PORTAL
Program on Regulation, Therapeutics, And Law

DoPE BWH

Considerations for Conducting Affordability Reviews

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Program On Regulation, Therapeutics, And Law (PORTAL)
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HARVARD MEDICAL SCHOOL

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Founding Member, Mass General Brigham

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  - Washington State Health Care Authority

Outline

1. PDAB Process Overview
2. Defining Affordability
3. Q&A

Section 1.

PDAB Process Overview

Washington PDAB – Process Overview

"By June 30, 2023, and annually thereafter…the board must identify prescription drugs" that meet certain statutory criteria.

RCW [70.405.030]

"The board may choose to conduct an affordability review of up to 24 prescription drugs per year identified pursuant to RCW 70.405.030."

RCW [70.405.40]

"For prescription drugs chosen for an affordability review, the board must determine whether the prescription drug has led or will lead to excess costs to patients."

RCW [70.405.40]

"Each year, the board may set an upper payment limit for up to 12 prescription drugs" that were found to have led or will lead to excess costs.

RCW [70.405.50]

Board's Current Focus

Washington PDAB – Looking Ahead

Identify eligible drugs

"By June 30, 2023, and annually thereafter…the board must identify prescription drugs" that meet certain statutory criteria.

RCW 70.405.030

Select drugs for affordability review

"The board may choose to conduct an affordability review of up to 24 prescription drugs per year identified pursuant to RCW 70.405.030."

RCW 70.405.40

Conduct affordability review

"For prescription drugs chosen for an affordability review, **the board must determine whether the prescription drug has led or will lead to excess costs to patients**."

RCW 70.405.40

Establish upper payment limit

"Each year, the board may set an upper payment limit for up to 12 prescription drugs" that were found to have led or will lead to excess costs.

RCW 70.405.50

Affordability Review Components

Once a drug is selected for affordability review, **the Board <u>will</u> consider a broader set of factors and data elements than those considered during selection**:

- **Price Factors (e.g., WAC, rebate information)**
- **Average out-of-pocket costs**
- **Effect of price on consumer access**
- **Manufacturer patient assistance programs**
- **Price & availability of therapeutic alternatives**
- **Input from patients**
- **Input from individuals with medical/scientific expertise**
- **Impact of PBM policies on consumer price**
- **Other information submitted by the manufacturer or other entity**

RCW 70.405.040; WAC 182-52-0045

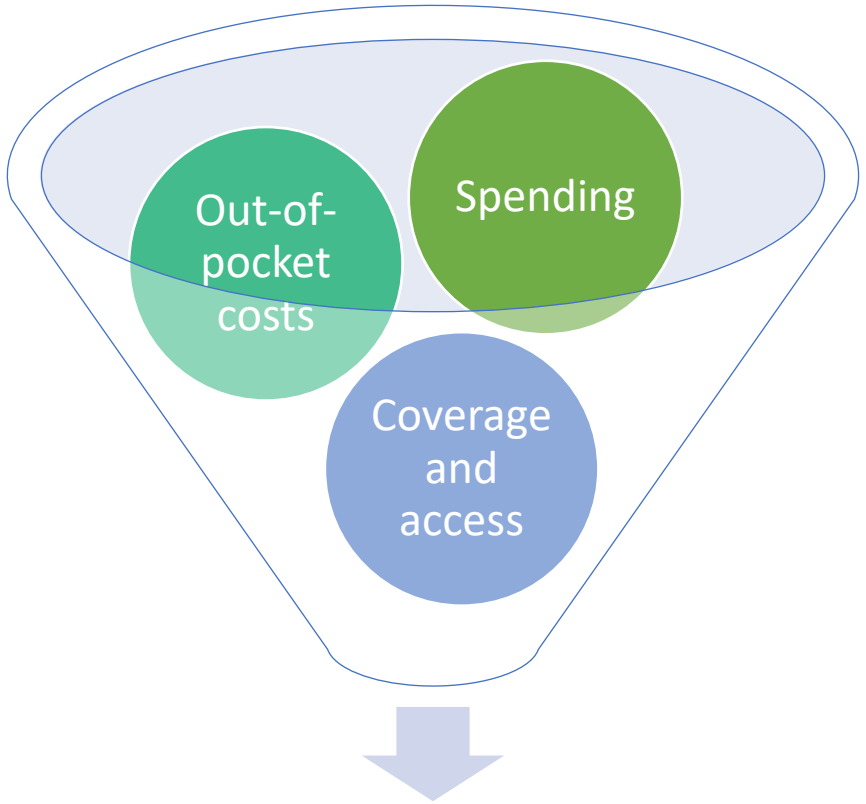
Affordability Review Components

In addition, **the Board <u>may</u> consider a variety of other factors during the affordability review**:

- **Life cycle management**
- **Average in-state cost of the drug**
- **Market competition & context**
- **Projected revenue**
- **Off-label use**
- **Any additional factors identified by the Board**

RCW 70.405.040; WAC 182-52-0045

The Central PDAB Challenge



Does the drug create excess costs to patients?

Section 2.

Defining Affordability

Defining "Excess Costs"

By statute, the Board is tasked with assessing **whether a drug has led or will lead to "excess costs to patients"** in the state.

"…**exceed the therapeutic benefit** relative to other alternative treatments"

"…are **not sustainable to public and private health care systems** over a 10-year time frame."

RCW 70.405.010

Three Perspectives on Affordability

When conducting 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.

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.

Price Factors
(e.g., WAC, rebate information)

Price & availability of therapeutic alternatives

Market competition & context

Input from individuals with medical/scientific expertise

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 A Drug To Its 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

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 all-payer claims
- 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.

Average out-of-pocket costs

Effect of price on consumer access

Manufacturer patient assistance programs

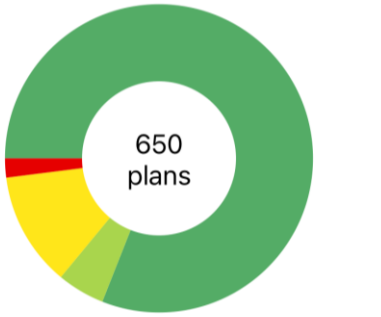
Impact of PBM policies on consumer price

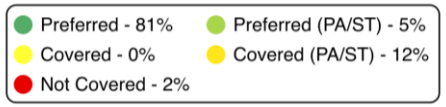
Input from patients

Insurance Coverage

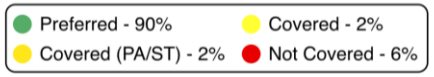
When assessing the in-state insurance coverage for a selected drug, it is important to note that **differences may exist between commercial, Medicaid, and Medicare plans**.

Eliquis has Unrestricted Access for 80% of Commercial lives in Washington

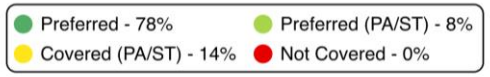




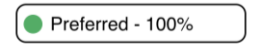
Eliquis has Unrestricted Access for 92% of Medicare lives in Washington



Eliquis has Unrestricted Access for 77% of Health Exchange lives in Washington



Eliquis has Unrestricted Access for 100% of Managed Medicaid lives in Washington



MMIT. Coverage Search

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

Other drugs may be cost-effective at their current price, yet **this price still poses financial risks to the broader 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

Price Factors
(e.g., WAC, rebate information)

Average in-state cost of the drug

Effect of price on consumer access

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 "creates excess costs to patients."

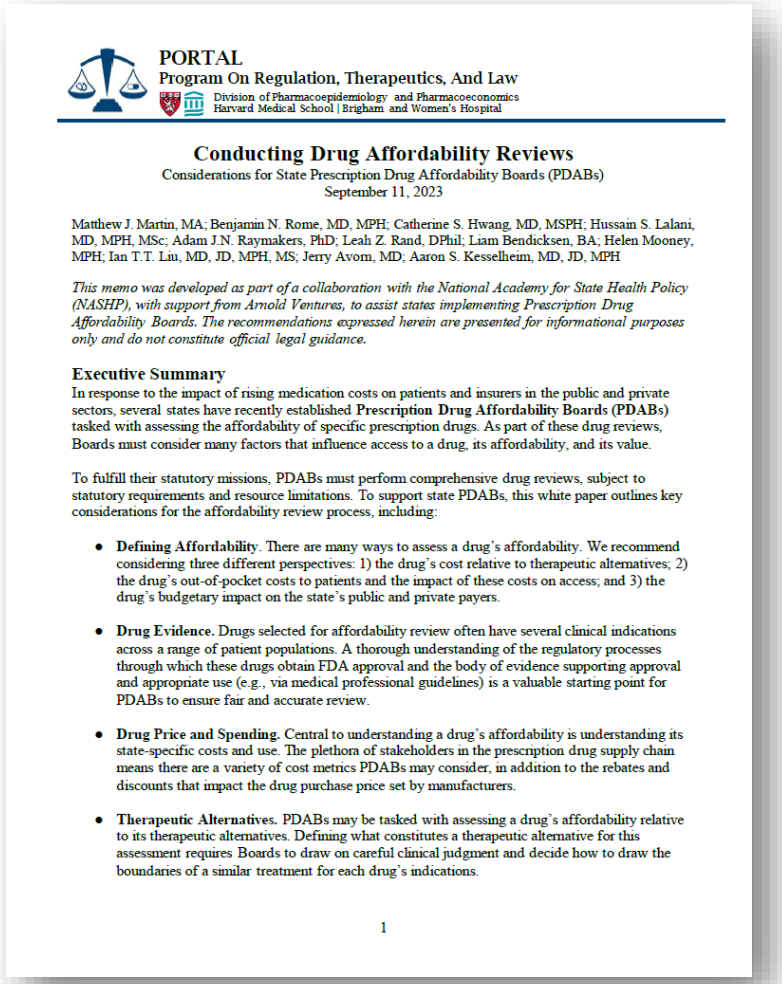
Cost Relative to Therapeutic Alternatives

Out-of-Pocket Costs for Patients

Budgetary Impact on the State Health Care System

Questions?

Additional information on the specific components that may make up an affordability review is available in our white paper, **Conducting Drug Affordability Reviews:**



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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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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.

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PORTAL. Conducting Drug Affordability Reviews. NASHP PDAB Toolkit. September 2023.