

September 24, 2025

Via Electronic Correspondence

Dr. Gail Mizner Colorado Division of Insurance 1560 Broadway, Suite 850 Denver, CO 80202

RE: Concerns About the Enbrel UPL Rulemaking Process

Dear Chair Mizner:

Aimed Alliance is a not-for-profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. We appreciate the Colorado Prescription Drug Affordability Board's ("PDAB" or "Board") commitment to addressing the rising cost of prescription drugs for Colorado patients. As the Board continues to move forward with the upper payment limit (UPL) rulemaking process for Enbrel, Aimed Alliance urges it to proceed with caution, carefully evaluating potential unintended consequences and ensuring that patient feedback is meaningfully prioritized during the process.

I. Exercise Caution as the Board Proceeds with the UPL Rulemaking Process and Consider Unintended Consequences

Aimed Alliance appreciates the inherent challenges and complexity of conducting affordability reviews. However, we are concerned by the Board's accelerated timeline and recent challenges in data collection and interpretation. Therefore, we urge the Board to proceed with caution and diligence to ensure the Board has the opportunity to consider and mitigate potential unintended consequences of a potential UPL, without the quality of the Board's decisions and the public's confidence in its work.

Aimed Alliance is particularly concerned given the recent issues with data accuracy during the affordability review process. During the April 2025 meeting, the Board acknowledged that data submitted by a pharmacy benefit manager (PBM) had been mischaracterized, creating confusion between Medicare and commercial data sets. Although the Board claimed this error would not affect its affordability reviews, it remained unclear to advocates and consumers how this mischaracterized data would not negatively influence the review process. Ultimately, the Board decided to proceed without fully addressing the public's concerns, jeopardizing public trust in this process.

Now, as the Board moves through the UPL rulemaking process for Enbrel, Aimed Alliance is concerned by the potential for significant unintended consequences. Data show that 57 percent of surveyed health plans expect both UPL-targeted drugs and their therapeutic alternatives to face formulary changes, and half anticipate increased utilization management. Thus, there is a strong

¹ Avalere Health, *Update: Health Plans' Perceptions of PDABs and UPLs* (Mar. 28, 2025), https://advisory.avalerehealth.com/insights/update-health-plans-perceptions-of-pdabs-and-upls.



likelihood that PBMs may choose to exclude Enbrel from formularies or subject patients to non-medical switching once a UPL is implemented.

While the Board acknowledged that non-medical switching already occurs, it is important to recognize that this practice is harmful to consumers who have spent months or years testing, trying, and failing on alternative treatments before identifying a treatment that works for them. For these patients, non-medical switching jeopardizes their health and all their hard-earned progress. Furthermore, when patients are currently stable on a treatment and forced to change medication, this risks disease flares, reduced treatment effectiveness, and higher downstream medical costs that could erase any short-term savings derived from a UPL.

Moreover, the Board's recognition that non-medical switching is an existing practice should not be considered an endorsement of this tactic in health insurance or a reason for the Board to dismiss how this practice may be expanded by a UPL. It is the job of policymakers, like this Board, to mitigate or prevent bad practices, not to perpetuate them.

Establishing a UPL is likely to intensify, not merely maintain, this practice. As such, the Board has an obligation to identify how it will ensure that consumers who are stable on their current treatments are not non-medically switched due to the implementation of a UPL. While the Board has recognized these potential unintended outcomes, the Board has only indicated that it could address this issue by withdrawing a UPL, if necessary. While Aimed Alliance appreciates the Board considering solutions to potential access challenges, this raises critical process questions regarding implementation. For example, what will be the threshold for establishing sufficient harm for a UPL to be withdrawn; can the harm only be to consumers, or will provider-harm be included as well; what data sources will be used; and how will it be collected and measured? Aimed Alliance believes these are all critical questions that must be answered, and without a clear, enforceable mechanisms to monitor patient impact, the ability to withdraw a UPL provides minimal protection.

Aimed Alliance does not intend for a slower process to halt, change, or alter the intent of the Colorado Board to develop upper payment limits for selected prescription drugs. However, considering the approach adopted and implemented by the Board will be replicated by the Board in future reviews, and potentially by other state PDABs, we urge the Board to develop a thoughtful process that ensures a meaningful way for consumers to engage the Board if a UPL establishes an access challenge.

Ultimately, Aimed Alliance urges the Board to exercise caution as it advances the rulemaking process and ensure a credible, meaningful, replicable, and sustainable process is developed that includes a mechanism to address unintended consequences. This will promote public trust in the process and ensure better outcomes for patients, providers, and caregivers in the long-term.

II. Prioritize the Patient Voice During the UPL Rulemaking Process

Aimed Alliance appreciates the Board's commitment to incorporating the patient voice into the cost review process. Patients are the individuals most directly impacted by affordability



determinations, yet their perspectives are far too often underrepresented in healthcare decisionmaking.

For example, a recent patient-led study found that prescription drug affordability was complex and varied between individuals.² Importantly, the survey found that access and affordability are often conflated, with 75% of respondents stating they skipped or stretched doses at least once due to insurance delays, not price. While less than 15% reported skipping or missing doses solely due to price.³ As such, Aimed Alliance urges the Board to not only engage with patients through information surveys and public comment periods, but to also meaningfully integrate and reconcile patient-reported feedback and data with its final affordability determinations. Reconciling decisions with feedback informs consumers on how their information was helpful and encourages consumers to continually engage with these processes.

Moreover, reconciliation of feedback and decision-making can provide greater clarity to regulators, policymakers, and legislators on the types of supplemental reforms that may be necessary to better and more directly address consumer affordability. For example, if a primary reason consumers report a drug as unaffordable is out-of-pocket costs resulting from delays in prior authorization—rather than the actual price of the drug—it is important to reconcile why the Board would pursue a UPL for a drug whose unaffordability is not driven by its cost. However, insights like this may not be adequately derived from survey questions that are not designed with patients, caregivers, and healthcare consumers in mind. Therefore, Aimed Alliance urges the Board to center patient experience throughout its affordability reviews to adequately understand the factors that make a prescription drug "unaffordable."

III. Conclusion

In conclusion, Aimed Alliance commends the Board for its commitment to addressing the rising cost of prescription drugs for Colorado patients. However, we urge the Board to proceed with caution, carefully evaluating potential unintended consequences and ensuring that patient feedback is meaningfully prioritized during the process. Aimed Alliance looks forward to continued engagement as the Board conducts its affordability reviews. If you have any questions or wish to discuss these matters further, please contact us at policy@aimedalliance.org.

Sincerely,

Olivia Backhaus Staff Attorney

² EACH/PIC Coalition, *EACH/PIC Releases Results from Patient-Led Survey on Drug Affordability* (Aug. 4, 2025), https://eachpic.org/each-pic-releases-results-from-patient-led-survey-on-drug-affordability/.

³ *Id*.