

November 7, 2023

## Colorado Pharma Drug Board Tees Up Votes

Genvoya, Enbrel & Trikafta '24 Affordability Review Votes by December 15

Relevant Companies



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## »» Our Take & Next Up

**The State of Colorado Prescription Drug Affordability Review Board (PDAB) is performing reviews for Genvoya (GILD), Enbrel (AMGN), Trikafta (VRTX) with key votes taking place in early-mid December.** The final review and the board's determination re: setting an upper payment limit (UPL) is expected on December 15. If the Board (1) determines a drug is unaffordable and (2) determines that a UPL is necessary, the board would undergo rulemaking in January 2024. Following a regulatory process, a UPL could be released in spring 2024 (as early as March/April) for the three cohort #1 medicines. There remain open questions about the law: Medicaid, for instance, isn't explicitly included as a "state plan" for UPL purposes. Rulemaking will seek to answer key questions in 2024. The board is operating with less-than-robust input from fall listening sessions (patients & providers) and a survey with tight deadlines.

**In January 2024, the affordability process is expected to repeat for cohort #2: Cosentyx (NVS) & Stelara (JNJ).** The final UPL for cohort #2, if determined, is not expected to be released until after May 2024. After a UPL is set, we may see requests for judicial review and potential lawsuits from manufacturers and patient groups. While state lawmakers can provide oversight, the state legislative body is expected to be largely supportive of PDAB's work.

## »» Key Points

**As a reminder, other state PDAB boards are in the process of setting UPLs with Maryland up next.** MD is currently in the process of setting a framework for their UPL process and are expected to select their list (~5 drugs) for affordability review in January 2024. Statutorily, WA's PDAB can't set UPLs until 2027. CO is expected to serve as a template for these states with affordability reviews on the horizon. MN has a board, and MI is looking to move forward.

**The selected medicines (5 total) are split into two cohorts for the review process.**

- The first cohort that is undergoing the affordability review process includes Genvoya, Enbrel, and Trikafta.
- The second cohort, with review starting fresh in 2024, includes Stelara and Cosentyx.
- CO has legislative authority to perform the same analysis for up to 18 drugs a year.

**We believe that Trikafta (cystic fibrosis, VRTX) may be deemed affordable and therefore not need a UPL to be set, based on the Board's discussions.** The Board spent a majority of its recent PDAB meeting (link [here](#)) discussing the affordability of Trikafta. Patient feedback was generally unanimous that it is affordable to patients in Colorado through the manufacturer's co-pay program. Patients also note the need to consider Orphan Drug status as the drug fills an unmet need.

**Stakeholder feedback – patients & providers – on the process has not been robust.** In early October, the Board held several stakeholder sessions that had limited patient and provider participation. The only physicians & researchers that attended stakeholder sessions were those from the pharmaceutical companies. On Genvoya (HIV medication), the Board was unable to collect robust stakeholder feedback in the public listening sessions as patients typically do not feel comfortable disclosing HIV status.

**Colorado’s program is understaffed at the state level (3 FTEs), with a paucity of data to work from as they go into December, with a couple of big votes dictating 2024 action.** As a reminder, the Board is determining affordability with only 3 full-time employees and has provided limited opportunities for stakeholder input. A stakeholder survey intended to collect publicly submitted info was available until early October, but the Board has faced difficulties in collecting prescriber and physician input due to timing. The survey asked for input on the impact of the disease, perspectives on benefits and disadvantages of the drug, and therapy applications, including off-label usage.

**Medicaid is not explicitly designated in the Colorado law for Upper Payment Limits (UPLs).** Once rulemaking occurs, we can expect more clarity on UPL qualifying insurances. We expect UPLs to apply to state employee health plans, and ERISA plans have the ability, per statute, to opt-in if prices are lower than their discounts. Despite Medicaid being state funded, it remains unclear if UPLs will apply as Colorado is likely already seeing heavily rebated prices on the therapies and UPLs may not be cheaper for patients (net).

**What is a UPL?** A UPL is the maximum amount that may be paid or billed for a drug that is dispensed or distributed in Colorado. Under an active UPL, pharmacies will pay a maximum at the UPL, and providers will have to reimburse at a maximum at the UPL. Statutory language remains unclear if the UPL will be set at a per dose or per month amount.

## IRA INTERACTIONS

**As a reminder, Enbrel (AMGN) and Stelara (JNJ) are also on the Medicare drug negotiation list for 2026.** The IRA negotiation period runs until August 2024. We expect continued state and federal interactions as CMS determines the price for Enbrel. CO PDAB will likely take into account the maximum fair price (MFP) as it determines UPL. We should see IRA prices by Sept 1, 2024.

**Stelara (JNJ) may be taken off the IRA negotiation list for 2026, with recent biosimilar approval.** In a pending PhRMA lawsuit, HHS [acknowledged](#) the possibility of Stelara not seeing negotiated prices in their supplemental notice that supported their motion to dismiss the case. On October 31, the FDA approved the first biosimilar to Stelara, Wezlana (AMGN) for interchangeable use in treating multiple inflammatory disease. Under the current negotiation guidelines, CMS can reconsider a drug product for price negotiations when it is “subject to meaningful competition.” Wezlana is expected to hit the market in 2025 (due to a settlement with JNJ), and depending on how early it is launched, Stelara may be deselected.

**Lawsuits march on: Following the denial of a preliminary injunction (Dayton Chamber of Commerce), 9 legal cases continue to challenge Medicare drug negotiations, with varying arguments and approaches.** They include MRK’s [lawsuit](#) filed in the District Court for DC, BMY’s [lawsuit](#) filed in a District Court for NJ, the Chamber of Commerce’s [lawsuit](#) filed in a District Court for OH, PhRMA’s [lawsuit](#) filed in District Court for the Western District of TX, JNJ’s [lawsuit](#) filed in NJ, AstraZeneca’s [lawsuit](#) filed in DE, Boehringer Ingelheim’s [lawsuit](#) filed in a District Court in MA, Novartis’ [lawsuit](#) filed in NJ, and Novo Nordisk’s [lawsuit](#) filed in NJ. Companies likely wish for Supreme Court consideration by filing in myriad district courts across the country.

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