

Cost Review Study Process Update and Next Steps

PDASC Meeting

August 25, 2025

Andrew York, Executive Director



Agenda

- **Cost Review Study Process- Update**
- **Board Resolutions**
- **Policy Review Process**
- **Next Steps and Role of the PDASC**



Cost Review Study Process- Update



Drugs Selected for Cost Review Study Process

- **Farxiga (dapagliflozin)**
- **Jardiance (empagliflozin)**
- Ozempic (semaglutide)
- Trulicity (dulaglutide)
- Dupixent (dupilumab)
- Skyrizi (risankizumab)



COMAR 14.01.04.05A- Cost Review Study

Board May Determine

July 28, 2025 Board Meeting. The Board had the opportunity to examine Farxiga and Jardiance:

- (1) Whether use of the prescription drug product has led or will lead to:
 - (a) Affordability challenges to the State health care system; or
 - (b) High out-of-pocket costs for patients;
- (2) Whether the use that has led to affordability challenges or high out-of-pocket costs is consistent with:
 - (a) The labeling approved by the FDA; or
 - (b) Standard medical practice.
- (3) Identify the circumstances under which the prescription drug product has or will lead to an affordability challenge to the State health care system or high out-of-pocket costs to patients under §A(1) of this regulation.



14.01.04.05.F Preliminary Determination

Preliminary Determination.

(1) In accordance with §C of this regulation, the Board may make a preliminary determination of whether use of the prescription drug product has led or will lead to affordability challenges for the State health care system or high out-of-pocket costs for patients.

(2) A preliminary determination is non-final and subject to revision and modification.



Next Step after a Preliminary Determination - Draft Report

- Board staff shall prepare a draft of the preliminary determination cost review report that summarizes:
 - the information considered by the Board in conducting the cost review study,
 - the Board's deliberations,
 - the circumstances or indicia reflecting the affordability challenge, and
 - the Board's preliminary determination.
- The public may comment on the draft of the preliminary determination cost review report.



Board Resolutions



14.01.04.05.F Preliminary Determination

The Board made two preliminary determinations that the use of Farxiga and Jardiance have each created an affordability challenge for the State health care system at the July 28, 2025 Board Meeting.

The circumstances under which the prescription drug products have led to affordability challenges include:

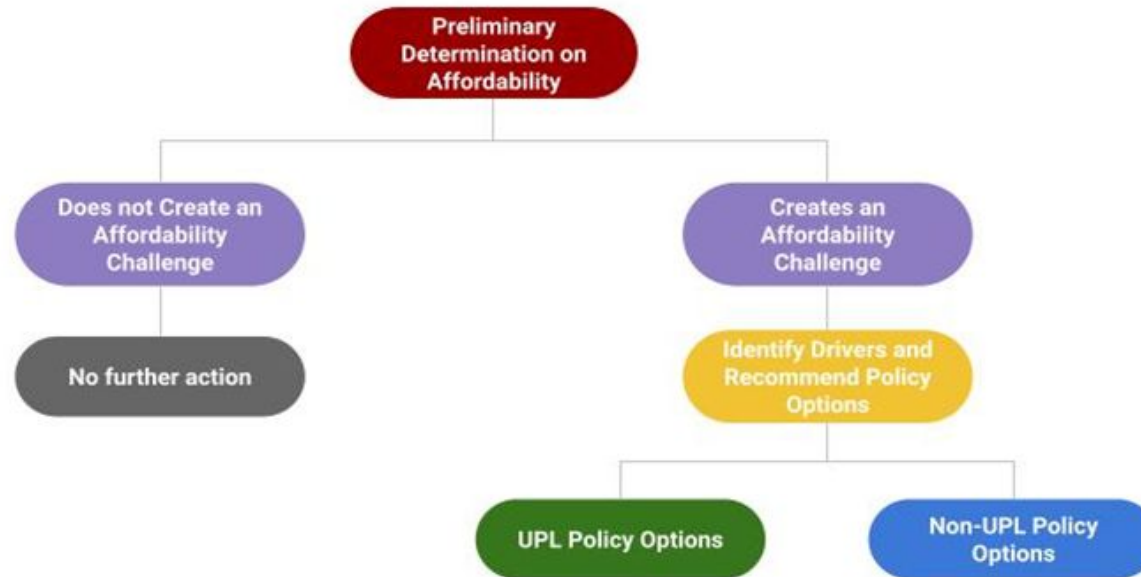
- the percentage change in WAC over time is substantially larger than the percentage change in inflation (rate of increase in inflation) (both drugs);
- at the 90 percentile, patient out of pocket (OOP) costs in certain markets is disproportionate to the net cost paid by payors (both drugs);
- total gross spending for Farxiga for state and local governments exceeds 1% of gross prescription drug spend for state and local governments; and
- total gross spending for Jardiance for state and local governments exceeds 1.8% of gross prescription drug spend for state and local governments.



Policy Review Process



Process after Board Makes Preliminary Determination on Affordability



Policy Review Process and Upper Payment Limit (UPL) Development

Policy Review Process

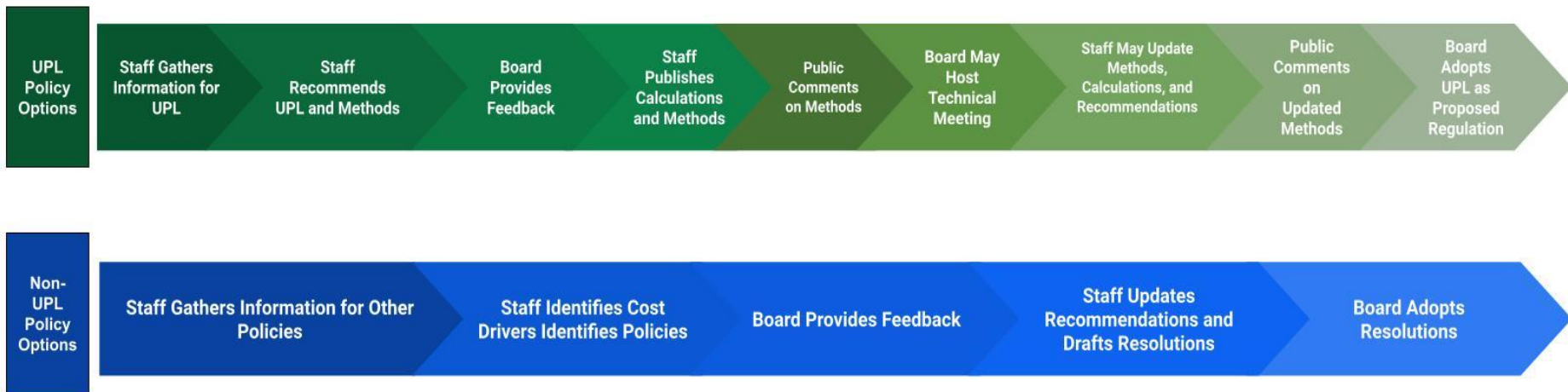


Green= Upper Payment Limit Policy Review Process
Blue= Non-UPL Policy Review Process
Red= Cost Review Study Process



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Policy Options- Drug Deemed to Create Affordability Challenges



Next Steps and Role of the PDASC



Next Step after a Preliminary Determination - Policy Review Process

The purpose of the policy review process is to:

- (1) Based on the best available information, confirm the drivers and market conditions causing the affordability challenge phenomena; and
- (2) Identify the policies that may address those drivers and redress the affordability challenges.



Policy Review Process - Information Gathering

Information gathering:

- (a) Informational hearings;
- (b) Stakeholder Council input;
- (c) Expert testimony hearings;
- (d) Board staff research and analysis; and
- (e) Request eligible governmental entities' information.



Policy Review Process - Information Gathering

COMAR 14.01.05.04(D)(2)

Stakeholder Council Input.

- (a) The Board may request input from the Stakeholder Council. This input can be a request for general input and ideas on policies or more specific requests for specific information.
- (b) Board staff may provide the Board with summaries of input from the Stakeholder Council.





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