

Prescription Drug Affordability Board Meeting

August 22, 2025

August 22 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
- Board Deliberation
- Witness Testimony

10:10 am - 12:30 pm*

Break

12:30 - 12:40 pm

Board Business

- APCD Data Validation - Cosentyx Validated Data Addendum
- UPL Implementation
- Stakeholder Workgroup Update
- 2026 PDAB Meeting Schedule
- Presentation on Stelara Biosimilars from PORTAL
- APCD Data Validation - Stelara Validated Data Addendum

12:40 - 2:00 pm

**Due to the number of agenda items and the rulemaking hearing, a general public comment session has not been scheduled for this meeting.*

- 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 August 22, 2025 PDAB meeting and may provide public comment.



Call to Order Roll Call Minutes Approval

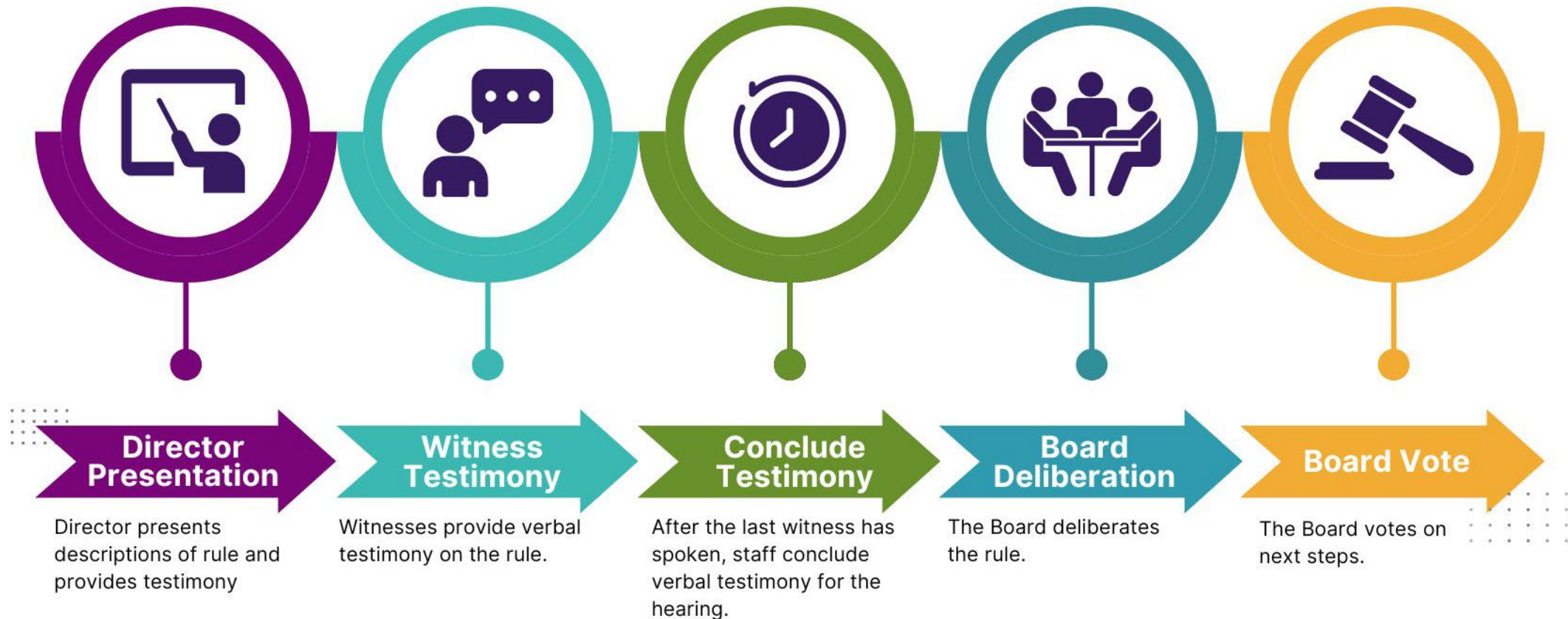
July 11 Meeting Minutes

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



Rulemaking Hearing

Staff Presentation of Prescription Drug Affordability Board Rule 3 CCR 702-9: Part 4.2.C. Upper Payment Limit for Enbrel/Etanercept

Enbrel UPL Rulemaking Hearing

Data Previously Presented by Staff

Staff presented the following data at Enbrel's May 23rd UPL rulemaking hearing:

Excel workbook of UPL price and cost metric data

Graph packet visualizing price and cost metrics for Enbrel and its therapeutic alternatives (TAs)

Enbrel UPL benchmark data presented in Tableau & Excel

Enbrel UPL Rulemaking Hearing

Other UPL Factors

Drug Shortage List

- Enbrel and TAs* have not been in shortage as of August 11, 2025.
- Each month since Nov., staff check the status of Enbrel and its TAs on the Drug Shortage List as reported by:
 - Food and Drug Administration (FDA)
 - American Society for Health System Pharmacists (ASHP)

Retail Discount Amounts

- Analysis of GoodRx to determine available retail discounts for Enbrel.
- Enbrel coupon amounts = \$5-12
- Lowest price on GoodRx:
 - 1 vial of 25mg = \$2,333 at Walmart for ~2-week supply

Impacts to Older Adults & Persons with Disabilities

- Staff have updated the graph packet with additional data to include the age distribution of Enbrel utilizers in CO.
- The Board will not consider research and methods that employ a dollars per QALY or similar measure.

**Enbrel's therapeutic alternatives: Humira, Hadlima, Cimzia, Hyrimoz, Simponi, Abrilada, Remicade, Cyltezo, Infliximab, Hulio, Inflectra, Idacio, Renflexis, Simlandi, Avsola, Yuflyma, Amjevita, Yusimry, and Hadlima.*

Enbrel UPL Rulemaking Hearing

Board Deliberation & Vote: Amendments to Draft Proposed Enbrel UPL Rule



Board Action Item

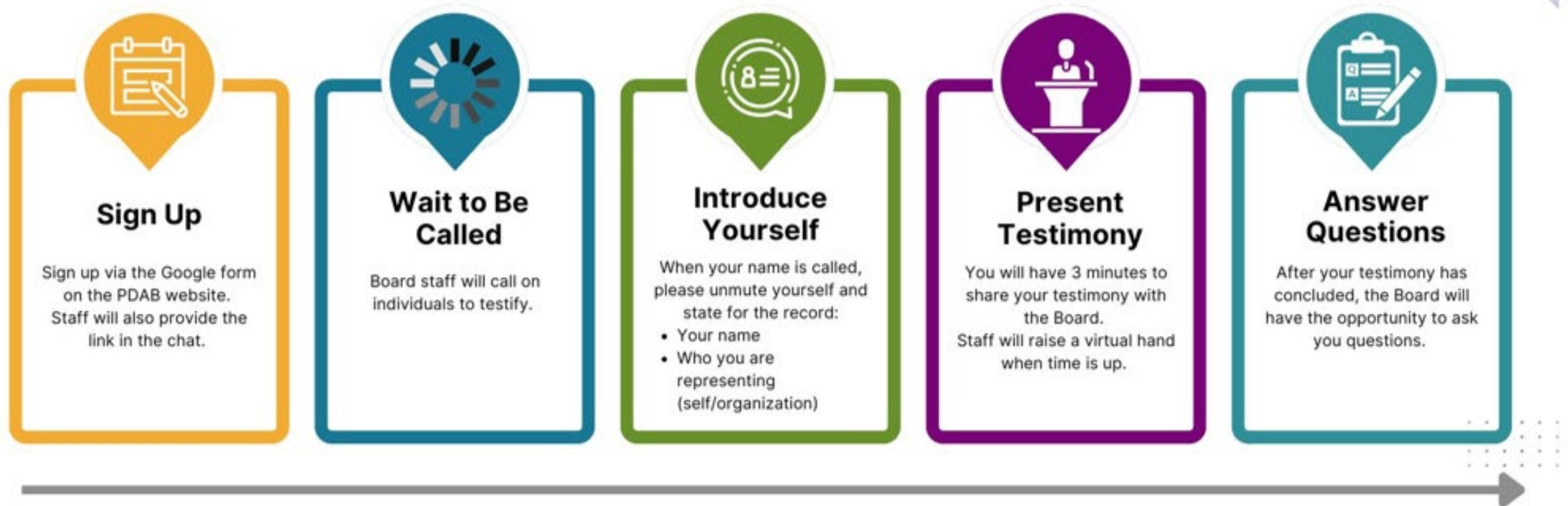
Board deliberates.

Board may vote to:

- Amend the draft proposed UPL rule for Enbrel (Etanercept), and direct staff to publish amended rule on the Board's website for public comment.

Enbrel UPL Rulemaking Hearing

Providing Testimony During Today's Hearing



Enbrel UPL Rulemaking Hearing

Board Deliberation & Vote: Continue Enbrel UPL Rulemaking



Board Action Item

Board deliberates.

Board may vote to:

- Continue Enbrel's UPL rulemaking hearing Part 4.3 at the October 3, 2025 PDAB meeting to allow additional stakeholder input and Board deliberation.

Break

The meeting will resume after a 10-minute break.

Board Business

- *APCD Data Validation - Cosentyx Validated Data Addendum*
- *UPL Implementation*
- *Stakeholder Workgroup Update*
- *2026 PDAB Meeting Schedule*
- *Presentation on Stelara Biosimilars from PORTAL*
- *APCD Data Validation - Stelara Validated Data Addendum*

Board Business

APCD Data Validation Overview

At the April 11 PDAB meeting, the Board discussed a miscategorization of commercial and Medicare claims data by a PBM.

Staff has since presented corrected data on:

Price & cost
statistics

Annual utilization &
expenditures

The Board directed staff to include an addendum to the Affordability Review Summary Reports for Enbrel, Cosentyx, and Stelara. Each addendum includes corrected tables and figures that were impacted by the data miscategorization.

Enbrel's addendum was approved by the Board on May 23rd.

Board Business

APCD Data Validation: Cosentyx Validated Data Addendum

Staff have confirmed the eligibility of Cosentyx.

Cosentyx's addendum includes the following corrected tables and figures:

Tables	Figures
Table 2: Utilization of Cosentyx (All Lines of Business)	Figure 1: Cosentyx Utilization by Payer Type
Table 5: Utilization of Cosentyx and Identified Therapeutic Alternatives	Figure 2: Insurance Information
Table 6: Cosentyx's 2022 Price & Cost Per person Statistics	Figure 4: Insurance Information for Therapeutic Alternatives
Table 7: Cosentyx's 2022 Statewide Price & Cost Statistics	Figure 6: Average Commercial Out-of-Pocket Cost Comparison
Table 8: Average Monthly Commercial Out-of-Pocket Cost Information in 2022	Figure 7: Changes in Copay Amounts by Year and Drug 2019-2022
Table 9: Annual Utilization and Expenditures	Figure 10: Monthly Utilizers for Cosentyx and Therapeutic Alternatives
	Figure 11: Monthly Total Paid and Average Total Paid

Board Business

APCD Data Validation: Cosentyx Validated Data with Percent Changes

Annual Utilization and Expenditures

Table 9 shows the percent change in the Annual Utilization and Expenditures for Cosentyx in 2019-2022.

	Percent Change			
	2019	2020	2021	2022
Patient Count	-1%	-2%	-12%	-10%
Total Paid	-3%	41%	8%	-4%
Average Paid Per Person	-2%	-2%	5%	4%
Total Patient Paid	0%	-2%	-18%	1%
Average Out-of-Pocket (OOP)	-12%	-25%	-26%	-12%

Board Business

Deliberate & Vote: Cosentyx



Board Action Item

Board deliberates.

Board may vote to:

Vote #1

- Approve the addendum to Cosentyx's Affordability Review Summary Report as amended/presented.

Vote #2

- Confirm Board's findings on June 14, 2024, that Cosentyx is unaffordable to Colorado consumers.

Vote #3

- Begin rulemaking to establish an upper payment limit (UPL) for Cosentyx.

Board Business

- *APCD Data Validation - Cosentyx Validated Data Addendum*
- ***UPL Implementation***
- *Stakeholder Workgroup Update*
- *2026 PDAB Meeting Schedule*
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Board Business

UPL Implementation & Monitoring

UPL Implementation

- UPL effective date
- Manufacturer inquiry process
- UPL appeal process
- Use of savings report
- General Assembly report

UPL Monitoring

- Patient access
- Pharmacy/provider access
- Formulary analytics
- Therapeutic alternatives
- Prior authorization changes
- Complaints investigation

Staff are also drafting a communication plan for UPL implementation.

Board Business

- *APCD Data Validation - Cosentyx Validated Data Addendum*
- *UPL Implementation*
- ***Stakeholder Workgroup***
- *2026 PDAB Meeting Schedule*
- *Presentation on Stelara Biosimilars from PORTAL*
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Board Business

Stakeholder Workgroup

The updated PDAB Policy No. 4 adds a staff-facilitated stakeholder workgroup to include:

- PDAAC members
- RDAC members
- Members of organizations representing patients affected by a condition or disease treated by a prescription drug under the Board's review
- Other stakeholders

The Board delegated staff to conduct this workgroup before the Board begins the second round of Affordability Reviews.

Board Business

Stakeholder Workgroup

Goals for Patient Engagement

Trust

- Build trust and rapport with PDAB stakeholders and adopt a culture of process improvement.

Clarity

- When the Board is seeking input, patients are clear of what is being asked and how feedback will be used.

Analysis

- Patients participating in the Board's work feel heard by the Board and that their feedback has been considered.

Workgroup Objectives

Improve Board processes for collecting patient experience information during affordability reviews

Identify best practices & recommendations regarding:

- Tools (e.g. surveys, meetings, etc.)
- Timeline for collecting feedback
- Establishing clear communication channels and outreach with collaborators
- Assessing information received from stakeholders
- Disclosure of conflicts of interest from stakeholders

Board Business

Stakeholder Workgroup Format



Location

- Virtual ad hoc PDAAC meetings

Facilitator

- PDAAC chair leads a town hall session

Attendees

- PDAAC members
- RDAC members
- Members of the public
- Advocacy organizations (stakeholder outreach on next slide)

Pre-Meeting Materials

- Evidence-based research on collecting patient experience

Work Product

- Recommendations report presented to the Board at November 14 PDAB meeting
- Board response to stakeholder workgroup recommendations report

Board Business

Stakeholder Workgroup Outreach

Organizations Representing Consumers

- Rare Disease Advisory Council (RDAC)
- Colorado Consumer Health Initiative (CCHI)
- Centennial State Prosperity
- Center for Health Progress (CHP)
- Young Invincibles
- Colorado Center on Law and Poverty (CCLP)
- Colorado Cross Disability Coalition (CCDC)
- Chronic Care Collaborative (CCC)
- AiArthritis
- Advocates for Compassionate Therapy Now (ACT Now)

Organizations Representing Providers

- Colorado Hospital Association (CHA)
- Colorado Community Health Network (CCHN)
- Colorado Medical Society (CMS)
- American Academy of Pediatrics (AAP)
- Colorado Academy of Family Physicians (CAFP)
- Colorado Nurses Association (CNA)
- Colorado Pharmacists Society (CPS)

Board Business

- *APCD Data Validation - Cosentyx Validated Data Addendum*
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- ***2026 PDAB Meeting Schedule***
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Board Business

Proposed 2026 Meeting Schedule

January 9

February 20

April 3

May 15

June 26

August 7

September 18

October 30

December 11



Board Business

- *APCD Data Validation - Cosentyx Validated Data Addendum*
- *UPL Implementation*
- *Stakeholder Workgroup*
- *2026 PDAB Meeting Schedule*
- ***Presentation on Stelara Biosimilars from PORTAL***
- *APCD Data Validation - Stelara Validated Data Addendum*

Board Business

Deliberate Stelara Biosimilars



Board Action Item

Board deliberates.

Board Business

- *APCD Data Validation - Cosentyx Validated Data Addendum*
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- *2026 PDAB Meeting Schedule*
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- *APCD Data Validation - Stelara Validated Data Addendum*

Board Business

APCD Data Validation: Stelara Validated Data Addendum

Staff have confirmed the eligibility of Stelara.

Stelara's addendum includes the following corrected tables and figures:

Tables	Figures
Table 2: Utilization of Stelara (All Lines of Business/Both Claim Types)	Figure 1: Stelara Utilization by Payer Type
Table 6: Utilization of Stelara and Identified Therapeutic Alternatives (All Lines of Business/Both Claim Types)	Figure 2: Insurance Information
Table 7: Stelara's 2022 Price & Cost Per person Statistics (All Lines of Business/Both Claim Types)	Figure 4: Insurance Information for Therapeutic Alternatives
Table 8: Stelara's 2022 Statewide Price & Cost Statistics (All Lines of Business/Both Claim Types)	Figure 6: Average Commercial Out-of-Pocket Cost Comparison (Pharmacy Claims)
Table 9: Average Monthly Commercial Out-of-Pocket Cost Information in 2022 (Pharmacy Claims)	Figure 7: Changes in Copay Amounts by Year and Drug 2019-2022 (Pharmacy Claims)
Table 10: Annual Utilization and Expenditures (All Lines of Business/Pharmacy Claims)	Figure 10: Monthly Utilizers for Stelara and Therapeutic Alternatives (Both Claim Types)
	Figure 11: Monthly Total Paid and Average Total Paid (All Lines of Business/Both Claim Types)

Board Business

APCD Data Validation: Stelara Validated Data with Percent Changes

Annual Utilization and Expenditures (All Lines of Business/Pharmacy Claims)

Table 10 shows the percent change in the Annual Utilization and Expenditures for Stelara in 2019-2022.

	Percent Change			
	2019	2020	2021	2022
Patient Count	-2%	-3%	-5%	-5%
Total Paid	-1%	-12%	-30%	-28%
Average Paid Per Person	3%	-13%	-28%	-33%
Total Patient Paid	0.1%	0.1%	-2%	-15%
Average Out-of-Pocket (OOP)	-28%	-33%	-30%	-32%

Board Business

Deliberate & Vote: Stelara



Board Action Item

Board deliberates.

Board may vote to:

Vote #1

- Approve the addendum to Stelara's Affordability Review Summary Report as amended/presented.

Vote #2

- Confirm Board's findings on June 7, 2024, that Stelara is unaffordable to Colorado consumers.

Vote #3

- Begin rulemaking to establish an upper payment limit (UPL) for Stelara.

Upcoming Meetings

PDAB Meeting: October 3 at 10 am 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.

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



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.