

Overview- Cost Review Study Process

PDAB Meeting

November 17, 2025

Andrew York, Executive Director



Agenda

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



Process for Preliminary Determination for Today

- 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

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



COMAR 14.01.04.05A- Cost Review Study

Board May Determine

- (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

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

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.

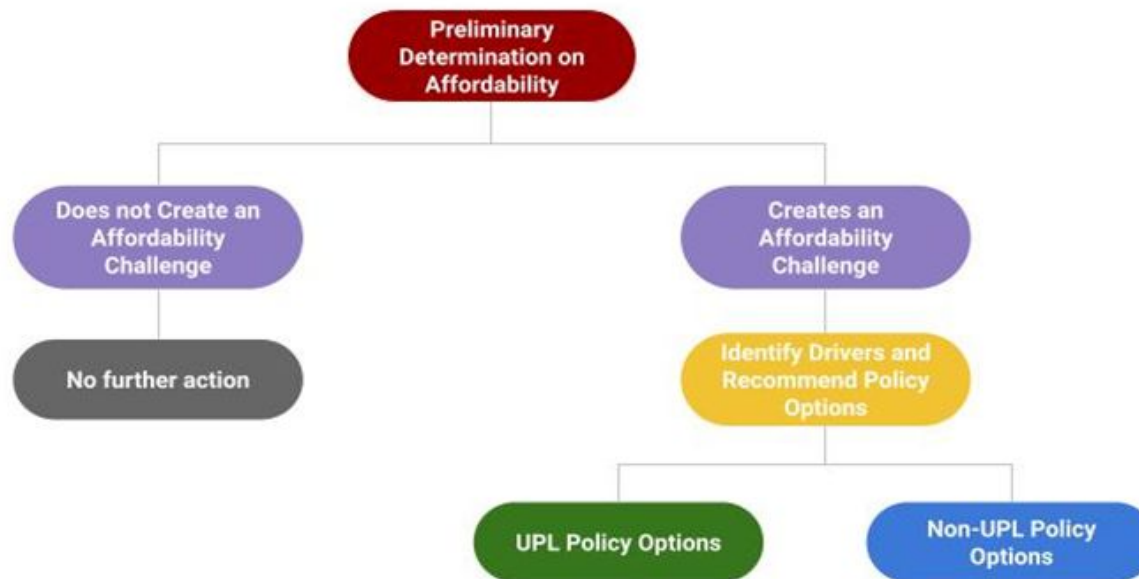


Next Step after a Preliminary Determination - Draft Report

- 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.



Process after Board Makes Preliminary Determination on Affordability



Policy Review Process and Upper Payment Limit (UPL) Development

Policy Review Process

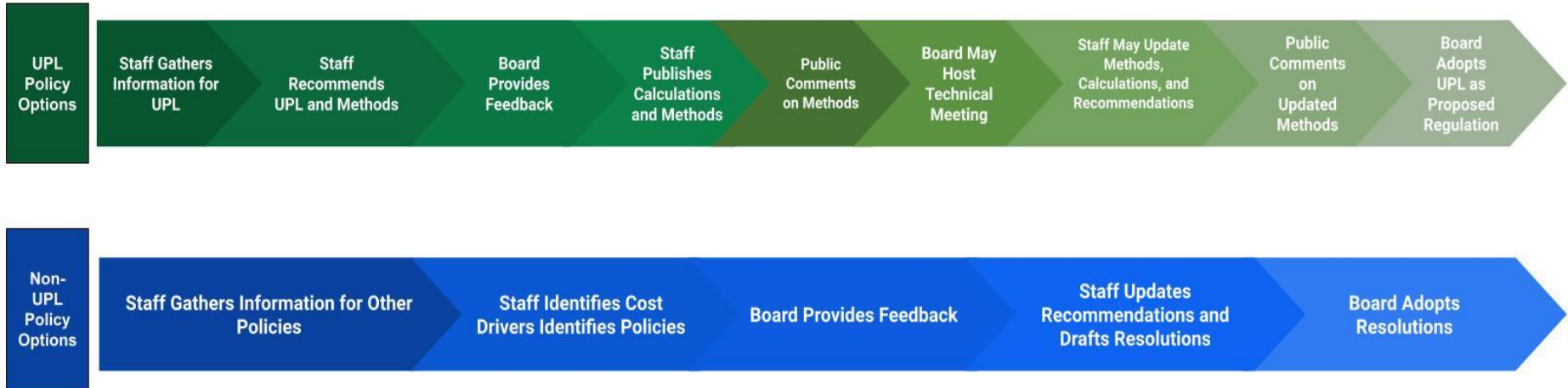
Board Makes Preliminary Determination



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



Policy Options- Drug Deemed to Create Affordability Challenges



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 - Policy Action Other than UPL

- (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

- (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

- (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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