Farxiga
Consideration of Upper Payment Limit

PDAB Meeting

April 13, 2026

PDAB Staff

MARYLAND
Prescription Drug Affordability Board

UPL Chronology

- Preliminary Determination - Affordability Challenge 07/28/2025
- Policy Review Process and Preliminary Policy Recommendations 09/29/2025
    - Public Information Hearings 09/03/25 at 1:00 & 6:00 pm
    - Stakeholder Council Input
    - Staff research & analyses; Eligible gov't entity info

UPL Chronology

- Board provided guidance and direction to further develop UPLs for the Board’s consideration 09/29/2026
- Staff recommended UPL Framework and Contextual Information – 11/17/2025
  - Domestic Reference Pricing (COMAR 14.01.05.06B(5))- Medicare Maximum Fair Price (MFP)
  - Contextual Information: COMAR 14.01.05.06C(1), (2), (4), (6), and (8)

UPL Chronology

- Staff posted UPL Amount and Methodology Document (Calculations and Analyses Underpinning Potential UPL Values) 02/17/2026; public comment due 03/04/2026
- Revised Calculations and Analyses Underpinning Potential UPL Values document posted 3/30/2026; public comment due 04/06/2026

Board UPL Decision Structure

- Guided by the following considerations and principles, and considering all the information presented, including public comments, the Board now:
  - **Determines whether, as a matter of public policy, to set a UPL for this drug and if so, the UPL value**
- This ultimately is done through notice and comment rulemaking under the Administrative Procedure Act - proposing and taking final action on a regulation

Board UPL Tasks

- **Review**: Public comments on draft UPL COMAR 14.01.07
- **Review**: Revisions to UPL COMAR 14.01.07
- **Consider**: UPL Criteria
- **Move:** To Set UPL and Adopt Proposed Regulation
- **Deliberate**: UPL Appropriate Policy; UPL Value
- **Vote**: Proposed New Regulation

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Summary of Comments Received on Draft UPL Regulations -Farxiga

- Comments were received from the following:
  - AARP
  - AbbVie
  - AstraZenca
  - Boehringer Ingelheim
  - Diabetes Patient Advocacy Coalition (DPAC)
  - Frederick County Government
  - PhRMA
  - Value of Care Coalition
- Comment summaries and responses on 14.01.06 are in a separate document.

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Summary of Comments Received on Draft UPL Regulations - COMAR 14.01.07.01

- **Multiple commenters noted concern with using the using the Medicare Maximum Fair Price as a benchmark for a state upper payment limit due the unique dynamics of the Medicare market.**

Response: The Board received and considered this comment during approval of the Farxiga Framework document and the Calculations and Analyses Underpinning Potential Upper Payment Limits documents. The Board understands the input from the commenters, but disagrees that the analyses underpinning MFP are fundamentally different from considerations from the state and local government market. Additionally, COMAR 14.01.05.02D(1) sets the MFP as a UPL amount floor if it exists, which limits the Board from setting the UPL lower.

Proposed Updates: None.

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Summary of Comments Received on Draft UPL Regulations - COMAR 14.01.07.01

- **One commenter noted concern with the state not having a Medicare transaction facilitator if the UPL is based on the Medicare MFP.**

Response: While the proposed UPL is benchmarked off of the Medicare MFP, it will be implemented in a different way than the Medicare MFP that does not require the use of a transaction facilitator. Additionally, the method of implementation minimizes any risk to the supply chain because the Board recommends implementing the UPL through supplemental rebates that should not impact the rest of the amounts paid through the rest of the supply chain.

Proposed Updates: None.

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14.01.05.02 Criteria for Setting UPL
Guiding Principles

B. The Board shall:

(1) Consider the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs;

(2) Determine whether an upper payment limit is an appropriate tool to address the drivers of the affordability challenge identified for the prescription drug product;

(3) Set an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences; and

(4) Prioritize drugs that have a high proportion of out-of-pocket costs compared to the system net cost of the drug.

C. The Board shall not set an upper payment limit if:

(1) Spending on the prescription drug product by the eligible governmental entities is less than the administrative cost to implement an upper payment limit; or

(2) The prescription drug product is a generic and there are nine or more marketed therapeutic equivalents for the product.

D. The Board shall not set an upper payment limit at an amount that:

(1) Impacts statutory or regulatory amounts, such as Medicaid Best Price; or

(2) Is lower than the Medicare Maximum Fair Price.

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UPL CRITERIA
COMAR 14.01.05.02B(1); Health-Gen. 21-2c-13(b)(1)-(2)

Consider the cost of administering the drug and delivering the drug to consumers, as well as other relevant administrative costs

As a small molecule drug that does not require special handling, there were no substantial factors related to administering and delivering the drug that would justify unique cost considerations. Dispensing fees are not included in the UPL to ensure that pharmacies are reimbursed for their professional services.

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UPL CRITERIA
Md. Code Ann., Health-Gen. 21-2c-13(b)(3)

Consider the effect the UPL will have on providers of 340B drugs

Because the implentation of UPLs for state and local government should not impact payment amounts to pharmacies and hospitals, the Board does not forsee any impact on providers of 340B drugs.

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UPL CRITERIA
COMAR 14.01.05.02B(4)

Prioritize drugs that have a high proportion of out-of-pocket costs compared to the system net cost of the drug.

At the 90 percentile, patient out-of-pocket (OOP) costs for Farxiga in certain markets is disproportionate to the net cost paid by payors (circumstance 2)

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UPL CRITERIA
COMAR 14.01.05.02B(2)

Determine whether an upper payment limit is an appropriate tool to address the drivers of the affordability challenge identified for the prescription drug product

Earlier Staff Identified Six Drivers for Farxiga

Six Drivers were mapped to the Three Circumstances

1. WAC/Inflation - drivers 1.1 and 1.2
2. Disproportionate OOP cost - drivers 2.1, 2.2 and 2.3
3. Gross Spending - driver 3.1

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UPL May Address Drivers

- UPLs address drivers 1.1, 1.2, and 3.1
- UPLs limit the effect of the WAC increase (list prices) on certain state and local governmental entities by establishing a ceiling net price that is not contingent on WAC increases.
- A UPL reduces the amount paid by state and local government payers for these drugs, which allows the allocation of those resources to other needs and uses

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Driver 1.1: Incentive to Maximize Rebates Instead of Minimizing Net Costs

- Manufacturers and PBMS negotiate drug rebates. Some PBM contracts with payors provide for compensation of the PBM based on those rebates.
- Because PBMs are paid a portion of those rebates, PBMs have a financial incentive to prefer the drug with a larger rebate over the drug with the lowest net cost.
- An increase in list price (WAC) allows rebate amounts to increase without lowering the net cost.
- To effect an increase in rebates, manufacturers historically have increased the list price (WAC) rather than reduced the net cost. This demonstrates an exercise of market power.

NOTE: An increasing list price (WAC) may directly impact patients by influencing patient cost sharing.

Driver 1.2: Increased List Prices (WAC) Gives Manufacturers More Leverage in Negotiations

- Increasing list prices (WAC) puts pressure on insurer to negotiate or face increased costs to insurers and patients.
- Increasing list price (WAC) maximizes manufacturers profits, irrespective of whether the manufacturer has negotiated a rebate with the insurer.

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Driver 3.1: Gross Spending is High Because these Drugs have High Utilization and High Price

- These drugs have a special place in therapy for treating patients with comorbidities, which represents a large portion of patients with diabetes
- Gross spend is high because there are a large number of users (*i.e.*, high utilization) and the drug has a high price (*i.e.*, high cost)

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Additional Information from Policy Review Process on Appropriateness of UPL to Address Affordabiltiy Challenge

- **Decreases in WAC**- One commenter noted a substantial decrease in the WAC of Farxiga starting on January 1, 2026.
- **Potential Generic Competition-** One commenter noted that the primary patent for Farxiga is expected to expire in April 2026, with 18 generics applications tentatively approved by the FDA. However, the commenter did not provide an assurance that the generics would immediately come to market.
- **Savings Estimates for UPL-** The Farxiga Framework document (11/17/25, at p.5) estimated a nominal savings for state and local governments. While the Medicare MFP is estimated to be close to the average commercial net price, there may be some Eligible Governmental Entities that are paying more than the average, and they may achieve some savings.

UPL CRITERIA
Md. Code Ann., Health-Gen. 21-2c-13(b)(3)

For a UPL on a drug that is designated as a drug for a rare disease or condition, consider the impact of the upper payment limit on patients with rare diseases.

Not applicable. Farxiga has not been so designated.

COMAR 14.01.04.03B(1)(d) ("Whether the prescription drug product is designated by the Secretary of the FDA, under 21 U.S.C. §360bb, as a drug for a rare disease or condition").

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UPL CRITERIA
COMAR 14.01.05.02B(3)

Set an upper payment limit in a way to minimize adverse outcomes and minimize the risk of unintended consequences

The Boards proposed method of UPL implementation through supplemental rebates is designed to minimize unintended consequences, such as impacts on supply chain entities or impacts of access to the drug for patients.

Leverage state and local government contracts for implementation; ongoing feedback

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COMAR 14.01.05.02C
The Board shall not set an upper payment limit if:

(1) Spending on the prescription drug product by the eligible governmental entities is less than the administrative cost to implement an upper payment limit;

The Board's review of state and local government spending, and determinations based on the gross spend of state and local government confirm that spending on Farxiga is more than the cost to implement a UPL.

(2) The prescription drug product is a generic and there are nine or more marketed therapeutic equivalents for the product.

Not applicable.

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COMAR 14.01.05.02D - The Board shall not set an upper payment limit at an amount that:

(1) Impacts statutory or regulatory amounts, such as Medicaid Best Price;

Best price is at least MFP, if not lower. Benchmarking on the MFP ensures that no statutory or regulatory amounts are impacted.

(2) Is lower than the Medicare Maximum Fair Price.

The Staff recommended UPL value is not lower than MFP.

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Board UPL Tasks

Having Reviewed the Public Comments and Draft Regulation, and Having Considered the UPL Criteria, the Board may now:

- **Move to Set UPL by Proposing New Regulation**
- **Deliberate**: UPL Appropriate Policy; UPL Value
- **Vote**: Propose New Regulation

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