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Maryland Drug Board Gets Going

8 Drugs for Potential Cost Review, CO Seeks to Exempt Orphan Drugs

Relevant Companies

Our Take & Next Up

The Maryland Prescription Drug Affordability Board (PDAB) is moving ahead, on the heels of CO moving ahead (and now being sued AMGN), discussing 8 drugs for potential review & UPLs. The Board met yesterday to discuss the potential list of drugs that could undergo a cost review study and be subject to an upper payment limit (UPL) here. The selected drugs will be referred to the Prescription Drug Affordability Stakeholder Council that will hold an open meeting April 29 to discuss the referred drug products. There is also a 30-day public comment period. The final list of selected drugs could be decided at the soonest by the May PDAB meeting (May 20). An update on Colorado PDAB (lawsuit from AMGN) and IRA is below. We will provide updates on State efforts as they move ahead (slow going) in 2024+.

Key Points

The eight (8) drugs that may be subject to the cost review process are Biktarvy (GILD), Dupixent (SNY, Regeneron), Farxiga (AZN, BMY), Jardiance (Boehringer Ingelheim), Ozempic (NVO), Skyrizi (ABBV), Trulicity (LLY), and Vyvanse (Takeda). However, this list is not final and additional drugs for the cost review process are being sought via public comments and could be added in subsequent meetings.

Following the finalization of the selected drugs (early summer), the board staff will start the cost review process which will take several more months. The board is drafting a plan of action to implement upper payment limits for state, local, and county government payers and purchasers that will determine how UPLs will apply if there is a board recommendation to do so.

The MD upper payment limits (UPLs) would likely start in 2025 at the earliest and apply to government employee health plans, Medicaid, and direct purchases by the state like corrections facilities and state

hospitals. This could have a significantly wider purchasing impact compared to Colorado's PDAB where the UPL application remains unclear.

How were the drugs selected? The MD drugs were selected from a total of 2298 eligible National Drug Codes (NDCs) with each drug meeting 2 statutory or regulatory metrics. Per the law, the Board must select from name brand drugs with a launch WAC over $30,000 per year, name brand drugs increase by $3,000 over a year, biosimilars that are not at least 15% less than the reference biologic, and generic drugs that are more than $100 per month AND go up in price by 200% or more in a year. Drugs can also be eligible if they fall within the top 100 drug products with the highest gross spending or with the highest total patient out of pocket costs.

In January 2024, the Board started their drug selection process after delays during the pandemic. Gov. Moore re-established PDAB's authority to set upper payment limits in April 2023 that was set to subset. The state is likely to be sued if a UPL goes into effect and the DCC argument may be revived in future lawsuits. When the Board was originally created, there were concerns about a potential legal challenge to the PDAB's authority after the federal Fourth Circuit Court of Appeals ruled that Maryland's 2017 anti-price-gouging drug law (HB 631) for generics violated the Dormant Commerce Clause (DCC) of the US Constitution. The Dormant Commerce Clause is used to prohibit state legislation that discriminates against, or unduly burdens, interstate commerce.

IRA & COLORADO UPDATE

On IRA interactions, Farxiga and Jardiance are currently being negotiated by CMS for 2026. The Board is considering if a drug is selected for negotiations as a selection factor with Board Member Gerard Anderson, PhD, recommending keeping negotiated drugs so the PDAB can compare methodology with CMS's process.

On February 23, the Colorado PDAB voted unanimously to move forward with establishing a UPL for Enbrel (AMGN). The PDAB is currently undergoing the rulemaking process to determine an appropriate UPL. AMGN has also sued Colorado PDAB and its members to halt the UPL process. The lawsuit asserts that PDAB (and the CO law that created it) conflicts with federal patent laws, denies due process to drug manufacturers, and attempts to regulate transactions for federal healthcare programs and out-of-state transactions.

Affordability reviews for Stelara (JNJ) and Cosentyx (NVS) are also ongoing for Colorado. The board collected additional information on Cosentyx and Stelara from stakeholders and draft affordability review results were presented to the board in March. A final affordability review report is expected in early May with votes on possible UPLs at that time.

Orphan exemption is sought in CO. Earlier this year, Colorado state senators Republican Sen. Barbara Kirkmeyer and Democratic Sen. JoAnn Ginal introduced **Senate Bill 60**, which would exempt orphan drugs (like Trikafta) from PDAB review. The bill passed out of the Senate Committee on State, Veterans, & Military Affairs on February 22.

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