COLORADO
Department of Regulatory Agencies
Division of Insurance

Regulatory Analysis - Proposed Rule # 3 CCR 702-9 Part 4.3 Upper Payment Limit for Enbrel

(I) A description of the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule; (Colo. Rev. Stat. § 24-4-103(4.5)(a)(I))

The classes of persons affected by the proposed rule to establish an upper payment limit (UPL) for Enbrel may include several actors in the state, including consumers, pharmacies, healthcare providers, and carriers.

Carriers may incur minor administrative and compliance expenses, for example, by implementing new systems or adjusting reporting practices. Furthermore, pharmacies and providers may bear certain administrative burdens if the rule changes documentation, billing, or data-sharing processes; however, the magnitude of these burdens is estimated to be minimal and will vary depending on each entity's current practices.

Colorado consumers may experience increased transparency, more consistent access to prescription benefits, and potentially lower or more predictable costs[1].

Pharmacies and providers may also benefit from clearer regulatory guidelines, potentially fairer reimbursement processes, and improved coordination with carriers and pharmacy benefit managers (PBMs). Carriers may also benefit from standardized regulations, reduced uncertainty in compliance, and possibly a more streamlined claims environment.

- For pharmacies and providers, clearer regulatory guidelines and fairer reimbursement processes may lead to more predictable revenue streams and lower administrative burdens. With standardized rules, they can better plan for operational costs, reduce billing disputes, and streamline processes across different payers. Improved coordination with carriers may also foster more efficient supply chain and claims management, enhancing profitability and supporting growth in a competitive market.[2]

- For carriers, having standardized regulations reduces uncertainty and compliance variability, allowing them to forecast expenses and manage risk more accurately. A streamlined claims environment can decrease administrative costs and improve customer satisfaction by ensuring quicker, more reliable reimbursements. This consistency supports a more robust business model by stabilizing cash flow and reducing the costs associated with regulatory compliance.[3]

It is important to note that while these identified benefits and costs may exist for each class of persons, some economic impacts remain unknown or difficult to quantify until the rule is fully implemented. For example, exact compliance costs depend on the complexity of each carrier's existing systems, pass-through costs to consumers can fluctuate based on broader market conditions, and long-term savings for any group—whether consumers, providers, or carriers—may not be evident until after the rule has operated in practice for a certain period.

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[1] https://www.healthaffairs.org/doi/10.1377/hlthaff.2024.00469
[2] https://pubmed.ncbi.nlm.nih.gov/37200029/
[3] https://pubmed.ncbi.nlm.nih.gov/17609491/

(II) To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons; (Colo. Rev. Stat. § 24-4-103(4.5)(a)(II))

As the Board embarks on a rulemaking process—reviewing an extensive volume of quantitative and qualitative data to determine a specific UPL amount—the full range of economic benefits, as well as the short- and long-term impacts of regulatory actions on the prescription drug supply chain, remains to be seen. Without knowing the specific dollar amount the Board may eventually choose, it is difficult to make more precise estimates of the economic benefits.

The proposed rule is designed to reduce prescription drug costs for consumers through reduced out-of-pocket costs and premiums, increased consumer access and adherence, and increased market competition. By statute, carriers must use savings from a UPL to reduce consumer costs via reduced out-of-pocket costs and lower premiums.[4] Consumer access to a drug may be increased by improving patient adherence and pharmacy fill rates, which can improve the health of consumers and limit increased use of additional medical services for worsening conditions.[5,6] Additionally, these efforts also aim to reduce prescription drug costs for consumers through increased competitiveness in the market and lower costs due to the availability of therapeutic alternatives.[7] If the Board considers therapeutic alternatives to establish a specific UPL, this could result in increased use of targeted drugs and lower drug spending by consumers and payers, while maintaining access.

The proposed rule is intended to Improve affordability for the health care system by reducing health plan costs for the drug. Additionally, these efforts seek to decrease overall healthcare system expenses by lowering health plan costs and adjusting pharmacy reimbursements in line with reduced drug prices.

While some cost reductions may appear soon after implementation, other benefits—such as improved adherence or lower premiums—could take longer to materialize as carriers, pharmacies, and other stakeholders adapt to the new UPL. This process may involve updates to reimbursement systems, contract negotiations, and changes in benefit design, all of which can influence the timing and scope of realized savings.

Prescription drug regulations are created and updated at the federal and state levels frequently. The exact impact of such regulations depends on how the various, and often complex and opaquely related prescription drug supply chain entities respond. The Board encourages direct input from prescription drug supply chain entities during the rulemaking process to better understand the economic benefits of a UPL.

(III) The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues; (Colo. Rev. Stat. § 24-4-103(4.5)(a)(III))

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[4] *See* § 10-16-1410(1), C.R.S.
[5] https://pubmed.ncbi.nlm.nih.gov/37200029/
[6] https://pubmed.ncbi.nlm.nih.gov/17609491/
[7] https://eadn-wc03-8290287.nxedge.io/wp-content/uploads/2024/04/Upper-Payment-Limit-White-Paper.pdf

The direct cost to the government of administering the rule is equivalent to the cost of Board staff time and contractor resources spent preparing data for the Board to review during the UPL rulemaking process.

If the Board establishes a UPL, the following direct costs to the government may occur:

- Board staff time - If a UPL is established, staff time will be spent inquiring whether manufacturers intend to make the prescription drug available for sale in the state and rationale, notifying consumers of a decision to establish a UPL, and reporting on UPL and manufacturer responses to the General Assembly.
- Attorney General Office (AGO) staff time - Pursuant to section 10-16-1411(3), C.R.S., the attorney general is authorized to enforce the UPL. If a UPL is established, the AGO has enforcement authority.

It is difficult to estimate the direct and indirect costs to businesses and other entities because of the reasons listed above. The Board has not yet specified the UPL amount - the Board is beginning a rulemaking process to review a significant volume of quantitative and qualitative data in determining whether to establish a UPL and what specific dollar amount the UPL should be. Without knowing the specific dollar amount the Board may eventually choose, it is difficult to make more precise estimates of anticipated costs.

(IV) A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction;

The probable costs of the rule are direct costs to the government, including implementation by PDAB Staff and enforcement by the AGO as outlined above, and potentially other direct and indirect costs to businesses and other entities, including consumers, health care providers, pharmacies, and health insurance carriers, based on the implementation of a UPL. The benefits of the rule are numerous, including reduced costs for consumers, increased market competitiveness, and increased consumer access.

Inaction could mean that some Colorado consumers may not be able to access Enbrel at a lower cost. If this regulation isn't adopted, prescription drug supply chain entities would likely continue operating as usual.

(V) A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule;

The Board is tasked with enacting existing statutes, which include reviewing prescription drug costs, evaluating a drug's impact on Coloradans through affordability reviews, and may set an upper payment limit for certain prescription drugs.

Additionally, the Board has the authority to make recommendations to the General Assembly regarding payment-specific, legislative strategies to address Enbrel's unaffordability for Colorado consumers. While the Board already has the ability to make recommendations to the General Assembly, the Board could provide payer- and payment-focused recommendations specific to the prescription drugs it finds unaffordable. Examples of recommendations could include co-payment caps for unaffordable prescription drugs and limits on utilization management. In addition, the federal government could act to reduce pharmaceutical costs.

(VI) A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule.

As previously stated, the Board is tasked with enacting existing statutes, which include reviewing prescription drug costs, evaluating a drug's impact on Coloradans through affordability reviews, and may set an upper payment limit for certain prescription drugs. At this time, the Board is continuing to focus efforts on assessing prescription drug affordability through its established processes of conducting affordability reviews and may begin to set upper payment limits on select drugs, as these are the current tools the Board has the authority to enact.