United States Court of Appeals

FOR THE EIGHTH CIRCUIT

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- -	No. 04-1	1383
Jo Ortlieb,	*	
Appellant,	*	
•	*	Appeal from the United States
VS.	*	District Court for the
	*	District of Nebraska.
United HealthCare Choice Plans,	*	
c/o United HealthCare of the	*	
Midlands, Inc.; United HealthCare	*	
of the Midlands, Inc., as Administra	ator *	
Fiduciary of the Plan; United	*	
HealthCare Insurance Company,	*	
	*	
Appellees.	*	
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Submitted: August 26, 2004 Filed: October 28, 2004

Before BYE, LAY, and RILEY, Circuit Judges.

RILEY, Circuit Judge.

Jo Ortlieb (Ortlieb) was insured under a United HealthCare Choice Plus Plan (Plan) when she became seriously ill. Her treating physician prescribed Total

Parenteral Nutrition (TPN).¹ Ortlieb requested coverage for TPN, but the defendants (collectively United HealthCare) denied coverage. After exhausting her administrative remedies, Ortlieb filed an action under the Employees Retirement Income Securities Act of 1974 (ERISA) to recover unpaid health care benefits. The district court² granted summary judgment in favor of United HealthCare. Ortlieb appeals. We affirm.

I. BACKGROUND

While working for her husband's business, Ortlieb enrolled for healthcare benefits under the group Plan issued by United HealthCare. The Plan provided that United HealthCare "has sole and exclusive discretion in interpreting the benefits Covered under the Policy and the other terms, conditions, limitations and exclusions set out in the Policy and in making factual determinations related to the Policy and its benefits." The Plan excluded certain healthcare services, including experimental, investigational, or unproven services. However, the Plan contained an express life-threatening condition exception to the experimental, investigational, or unproven service exclusion. The exception provided:

The PLAN, in its judgment, may deem an Experimental, Investigational or Unproven Service a Covered Health Service for treating a life threatening Sickness or condition if it is determined by the

¹Total Parenteral Nutrition describes the delivery of nutrients for assimilation and utilization of nutrients via solutions administered to patients intravenously, subcutaneously, or by some other non-alimentary route. Protein hydrolysates or free amino acid mixtures, monosaccharides, and electrolytes are the basic components of TPN solutions, which are selected for their ability to reverse catabolism, promote anabolism, and build structural proteins. <u>See</u> http://www.online-medical-dictionary.org.

²The Honorable Thomas M. Shanahan, United States District Judge for the District of Nebraska.

PLAN that the Experimental, Investigational or Unproven Service at the time of the determination:

- A. Is safe with promising efficacy; and
- B. Is provided in a clinically controlled research setting; and
- C. Uses a specific research protocol that meets standards equivalent to those defined by the National Institutes of Health.

When Ortlieb became seriously ill, she initially received medical treatment in Lincoln, Nebraska, and later at the Mayo Clinic in Rochester, Minnesota. As her health continued to fail, she sought treatment at the Environmental Health Center (EHC) in Dallas, Texas, under the medical supervision of Dr. William J. Rea (Dr. Rea). Dr. Rea diagnosed Ortlieb with a myriad of illnesses, including toxic encephalopathy, malnutrition, malabsorption, irritable bowel syndrome, allergic food gastroenteritis, toxic effect petrochemicals and solvents, and fatigue. Dr. Rea prescribed Ortlieb various treatments, including TPN therapy, which she began in late October 1999.

The pharmacy supplying Ortlieb's TPN services submitted a coverage request to United HealthCare for TPN and TPN-related services. Based on an internal medical review conducted by Dr. Debra Esser (Dr. Esser), United HealthCare denied the coverage request finding that TPN, as it related to malnutrition, fell within the Plan's experimental, investigational, or unproven service exclusion. In December 1999, United HealthCare notified Ortlieb of its decision to deny coverage.

In February 2000, the pharmacy sought reconsideration of the coverage denial, and attached to its request a letter written by Dr. Rea describing Ortlieb's medical condition and Dr. Rea's course of treatment. Later, in March 2000, Ortlieb appealed the initial denial of coverage. United HealthCare hired Dr. Robert A. Beer (Dr. Beer), an outside consulting physician, to review Ortlieb's medical records and to

recommend a benefit determination under the Plan. Dr. Beer recommended United HealthCare deny coverage, which it did.

Ortlieb appealed the second coverage denial. Her intermediate appeal was reviewed by United HealthCare's Consumer Affairs Committee (CAC), which included an internal physician member, Dr. Tim Mergens (Dr. Mergens). The CAC upheld the denial of coverage for TPN and related services. Ortlieb made a final appeal to the National Appeals Service Center (NASC). NASC is administered by Edina, an external review company. Edina, in turn, hired Dr. Arnold Flick (Dr. Flick), an independent, board-certified gastroenterologist to review Ortlieb's medical records. Dr. Flick concluded insufficient medical literature existed to support TPN treatment for any of Ortlieb's proven medical conditions.

Thereafter, Ortlieb contested the denial of coverage by filing her case in the district court. The district court reviewed the benefit determination using an arbitrary and capricious standard of review. In opposing United HealthCare's motion for summary judgment, Ortlieb submitted four technical documents discussing TPN, none of which were included in the administrative record. The district court declined to consider the new evidence. Based on the administrative record, the district court determined United HealthCare reasonably relied on the assessments of multiple doctors that TPN was an unproven therapy for Ortlieb's medical conditions. The district court rejected Ortlieb's argument that United HealthCare had failed to consider the "life-threatening condition" exception to the unproven service exclusion. The court granted summary judgment in favor of United HealthCare. Ortlieb now appeals.

II. DISCUSSION

A. Standards of Review

We review de novo a district court's grant of summary judgment, viewing the record in the light most favorable to the nonmoving party. <u>Butts v. Cont'l Cas. Co.</u>, 357 F.3d 835, 837 (8th Cir. 2004) (citing <u>Woo v. Deluxe Corp.</u>, 144 F.3d 1157, 1160 (8th Cir. 1998)). We also review de novo a district court's determination of the standard of review of an ERISA benefit plan determination. <u>See Ferrari v. Teachers Ins. and Annuity Ass'n</u>, 278 F.3d 801, 806 (8th Cir. 2002).

The Supreme Court has declared a de novo standard of review applies to a challenge to the denial of benefits, unless the benefit plan grants the plan administrator discretionary authority to determine eligibility for benefits or to construe the terms of the plan. Firestone Tire & Rubber Co. v. Bruch, 489 U.S. 101, 115 (1989). When a plan gives discretion to the plan administrator, then a plan administrator's decision is reviewed judicially for an abuse of discretion. Id. Under an abuse of discretion standard of review, a plan administrator's decision will stand if reasonable; "i.e., supported by substantial evidence." Fletcher-Merrit v. Noram Energy Corp., 250 F.3d 1174, 1179 (8th Cir. 2001) (quoting Donaho v. FMC Corp., 74 F.3d 894, 899 (8th Cir. 1996)). "Substantial evidence . . . means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Id. (quoting Consol. Edison Co. of New York v. NLRB, 305 U.S. 197, 229 (1938)).

In order for a plan beneficiary to obtain a less deferential standard of review, she "must present material, probative evidence demonstrating that (1) a palpable conflict of interest or a serious procedural irregularity existed, which (2) caused a serious breach of the plan administrator's fiduciary duty to her." Woo, 144 F.3d at 1160. To establish the second requirement, a plan beneficiary "must only show that the conflict or procedural irregularity has 'some connection to the substantive decision reached." Id. at 1161 (quoting Buttram v. Central States, S.E. & S.W. Areas Health & Welfare Fund, 76 F.3d 896, 901 (8th Cir. 1996)).

In this case, the Plan granted United HealthCare, as plan administrator, "sole and exclusive discretion in interpreting the benefits Covered under the Policy." We agree with the district court that the Plan's "express discretion-granting language" is sufficient to confer discretionary authority upon United HealthCare. Therefore, the district court properly reviewed the benefit decision for an abuse of discretion. We also agree with the district court that Ortlieb failed to present material, probative evidence demonstrating either a "palpable conflict of interest" or "a serious procedural irregularity," which would warrant applying a less deferential standard of review.

B. Reasonableness of Benefit Decision

Our record review convinces us that United HealthCare's decision to deny coverage is supported by substantial evidence and is, therefore, reasonable. The record indicates that, at the direction of Dr. Rea, Ortlieb commenced TPN treatment in late October 1999 and then sought coverage from United HealthCare. Upon receiving a request for TPN coverage, United HealthCare requested additional medical records, which were received in mid-November 1999. Dr. Esser initially reviewed Ortlieb's medical records and consulted with Ortlieb's primary care physician and gastroenterologist. Based on her record review and consultations, Dr. Esser determined TPN services were investigational and were not supported by peer literature. On December 7, 1999, Dr. Esser wrote Ortlieb explaining United HealthCare was denying coverage based on the Plan's exclusion for experimental, investigational, and unproven services.

Within weeks of denying coverage, United HealthCare received a request for reconsideration accompanied by a detailed letter from Dr. Rea. Although Dr. Rea's letter declared Ortlieb's receipt of TPN services was "a medical necessity" and also stated TPN therapy had been used at the EHC clinic "for over twenty-five years with more than five thousand patients and . . . no significant long-term effects have been

noted," Dr. Rea's letter cited no peer-reviewed medical literature indicating TPN services are a safe and effective treatment for Ortlieb's medical conditions.

Because the reconsideration request included a first-time coverage request for intravenous mineral and antibiotic therapy, United HealthCare requested additional medical records. In March 2000, Ortlieb formally appealed the initial denial of coverage, and in April 2000, United HealthCare hired Dr. Beer, an outside physician consultant, to review Ortlieb's medical records and to make an independent benefit determination. Dr. Beer determined (1) the records reflected "insufficient objective data for cause of malnutrition"; and (2) the requested TPN services were "investigational" and unsupported by sufficient medical evidence in Ortlieb's case or in the literature indicating any clinical improvement. Based on these findings, Dr. Beer recommended denial of coverage.

Near the same time, Dr. Esser reviewed the coverage request for Ortlieb's supplemental intravenous mineral and antibiotic therapy services. Relying on the documentation provided, Dr. Esser determined the requested TPN therapy services were investigational and not a covered benefit. On May 23, 2000, Dr. Esser wrote two denial-of-coverage letters. One letter notified Ortlieb that United HealthCare was denying the coverage request for supplemental, intravenous mineral and antibiotic therapy services. Dr. Esser's letter explained:

There is no documentation of positive cultures of an infection that would require intravenous antibiotics. It is also documented in your records that you are "allergic to all antibiotics," yet intravenous antibiotics were given. Without supporting documentation of an infection, use of antibiotics is considered investigational and not a covered benefit.

Dr. Esser's second letter denied Ortlieb's request to reconsider the initial denial of coverage for TPN services. Although the letter did not refer to Dr. Beer by name, Dr. Esser informed Ortlieb her file "has been carefully reviewed by a physician

consultant who was not involved in the initial decision," which had resulted in an independent determination that the previous decision should be upheld. Dr. Esser explained:

There is also insufficient evidence in your medical records and peerreviewed medical literature that TPN (and especially vitamin/mineral/anti-oxidant supplementation) results in clinical improvement. Therefore, the use of TPN is considered investigational and the TPN, supplies, and skilled nursing visits are not covered under your benefit plan.

Ortlieb then pursued an intermediate appeal to the CAC. United HealthCare representatives, including physician member Dr. Mergens, reviewed Ortlieb's file and upheld the decision to deny coverage. United HealthCare notified Ortlieb of the CAC's decision in January 2001, citing, as the basis for denial, the experimental, investigational, or unproven service exclusion.

Ortlieb filed her final administrative appeal with the NASC, which was independently processed by Edina, an external review company. Edina retained Dr. Flick, an independent, board certified, gastroenterology consultant. In August 2002, Dr. Flick reviewed Ortlieb's medical records and found no peer-reviewed literature supporting TPN therapy treatment for any of Ortlieb's proven diagnoses. Dr. Flick concluded TPN treatment to be "unproven for [Ortlieb's] clinical condition(s)." Edina notified Ortlieb that, based upon an independent external review, TPN was not a covered service because "TPN treatment is unproven for Ms. Ortlieb's clinical condition," and unproven services are excluded under the Plan.

This recitation of the record illustrates that Ortlieb's coverage request for TPN therapy was reviewed at least four times by four physicians, two of whom were external, independent physician consultants. Each of the physicians reviewing Ortlieb's medical file consistently determined TPN therapy was an unproven therapy for Ortlieb's medical conditions. At least three of the four reviewing physicians

concluded there was insufficient peer-reviewed literature supporting TPN therapy for Ortlieb's medical conditions. All five denial-of-coverage notices explained Ortlieb's coverage request for TPN therapy and related services was being denied based on the Plan's exclusion for experimental, investigational, or unproven services. All but the final denial notice, which was issued by Edina, specifically cited to and quoted the Plan's exclusion provision. Moreover, Dr. Esser's May 2000 letter informed Ortlieb there was "insufficient . . . peer-reviewed medical literature that TPN . . . results in clinical improvement." Despite receiving these notices that clearly and consistently identified the bases for coverage denial—unproven service and insufficient peer-reviewed medical literature—neither Ortlieb nor her treating physician provided United HealthCare with clinical evidence or peer-reviewed literature establishing TPN therapy was a proven therapy for Ortlieb's medical conditions. For these reasons, we conclude Ortlieb's arguments are without merit, and United HealthCare's denial of coverage is reasonable.³

C. Life-Threatening Condition Exception

Ortlieb also argues United HealthCare was not entitled to summary judgment, because a genuine issue of material fact exists as to whether United HealthCare considered Ortlieb's medical condition as life threatening, an express exception to the Plan's experimental, investigational, or unproven service exclusion. United HealthCare contends the life-threatening exception does not apply for two reasons:

(1) Ortlieb's medical records do not establish her medical condition was life

³Ortlieb also argues United HealthCare should be strictly bound to the grounds for its original denial. After initially denying coverage for TPN therapy, United HealthCare continued to assess and investigate Ortlieb's claim, at Ortlieb's request. As the administrative process evolved, United HealthCare learned more about Ortlieb's claim and the medical field's recognition of her conditions and TPN therapy. United HealthCare's further investigation is commendable and should be encouraged, not discouraged. On this record, to the extent United HealthCare's grounds for denial changed, we see no justification for limiting United HealthCare's reasons for denial.

threatening, and (2) TPN therapy, as utilized in this case, was not a treatment "safe with promising efficacy," part of a clinical study, or performed according to specific research protocol.

The district court concluded that, although United HealthCare never expressly stated it considered and rejected the Plan's life-threatening condition exception, Dr. Flick addressed the first required element of the exception by questioning the efficacy of TPN treatment for Ortlieb's medical conditions and by identifying several adverse side effects related to TPN therapy. Moreover, the district court determined the record contained no evidence that Ortlieb's TPN therapy at EHC was "provided in a clinically controlled research setting" and "[used] specific research protocol that meets standard[s] equivalent to those defined by the National Institutes of Health." We agree with the district court's conclusion that United HealthCare's independent medical expert, Dr. Flick, at least implicitly considered and rejected the life-threatening condition exception, and his decision in doing so was reasonable. If Ortlieb's medical condition were life-threatening, which is dubious based on this record, United HealthCare's reliance on Dr. Flick's opinions and on the administrative record is reasonable, and its decision to deny benefits is supported by substantial evidence.

III. CONCLUSION

For the foregoing reasons, we affirm the well-reasoned judgment of the district court.