



COLORADO

**Department of
Regulatory Agencies**

Executive Director's Office

MEMORANDUM

To: Joint Budget Committee
From: Department of Regulatory Agencies
Re: Update on Prescription Drug Affordability Board information
Date: March 12, 2025

Please find below a summary of updated information with respect to the Prescription Drug Affordability Board (PDAB) since the time of the Department's hearing before JBC in December.

Amgen filed suit against the PDAB, PDAB Members, Commissioner Conway, and AG Weiser in federal district court. To date, the total cost of defending the litigation against these parties has been \$154,255. Those costs have been primarily associated with preparing and arguing on motions for summary judgment; the motions were argued in October 2024. At this time, we are unable to estimate the ongoing costs with the litigation as those costs are dependent on the court's decision on the summary judgment motions.

Regarding the progress of the PDAB Board's drug review, in 2023, the Board approved a list of 604 drugs that met the thresholds outlined in the law and therefore were eligible for an affordability review. The Board determined which of the 604 drugs to select for affordability review by applying 19 data requirements (referred to as selection criteria) listed in the statute (Section 10-16-1406(2), C.R.S.) to those 604 drugs. After extensive public comment, input from the Advisory Council, and with the support of two experts from the Skaggs School of Pharmacy who led the Board in a multicriteria decision making exercise to rank and weight selection, the Board narrowed the 604 drugs by setting thresholds that aligned with their priorities of number of patients impacted, change in WAC, and patient spending.

On August 4, 2023, the Board adopted resolutions to select the following five (5) drugs for affordability review:

- Trikafta
- Genvoya
- Enbrel
- Stelara
- Cosentyx

The affordability reviews for each of these drugs has been completed. Each affordability review contained 15 statutorily set criteria for the Board to consider in determining whether the use of a prescription drug was unaffordable to Colorado consumers. Each review involved extensive data analysis as well as input from patients, caregivers, providers, consumer groups, individuals with scientific and medical training, industry, and other experts. Feedback was obtained through surveys as well as at 14 drug specific stakeholder meetings. Those reports run anywhere from 200 pages (Genvoya) to almost 600 pages (Trikafta).

Although there are currently 7 states with PDABs, many of which became law prior to Colorado's PDAB, Colorado's PDAB is the first PDAB in the country to complete any affordability reviews. Based on the Board's review of the reports and considering feedback from the community at large over multiple Board meetings, the Board voted that two drugs, Trikafta and Genvoya, were not unaffordable for Coloradans. That concluded the process for those drugs.



Again, based on the Board’s review of the reports and considering feedback from the community at large over multiple Board meetings, the Board voted that three drugs, Enbrel, Stelara, and Cosentyx, were unaffordable for Coloradans. As a result of the Board’s decisions, Enbrel, Stelara, and Cosentyx are eligible for an upper payment limit (UPL), which is established via the Board’s rulemaking process. The Board has said it plans to hold at least three UPL rulemaking hearings for each prescription drug. Enbrel’s first UPL rulemaking hearing will begin in Spring 2025; it is anticipated that the rulemaking hearings for Stelara and Cosentyx will begin later in 2025.

In late 2024, the Board adopted updated regulations to align the affordability review process with new statutory criteria related to prescription drug eligibility and selection, including incorporating patient feedback for prescription drugs that treat rare diseases (HB23-1225 and SB24-203). Board staff anticipate that the number of prescription drugs that will be eligible for the next round of affordability reviews will likely be in the 600 range, similar to the first round of affordability reviews.

If you would like any further information, please do not hesitate to reach out.

