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ERISA Group Health Plan Administration
by Roy Harmon III

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:: Clinical Evidence Protocols Rejected Under ERISA Plan's Medical Necessity Standard

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While a plan administrator need not “accord special weight to the opinions of a claimant’s physician,” it also “may not arbitrarily refuse to credit a claimant’s reliable evidence, including the opinions of a treating physician.” *Black & Decker Disability Plan v. Nord*, 538 U.S. 822, 834 (2003); *see also Demirovic v. Bldg. Serv. 32 B-J Pension Fund*, 467 F.3d 208, 212 (2d Cir. 2006).

If BCBS “impose[d] a standard not required by the plan’s provisions, or interpret[ed] the plan in a manner inconsistent with its plain words, its actions may well be found to be arbitrary and capricious.” McCauley, 551 F.3d at 133 [*3] (internal quotation marks omitted).

Durgin v. Blue Cross & Blue Shield of Vt., 2009 U.S. App. LEXIS 25139 (2d Cir. Nov. 17, 2009)

This unpublished opinion from the Second Circuit is instructive in showing that evidence-based protocols, e.g., clinical studies, may exceed what is required to show medical necessity, even under an abuse of discretion standard of review.

In this case, the claimant, Richard Durgin, challenged Blue Cross' denial of coverage for a "standing component" on his motorized wheelchair under BCBS's "Vermont Freedom Plan".

Blue Cross asserted the following grounds:

1 that "[t]here are no peer reviewed clinically controlled studies available showing that the stander improves net health outcomes," and

2 that there is "no evidence showing the benefit of the standing feature and that it will help restore or maintain [Durgin's] health."

1 Lack Of Peer Reviewed Clinical Studies

On the first point, Blue Cross asserted a lack of medical necessity. In support of this rationale, Blue Cross claimed that there were no "peer reviewed clinically controlled studies" showing "improve[d] net health outcomes."

Citing *McCauley v. First Unum Life Ins. Co.*, 551 F.3d 126, 130 (2d Cir. 2008), the district court rejected this defense stating:

. . . the Plan does not contain any requirement that a service be supported by "peer reviewed clinically controlled studies" before BCBS will provide coverage, and such a requirement is impossible to square with the lower standard that the Plan establishes for "Medical and Scientific Evidence." BCBS's atextual requirement therefore "impose[d] a standard not required by the plan's provisions," . . . and accordingly was arbitrary and capricious.

2 No Evidence Showing Benefit

Durgin met Blue Cross' second argument by proffering "ten articles from medical journals providing varying degrees of support for the medical benefits of the standing component."

Further, he submitted as evidence his treating physician's statement that the standing component had led to "a marked decrease in spasticity, as well as an overall improvement in maintaining his skin integrity," had "very positively impacted his history of decubitus ulcers," and had "helped [him] maintain bone density and has prevented osteoporosis."

The court agreed with Durgin, observing that:

While this evidence might ultimately be deemed inadequate to require BCBS to insure the standing component (a question we need not and do not reach), it cannot be said that "no evidence" showed the medical benefits that Durgin alleged. BCBS's second ground thus "arbitrarily refuse[d] to credit a claimant's reliable evidence," *Black & Decker*, 538 U.S. at 834, and cannot support BCBS's denial of the claim.

Remand To Blue Cross

Thus, the court vacated the district court' opinion and directed that the case be remanded to Blue Cross, stating:

Whether the articles and other evidence proffered by Durgin, along with any additional evidence that may have come into being since this claim was last before BCBS's internal review panel, are sufficient to bring the standing option within generally accepted practice parameters, when the Plan is construed in a reasonable manner, is a question to be considered in the first instance by BCBS.

Note - The Blue Cross defense was couched in terms of clinical evidence, or more accurately, the lack of authority linking the standing component with improvement in patient outcomes.

Thus, it challenged Durgin's citation of medical journals, asserting that the articles

were not published in peer-reviewed journals and that the standing component was accordingly “experimental” or “investigational” under the Plan.

The court found this assertion to be “factually erroneous” as “a significant number of the articles Durgin proffered did in fact appear in peer-reviewed journals.”

It is by no means clear that the criticisms that BCBS levels against the substance of the six peer-reviewed articles even support BCBS’s conclusion, let alone justify a denial of coverage. BCBS acknowledges that one of the articles “recommends standing devices for persons with spinal cord injury,” which if anything appears to strengthen Durgin’s contention that the standing option is “consistent with generally accepted practice parameters,” as the Plan requires.

Clinical Evidence Versus Medical Necessity - In an important distinction the court observes that the requirement of clinical evidence oversteps the requirement of medical necessity imposed by the plan:

[BCBS's] primary complaint regarding four other articles is that they lack clinical evidence. But, for the reasons given above, this is insufficient to support denial of the claim. As to the final peer-reviewed article, BCBS merely notes that it concludes that controlled studies are needed, and says nothing about any other recommendations or conclusions that that article makes.

More on Evidence-Based Medicine - The intersection of evidence based medicine and benefit payment protocols is very much at the center of “quality metrics” proposed by health care reformers. These limitations on treatment options are controversial, as noted in the following article:

Health-policy planners define quality as clinical practice that conforms to consensus guidelines written by experts. The guidelines present specific metrics for physicians to meet, thus “quality metrics.”

[Yet], [r]ather than rigidity, flexibility is appropriate in applying evidence from clinical trials. To that end, a good doctor exercises sound clinical judgment by consulting expert guidelines and assessing ongoing research, but then decides what is quality care for the individual patient. And what is best sometimes deviates from the norms.

[Why “Quality Care” Is Dangerous](#), Wall Street Journal (April 8, 2009)

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