IN THE DISTRICT COURT OF THE UNITED STATES
FOR THE WESTERN DISTRICT OF NORTH CAROLINA
ASHEVILLE DIVISION

CIVIL CASE NO. 1:10cv076

JULI ANN O. NISHIMUTA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**O R D E R**
	)	
KATHLEEN SEBELIUS, Secretary of Health and Human Services,	)	
	)	
Defendant.	)	
	)	

THIS MATTER is before the Court on the Plaintiff's Motion for Summary Judgment [Doc. 16] and the Defendant's Motion for Summary Judgment. [Doc. 19].

I. INTRODUCTION

Plaintiff Juli Ann Nishimuta, a Medicare beneficiary enrolled in a Medicare Advantage plan under Medicare Part C, appeals the denial of her advance request for approval and payment of a lumbar artificial disc replacement procedure (LADR) at two levels of her spine (a "two-level LADR") to alleviate symptoms of degenerative disc disease. Because the Medicare Appeals Council correctly concluded that a single-level LADR

procedure is covered under Plaintiff's Medicare Advantage Plan but that a two-level LADR procedure is not, the Court hereby grants summary judgment in favor of the Defendant.

II. MEDICARE AND ITS APPEALS PROCESS

Medicare is the federal health insurance program for the elderly and the disabled. See 42 U.S.C. §§ 1395 et seq. Congress created Medicare in 1965 under Title XVIII of the Social Security Act. The Medicare program is operated by the U.S. Department of Health and Human Services (HHS), through a component agency known as the Centers for Medicare & Medicaid Services (CMS). It is governed by numerous statutes and regulations, as well as an extensive system of manuals that contain guidelines for the administration of the program.

Medicare has four parts: Parts A through D. Medicare Part A is automatic and premium-free; it provides reimbursement for inpatient hospital services, post-hospital extended care services, home health services, and hospice care. See McCreary v. Offner, 172 F.3d 76, 78 (D.C. Cir. 1999) (citing 42 U.S.C. §§ 1395c-i). Medicare Part B is a voluntary supplemental program that covers medical and other health care services.

See 42 U.S.C. §§ 1395j-x; 42 U.S.C. § 1395w-21 et seq.; 42 C.F.R. § 422.101(a). Medicare Part D provides certain prescription drug coverages.

Medicare Part C is an alternative to the traditional fee-for-service payment method for the coverages available under Parts A and B, in the form of a managed care plan for the Parts A and B services. Part C is currently known as Medicare Advantage. See Pub.L. 108-173, Title II, § 201, Dec. 8, 2003, 117 Stat. 2176, set out as a note to 42 U.S.C.A. § 1395w-21 ("References to Medicare+Choice deemed to refer to Medicare Advantage"); see also 70 Fed. Reg. 4855 (Jan. 28, 2005) (Medicare Advantage program "replaces the Medicare+Choice program . . . while retaining most key features . . ."). A "Medicare Advantage organization" is a private organization that operates a Medicare Advantage plan, under contract with HHS. 42 U.S.C. § 1395w-22(a)(1). A "Medicare Advantage plan" covers the services covered by Medicare Parts A and B that are available to beneficiaries residing in the plan's service area. 42 C.F.R. § 422.101(a). Such a plan must comply not only with the statutes and regulations governing Medicare, but also with the Medicare program's national coverage determinations and any applicable written coverage decisions of local Medicare contractors. 42 C.F.R. § 422.101(b).

A Medicare Advantage plan enrollee has appeal rights that may be exercised if he or she is dissatisfied with an "organization determination" made by his or her Medicare Advantage organization. The Defendant concedes that the initial action on the Plaintiff's claim constituted an "organization determination" as defined by the applicable regulation, 42 C.F.R. § 422.566(b). [Doc. 20 at 6].

An enrollee may seek reconsideration of a decision by the Medicare Advantage organization. 42 C.F.R. §§ 422.578, 422.580. If the reconsideration decision is unfavorable to the enrollee, the matter must be reviewed by an independent outside entity that contracts with the Secretary for this purpose. 42 C.F.R. § 422.592. If that outside entity issues an unfavorable decision, the enrollee may request a hearing before an ALJ. 42 C.F.R. § 422.600. If the decision of the ALJ is unfavorable, the enrollee then may request that the Medicare Appeals Council (MAC) review the ALJ's decision. The decision of the Council concludes the administrative appeals process.

If the enrollee remains dissatisfied, and if the amount in controversy exceeds a certain threshold, the enrollee may seek judicial review of the final agency decision. 42 U.S.C. 1395w-22(g)(5); 42 C.F.R. § 422.612.

III. STANDARD OF REVIEW

Judicial review of final agency decisions under 42 USC § 405(g) is made "solely on the administrative record." MacKenzie Medical Supply, Inc. v. Leavitt, 506 F.3d 341, 346 (4th Cir. 2007). If the Secretary's findings of fact are supported by substantial evidence, they are conclusive. Id. Substantial evidence is "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Richardson v. Perales, 402 U.S. 389, 401, 91 S.Ct. 1420, 28 L.Ed.2d 842 (1971). While the reviewing court must defer to the Secretary's supported findings of fact, it "is not bound by the Secretary's conclusions or interpretations of law, or an application of an incorrect legal standard." Gartmann v. Sec'y of Dept. of Health and Human Servs., 633 F.Supp. 671, 679 (E.D.N.Y. 1986). Therefore, "'[b]efore the insulation of the substantial evidence test comes into play, it must first be determined that the facts of a particular case have been evaluated in light of correct legal standards.'" Id. at 680 (quoting Klofta v. Mathews, 418 F.Supp. 1139, 1142-44 (E.D. Wis. 1976)); see also Bergeron v. Shalala, 855 F.Supp. 665, 667 (D.Vt.1994).

IV. FACTUAL AND PROCEDURAL BACKGROUND

Plaintiff's medical history is relatively straightforward. She suffers from degenerative disc disease, which progressed over her working life, reducing her from working full-time as a veterinary assistant to working part-time as a library clerk. Ultimately, the Social Security Administration determined in 2006 that she was totally disabled under its rules. [T. 28-30]. The Plaintiff continued to experience pain as a result of degenerative disc disease. She testified before ALJ MacDougall that she visited many doctors of various specialties and considered many procedures in an effort to alleviate her pain. [T. 30-43]. Her efforts led her to Jack E. Zigler, M.D. of the Texas Back Institute of Plano, Texas in late 2008. [T. 239 et seq.]. After performing a discogram [T. 44] and other testing [T. 239-266], Dr. Zigler opined to Plaintiffs' Medicare contractor carrier that a two-level LADR was medically necessary and the better choice over a spinal fusion. [T. 244]. On April 3, 2009, he opined that Plaintiff needed an expedited decision on the advance request she made for coverage of this procedure. [T. 242].

The Plaintiff made an advance request through CIGNA, her plan sponsor, for CIGNA's approval and payment of a two-level LADR

procedure. CIGNA denied her request on the grounds that a two-level LADR "is not a Medicare covered benefit and is therefore excluded from coverage" under her plan. [T. 320]. She sought reconsideration of this decision, which CIGNA denied. [T. 312, 310]. She then pursued the next level of appeal, that being an independent review by an outside entity, MAXIMUS Federal Services (Maximus). A medical consultant for MAXIMUS reviewed the matter and opined that "a two-level artificial disc replacement . . . goes beyond the level of investigational into true human experimentation." [T. 275, 287]. MAXIMUS thus issued a decision denying the Plaintiff's request. [T. 273-275].

The Plaintiff next filed a request for hearing before an Administrative Law Judge. On October 6, 2009, her request for a hearing was heard before ALJ Bruce MacDougall. [T. 322 *et seq*.[1]]. He issued a decision on November 16, 2009 that was unfavorable to the Plaintiff. [T. 26-34].

The Plaintiff then filed a request that the Appeals Council review the ALJ's decision. [T. 14-22]. The Appeals Council reviewed the ALJ's

[1]The administrative record is paginated consecutively through page 321. The next, and every subsequent, page is marked 003. The Court is utilizing the convention introduced in Defendant's brief [Doc. 20 at 6] of referring to the first page 003 as page 322, the set of 30 pages that are all marked 003 as "T. 322 *et seq*.," and individual pages after 321 accordingly.

decision *de novo*. On February 4, 2010, the Appeals Council adopted the ALJ's decision. [T. 4-10]. The Plaintiff, proceeding *pro se*, then filed a complaint for judicial review of the final agency decision. [Doc. 1].

Plaintiff's administrative remedies having been exhausted, this matter is ripe for judicial review pursuant to 42 U.S.C. § 1395w-22(g)(5) and 42 U.S.C. § 405(g). See Anderson v. Sullivan, Civ. No. 90-33-W, 1990 WL 358303, at *2 (S.D. Iowa Sep. 28,1990) (quoting Weinberger v. Salfi, 422 US 749, 756-58, 95 S.Ct. 2457, 45 L.Ed.2d 522 (1975)).

V. ANALYSIS

Coverage is a fundamental initial question in Medicare's consideration of any claim. See Schweiker v. McClure, 456 U.S. 188, 191, 102 S.Ct. 1665, 72 L.Ed.2d 1 (1982) (superceded by statute on other grounds). Congress did not mandate that Medicare cover all medical services, even when medically necessary. See Goodman v. Sullivan, 891 F.2d 449, 450 (2d Cir. 1989); MacKenzie Med. Supply, Inc. v. Leavitt, 419 F.Supp.2d 766, 773 (D. Md. 2006). "The Medicare program . . . is not a comprehensive health insurance program and still contains significant gaps in its coverage . . . in areas of immunizations, drugs, therapeutics,

optometrics, and dental care services." Bussey v. Harris, 611 F.2d 1001, 1006 (5th Cir. 1980). It pays for "some but not all of the vast spectrum of medical needs." Id.

In the present case, substantial evidence supports the Council's decision to deny the Plaintiff's request for a two-level LADR. First, the Secretary has issued a National Coverage Determination (NCD) that specifically provides that coverage for *one-level* LADR may be approved at a Medicare contractor's discretion in the case of a beneficiary who is 60 years old or younger and who has degenerative or discogenic disc disease at one level for L3 to S1. Medicare National Coverage Determinations Manual, CMS Publication 100-03, Chapter 1, Part 2, § 150.10 (LADR; effective August 14, 2007), at subsection A (emphasis added); see T. 7-8 (Council's quotation from NCD). The Secretary's NCDs are binding upon all administrative adjudicators. 42 C.F.R. §§ 405.1060(a)(4). Notably, the NCD does not even contemplate coverage of LADR at more than one level of the spine.

Additionally, as the Council correctly noted, CIGNA's Medical Coverage Policy, which "applies to all plans administered by CIGNA Companies," limits coverage for LADR to instances of "[s]ingle-level disc

degeneration." [T. 295].[2] Like the NCD issued by the Secretary, CIGNA's coverage policy does not contemplate coverage of LADR performed at more than one spinal level.

In challenging the Council's decision, the Plaintiff contends that the FDA "has approved Prodisc L for use in the United States." [Doc. 16 at 27]. The fact that the FDA has approved the use of a medical device, however, does not mean that Medicare is required to provide coverage for the item. See Diapulse Corp. of America v. Sebelius, No. 06-CV-2226, 2010 WL 1037250, at *10 (E.D.N.Y. Jan. 21, 2010). In any event, the FDA evidence of record only serves to support the Council's decision. As the Council noted, the ProDisc-L invertebral disc prosthesis was approved by the FDA for certain "patients with degenerative disc disease (DDD) *at one level* from L3-S1." [T. 51] (emphasis added). By its terms, the FDA's approval of the ProDisc-L device applies only to single-level disc disease. The Plaintiff's contention that the FDA has approved the use of the ProDisc-L for "multi-level LADR procedure[s]" is simply unsubstantiated. [T. 8].

[2]Plaintiff has stated that her Medicare Advantage plan, which is sponsored by CIGNA, has indicated to her that it was willing to cover a one-level LADR procedure. [T. 300, 33].

VI. CONCLUSION

For the foregoing reasons, the Court concludes that the Secretary's final agency decision denying Plaintiff's request for Medicare payment of a two-level LADR procedure comports with the applicable legal standards and is supported by substantial evidence. Accordingly, the Secretary's motion for summary judgment is hereby granted.

O R D E R

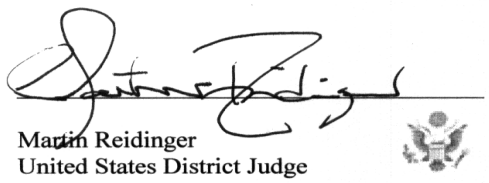
IT IS, THEREFORE, ORDERED that the Defendant's Motion for Summary Judgment [Doc. 19] is **GRANTED**.

IT IS FURTHER ORDERED that the Plaintiff's Motion for Summary Judgment [Doc. 16] is **DENIED.**

A judgment shall be entered simultaneously herewith.

IT IS SO ORDERED.

Signed: August 10, 2011



Martin Reidinger
United States District Judge