February 23, 2024

CO Seeks Upper Payment Limit for Enbrel

PDAB to Start 6 Month UPL Process; Enbrel Also on Top 10 IRA Drug List

Relevant Companies



>>> Our Take & Next Up

Today, Colorado's Prescription Drug Affordability Board voted yes unanimously (with 2 absences) to start the process of determining an upper payment limit (UPL) for Enbrel (AMGN) (here). The Board now will undergo a rulemaking process to determine an appropriate UPL which is expected to take roughly 6 months. We expected Enbrel to be the most likely to be subject to a UPL based on the Board's comments in December during the affordability review data collection. As a reminder, PDAB has split their affordability review into 2 cohorts. Affordability reviews for Stelara (JNJ) and Cosentyx (NVS) are ongoing with a final affordability review report expected in early May. See our 11/7 memo here.

>>> Key Points

As a reminder, Enbrel and Stelara are also on the Medicare drug negotiation list for 2026. On the IRA front, manufacturers have until <u>March 2</u> to respond to CMS's initial offer or propose a counteroffer. The negotiation period is ongoing and ends on <u>August 1, 2024</u>.

Enbrel could be subject to a UPL by the end of 2024 (if the process is completed). The public was reminded that the UPL setting vote only initiates the UPL process and PDAB will now have to undertake the arduous process of determining the appropriate price. In the previous meeting, PDAB staff noted that patients were paying up to \$3000 to \$4000 a month out of pocket without insurance and the co-pays were as high as \$1000 a month. The staff also highlighted the 36x rise in Enbrel's WAC (~1600% increase) since it was approved by the FDA in 1998 as a supporting piece of evidence on drug unaffordability.

What is an UPL? An 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. The UPL would apply to (potentially) Medicaid, state workers and possibly a spillover to commercial as self-funded plans are able to opt-in. Medicaid is not explicitly included in the statutory language.

Cohort #2: Cosentyx & Stelara are up next in determining affordability. During the review of the first cohort of drugs, PDAB has faced delays in data weighing, determining standards of review and in eliciting stakeholder feedback. These issues may continue to persist as PDAB completes this year's list of drugs and in subsequent drug affordability reviews in the future. For Cosentyx and Stelara, the PDAB is expected to discuss their draft affordability reviews on <u>April 26</u> and final affordability review adoption on <u>May 3</u>.

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