

Prescription Drug Affordability Board Meeting

April 11, 2025

April 11 Meeting Agenda

Call to Order, Roll Call, & Minutes Approval

10:00 - 10:05 am

Board Member Updates & Director Updates

10:05 - 10:10 am

Board Business

10:10 - 11:30 am

APCD Data Validation Overview

- *Enbrel Validated Data Presentation and Discussion*
- *Cosentyx Validated Data Presentation and Discussion*
- *Stelara Validated Data Presentation and Discussion*

Public Comment

11:30 am - 12:00 pm

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

Break

12:00 - 12:10 pm

Board Business

12:10 - 12:40 pm

- *Approve Revised PDAB Policy and Procedures: Policy No. 4 (Affordability Review Policy and Procedure)*
- *Stakeholder Workgroup Discussion*

Public Comment

12:40 - 1:00 pm

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

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.

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

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



COLORADO

**Prescription Drug
Affordability Board**

Division of Insurance

Call to Order Roll Call & Minutes Approval

January 17 & February 21 Meeting Minutes

Board Member Updates & Director Updates

Director Updates

New Prescription Drug Affordability Director

Sophie Thomas, MPH

- Over 10 years of experience in health care policy, program management, and health plan operations in Colorado
- Expertise in Medicaid, regulatory compliance, and program operations
- Current PBM Enforcement Director within the Division, overseeing implementation of the new PBM Compliance & Enforcement program
- PBM registration & transparency efforts
- Provider & pharmacist complaint process
- Director overseeing Prescription Drug Affordability Programs, including PDAB & PBM Enforcement

Director Updates

- Enbrel UPL Rulemaking: The Board will not hold a UPL rulemaking hearing today in lieu of a discussion about APCD data validation. During the May 23 PDAB meeting, the Board may vote on whether or not to begin UPL rulemaking for Enbrel.
- Amgen v. Mizner, et al. update
- Cost Benefit Analysis and Regulatory Analysis are posted on the PDAB website.

Board Business

APCD Data Validation Discussion

- *Enbrel Validated Data Presentation and Discussion*
- *Cosentyx Validated Data Presentation and Discussion*
- *Stelara Validated Data Presentation and Discussion*

Board Business

APCD Data Validation Discussion

Today:

- Overview of data miscategorization
- Revisit data sources used by the Board
- For Enbrel, Cosentyx, and Stelara:
 - Review validated data & discuss changes
 - Take Direction from the Board regarding next steps
- Public comment

Board Business

APCD Data Validation Discussion



Overview of Miscategorization

- A PBM miscategorized its commercial and Medicare claims data.
- For pharmacy claims, the PBM mislabeled commercial claims as Medicare claims, and vice versa.
- These pharmacy claims accounted for 6.9% of total pharmacy claims in the APCD.
- Even though the categorization of data changed, utilization still occurred on Medicare claims.
- However, the DOI does not have access to all Medicare claims.
- As a result, corrected data shows up as changes in APCD-related utilization and expenditure data.
- The data miscategorization will not affect the data presented to the Board by staff during its UPL rulemaking.

Board Business

APCD Data Validation Discussion



Revisit data sources used by the Board

- While APCD is an important data source for Colorado-specific data, it is not the *only* data source utilized by the Board in its work.
- The following slides highlight the data sources the Board used throughout the Affordability Review process - including eligibility and selection of drugs, in addition to conducting of Affordability Reviews of selected drugs.

Board Business

APCD Data Validation Discussion



Data Sources Used by PDAB Overview of Information Provided	
Colorado All-Payer Claims Database (APCD)	Utilization and expenditure data in Colorado
First Data Bank/Analysource	Wholesale Acquisition Cost (WAC), average sales price (ASP), date of FDA approval, therapeutic class, therapeutic equivalent market entry date and price difference
SSR Health	Net price estimates (e.g., rebates)
FDA website	Expedited approval pathway information (e.g., accelerated approval, orphan drug designation, etc.)
DA Orange & Purple books	Generic/biosimilar availability, number of therapeutic equivalents
Center for Medicare and Medicaid Services (CMS)	National Average Drug Acquisition Cost (NADAC), Healthcare Common Procedure Coding System crosswalk
Peer-reviewed health outcomes research	Various clearing houses and health technology assessment data bases utilized to identify studies that examine the effectiveness of prescription drugs.

Board Business

APCD Data Validation Discussion



Data Sources Used by PDAB	Definition or Usage
CDC Social Vulnerability Index (SVI)	Quantitative analyses of potential health equity impacts by location.
Bureau of Labor Statistics (BLS)	Inflation data.
Surveys	Qualitative data collected by staff from multiple stakeholders, including patients, caregivers, and individuals with scientific or medical training
Voluntarily Submitted Info	Qualitative and quantitative information submitted by stakeholders, including manufacturers, patients, caregivers, and others
Stakeholder Meetings	Qualitative and quantitative information submitted by stakeholders, including manufacturers, patients, caregivers, and others

Board Business

APCD Data Validation Discussion



The following APCD data points were impacted due to the PBM's data miscategorization

Data Point	Description
Patient Count	The number of patients utilizing the prescription drug in a year.
Average WAC per Course of Treatment	The average wholesale acquisition cost (WAC) per course/period of treatment.
Average Paid per Person per Year (APPY)	The average amount paid for the drug by both (patients and payer) per person per year.
APPY - Plan Paid	The average amount paid for the drug by the payer per person per year.
APPY - Out-of-Pocket (OOP)	The average amount paid for the drug by the patient per year.
Total Paid	Total amount paid by payers and patients for the drug within one year.
Total Patient Paid	Total amount paid by all patients for the drug within one year.

Board Business

APCD Data Validation Discussion: Prescription Drug

Prescription Drug's 2022 Price & Cost per Person Statistics

Tables 1 (left) and 2 (right) outline how the Price & Cost per Person Statistics will be displayed for each drug in the upcoming slides.

2022 Affordability Review	
Price & Cost Statistic	Amount
Average WAC per Course of Treatment	
Average Paid per Person	
APPY - Plan Paid	
APPY - Out of Pocket	

2022 Corrected Data	
Price & Cost Statistic	Amount
Average WAC per Course of Treatment	
Average Paid per Person	
APPY - Plan Paid	
APPY - Out of Pocket	

Board Business

APCD Data Validation Discussion: Prescription Drug

Affordability Review Annual Utilization & Expenditures				
	2019	2020	2021	2022
Patient Count				
Total Paid				
Average Paid per Person				
Total Patient Paid				
Average OOP (APPY - OOP)				

Tables 3 (top) and 4 (bottom) outline how the Annual Utilization & Expenditures will be displayed for each drug in the upcoming slides.

Corrected Annual Utilization & Expenditures				
	2019	2020	2021	2022
Patient Count				
Total Paid				
Average Paid per Person				
Total Patient Paid				
Average OOP (APPY - OOP)				

Board Business

APCD Data Validation Discussion

- *Enbrel Validated Data Presentation and Discussion*
- *Cosentyx Validated Data Presentation and Discussion*
- *Stelara Validated Data Presentation and Discussion*

Board Business

APCD Data Validation Discussion: Enbrel

Enbrel's 2022 Price & Cost per Person Statistics

Table 5 (left) shows the 2022 Affordability Review Price & Cost per Person Statistics for Enbrel. Table 6 (right) shows the 2022 Corrected Data for Enbrel.

2022 Affordability Review	
Price & Cost Statistic	Amount
Average WAC per Course of Treatment	\$50k - \$60k
Average Paid per Person	\$46,772
APPY - Plan Paid	\$41,769
APPY - Out of Pocket	\$2,295

2022 Corrected Data	
Price & Cost Statistic	Amount
Average WAC per Course of Treatment	\$50k- \$60k
Average Paid per Person	\$49,297
APPY - Plan Paid	\$46,460
APPY - Out of Pocket	\$3,536

Board Business

APCD Data Validation Discussion: Enbrel

Affordability Review Annual Utilization & Expenditures				
	2019	2020	2021	2022
Patient Count	3,653	3,440	3,692	3,406
Total Paid	\$127,959,896	\$134,815,241	\$161,483,771	\$159,305,653
Average Paid per Person	\$35,029	\$39,190	\$43,739	\$46,772
Total Patient Paid	\$7,399,691	\$7,700,602	\$10,524,066	\$9,860,820
Average OOP	\$1,866	\$2,189	\$2,526	\$2,295

Tables 7 (top) shows the 2022 Affordability Review Annual Utilization & Expenditures for Enbrel. Table 8 (bottom) shows the 2022 Corrected Data for Enbrel.

Corrected Annual Utilization & Expenditures				
	2019	2020	2021	2022
Patient Count	2,567	2,508	2,744	2,585
Total Paid	\$95,178,318	\$103,079,777	\$124,248,172	\$127,437,778
Average Paid per Person	\$37,078	\$41,100	\$45,280	\$49,299
Total Patient Paid	\$4,356,574	\$4,831,893	\$7,305,304	\$6,921,218
Average OOP	\$2,207	\$2,532	\$3,438	\$3,536

Board Business

APCD Data Validation Discussion: Enbrel

Board Deliberation Enbrel Next Steps

- What additional information does the Board need from staff for its next meeting?
- The Board may request that staff:
 - Add an addendum to the executive summary of Enbrel's Affordability Review to include updated tables with corrected data; and
 - Update data to allow the Board to confirm Enbrel's eligibility.

Board Business

APCD Data Validation Discussion

- *Enbrel Validated Data Presentation and Discussion*
- *Cosentyx Validated Data Presentation and Discussion*
- *Stelara Validated Data Presentation and Discussion*

Board Business

APCD Data Validation Discussion: Cosentyx

Cosentyx's 2022 Price & Cost per Person Statistics

Table 9 (left) shows the 2022 Affordability Review Price & Cost per Person Statistics for Cosentyx. Table 10 (right) shows the 2022 Corrected Data for Cosentyx.

2022 Affordability Review	
Price & Cost Statistic	Amount
Average WAC per Cost of Treatment	\$70k - \$80k
Average Paid per Person	\$46,948
APPY - Plan Paid	\$44,963*
APPY - Out of Pocket	\$3,297

2022 Corrected Data	
Price & Cost Statistic	Amount
Average WAC per Cost of Treatment	\$90k - \$100k
Average Paid per Person	\$48,827
APPY - Plan Paid	\$46,592
APPY - Out of Pocket	\$2,865

*value changed from \$46,948 to the correct amount after being initially flagged by staff as incorrect during the April 11 meeting.

Board Business

APCD Data Validation Discussion: Cosentyx

Affordability Review Annual Utilization & Expenditures				
	2019	2020	2021	2022
Patient Count	727	956	1149	1128
Total Paid	\$29,831,351	\$43,762,979	\$51,499,809	\$52,957,875
Average Paid per Person	\$41,033	\$45,777	\$44,821	\$46,948
Total Patient Paid	\$903,303	\$1,442,560	\$2,721,858	\$2,197,945
Average OOP	\$2,113	\$3,024	\$4,048	\$3,297

Tables 11 (top) shows the 2022 Affordability Review Annual Utilization & Expenditures for Cosentyx. Table 12 (bottom) shows the 2022 Corrected Data for Cosentyx.

Corrected Annual Utilization & Expenditures				
	2019	2020	2021	2022
Patient Count	718	938	1,008	1,013
Total Paid	\$28,893,718	\$42,003,868	\$47,344,297	\$49,461,436
Average Paid per Person	\$40,242	\$44,780	\$46,969	\$48,827
Total Patient Paid	\$903,303	\$1,414,213	\$2,240,744	\$2,221,745
Average OOP	\$1,850	\$2,272	\$2,998	\$2,865

Board Business

APCD Data Validation Discussion: Cosentyx

Board Deliberation Cosentyx Next Steps

- What additional information does the Board need from staff for its next meeting?
- The Board may request that staff:
 - Add an addendum to the executive summary of Cosentyx's Affordability Review to include updated tables with corrected data; and
 - Update data to allow the Board to confirm Cosentyx's eligibility.

Board Business

APCD Data Validation Discussion

- *Enbrel Validated Data Presentation and Discussion*
- *Cosentyx Validated Data Presentation and Discussion*
- *Stelara Validated Data Presentation and Discussion*

Board Business

APCD Data Validation Discussion: Stelara

Stelara's 2022 Price & Cost per Person Statistics

Table 13 (left) shows the 2022 Affordability Review Price & Cost per Person Statistics for Stelara. Table 14 (right) shows the 2022 Corrected Data for Stelara.

2022 Affordability Review	
Price & Cost Statistic	Amount
Average WAC per Cost of Treatment	\$150k - \$160k
Average Paid per Person	\$150,176
APPY - Plan Paid	\$143,769
APPY - Out of Pocket	\$7,365

2022 Corrected Data	
Price & Cost Statistic	Amount
Average WAC per Cost of Treatment	\$140k - \$150k
Average Paid per Person	\$113,093
APPY - Plan Paid	\$107,026
APPY - Out of Pocket	\$5,008

Board Business

APCD Data Validation Discussion: Stelara

Affordability Review: Annual Utilization & Expenditures

	2019	2020	2021	2022
Patient Count	817	1007	1346	1606
Total Paid	\$59,729,276	\$101,876,203	\$199,079,735	\$247,968,382
Average Paid per Person	\$73,108	\$101,168	\$147,904	\$154,401
Total Patient Paid	\$1,081,845	\$2,272,199	\$4,191,826	\$7,320,547
Average OOP	\$2,273	\$4,254	\$5,407	\$7,365

Tables 15 (top) shows the 2022 Affordability Review Annual Utilization & Expenditures for Stelara. Table 16 (bottom) shows the 2022 Corrected Data for Stelara.

Corrected Annual Utilization & Expenditures

	2019	2020	2021	2022
Patient Count	792	970	1,272	1,512
Total Paid	\$58,971,557	\$89,332,327	\$138,332,014	\$177,136,125
Average Paid per Person	\$74,459	\$92,095	\$108,752	\$117,154
Total Patient Paid	\$1,082,904	\$2,274,472	\$4,123,617	\$6,182,939
Average OOP	\$1,642	\$2,834	\$3,768	\$5,008

Board Business

APCD Data Validation Discussion: Stelara

Board Deliberation Stelara Next Steps

- What additional information does the Board need from staff for its next meeting?
- The Board may request that staff:
 - Add an addendum to the executive summary of Stelara's Affordability Review to include updated tables with corrected data; and
 - Update data to allow the Board to confirm Stelara's eligibility.

Public Comment

- *Comments will be limited to 2 minutes per person or organization.*
- *Please sign up via the link in the chat.*
- *Please keep your comments civil. Personal attacks against Board members, Division staff, stakeholders, or other individuals will not be recognized.*

Break

The Board will resume the meeting after a 10 minute break.

Board Business

APCD Data Validation Discussion: Future Action

How can this data issue be mitigated in the future?

- CIVHC's data intake and validation team is working to determine how to identify and alleviate similar errors in the future.
- CIVHC goes through a rigorous, multi-step, data intake and validation process before incorporating claims into the data warehouse.
- Ongoing collaboration across CIVHC and the Department Health Care Policy and Financing (HCPF) for enforcement.
- HCPF has statutory authority, on behalf of CIVHC, to fine entities for misreporting data to the APCD.

Board Business

- *Approve Revised PDAB Policy and Procedures: Policy No. 4 (Affordability Review)*
- *Stakeholder Workgroup Discussion*

Board Business

Affordability Review Policy Deliberation and Vote



Board Action Item

Board deliberates

Board may vote on whether to:

- Adopt proposed updates to Part 4 of the Affordability Review policy as presented
- Adopt proposed updates to Part 4 of the Affordability Review policy as amended

Board Business

Stakeholder Workgroup Discussion

PDAB Policy No.4: Affordability Reviews

“Prior to or while gathering input from specified stakeholders, the Board may direct Board staff to facilitate a public meeting or workgroup with members of PDAAC, RDAC, or other stakeholders, including organizations representing or advocating for patients affected by a condition or disease treated by the prescription drug, to identify best practices regarding: gathering sensitive patient experience information, requesting voluntary disclosures of conflicts of interest; and determining preferred methods to gather information.”

Public Comment

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- *Please keep your comments civil. Personal attacks against Board members, Division staff, stakeholders, or other individuals will not be recognized.*

Upcoming Meetings

PDAB Meeting: May 23 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.



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