Prescription Drug Affordability Board upper payment limit (UPL) overview

Ralph Magrish MPA
Executive director, Oregon Prescription Drug Affordability Board
and Drug Price Transparency Program
Oregon Department of Consumer and Business Services

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Oregon Senate Health Care Committee

Oregon Prescription Drug
Affordability Board

Agenda

- PDAB introduction and functions
- SB 192 direction and deliverables for the board
- What is a UPL?
- What it would look like
- Consumer outreach
- Constituent outreach
- 192 report
- MFP analysis
- OEBB/PEBB impacts

Prescription Drug Affordability Board (PDAB) introduction

Purpose

- Created under SB 844 (2021) to protect Oregonians, state and local governments, commercial health plans, health care providers, pharmacies, and others in the health care system from the high costs of prescription drugs

Composition

- Eight members appointed by the governor and confirmed by the Senate
- Required background in clinical medicine or healthcare economics

PDAB functions

- Drug affordability reviews – identify nine drugs and at least one insulin product that may create affordability challenges for health care systems or high out-of-pocket costs for patients based on criteria adopted by the board
- Study the entire prescription drug distribution and payment system in Oregon and around the world designed to lower the list price of prescription drugs
- Make recommendations to the Oregon Legislature for statutory changes

PDAB responsibilities

Rulemaking input

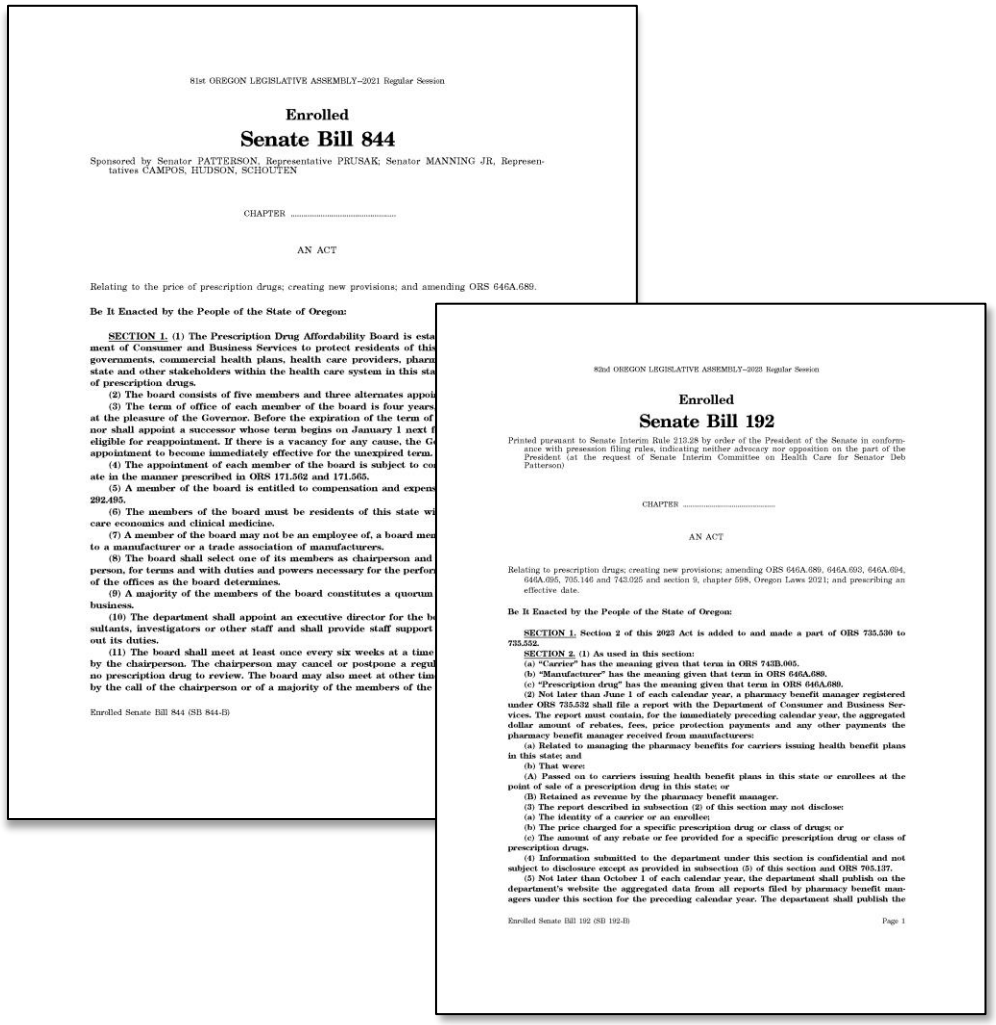
- Affordability review criteria
- Manufacturer fee structure

Annual reporting requirements

- Generic marketplace report to legislature
- Report to legislature and Cost Growth Target Program (OHA) on:
  - Price trends
  - Drug affordability reviews conducted
  - Recommendations for changes to make drugs more affordable

Where is Oregon regarding UPL?

- In 2021, Senate Bill 844, the board's founding legislation, did not include UPL authority.
- In 2022, the Oregon PDAB recommended to the Legislature setting UPLs only for government payers.
- In 2023, Senate Bill 192 directed the Oregon PDAB to study the implementation of UPLs.



81st OREGON LEGISLATIVE ASSEMBLY–2021 Regular Session

Enrolled

Senate Bill 844

Sponsored by Senator PATTERSON, Representative PRUSAK; Senator MANNING JR, Representatives CAMPOS, HUDSON, SCHOUTEN

CHAPTER .....

AN ACT

Relating to the price of prescription drugs; creating new provisions; and amending ORS 646A.689.

Be It Enacted by the People of the State of Oregon:

SECTION 1. (1) The Prescription Drug Affordability Board is esta
ment of Consumer and Business Services to protect residents of this
governments, commercial health plans, health care providers, pharm
state and other stakeholders within the health care system in this sta
of prescription drugs.
(2) The board consists of five members and three alternates appoi
(3) The term of office of each member of the board is four years
at the pleasure of the Governor. Before the expiration of the term of
nor shall appoint a successor whose term begins on January 1 next f
eligible for reappointment. If there is a vacancy for any cause, the G
appointment to become immediately effective for the unexpired term.
(4) The appointment of each member of the board is subject to co
ate in the manner prescribed in ORS 171.562 and 171.565.
(5) A member of the board is entitled to compensation and expens
292.495.
(6) The members of the board must be residents of this state wi
care economics and clinical medicine.
(7) A member of the board may not be an employee of, a board mem
to a manufacturer or a trade association of manufacturers.
(8) The board shall select one of its members as chairperson and
person, for terms and with duties and powers necessary for the perfor
of the offices as the board determines.
(9) A majority of the members of the board constitutes a quorum
business.
(10) The department shall appoint an executive director for the b
sultants, investigators or other staff and shall provide staff support
out its duties.
(11) The board shall meet at least once every six weeks at a time
by the chairperson. The chairperson may cancel or postpone a regu
no prescription drug to review. The board may also meet at other tim
by the call of the chairperson or of a majority of the members of the

Enrolled Senate Bill 844 (SB 844-B)

82nd OREGON LEGISLATIVE ASSEMBLY–2023 Regular Session

Enrolled

Senate Bill 192

Printed pursuant to Senate Interim Rule 213.28 by order of the President of the Senate in conformance with precession filing rules, indicating neither advocacy nor opposition on the part of the President (at the request of Senate Interim Committee on Health Care for Senator Deb Patterson)

CHAPTER .....

AN ACT

Relating to prescription drugs; creating new provisions; amending ORS 646A.689, 646A.693, 646A.694, 646A.695, 705.146 and 743.025 and section 9, chapter 598, Oregon Laws 2021; and prescribing an effective date.

Be It Enacted by the People of the State of Oregon:

SECTION 1. Section 2 of this 2023 Act is added to and made a part of ORS 735.530 to 735.552.

SECTION 2. (1) As used in this section:
(a) "Carrier" has the meaning given that term in ORS 743B.005.
(b) "Manufacturer" has the meaning given that term in ORS 646A.689.
(c) "Prescription drug" has the meaning given that term in ORS 646A.680.
(2) Not later than June 1 of each calendar year, a pharmacy benefit manager registered under ORS 735.532 shall file a report with the Department of Consumer and Business Services. The report must contain, for the immediately preceding calendar year, the aggregated dollar amount of rebates, fees, price protection payments and any other payments the pharmacy benefit manager received from manufacturers:
(a) Related to managing the pharmacy benefits for carriers issuing health benefit plans in this state; and
(b) That were:
(A) Passed on to carriers issuing health benefit plans in this state or enrollees at the point of sale of a prescription drug in this state; or
(B) Retained as revenue by the pharmacy benefit manager.
(3) The report described in subsection (2) of this section may not disclose:
(a) The identity of a carrier or an enrollee;
(b) The price charged for a specific prescription drug or class of drugs; or
(c) The amount of any rebate or fee provided for a specific prescription drug or class of prescription drugs.
(4) Information submitted to the department under this section is confidential and not subject to disclosure except as provided in subsection (5) of this section and ORS 705.137.
(5) Not later than October 1 of each calendar year, the department shall publish on the department's website the aggregated data from all reports filed by pharmacy benefit managers under this section for the preceding calendar year. The department shall publish the

Enrolled Senate Bill 192 (SB 192-B) Page 1

What is an upper payment limit (UPL)?

- The maximum reimbursement rate above which purchasers throughout the state may not pay for prescription drug products
- It creates a ceiling on what a payer can pay for a drug
- It does not set the price a manufacturer can charge

Prescription Drug Affordability Boards across the U.S.

Boards with upper payment limits:

- **CO, MD, MN,** and **WA** have full UPL authority
- **OR** and **NJ** must return to legislature with a plan
- **ME, NH,** and **NY** have PDABs but not designed to lower costs statewide
- **MN, VA, MI, IL,** and **PA** PDAB bills include Medicare maximum fair price as statewide UPL (extends Medicare's effort to all residents)

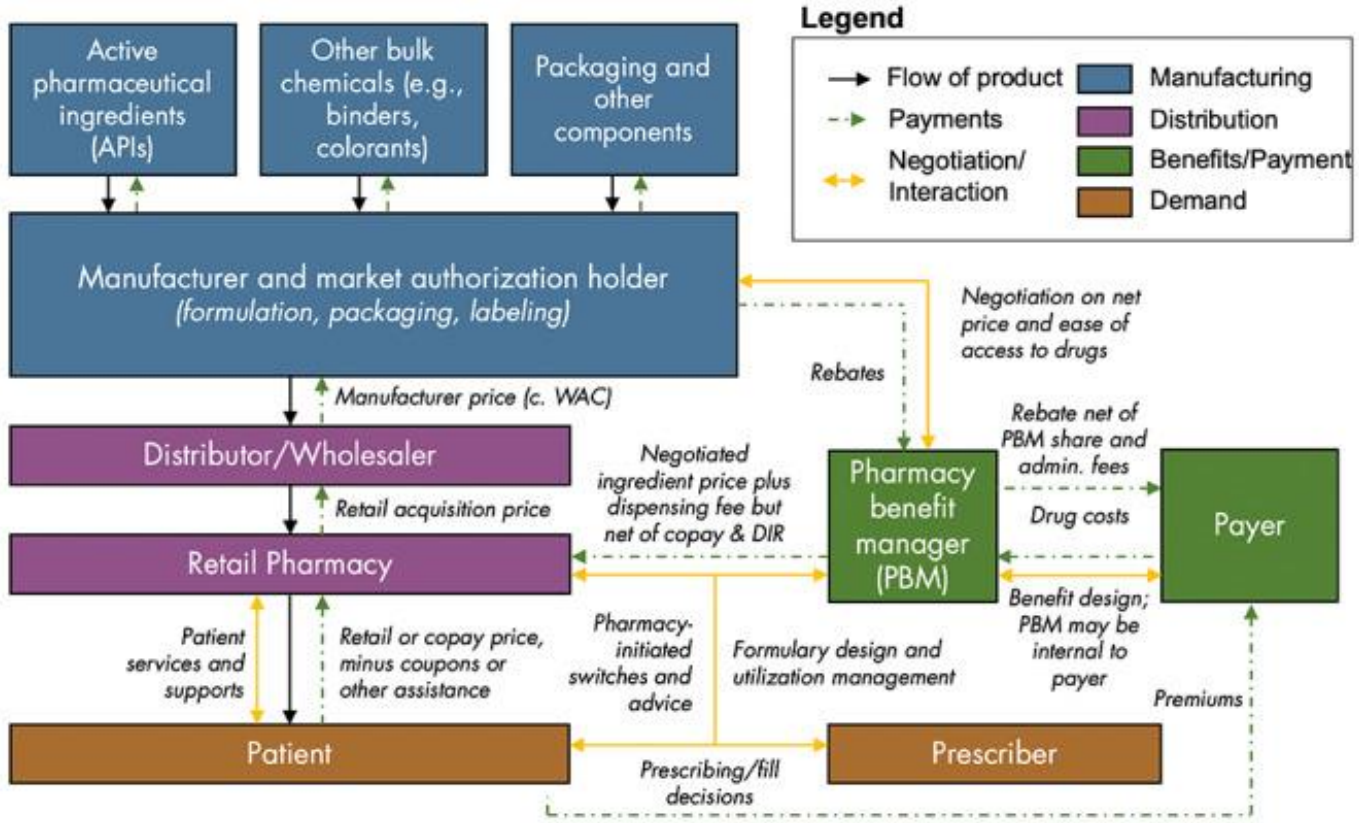
Prescription drug costs affect public health

The state of Oregon is a major purchaser of prescription drugs

- Oregon Health Plan: $1.46 billion in 2023
- Public Employees' Benefit Board (PEBB): $145 million in paid pharmacy costs after rebates in 2023
- Oregon Educators Benefit Board (OEBB): $102 million in paid pharmacy costs after rebates for the 2022-2023 plan year (10/22 to 9/23)
- CAREAssist (Oregon's AIDS Drug Assistance Program): $17 million in 2023

Rx supply chain: everyone plays a role

- Manufacturers – brand, generic, biosimilars
- Wholesale distributors
- Pharmacies
- Pharmacy benefit managers
- Insurance companies
- Medical providers
- Consumers
- Government agencies and others



Source: Mulcahy, Andrew W. and Kareddy, Vishnupriya. "Prescription Drug Supply Chains: An Overview of Stakeholders and Relationships." RAND Health Quarterly, June 2022. https://pubmed.ncbi.nlm.nih.gov/35837523/. Accessed March 12, 2024.

Basics of Rx UPL acquisition cost, billing, and payment

Manufacturer

Agrees to sell to wholesaler at UPL price for drugs used in the state. Provides standard volume-based discount for wholesalers (UPL minus discount). May choose to also negotiate additional discounts with large healthcare entities. (This is routine in today's market.)

Wholesaler

Buys at UPL minus discount. Sells to pharmacies and hospitals at UPL minus discount but above what wholesaler paid manufacturer. (This is the mark up). Fulfills manufacturer UPL minus discount agreements with hospitals and is reimbursed from manufacturer.

Hospital, doctor, pharmacy

Buys at UPL minus discount. Bills, or submits a claim to, insurer, PBM, or patient, based on UPL.

Patient

Patient pays deductible, coinsurance, based on UPL.

Insurer's PBM

PBM reimburses pharmacy at UPL price. Bills insurers at UPL price for pharmacy claims paid.

Insurer

Insurer is billed by PBM for Rx claims paid on behalf of insurer's enrollees at UPL price. Insurer reimburses PBM at UPL price for paid claims. Since UPL is public, insurers can discern if PBM is charging insurer more than PBM reimbursed pharmacies. (This is called spread pricing.)

Note: UPL replaces WAC, AWP, AAC, EAC etc. UPL is the metric for all financial transactions for the drug.
Like existing metrics, there will be 'UPL minus' in the supply chain.

Consumer outreach

- PDAB hosted seven in-person and online community forums across Oregon
- 156 people attended
- 28 people testified about skipping prescriptions because they can't afford them, battling insurance companies over coverage, and struggling to find medications in short supply
- Read the report here: https://dfr.oregon.gov/pdab/Documents/reports/PDAB-Consumer-Report-2024.pdf

Outreach to constituents

Background

- SB192 tasked the board with developing a UPL plan
- Myers and Stauffer engaged to support UPL plan development
- Scope of work includes constituent engagement to:
  - Identify concerns, questions, support, or opposition to UPLs
  - Solicit input about UPL process, utilization, and implementation
  - Solicit input about data and alternative approaches

Approach

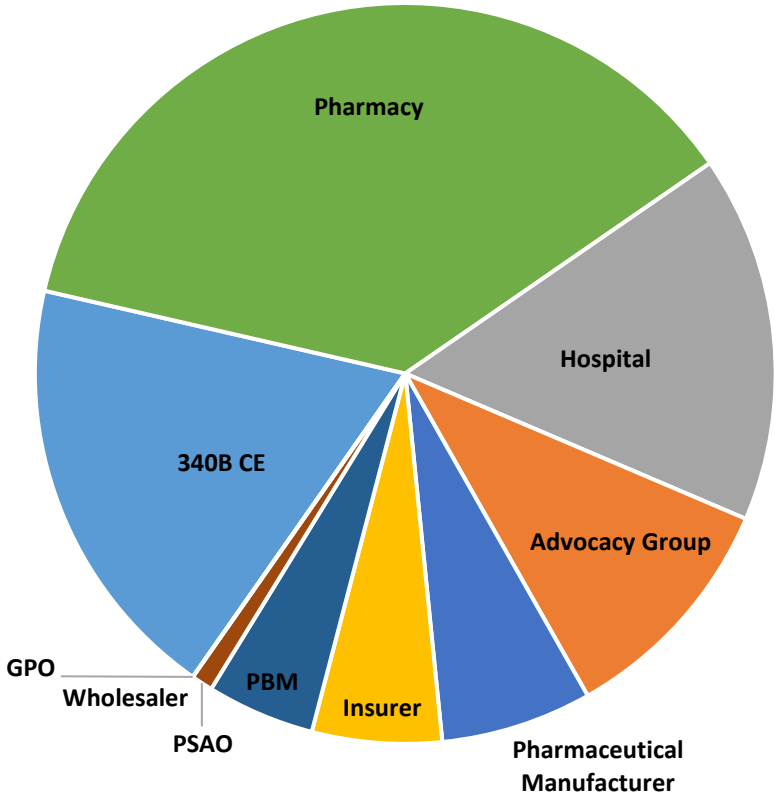
Constituent groups

- **Under SB 192**
  - The state
  - Insurers
  - Hospitals
  - Pharmacies
  - Consumers
- **Additionally**
  - 340B Covered Entities (CEs)
  - Patient Advocacy Groups
  - Pharmaceutical Manufacturers
  - Pharmacy Benefit Managers (PBMs)

Mechanisms for engagement

- **Online Survey**
  - Non-mandatory Likert scale and free text questions
    - Affordability, UPL impact, methodology, recommendations
  - Inform focus groups
- **Focus Groups**
  - 2 X 1-hour meetings per group
  - Expand on survey responses
  - Solicit additional feedback

Survey participation



Constituents	Sent	Responses
340B CE*	34	20
Advocacy Groups	60	11
Hospital	51	17
Insurer	53	6
Pharmaceutical Manufacturer*	56	7
Pharmacies	429	39
PBMs*	159	5
PSAOs*	6	1
Wholesalers*	4	0
GPOs*	4	0
Total	**856**	**106**

Synthesis of feedback: Survey

Survey responders were concerned with:

- Cost of drugs to organizations and patients
- UPL financial impact on organizations
- UPL impact on patient access and costs
- Increased administrative burden, infrastructure costs, and operational challenges

Synthesis of feedback: Focus groups

- Drug affordability concerns
- Unsure how to assess the impact of a UPL, particularly given the strategy has yet to be implemented in other states
- Concerned about loss of revenue, decreased patient access, and increased patient costs
- Questions about delivery system complexity and limitations of a state-based solution
- Administrative burden, especially effort required to serve patients, perform business operations, and manage contracts
- Questioned how a UPL would be developed, implemented, and enforced

Summary of outreach recommendations, concerns, and obstacles

- Most common recommendations focused on affordability determinations, drug selection for affordability review, PBM reform, and transparency
- Concerns regarding negative impact a on provider revenue, patient access, and supply chain operations
- Lack of information regarding affordability determinations, as well as how a UPL would be established, implemented, and enforced

UPL report – November 2024

- Outlines structured methodologies to establish UPLs subject to affordability review under ORS 646A.694
- Recognizes complexities of supply chain and different approaches may be necessary for different drugs and distribution channels.
- Brings to light perspectives on UPLs from a broad spectrum of stakeholders and examines models used by PDABs in other states.
- Offers a toolkit for the legislature to consider both the potential and complexities of UPLs.
- Acknowledges fine operational details would need to be developed in Administrative Rules

UPL report – considerations

- The effective implementation of UPLs requires careful administrative planning and standardized processes
- Experiences in other states reveal the need for a comprehensive approach to affordability reviews, with detailed drug price modeling and periodic reassessment to adapt to market conditions
- Oregon's PDAB considers these insights crucial, as a structured, phased approach could provide a balanced foundation for Oregon's UPL framework while facilitating administrative clarity and stakeholder engagement

PDAB UPL analysis for state payers (PEBB, OEBB, Medicaid)

- Myers and Stauffer LC, at the request of PDAB staff, created three upper payment limit scenarios for eight prescription drugs to consider for modeling and analysis by state payers.
- These drugs were pulled from the 2023 PDAB Prescription Drug Top Drug Subset List: Cosentyx, Entyvio, Inflectra, Keytruda, Ocrevus, Ozempic, Tremfya, and Trulicity.

PDAB UPL analysis for state payers

PEBB/OEBB analysis[1]

- Under the scenario where it is assumed there are no rebates due to an implemented UPL, the most likely outcomes range from a combined increase of $12.1M in plan spend (where the modest price reduction is less than existing rebates) to a cost savings of $18.7M (price reduction exceeds existing rebates).

Medicaid/Oregon Health Plan

- For both Fee for Service (FFS) and Coordinated Care Organizations (CCO), the modeling assumed no changes to existing rebates. Both assumptions mean that attainable savings will be lower.
- Additionally, due to state and federal budget mechanics, OHA advised that reductions in cost from implementing a UPL would more likely be reinvested in other OHP services rather than directly reducing state costs.
    - For the UPL scenarios, the potential net savings range from $1.1M to $2.3M for FFS, and $25M to $56M for CCO.[2]

1. *Mercer Health & Benefits LLC analysis, Aug. 26, 2024. Analysis does not include Kaiser Permanente medical claims.*
2. *Oregon Health Authority, Office of Actuarial and Financial Analytics, Sept. 6, 2024.*

Maximum Fair Price (MFP) modeling analysis

- CMS released the Maximum Fair Price (MFP) in September for the first series of 10 single source drugs without generic or biosimilar competition that were subject to negotiation with manufacturers under the Inflation Reduction Act. MFPs to become effective for plan year 2026

- As a state analog to MFPs, PDAB staff completed an analysis to examine the potential estimated savings in the state using the recent CMS negotiated drug prices.

Maximum Fair Price (MFP) modeling analysis (continued)

- Analysis shows carrier's annual expenditure based on the number of prescriptions and number of enrollees for a drug. These sections are highlighted in blue.
- The annual expenditures were then recalculated using Medicare's MFP (highlighted in orange). These potential cost savings calculations are shown in purple and include the percentage savings that could be afforded by a UPL.
- Analysis Caveats – Not a one-to-one market comparison
  - Data is limited to commercial insurance carrier reporting to the Drug Price Transparency program.
  - Only includes specific plan types (large, small, individual) while excluding groups such as Medicare, Medicaid, self-insured, PEBB, and OEBB.
  - Intended only to model the potential effects of a UPL.
- Percentages of savings vary between 51 percent and 81 percent totaling a potential savings of $49M.

Maximum Fair Price (MFP) modeling analysis for potential UPL

*Proprietary name(s)	Non-proprietary name	**Number of carriers reported out of 12	Number of enrollees prescribed Rx in 2023	Number of prescriptions in 2023	Total (net of rebate) annual spend in 2023	Total annual spend per enrollee in 2023	Average cost per prescription in 2023	Medicare MFP negotiated price for 30-day supply	Potential OR estimated total annual spend per enrollee using Medicare MFP	Potential OR total annual spend using Medicare MFP based on number of prescriptions	Potential OR estimated savings using Medicare MFP (based on total spend)	Potential OR percent savings using Medicare MFP
Eliquis	Apixaban	12	3,822	17,034	$9,848,225	$2,577	$578	$231	$1,030	$3,934,854	$5,913,371	60%
Enbrel / Enbrel SureClick	Etanercept	9	607	4,648	$22,380,528	$36,871	$4,815	$2,355	$18,033	$10,946,040	$11,434,488	51%
Entresto	Sacubitril-Valsartan	8	1,097	4,374	$3,742,550	$3,412	$856	$295	$1,176	$1,290,330	$2,452,220	66%
Farxiga	Dapagliflozin Propanediol	6	821	3,838	$1,531,108	$1,865	$399	$179	$834	$685,083	$846,025	55%
Imbruvica	Ibrutinib	1	3	11	$241,556	$80,519	$21,960	$9,319	$34,170	$102,509	$139,047	58%
Januvia	Sitagliptin Phorphate	3	28	103	$95,879	$3,424	$931	$113	$416	$11,639	$84,240	88%
Jardiance	Empagliflozin	12	5,892	23,825	$10,569,483	$1,794	$444	$197	$797	$4,693,525	$5,875,958	56%
Stelara	Ustekinumab	10	648	2,995	$31,156,649	$48,081	$10,403	$4,695	$21,700	$14,061,525	$17,095,124	55%
Xarelto	Rivaroxaban	12	2,160	7,746	$4,908,208	$2,272	$634	$197	$706	$1,525,962	$3,382,246	69%
Fiasp	Insulin Aspart	2	15	50	$55,000	$3,667	$1,100	$119	$397	$5,950	$49,050	89%
Novolog	Insulin Aspart	3	563	2,163	$2,122,013	$3,769	$981	$119	$457	$257,397	$1,864,616	88%
Novolog Flexpen	Insulin Aspart	4	65	164	$44,456	$684	$271	$119	$300	$19,516	$24,940	56%
				TOTAL Spend =	**$86,695,655**					**POTENTIAL Total Savings =**	**$49,161,325**	

This data set is limited to Drug Price Transparency insurance carrier reporting that only includes Large, Small, and Individual plan groups. This excludes groups such as Medicare, Medicaid, self -insured, PEBB, OEBB,

*The proprietary name information is represented by the most frequently used NDC reported in 2023 by Oregon's commercial health insurance carriers.

**The number of carriers that reported the drug under ORS 743.025 for their 2023 top 25 most costly or greatest increase.

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Questions?

Ralph Magrish MPA

Executive director, Oregon Prescription Drug Affordability Board and Drug Price Transparency Program

Oregon Department of Consumer and Business Services

Ralph.M.Magrish@dcbs.oregon.gov

(971) 375-7591