Cost Review Study Report- Farxiga

PDAB Meeting

April 13, 2026

PDAB Staff

MARYLAND
Prescription Drug Affordability Board

Actions Taken As Part of the Cost Review Study Process

- **Board Deliberated on July 28, 2025 and made preliminary determinations**
- **Board Staff prepared a draft cost review study report containing**
  - Summary of Information Considered by the Board
  - Summary of Deliberations
  - Circumstances and Indicia Reflecting the Affordability Challenge
  - Preliminary Determination
- Draft Posted for Public Comment: March 16, 2026
  - Comments Due: March 30, 2026
- Staff Published an Revised Draft on April 6, 2026

Finalizing the Cost Review Study Report

- G. Final Determination Concerning Affordability Challenge and Final Cost Review Study Report.
  - (1) The Board may vote to finalize the preliminary determination and approve the draft cost review report as final.
  - (2) The Board's determination of whether a prescription drug has or will lead to an affordability challenge is not final until the final cost review report is adopted by the Board.
  - (3) The Board shall create and adopt a final report of the cost review study that, to the extent permitted by Health-General Article, §§21-2C-03 and 21-2C-10, Annotated Code of Maryland, summarizes the information considered by the Board in conducting the cost review study, the Board's deliberations, and the Board's determination.

Board Cost Review Tasks for this Meeting

- **Review**: Public comments on draft report
- **Discuss**: Revised draft report
- **Move**: Adopt Final determination of affordability challenge
- **Deliberate**: Final determination of affordability challenge
- **Vote**: Adopt resolution with final affordability challenge determination
  - Staff will update the report to reflect these deliberations
- **Vote**: Adopt the final cost review study report

Summary of Comments Received on Draft Report- Farxiga

- **3 Comment Letters Received**
  - AstraZeneca
  - Maryland Health Benefit Exchange (MHBE)
  - PhRMA
- **Feedback Themes Included:**
  - Concerns about validity of the Board's preliminary affordability determination
  - "Affordability challenge" lacks clear definition
  - Call for transparency in data weighting and analysis methodology from closed session
  - Highlighted market shifts and upcoming changes that impact current analysis
    - Farxiga price reduction
    - Farxiga patent expiration
  - Consideration of clinical value and cost offsets in analysis
    - Specifically the prevention of expensive medical outcomes
  - The fiscal impact of Farxiga on Maryland's individual health insurance market and the State Reinsurance Program

Support of Farxiga Findings in the Cost Review Study Report

- **One commenter noted the importance of findings of the Cost Review Study Report for Farxiga because of the impact that Farxiga has on the health plans**
  - **The commenter supported the Board's findings, with spending on less than 1000 patients taking Farxiga representing over 1% of the total prescription drug spend brand name prescription drug claims costs in the individual market**

Reponse: The PDAB thanks the commenters for their input

Proposed Updates: No changes

Need for Certain Definitions

- **Two commenters noted concerns with the standards for making the determination if a drug has led or will lead to affordability challenges for the state health care system or high out-of-pocket costs for patients. This includes the circumstances identified by the Board under which the cost of a prescription drug product has led or will lead to affordability challenges for the State health care system and patients without explicitly defining affordability.**

Reponse: The PDAB thanks the commenters for their input. The Board's current process aligns with the statutory requirements. The Board may update the process for future rounds of Cost Review Studies to define and standardize the determination that drugs have led or will lead to an affordability challenge.

Proposed Updates: No changes.

Need for Additional Transparency in the Process

- **Two commenters noted concerns with transparency in the Cost Review Study Process, including substantial deliberations occurring in Closed Session to allow the Board to discuss confidential, trade-secret, and proprietary information.**

Reponse: The PDAB thanks the commenters for their input. The Board's current process aligns with the statutory requirements. However, the Board supports a clear and transparent process. The Board complies with its obligation to consider confidential, trade-secret, and proprietary information in closed session.

Proposed Updates: Board has revised the cost review study report to include closed session deliberations but has protected the confidential data and information through redaction.

Clear Process for Accounting for Comments and Stakeholder Input

- **Two commenters noted concerns with how comments are being captured and considered as part of the Cost Review Study Process.**

Reponse: The PDAB thanks the commenters for their input. The Board receives and considers all comments and public input collected in the Cost Review Study Process. The Board will continue to look for opportunities to clearly demonstrate how comments are considered.

Proposed Updates: No changes

Need to Consider Context on Disease Burden

- **One commenter noted that the Board must evaluate the cost of Farxiga in the context of the overall disease burden.**

Reponse: The Board considered the overall disease burden and the valuable role of sodium-glucose transport 2 (SGLT-2) inhibitors in diabetes care. *See* Dossier, Factors 2.1, 2.2, 6.4, and 6.5.

Proposed Updates: No changes

Some Circumstances are Based on Data that Does Not Capture the Full Picture

- **One commenter noted that determinations based on WAC and gross spend may not capture the full picture of an affordability challenge because the health system is most affected by the net cost of prescription drugs, after all rebates and discounts.**

Reponse: The Board made the determination based on the best available, verifiable data. Because the WAC and gross spend represent real funds moving through the health care system, distortions of these numbers reflect significant adverse impacts to the health system and patient costs.

The Board agrees that the opacity of the prescription drug market is a substantial problem that makes it difficult for a competitive market to function, and for policy makers to get a full picture of the challenges in the system. The Board thanks the stakeholders for providing clarifying information through the Request for Information Process.

Proposed Updates: No changes

Some Circumstances are Based on Arbitratary Thresholds

- **One commenter noted that using 1% of gross spending as a threshold is inappropriate**

Reponse: The Board utilized its expertise and judgment to identify this circumstance as reflecting an affordability challenge: a single drug (out of thousands of NDCs) makes up over 1% of the total gross prescription drug spend.

Proposed Updates: No changes

Some Circumstances are Based on Outlier Numbers

- **One commenter noted that out-of-pocket costs for patients at the 90th percentile represents outlier cases.**

Reponse: The Board makes their determination based on all patients in Maryland. It is not accurate to say that the experience of 10% of Maryland patients should not inform a determination because they are "outliers."

Proposed Updates: No changes

Circumstances based on Out-of-Pocket Costs is a Plan Design Issue that is Outside of the Control of the Manufacturer

- **One commenter noted out-of-pocket costs are a plan design issue that are outside of the control of manufacturers**

Reponse: An affordability challenge reflects a market and system failure. That failure may have may causes and contributors and is not necessarily attributable to a specific stakeholder group.

Proposed Updates: No changes

New Data and Market Changes that May Impact the Findings of the Cost Review Study

- **One commenter noted a number of market updates and changes that may impact the Board's affordability challenge preliminary determination. Specifically, the commenter noted that Farxiga's WAC was reduced by 30% January 1, 2026, and that the primary patent expires in April 2026, potentially allowing substantial generic competition to come to the market.**

Reponse: The Board made a preliminary determination that use of Farxiga "has led" to an affordability challenge. That determination was based on the data before the Board. The prescription drug market is dynamic and constantly changing, and that any findings of the Board will be based on the data available at a specific period of time, here August 1, 2024. The Policy Review Process and the comment allows for the incorporation of new data for the Board to determine the appropriate policies to address affordability challenges.

Additionally, the commenters noted that generics may come to market, but did not provide assurances that this will be the case.

Proposed Updates: No changes

Incorporated Changes

- Staff has updated the draft report to include:
  - More details about the deliberations and the analyses that went into the determinations made in closed session;
  - Additional comments on the study report

Next Steps

- **Move**: To adopt final affordability challenge determination
- **Deliberate**: On final affordability challenge determination
- Board staff prepares final resolution and a final report
- **Vote**: Adopt resolution with final affordability challenge determination
    - Staff will update the report to reflect these deliberations
- **Vote**: Adopt the final cost review study report

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