

Oregon Prescription Drug Affordability Board

Preliminary Drug List Data Process

PDAB Staff January 2025

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Document History

Version	Date	Description	Author
v01		Original draft	PDAB Staff

Overview

The following methodology was used to develop the preliminary drug lists from health insurance carriers reported under ORS 743.025 for the 2025 Oregon Prescription Drug Affordability Board (PDAB) affordability review. The data used to produce the lists is from the calendar year 2023.

Data Sources

- Drug Price Transparency Oregon's Drug Price Transparency (DPT) program is responsible for collecting various health care data under ORS 743.025 from health insurance companies offering a health benefit plan in Oregon. Primarily, the data that is collected are the top 25 drugs from each plan of the health insurance companies that qualify for the greatest increase, most costly, and most prescribed lists. Other information include national drug codes (NDC), plan type, number of prescriptions, number of enrollees, and total annual spend. The information collected by DPT is aggregated and calculated net of rebate.
- Centers for Medicare & Medicaid Services (CMS) The "Selected Drug List" for the Medicare Drug Price Negotiation was used as a resource to verify if a drug was present or absent from the current drug price negotiation list.¹
- 3. Federal Drug Administration (FDA) The administration is part of the U.S. Department of Health and Human Services. The FDA was used to determine Orphan drug designation of drugs by proprietary and non-proprietary name, as well as a source for patents, approvals, exclusivity, and bioequivalents of drugs. Information published by the FDA was used to as a secondary source for general information relevant to NDC values of interest.²

¹ <u>https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation</u>

² <u>Search Orphan Drug Designations and Approvals</u>; <u>See also Approved Drug Products with Therapeutic Equivalence</u> <u>Evaluations | Orange Book | FDA</u>; <u>See also https://open.fda.gov/data/ndc/</u>

- 4. **Medi-Span** This Wolters Kluwer drug database was the primary source for NDC and wholesale acquisition cost (WAC) information.³
- 5. **Contracted Clinician** This resource provided assistance and validation for, insulin therapeutic class level (Medi-Span classification), naming conventions, insulin subclass categorization, and the presence and number of therapeutic alternatives.

Assumptions and Constraints

- 1. Data provided or acquired by all listed sources is true, accurate, and as complete as possible.
- 2. Due to confidentiality constraints, the analysis outputs must be deidentified and in aggregated form. No individual claim data can be represented.
- 3. The carrier data does not provide information on patients paying out-of-pocket for their medical and pharmaceutical expenses and are not included in the aggregated analysis.

Process – Preliminary Aggregated Drug Data

1. Request and received data from the healthcare carriers

- a. The 2023 drug data was reported by the health insurance carriers to the DPT program as required under ORS 743.025.
- b. DPT received, validated, and aggregated the data that was submitted in Excel format by the health insurance carriers.
- c. The PDAB staff received the aggregated information from the DPT program in various Excel workbooks and combined the information into one singular Excel sheet.

2. Standardizing drug names and carrier codes.

- a. A proprietary naming convention was created in order to unify drug names that differ slightly according to the reporting. A new column of "Proprietary Name Summarized" was created based off of the proprietary names given by carriers.
- b. Each healthcare carrier was given an unique carrier code to identify the individual entries of drugs. A new column of "carrier_id" was created and other columns were added as well to further distinguish the reporting such as "carrier_group_type".

3. Identification of preliminary drugs for investigation

a. Using the pivots in Excel, all drugs reported by healthcare carriers were identified and sorted by the number of Top 25 lists (Greatest Increase, Most Costly, and Most

³ https://www.wolterskluwer.com/en/solutions/medi-span/medi-span/drug-pricing-data

Prescribed) they were on. If a drug was reported by 5 or more carriers for the Greatest Increase and Most Costly lists they were included in the preliminary drug list. The drugs were identified by their "Proprietary Name Summarized".

b. Precursory edits of the list resulted in insulin products and medical devices being removed from the preliminary drug list.

4. Aggregation of drug data

- a. An unique ID for each entry of the drugs were created from carrier id, carrier type, and proprietary drug name summarized. Based on the unique ID, duplicate entries were removed from the raw data in the Excel workbook.
- b. Mathematical functions were used to calculate sums and averages of the values represented. (See Calculations Section.)
- c. The resulting information was exported to an Excel workbook with multiple tabs representing the functional aggregated data.
- d. The WAC data was calculated using Medi-Span as the source. Using the NDC's provided by the carriers, PDAB staff used SQL and Medi-Span to pull WAC information on the drugs on the preliminary list.

5. Spreadsheet tabs

- a. The Excel workbook, generated in step 4c, was formatted for aesthetics.
 - i. Additional tabs were created for terms and sources for continuity of information.
- b. Workbook tabs are as follows:
 - i. Terms
 - ii. Sources
 - iii. Carrier Prelim Rx List 2024-2025

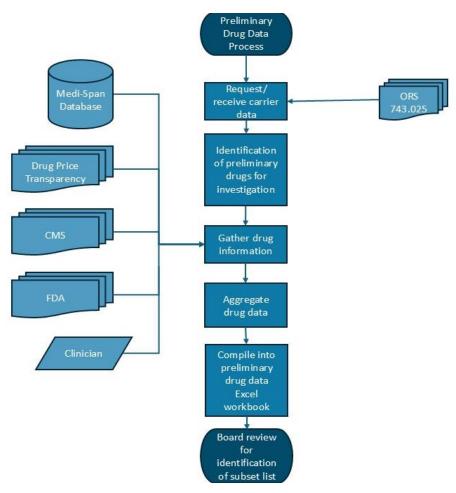


Figure 1 - Preliminary Drug Data Process Overview

Calculations

The below calculations were performed to create the preliminary drug lists for 2023.

- 1. **Total Annual Net of Rebate Spend Per Enrollee** This calculation is the Total Annual Net of Rebate Spend divided by the Number of Enrollees. The annual net is the total aggregated amount spent per enrollee from all reporting health insurance carriers. This value is formatted as currency in U.S. dollars.
- 2. Average Cost Net of Rebate Per Prescription This calculation is the Total Annual Net of Rebate Spend divided by the Number of Prescriptions. The average cost is the amount spent that included rebates or other discounts per prescription. This value is formatted as currency in U.S. dollars.

- 3. WAC Price Change Percentage in 2023 End of year package (or unit) price minus the beginning of year package (or unit) price the result of which is divided by the beginning of year package (or unit) price. This value is formatted as a percentage.
- 4. **Greatest Increase (GI) Rank** Carriers are required to report the prescription drugs causing greatest increase in total plan spending from the current experience period to the previous experience period. This list must consider total annual spending including the net impact of any rebates or other price concessions. Drugs are ranked beginning with the drug causing the largest year over year increase, when factoring in the impact of rebates and price concessions. The value is formatted as a whole number.
- 5. **Most Costly (MC) Rank** The most costly drugs are required to be reported by prescription drug products, from both pharmacy and medical benefits. This list considers the net impact of any rebates or other price concessions that have or will impact the total annual spending for the year reported. Drugs are ranked beginning with the drug causing the largest cost to total annual spending, when factoring in the impact of rebates and price concessions. The value is formatted as a whole number.
- 6. **Most Prescribed (MP) Rank** The most prescribed drugs are required to be reported by the number of claims received. This includes prescription drugs covered under both the pharmacy and medical benefits. Drugs are ranked beginning with highest numbers of prescription drug claims. The value is formatted as a whole number.
- 7. Most Expensive (ME) Rank The most expensive drugs are calculated by PDAB staff and are identified by calculating the cost per enrollee, including the impact of rebates and price concessions. Total Annual Net of Rebate Spend is divided by the Number of Enrollees using RStudio to determine the most expensive drugs. Drugs are ranked beginning with the drug causing the most cost per enrollee, when factoring in the impact of rebates and price concessions. The value is formatted as a whole number.

Definitions

1. **Bioequivalence** – "Bioequivalence is, in pertinent part: the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site

of drug action when administered at the same molar dose under similar conditions in an appropriately designed study."⁴

- 2. Biosimilar "A biosimilar is a biologic medication. It is highly similar to a biologic medication already approved by FDA the original biologic (also called the reference product). Biosimilars also have no clinically meaningful differences from the reference product. This means you can expect the same safety and effectiveness from the biosimilar over the course of treatment as you would the reference product. Biosimilars are made from the same types of sources (e.g., living cells or microorganisms) and are just as safe and effective as their reference products."⁵
- 3. **Brand-name drug** A drug sold by a drug company under a specific name or trademark and that is protected by a patent.⁶ Brand name drugs may be available by prescription or over the counter.
- 4. **Carrier (aka payer)** Any person or entity that provides health benefit plans in the state that include but are not limited to licensed insurance companies, health care service contractors, health maintenance organizations, and any other corporation responsible for the payment of benefits or provisions of services.⁷
- 5. Enrollee (aka patient) Individual enrolled for coverage under a health benefit plan.⁸
- 6. **Generic Drug** A generic drug is a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use.⁹
- 7. National Drug Code (NDC) This code is a unique identifier for drug products.¹⁰
- 8. Non-proprietary name The chemical name for a drug.¹¹

⁴ https://www.fda.gov/media/160054/

⁵ <u>https://www.fda.gov/drugs/biosimilars/</u>

⁶ Drugs@FDA Glossary of Terms | FDA

⁷ https://oregon.public.law/statutes/ors_743b.005

⁸ Ibid

⁹ Generic Drugs: Questions & Answers | FDA

¹⁰ <u>https://open.fda.gov/data/ndc/</u>

¹¹ <u>https://medical-dictionary.thefreedictionary.com/nonproprietary+name</u>

- 9. **Number of Enrollees** The number of enrollees who filed claims for the prescription drugs in the reporting year.
- 10. **Number of Prescriptions** The number of claims received for the prescription drug in the reporting year.
- 11. **Orphan designation** A drug designated by the FDA as a treatment for a rare disease and when the drug has been granted exclusive marketing rights for a seven-year period to treat rare diseases.¹²
- 12. **Pharmaceutical equivalence** Drug products that have "identical dosage form and route(s) of administration; contain identical amounts of the identical active drug ingredient, i.e., the same salt or ester of the same therapeutic moiety, or, in the case of modified-release dosage forms that require a reservoir or overage or such forms as prefilled syringes where residual volume may vary, that deliver identical amounts of the active drug ingredient over the identical dosing period; do not necessarily contain the same inactive ingredients; and meet the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates."¹³
- 13. **Priority review** Priority review status for a drug application indicates that the FDA will review the drug within 6 months (at a faster rate than the 10 month standard review).¹⁴
- 14. **Proprietary name** "The protected brand name or trademark, registered with the U.S. Patent Office, under which a manufacturer markets its product. It is written with a capital initial letter and is often further distinguished by a superscript R in a circle (®)." ¹⁵ The Medispan designated proprietary name was used throughout this analysis.
- 15. **Therapeutic alternative** A "drug product that contains a different therapeutic agent than the drug in question, but is FDA-approved, compendia-recognized as off-label use for the same indication, or has been recommended as consistent with standard medical practice by medical professional association guidelines to have similar therapeutic effects, safety

¹² <u>https://www.fda.gov/industry/medical-products-rare-diseases-and-conditions</u>

¹³ <u>https://www.fda.gov/media/160054</u>

¹⁴ <u>https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/priority-review</u>

¹⁵ <u>https://medical-dictionary.thefreedictionary.com/proprietary+name</u>

profile, and expected outcome when administered to patients in a therapeutically equivalent dose."¹⁶

- 16. Therapeutic equivalence "The scientific and regulatory foundation for the evaluation of therapeutic equivalence of prescription drug products involves pharmaceutical equivalence, bioequivalence, and the same clinical effect and safety profile for the conditions of use specified in the labeling."¹⁷
- 17. Wholesale Acquisition Cost (WAC) The price paid by a wholesaler to purchase drugs from a supplier, typically the manufacturer.¹⁸

Tools

- 1. **Microsoft Excel** This tool is the industry leading spreadsheet software program, data visualization and analysis tool.
- 2. **RStudio** RStudio is programming software used to import, clean, organize, query, and analyze data that comes from a variety of sources, including insurance carriers. R has the versatility to process large amounts of data and read the multiple file formats that are encountered in the prescription drug affordability program enabling flexibility in data modeling.
- SQL (Structured Query Language) SQL is a standardized programming language used for searching, manipulating, and combining data from relational databases. SQL enables efficiency in retrieving and analyzing data as well as generating reports to inform business decisions.

Conclusion

This document is a living document and will be updated as needed as the affordability review process progresses. The above information is pertinent to the development of the health insurance carrier preliminary drug list. Additional processes will be required for the subset list once the drugs listed for review are selected.

¹⁶ PDAB Administrative Rule 925-200-0020

¹⁷ www.FDA.gov

¹⁸ <u>https://prescriptionanalytics.com/white-paper/key-terms-in-pharmaceutical-government-pricing/</u>