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An Overview of Cost Reviews: Minnesota PDAB

July 23, 2024

Program On Regulation, Therapeutics, And Law (PORTAL)
Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine
Brigham and Women's Hospital and Harvard Medical School

HARVARD MEDICAL SCHOOL

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Disclosures

- PORTAL does not receive any funding from pharmaceutical or medical device companies.
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Outline

1. About PORTAL
2. PDAB Process Overview
3. Identifying & Selecting Drugs for Cost Review
4. Defining Affordability

Section 1.

About PORTAL

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About PORTAL

The **Program On Regulation, Therapeutics, And Law (PORTAL)** is an interdisciplinary research group based in the **Division of Pharmacoepidemiology & Pharmacoeconomics** at Brigham & Women's Hospital and Harvard Medical School.

We study the intersections between **evidence-based use, regulation, and affordability of prescription medications**, and publish on a variety of topics in these areas.

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PORTAL Involvement with PDABs

National Academy for State Health Policy	Colorado PDAB	Oregon PDAB	Washington PDAB
• Prepare **white papers and memos** on PDAB processes and the prescription drug supply chain. • Provide **technical assistance** relevant to the cohort of state PDABs. • Work with NASHP on **PDAB implementation** and legislative developments.	• Support **methodology development** for the first affordability reviews, including identifying therapeutic alternatives. • Participated in **educational series** for Board members • Provide **guidance and data support** as Colorado begins upper payment limit deliberations.	• Provide **technical guidance** for individual affordability reviews, including strategies for presenting data. • Conduct **literature reviews** to support the development of sections of affordability reviews • Support staff in preparing **annual reports** required under statute.	• Provide **technical guidance and feedback** on drug identification and eligibility methodologies • Deliver **presentations** to highlight the PDAB process and Board considerations for the affordability review process

Section 2.

PDAB Process Overview

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Minnesota PDAB – Process Overview

Based on statutory criteria or drugs "that may impose costs that create significant affordability challenges for the state health care system or for patients."

Minn. Stat. 62J.90.2

"The board may initiate a cost review of a prescription drug product identified by the board" and "consider requests from the public" to proceed with a review.

Minn. Stat. 62J.90.3

The board will determine whether use of the drug "has led or will lead to affordability challenges for the state health care system or for patients."

Minn. Stat. 62J.91.1

If a drug is found to create an affordability challenge, the board shall establish an upper payment limit that "applies to all purchases of and payer reimbursements for [the drug that are] dispensed or administered to individuals in the state."

Minn. Stat. 62J.92.1

The Board is tasked with considering various criteria and data elements at each step in this process.

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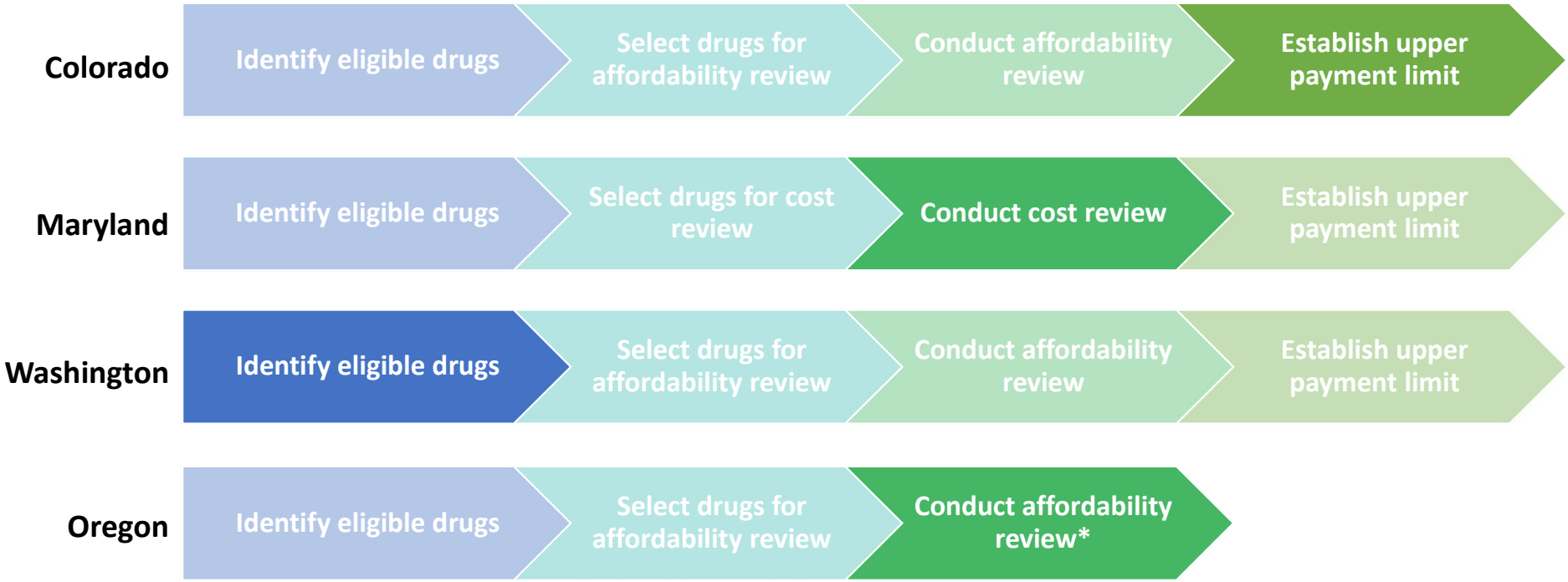
Progress of Other PDABs



*As of June 26, 2024, the Oregon PDAB voted to pause its affordability reviews for 2024.

Section 3.

Identifying & Selecting Drugs for Cost Review

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Minnesota PDAB – Process Overview

Identify eligible drugs	Select drugs for cost review	Conduct cost review	Establish upper payment limit
"The board, in consultation with the advisory council, shall identify selected prescription drug products" based on certain statutory criteria. **Minn. Stat. 62J.90.2**	"The board may initiate a cost review of a prescription drug product identified by the board" and "consider requests from the public" to proceed with a review. **Minn. Stat. 62J.90.3**	The board will determine "whether appropriate utilization of the [drug]…has led or will lead to affordability challenges for the state health care system or for patients." Minn. Stat. 62J.91.1	If a drug is found to create an affordability challenge, the board shall establish an upper payment limit that "applies to all purchases of and payer reimbursements for [the drug that are] dispensed or administered to individuals in the state." Minn. Stat. 62J.92.1

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Eligibility Criteria

The Board must identify prescription drugs that meet one of the following thresholds:

Branded Drugs & Biologics	Generics	Biosimilars
• WAC $60k+ per year or course of treatment; **OR** • Price increase >15% or >$3k in any 12-month period or course of treatment	• WAC of $100+ for a 30-day supply or course of treatment; **AND** • Price increase of ≥ 200% in the preceding 12 months	• WAC not at least 20% lower than the reference biologic WAC at the time of biosimilar launch

The Board may also identify drugs beyond these thresholds that may pose affordability challenges, in consultation with the advisory council and commissioner of health.

Minn. Stat. 62J.90.2

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Eligibility: Branded Drugs & Biologics

WAC $60k+ per year or course of treatment; OR

Price increase >15% or >$3k in any 12-month period or course of treatment

Brand-name drugs and biologics are likely to represent most drugs eligible for cost review.

Branded drugs account for **~10% of prescriptions** in the US but **~90% of spending**.

In general, US list prices of brand-name drugs are **4x higher than those in comparable high-income countries.** (3x higher when accounting for rebates/discounts)

Minn. Stat. 62J.90.2; Mulcahy et al. RAND. 2024.; IQVIA, Use of Medicines in the US. 2021.

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Eligibility: Branded Drugs & Biologics

In 2021, the median list price (WAC) for newly marketed drugs was **$180k per year**.

- From 2008-2021, launch prices increased by 20%/year

Annual increases in drug list prices have slowed in recent years.

- Median increase of ~5%/year from 2019-2024

However, **the gap between list and net price continues to widen**. This has implications for patient OOP costs, which are derived from drug list prices, not the post-rebate net price.

46brooklyn. Brand Drug List Price Change Box Score. March 2024; Rome et al. JAMA. 2022

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Eligibility: Generic Drugs

WAC of $100+ for a 30-day supply or course of treatment with a **price increase of ≥ 200%** in the preceding 12 months

Most generic drugs cost <$100 per 30-day supply, and price increases >200% are uncommon (<5%).

Generic price spikes are more common among **sterile injectables and drugs with 3 or fewer manufacturers**.

Generic drugs in **shortage** are twice as likely to experience price increases.

Minn. Stat. 62J.90.2; Patel, Kesselheim, Rome. *Health Affairs.* 2021; Trujillo et al. *Health Economics Review*. 2022; Hernandez et al. *Annals of Internal Medicine.* 2018

Eligibility: Biosimilars

WAC not at least 20% lower than the reference biologic WAC at the time of biosimilar launch

The biosimilar market is just emerging. As of June 2024, 39 biosimilars were approved and marketed in the US for 10 reference biologics.

- 8 additional biologics have FDA-approved biosimilars that are not yet marketed.

Concerns about biosimilar pricing strategy. In the case of Humira, some biosimilar makers set prices 5% less than the reference drug, offering rebates to compete for formulary position.

Minn. Stat. 62J.90.2; Samsung Bioepis. Biosimilar Market Report. 2024. Rome, Kesselheim. *Arthritis Rheumatol.* 2023

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Example: Eligible Drugs in Colorado

Colorado Eligibility Criteria	No. of Eligible Drugs (2023)
Branded drugs or biologics with WAC **≥$30k per year** or course of treatment*	582
Branded drugs or biologics with a WAC **increase of ≥10%** in the preceding 12 months*	9
Generic drugs with a WAC of ≥$100 and with a WAC increase of 200%+ in the preceding 12 months	0
Biosimilars with an initial WAC not at least 15% lower than the reference biologic*	13

*Colorado thresholds for brand-name prices and price increases differ from Minnesota.

Colorado Division of Insurance. CO PDAB 2023 Eligible Drug Dashboard. 2023

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Example: Eligible Drugs in Maryland

The Maryland PDAB did not publicly release a list of *all* drugs eligible for cost review, though Board staff reported a total of **2287 eligible NDCs** (across all criteria).

Statutory Eligibility Criteria	Additional Eligibility Criteria Established in Rule
Branded drugs or biologics with a launch WAC **≥$30k per year** or course of treatment	**Top 100 drugs with the highest:** • **Total gross spending** in the most recent year • **Total gross spending per patient** in the most recent year • **Percent WAC increase** in the most recent year or 5-year period • **Dollar increase in WAC per year or course of treatment** in the most recent year or 5-year period • **Percent increase in total gross spending** • **Total patient out-of-pocket costs** in the most recent year • **Average patient total out-of-pocket costs** in the most recent year
Branded drugs or biologics with WAC **increase of ≥$3k** in any 12-month period	
Generic drugs with a WAC of ≥$100 and a WAC increase of 200%+ in the preceding 12 months	**Top 100 drugs ranked** at the: • **50th percentile for patient total out-of-pocket costs** in the most recent year • **90th percentile for patient total out-of-pocket costs**
Biosimilars with an initial WAC not at least 15% lower than the reference biologic	

Md. Code Ann., Health-Gen. § 21-2C-08(c); COMAR 14.01.04.02; Maryland PDAB. Cost Review Study Process. March 25, 2024

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Selecting Drugs for Cost Review

Per statute, the Board may initiate a cost review on any drug identified from the previously described process. The Board can also consider **public requests** to move forward with a cost review.

The exact process for drug selection and the data elements considered during this stage will depend on Board priorities and available resources.

PDABs in other states have taken different paths to select drugs that may inform the Minnesota PDAB's methodology development.

Minn. Stat. 62J.90.3

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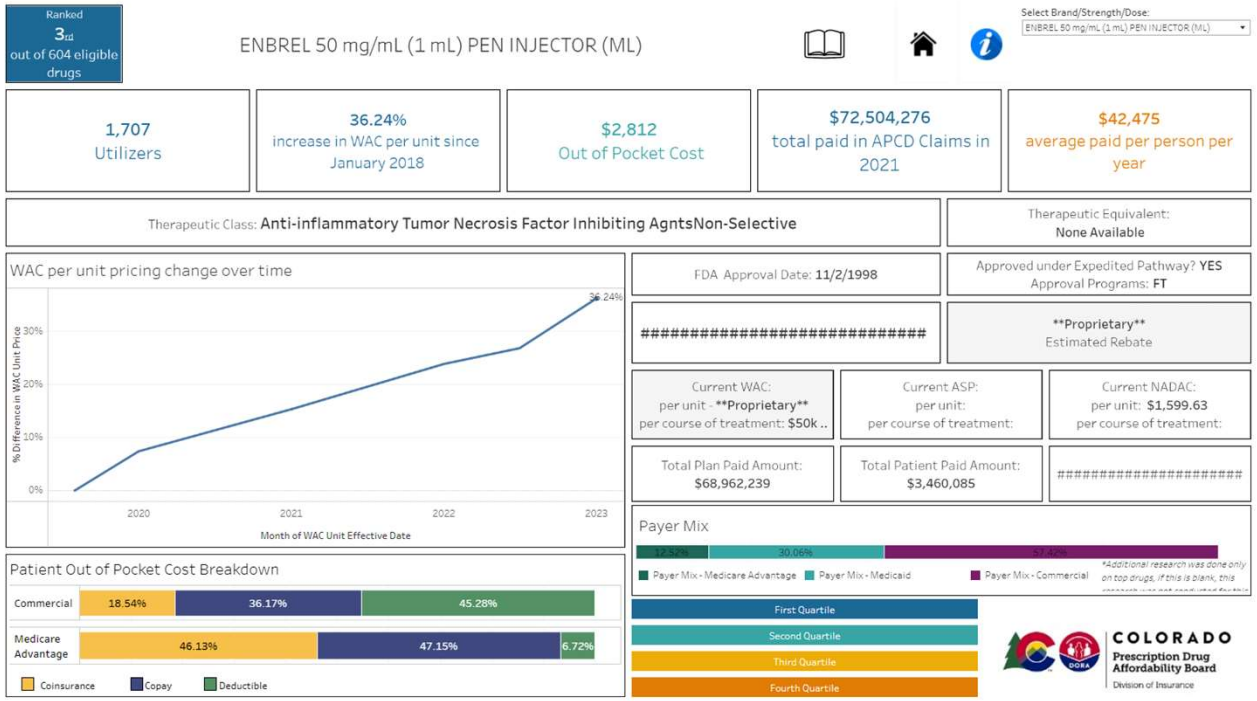
Drug Selection in Colorado

The Colorado PDAB considers patient **out-of-pocket costs, therapeutic class,** and **aggregated data on drug spending & utilization** to select drugs.

Data was presented to the Board in the form of a public dashboard, with individual profiles on each drug.



Colorado Division of Insurance. CO PDAB 2023 Eligible Drug Dashboard. 2023

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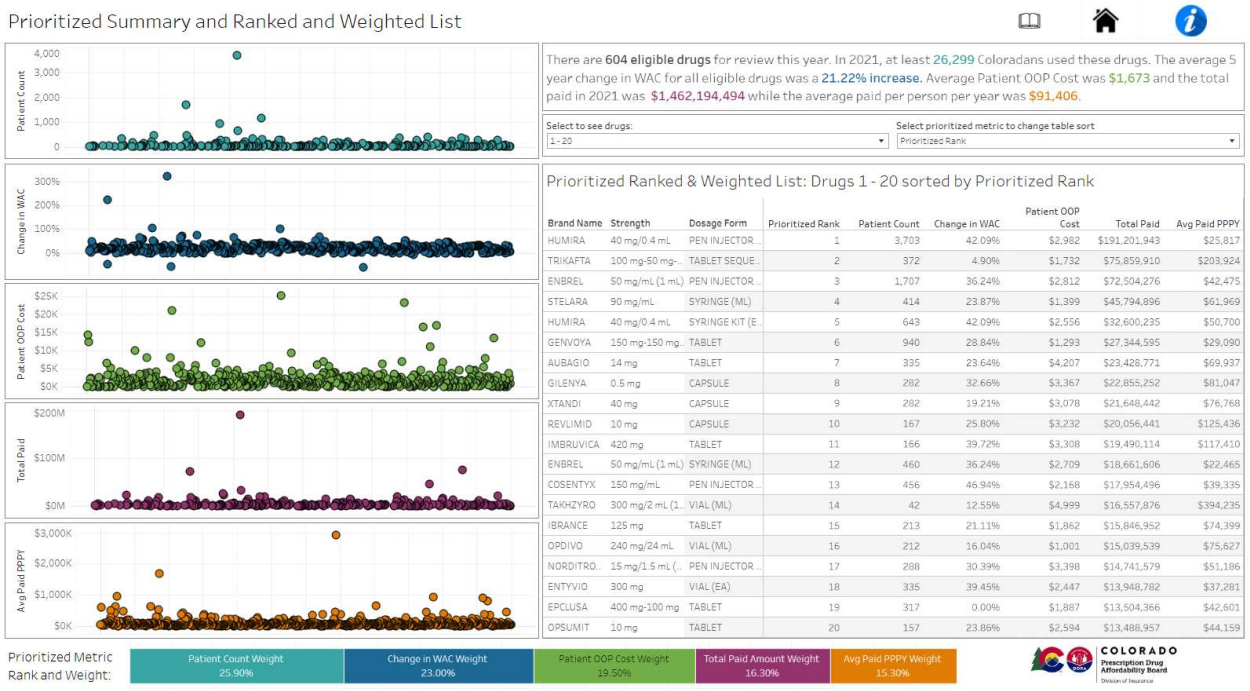
Drug Selection in Colorado

The Colorado PDAB **weighted selection criteria** through a guided prioritization exercise, resulting in a **prioritized drug list** that reflected the Board's priorities.

This prioritized list informed the Board's selection.



Colorado Division of Insurance. CO PDAB 2023 Eligible Drug Dashboard. 2023

Drug Selection in Maryland

The Maryland PDAB uses an **internal dashboard** with data on **each eligible drug's FDA approval and therapeutic class**; **spending and price**; **out-of-pocket costs**; and other factors.

Members of the public could also submit drugs for Board consideration.

Board members used this data to **individually propose drugs** for cost review consideration, forming a **preliminary list of drugs** as the baseline for full Board discussion.

Attachment A:
March 25, 2024 Preliminary Identification of Potential Drugs for Referral to the Stakeholder Council

Drug	Drug Name	Dose Strength	Dose Strength Unit of Measure
BIKTARVY	Biktarvy	50-200-25	MG
DUPIXENT	Dupixent	300	MG/2ML
	Dupixent	200	MG/1.14ML
FARXIGA	Farxiga	10	MG
	Farxiga	5	MG
JARDIANCE	Jardiance	25	MG
	Jardiance	10	MG
OZEMPIC	Ozempic (0.25 or 0.5 MG/DOSE)	2	MG/1.5ML
	Ozempic (1 MG/DOSE)	2	MG/1.5ML
	Ozempic (1 MG/DOSE)	4	MG/3ML
	Ozempic (2 MG/DOSE)	8	MG/3ML
SKYRIZI	Skyrizi	150	MG/ML
	Skyrizi (150 MG Dose)	75	MG/0.83ML
	Skyrizi Pen	150	MG/ML
TRULICITY	Trulicity	0.75	MG/0.5ML
	Trulicity	1.5	MG/0.5ML
	Trulicity	3	MG/0.5ML
	Trulicity	4.5	MG/0.5ML
VYVANSE	Vyvanse	70	MG
	Vyvanse	60	MG
	Vyvanse	50	MG
	Vyvanse	40	MG
	Vyvanse	30	MG
	Vyvanse	20	MG

Maryland PDAB. March 25, 2024 Meeting Agenda; Maryland PDAB. Cost Review Process Overview. 2024.

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Drug Selection in Maryland

The Board discussed the preliminary list of drugs, with Board members able to recommend adding or removing a given drug.

The refined list was **referred to the stakeholder council** and **public** for additional input.

With this stakeholder feedback, the Board finalized the **list of drugs to review.**

Farxiga (dapagliflozin)
Drug Brand Name: Farxiga
Active Moiety or Active Ingredient: dapagliflozin
Application Number: NDA202293
NDC 11s in the Cost Review Study Process

Jardiance (empagliflozin)
Drug Brand Name: Jardiance
Active Moiety or Active Ingredient: empagliflozin
Application Number: NDA204629
NDC 11s in the Cost Review Study Process

Ozempic (semaglutide)
Drug Brand Name: Ozempic
Active Moiety or Active Ingredient: semaglutide
Application Number: NDA209637
NDC 11s in the Cost Review Study Process

Trulicity (dulaglutide)
Drug Brand Name: Trulicity
Active Moiety or Active Ingredient: dulaglutide
Application Number: BLA125469
NDC 11s in the Cost Review Study Process

Dupixent (dupilumab)
Drug Brand Name: Dupixent
Active Moiety or Active Ingredient: dupilumab
Application Number: BLA761055
NDC 11s in the Cost Review Study Process

Skyrizi (risankizumab)
Drug Brand Name: Skyrizi
Active Moiety or Active Ingredient: risankizumab
Application Number: BLA761105
NDC 11s in the Cost Review Study Process

Maryland PDAB. Board Selected Drugs; Maryland PDAB. Cost Review Process Overview. 2024.

Section 4.

Defining Affordability

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Minnesota PDAB – Process Overview

"The board, in consultation with the advisory council, shall identify selected prescription drug products" based on certain statutory criteria.

Minn. Stat. 62J.90.2

"The board may initiate a cost review of a prescription drug product identified by the board" and "consider requests from the public" to proceed with a review.

Minn. Stat. 62J.90.3

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Minn. Stat. 62J.92.1

The Board is tasked with considering various criteria and data elements at each step in this process.

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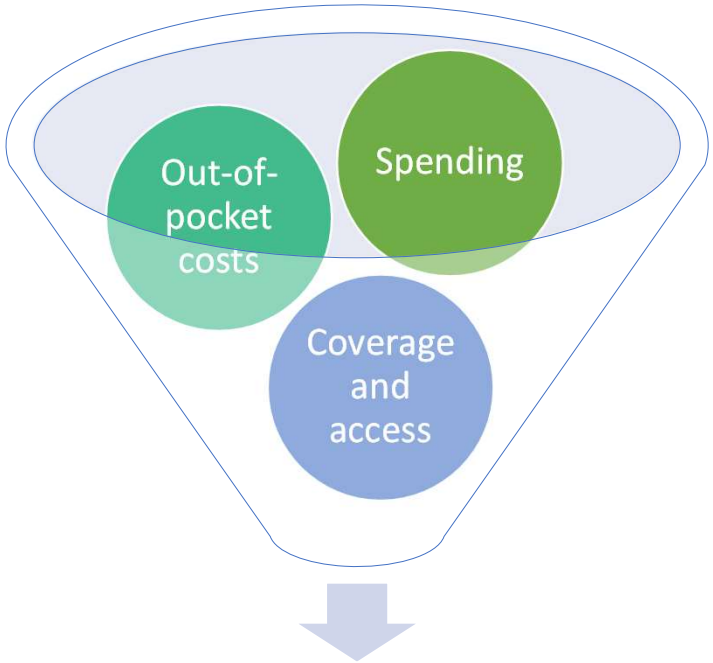
Cost Review Components

Once a drug is selected for cost review, **the Board can consider a broad set of factors and data elements**:

- **Drug price in the state**
- **Manufacturer rebates and discounts**
- **Manufacturer patient assistance programs**
- **Price of therapeutic alternatives**
- **Cost to group purchasers**
- **Patient access and cost-sharing**
- **Determination of "excessive" price increase (for generic drugs)**
- **Manufacturer-submitted information**
- **Other factors determined by the Board**

Minn. Stat. 62J.91.2

The Central PDAB Challenge



Does the drug create affordability challenges?

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Three Perspectives on Affordability

When conducting cost reviews, a drug's affordability can be considered from various perspectives:

Cost Relative to Therapeutic Alternatives

Out-of-Pocket Costs for Patients

Budgetary Impact on the State Health Care System

Considering <u>each</u> perspective (or others) during the review process can promote a more well-rounded view of each selected drug.

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Affordability Challenges for *Whom*?

"Patients"

- **Out-of-pocket costs** are borne by patients using the drug.
- High out-of-pocket costs are associated with lower medication adherence and poor clinical outcomes.
- Depends on drug price and **insurance plan design** (copayments, coinsurance, deductibles).

"The State Health Care System"

- Spending on prescription drugs is ultimately borne by **all consumers** via:
  - Health care premiums
  - Lower wages due to premiums paid by employers
  - Taxes for public insurance (state-sponsored, Medicaid, Medicare)

What if drug manufacturers offset out-of-pocket spending using **patient assistance programs and coupons?**

Cost Relative to Therapeutic Alternatives

- For some drugs, **the added clinical benefit provided may not align with its cost(s)** when compared to treatments indicated to treat the same disease/condition (i.e., **therapeutic alternatives**).

- **Requires separate analyses for drugs with multiple indications.**

Defining Therapeutic Alternatives

- "**Therapeutic alternative**" (TA) **does not mean treatments must be identical** in terms of safety, efficacy, or mode of delivery (e.g., injected vs. oral)
  - It also **does not mean the products are interchangeable** for individual patients.

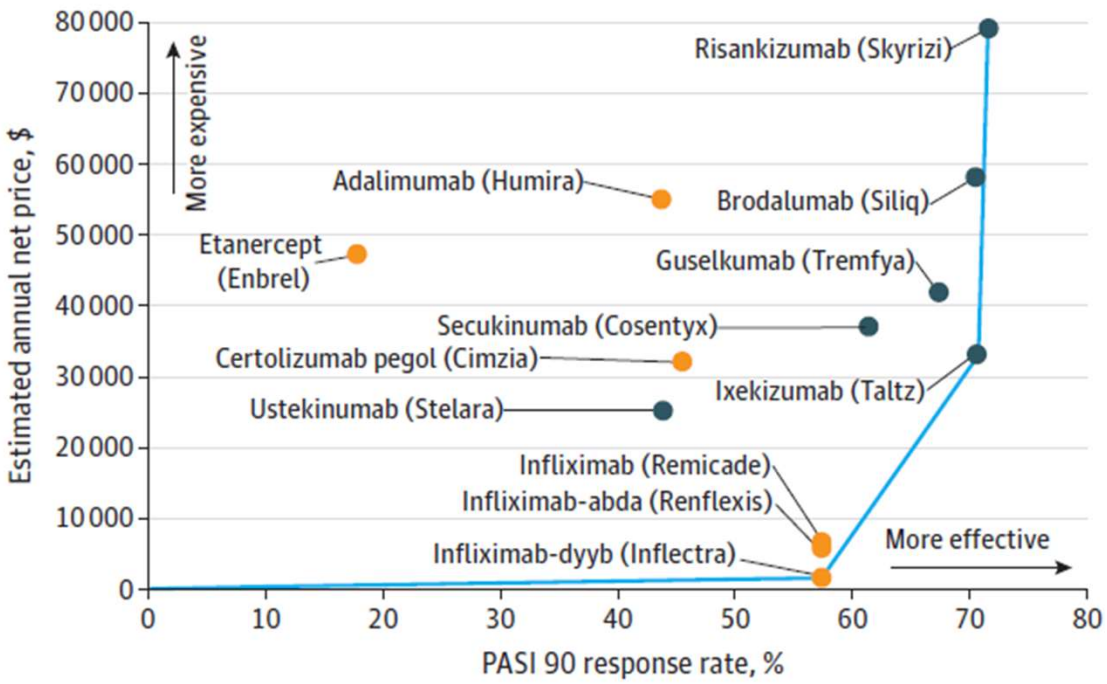
- How the Board defines therapeutic alternatives should be guided by how TAs will be used to inform the affordability review.
  - **Narrower definition**: Drugs within the same pharmacologic class
  - **Broader definition**: Drugs in different classes or non-pharmaceutical alternatives (e.g., devices, procedures)

Comparing Drugs to Therapeutic Alternatives

Analysis	Description	Data Sources
Comparative Effectiveness	Drugs' effectiveness, safety, and ease of use relative to those of the therapeutic alternatives.	Pre- and post-market clinical trials, comparative effectiveness trials, meta-analyses, real-world evidence, international health technology assessments, input from patients and experts
Economic Analysis	Measures the incremental costs and benefits, compared to the therapeutic alternative. *Examples: Cost-effectiveness analysis, efficiency frontier*	Published literature, Institute for Clinical and Economic Review (ICER), international health technology assessments

Example: Efficiency Frontier Comparing the Prices and Effectiveness of Psoriasis Biologics

Figure 1. Efficiency Frontier for Psoriasis Biologics in the US



Egilman et al. *JAMA Dermatology.* 2024.

Patient Out-of-Pocket Costs

- Some drugs may be clinically effective, yet **patients face significant financial barriers** to accessing the drug. This can have implications for medication adherence and clinical outcomes.

- **Information That Can Inform This Perspective:**
  - Out-of-pocket cost data from Minnesota All-Payer Claims Database
  - Insurance coverage (e.g., formulary inclusion, tier, utilization management)
  - How manufacturer rebates affect coinsurance and deductibles
  - Manufacturer assistance (e.g., copayment cards, patient assistance programs)

- **Important to consider health equity and to engage patient stakeholders to solicit feedback.**

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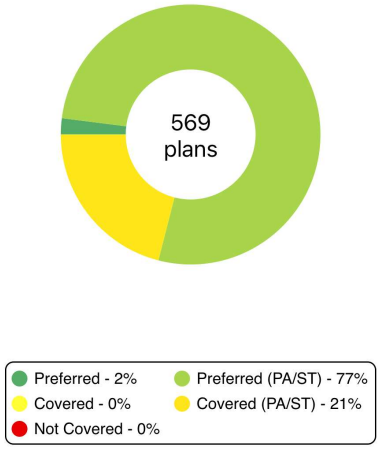
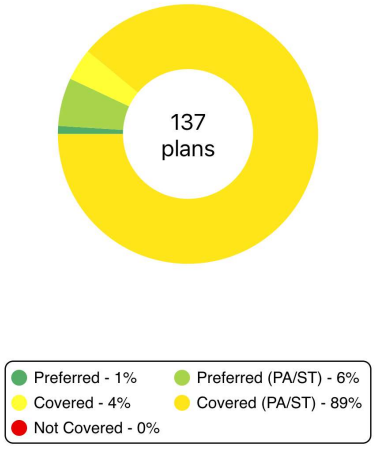
Insurance Coverage

When assessing the in-state insurance coverage for a selected drug, it is important to note that **differences may exist between commercial, Medicaid, and Medicare plans**.

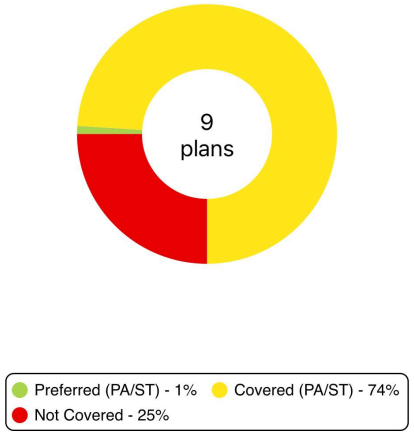
Stelara has Unrestricted Access for 2% of Commercial lives in Minnesota



Stelara has Unrestricted Access for 6% of Medicare lives in Minnesota



Stelara has Unrestricted Access for 0% of Health Exchange lives in Minnesota



Stelara has Unrestricted Access for 0% of Managed Medicaid lives in Minnesota

MMIT. Coverage Search

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Manufacturer Assistance

Copayment Cards

- Typically lower costs to <$30/month, but monthly and annual limits vary and can change year-to-year
- Only available to those with private insurance (not Medicare)
- No income/asset eligibility criteria

Patient Assistance Programs

- Strict financial eligibility criteria
- Lengthy and onerous application process
- More limited use than copayment cards

Budgetary Impact

Some drugs may be cost-effective at their current price, yet **this price still poses financial risks to the health care system**. This could impact insurance premiums for *all* patients and require other budgetary trade-offs.

Information That Can Inform This Perspective:

- Budget Impact Analysis
- State-Level Spending Estimates
- Input from Payers and PBMs
- Minnesota Rx Transparency Program "Drugs of Public Interest" Data

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Additional Considerations

Incorporating data to inform **each perspective** on affordability will be useful to ensure the affordability review process is robust to a variety of drugs.

The Board may need to balance **complex and, in some cases, contrasting information** to arrive at a conclusion about whether the drug may create affordability challenges.

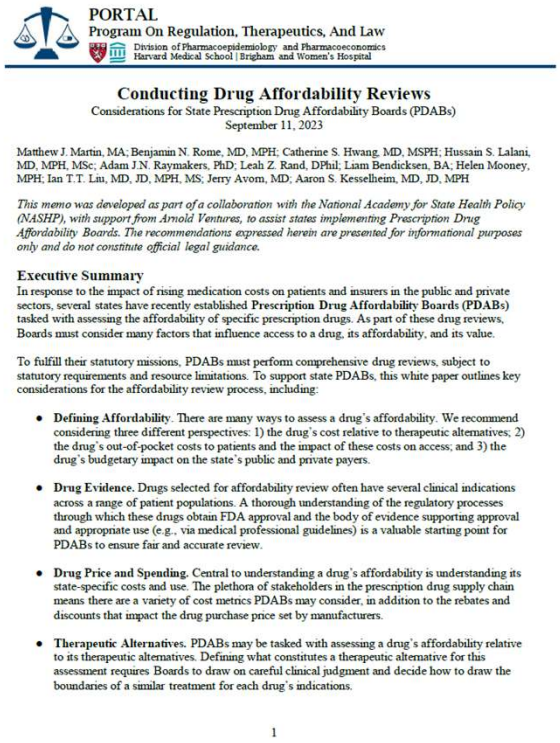
Cost Relative to Therapeutic Alternatives

Out-of-Pocket Costs for Patients

Budgetary Impact on the State Health Care System

Questions?

Additional information on cost reviews and other considerations for PDABs are available as white papers and memos in the **NASHP PDAB Toolkit:**



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Division of Pharmacoepidemiology and Pharmacoeconomics
Harvard Medical School | Brigham and Women's Hospital

Conducting Drug Affordability Reviews
Considerations for State Prescription Drug Affordability Boards (PDABs)
September 11, 2023

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This memo was developed as part of a collaboration with the National Academy for State Health Policy (NASHP), with support from Arnold Ventures, to assist states implementing Prescription Drug Affordability Boards. The recommendations expressed herein are presented for informational purposes only and do not constitute official legal guidance.

Executive Summary

In response to the impact of rising medication costs on patients and insurers in the public and private sectors, several states have recently established **Prescription Drug Affordability Boards (PDABs)** tasked with assessing the affordability of specific prescription drugs. As part of these drug reviews, Boards must consider many factors that influence access to a drug, its affordability, and its value.

To fulfill their statutory missions, PDABs must perform comprehensive drug reviews, subject to statutory requirements and resource limitations. To support state PDABs, this white paper outlines key considerations for the affordability review process, including:

- **Defining Affordability**. There are many ways to assess a drug's affordability. We recommend considering three different perspectives: 1) the drug's cost relative to therapeutic alternatives; 2) the drug's out-of-pocket costs to patients and the impact of these costs on access; and 3) the drug's budgetary impact on the state's public and private payers.
- **Drug Evidence.** Drugs selected for affordability review often have several clinical indications across a range of patient populations. A thorough understanding of the regulatory processes through which these drugs obtain FDA approval and the body of evidence supporting approval and appropriate use (e.g., via medical professional guidelines) is a valuable starting point for PDABs to ensure fair and accurate review.
- **Drug Price and Spending.** Central to understanding a drug's affordability is understanding its state-specific costs and use. The plethora of stakeholders in the prescription drug supply chain means there are a variety of cost metrics PDABs may consider, in addition to the rebates and discounts that impact the drug purchase price set by manufacturers.
- **Therapeutic Alternatives.** PDABs may be tasked with assessing a drug's affordability relative to its therapeutic alternatives. Defining what constitutes a therapeutic alternative for this assessment requires Boards to draw on careful clinical judgment and decide how to draw the boundaries of a similar treatment for each drug's indications.

1

NASHP. Prescription Drug Affordability Board Toolkit. April 2024.