

# Overview- Cost Review Study Process

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PDAB Meeting

July 28, 2025

Andrew York, Executive Director



# Agenda

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- **Overview Cost Review Study Process**
- **Overview of Potential Next Steps- Policy Review**



# Process for Preliminary Determination for Today

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- Overview of Cost Review Study Process and Policy Review Process
- Analysis and Data Compilation- Dossier Presentation which includes Factors Considered and Comments
- Closed session to discuss confidential, trade-secret, and proprietary information
- Deliberation on Affordability Challenge based on the information provided
- Preliminary Determination of Affordability Challenge
- Policy Review Process and possible next steps



# Drugs Selected for Cost Review Study Process

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



# COMAR 14.01.04.05A- Cost Review Study

## Board May Determine

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- (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.



## 14.01.04.05B and C Cost Review Study Dossier and Factors

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### COMAR 14.01.04.05B

Staff may assemble data and analyses for Board's consideration (dossier)

Final version posted

### COMAR 14.01.04.05C

Board may consider factors (data, information, and analyses) specified in regulation and contained in dossier



## 14.01.04.05.F Preliminary Determination

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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

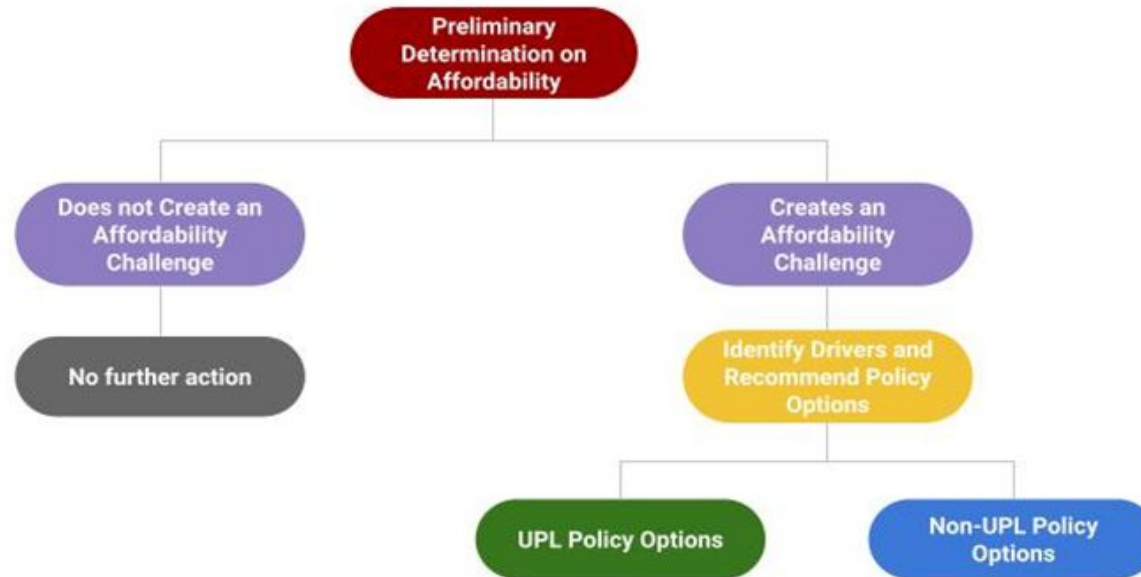
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- Board staff shall prepare a draft of the preliminary determination cost review report that summarizes:
  - the information considered by the Board in conducting the cost review study,
  - the Board's deliberations,
  - the circumstances or indicia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





# Process after Board Makes Preliminary Determination on Affordability



# Policy Review Process and Upper Payment Limit (UPL) Development

## Policy Review Process

Board Makes Preliminary Determination



**Green**= Upper Payment Limit Policy Review Process

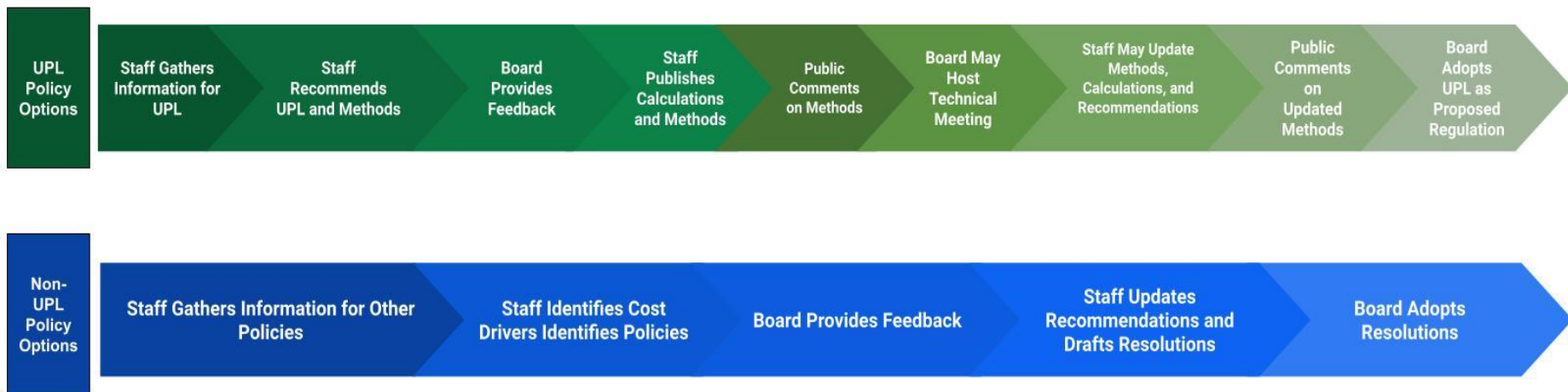
**Blue**= Non-UPL Policy Review Process

**Red**= Cost Review Study Process



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# Policy Options- Drug Deemed to Create Affordability Challenges



# Next Step after a Preliminary Determination - Policy Review Process

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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

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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 - Policy Action Other than UPL

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- (1) Board staff may recommend policy options to redress the affordability challenge.
- (2) When recommending policy options, Board staff may analyze the:
  - (a) Drivers of the affordability challenge;
  - (b) How the policy addresses a driver;
  - (c) Strengths and weaknesses of the policy;
  - (d) Possible implementation of the policy through legislation, regulation, or enforcement; and
  - (e) Potential impacts of the policy.



# Policy Review Process - Policy Action UPL

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- (2) When recommending policy options, Board staff may analyze the:
  - (a) Drivers of the affordability challenge;
  - (b) How the policy addresses a driver;
  - (c) Strengths and weaknesses of the policy;
  - (d) Possible implementation of the policy through legislation, regulation, or enforcement; and
  - (e) Potential impacts of the policy.



# Policy Review Process - Policy Action UPL

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- (3) Board staff may provide recommendations related to establishing a UPL including:
  - (a) An assessment of the drivers of the affordability challenge; and
  - (b) The extent to which a UPL may address the drivers.
  
- (4) The Board may pursue development of a UPL as a policy option and direct Board staff to provide recommendations concerning the frameworks and contextual information that may be used to set a UPL in accordance with the UPL process set forth in Regulation .06 of this chapter.







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