72.)

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

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1 7. The Plan defines the “Plan Administrator” as the HCA Plan Administration
2 Committee. “The HCA Plan Administration Committee is the Plan Administrator for the
3 HCA 401(k) Plan and the HCA Health and Welfare Benefits Plan.” (A.R. at 366.)

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

7 9. The Plan states that “[f]or the self-funded benefits (Medical, Dental,
8 Wellness, HRA and Health Care FSA), HCA has delegated to the Claims Administrator
9 initial claims determinations.

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

13 11. Regarding appeals, the Plan states:

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

23 (A.R. at 357.)

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

Dubaich's Initial Claim

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2 13. On or about June 15, 2011, Dubaich was seen by her physician, Dr. Brian D.
3 Rudin, for complaints of bilateral foot pain, low back pain, left arm and hand weakness,
4 right thigh numbness, right hip pain, and headaches. (A.R. at 24.)

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

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

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

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

15 18. According to the CIGNA Medical Coverage Policy, the standard surgical
16 treatment for pain caused by degenerative disc disease is spinal fusion. (A.R. at 151.)
17 This involves immobilizing the unstable disc by fusing it to the stable adjacent discs.
18 “Spinal fusion alters the biomechanics of the spine, reducing motion of the spinal
19 segments, potentially leading to premature disc degeneration at adjacent levels.” (*Id.*)
20 “Preservation of motion within the spinal column and avoidance of adjacent segment
21 disease are goals for treatment of patients with degenerative disc disease.” (*Id.*) Dr.
22 Rudin concluded that conservative treatment had failed and that Dubaich was a good
23 candidate for an L5-S1 artificial disc replacement (“ADR”), designed as an alternative to
24 fusion.

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

27 20. To date, the U.S. Food and Drug Administration has approved only two
28 lumbar intervertebral disc prostheses: the Charité Artificial Disc and the ProDisc-L

1 Lumbar. (A.R. at 151.) The FDA granted premarket approval to the ProDisc-L in
2 August 2006 for “spinal arthroplasty in skeletally mature patients with [degenerative disc
3 disease (“DDD”)] at one level of the lumbar spine from L3-S1.” (*Id.* at 155; Pl.’s
4 Request for Judicial Notice, Ex. A [Doc. 21-1]). While Plaintiff disputes that the FDA
5 only approved the device for single-level DDD, the approval letter clearly contemplates
6 single-level use only. (*Id.* (“These DOD patients should have no more than Grade 1
7 spondylolisthesis at the involved *level.*” (emphasis added)).)

8 21. On July 11, 2011, Kim Jones, a Prior Authorization Nurse, reviewed the file.
9 Jones determined that the treatment should be denied as it was not medically necessary.
10 Specifically, Jones found that “the documentation submitted does not confirm that disc
11 degeneration has been confirmed on complex imaging studies such as magnetic
12 resonance imaging or computerized tomography.” (A.R. at 15.) This was an internal
13 finding, and no communication regarding medical necessity was shared with Dubaich.

14 22. The file was then reviewed by Dr. Granato, a urologist. Dr. Granato opined
15 that the treatment should be denied as experimental. Dr. Granato’s notes read as follows:

16 Based upon current available information, coverage cannot be approved because
17 there is insufficient scientific evidence to demonstrate the safety and/or
18 effectiveness of any of the following in treating degenerative disc disease:

- 19 - Charité or ProDisc-L lumbosacral intervertebral disc prosthesis when any
20 of the following apply :
- 21 ○ the planned procedure includes the combined use of a prosthesis
22 and spinal fusion
 - 23 ○ simultaneous multi-level implantation is planned
 - 24 ○ the implant will be inserted outside of the L4-S1 region (Charité)
25 or outside of the L3-S 1 region (ProDisc-L-L) [sic]
 - 26 ○ the individual has osteopenia or osteoporosis (T-score less than -
27 1.0) –the individual has a history of a prior lumbar fusion
- 28

1 o there is evidence on imaging studies the spine [sic] of any of the
2 following:

- 3 ▪ degenerative spondylolisthesis of Grade 2 or greater
- 4 ▪ infection
- 5 ▪ multi-level degenerative disc disease
- 6 ▪ nerve root compression or spinal stenosis
- 7 ▪ pars interarticularis defect with either spondylolysis or
- 8 spondylolisthesis
- 9 ▪ scoliosis
- 10 ▪ severe facet joint arthrosis
- 11 ▪ spinal fracture
- 12 ▪ tumor

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

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

17 (A.R. at 12.)

18 23. The above language is taken directly from the Plan, which lists all the
19 conditions for which ADR is not covered. (A.R. at 150-51). Prior to the last paragraph,
20 the above language is quoted verbatim from the Policy, except for two typographical
21 errors – the use of “ProDisc-L-L” instead of “ProDisc-L” and the space between “apply”
22 and the colon in the 7th line – and the omission of the word “isthmic” before
23 “spondylolisthesis.” (*Compare* A.R. at 11-12 *with* A.R. at 150-51.)

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

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1 appearance of the word “Charité.” As demonstrated by the repeated inclusion of the
2 typographical errors, this rationale was copied from the earlier decision. (A.R. at 9-10.)

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

4 The quality and quantity of data in the current peer-reviewed scientific medical
5 literature is inadequate to establish the clinical utility, safety and efficacy of the use
6 of an intervertebral disk prosthesis in any of these clinical presentations. The
7 requested service is therefore excluded from coverage under your medical benefit
8 plan as experimental/investigational/unproven.

9 31. On August 10, 2011, Dr. Mino wrote to Dubaich informing her of his
10 decision to uphold the denial. (“First Appeal Letter”) (A.R. at 80-82.)

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

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

16 **Dubaich’s Appeal to the Benefit Appeals Committee**

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

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

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

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

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

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

10 40. On September 28, 2011, CIGNA communicated the Benefit Appeals
11 Committee's upholding of the denial to Dubaich (“Second Appeal Letter”). This letter
12 repeated the rationale of the Benefit Appeals Committee. The letter also identified the
13 provisions of the Plan that pertain to the denial. (A.R. at 141-143.)

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

17 **Dubaich Did Not Request an External Review and No Record Exists of One**

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

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

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

25 **The Plan Administrator Was Not Involved in the Decision**

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

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

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

3 **II. CONCLUSIONS OF LAW**

4 1. Dubaich's health benefits claims are governed by the Employee Retirement
5 Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 *et seq.*

6 2. This Court has subject matter jurisdiction pursuant to ERISA, 29 U.S.C.
7 § 1132(a), and 28 U.S.C. § 1331.

8 **The Standard Of Review is De Novo**

9 3. A district court reviews an administrator's denial of benefits *de novo* "unless
10 the benefit plan gives the administrator or fiduciary discretionary authority to determine
11 eligibility for benefits." *Saffon v. Wells Fargo & Co. Long Term Disability Plan*, 522
12 F.3d 863, 866 (9th Cir. 2008) (citing *Firestone Tire & Rubber Co. v. Bruch*, 489 U.S.
13 101, 115 (1989)). If the benefit plan does grant the administrator discretionary authority,
14 then the district court reviews the administrator's decision for an abuse of discretion. *Id.*

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

20 5. CIGNA bears the burden to prove that the entity which actually denied
21 Dubaich's claim was delegated or granted discretionary authority by the Plan. *Sharkey v.*
22 *Ultramar Energy Ltd., Lasmo plc, Lasmo (AUL Ltd.)*, 70 F.3d 226, 229-230 (2d Cir.
23 1995) ("the party claiming deferential review should prove the predicate that justifies it").

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

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

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

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

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

10 **The Plan Unambiguously Excludes Multi-Level ADR from Coverage**

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

18 11. The Plan states: “CIGNA covers the surgical implantation of the Charité or
19 ProDisc-L . . . as medically necessary” when the required criteria are met. (A.R. at 150.)
20 This language demonstrates that the basis for the coverage is medical necessity. Plaintiff
21 has put forth evidence of medical necessity, and Defendant has waived the defense of
22 lack of medical necessity. Plaintiff has therefore established medical necessity for the
23 requested treatment and has met her burden to demonstrate coverage.

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

1 *Engineers Beneficial Ass'n-Associated Mar. Officers, Med. Plan*, 857 F.2d 514, 516 (9th
2 Cir. 1988); *McHenry v. PacificSource Health Plans*, 679 F. Supp. 2d 1226, 1237 (D. Or.
3 2010), there is no room for interpretation here. The Plan states: “CIGNA does not cover
4 the surgical implantation of any of the following **because they are considered**
5 **experimental, investigational or unproven**: Charité or ProDisc-L lumbosacral
6 intervertebral disc prosthesis when any of the following apply:

7 * * *

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

9 * * *

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

12 * * *

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

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

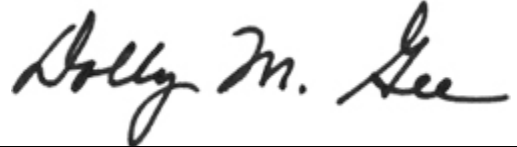
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25 ² Plaintiff also has spinal stenosis at C5-C6. (A.R. at 31.) The Plan language is ambiguous as to
26 whether spinal stenosis anywhere on the spine or only at the implant location disqualifies Plaintiff from
27 ADR. Under the doctrine of *contra proferentem*, ambiguities in insurance contracts are construed in
28 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.

1 **III. CONCLUSION**

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

4 2. Judgment shall be entered in favor of CIGNA.

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6 DATED: April 25, 2013



8 DOLLY M. GEE
9 UNITED STATES DISTRICT JUDGE

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