

Updates for Draft Cost Review Study Report, Policy Review, and UPL Farxiga and Jardiance

PDAB Meeting

March 23, 2026

PDAB Staff



Purpose

1. **Draft Cost Review Study Report**
 - a. **Farxiga**
 - b. **Jardiance**
2. **Non-UPL Policies**
3. **Calculations and Analyses Underpinning Potential UPL Values**
4. **Draft UPL Rules**
 - a. **14.01.07**



Cost Review Study Process



PDAB Meeting	PDAB Meeting	Stakeholder Council Meeting	Interim	PDAB Meeting
<p>Public Reporting of Drug Affordability Issues</p> <p>Board has opportunity to add prescription drug products for inclusion on the list of eligible drugs for cost review</p>	<p>Identifying prescription drug products to consider for cost review- this is a subset from eligibility list</p> <p>Refer prescription drug products to the Stakeholder Council for input</p>	<p>PDASC will review and discuss the referred prescription drug products at an open meeting</p>	<p>Public comment</p>	<p>Board selects prescription drug product(s) for cost review</p> <p>Next Steps:</p> <ul style="list-style-type: none">→ Collect→ Analyze→ Results

Cost and Policy Review Process



Drug(s) in Cost Review	Data Collection	Analyze	Preliminary Determination	Policy Review Process	Final Results
<p>Drug(s) selected for Cost Review Study will be posted on the Board's Website.</p> <ul style="list-style-type: none"> - 60 day written comment period begins with posting 	<p>PDAB may request information from, and post request:</p> <ul style="list-style-type: none"> - Manufacturers - Carrier, HMO and MCO - Pharmacy Benefits Managers - Wholesale Distributor 	<p>Board Staff may assemble a dossier of data and analyses for consideration in cost review study as outlined in COMAR 14.01.04.05.</p>	<p>Board may preliminarily determine whether the prescription drug has led or will lead to:</p> <ul style="list-style-type: none"> - Affordability challenges to the State health care system or - High out of pocket costs for patients 	<p>Board may perform the policy review process to identify and recommend policies to address affordability challenges:</p> <ul style="list-style-type: none"> - Process for setting upper payment limits - Process for all other policies that are not upper payment limits 	<p>Board takes final action:</p> <ul style="list-style-type: none"> - Board Finalizes Determination and Adopts Final Cost Review Study Report - Board Adopts Policy Recommendations - Board Adopts Proposed UPL Regulation

Draft Cost Review Study Reports Farxiga and Jardiance

- **Overview of Draft Cost Review Study Report:**
 - Summary of Information Considered by the Board
 - Summary of Deliberations
 - Circumstances and Indicia Reflecting the Affordability Challenge
 - Preliminary Determination
- **Draft Farxiga Cost Review Study Report**
 - Draft Posted for Public Comment: March 16, 2026
 - Comments Due: March 30, 2026
- **Draft Jardiance Cost Review Study Report**
 - Draft Posted for Public Comment: March 16, 2026
 - Comments Due: March 30, 2026



Overview-

Policy Review Process and UPL Development

1. Optional Information Gathering

2. Staff Recommends Policy Options

- Drivers of Affordability Challenges
- Policy Options to Address Identified Drivers
 - Non-UPL Policy
 - UPL Policy

3. Final Actions

- Adopt Final Determination Concerning Affordability Challenge
- Adopt (a) other (non-UPL) policy recommendations; (b) proposed regulations setting the UPL at the specified amount; or (c) both.



Overview-

Policy Review Process and UPL Development

1. Optional Information Gathering

2. Staff Recommends Policy Options

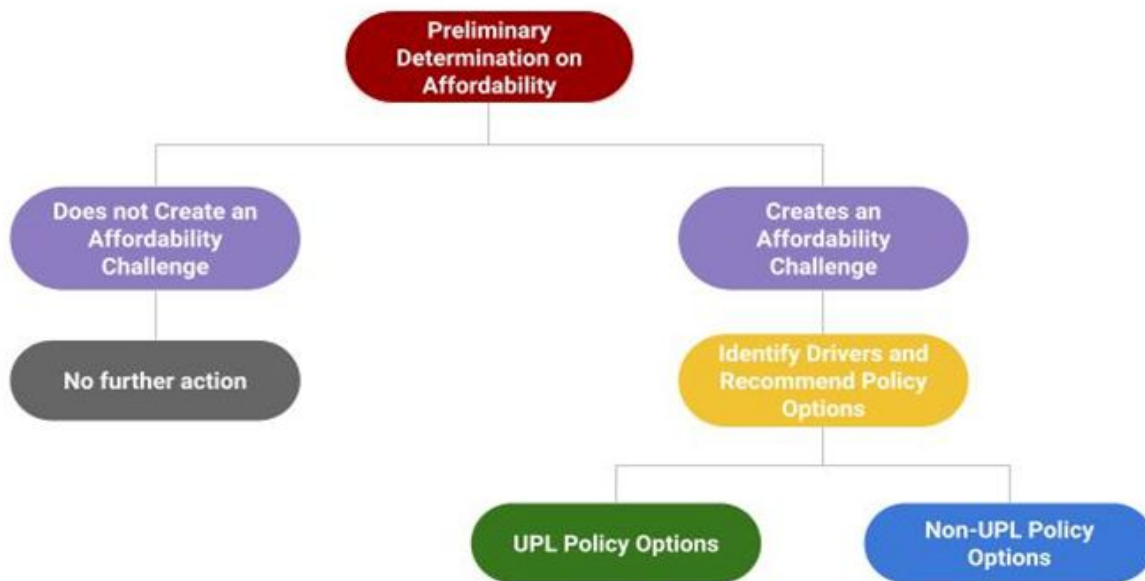
- Drivers of Affordability Challenges
- Policy Options to Address Identified Drivers
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 - UPL Policy

3. Final Actions

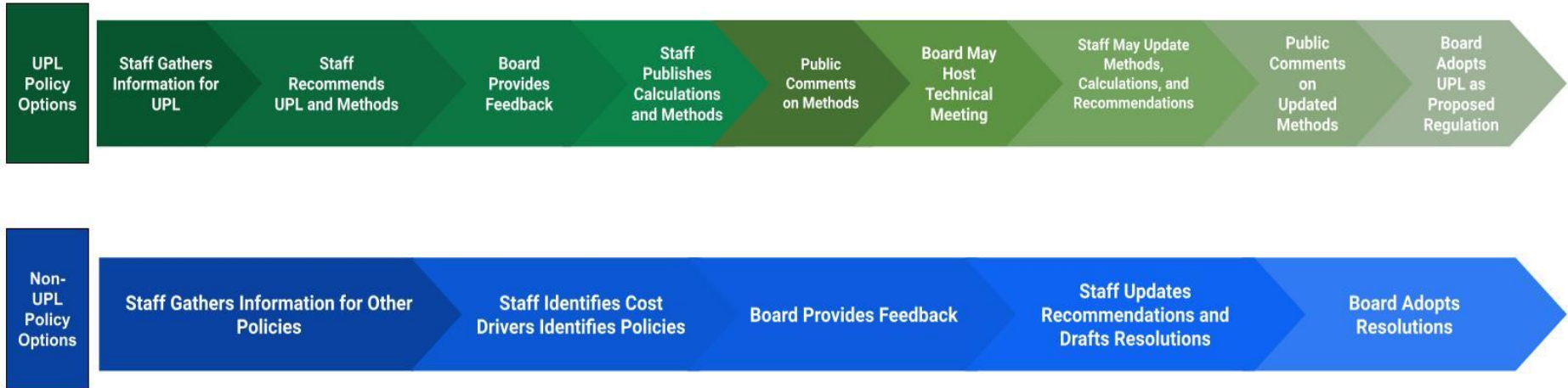
- Adopt Final Determination Concerning Affordability Challenge
- Adopt (a) other (non-UPL) policy recommendations; (b) proposed regulations setting the UPL at the specified amount; or (c) both.



Process after Board Makes Preliminary Determination on Affordability



Policy Options- Drug Deemed to Create Affordability Challenges



Non-UPL Policies Farxiga and Jardiance

- **The Board may adopt a final policy recommendation only after the Board has:**
 - Made a final affordability challenge determination; and
 - Adopted the final cost review study report under COMAR 14.01.04.05G.
- **Draft Non-UPL Policy Recommendations**
 - Inflation Penalty
 - Delinking PBM Compensation from Rebates
 - Navigator Program



Calculations and Analyses Underpinning Potential UPL Values

- Board Staff Published the Calculations and Analyses Underpinning Potential UPL Values
 - Posted on: February 17, 2026
 - Comments Received: March 4, 2026

Farxiga- 8 Comment Letters

- AARP
- Aimed Alliance
- AstraZeneca
- EACH/PIC Coalition
- Healthcare Distribution Alliance
- Maryland Healthcare for All Coalition
- PhRMA
- Unitarian Universalist Legislative Ministry of Maryland (UULM-MD)

Jardiance- 8 Comment Letters

- AARP
- AimedAlliance
- Boehringer Ingelheim USA Corporation
- EACH/PIC Coalition
- Healthcare Distribution Alliance
- Maryland Healthcare for All Coalition
- PhRMA
- Unitarian Universalist Legislative Ministry of Maryland (UULM-MD)



Calculations and Analyses Underpinning Potential UPL Values- Farxiga Comments

- **Some Commenters Supported the UPL Calculation**
- **Many Commenters Reiterated Concerns with UPLs as a Policy Option**
- **Some Commenters Provided Substantive Comments on the Calculations and Analyses**
 - One commenter noted the need to address all COMAR Requirements for UPL Determination
 - One commenter noted market changes, including a lowered list price and anticipated expiration of patents
 - Multiple commenters noted that the CMS MFP may not be an appropriate amount because it is not specific to the Maryland market and may not result in savings



Calculations and Analyses Underpinning Potential UPL Values- Jardiance Comments

- **Some Commenters Supported the UPL Calculation**
- **Many Commenters Reiterated Concerns with UPLs as a Policy Option**
 - Multiple commenters asked for additional time for public comment
- **Some Commenters Provided Substantive Comments on the Calculations and Analyses**
 - Multiple commenters noted that the CMS MFP may not be an appropriate amount because it is not specific to the Maryland market and may not result in savings



Calculations and Analyses Underpinning Potential UPL Values- Updates

- **No substantive changes to the UPL values or calculations**
- **Clarification that document is limited calculations and analyses underpinning potential UPL values**
- **Including additional documentation of consideration of all COMAR Requirements**



Draft Upper Payment Limit Regulations

- **Overview of Upper Payment Limit Regulations:**
 - 14.01.06- Implementation and Monitoring of Upper Payment Limits
 - .01- Scope
 - .02- Contracting and Initial Reporting Requirements
 - .03- Application of Upper Payment Limits
 - .04- UPL Monitoring and Data Reporting
 - 14.01.05- Upper Payment Limit
 - .01- Upper Payment Limit for Farxiga (dapagliflozin).
 - .02- Upper Payment Limit for Jardiance (empagliflozin).
- **Draft Upper Payment Limit Regulations**
 - Draft regulations posted for public comment on March 16, 2026
 - Comments Due: March 30, 2026





MARYLAND

Prescription Drug Affordability Board

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