The Cost of Omission: How Anthem's Lack of Required Documentation to Manage Drug Availability Sparked a Class Action Over Zepbound® Coverage

Introduction

In September 2025, a class action lawsuit was filed in the Southern District of Indiana, *Newkirk v. Elevance Health, Inc*. This federal lawsuit, recently amended, underscores and puts into sharp focus a critical compliance failure in prescription drug plan administration: the lack of necessary Prescription Drug Benefit Plan documentation to support the management and application of a particular drug and the ability to enforce the management of use and related benefit exclusions. The plaintiff, Amy Newkirk, was prescribed Zepbound® (tirzepatide) to treat moderate obstructive sleep apnea (OSA), a condition for which the drug received FDA approval in December 2024. Anthem denied coverage, citing a vague and amorphous rule that does not permit use of "any drug mainly *used* for weight loss." But the plan documentation, consisting of less than 9 pages in total, was virtually non-existent and utterly failed to properly address and define the use and management of Zepbound; in fact, it did not mention GLP-1 medications at all. Making matters worse, in response to a direct request, Anthem/CarelonRx failed to produce any internal documents to justify its interpretation of this vague term.

This case is <u>not</u> about a gray area in coverage; it's about the absence of documented fundamental rules to provide for the management of prescription drugs. And yes. It is also a direct violation of ERISA to fail to have a proper Plan Document (ERISA §402) and a complete Summary Plan Description (ERISA §102).

This lawsuit serves as a ***WARNING***: When Plan Sponsors and Plan fiduciaries fail to provide full written rules, and they cannot produce the documents that govern Prescription Drug Plan management program terms, limits, and exclusions, they risk exposure to litigation, penalties, and reputational harm, and of course, substantially increased costs!

The Factual Record: A Denial Without Clear Written Rules

Amy Newkirk had long suffered from moderate OSA and had tried CPAP and BiPAP therapies without success. In early 2025, her endocrinologist prescribed Zepbound, which had recently been approved by the FDA as the first and only medication for moderate to severe OSA. When her provider attempted to submit a prior authorization request, Anthem's pharmacy benefit manager blocked the submission, stating that the drug was not covered. Anthem later confirmed the denial, asserting that Zepbound was excluded because the plan does not cover a "[a]ny drug mainly *used* for weight loss."

However, the plan documents did not list Zepbound or GLP-1s as excluded medications. It did not provide for protocols or specific GLP-1 strategies, or, for example, there are no rules that specifically limit the use of these GLP-1 type drugs only for diabetes. The language relied upon was ambiguous, without a clear rule to apply, which is also contradicted by other terms in the too skinny (no pun intended) prescription drug provision in the Anthem Plan booklet. If anything, the FDA-approved use significantly cuts against the Anthem claim determination, and its utter failure to provide clear benefit plan terms makes Ms. Newkirk's claims more than facially valid. In fact, Anthem's denial letter failed to explain why Zepbound, when prescribed for OSA, a non-weight loss use, fell under the exclusion, and failed to address other terms or provide any substantive documentation for its denial.

Newkirk appealed the denial and requested that it be treated as a non-formulary exception request. She also asked Anthem to produce all documents related to the denial, including internal formulary decisions, clinical

reviews, and any rationale used by its pharmacy and therapeutics committee. Anthem failed to provide any of these materials. The only documents it eventually produced were an appeal letter, the plan certificate, and the denial notice – none of which addressed the core issue: why Zepbound was excluded for OSA. The unfortunate reality is that if the Plan documentation were clear about a management program or limit on GLP-1 drugs, there would be no case – period.

Legal Claims: ERISA Violations and Failed Benefit Plan Management Rooted in Documentation Failures

The failure to properly articulate plan rules and policies around prescription drugs is particularly surprising here, because Anthem is a large and sophisticated health plan insurer. But, the failed tradition of poor prescription drug plan benefit documentation is more than highlighted by the shoddy approach taken to the management of prescription drug benefits in the Anthem booklet.

This has led to serious allegations and potential risks and losses for Anthem. Aside from a failure on management of benefits, the complaint alleges multiple violations of ERISA, all stemming from Anthem's failure to document and disclose the basis for its denial:

- Under ERISA §502(a)(1)(B), Newkirk seeks benefits due under the plan, arguing that Zepbound meets the plan's definition of a covered prescription drug and that no valid exclusion applies.
- Under ERISA §503, she alleges that Anthem failed to provide a full and fair review of the denial. The denial notice lacked the specific reasons and plan provisions required by 29 C.F.R. § 2560.503-1(g)(1).
- Under ERISA §104(b)(4) and § 502(c)(1), she seeks statutory penalties for Anthem's failure to produce "other instruments under which the plan is established or operated," including internal documents that would justify the exclusion.
- She also seeks classwide relief for similarly situated individuals who were prescribed Zepbound for OSA and denied coverage under plans that lacked the necessary documentation to support such exclusions.

The Compliance Breakdown: A Lack of Necessary Documentation

This case is not about a dispute over medical necessity or clinical judgment. It is about the absence of the documents that ERISA requires Plan Sponsors to maintain and disclose, and Plan fiduciaries to follow. Anthem's failure to produce any documentation to explain its rationale for excluding Zepbound for OSA under the terms of the Plan – despite FDA approval for a non-weight loss use, and a physician's prescription – suggests that no such documentation exists. That is a fundamental breach of fiduciary duty.

ERISA requires that plan sponsors and administrators maintain and disclose all documents that govern plan operations. This includes not only the SPD and plan document, but also internal policies, formulary decisions, and clinical evaluations. When a denial is issued, the plan must be able to point to specific language and supporting materials. In Newkirk's case, Anthem could not.

So, from a breach of ERISA fiduciary duty, we also have the potential mismanagement of Anthem's own insured product through the use of a limited, short, generic form of prescription drug documentation that lacks plan-specific documentation for prescription drug benefits.

Implications for Plan Sponsors

The Newkirk lawsuit illustrates the legal and operational risks of relying on vague exclusions or failing to update plan documents in response to evolving medical standards. GLP-1 medications like Zepbound are gaining

new FDA indications beyond weight loss, including for OSA, cardiovascular risk reduction, and liver disease. If a plan intends to exclude these drugs, it must do so with precision – and it must be able to produce the documentation to support that decision. And, it must eliminate the use of vague and unavailing plan terms that lead not only to confusion, but to management and compliance failures.

Plan sponsors should make sure they actually have proper documentation and language for prescription drug benefits!

Band-Aid approaches, limited language, failed efforts to incorporate supplements, and other poor approaches are not only a failure to manage prescription drug benefits and fail the compliance basics, but also result in increased liability and costs. Sponsors must be sure that Prescription Drug Plan Documents and SPDs (and Summaries for Non-ERISA Plans) are well constructed and reviewed, include appropriate formulary references and required PBM program language. Management through solid documentation ensures that all governing instruments, including internal formulary policies and clinical justifications, are maintained and readily producible. Without this documentation, even a defensible denial can become indefensible in court.

Conclusion

The Newkirk case is a powerful reminder that in ERISA compliance, documentation is everything and an absolute mandate now. Anthem's denial of coverage for Zepbound was not challenged because of an individual's particular need; it was challenged because the denial was unsupported. The total lack of necessary documentation turned a routine coverage decision into a federal class action. For plan sponsors and fiduciaries, the lesson is clear: if you can't produce it, you can't defend it.

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