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ERISA: Cancer treatment denial

Taking aim at insurance companies' denials of proton therapy cancer treatment

By Timothy J. Rozelle

In October 2015, Boston-area resident, Kate Weissman was diagnosed with stage 2B cervical cancer. She was treated with standard chemotherapy and radiation, but by spring 2016, a biopsy confirmed that the cancer had spread to her paraaortic lymph nodes, tucked behind the bowels and lying in front of the lumbar vertebrae. Time was of the essence. After her lymph nodes were removed, her team of doctors wanted to target the cancerous area with a specialized treatment called proton therapy.

Weissman was treated by six highly experienced oncologists, including five who also teach at Harvard Medical School, and all of whom agreed that proton therapy would be the most effective treatment in curing her cancer because it could pinpoint the area around her lymph nodes without causing damage to nearby organs. Her doctors believed that standard radiation could damage her small intestines, leading to life-threatening complications later, including ulceration, bleeding, and severe narrowing of the bowel that could cause bowel perforation/rupture, which can be fatal if not treated in a timely fashion. It could also damage her kidneys and cause long-term bone marrow issues.

Enter Kate's insurer at the time, UnitedHealthcare (UHC), the nation's largest health insurance company. UnitedHealthcare disagreed with Kate's doctors. The insurer denied Weissman coverage for proton beam therapy after multiple appeals, saying "there is not enough medical evidence to show proton beam therapy is effective for your particular condition." One of the insurance medical directors who twice reviewed Weissman's appeals claimed to be board-certified in "gynecologic oncology" but actually was not, after further investigation.

The denials put Weissman in a horrifying predicament: pay $95,000 out of pocket for what her doctors said was the best chance at a cure or continue with fully covered standard radiation, which could lead to lifelong complications. Weissman's case is just one example of the persistent health insurer practice of stepping into the role of determining when covered care is needed. Decisions that should be made exclusively by patients and their physicians (who have critically important medical expertise and firsthand knowledge of the patient's unique clinical situation) are being trounced by insurers' decisions. Peer-reviewed published data shows that proton therapy can significantly reduce the (radiation) dose to bone marrow, bladder and small bowel compared with the treatment UHC authorized Weismann move forward with. UnitedHealthcare denied coverage for Weissman's proton therapy, relying heavily on the reports of three unidentified radiation oncologists who agreed that proton beam therapy was not safer or more effective than the proven standard of care.

Trauma on top of trauma

Every month insureds dutifully pay their insurance premiums. When premium payments are missed for whatever reason, insurance companies normally require some sort of immediate response from insureds to fix the lapse or risk termination of coverage. When the shoe is on the other foot – when insureds most need their health insurance to work – the insurance company finds ways to drop the ball and leave you between a rock and a hard place. Insureds suffering from a cancer diagnosis take on the additional emotional trauma of facing off with their insurance company when insurance denies claims that their doctors clearly prescribe for their treatment.

On March 26, 2019, cancer survivor, Kate Weismann, whose plight caught the attention of Massachusetts Democrat Senators Elizabeth Warren and Edward Markey as well as former Rep. Michael Capuano, filed a putative class action suit in Boston federal court alleging UnitedHealthcare of violating ERISA. (*Weissman v. UnitedHealth Insurance Co., et al.*, Case No. 1:19-cv-10580 (D. Mass. Mar. 26, 2019).) Weissman asserts that UnitedHealthcare adhered to an outdated internal clinical guideline in order to deny coverage, breaching its obligations under ERISA and leaving her on the hook for $95,000 in proton therapy treatment bills. Weissman seeks to represent a class made up of people covered by ERISA plans that UnitedHealthcare insured or administered, who had or will have proton therapy requests denied based on the determination that proton therapy was not considered medically necessary or considered "experimental" or "investigational."

The most important thing for health insurance consumers like Kate to understand is that if their insurance coverage is obtained through their private employer (meaning their employer is not a church, government or public entity, for example), then their claim for health benefits made to their carrier is governed by the federal ERISA statute (Employee Retirement Income Security Act). ERISA has been federal law for 45 years and constitutes the exclusive legal scheme governing employee benefits (health insurance, 401(k), pension, disability insurance, life insurance, etc.).

ERISA confounds many and remains to insurance industry stakeholders, who *are* familiar with it, a notoriously limited statutory scheme for health care consumers. This relatively confused and perhaps negative view of ERISA has wide-ranging consequences for patients seeking coverage for expensive and life-saving care. Even more so considering that a plurality, and near majority, of Americans (49%[1]) are covered by health insurance obtained through an employer-based, ERISA-governed health plan. Compounding this lack of ERISA comprehension is the fact that ERISA's implementing regulations place little pressure, and nearly incentivize, employer- funded plans or health insurers to shirk their claims-handling responsibilities. The lack of real punitive consequence for procedural violations under ERISA favors the suppression of claims and appeals, effectively shuttering the doors to enforcement in federal court.[2]

After a carrier denies an insured's health claim, federal law only requires the insured to appeal a denial only up to two times (some plans only have one mandatory appeal). An insured also has a statutory right to an "external" review with an "independent" medical review organization but is by no means obligated to pursue such an external review. Typically, external reviews only serve to add an additional layer of justification for the carrier's denial if a case gets to litigation. External reviews rarely overturn carrier denials, and as a consequence, insurance companies will rely heavily on external review decisions that agree with their denial decisions during the course of litigation.

The denial problem

According to patient data provided by several proton-therapy centers, nearly two-thirds (63 percent) of cancer patients aged 18 to 64 whose physicians recommend proton therapy as the best course of treatment for their disease are initially denied by their insurer.[3] The report

reveals that patients and their physicians are sometimes successful in reversing the initial denial, but time spent waiting – and delaying treatment – averages nearly three weeks (13 working days). In the end, proton therapy is denied more than four times out of ten (42 percent) and it takes an average of more than five weeks (27 working days) to receive that final denial.

In fact, "more than ninety percent of claim denials, according to most estimates, are never appealed."[4] Of those appealed, less than half are overturned in favor of the insured.[5] Although the Affordable Care Act appears to provide added protections for consumers by establishing a federal right to appeal health insurance coverage determinations and claims to an external reviewer, this right is illusory at best.

The nature of denials

At first, insurers relied on internal guidelines to deny treatment on the basis that proton therapy was considered "experimental" or "investigational." More recently, however, denials are based on a determination that proton therapy is "not medically necessary." These are two very distinct bases for denial with significant legal implications. A denial on the basis that the requested therapy is "experimental" or "investigational" draws from exclusionary language under the plan. Such a denial places the burden of proof on the insurer to show that proton therapy is, in fact, "experimental" or "investigational" under the terms of the plan.

On the other hand, federal courts have held that plan language limiting coverage to treatment considered "medically necessary" is a term of coverage. (*Baxter v. MBA Grp. Ins. Tr. Health & Welfare Plan*, 958 F. Supp. 2d 1223, 1228-30 (W.D. Wash. 2013).) The burden of proof in an ERISA case to establish that proton therapy is "medically necessary" rests with the requesting insured. As such, it is now more common to see proton therapy denied on the basis of medical necessity. An insurer may define "medically necessary" with a series of bullet-pointed requirements including that the requested procedure be "not investigational." (*Woodruff v. Blue Cross & Blue Shield of Alabama*, No. 2:16-CV-00281-SGC, 2018 WL 571933, at *6 (N.D. Ala. Jan. 26, 2018).) Nevertheless, the burden of proof remains on the insured to prove that proton therapy meets all terms of the definition. For example, the insured may have to prove that proton therapy is "appropriate and necessary for the diagnosis or treatment," "in accordance with standards of good medical practices accepted by the organized medical community," and "performed in the least costly setting, method or manner, or with the least costly supplies required by your medical condition." (*Ibid.*)

Currently filed and future ERISA proton therapy denial will challenge insurers' internal guidelines and unmask the inherent profit motivation built into the development of these guidelines. Financial incentives and considerations that infect the development of insurers' internal guidelines and proper discovery will reveal that insurers' motivations violate Supreme Court precedent imposing "higher-than-marketplace quality standards on insurers" including that the insurer "'discharge [its] duties'" "'solely in the interests of the participants and beneficiaries.'" (*Metro. Life Ins. Co. v. Glenn* (2008) 554 U.S. 105, 115, 128 S. Ct. 2343, 2350, 171 L. Ed. 2d 299.)

How external medical reviews are used to solidify erroneous denials

Many of the independent review organizations (IROs)[6] that conduct external reviews for state insurance or managed care regulatory agencies are employed by the same health insurance companies whose denial decisions these IROs are asked to review. A survey of six ERISA proton therapy denial cases tried in federal court leaves little doubt as to why health insurers are eager to promote external review. Even though federal law requires state agencies to assign an IRO for each appeal from a list of authorized, accredited organizations, many times health plans will have language that sends denied patients to a hand-picked, pre-selected IRO.

Conflicts of interest abound in these external medical reviews because "health plans frequently employ independent review organizations to perform utilization reviews, conduct quality assurance, and oversee internal appeals – work that generates more revenue for the organizations than performing medical reviews does."[7] IROs have every incentive to rule in favor of plans. Often times, IRO external reviewers' reports do not identify the individual who has upheld the health insurance denial, rely on the same outdated medical literature cited by the insurance company whose decision is under review, and largely read like a boilerplate template with very little real independent analysis.

Proton therapy litigation and *Wit v. UBH*

Successful challenges to proton therapy denials will turn on challenging commercial insurers' internally developed clinical guidelines that are at odds with generally accepted standards of care. On March 5, 2019, U.S. Magistrate Judge Joseph C. Spero (Northern District of California-San Francisco) issued a 100-page decision criticizing United Behavioral Health's ("UBH") use of narrow and restrictive internal clinical guidelines for mental health and substance abuse coverage. (*Wit v. United Behavioral Health*, No. 14-CV-02346-JCS, 2019 WL 1033730, at *48 (N.D. Cal. Mar. 5, 2019).) The Plaintiffs in *Wit* asserted two claims against UBH: (1) breach of fiduciary duty (the "Breach of Fiduciary Duty Claim"), and (2) arbitrary and capricious denial of benefits (the "Denial of Benefits Claim") based on a facial challenge to UBH's Level of Care Guidelines and Coverage Determination Guidelines. Both claims arose under ERISA. Plaintiffs argued that these

Guidelines did not comport with generally accepted behavioral health standards of care and thus, wrongfully denied coverage to many patients, including both adults and children.

According to Plaintiffs, UBH breached the duties it owed as an ERISA fiduciary to the class members by (1) developing guidelines for making coverage determinations that are far more restrictive than those that are generally accepted even though Plaintiffs' health insurance plans provide for coverage of treatment that is consistent with generally accepted standards of care; and (2) prioritizing cost savings over members' interests. As to the second claim, Plaintiffs alleged that the Denial of Benefits Claim was based on the theory that UBH improperly adjudicated and denied Plaintiffs' request for coverage by using its overly restrictive Guidelines to deny benefits.

Magistrate Judge Spero agreed and found that the Guidelines were fundamentally flawed and "tainted by the involvement of the Financial Department in the development of the Guidelines. (*Wit*, 2019 WL 1033730, at *53.) The court explained that the preponderance of the evidence showed that the *only* reason UBH declined to adopt criteria following the generally accepted standards of care, despite a clear consensus among UBH's addiction specialists that those generally accepted standards of care criteria were preferable to UBH's own Guidelines, was that its Finance Department would not sign off on the change. "The Court finds that the financial incentives … have, in fact, infected the Guideline development process." (*Id.* at *47.)"In other words, UBH's Finance Department had veto power with respect to the Guidelines and used it to prohibit even a change in the Guidelines that all of its clinicians had recommended." (*Id.*, at *53.)

Magistrate Judge Spero highlighted problematic language in several years' worth of UBH guidelines that he said proved the insurer did not take into account what beneficiaries actually need, general standards of care and treating underlying conditions. He repeatedly called the polices "unreasonable and do not reflect generally accepted standards of care." (*Ibid.*)

Wit serves as a beacon for challenging systematic and widespread denials of proton therapy cancer treatment. Just one month after the *Wit* decision, on April 16, 2019, UnitedHealthcare agreed to settle an ERISA class action brought by patients denied coverage for lumbar artificial disc replacement surgery on the grounds that L-ADR was considered "investigational" by UnitedHealthcare's clinical guidelines. According to the patients' motion for preliminary settlement approval in *Hill v. UnitedHealthcare Ins. Co.*, No. 2018 WL 6112660, at *1 (C.D. Cal. 2018), UnitedHealthcare agreed to reverse its position and find that L-ADR can be medically necessary. This settlement, approved on May 14, 2019 by Judge David Carter in Orange County federal court, requires UnitedHealthcare to adhere to a new coverage policy for L-ADR, and reprocess patients' claims under UnitedHealthcare's revised coverage guidelines.

"Immoral and barbaric"

On April 3, 2019, another putative class action was filed in Miami federal court by a prominent Miami attorney, Richard Cole of Cole Scott & Kissane PA, who alleges that UnitedHealthcare improperly denied proton therapy for prostate cancer patients, including himself, prior to January 2019 and should therefore reprocess and reimburse patients for those claims. Cole, who was diagnosed with prostate cancer in April 2018, seeks to represent a class consisting of all participants in UnitedHealthcare plans covered by ERISA who were denied coverage for proton therapy to treat prostate cancer based on UnitedHealthcare's internal clinical guidelines in place before January 2019 that asserted it was "experimental or investigational."

On April 29, 2019, Florida federal Judge Robert N. Scola Jr. recused himself from this class action suit challenging UnitedHealthcare's denial of proton therapy. In his one-page recusal, Judge Scola made it publicly known that the denial of proton therapy is "immoral and barbaric." (*Cole v. United Healthcare Insurance Co.*, No. 1:19-cv-21258 (S.D. Fla. Apr. 29, 2019).)

On May 9, 2019, a class action lawsuit against Humana Insurance Company was filed over systematic proton therapy denials. Plaintiff Brittany Day was denied proton therapy treatment for a brain tumor. Due to Humana's wrongful denials, Ms. Day was forced to pay $110,000 out of pocket. Ms. Day's claim was reviewed and denied by David Spiro, M.D., a Humana medical director *board certified in pediatric emergency medicine*, a field of medicine wholly unrelated to cancer treatment. ERISA's claims handling regulations clearly state that "in deciding an appeal of any adverse benefit determination that is based in whole or in part on a medical judgment, including determinations with regard to whether a particular treatment. . . is experimental, investigational, or not medically necessary or appropriate, the appropriate named fiduciary shall consult with a health care professional who has appropriate training and experience in the field of medicine involved in the medical judgment." (29 C.F.R. § 2560.503-1.) Humana's failure to have a trained radiation oncologist review Day's claim is emblematic of a broader practice of various carriers to fail to even dignify proton therapy claims with review from an appropriate health care provider.

There is hope and optimism for patients who have been denied proton therapy cancer treatment. Various insurer practices, which have long served as impediments to proton therapy claim approvals will now come under the microscopes of federal judges around the country. Insurance companies rely on the fact that many members cannot, will not

or are unable to fight them when they deny claims. This is especially so in the context of proton therapy cancer treatment. With the emergence of new legal challenges in courtrooms around the country, insurance companies' shortsighted and destructive practices can be reformed.

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Endnotes:

[1] Kaiser Family Foundation <https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.>

[2] Katherine T. Vukadin, *Delayed and Denied: Toward an Effective ERISA Remedy for Improper Processing of Healthcare Claims* (2011) 11 Yale J. Health Pol'y, L. & Ethics 331, 348.

[3] The Alliance for Proton Therapy Access, Cancer Care Denied: The Broken State of Patient Access to Proton Therapy (May 17, 2018).

[4] *Id.* (citing Caroline E. Mayer, The Claim Game, AARP The Magazine, Nov.-Dec. 2009, at 32 (quoting Connecticut's health care advocate Kevin Lembo as stating that ninety-six percent of denials are not appealed).

[5] Health Affairs Blog, June 23, 2011, Implementing Health Reform: The Appeals Process Amended Rule. https://www.healthaffairs.org/do/10.1377/hblog20110623.011968/full/.

[6] Medical Review Institute of America, Advanced Medical Reviews and AllMed Healthcare Management, Inc. to name just a few.

[7] Health Affairs, *New Standards For Medical Review Organizations: Holding Them And Health Plans Accountable For Their Decisions* (1 Mar 2011), https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2010.0646.