COLORADO
Prescription Drug Affordability Board
Division of Insurance

Prescription Drug Affordability Board - Board Staff Memo

To: Members of the Colorado Prescription Drug Affordability Board
From: Prescription Drug Affordability Board Staff
Date: November 22, 2024
Title: Upper Payment Limit Benchmarks - Cost & Price Metrics and Data Details

Memorandum Purpose: This document is meant to provide the Prescription Drug Affordability Board (PDAB) with an overview of the data that Board staff will gather for the upper payment limit (UPL) rulemaking process that the Board may use to establish a UPL for Enbrel, Cosentyx, and Stelara.

Background

Colorado's Prescription Drug Affordability Board (PDAB), established under Senate Bill 21-175, is a Type-1 Board within the Division of Insurance that has the authority to review prescription drug costs, perform affordability reviews on selected prescription drugs, and establish upper payment limits on drugs the PDAB deems unaffordable for Colorado consumers. The Board may establish upper payment limits using the rulemaking process.

Between 2023 and 2024, the Board completed five affordability reviews and determined that Enbrel, Cosentyx, and Stelara are unaffordable for Colorado consumers and are eligible for UPLs. The Board will hold separate rulemaking hearings for each of the three drugs to gather information from stakeholders and analyze data. Information and data provided by stakeholders and prepared by staff will be submitted to the Board as part of the rulemaking record for each drug.

For the purposes of establishing a UPL, Board staff will prepare information outlined in sections 10-16-1407(2)-(4), C.R.S., PDAB Rule, 3 CCR 702-9, Part 4.1.C and 4.1.D, and PDAB Policy 05. The Board will receive the following information for each drug under review:

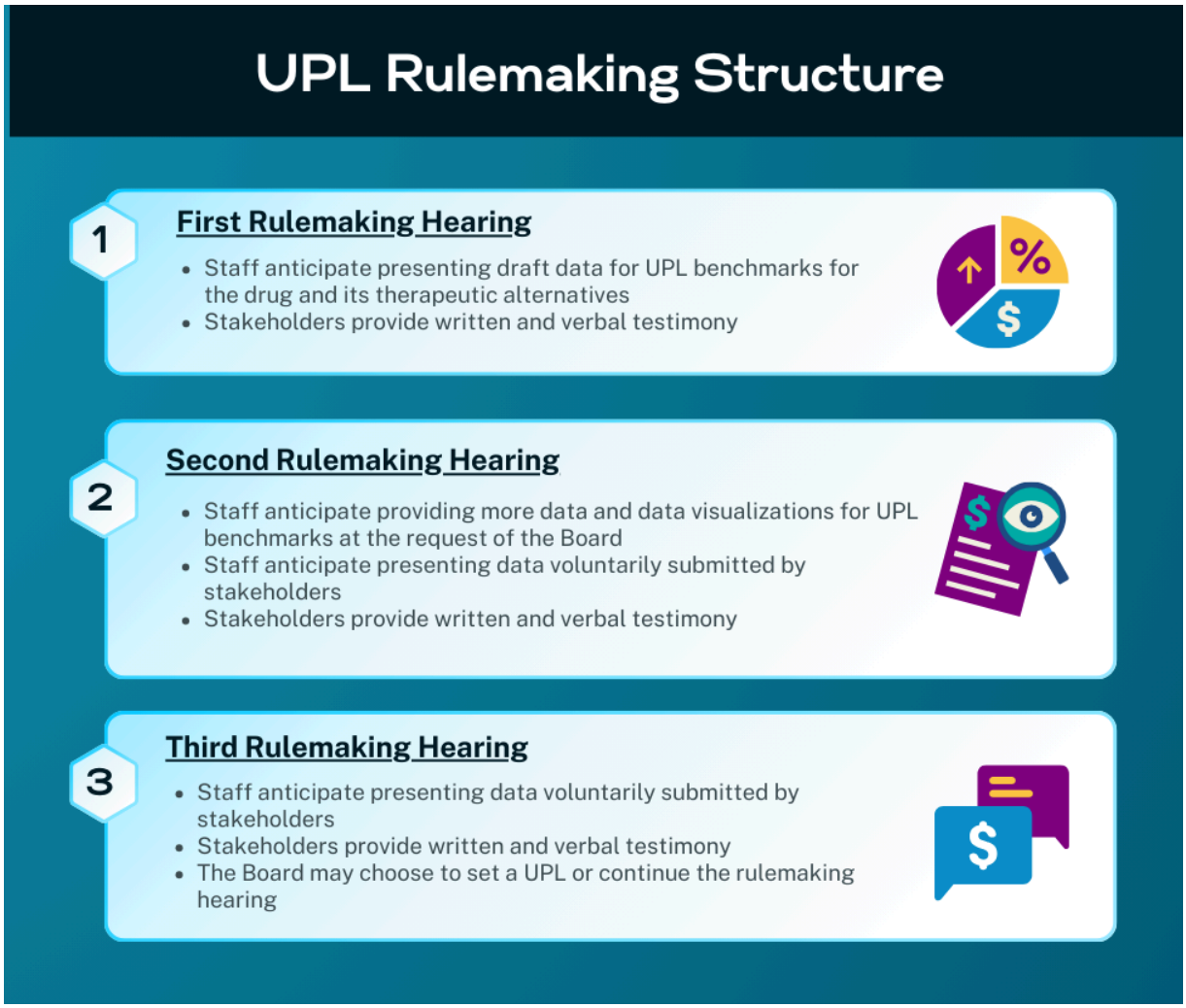
- Prescription Drug and Utilization Data: Background data for each drug, as well as utilization and demographic data;
- UPL Benchmark Data: Detailed data on each of the UPL benchmarks listed in rule and policy for each drug under review and each of the drug's identified therapeutic alternatives;
- Drug Shortage List Data: The drug's status on drug shortage lists;
- Older Adults and Individuals with Disabilities Data: The impact to older adults and individuals with disabilities; and
- Stakeholder Input: Voluntarily submitted information from stakeholders and written and verbal comment at rulemaking hearings.

Pursuant to section 10-16-1407(4)(b), C.R.S., a UPL established by the Board does not preclude a pharmacy from charging reasonable fees for dispensing or delivering a drug for which the Board has set a UPL. The Board will receive available, generalized data related to pharmacy dispensing fees and information voluntarily provided by stakeholders.

Finally, the Board is prohibited from considering research or information that employs a quality-adjusted-life-year (QALY) or similar measure when establishing a UPL pursuant to section 10-16-1407(4)(a), C.R.S. Board staff will take steps to ensure that QALY's or similar measures are not included in the Board's UPL decisionmaking.

UPL Rulemaking

The Board has indicated that it plans to hold at least three rulemaking hearings for each prescription drug for which it is considering setting a UPL. At a high level, the three rulemaking hearings could be structured in the following manner:



Note that while this is the current proposed structure for UPL rulemaking hearings, rulemaking hearings will proceed in the manner and form the Board directs and will adhere to the rulemaking hearing standards outlined in the Administrative Procedure Act. For more information regarding how to engage in the Board's rulemaking process, see the Rulemaking Guide folder.

UPL Data Information

Information regarding the four categories of data the staff will prepare for the Board's consideration during the UPL rulemaking process is outlined in this section, as well as information regarding general data considerations and limitations.

Prescription Drug and Utilization Data

Staff will provide information that gives background and context unique to each prescription drug. Information may include national drug codes (NDCs) associated with the prescription drug, FDA-approval dates, FDA-approved indications, and similar information for therapeutic alternatives. Utilization data may include demographic information and utilization by indication for the prescription drug under review. Demographic data may include age, gender, geographic location, and the number of individuals with at least one claim with a diagnosis code for the indications treated by the drug, and the number of utilizers of each drug.

Prescription drug and utilization data may be pulled from the prescription drug's affordability review, as well as relevant databases like the FDA website and APCD.

UPL Benchmark Data[1]

The following information will be provided for each of the ten benchmarks outlined in Rule Part 4 and Policy 05:

Description: A definition of each benchmark and any additional contextual information.

Method of Calculation: How the benchmark is calculated.

Includes Rebates & Discounts: Whether the benchmark amount includes estimated rebates or discounts.

Data Source & Access: The data source(s) staff will use to access the benchmark, and whether the information is public or proprietary.

Data Availability: Whether the benchmark is available for Cosentyx, Stelara, and Enbrel. An explanation will be provided if data on the UPL benchmark is not available for a drug.

During UPL rulemaking, the Board will receive available benchmark data for the prescription drug under consideration as well as identified therapeutic alternatives. Data considerations and limitations exist for each of these metrics, including the types of drugs to which such benchmarks apply, the entity calculating the benchmark, and the accessibility of the benchmark.

Average Sale Price (ASP)

Description: ASP reflects the weighted average of the manufacturer's sales of clinician-administered drugs . ASP is generally used to reimburse physician-administered drugs that are covered under Medicare Part B. The ASP is not generally available or used for prescription drugs filled at a pharmacy and does not impact the amounts paid by patients or insurers in the pharmacy benefit. ASP is defined in federal law [42 CFR § 414.904].

Method of Calculation: ASP is calculated using data from a manufacturer's sales reports, including details on total units sold and overall revenue earned from each drug. Manufacturers must calculate their ASP every calendar quarter and submit it to CMS.

Includes Rebates & Discounts: Yes.

Data Source and Access: Publicly reported by the Center for Medicare and Medicaid Services (CMS).

[1] Benchmarks refer to price and cost metrics referred to in the rule and policy. Price vs cost: what different entities on the prescription drug supply chain charge for a drug, as well as what different entities pay for a drug.

Data availability:

- Enbrel: Enbrel is not a physician-administered drug and does not have an ASP estimate.
- Stelara: ASP estimates are only available for the loading dose of Stelara, as that first dose is physician-administered. Therefore, the ASP estimate will be limited in its applicability.
- Cosentyx: Cosentyx has recently been approved for additional indications that have a physician-administered dose of the drug. Staff will include the ASP estimates for Cosentyx for these indications, however, there may not be accompanying claims data for this utilization because of its more recent FDA approval date.

Carrier Paid Amounts

Description: The dollar amount reflecting how much a carrier paid for the drug.

Method of Calculation: Board staff will provide totals, ranges, and averages of carrier paid amounts including information regarding the variation across different payers in the commercial market.

Includes Rebates & Discounts: No.

Data Source and Access: Colorado All Payer Claims Database (APCD) data from January 2019 through December 2023, with incomplete claims through July 2024.

Data availability:

- Enbrel: Carrier paid amounts are available in the APCD, considering data limitations[2].
- Stelara: Carrier paid amounts are available in the APCD, considering data limitations.
- Cosentyx: Carrier paid amounts are available in the APCD, considering data limitations.

Cost Information Voluntarily Provided By A Wholesaler, Pharmacist, Or Provider

Description: Information voluntarily submitted by members in the supply chain such as wholesalers, pharmacists, or providers.

Method of Calculation: Voluntarily provided.

Includes Rebates & Discounts: Unknown.

Data Source and Access: Voluntary submitted information from wholesalers, pharmacists, and providers. Potentially confidential.

Data availability:

- Enbrel: Data availability is determined based on whether any stakeholder submits voluntary data.
- Stelara: Data availability is determined based on whether any stakeholder submits voluntary data
- Cosentyx: Data availability is determined based on whether any stakeholder submits voluntary data

Public Health Care Program Fee Schedules

Description: A fee schedule is a full list of the prices a provider will pay for services.

Method of Calculation: Different state and federal agencies set fee schedules based on statute, preferred drug list status, or negotiations.

Includes Rebates & Discounts: Dependent on which fee schedule.

Data Source and Access: Publicly reported by state and federal agencies.

[2] Please refer to the Data limitation consideration after UPL Benchmarks.

Data availability:

- Enbrel: Data is available.
- Stelara: Data is available.
- Cosentyx: Data is available.

Medicare's Maximum Fair Price (MFP)

Description: MFP is the highest price that a Medicare beneficiary or plan sponsor can reimburse for a selected prescription drug. It is the outcome of negotiations between the manufacturer and CMS. Negotiations apply to 10 Part D drugs in 2026 and will expand to include Part B drugs. MFP is defined in 42 U.S.C. § 1320f(c)(3).[3]

Method of Calculation: CMS negotiates prices with manufacturers for selected Part D drugs. A ceiling for the MFP is set at the lower of (1) the price paid by Part D plans (net of price concessions) or (2) a percent of the drug's non-federal average manufacturer price (non-FAMP)[4]. CMS will determine its initial offer for a drug's MFP by analyzing data related to the net price and clinical benefits of therapeutic alternatives, research and development costs, and other factors. CMS can make further adjustments to the offer price below the ceiling based on drug-specific data.

Includes Rebates & Discounts: No.

Data Source and Access: Most recent data publicly reported by the Center for Medicare and Medicaid Services (CMS).

Data availability:

- Enbrel: Data is available as Enbrel was negotiated as part of Medicare Drug Negotiation during 2024.
- Stelara: Data is available as Stelara was negotiated as part of Medicare Drug Negotiation during 2024.
- Cosentyx: Data is not available for Cosentyx as it was not part of Medicare Drug Negotiation.

National Average Drug Acquisition Cost (NADAC)

Description: A federally administered, voluntary survey that captures the average price pharmacies pay to acquire a drug from a wholesaler or manufacturer. NADAC includes only the discounts received by pharmacies at a drug's acquisition; it does not include subsequent off-invoice discounts or back-end rebates from manufacturers to wholesalers or pharmacies. NADAC often represents actual amounts paid within the supply chain. It is commonly used by Medicaid programs. NADAC is defined in [42 USC 1396r-8(f)].

Method of Calculation: A federally administered, voluntary survey.

Includes Rebates & Discounts: No.

Data Source and Access: Publicly reported by Medicaid, including equivalencies to other measures covering data from 2019 to 2024.

Data availability:

- Enbrel: Data is available.
- Stelara: Data is available.
- Cosentyx: Data is available.

[3] https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation
[4] The non-FAMP is a confidential price reported to the VA by manufacturers and reflects the average price wholesalers pay for drugs distributed to non-federal purchasers.

Net Price

Description: The dollar amount that the manufacturer earns after accounting for rebates and discounts across the supply chain.

Method of Calculation: SSR Health confidential and proprietary methodology for calculating the gross and net sales of a brand name drug in the United States.

Includes Rebates & Discounts: Yes. SSR Health estimates rebates and price concessions including 340B discounts.

Data Source and Access: Most recently available data from SSR Health, including any changes since the affordability review. Confidential: may only be disclosed through secure channels and may only be discussed by the Board in Executive Session.

Data availability:

- Enbrel: Data is available considering data confidentiality
- Stelara: Data is available considering data confidentiality
- Cosentyx: Data is available considering data confidentiality

Out-of-Pocket Spending

Description: Prescription drug costs paid by patients after the amount covered by insurance. Out-of-pocket costs include coinsurance, copayments, and deductibles.

Method of Calculation: Board staff will provide totals, ranges, and averages of out-of-pocket spending amounts; including information regarding the variation across different payers in the commercial market and details about coinsurance, copays, and deductible spending.

Includes Rebates & Discounts: No.

Data Source and Access: APCD data from January 2019 through December 2023, with incomplete claims through to July 2024.

Data availability:

- Enbrel: Out-of-pocket data are available in the APCD, considering data limitations
- Stelara: Out-of-pocket data are available in the APCD, considering data limitations
- Cosentyx: Out-of-pocket data are available in the APCD, considering data limitations

Retail Discount Amounts

Description: A dollar amount or percent discount amount patients may receive from a retail pharmacy when using discount cards or coupons.

Method of Calculation: Board staff will provide information from different prescription drug discount programs which may include Pharmacy Checker, GoodRx, America's Pharmacy, Rx Outreach, and/or Colorado Drug Card.

Includes Rebates & Discounts: No

Data Source and Access: Publicly reported by discount program.

Data availability:

- Enbrel: Data is available to the extent practicable variations in price and discount amounts will be included.

- Stelara: Data is available to the extent practicable variations in price and discount amounts will be included.
- Cosentyx: Data is available to the extent practicable variations in price and discount amounts will be included.

Wholesale Acquisition Cost (WAC)

Description: WAC is the list price that manufacturers make available to wholesalers or direct purchasers.

Method of Calculation: WAC is set by the manufacturer. Board staff obtains this information via a third-party vendor or contractor.

Includes Rebates & Discounts: No.

Data Source and Access: Most recently available data from First Databank/Analysource, including any changes since the affordability review. Confidential: may only be disclosed through secure channels and may only be discussed by the Board in Executive Session.

Data availability:

- Enbrel: Data is available
- Stelara: Data is available
- Cosentyx: Data is available

Data Considerations and Limitations

Confidential, Proprietary, and Trade-Secret Information: Net price and WAC benchmarks are proprietary and will not be made public. Discussion of these benchmarks with Board staff will occur in executive session.[5]

Additionally, any information voluntarily submitted by wholesalers, providers, or pharmacists that is marked as proprietary, confidential, or trade secret will be considered by the Board in executive session. This includes Board deliberation of the voluntarily submitted information and/or the Board asking questions of the individual or group who submitted the information.

Colorado All Payer Claims Database (APCD): When reviewing data from the APCD, it is important to remember some considerations and limitations:

- The APCD receives claims from Medicaid, Medicare Advantage, and over 40 commercial payers, representing approximately 4.5 million lives and over 75% of insured Coloradans. The APCD does not have claims data for uninsured Coloradans and some commercial payers.
- As the APCD does not include claims for all Coloradans, it is a conservative estimate, where utilizers, claims, and associated paid amounts are under-represented.
- Annual estimates of utilization are also likely under-represented as individuals change insurance and move and their entire year of utilization may not be captured in the APCD claims.
- Under federal and state privacy laws, information about drugs with fewer than 12 utilizers in the database must be protected, as it is potentially identifiable at such low numbers. Where utilization is below 12 individuals there will be less information available.
- Pharmacy claims do not include diagnosis codes. As such, utilization and paid amount data will be provided for each of the three drugs, and not by indication.

[5] *See* § 10-16-1404(3).

Drug Shortage List

Staff will prepare information regarding a drug's status on the Drug Shortage List as reported by the Food and Drug Administration (FDA) and the American Society for Health System Pharmacists (ASHP). Prior to a drug's first UPL rulemaking hearing, Board staff will regularly review the drug shortage lists to identify if the drug and/or its therapeutic alternatives has appeared on the list. During each UPL rulemaking hearing, Staff will report whether the prescription drug is on a drug shortage list as of that week. On the day the Board adopts a UPL, the Board may consider whether the prescription drug is listed on a drug shortage list if the drug is subject to a resolved or discontinued shortage. If the drug is listed on the Drug Shortage List, the Board will receive information regarding the availability and estimated shortage duration, reason for the shortage, and other related information.

Impact to Older Adults and Persons with Disabilities

Staff will prepare the following information for older adults and persons with disabilities for the Board to consider during UPL rulemaking.

Impact to Older Adults

Older adults are defined in the PDAB Policy 05 as individuals aged 65 and older.

Board staff will present APCD data regarding utilization and payment amounts for older adults. Board staff will also compile stakeholder input related to a drug's impact on older adults, including input on the specific drug and/or the indications the drug treats.

Impact to Persons with Disabilities

The Americans with Disabilities Act defines a person with a disability as a "person who has a physical or mental impairment that substantially limits one or more major life activities, a person who has a history or record of such an impairment, or a person who is perceived by others as having such an impairment".[6] Staff will provide data regarding whether the Social Security Administration lists any of the conditions or diseases which the drug is indicated to treat as a condition or disease that could be considered a disability.[7]

Whether a condition is considered a disability can depend on severity of the disease, how long someone has had the condition,and other factors that might only be identified through the lived experience of an individual diagnosed with the condition. While Board staff may provide therapeutic classification, demographic, utilization, and payment data from the APCD for the Board to consider, staff do not plan to make a proactive determination regarding if a prescription drug treats a disability. Staff recommend the Board review stakeholder input regarding whether the prescription drug impacts individuals with a disability.

Stakeholder Input

Stakeholders can submit written and verbal testimony and quantitative data to the Board as part of the rulemaking record for each drug. Information should be relevant to any of the considerations that the Board may take into account in establishing a UPL, pursuant to Rule 3 CCR 702-9, Part 4.1.C.2.f. Per Policy 05, stakeholders are encouraged to disclose affiliations and experiences with the drug. Stakeholders will be required to identify if the data they are submitting includes QALYs or other similar measures before they submit their input. Board staff have provided a Data Submission Guide to assist stakeholders with the submission of written testimony and quantitative data.

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[6] https://www.ada.gov/resources/disability-rights-guide/#:~:text=An%20individual%20with%20a%20disability%20is%20defined%20by%20the%20ADA,as%20having%20such%20an%20impairment

[7] https://www.ssa.gov/disability/professionals/bluebook/AdultListings.htm

Reasonable Pharmacy Fees

Any UPL established by the Board does not preclude a pharmacy from charging reasonable fees for dispensing or delivering a drug.[8] Staff may provide the Board with any pharmacy fee information that is voluntarily submitted by stakeholders, as well as pharmacy dispensing fee data from the APCD.

Research and Methods that Employ a Dollars-per-QALY

To ensure the Board does not consider research or methods that use a QALY or similar measure, Board staff and contractors will review data and information submitted to the Board for QALY usage. Additionally, stakeholders submitting information for the Board's consideration will be asked to attest that either:

- The data or research submitted does not use a QALY or similar measure, or
- Identify that the data or research submitted uses a QALY so that Board staff may remove it from the Board's consideration.

[8] 10-16-1407(4)(b), C.R.S.