Methodology for Selecting Prescription Drugs for Affordability Review

Purpose

This policy establishes the methodology for how the Washington State Prescription Drug Affordability Board (PDAB) will:

- Select data measures for evaluating prescription drugs on the list prescription drugs eligible for affordability review;
- Review and utilize data measures to measure and rank prescription drugs; and
- Create criteria to nominate, vote, and approve prescription drugs for the affordability review.

Background

Staff prepared and presented to the Board a list of eligible prescription drugs that met the criteria set forth in section 70.405.030 RCW to be considered by the Board for an affordability review.

Section 70.405.030 RCW requires that the Board annually identify prescription drugs that have been on the market for at least seven years, are dispensed at a retail, specialty, or mail-order pharmacy, are not designated by the United States food and drug administration under 21 U.S.C. Sec. 360bb as a drug solely for the treatment of a rare disease or condition, and meet the following thresholds:

(1) Brand name prescription drugs and biologic products that:

(a) Have a wholesale acquisition cost of $60,000 or more per year or course of treatment lasting less than one year; or

(b) Have a price increase of 15 percent or more in any 12-month period or for a course of treatment lasting less than 12 months, or a 50 percent cumulative increase over three years;

(2) A biosimilar product with an initial wholesale acquisition cost that is not at least 15 percent lower than the reference biological product; and

(3) Generic drugs with a wholesale acquisition cost of $100 or more for a 30-day supply or less that has increased in price by 200 percent or more in the preceding 12 months. [2022 c 153 § 3.]

From the list of eligible prescription drugs, in accordance with section 70.405.040 RCW, the Board may select up to 24 prescription drugs for affordability review per year. In determining whether to conduct an affordability review for each identified prescription drug, the Board must consider:

- The class of the prescription drug and whether any therapeutically equivalent prescription drugs are available for sale;
- Input from relevant advisory groups established pursuant to RCW 70.405.020; and
- The average patient's out-of-pocket cost for the drug.

Choosing the Selection Criteria

In addition to considering the required selection criteria set forth in section 70.405.040 RCW, each board member met with PDAB staff and set forth additional selection criteria they thought as important when deciding whether to select a prescription drug for affordability review. The final 12 proposed and required selection criteria from 70.405.040 RCW were:

1. Total plan paid amount
2. Total out-of-pocket cost
3. Total paid amount
4. Average plan paid amount
5. Average out-of-pocket cost
6. Average paid amount
7. Patient liability proportion
8. Total number of people using the prescription drug
9. Therapeutic equivalent availability
10. Generic availability
11. If the drug meets multiple thresholds of the legislative definition
12. Input from the Washington State PDAB advisory group

Data Sources

Washington State All Payer Claims Database (WA-APCD)

The APCD is Washington State's most complete source of health and dental insurance data, representing about 70% of the state's population, or over 5 million people. All health carriers in Washington State are required to report their data to the APCD, as well as state Medicaid plans, public employee benefit plans (PEBB), school employee benefit plans (SEBB), third party administrators, and the Washington State labor and industries program. Self-insured plans submit data to the APCD on a voluntary basis.

First Databank (FDB) and Medi-Span

FDB and Medi-Span are commercial databases containing drug pricing and clinical information for drugs approved by the US Food and Drug Administration (FDA).

Proposed Selection Criteria Definitions & Methodologies

Prescription drugs in the list of prescription drugs eligible for affordability review were aggregated by labeler code (the first 5 digits of the prescription drug's NDC, which uniquely identifies the company who manufactures and/or distributes the prescription drug) and generic name. For each labeler code and generic name, the Board was presented with:

- Therapeutic class,
- Which section 70.405.030 RCW requirement NDC's within the labeler code and generic name met, and
- 11 proposed and mandatory selection criteria (minus input from the Washington State PDAB advisory group, which will be provided to the Board separately) detailed below in the following format:

Criterion	Definition	Data Field	Data Source	Methodology	Criterion Type
Name of criterion	An explanation of the selection criterion	The type of data the selection criterion provides, i.e. a number, a dollar amount, a text field	The data source Staff used to calculate the selection criterion	The formula or calculation used to obtain the selection criterion result	Whether the criterion is quantifiable (numeric data that can be measured) or not quantifiable (data that cannot be measured or expressed as numeric data)

Proposed Selection Criteria

Criterion	Definition	Data Field	Data Source	Methodology	Criterion Type
Total plan paid amount	Dollar amount showing what health plans paid for each labeler code and generic name within one year	Dollar amount	WA-APCD	Sum of the dollar amount paid to the provider by the health plan for the labeler code and generic name in calendar year 2022	Quantifiable
Total out-of-pocket cost	Dollar amount showing patient	Dollar amount	WA-APCD	Sum of total copay,	Quantifiable

	paid amounts for the labeler code and generic name. Patient paid amounts include deductibles, coinsurance, and copayments within one year.			coinsurance, and deductible amounts paid by patients for the labeler code and generic name in calendar year 2022. Formula: Total copay amount + Total coinsurance amount + Total deductible amount	
Total paid amount	Dollar amount showing the total amount paid by health plans and patients for each labeler code and generic name within one year.	Dollar amount	WA-APCD	Total amount paid, or allowed amount, by the health plan and patients for the labeler code and generic name in calendar year 2022 Formula: Total out-of-pocket cost + Total plan paid amount	Quantifiable
Average annual plan paid amount	Dollar amount per person per year showing the total amount paid by health plans for the labeler code and generic name divided by the number	Dollar amount	WA-APCD	Sum of the dollar amount paid to the provider by health plans for the labeler code and generic name in calendar year 2022 divided by the number of	Quantifiable

	of distinct patients who had a claim for that labeler code and generic name within one year			distinct patients who had a claim for the labeler code and generic name in calendar year 2022. Formula: Total plan paid amount/Number of distinct patients using the labeler code and generic name	
Average annual out-of-pocket cost	Dollar amount showing an annual cost of the patient paid amounts per person per year for the labeler code and generic name divided by the number of distinct patients who had a claim for that drug within one year	Dollar amount	WA-APCD	Sum of total copay, coinsurance, and deductible amounts for the labeler code and generic name in calendar year 2022 divided by the number of distinct patients who had a claim for the labeler code and generic name in calendar year 2022. Formula: Total out-of-pocket cost/Number of distinct patients using the labeler	Quantifiable

				code and generic name	
Average annual paid amount	Dollar amount per person per year showing the total amount paid by health plans and patients for each labeler code and generic name divided by the number of distinct patients who had a claim for that drug within one year.	Dollar amount	WA-APCD	Sum of the total amount paid by health plan and patients for each labeler code and generic name in calendar year 2022 divided by the number of distinct patients who had a claim for the labeler code and generic name in calendar year 2022. Formula: Total paid amount/Number of distinct patients using the labeler code and generic name	Quantifiable
Patient liability proportion	A proportion showing the share of the total amount that a patient pays towards the total amount paid by health plans and patients for each labeler	Number	WA-APCD	Average out-of-pocket cost in calendar year 2022 divided by average paid amount in calendar year 2022 Formula: Average annual	Quantifiable

	code and generic name within one year			out-of-pocket cost/Average annual paid amount	
Total number of people using the labeler code and generic name	The number of distinct patients who had a claim for the labeler code and generic name within one year.	Number	WA-APCD	The count of distinct patients who had a claim for the labeler code and generic name in calendar year 2022.	Quantifiable
Therapeutic equivalent availability	One or more NDC's in the labeler code and generic name has a therapeutic equivalent, according to the definition of therapeutic equivalent in section 69.41.110 RCW: "Therapeutically equivalent" means a drug product of the identical base or salt as the specific drug product prescribed with essentially the same efficacy and toxicity when administered to an individual in	Text (Yes/No)	First Databank (FDB)	Retrieve a list of therapeutically equivalent products from the FDB, whose data is based on the FDA Orange Book. Based on the definition of therapeutic equivalent in section 69.41.110 RCW, a practitioner may substitute a drug with a "therapeutically equivalent" drug product or "interchangeable biological" drug product. When reviewing labeler code and generic name data, the Board will consider any	Not quantifiable

	the same dosage regimen.			biologic with a biosimilar (interchangeable or not) as having a therapeutic equivalent. Biosimilar products and corresponding reference biological products are identified utilizing FDB's NDC attribute indicators for linking reference biologic and biosimilar NDCs.	
Generic availability	One or more brand name NDC in the labeler code and generic name has an FDA-approved drug that is chemically identical or bioequivalent to the brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics,	Text (Yes/No)	First Databank (FDB), Medi-Span	Link generic labeler code and generic names to their brand counterparts utilizing their shared unique clinical formulation identifier.	Not quantifiable

	and intended use.				
If the drug meets multiple thresholds of the legislative definition	Whether the labeler code and generic name meets multiple selection criteria set forth in section 70.405.030 RCW. If this number differs across NDC's within the same labeler code and generic name, the highest value will be shown.	Number	List of eligible prescription drugs for affordability review	The labeler code and generic name meets multiple selection criteria set forth in section 70.405.030 RCW	Not quantifiable

Exclusions

Labeler code and generic names with no claims in the WA-APCD in calendar year 2022 were excluded from affordability review eligibility.

Narrowing Down the Selection Criteria

The Board considered and discussed the 12 proposed and required selection criteria set forth in section 70.405.040 RCW and chose six criteria they thought were the most important when selecting labeler code and generic names for affordability review:

- Total number of people using the labeler code and generic name
- Average out-of-pocket cost
- Total out-of-pocket cost
- Total paid amount
- Therapeutic equivalent or generic availability
- If the labeler code and generic name meets multiple thresholds of the legislative definition

Applying the Selection Criteria

The Board and Staff worked together to develop a two-step approach of 1) conducting a points exercise by the Board to weigh and prioritize their six chosen selection criteria and 2) ranking the data within each of the four quantifiable selection criterion to maximize the utilization of data provided by each criterion when selecting labeler code and generic names for affordability review. The two remaining non-quantifiable selection criteria will be reviewed by the Board once the affordability review shortlists are created.

Weighting

Each of the five board members received 20 points (totaling 100 points) to distribute among the following four quantifiable selection criteria below. The more points distributed to a criterion by a board member, the more important the criterion is to the board member when selecting labeler code and generic names for affordability review.

- Total number of people using the labeler code and generic name
- Average out-of-pocket cost
- Total out-of-pocket cost
- Total paid amount

The two remaining selection criteria are non-quantifiable text data fields and cannot be ranked in the second step of the process and are therefore excluded from the weighting process:

- Therapeutic equivalent or generic availability and,
- If the labeler code and generic name meets multiple thresholds of the legislative definition

The two non-quantifiable selection criteria will be reviewed by the Board for the labeler code and generic names placed on the affordability review shortlists - two lists of the top 25 specialty and non-specialty labeler code and generic names with the lowest weighted rank created after the weighting and ranking process is completed. Similarly, PDAB advisory group input will be collected after the affordability review shortlists are created.

Ranking

While the Board allocated their points, Staff separated the eligible prescription drugs into specialty and non-specialty prescription drugs. Specialty prescription drugs were defined as medications that require special storage, handling, administration, or monitoring. Biologic and biosimilar prescription drugs were categorized as specialty drugs, except those that were reclassified as biologics under the Biologics Price Competition and

Innovation (BPCI) Act. Brand and generic prescription drugs were considered non-specialty drugs.

Four prescription drugs from the original list of 294 prescription drugs eligible for affordability review were removed from the list for having manufacturers that do not meet the definition of manufacturer as per Chapter 70.405 RCW. Of the 290 remaining prescription drugs eligible for affordability review, 58 were categorized as specialty drugs, and 232 were categorized as non-specialty drugs. The prescription drugs were then aggregated by labeler code (the first 5 digits of the prescription drug's NDC, which uniquely identifies the company who manufactures and/or distributes the prescription drug) and generic name.

For each specialty and non-specialty labeler code and generic name list, Staff sorted each of the four quantifiable selection criteria in descending order and assigned rankings. For example, the total paid amount was sorted from highest to lowest with the highest total paid amount given the rank of one, the second highest total paid amount given the rank of two, and so forth. This process was repeated for the other three selection criteria.

For tied rankings, the average ranking was assigned to each tied rank. In the example below, since labeler code and generic names C and D had the same total paid amount and were ranked in positions 3 and 4, their final points rank is the average of their rankings: (3+4)/2=3.5.

Labeler Code and Generic Name	Total Paid Amount	Total Paid Amount Rank
A	$4	1.0
B	$7	2.0
C	$12	3.5
D	$12	3.5
E	$19	5

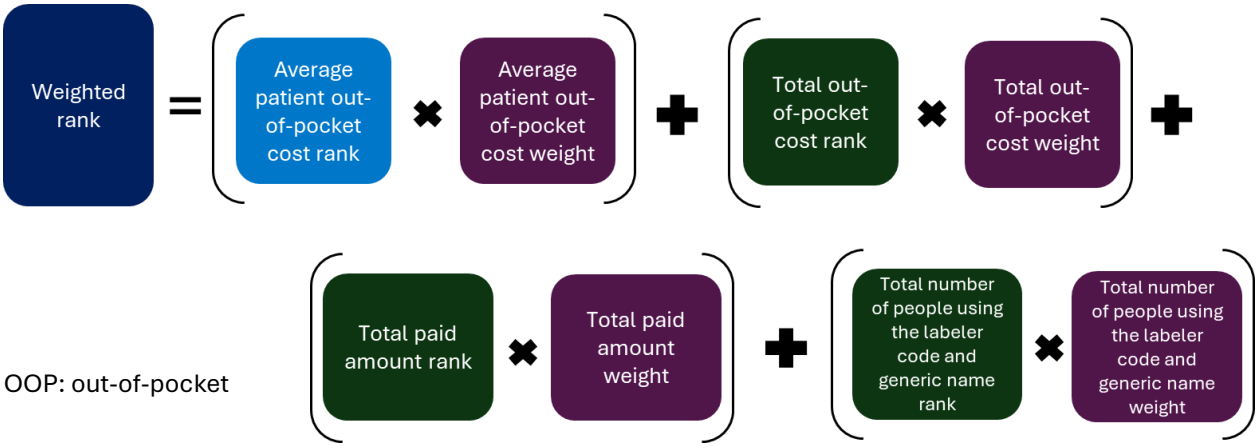
Calculating Weighted Rank

Board members' point allocation results (see table below) were collected and their assigned points for each selection criterion totaled.

Then, the following steps were taken:

1. The weights for each selection criterion were created by dividing the total points assigned to each criterion by the total amount of points (100) assigned to the Board.

2. A weighted rank was obtained for each labeler code and generic name by summing the values of the ranking for each selection criterion multiplied by their corresponding weights created in step 1.



OOP: out-of-pocket

Board member point allocation results:

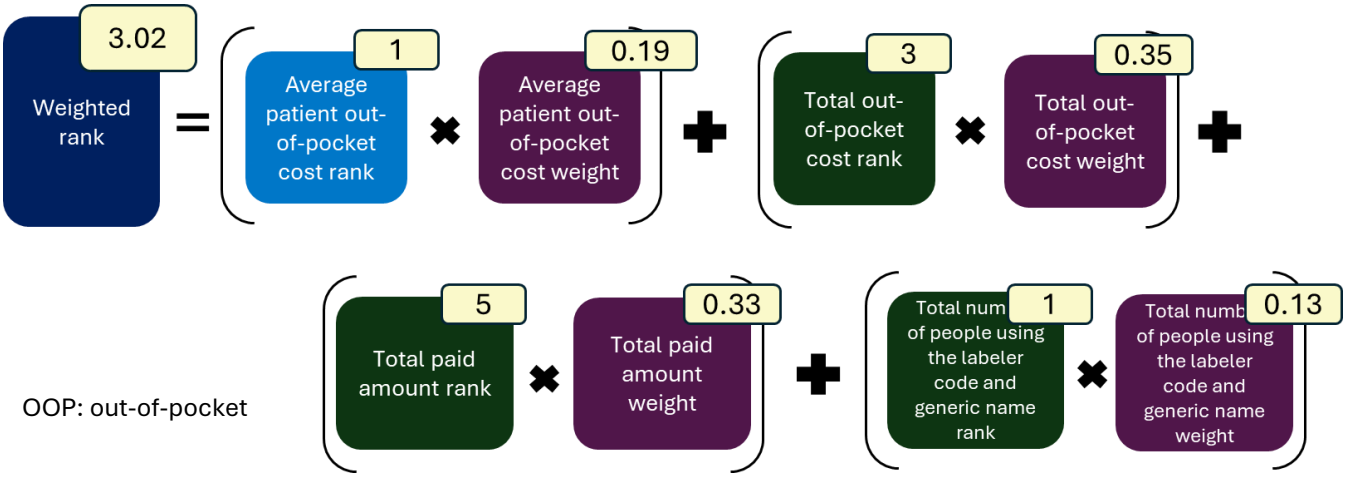
Board Member	Average Patient Out-of-Pocket Cost	Total Out-of-Pocket Cost	Total Paid Amount	Total Number of People Using the Labeler Code and Generic Name	Total
1	7	13	0	0	20
2	5	7	5	3	20
3	2	5	8	5	20
4	5	0	10	5	20
5	0	10	10	0	20
Total	**19**	**35**	**33**	**13**	**100**
Weight (Total/100)	**0.19**	**0.35**	**0.33**	**0.13**	

<u>Example weighted rank calculation:</u>

Suppose a labeler code and generic name has the ranks below for each selection criteria. Note that out-of-pocket cost is abbreviated as OOP.

Labeler Code and Generic Name	Average OOP Cost	Average OOP Cost Rank	Total OOP Cost	Total OOP Cost Rank	Total Paid Amount	Total Paid Amount Rank	Total # of People Using the Labeler Code and Generic Name	Total # of People Using the Labeler Code and Generic Name Rank
A	$427	1	$5,000	3	$10,000	5	356	1

The weighted rank for this labeler code and generic name would be calculated by multiplying the ranks for each selection criteria by their weights and adding them together:



OOP: out-of-pocket

Creating the Prioritized Shortlists

The labeler code and generic names were sorted from lowest to highest by weighted rank within their respective specialty and non-specialty lists, and the top 25 labeler code and generic names with the lowest weighted ranks in each list were used to create specialty and non-specialty shortlists for the Board and PDAB advisory group to study and select labeler code and generic names for affordability review.