LEUKEMIA & LYMPHOMA SOCIETY®

US Department of Labor
Advisory Council on Employee Welfare and Pension Benefit Plans
200 Constitution Ave NW
Washington, DC 20210

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Written Witness Statement by Steve Butterfield, Senior Director of State Public Policy
On Behalf of The Leukemia and Lymphoma Society
Regarding Claims and Appeals Procedures

The Leukemia and Lymphoma Society (LLS) appreciates the opportunity to provide this statement to the Advisory Council on Employee Welfare and Pension Benefit Plans ("the Council") regarding claims and appeals procedures.

LLS's mission is to cure leukemia, lymphoma, Hodgkin's disease, and myeloma, and to improve the quality of life of patients and their families. We advance that mission by advocating that blood cancer patients have sustainable access to quality, affordable, coordinated healthcare, regardless of the source of their coverage.

Our goal in furnishing this witness statement is to provide the Council with information on and insight into the experience of blood cancer patients as they navigate their disease, and in particular, the ways in which that experience can and oftentimes is disrupted by insurance denials.

Evidence and research suggests that denials are far more common for patients with commercial coverage than those with public (Medicare or Medicaid) coverage. Evidence and research also suggests that delays due to private insurance denials are common, and that these delays can impact treatment access and outcomes for cancer patients. Data also shows that appeals are vanishingly rare, yet some research on appeals outcomes suggests that insurers may be issuing denials without sufficiently examining the validity or necessity of a claim before denying it. We offer recommendations for policymakers to remedy key deficiencies that may be contributing to this situation.

Blood cancer patient profile and experience

"Blood cancer" is a term that encompasses numerous cancers impacting a person's blood, bone marrow, or lymphatic system. Blood cancers typically affect older individuals, although they are also

among the most commonly diagnosed pediatric cancers, with leukemia accounting for 30% of all child cancer diagnoses.

In the past few decades, treatment advances have led to significant improvements in overall survival rates for nearly all blood cancers, and in many cases have converted a once-devastating prognosis into a disease that can be effectively managed as a long-term, chronic condition.[i]

Those scientific and medical advancements, however, have often outpaced the ability of our healthcare and health coverage systems to keep up. A blood cancer diagnosis initiates a complex and terrible choreography, putting patients at the center of abrupt and monumental disruptions that layer immense financial, logistical, and psychosocial pressures on top of the obvious health-related concerns. A blood cancer patient must not only manage their physical health, often while undergoing treatments that can be exhausting, painful, and come with significant side effects including memory loss and cognitive impacts: they must also now be their own care coordinators, medical billing specialists, insurance experts, schedulers, and, sometimes, legal advocates, while also navigating impacts to their daily lives such as their ability to continue working.

Survivorship brings its own challenges. Even patients who achieve stable long-term remission will likely need to undergo more, or more frequent, monitoring and surveillance than the average healthy individual (more frequent lab work, more doctor's appointments), and patients who achieve stability on long-term prescription maintenance therapies will have ongoing and elevated insurance utilization needs in perpetuity.

For pediatric patients, long-term remission and survivorship can mean decades of post-treatment impacts – including increased risk of other long-term health issues - that carry them through working adulthood, when they are most likely to be covered under ERISA-regulated plans. A pediatric survivor may require certain monitoring and diagnostic needs that could, at face value, appear unusual under an insurance company's coverage guidelines. For instance, some pediatric blood cancer treatments are cardiotoxic, resulting in long-term impacts to heart health; some radiation therapies can impact the gastrointestinal system. Expert medical guidance on survivorship treatment for pediatric cancer patients recommends enhanced cardiac and GI monitoring and screening for survivors of pediatric cancers.[ii] However, to an insurance company, an order for a colonoscopy, or a comprehensive cardiac work-up, for an evidently healthy individual in their 20s may well result in a denial if the insurer is not applying appropriately careful scrutiny to the medical rationale behind the claim.

How insurance denials impact blood cancer patients

"Blood cancer" may be a singular term, but patients do not experience cancer as a singular event. Rather, patients experience a huge volume of healthcare needs and health system interactions – and, consequently, discrete insurance claims – in a compressed window following diagnosis, followed by a

steadier but still elevated number of claims over a much longer period. The simple fact is that a higher volume of claims means more opportunities to receive a denial.

The careful sequencing and coordination of these services and claims, particularly early in treatment, is critical. A primary care visit to discuss lingering fatigue may lead to initial blood work that indicates a problem, which necessitates additional lab draws, the results of which may dictate when treatment needs to be initiated (sometimes immediately, in acute cases); ongoing real-time monitoring of the evolving pathologies can be necessary in order to tailor treatment to disease responses, or provide evidence of a patient's eligibility or suitability for a clinical trial that may represent their best chance at receiving optimal care.

A delay – or a denial – of any one of these individual services can imperil the steady progress of a treatment plan, and even minor delays in initiating or continuing treatment can have significant consequences for cancer patient outcomes.[iii] A report released by LLS in 2023 includes the story of a 9-year-old blood cancer patient who was found to be a candidate for a clinical trial. However, insurance denials for needed air transport led to a delay in his enrollment: by the time he arrived at the trial center, his liver enzyme levels had increased and rendered him ineligible for participation.[iv]

Claims denials are particularly problematic when insurer medical standards and approval guidelines are out of sync with the medical community on newer treatments and therapies, or advancements in standards of care. Insurer guidance can also fail to adequately accommodate even basic standards of care for particularly rare disorders or diseases, a category that includes several blood cancers.

Last year, ProPublica published a series of articles investigating insurance claims denials.[v] They found that insurers frequently denied coverage for newer therapies, even after regulatory approval or their adoption as the standard of care by relevant expert medical organizations.

In one case, a throat cancer patient with an ERISA-regulated insurance plan was denied coverage for proton beam radiation therapy because his plan required patients to endure older, less effective, or more toxic treatments before approving newer, more effective, or less toxic ones. After exhausting his appeal rights, the patient sued, and two federal courts have now found that the insurer relied on outdated or insufficient evidence in determining the medical necessity of the patient's treatment, ignoring research specific to the patient's type and location of cancer and newer evidence-based guidance from the National Comprehensive Cancer Network (NCCN).[vi]

In another case reported on by ProPublica, an insurer held that it was not required to cover FDA-approved gene therapy treatments known as CAR T[1] under a state law mandating insurer coverage for

[1] CAR T stands for "chimeric antigen receptor T-cells" and, in this context, refers to a class of immunotherapy treatments for cancers that modify an individual patient's T-cells in order to produce an immune response to their cancer. The FDA has approved a number of CAR T therapies to treat several blood cancers. More information at: https://www.lls.org/treatment/types-treatment/immunotherapy/chimeric-antigen-receptor-car-t-cell-therapy

all approved cancer therapies because CAR T was not a "drug" and therefore excluded from the state mandate. At least one patient died from their lymphoma while fighting this coverage exclusion.[vii]

Data on denials is limited, but concerning

Robust data on commercial health insurance denials is extremely limited, but what data does exist uniformly paints an alarming picture of high denial rates with vanishingly few appeals.

One of the few sources of consistent, centralized data on denials comes from the Center for Medicare and Medicaid Services (CMS). The federal government has expansive authority under the Affordable Care Act (ACA) to collect, compile, and disseminate data from commercial insurance carriers – *including ERISA regulated plans* - but currently exercises that authority minimally, requiring only limited annual reporting from insurers on their individual market/nongroup "qualified health plans" (QHPs) offered through the federally facilitated marketplace (FFM), also known as Healthcare.gov.[viii]

A KFF analysis of the data reported by QHP issuers shows that while plan- or carrier-level denial rates vary widely, the industry as a whole denied nearly 17% of all claims for in-network services received in 2021 (totaling more than 48 million denied claims).[ix] CMS requires these carriers to include data on the reason for the denial, and allows 5 options: lack of prior authorization (PA), excluded service under the plan benefits, denials by medical necessity, denials for out-of-network care, and "all other reasons." Of those denied claims, insurers categorized nearly 77% (or slightly more than 34 million discrete claims) as having been denied for "all other reasons", which means that nobody but the issuers has any information on why nearly 12% of *all* claims reported for the plan year were denied.

KFF analysis of CMS data also reveals that a miniscule number of these denied claims are appealed: just more than 90,000 of the 48 million denied claims were reported as having been appealed, resulting in an appeal rate of less than two-tenths of a percent; of the claims that were appealed, nearly 60% of the initial denials were upheld by issuers.[x]

In a consumer survey conducted in 2023 in which participants were asked whether they had experienced an insurance claims denial, KFF found that commercial denials are significantly more common than Medicare or Medicaid denials; that high or frequent healthcare utilizers (such as cancer patients) are more likely to receive a denial; that consumers who experience a denied claim report significant "serious consequences" as a result, such as delayed care or not receiving the care they needed at all; and, perhaps most alarmingly, that 69% of respondents with denied claims did not know that they had appeal rights at all.[xi]

CMS data raises questions about the sheer volume of claims being denied, but more focused studies also bring into question the decision-making rationales behind these denials. A recent study in the Journal of the American Medical Association examined more than 200 denied claims for cancer-related

radiotherapy at a single large academic cancer hospital. 199 of those claims were submitted to commercial insurers. The study found that these denials resulted in multi-day delays to treatment initiation, which, as previously noted, can impact treatment efficacy and patient outcomes. However, the study also found that the treatment plan requested in a significant number of the cases was "guideline concordant" – that is, the treatment request was in line with the best expert medical guidance on standard of care. Furthermore, when appealed, most of the claims in this study (61.7%) were ultimately approved with no alteration to the initial treatment request or treatment plan.[xii]

Even when consumers do appeal, the process is daunting, opaque, and exhausting – particularly for patients who are navigating the burdensome process of treating and managing cancer, as described above. In one of the articles ProPublica published on denials, a leading national expert on insurance coverage and claims denials noted that when she, herself, was undergoing cancer treatment, "sometimes it would just make me cry when insurance would deny a claim…it was like, 'I can't deal with this now.'"[xiii]

Recommendations

- **Better data collection**: better data is needed across all plan types, but in particular, *any* data or reporting by ERISA-regulated plans would be a significant improvement over the current status quo. In general, there is a large unmet need for complete encounter records from Medicare, Medicaid, and private insurance that can be used to compare care experiences and outcomes among patients. Federal agencies need to exercise the significant existing authority already granted them to collect, aggregate, and report on claims-level data, including denials.

  While states have a clear interest in collecting and acting on data regarding insurance denials, regulatory preemption limits their ability to collect data on ERISA-regulated plans through existing data collection approaches such as all-payer claims databases (APCDs). A federal APCD would provide a source for like-to-like claims-level comparisons that includes data on ERISA-regulated plans.

  That data should be far more granular and detailed than what is currently required. For instance, if the current selection of denial rationales is insufficient (as is suggested by the fact that more than three-fourths of all denials are categorized as "other"), then agencies should work with carriers to identify additional rationale categories that would provide a more useful understanding of why insurers are denying so many claims.

  Federal agencies should also require better and more detailed reporting on appeals and appeals outcomes. For instance, carriers should have to report how many successfully appealed claims were ultimately approved as originally requested; the length of time from initial denial

to overturn; and how many successfully appealed claims were ultimately found to have been concordant with either the carrier's own medical guidelines or 3rd party medical guidance.

- **Medical guidelines**: ERISA-regulated plans and third-party administrators (TPAs) should be required to report and publicly display the criteria used to make medical necessity determinations for claims. If the plan/TPA uses proprietary guidance they have developed themselves, or uses guidance from a third-party source that is *not* a professional medical association (for instance, a company or firm that specializes in providing such services for insurers, such as Carelon), the plan/TPA should have to provide information on how and why the standards they use deviate from general standard of care or clinical guidance from relevant expert medical associations (such as the National Comprehensive Cancer Network), how frequently such standards are reviewed and/or updated, and how the standards track and incorporate new therapies (for instance, how a plan/TPA incorporates newly FDA-approved drugs into its coverage).

- **Consumer-friendlier appeals**: appeal rights and any pertinent related information, such as details on or descriptions of the appeals process, should be prominently included on and displayed in every claims-related communication between a plan/TPA and a member. For instance, basic information about the right to appeal could be required to be displayed in a large, visually engaging font on every page of a claims-related communication. More detailed information about appeals rights should be required to be provided in plain and accessible language, assessed against readability guidelines and incorporating best practices related to health literacy. Carriers should be required to conduct specific outreach to patients and consumers with denied claims informing them of their appeals rights, including in both written form and at least one other form of communication, such as a telephone call, email, or text message. Regulators should also explore the possibility of requiring carriers/TPAs to automatically initiate first-level internal reviews of denied claims, as is required practice for Medicare Advantage (MA) plans.

- **Monitor and regulate artificial intelligence (AI) and other claims automations**: as more automated claims systems are adopted, regulators must carefully monitor and scrutinize the use of such systems and be prepared to take swift action as needed to regulate the use of such systems. Plans/TPAs should be required to report on their use of any automated system, including one based on algorithmic or AI models, to determine claims coverage. This reporting should include significant detail on the data, guidance, or other information sources used to "train" or calibrate the algorithm/system; which clinician within the plan/TPA is ultimately responsible for overseeing and managing the system and, ultimately, accountable for the decisions made by the system; and how the company monitors or plans to monitor any coverage determinations made by such system and evaluate their validity against the relevant coverage criteria.

Regulators should also curtail the ability of plans/TPAs to use such systems to conduct mass claims reviews by ensuring that a human with relevant knowledge and expertise is required to review every denial made by such a system for an amount of time that would be reasonably necessary to determine the claim validity based on the specifics of the case, and require that human to reject any automated denial that is found to be discordant with the relevant medical or coverage criteria. Regulators should also ensure that both plans and TPAs are jointly responsible and held accountable to patients for the use of automated claims and denials systems, regardless of which entity technically possesses the license to use such system.

Finally, if plans/TPAs utilize such automated systems in the claims determination process, they should be required to prominently inform consumers that a coverage decision was made in whole or in part by such an automated system in all claims-related communications with that consumer.

Conclusion

The Leukemia and Lymphoma Society again expresses its gratitude for the opportunity to provide these comments. Any questions or requests for additional information can be directed to Steve Butterfield, Senior Director of State Public Policy.

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