

Prescription Drug Affordability Board Meeting

October 3, 2025

October 3 Meeting Agenda

Call to Order, Roll Call, Minutes Approval

10:00 - 10:05 am

Board Member & Director Updates

10:05 - 10:10 am

Rulemaking Hearing

Prescription Drug Affordability Board Rule 3 CCR 702-9: Part 4.3. Upper Payment Limit for Enbrel/Etanercept

- *Rule Introduction*
- *Staff Presentation*
- *Board Deliberation*
- *Witness Testimony - Witness testimony will be limited to 3 minutes per person. Board members may ask questions of witnesses, and the time limit does not apply to answering questions from the Board.*
- *Board Deliberation*

10:10 am - 12:00 pm*

Break

12:00 - 12:10 pm

Board Business

- *UPL Implementation*

12:10 - 12:40 pm

Public Comment

Comments will be limited to 2 minutes per person or organization.

12:40 - 1:00 pm

***Please note:** *The rulemaking hearing for Enbrel UPL may run longer than the time allotted on the agenda.*

The Board may meet in Executive Session to discuss confidential, trade-secret, or proprietary information pursuant to sections 24-6-402(3)(a)(III), C.R.S., and 10-16-1404(3), C.R.S.

If you need an accommodation to access PDAB meetings or materials, please notify staff at dora_ins_pdab@state.co.us.

Prescription Drug Affordability Advisory Council members may attend the October 3, 2025 PDAB meeting and may provide public comment.



Call to Order Roll Call Minutes Approval

August 22 Meeting Minutes

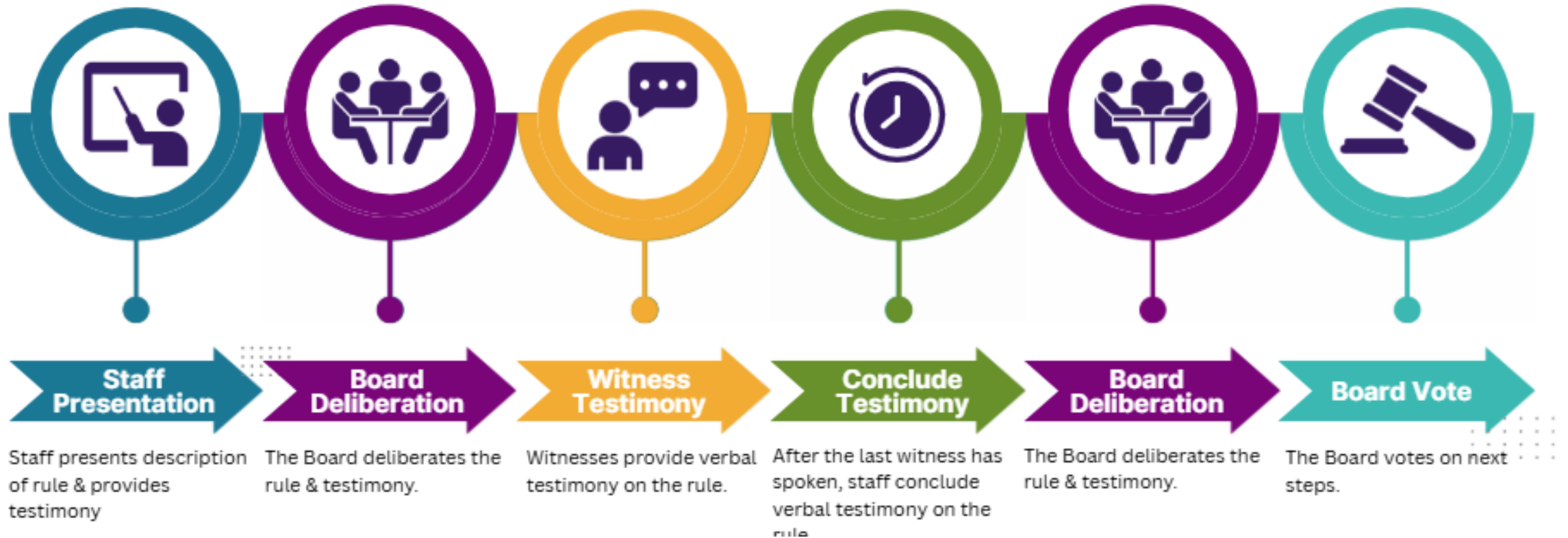
September 29 Meeting Minutes

Board Member & Director Updates

Rulemaking Hearing

*Prescription Drug Affordability Board Rule 3 CCR 702-9: Part 4.3
Upper Payment Limit for Enbrel (Etanercept)*

Rulemaking Hearing Overview



Staff Presentation

*Prescription Drug Affordability Board Rule 3 CCR 702-9: Part 4.3.
Upper Payment Limit for Enbrel/Etanercept*

Enbrel UPL Rulemaking Hearing: Staff Presentation

Outline

- Implementation monitoring and enforcement next steps
- Review of UPL benchmarks and data
- Proposed changes to Prescription Drug Affordability Board Rule 3 CCR 702-9: Part 4.3. Upper Payment Limit for Enbrel

Enbrel UPL Rulemaking Hearing: Staff Presentation

Implementation Monitoring & Enforcement Next Steps

Implementation Monitoring

Prescription Drug Affordability Board

After a UPL is established, the Board may monitor implementation by:

- Receiving and reviewing use of savings reports from carriers. These reports include detail on how carriers use savings from a UPL to lower costs for consumers.
- Requesting information for annual General Assembly reports, including assessing the impact of a UPL on access from providers, pharmacies, and patients.
- Accepting public comment regarding implementation.

Division of Insurance

After a UPL is established, the Division may monitor implementation by:

- Accepting information from providers, pharmacies, and patients regarding access.
- Conducting market analysis of carrier and PBM behaviors regarding cost and utilization of drugs subject to a UPL.
- Examining cost and utilization data as reported in the APCD.
- Examining formularies and prior authorization data submitted by carriers in annual filings.
- Examining changes in rebates and drug-specific impacts on premiums (per 10-16-1405 CRS).

Enforcement

The Attorney General, and their office, is responsible for determining when and how to enforce the UPL.

Enbrel UPL Rulemaking Hearing: Staff Presentation

Review of UPL Benchmarks & Data

The following information has been discussed at rulemaking hearings:

May 2025:	July 2025:	August 2025:	October 2025:
<p>Staff presentation on data for UPL methodology:</p> <ul style="list-style-type: none">Price and cost metric information for Enbrel: WAC, ASP, NADAC, patient out-of-pocket spending amounts, carrier paid amounts, public program fee schedules, Medicare's MFP, estimates of manufacturer net price. <p>Testimony:</p> <ul style="list-style-type: none">7 written(No time for verbal)	<p>Testimony:</p> <ul style="list-style-type: none">21 written11 verbal	<p>Additional data for UPL methodology:</p> <ul style="list-style-type: none">Retail discount amountsDrug shortage statusData on the age distribution of Enbrel utilizers, including older adults <p>Testimony:</p> <ul style="list-style-type: none">12 written12 verbal	<p>Testimony:</p> <ul style="list-style-type: none">~17 writtenVerbal

Enbrel UPL Rulemaking Hearing: Staff Presentation

Review of UPL Benchmarks & Data

Enbrel and TAs are not in shortage as of October 2, 2025.

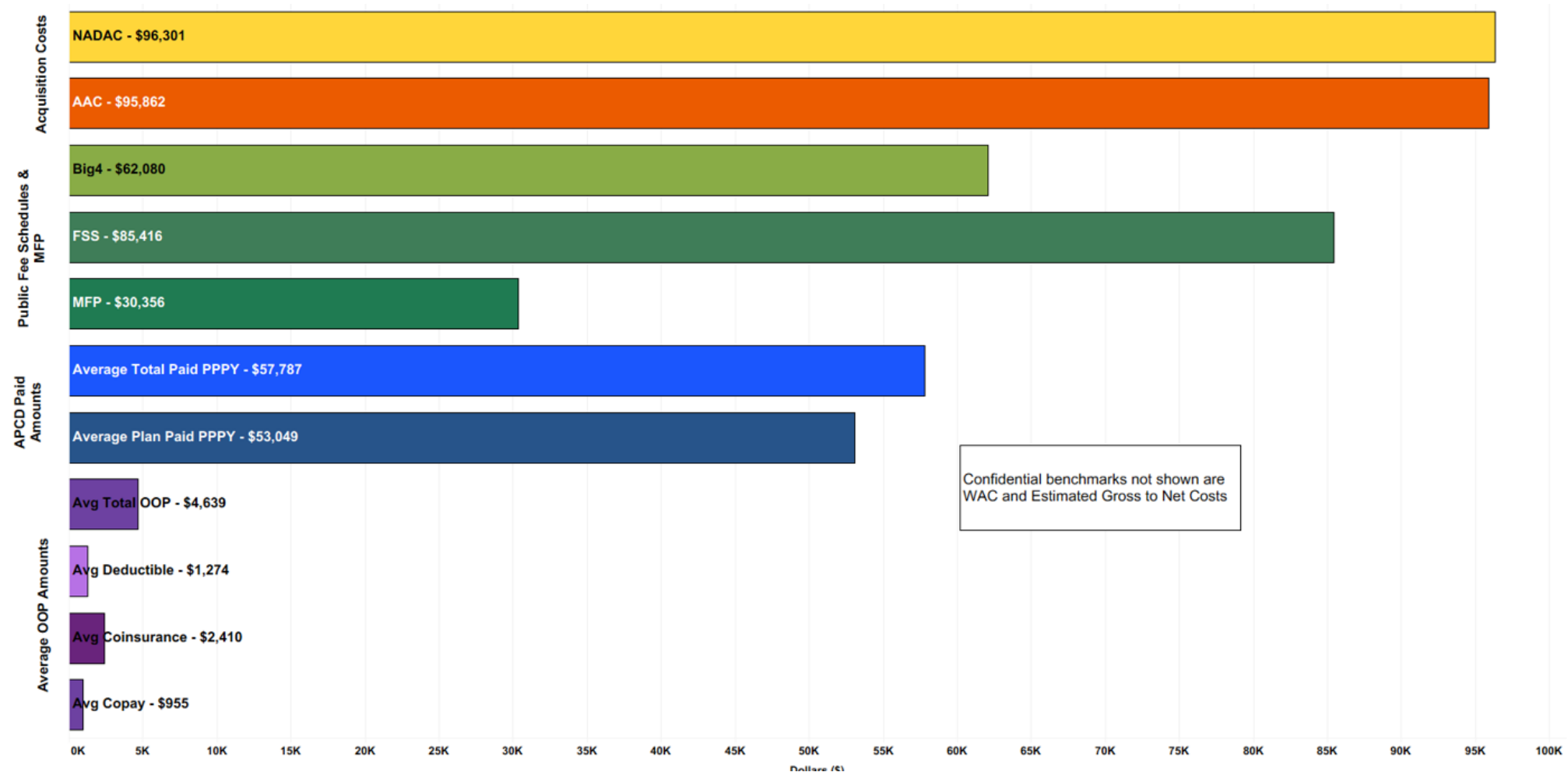
The Board shall not consider research or methods that use QALYs.

A UPL does not preclude a pharmacy from charging reasonable dispensing fees.

Information on the impact to older adults and persons with disabilities is provided through testimony.

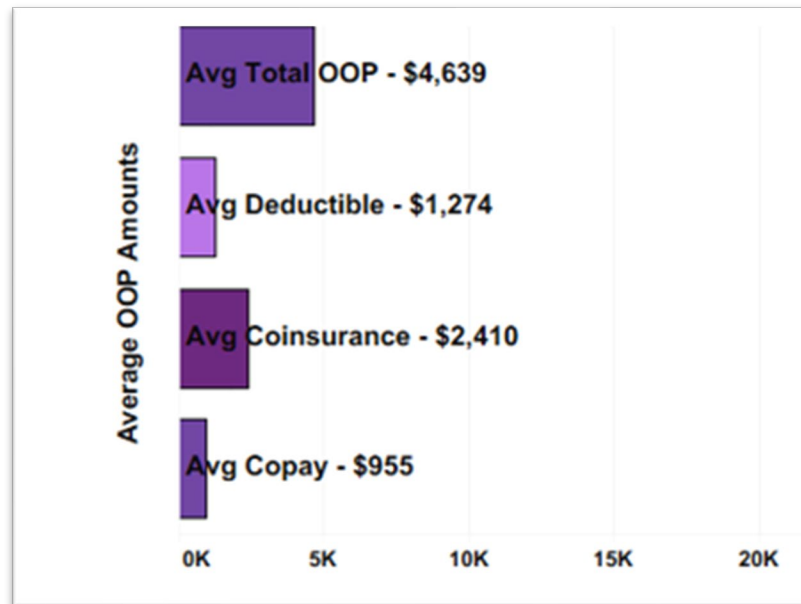
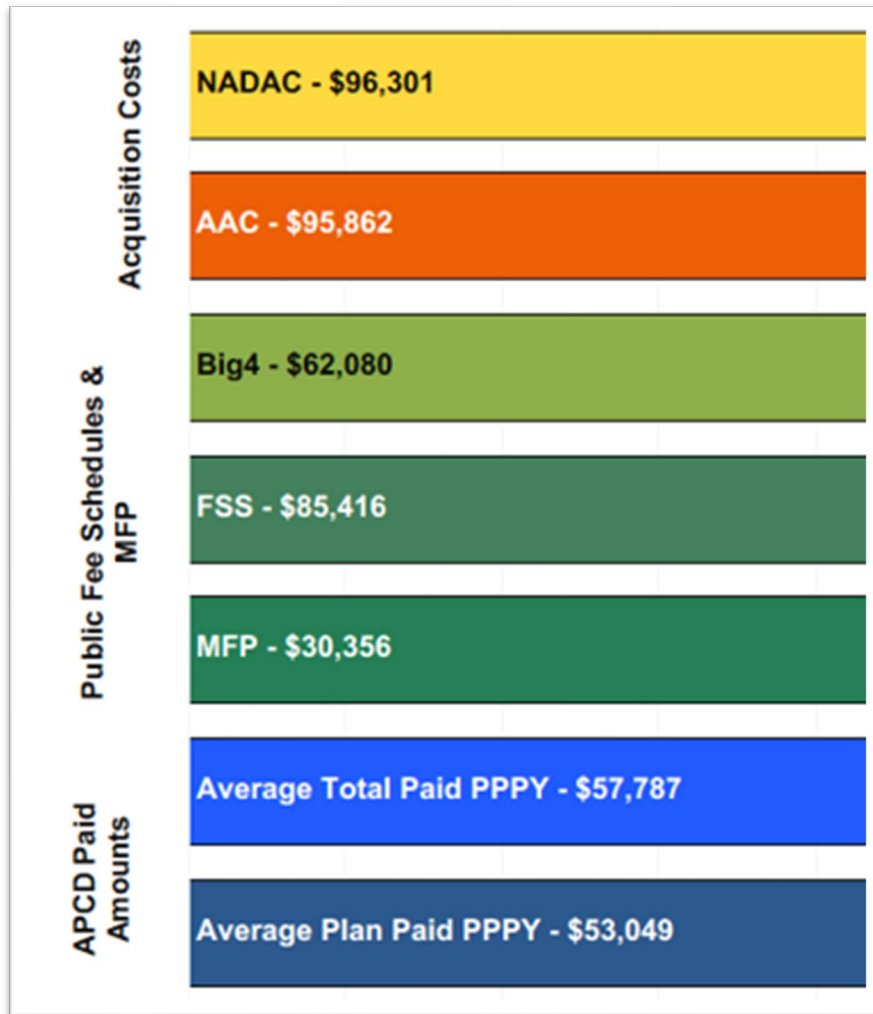
Enbrel UPL Rulemaking Hearing: Staff Presentation

Review of UPL Benchmarks & Data



Enbrel UPL Rulemaking Hearing: Staff Presentation

Review of UPL Benchmarks & Data



Enbrel UPL Rulemaking Hearing: Staff Presentation

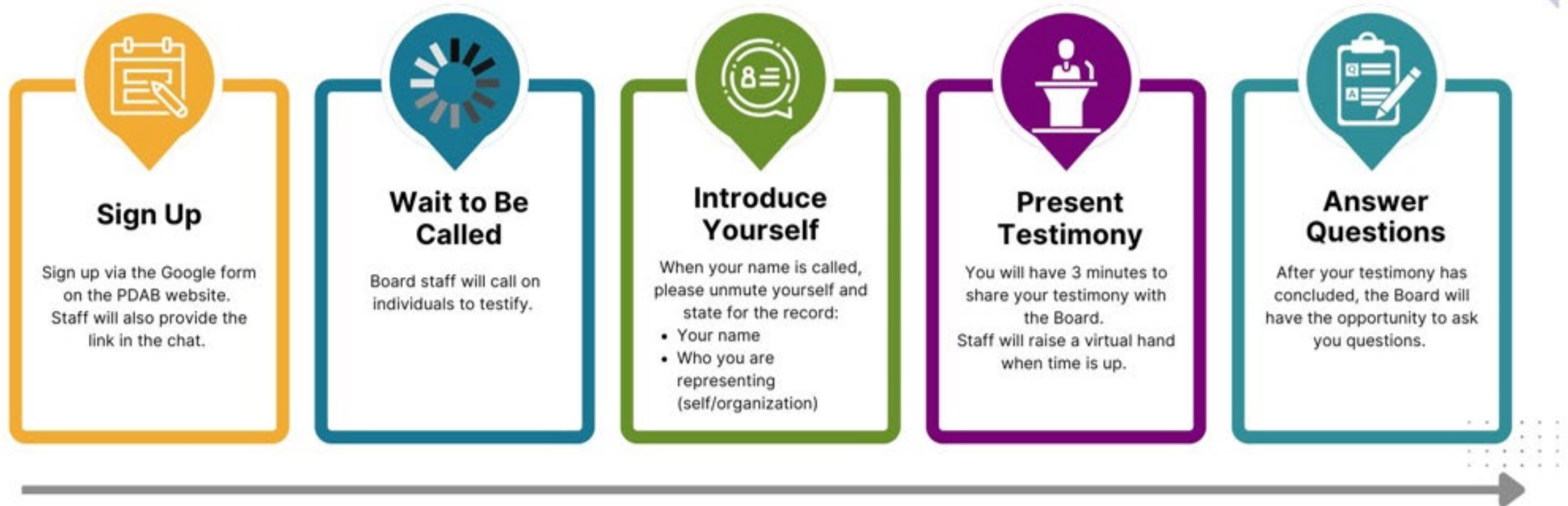
Proposed Changes to Rule

Staff are suggesting the following changes to Rule 3 CCR 702-9: Part 4.3. Upper Payment Limit for Enbrel:

- Minor change in the UPL dollar amount,
- Inclusion of a defined unit, and
- Defined effective date.

Enbrel UPL Rulemaking Hearing

Providing Testimony During Today's Hearing



Enbrel UPL Rulemaking Hearing

Board Deliberation & Vote: Adopting Proposed Enbrel UPL Rule



Board Action Item

Board deliberates.

Board may vote to:

Motion: “Adopt Prescription Drug Affordability Board Rule 3 CCR 702-9: Part 4.3. Upper Payment Limit for Enbrel, an upper payment limit for Enbrel (Etanercept), as amended on October 3, 2025.”

Break

The meeting will resume after a 10-minute break.

Board Business

UPL Implementation

Board Business

UPL Implementation

Staff are in the process of creating guides for UPL implementation.

Communication plan for carriers, providers, and consumers

Manufacturer inquiry process

Partnership with carriers to implement:

- Carrier appeal process for UPLs
- Carrier use of savings report

UPL monitoring and Board communication roadmap

Board Business

UPL Implementation Timeline



Upcoming Meetings

PDAB Meeting: November 14 at 10 am MT

PDAAC/Stakeholder Workgroup Meeting: October 14 at 12 pm MT

For meeting minutes, agendas, and general information about PDAB, visit <https://doi.colorado.gov/insurance-products/health-insurance/prescription-drug-affordability-review-board>

Questions about the Prescription Drug Affordability Board and Advisory Council can be sent to dora_ins_pdab@state.co.us.

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The Prescription Drug Affordability Board is in Executive Session

The Board may meet in Executive Session to receive legal advice pursuant to section 24-6-402(3)(a)(II), C.R.S.



The Prescription Drug Affordability Board is in Executive Session

The Board may also meet in Executive Session to discuss confidential, trade-secret, or proprietary information pursuant to sections 24-6-402(3)(a)(III), C.R.S., and 10-16-1404(3), C.R.S.



The Prescription Drug Affordability Board is in Executive Session

The Board may also meet in Executive Session to discuss confidential, trade-secret, or proprietary information regarding Enbrel's WAC and net price, pursuant to sections 24-6-402(3)(a)(III), C.R.S., and 10-16-1404(3), C.R.S.



The Prescription Drug Affordability Board is in Executive Session

*The Board may meet in Executive Session to receive legal advice regarding use of data by the Board in setting an upper payment limit, pending litigation, **section 24-4-105, C.R.S., and section 24-4-103(4)(a), C.R.S.,** pursuant to section 24-6-402(3)(a)(II), C.R.S.*