Oregon Prescription Drug Affordability Board

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Agenda

This is a regular meeting. *Date*: **December 13, 2023** | *Time*: **9:30 a.m.**

This is a draft agenda and subject to change.

Meeting name	**Prescription Drug Affordability Board**
Meeting location	Virtual
Zoom link	Register for the meeting

Board Members: Chair Akil Patterson; Vice Chair Shelley Bailey; Daniel Hartung; Dr. Richard Bruno; Amy Burns; Robert Judge; John Murray

Staff: Ralph Magrish, executive director; Cortnee Whitlock, policy analyst; Stephen Kooyman, project manager; Brekke Berg, policy analyst, Amanda Claycomb, research analyst, Melissa Stiles, administrative specialist; Jake Gill, counsel; Pramela Reddi, counsel

Purpose	Subject	Presenter	Estimated Time Allotted
Informational and vote	Call to order, roll call, and approval of **11/15/2023 minutes**	Chair Patterson	5 minutes
Informational	Executive director's program update	Ralph Magrish	5 minutes
Discussion and vote	Board discussion and vote about filtering Rx and insulin **subset lists** for biosimilars and generics	Ralph Magrish and Cortnee Whitlock	20 minutes
Discussion	Board **survey overview** for OAR 925-200-0020	Brekke Berg	20 minutes
Discussion	2024 affordability review **work plan, template, and public comment** for stakeholder submissions	Ralph Magrish and Amanda Claycomb	30 minutes
Discussion and vote	Board discussion and vote on **policy recommendations and letter** for the Oregon Legislature	Cortnee Whitlock	20 minutes
Informational	Announcements	Staff	5 minutes
Informational	Public comment	Chair Patterson	10 minutes
Informational	Adjournment	Chair Patterson	5 minutes

Next meeting

Jan. 17, 2024, at 9:30 a.m.

Accessibility

Anyone needing assistance due to a disability can contact Melissa Stiles at least 48 hours ahead of the meeting at pdab@dcbs.oregon.gov or 971-374-3724. advance.

How to submit public comment

Oral testimony

For oral comments, please submit the PDAB Public Comment Form no later than 24 hours before the PDAB meeting. The form is located on the Oregon Prescription Drug Affordability Board website here: https://dfr.oregon.gov/pdab/Pages/public-comment.aspx

Written testimony

For written comments, please submit the PDAB Public Comment Form no later than 72 hours before the PDAB meeting. The form is located on the Oregon Prescription Drug Affordability Board website here: https://dfr.oregon.gov/pdab/Pages/public-comment.aspx
Written comments will be posted to the PDAB website.

Open and closed sessions

All board meetings except executive sessions are open to the public. Pursuant to ORS 192.660, executive sessions are closed, with the exception of news media and staff. No final actions will be taken in the executive session. When action is necessary, the board will return to an open session.

Oregon Prescription Drug Affordability Board

Oregon Prescription Drug Affordability Board (PDAB) Regular Meeting
Wednesday, November 15, 2023
Draft Minutes

Web link to the meeting video: https://www.youtube.com/watch?v=6Gk2182MFZw
Web link to the meeting materials: https://dfr.oregon.gov/pdab/Documents/20231115-PDAB-document-package.pdf.
Web link to Excel spreadsheets and data information: https://dfr.oregon.gov/pdab/Pages/data.aspx

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Call to order and roll call: Chair Akil Patterson called the meeting to order at 9:30 am and roll was called.
Board members present: Chair Akil Patterson, Vice Chair Shelley Bailey, Dr. Richard Bruno, Dr. Amy Burns, Dr. Daniel Hartung.
Board members absent: Robert Judge, John Murray

Approval of minutes: Richard Bruno made a motion and **Shelley Bailey** provided a second to approve the minutes on Pages 3-4 in the agenda packet. View the approval in the meeting video at 00:01:01.
MOTION to approve the minutes.
Board Vote:
Yes: Richard Bruno, Amy Burns, Daniel Hartung, Vice Chair Shelley Bailey, Chair Akil Patterson
No: None
Motion passed 5-0

Program update by Executive Director Ralph Magrish. View the executive director's report in the meeting video at minute 00:02:15.

Presentation on insulin by Dr. Yan Emily Yuan of Brigham and Women's Hospital in Boston, Mass: View the slide presentation on Pages 7-29 of the agenda packet. View Dr. Yuan's presentation in the meeting video at minute 00:07:18.

OAR 925-200-0010 board discussion and vote on insulin subset list: Amanda Claycomb, data analyst, began the discussion about the data on Pages 30-39 of the agenda packet. The Excel files are located on the PDAB website under the heading "Data for board review on November 15, 2023." View video of the board discussion and votes on subset of insulin products at 00:30:38. The board voted on subset lists for long acting, short acting and rapid-acting insulin. See Table 1 for the list of drugs the board voted on and approved. While the board voted on four motions, one motion failed but passed after an amendment to include an additional insulin product. The votes were:

Dr. Bruno made the motion and Shelley Bailey provided the second for the long-acting insulin list.
MOTION on the long-acting subset list of Tresiba, Soliqua, Zultophy.
Board Vote:
Yes: Daniel Hartung
No: Amy Burns, Richard Bruno, Shelley Bailey, Akil Patterson
Motion failed 1-4.

Amy Burns made the amended motion to also include the flex pen and Richard Bruno provided the second.
MOTION on the long-acting subset list of Tresiba, Tresiba FlexTouch, Soliqua, Zultophy.
Board Vote:
Yes: Daniel Hartung, Amy Burns, Richard Bruno, Shelley Bailey, Akil Patterson

No: None
Motion passed 5-0.

Shelley Bailey made the motion and Richard Bruno provided the second for the short-acting insulin list.
MOTION on the short-acting subset list of HumuLIN R and HumuLIN R U-500 KwikPen.
Board Vote:
Yes: Daniel Hartung, Amy Burns, Richard Bruno, Shelley Bailey, Akil Patterson
No: None
Motion passed 5-0.

Richard Bruno made the motion and Amy Burns provided the second for the rapid-acting insulin list.
MOTION on the rapid-acting subset list of Insulin Aspart, Insulin Aspart PenFill, Lyumjev, Lyumjev KwikPen.
Board Vote:
Yes: Daniel Hartung, Amy Burns, Richard Bruno, Shelley Bailey, Akil Patterson
No: None
Motion passed 5-0.

Table 1: Board approved subset list of insulin products pursuant to OAR 925-200-0010

Insulin type	Proprietary name(s)	Non-proprietary name
Long-Acting	Tresiba	Insulin Degludec
Long-Acting	Tresiba FlexTouch	Insulin Degludec
Long-Acting	Soliqua	Insulin Glargine-Lixisenatide
Long-Acting	Xultophy	Insulin Degludec-Liraglutide
Rapid-Acting	Insulin Aspart	Insulin Aspart
Rapid-Acting	Insulin Aspart PenFill	Insulin Aspart
Rapid-Acting	Lyumjev	Insulin Lispro-aabc
Rapid-Acting	Lyumjev KwikPen	Insulin Lispro-aabc
Short-Acting	HumuLIN R	Insulin Regular (Human)
Short-Acting	HumuLIN R U-500 KwikPen	Insulin Regular (Human)

OAR 925-200-0010 board discussion and vote on orphan designation of prescription drugs and vote on updated subset list: Amanda Claycomb, data analyst, reviewed data changes on Pages 49-52 of the agenda packet. View the board discussion in the meeting video at 01:34:45. Board members voted on an update subset list of prescription drugs as shown in Table 2.

Shelley Bailey made the motion and Richard Bruno provided the second for updated subset list.
MOTION on updated subset list of prescription drugs as shown in Table 2:
Board Vote:
Yes: Daniel Hartung, Amy Burns, Richard Bruno, Shelley Bailey
No: None
Abstain: Akil Patterson
Motion passed 4-0.

Table 2: Board approved updated subset list of prescription drugs pursuant to OAR 925-200-0010

Proprietary name(s)	Non-proprietary name
Albuterol Sulfate / Albuterol Sulfate ER / Albuterol Sulfate HFA / ProAir HFA / ProAir RespiClick / Proventil HFA / Ventolin HFA	Albuterol Sulfate
Budesonide-Formoterol Fumarate / Symbicort	Budesonide-Formoterol Fumarate Dihydrate
Bunavail / Buprenorphine HCl-Naloxone HCl / Suboxone / Zubsolv	Buprenorphine HCl-Naloxone HCl Dihydrate
Cosentyx / Cosentyx Sensoready Pen / Cosentyx Sensoready	Secukinumab
Creon / Pancreaze / Pertzye / Viokace / Zenpep	Pancrelipase (Lipase-Protease-Amylase)
Entyvio	Vedolizumab
Genvoya	Elvitegravir-Cobicistat-Emtricitabine-Tenofovir Alafenamide
Inflectra	Infliximab-dyyb
Ocrevus	Ocrelizumab
Rybelsus / Ozempic	Semaglutide
Shingrix	Zoster Vaccine Recombinant Adjuvanted
Skyrizi / Skyrizi Pen	Risankizumab-rzaa
Tremfya	Guselkumab
Triumeq / Triumeq PD	Abacavir-Dolutegravir-Lamivudine
Trulicity	Dulaglutide
Vyvanse	Lisdexamfetamine Dimesylate

Board review of policy submissions: Ralph Magrish, executive director, and Cortnee Whitlock, policy analyst, reviewed the proposed policy recommendations submitted by the public shown on Pages 61-66 in the agenda packet. View the discussion in the meeting video at 01:46:36. The board voted to approve policy recommendations 1, 2, and 5, with 4 having provisional approval based on the board learning more information at the Dec. 13 meeting. The board will review and vote on the final report with recommendations on Dec. 13.

Amy Burns made the motion and Daniel Hartung provided the second.
MOTION to approve policy recommendations 1, 2, and 5, with 4 having provisional approval.
Board Vote:
Yes: Daniel Hartung, Amy Burns, Richard Bruno, Shelley Bailey, Akil Patterson
No: None
Motion passed 5-0.

Announcements: Ralph Magrish said staff will present a work plan and affordability review template for the board to review at the Dec. 13 meeting. The board will announce in December how and when manufacturers may submit information about prescription drugs. All public comments are posted on the PDAB website. In addition, Dr. Richard Bruno announced his resignation from the board beginning in January due to taking a new position as the Multnomah County Health Officer. View these comments in the meeting video at 2:14:42.

Public comment: Chair Akil Patterson called on the people who signed up to speak to the board: John Mullin, president, Oregon Coalition for Affordable Prescriptions (OCAP); Dharia McGrew, director of state policy, PhRMA; Brian Warren, senior director, state government affairs; Biotechnology Innovation Organization; and Terri Lee, vice president of state government affairs and policy, Merck. View the oral testimony in the meeting video at 02:19:57.

In addition, OCAP, Bio and Oregon Bioscience Association, Bristol Myers Squibb, Genentech, Merck, and PhRMA provided written testimony to the board. The written testimony is posted on the PDAB website.

Adjournment: The meeting was adjourned at 12 p.m. by Chair Patterson.

Oregon Prescription Drug
Affordability Board

Email: pdab@dcbs.oregon.gov Phone: 971-374-3724 Website: dfr.oregon.gov/pdab

Date: Dec. 1, 2023

To: Chair, Akil Patterson
Vice-Chair, Shelley Bailey
Dr. Richard Bruno
Dr. Amy Burns
Dr. Daniel Hartung
Mr. Robert Judge
Mr. John Murray

From: Ralph Magrish, Executive Director

Re: Staff Recommendation to update prescription drug and insulin subset lists

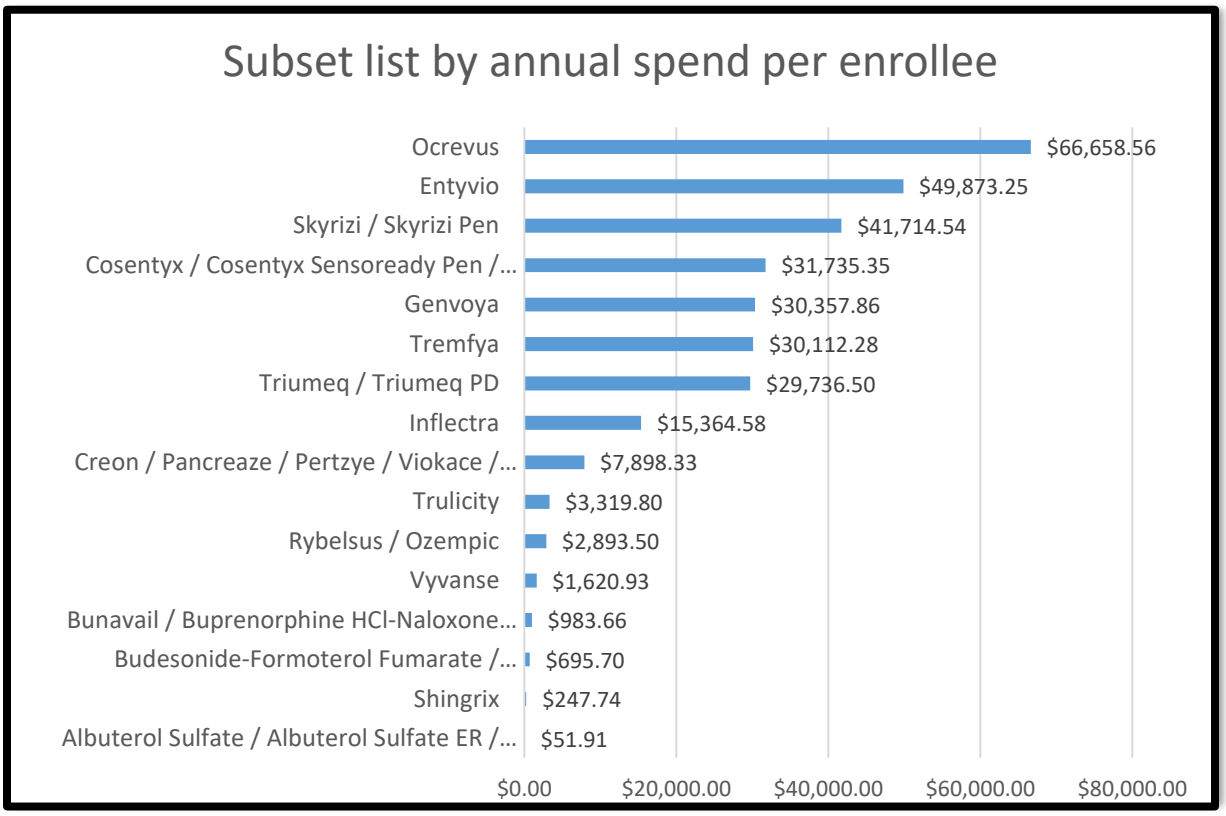
Staff has been working to set up the drugs you selected for the subset lists for affordability reviews. In doing so, we realized that a full discussion did not occur around OAR 925-200-0010(4), which states the board shall consider, "For brand-name drugs and biological products, whether there are any approved and marketed generic drugs or biosimilar drugs for the specific brand-name drug or biological product."

Prior to proceeding with affordability reviews, we recommend revisiting this criterion and confirming the subset lists before proceeding to the process under OAR 925-200-0020.

This recommendation comes following our consultation with PORTAL and a clinical consultant for the review process. Their collective feedback was to remove four drugs from the prescription drug subset list due to having multisource drugs, multiple manufacturers, or generic or therapeutic equivalents. Additionally, there have been stakeholder comments regarding the grouping of drugs in the prescription drug subset list. Based on the totality of feedback provided, staff recommends the board consider removing the Creon group, Albuterol Sulfate group, Symbicort group, and Suboxone group from the prescription drug subset list.

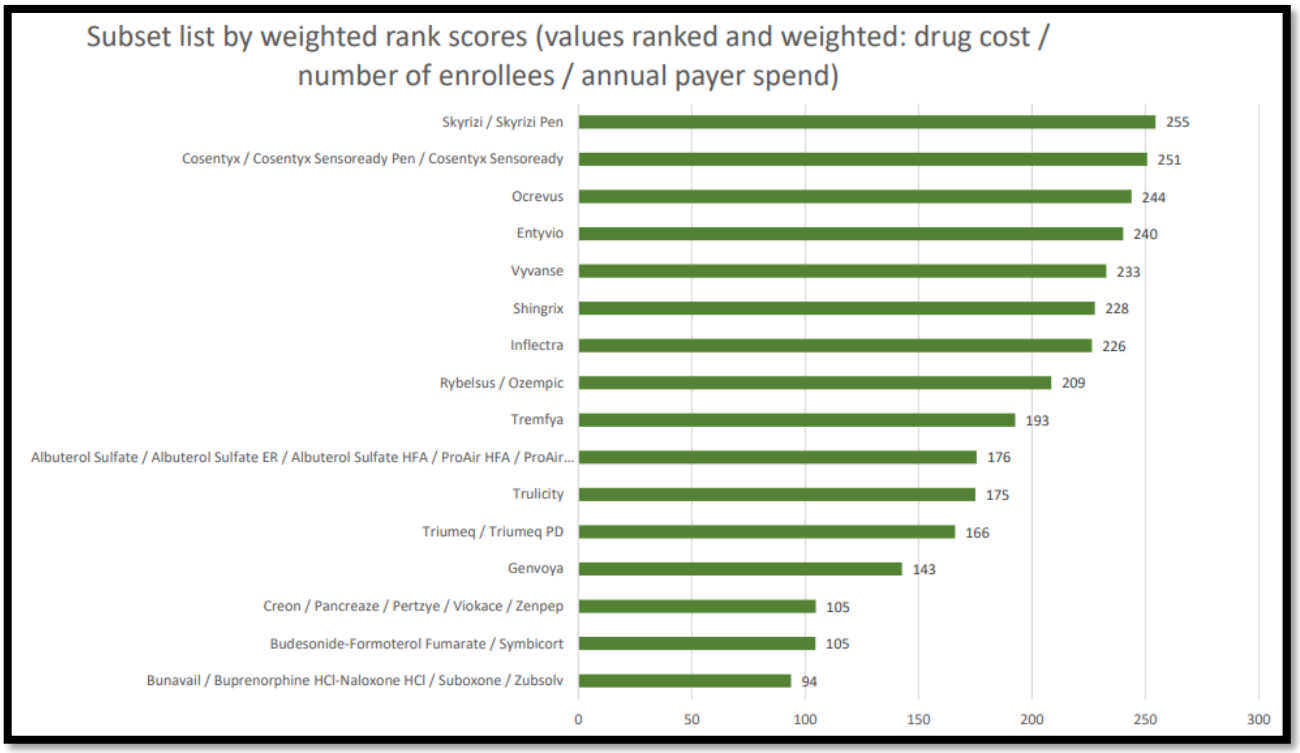
Table 1 shows an analysis of the total annual spend for the drugs. Suboxone, Symbicort, and Albuterol Sulfate are at the bottom for least costly spend in 2022. Table 2 shows the weighted rank scores for drug cost, number of enrollees, and annual payer spend. Suboxone, Symbicort and Creon are the bottom three drugs.

Table 1: Total annual spend per enrollee[1]



[1] Annual spend per enrollee based on DPT carrier data reporting for 2022.

Table 2: Weighted rank[2]



Additionally, feedback provided from program consultants suggest removing insulin products Soliqua, Xultophy, Lyumjev, and HumuLIN R due to being a generic or combination product. Based on this feedback, staff recommends removing these insulin products.

In sum, staff recommends these noted prescription drugs and insulin products be removed, consistent with OAR 925-200-0010(4) and input received by stakeholders and our consultants. Please come prepared to the next board meeting to discuss whether the four drugs and four insulin products should be removed from these subset lists, as well as to vote to address any changes made to the current subset lists.

[2] Weighting method: End-of-year 2022 package WAC ascending rank x 10, number of enrollees ascending rank x 7.1, annual plan spend ascending rank x 6.4. Values for ranking/weighting from previously reported DPT carrier data and Medi-Span WAC history for 2022. Weighting based on board survey scores.

Oregon Prescription Drug
Affordability Board

The data on the following pages of the agenda packet is in PDF format. Click on the Prescription Drug Affordability Board data web page to access the data in Excel format:

- 2022 insulin data
- 2023 PDAB subset drug list

Also included in this agenda packet is the PDAB data calculations and methodology document which provides data sources, definitions, formulas, methodologies, and technical information. This document is also posted on the website.

2023 PDAB Subset Drug List

Data source:

Data pulled from the annual insurance carrier reporting to the Oregon Drug Price Transparency (DPT) program. Data for the year 2022.
FDA approval dates and therapeutic equivalence information pulled from the FDA's orange and purple books.

Abbreviations and definitions

List abbreviation	List name	List details and notes
GI	Greatest increase	The top 25 drugs from carrier reporting causing the greatest increase in total plan spending one year to the next. 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 considered total annual spending, including the net impact of any rebates or other price concessions. Drugs were ranked by the drug causing the largest year-over-year increase, when factoring in the impact of rebates and price concessions. Year-over-year increase is reported as the total annual spending from the previous year minus the total annual spending from two years' prior to the reporting year. For example, during the 2023 reporting year, the year-over-year increase was the total annual spend from 2022 minus the total annual spend from 2021.
MC	Most costly	The top 25 most costly drugs from carrier reporting for both pharmacy and medical benefits, contributing the largest cost to total annual spending. This list considered the net impact of any rebates or other price concessions that impacted the total annual spending for the reported experience period. Drugs were ranked by the drug causing the largest cost to total annual spending, when factoring in the impact of rebates and price concessions.
ME	Most expensive	The top 25 drugs from carrier reporting that had the highest cost per prescription.
MP	Most prescribed	The top 25 most prescribed drugs from carrier reporting by the number of claims received. List includes prescription drugs covered under both the pharmacy and medical benefits. Drugs were ranked by the highest numbers of prescription drug claims.

Other terms

Term	Definition/ notes
Has orphan designation(s) per FDA	Values were marked in this field based on a list exported from the FDA's orphan drug designations and approvals database as of 07/27/23: https://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm
Drug has a therapeutic equivalent or biosimilar	At least one form of the drug shows a therapeutic equivalence evaluation (TEE) code beginning with "A" in the orange book, has a biosimilar listed in the purple book, or is listed as a biosimilar in the purple book.
Beginning 2022 package WAC	The average Wholesale Acquisition Cost (WAC)* for a package of the drug as of 1/1/2022.
End 2022 package WAC	The average Wholesale Acquisition Cost (WAC)* for a package of the drug as of 12/31/2022.
WAC price change % 2022	The price increase/decrease in the average package WAC from the beginning to the end of 2022.
Avg YoY price change (over past 5 years)	Average percent of the change in the year over year unit WAC for the last five years.
Drug approved through an expedited pathway	A FDA application for one ore more forms of the prescription drug qualified for one or more of the following expedited approval processes: fast track approval, priority review, accelerated approval, or breakthrough therapy designation.
Patent expiration date within 18 months	If "yes" is listed in this field, then the max patent expiration date listed for the drug application in the orange/purple book expires within the next 18 months. If "no" is listed in this field, then the max patent expiration date listed for the drug application in the orange/purple book does not expire within the next 18 months. If "no data" is listed in this field, then patent date information could not be located for the application associated with the drug.
Exclusivity expiration date within 18 months	(For non-biologics) If "yes" is listed in this field, then the max exclusivity expiration date listed for the drug application in the orange book expires within the next 18 months. If "no" is listed in this field, then the max exclusivity expiration date listed for the drug application in the orange book does not expire within the next 18 months. If "no data" is listed in this field, then exclusivity date information could not be located for the application associated with the drug. (For biologics) the exclusivity date used was based on 12 years from the date of the initial application approval. Drugs with a date set to expire in the next 18 months were marked as "yes", others were marked as "no".

Data notes:

** WAC represents package pricing. Because drugs may be repackaged at the pharmacy, the cost in claims data may reflect a different quantity than that represented in the WAC.*

Date	Change	Made By
10/31/2023	**Data corrections**: The top drug list was sent to an independent consultant for review. The following corrections and updates were made based on the feedback from the consultant: **Biktarvy** - Previously listed as "Orphan Only". Updated to "Both Orphan and Non-Orphan" **Bunavail / Buprenorphine HCl-Naloxone HCl / Suboxone / Zubsolv** - Previously listed as "Orphan only". Corrected to "No **Eylea** - Updated exclusivity expires within 18 months from "Yes" to "No" **Mavyret** - Previously listed as "Orphan Only". Updated to "Both Orphan and Non-Orphan" **Shingrix** - Previously listed as "Orphan only". Corrected to "No" **Ultomiris** - Updated exclusivity expires within 18 months from "No" to "Yes"	Staff
11/3/2023	**Stelara** - Updated the "Drug has a therapeutic equivalent or biosimilar" field to "Yes" due to FDA approval of Wezlana (ustekinumab-auub) as a biosimilar to and interchangeable with Stelara (ustekinumab) for multiple inflammatory diseases.	Staff
11/29/2023	Created a new document using the previously reported data, removed drugs that are not part of the 2023 PDAB Subset List (Non-insulin drugs).	Staff

2022 PDAB Subset Drug List - data

Therapy class	Proprietary name(s)	Non-proprietary name	Number of presciptions	Number of enrollees	Total annual spend	Year over year increase	Total annual spend per enrollee	Beginning 2022 package WAC	End 2022 package WAC	WAC price change % 2022	Avg YoY price change (over past 5 years)	Average cost per prescription	Has orphan designation(s) per FDA	Number of carriers	Percent of carriers	Brand or generic	Drug has a therapeutic equivalent or biosimilar	First FDA approval date	Drug approved through an expedited pathway	Patent expiration date within 18 months	Exclusivity expiration date within 18 months	Drug part of IRA CMS negotiation list	Drug also on the CCO list
ADHD/ANTI-NARCOLEPSY/ANTI-OBESITY/ANOREXIANTS	Vyvanse	Lisdexamfetamine Dimesylate	21,520	4,663	$7,558,385	$1,104,457	$1,620.93	$1,116.61	$1,172.44	5.00%	4.60%	$351.23	No	9	100%	Brand	None listed	2/23/2007	No	No	No Data	No	Top Costs
ANALGESICS - OPIOID	Bunavail / Buprenorphine HCl-Naloxone HCl / Suboxone / Zubsolv	Buprenorphine HCl-Naloxone HCl Dihydrate	18,576	2,268	$2,230,947	$189,468	$983.66	$130.75	$128.90	-1.42%	-2.92%	$120.10	No	8	89%	Both	Yes	8/30/2010	No	No	No Data	No	Top Costs / Top Claims / Top Cost Change
ANTIASTHMATIC AND BRONCHODILATOR AGENTS	Albuterol Sulfate / Albuterol Sulfate ER / Albuterol Sulfate HFA / ProAir HFA / ProAir RespiClick / Proventil HFA / Ventolin HFA	Albuterol Sulfate	141,372	68,376	$3,549,427	$470,108	$51.91	$295.08	$274.76	-6.89%	-1.30%	$25.11	No	9	100%	Both	Yes	12/5/1989	No	No	No Data	No	Top Costs / Top Claims
ANTIASTHMATIC AND BRONCHODILATOR AGENTS	Budesonide-Formoterol Fumarate / Symbicort	Budesonide-Formoterol Fumarate Dihydrate	7,183	2,351	$1,635,595	$318,280	$695.70	$272.33	$272.33	0.00%	1.77%	$227.70	No	7	78%	Both	Yes	7/21/2006	No	No	No Data	No	Top Costs
ANTIDIABETICS	Rybelsus / Ozempic	Semaglutide	16,774	3,657	$10,581,528	$3,238,534	$2,893.50	$816.12	$860.20	5.40%	4.55%	$631	No	9	100%	Brand	None listed	12/5/2017	Yes	No	Yes	No	Top Costs / Top Cost Change
ANTIDIABETICS	Trulicity	Dulaglutide	13,176	2,702	$8,970,087	$907,047	$3,319.80	$554.10	$554.10	0.00%	5.14%	$680.79	No	8	89%	Brand	None listed	9/18/2014	No	No Data	No	No	Top Costs / Top Cost Change
ANTIVIRALS	Genvoya	Elvitegravir-Cobicistat-Emtricitabine-Tenofovir Alafenamide	727	112	$3,400,080	No Data	$30,357.86	$3,583.80	$3,583.80	0.00%	5.20%	$4,676.86	No	5	56%	Brand	None listed	11/5/2015	Yes	No	No Data	No	Top Costs
ANTIVIRALS	Triumeq / Triumeq PD	Abacavir-Dolutegravir-Lamivudine	1,009	147	$4,371,265	$366,797	$29,736.50	$3,339.06	$2,170.39	-35.00%	5.31%	$4,332.27	No	7	78%	Brand	None listed	8/22/2014	Yes	No	No	No	Top Costs
DERMATOLOGICALS	Cosentyx / Cosentyx Sensoready Pen / Cosentyx Sensoready	Secukinumab	4,401	590	$18,723,855	$2,560,019	$31,735.35	$5,336.40	$5,824.14	9.14%	6.81%	$4,254	No	8	89%	Brand	None listed	1/21/2015	No	No Data	No	No	Top Costs / Top Cost Change
DERMATOLOGICALS	Skyrizi / Skyrizi Pen	Risankizumab-rzaa	1,199	372	$15,517,811	$8,385,287	$41,714.54	$12,760.33	$13,704.59	7.40%	7.65%	$12,942	No	8	89%	Brand	None listed	4/23/2019	No	No Data	No	No	Top Cost Change
DERMATOLOGICALS	Tremfya	Guselkumab	708	144	$4,336,168	$1,575,599	$30,112.28	$11,938.37	$12,583.04	5.40%	5.21%	$6,125	No	5	56%	Brand	None listed	7/13/2017	Yes	No Data	No	No	Top Cost Change
DIGESTIVE AIDS	Creon / Pancreaze / Pertzye / Viokace / Zenpep	Pancrelipase (Lipase-Protease-Amylase)	1,267	342	$2,701,230	$1,091,525	$7,898.33	$672.97	$697.91	3.71%	3.31%	$2,131.99	No	6	67%	Brand	None listed	4/30/2009	Yes	No Data	Yes	No	Top Costs
GASTROINTESTINAL AGENTS - MISC.	Entyvio	Vedolizumab	2,038	354	$17,655,131	$2,801,800	$49,873.25	$7,276.63	$7,713.23	6.00%	4.60%	$8,663	No	7	78%	Brand	None listed	5/20/2014	Yes	No Data	No	No	Top Costs / Top Cost Change
GASTROINTESTINAL AGENTS - MISC.	Inflectra	Infliximab-dyyb	6,209	1,075	$16,516,923	$5,489,239	$15,364.58	$946.28	$946.28	0.00%	0.00%	$2,660	No	8	89%	Brand	Yes	4/5/2016	No	No Data	No	No	Top Costs / Top Cost Change
PSYCHOTHERAPEUTIC AND NEUROLOGICAL AGENTS - MISC.	Ocrevus	Ocrelizumab	352	164	$10,932,003	$1,784,101	$66,658.56	$17,796.78	$17,796.78	0.00%	2.48%	$31,057	No	8	89%	Brand	None listed	3/28/2017	Yes	No Data	No	No	Top Costs
VACCINES	Shingrix	Zoster Vaccine Recombinant Adjuvanted	35,123	27,538	$6,822,359	$319,706	$247.74	$943.63	$943.63	0.00%	5.56%	$194.24	No	9	100%	Brand	None listed	10/20/2017	No	No Data	No	No	No

FDA insulin types

Term	Definition
Rapid-Acting	An insulin that starts working within 15 minutes after use. It is mostly gone out of the patient's body after a few hours. It should be taken just before or just after eating.
Short-Acting	An insulin that starts working within 30 minutes to 1 hour after use. It is mostly gone out of the patient's body after a few hours. It should be taken 30-45 minutes before eating.
Intermediate-Acting	An insulin that starts working within 2-4 hours after use. It reaches its highest level in the patient's blood around 6-8 hours after use. It is often used to help control blood sugar between meals. Some people use this type of insulin in the morning, at bedtime, or both.
Long-Acting	An insulin that starts working within 2 to 4 hours after use. It can last in the patient's body for up to 24 hours. It is often used in the morning or at bedtime to help control blood sugar throughout the day.
Pre-Mixed	A mix of two different types of insulin. It includes one type that helps to control your blood sugar at meals and another type that helps between meals.

Other definitions

Term	Definition/ notes
Drug has a therapeutic equivalent or biosimilar	At least one form of the drug shows a therapeutic equivalence evaluation (TEE) code beginning with "A" in the orange book, has a biosimilar listed in the purple book, or is listed as a biosimilar in the purple book.
Drug approved through an expedited pathway	The prescription drug application qualified for one or more of the following expedited approval processes: fast track approval, priority review, accelerated approval, or breakthrough therapy designation.
Patent expiration date within 18 months	If "yes" is listed in this field, then the max patent expiration date listed for the drug application in the orange/purple book expires within the next 18 months. If "no" is listed in this field, then the max patent expiration date listed for the drug application in the orange/purple book does not expire within the next 18 months. If "no data" is listed in this field, then patent date information could not be located for the application associated with the drug.
Exclusivity expiration date within 18 months	(For non-biologics) If "yes" is listed in this field, then the max exclusivity expiration date listed for the drug application in the orange book expires within the next 18 months. If "no" is listed in this field, then the max exclusivity expiration date listed for the drug application in the orange book does not expire within the next 18 months. If "no data" is listed in this field, then exclusivity date information could not be located for the application associated with the drug. (For biologics) the exclusivity date used was based on 12 years from the date of the initial application approval. Drugs with a date set to expire in the next 18 months were marked as "yes", others were marked as "no".
Beginning 2022 package WAC	The Wholesale Acquisition Cost (WAC)* for a package of the drug as of 1/1/2022.
End 2022 package WAC	The Wholesale Acquisition Cost (WAC)* for a package of the drug as of 12/31/2022.
WAC price change % 2022	The price increase/decrease in package WAC from the beginning to the end of 2022.
Avg YoY price change (over past 5 years)	Average percent of the change in the year over year unit WAC for the last five years.

Data notes:

** WAC represents package pricing. Because drugs may be repackaged at the pharmacy, the cost in claims data may reflect a different quantity than that represented in the WAC.*

Date	Change Made	Made By
11/29/2023	Created document using previously reported APAC data and the list of insulins for review per the November 2023 Prescription Drug Affordability Board Meeting.	Staff

	Drug type detail			2022 Volume data	2022 Cost data	Comparison of 2022 and 2021	Generic and Biosimilar Information	FDA approval data	WAC data	
Year	**Insulin Type FDA**	**Proprietary name**	**Non-proprietary name**	**Claimants**	**2022 per patient spend**	**Percent change per patient spend 2021-2022**	**Drug has a therapeutic equivalent or biosimilar**	**Exclusivity expiration date within 18 months**	**Avg YoY price change (over past 5 years)**	**Drug part of IRA CMS negotiation list**
2022	Rapid-Acting	Insulin Aspart	Insulin Aspart	847	$2,266.13	10%	None Listed	No	0.00%	No
2022	Rapid-Acting	Insulin Aspart PenFill	Insulin Aspart	195	$1,977.42	3%	None Listed	No	0.00%	No
2022	Rapid-Acting	Lyumjev	Insulin Lispro-aabc	76	$5,477.09	39%	None Listed	No	0.00%	No
2022	Rapid-Acting	Lyumjev KwikPen	Insulin Lispro-aabc	89	$3,517.45	43%	None Listed	No	0.00%	No
2022	Short-Acting	HumuLIN R	Insulin Regular (Human)	1,686	$615.39	-2%	None Listed	No	0.00%	No
2022	Short-Acting	HumuLIN R U-500 KwikPen	Insulin Regular (Human)	157	$12,064.03	-3%	None Listed	No	0.00%	No
2022	Long-Acting	Tresiba	Insulin Degludec	76	$3,016.12	9%	None Listed	No	0.98%	No
2022	Long-Acting	Tresiba FlexTouch	Insulin Degludec	2,279	$4,000.04	1%	None Listed	No	0.98%	No
2022	Long-Acting	Xultophy	Insulin Degludec-Liraglutide	14	$8,608.74	16%	None Listed	No	4.56%	No
2022	Long-Acting	Soliqua	Insulin Glargine-Lixisenatide	39	$4,089.51	14%	None Listed	No	4.78%	No

Oregon Prescription Drug Affordability Board

Email: pdab@dcbs.oregon.gov Phone: 971-374-3724 Website: dfr.oregon.gov/pdab

PDAB data calculations and methodology

About this document

This document provides data sources, definitions, formulas, methodologies, and technical information.

Manufacturer annual increase report

2022 calculated AWAC

Data sources: Medi-span

Definition: Average wholesale acquisition cost (AWAC) is the time-weighted price average for the year. Price history was pulled from Medi-span. The price listed in 2022 was multiplied by the number of days it spent at that price and divided by the number of days in the year. The results for each price were added together to obtain the AWAC.

Beginning WAC 2022

Data sources: Data reported by manufacturers in iReg as part of DPT reporting.

Definition: Wholesale acquisition cost (WAC) reported in iReg for 01/01/2022.

Beginning WAC 2023

Data sources: Data reported by manufacturers in iReg as part of DPT reporting and Medi-span.

Definition: The WAC listed in Medi-span at the beginning of January 2023 if the change to pricing occurred within four days of the end of calendar year 2022, or the December 31 WAC reported in iReg was not a price increase within four days of the end of the calendar year 2022.

Manufacturer new specialty drugs

Beginning 2022 package WAC

Data sources: Medi-span

Definition: Wholesale acquisition cost (WAC) for a package of the drug as of 01/01/2022.

Technical notes: The Medi-span's price history table was queried by pulling the most recent package WAC on or before 01/01/2022. If no WAC was identified in the price history table on or before 01/01/2022, the section was marked "No Data."

End 2022 package WAC

Data sources: Medi-span

Definition: Wholesale acquisition cost (WAC) for a package of the drug as of 12/31/2022.

Technical notes: The Medi-span's price history table was queried by pulling the most recent package WAC before or on 12/31/2022. If no WAC was identified price history table on or before 12/31/2022, the section was marked "No Data."

WAC price change % 2022

Data sources: Calculated using the "Beginning 2022 package WAC" and "End 2022 package WAC," which were pulled from Medi-span.

Definition: Average percent of the change in the year-over-year unit WAC for 2022.

Formula: (End of 2022 package WAC – Beginning of 2022 package WAC) / Beginning of 2022 package WAC

Avg YoY price change (over the past five years)

Data sources: Medi-span

Definition: Average percent of the change in the year-over-year unit WAC for the last five years.

Methodology notes:

Data pulled from Medi-span on 08/15/2023

All calculations below were conducted at the NDC level unless otherwise specified:

- Calculated **$ YoY change in Unit WAC** by subtracting **unit WAC from previous year** from **unit WAC from basis year.**
- Calculated **% YoY change in Unit WAC** by dividing **$ YoY change in Unit WAC** by **unit WAC from basis year.**
- Calculated **average % YoY change in Unit WAC over trailing 5 years** by taking the average of **% YoY change in Unit WAC** for all years with data.
- Aggregated data by named drug by averaging **average % YoY change in Unit WAC over trailing 5 years** for all NDCs.

Example

Year	previous year unit WAC	basis year unit WAC	$ YoY change in Unit WAC	% YoY change in Unit WAC
2019	$ 100	$ 110	$ 10	9.09%
2020	$ 110	$ 115	$ 5	4.35%
2021	$ 115	$ 120	$ 5	4.17%
2022	$ 120	$ 130	$ 10	7.69%
2023	$ 130	$ 137	$ 7	5.11%
Average % YoY change in Unit WAC over trailing 5 years				6.08%

Carrier data and working drug lists

Beginning 2022 package WAC

Data sources: Medi-span

Definition: The wholesale acquisition cost (WAC) for a package of the drug as of 12/31/2022.

Technical notes: The Medi-span's price history table was queried by pulling the most recent package WAC on or before 01/01/2022. If no WAC was identified in the price history table on or before 01/01/2022, the section was marked "No Data."

Data was aggregated across associated NDCs using the AVERAGEIF formula in Excel for NDCs tied to the grouped drug.

End 2022 package WAC

Data sources: Medi-span

Definition: The wholesale acquisition cost (WAC) for a package of the drug as of 12/31/2022.

Technical notes: The Medi-span's price history table was queried by pulling the most recent package WAC on or before 12/31/2022. If no WAC was identified in the price history table on or before 12/31/2022, the section was marked "No Data."

Data was aggregated across associated NDCs using the AVERAGEIF formula in Excel for NDCs tied to the grouped drug.

WAC price change % 2022

Data sources: Calculated using the "Beginning 2022 package WAC" and "End 2022 package WAC," which were pulled from Medi-span.

Definition: The price increase/decrease in the average package WAC from the beginning to the end of 2022.

Formula: (End of 2022 package WAC – Beginning of 2022 package WAC) / Beginning of 2022 package WAC

Avg YoY price change (over the past five years)

Data sources: Medi-span

Definition: Average percent of the change in the year-over-year unit WAC for the last five years.

Methodology notes

Data pulled from Medi-span on 08/15/2023

All calculations below were conducted at the NDC level unless otherwise specified:

- Calculated **$ YoY change in Unit WAC** by subtracting **unit WAC from previous year** from **unit WAC from basis year.**
- Calculated **% YoY change in Unit WAC** by dividing **$ YoY change in Unit WAC** by **unit WAC from basis year.**
- Calculated **average % YoY change in Unit WAC over trailing 5 years** by taking the average of **% YoY change in Unit WAC** for all years with data.
- Aggregated data by named drug by averaging **average % YoY change in Unit WAC over trailing 5 years** for all NDCs.

Example

Year	previous year unit WAC	basis year unit WAC	$ YoY change in Unit WAC	% YoY change in Unit WAC
2019	$ 100	$ 110	$ 10	9.09%
2020	$ 110	$ 115	$ 5	4.35%
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2022	$ 120	$ 130	$ 10	7.69%
2023	$ 130	$ 137	$ 7	5.11%
Average % YoY change in Unit WAC over trailing 5 years				6.08%

Data was aggregated across associated NDCs using the AVERAGEIF formula in Excel for NDCs tied to the grouped drug.

Affordability review

Average WAC

Data sources: Medi-span

Definition: The most recent package WAC[1] for the drug, averaged across all national drug codes.

[1] The date Medi-span data that was queried will be included in any affordability reviews

Technical notes: Medi-span's price history table was queried by pulling the most recent package WAC for each NDC. The average WAC was calculated by summing together the package WAC and dividing by the total count of NDCs with WAC data in Medi-span.

Percent average year-over-year change in WAC

Data sources: Medi-span
Definition: Average percent of the change in the year-over-year package WAC for the last five years.

Technical notes: Medi-span's price history table was queried by pulling the most recent package WAC for each NDC as of December 31st of the report year. The average package WAC was then calculated by summing together the package WAC and dividing by the total count of NDCs with WAC data in Medi-span for the report year. Next, the change in WAC between each year was calculated using the following formula:

(Current year average package WAC – prior year average package WAC)/ prior year average package WAC

In the final calculation step, the percentage change values for the last five years were averaged to calculate the percent average year-over-year change in package WAC for the last five years.

Oregon Prescription Drug
Affordability Board

Survey on Affordability Review Criteria

Brekke Berg, data analyst

Affordability review criteria survey

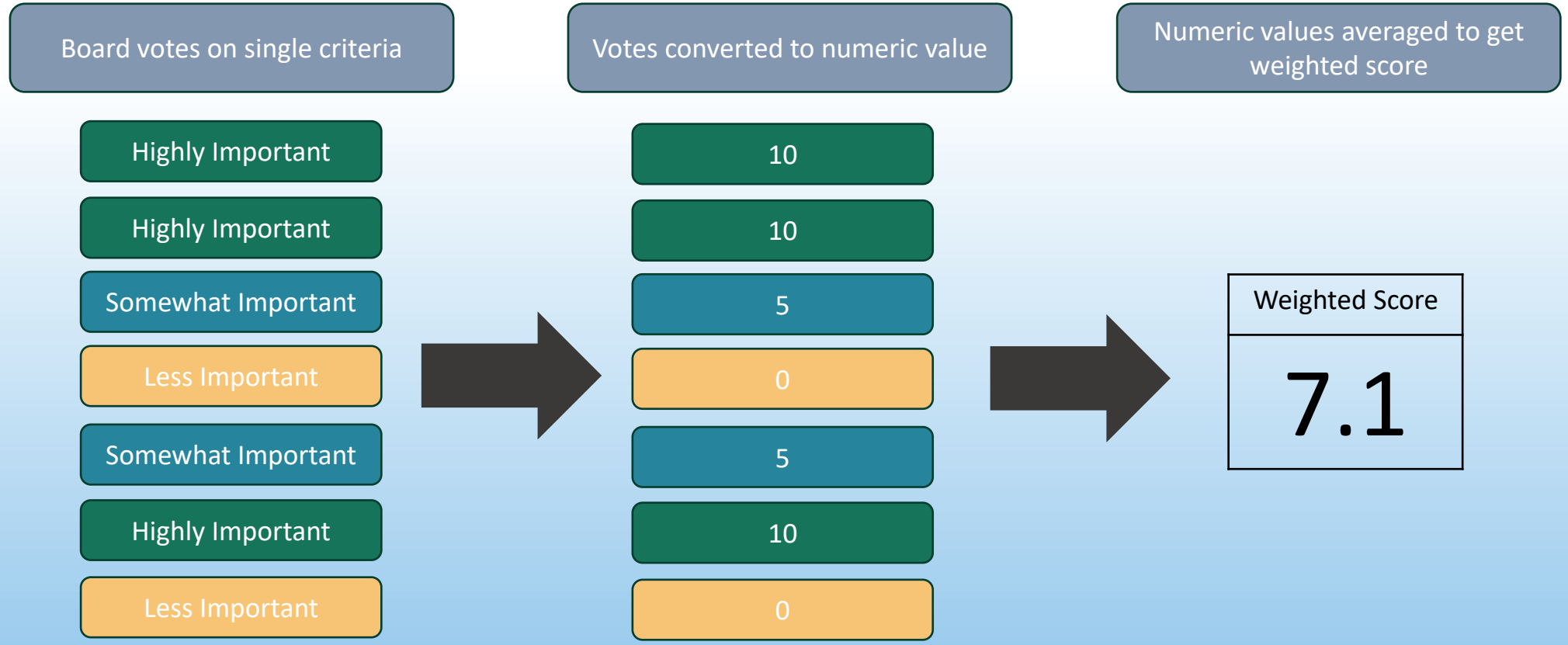
What we will discuss:

- Survey background
- Results
- How we use the results

Survey background

- Summarized 40 + criteria into 21 questions
- Asked board members to rank each criteria
- Calculated average rank

How results were calculated



Oregon Prescription Drug Affordability Board

Results Ranked Numerically

Criteria	Average Score
The price for the prescription drug sold in this state	10.0
The estimated average patient copayment or other cost-sharing for the prescription drug in this state.	10.0
Input from Patients and Caregivers	8.6
Whether the prescription drug has led to health inequities in communities of color.	7.9
The impact on patient access to the drug considering standard prescription drug benefit designs in health insurance plans offered in this state.	7.9
Effect of price on consumers' access to the prescription drug by reviewing changes in pricing, expenditure, and utilization over time.	7.9
The number of residents in this state prescribed the prescription drug	7.1
Input from Individuals with Scientific or Medical Training	7.1
The estimated price for therapeutic alternatives to the drug that are sold in this state	6.4
The estimated costs to health insurance plans based on patient use of the drug consistent with the labeling approved by the United States Food and Drug Administration and recognized standard medic...	6.4
The estimated average monetary price concession, discount or rebate the manufacturer provides to health insurance plans in this state or is expected to provide to health insurance plans in this st...	5.7

Criteria	Average Score
Whether the drug is designated by the United States Food and Drug Administration (FDA), under 21 U.S.C. 360bb, as a drug for a rare disease or condition	5.0
Input from Safety Net Providers	5.0
Input from Payers	5.0
The estimated manufacturer net-sales or estimated net-cost amounts (including rebates, discounts, and price concessions) for the prescription drug and therapeutic alternatives; and financial assis...	5.0
Information from the Oregon Health Authority (OHA), Health Evidence Review Commission (HERC), and Pharmacy and Therapeutics Committee (P&T) that is relevant to the prescription drug or therapeutic...	5.0
The estimated total amount of the price concession, discount or rebate the manufacturer provides to each pharmacy benefit manager registered in this state for the prescription drug under review, e...	4.3
The estimated average price concession, discount or rebate the manufacturer provides or is expected to provide to health insurance plans and pharmacy benefit managers in this state for therapeutic...	4.3
The relative financial impacts to health, medical or social services costs as can be quantified and compared to the costs of existing therapeutic alternatives.	3.6
Potential market for prescription drug for labeled and off-label indications and budget impact on various payors in the state.	2.9
Any information a manufacturer chooses to provide.	1.4

Survey results – highly important (Scores of 6.7 - 10.0)

- The price for the prescription drug sold in this state
- The estimated average patient copayment or other cost-sharing information
- Input from patients and caregivers
- Whether the prescription drug has led to health inequities in communities of color
- The impact on patient access to the drug considering standard prescription drug benefit designs in health insurance plans offered in this state
- Effect of price on consumer access to the prescription drug by reviewing changes in pricing, expenditure, and utilization over time
- The number of residents in this state prescribed the prescription drug
- Input from individuals with scientific or medical training

Survey results – somewhat important (Scores of 3.3 - 6.6)

- The estimated price for therapeutic alternatives to the drug that are sold in this state
- The estimated costs to health insurance plans based on patient use of the drug consistent with the labeling approved by the FDA and recognized standard medical practice
- Estimated average monetary price concession, discount or rebate the manufacturer provides to insurance plans in this state
- Whether the drug is designated by the FDA as a drug for a rare disease or condition
- Input from safety net providers
- Input from payers

Survey results – somewhat important (Scores of 3.3 - 6.6)

- The estimated manufacturer net-sales or estimated net-cost amounts (including rebates, discounts, and price concessions) for the prescription drug and therapeutic alternatives; and financial assistance the manufacturer provides to pharmacies, providers, consumers, and other entities
- Information from OHA, HERC and P&T that is relevant to the prescription drug or therapeutic alternative under review
- The estimated total amount of the price concession, discount or rebate the manufacturer provides to each PBM registered in this state
- The estimated average price concession, discount or rebate the manufacturer provides to health insurance plans and PBMs in this state for therapeutic alternatives
- The relative financial impacts to health, medical or social services costs as can be quantified and compared to the costs of existing therapeutic alternatives

Survey results – less important (Scores of 0.0 - 3.2)

- Potential market for prescription drug for labeled and off-label indications and budget impact on various payors in the state
- Any information a manufacturer chooses to provide

How we will use survey results

- Make them available to you
- Direct PDAB team research
- Get weighted rank for all drugs

Calendar Option 1 if the board removes four drugs and four insulin products suggestion by staff

Board meeting Month & Date	Drugs	Estimated time per drug to review, discuss & vote	Time per public comment or testimony	Cutoff date for manufacturer & stakeholder written materials/info received	PDAB staff deadline for posting agenda	PDAB staff deadline for packet material including: • Public comments • Rx report	PDAB staff for posting meeting material
Jan. 17	All Insulins • Long Acting: Tresiba & Tresiba Flextouch • Rapid Acting: Insulin Aspart & Aspart Pen • Short Acting: HumuLIN U-500	35 min.	10 min.	Dec. 27	Jan. 3	Jan. 8	Jan. 10
Feb. 21	Group 1: • Shingrix • Rybelsus/Ozempic • Trulicity	35 min.	10 min.	Jan. 31	Feb. 7	Feb. 12	Feb. 14
March 20	Group 2: • Ocvrevus • Entyvio • Inflectra	35 min.	10 min.	Feb. 28	March 6	March 11	March 13
April 17	Group 3: • Cosentryx • Skyrizi • Tremfya	35 min.	10 min.	March 31	April 3	April 8	April 10
May 15	Group 4: • Vyvanse • Genvoya • Triumeq	35 min.	10 min.	April 30	May 1	May 6	May 8

Calendar Option 2 if the board keeps all 16 drugs and insulin products for affordability review

Board meeting Month & Date	Drugs	Estimated time per drug to review, discuss & vote	Time per public comment or testimony	Cutoff date for manufacturer & stakeholder written materials/info received	PDAB staff deadline for posting agenda	PDAB staff deadline for packet material including: • Public comments • Rx report	PDAB staff for posting meeting material
Jan. 17	All Insulins • Long Acting: Tresiba, Tresiba FlexTouch, Soliqua, & Xultophy • Rapid Acting: Insulin Aspart, Insulin Aspart PenFill, Lyumjev, & Lyumjev KwikPen • Short Acting: HumuLIN R, and HumuLIN U-500	11 min.	10 min.	Dec. 27	Jan. 3	Jan. 8	Jan. 10
Feb. 21	Group 1: • Shingrix • Rybelsus/Ozempic • Trulicity • Creon/Pancreaze/Pertzye/Viokace/Zenpep	20 min.	10 min.	Jan. 31	Feb. 7	Feb. 12	Feb. 14
March 20	Group 2: • Ocvrevus • Entyvio • Inflectra • Budesonide-Formoterol Fumarate/ Symbicort	20 min.	10 min.	Feb. 28	March 6	March 11	March 13

April 17	Group 3: • Cosentryx • Skyrizi • Tremfya • Albuterol Sulfate/Albuterol Sulfate ER /Albuterol Sulfate HFA/ProAir HFA/ProAir RespiClick/Proventil HFA/ Ventolin HFA	20 min.	10 min.	March 31	April 3	April 8	April 10
May 15	Group 4: • Vyvanse • Genvoya • Triumeq • Bunavail/Buprenorphine HCl-Naloxone HCl/Suboxone/Zubsolv	20 min.	10 min.	April 30	May 1	May 6	May 8

Email: pdab@dcbs.oregon.gov Phone: 971-374-3724 Website: dfr.oregon.gov/pdab

[Drug Name] Affordability Review

Table of Contents

Review Summary

The Prescription Drug Affordability Board (PDAB) conducted an affordability review for **[drug name]**. In 2022, the drug was prescribed to **[APAC number of enrollees]** [1] Oregonians who have a prescription drug benefit from a health insurance carrier or government sponsored healthcare program.

Table 1 Summary of costs to the patient

Costs to the patient		
	Source	**Amount**
Average annual out of pocket cost per patient	**[APAC]**	**[Average Annual Out of Pocket Cost per Patient]**

Table 2 Summary of costs to the healthcare system

Costs to the healthcare system		
	Source	**Amount**
Total annual cost for payers	**[APAC]**	**[Total Annual Spend]**
Average annual cost for payers per enrollee	**[APAC]**	**[Cost per enrollee]**
Average annual drug price pre price concessions	**[Data call]**	**[Average cost pre-discounts]**
Average annual drug price post price concessions	**[Data call]**	**[Average cost post-discounts]**
Percentage of drug price concessions	**[Data call]**	**[Percent of price concessions for the drug]**
Medicaid fee for service cost		

[1] Number of 2022 unique enrollees from Oregon's All Payers All Claims (APAC) data. For more information regarding APAC data visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx

Review background

Senate Bill 844 (2021) created the Prescription Drug Affordability Board (PDAB) to evaluate the cost of prescription drugs and determine whether they may present an affordability challenge for consumers and health systems in Oregon.

In accordance with OAR 925-200-0020, the Prescription Drug Affordability Board (PDAB) will conduct an affordability review on the prioritized subset of prescription drugs, selected under OAR 925-200-0010 to identify nine prescription drugs and at least one insulin product that may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon.

Information in this report was provided by the Department of Consumer and Business Services (DCBS) for the PDAB to review per ORS 646A.694.

Additional information for this review was gathered from Oregon's All Payers All Claims (APAC) database, state licensed insurance carriers responding to a DCBS data call, Medi-Span, and resources from the U.S. Food and Drug Administration (FDA) such as the Orange Book (small molecule drugs) and the Purple Book (biologics).

Drug information

Drug proprietary name(s): **[proprietary name(s)]**

Non-proprietary name: **[generic/non-proprietary name]**

FDA approval

[Drug name] was first approved by the FDA on **[date of first FDA approval]**[2].

The drug qualified for the following expedited forms of approval: **[list of applicable expedited approvals, example "Breakthrough therapy, fast track" or list "None"]**

DCBS staff reviewed the FDA orphan drug database and determined, as of the time of the review, that the drug had no approved indications with designations under the Orphan Drug Act.

[2] FDA approval date based on the earliest occurring approval dates in the FDA Orange/Purple Book. For drugs with multiple forms/applications, staff used the earliest approval date across all related FDA applications.

Clinical profile

Drug indications

- List the FDA approved indications for the drug
- List common off label uses (if applicable)

Clinical Efficacy

- Brief, high-level summary of clinical efficacy data supporting FDA approval and showing improvement in clinical outcomes

Clinical Safety

- FDA safety warnings
- Safety advantages or disadvantages compared to alterative agents

Therapeutic alternatives

- List information regarding any identified therapeutic alternatives
- Drug's comparative effectiveness information to therapeutic alternatives

Additional information

- Oregon Health Authority, Health Evidence Review Commission data, and Oregon Pharmacy & Therapeutics (P&T) Committee input (if applicable)

Cost profile

Pricing information

The average package wholesale acquisition cost (WAC) for **[drug name]** was **[Average WAC]**[3] as of **[date of data pull]**.[4]

The WAC for the drug was reviewed using Medi-span's price history tables for the package WAC from **[date of first FDA approval or the beginning of the time frame we want to look at]** to **[date of data pull]**. Over **[timeframe to review the YoY change]** the average year-over-year change to the package WAC was calculated and determined to be **[insert the % average YoY change in WAC]**. This historical change in the package WAC is displayed in figure 1.

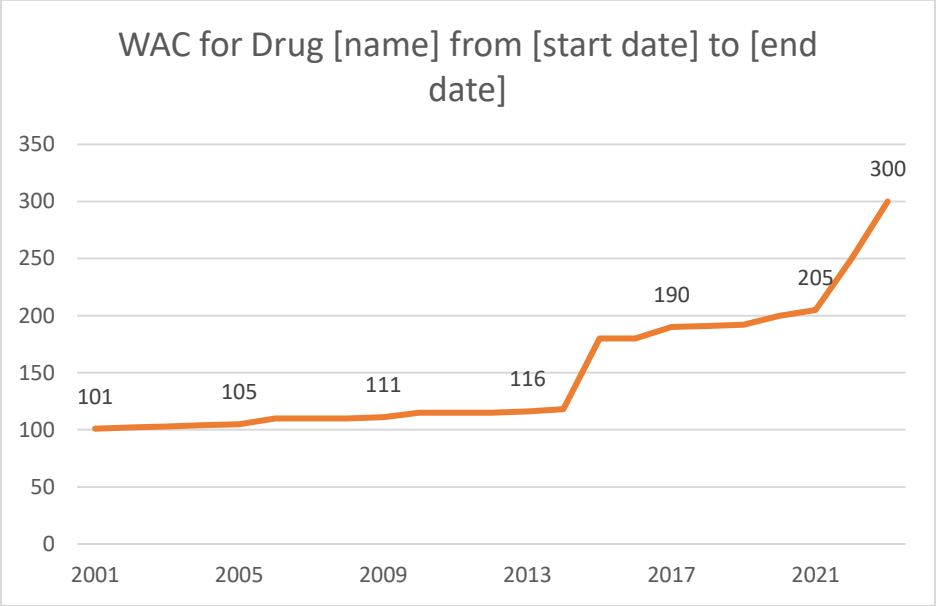


Figure 1 Drug WAC over Time

Package WAC was reviewed as an indication of historic price trends for the drug. However, as WAC does not account for discounts, rebates, or other changes to the drug's cost throughout the supply chain, DCBS staff reviewed APAC claims from 2022 and data call submissions from state insurance carriers to better determine costs associated with the drug.

Based on the data received from the carrier data call, the average annual price for insurance carriers to obtain the drug was **[average price pre-price concessions]** before any discounts, rebates, or other price concessions. The average annual price for insurance carriers to obtain the drug after discounts, rebates, and other price concessions was **[average price post price**

[3] The methodology used for calculating the average WAC is listed on the PDAB website at: https://dfr.oregon.gov/pdab/Documents/PDAB-Data-Calculations-Methodology.pdf
[4] Ibid.

concessions], meaning that insurers reported an average of a **[insert price concessions percentage]** discount on the initial drug price.

The breakdown of the pre-price concessions and percentage of reported price concessions is represented in figure 2.

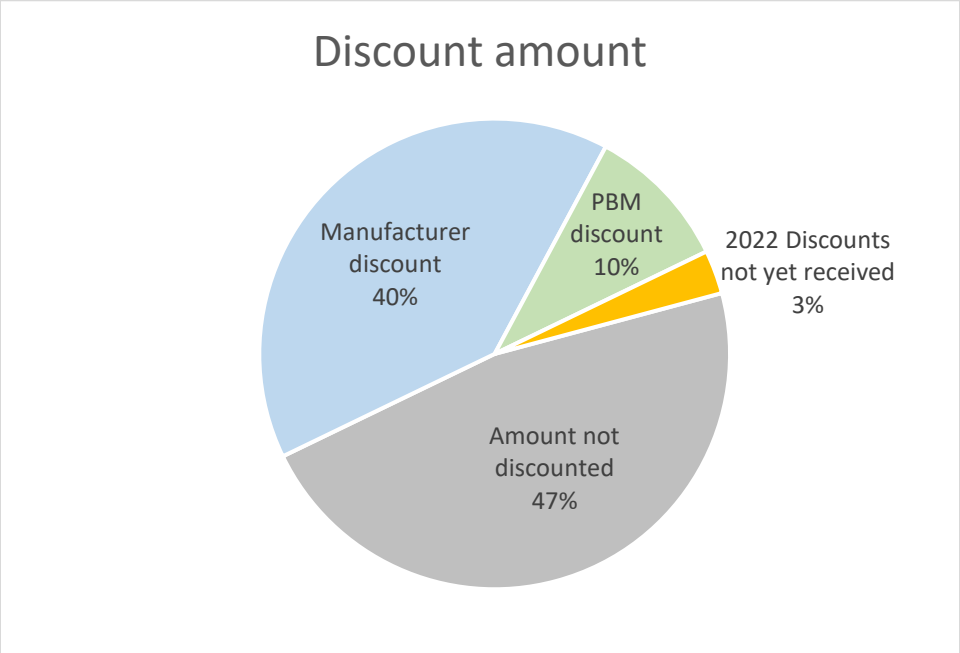


Figure 2 Impact of price concessions on drug price

To the extent such information can be quantified, the relative financial effects of the prescription drug on broader health, medical, or social services costs, compared with therapeutic alternatives or no treatment

To the extent such information can be quantified, the total cost of the disease and the drug price offset.

Cost to stakeholders

Cost to patients

DCBS staff reviewed data from the APAC database and the carrier data call[5] to determine the average patient copayment or other cost-sharing for the prescription drug.

Table 3 Out of Pocket Costs

2022 Average Annual Patient Out of Pocket Costs[6]		
Value	**APAC**	**Data Call**
Average Co-Pay	**[APAC Copay]**	**[Data Call Co Pay]**
Average Deductible	**[APAC Deductible]**	**[Data Call Deductible]**
Average Coinsurance	**[APAC Coinsurance]**	**[Data Call Coinsurance]**
Other Cost Sharing	**[APAC other cost sharing]**	**[Data Call other cost sharing]**
Total Out-of-Pocket Costs for Patients[7]	**[Sum of APAC out of pocket costs]**	**[Sum of data call out of pocket costs]**

Cost to health benefit plans

DCBS staff reviewed data from the APAC database and the data call[8] to determine both the total annual spend and cost per patient for health insurance benefit plans.

2022 Annual Costs to health plans[9]		
Value	**APAC[10]**	**Data Call[11]**
Total Annual Spend	**[APAC Total Annual Spend]**	**[Data Call Total annual spend]**
Total Annual Spend per Patient	**[APAC annual spend per patient]**	**[Data call annual spend per patient]**

- Include budget impact analysis if available

[5] Prices and costs from the All Payers All Claims (APAC) database are prior to any price concessions such as discounts or coupons. Price information from the data call is the price of the drug after price concessions.
[6] Medicaid and Medicare were excluded from cost information.
[7] For patients who used the drug at least once in the 2022 calendar year.
[8] Prices and costs from the All Payers All Claims (APAC) database are prior to any price concessions such as discounts or coupons. Price information from the data call is the price of the drug after price concessions.
[9] Medicaid and Medicare were excluded from cost information.
[10] APAC total cost may include a dispensing fee and physician administration fees.
[11] Data call information is only a sample from health insurance carriers and therefore will have a lower total annual spend amount than APAC data. Data call spend information includes discounts, rebates, and other price concessions.

Cost to the state medical assistance program[12]

Gross amount paid for Medicaid/Oregon Health Plan fee for service					
Drug	**Amount paid**	**% Total fee for service costs**	**Claim count**	**Average paid per claim**	**Preferred drug list (PDL)[13]**
[drug name]	[OSU DURM amount paid]	[OSU DURM percent of total fee for service costs]	[OSU DURM claim count]	[OSU DURM average paid per claim]	[OSU DURM preferred drug list]

Gross amount paid fee for Medicaid CCO			
Drug	**Amount paid**	**Claim count**	**Average paid per claim**
[drug name]	[amount paid]	[claim count]	[average paid per claim]

- List any relative financial effects on health, medical, & social service costs

Cost of Therapeutic Alternatives

- WAC

[12] Source: Oregon State University Drug Use and Research Management DUR utilization reports 2022. DUR Reports | College of Pharmacy | Oregon State University

[13] PDL key" Y = Preferred, V= Voluntary, Blank = Non PDL class

- National Average Drug Acquisition Cost (NADAC) or Oregon Average Actual Acquisition Cost AAAC[14] [15], Average Sales Price[16] (ASP) (if data is available)
- Percent difference in therapeutic alternative NADAC vs. baseline drug NADAC
- APAC data comparison table (if data is available)

Access profile

Review of rejected claims and drug benefit designs

Carriers reported **[total number of claims data call]** claims for **[drug]** in 2022. Of those claims **[total number of paid claims data call]** were paid and **[total number of rejected claims data call]** were rejected[17]. Based on this information, on average, **[percent of rejected claims]** of **[drug name]** were rejected in 2022.

Pharmaceutical claims may be rejected for a variety of reasons including patients trying to fill the prescription too soon or errors in the submitted claim. Pharmacists may also submit multiple claims for the same prescription should the initial claim be rejected. Therefore, claims information should only be used as a general baseline.

As part of the carrier data call, DCBS staff requested information regarding prior authorizations and approval for the drug. Insurers reported a wide variety of plan designs for **[drug name]**. Unfortunately, the data call did not include the number of Oregonians under each plan listed, so DCBS was unable to determine the volume of Oregonians under plans that required prior authorization. Carriers reported a variety of plans, some with a more restrictive plan design and other plans with a more accessible plan design for the drug.

Based on the information available, DCBS staff reviewed how many carriers had at least one plan that represented the following for **[drug name]**:

Table 4 Plan design analysis

Number of carriers that had one or more plans that:	
Required prior authorization	**[number of carriers requiring prior authorization]**
Did not require prior authorizations	**[number of carriers NOT requiring prior authorization]**

[14] https://secure.sos.state.or.us/oard/viewSingleRule.action?ruleVrsnRsn=242930#:~:text=(y)%20%E2%80%9COregon%20Average%20Actual,distribution%20centers%20for%20the%20product

[15] "Oregon Average Actual Acquisition Cost (OR-AAAC)" means the rate that is established by the Division or its contractor by rolling surveys of enrolled pharmacies to verify the actual invoice amount paid by the pharmacy or corporate entity to wholesalers, manufacturers, or distribution centers for the product.

[16] The ASP is the weighted average of all manufacturer sales prices, including most rebates and discounts. Manufacturers report the ASP for Part-B drugs to CMS.

[17] For the purpose of this review the terms "denied" and "rejected" for claims are used interchangeable.

Number of carriers that had one or more plans that:	
Drug was excluded on the plan formulary	**[number of carriers listing the drug as excluded]**
Drug was non-preferred on the plan formulary	**[number of carriers listing the drug as non-preferred]**
Drug was preferred on the plan formulary	**[number of carriers listing the drug as preferred]**
Required step therapy	**[number of carriers requiring step therapy]**
Did not require step therapy	**[number of carriers not requiring step therapy]**

Utilization and Health Equity

Based on APAC claims, **[number of enrollees]** Oregonians filled a prescription for **[drug name]** in 2022.

- List any available health disparity information (e.g., Social Vulnerability Index, rural pharmacy impacts)
- Patient and caregiver input
- 340B provider input

Stakeholder Feedback

Feedback was submitted from **[start date of the feedback period]** to **[end date of the feedback period]**.

Links to the full feedback documents are included in the sections below.

Input received from the medical and scientific community

- Bulleted list with links to the feedback documents. Include the name of the source, the affiliated organization/company they are representing, and the date the feedback was received.
- Alternatively, if including full documents in the appendix, list the associated appendix location (i.e., Appendix C or Appendix F, etc.).

Manufacturer submitted information

- Bulleted list with links to the feedback documents. Include the name of the source, the affiliated organization/company they are representing, and the date the feedback was received.
- Alternatively, if including full documents in the appendix, list the associated appendix location (i.e., Appendix C or Appendix F, etc.).

Patient feedback and additional stakeholder feedback

- Bulleted list with links to the feedback documents. Include the name of the source, the affiliated organization/company they are representing (if applicable), and the date the feedback was received.
- Alternatively, if including full documents in the appendix, list the associated appendix location (i.e., Appendix C or Appendix F, etc.).

Appendix

Potential appendix items may include:

- Links to any supporting documentation, resources, etc.
- Public comments
- Documents or data submitted by the manufacturer
- Institute for Clinical and Economic Review (ICER) data and reports

Oregon Prescription Drug Affordability Board

Public comment process for prescription drugs under board review

The Prescription Drug Affordability Board (PDAB) will conduct affordability reviews during the first five board meetings in 2024. The board will review insulin products at the January meeting. At each of the February, March, April, and May meetings, the board will review *three or four* drugs selected from the prioritized subset of prescription drugs identified by the board pursuant to OAR 925-200-0010. The list of prescription drugs to be reviewed at each board meeting will be posted in advance on the PDAB website.

The board invites the public to provide comments about the drugs under review, including comments from patients and caregivers affected by the conditions and diseases treated by those drugs, comments from individuals with scientific or medical training related to those conditions and diseases, and comments from the other stakeholders identified in OAR 925-200-0020(2)(k). All drug-specific comments submitted in accordance with board policy, this guidance, and the deadlines shown in Table 1 below will be considered by the board in connection with its affordability reviews.

Those who wish to provide written comments related to a particular prescription drug should complete and submit the public comment form located on the PDAB website at least nine days before the board meeting at which that particular drug will be reviewed. Compliance with this deadline is necessary to allow timely board review of all drug-specific written comments and to ensure the inclusion of all written comments in the materials posted on the PDAB website in advance of the board meeting. Written comments submitted after the applicable deadlines may not be considered by the board in connection with its affordability reviews.

Those who wish to provide oral comments related to a particular prescription drug during the public comment portion of the applicable board meeting should complete and submit the public comment form located on the PDAB website at least 24 hours before the meeting at which that particular drug will be reviewed. The meeting time allocated for public comment will be limited to allow the board sufficient time to conduct a thorough and complete discussion and review of the specific drugs on the meeting agenda. For this reason, it is recommended that those wishing to provide more extensive or detailed public comments submit their comments in writing.

No trade secret information should be included in public comments or manufacturer submissions. All public comments and manufacturer submissions will be posted on the PDAB website for public view.

Table 1: Deadlines for submitting public comments specific to prescription drugs under board review

Meeting date and time	Deadline for general written comments (not specific to drugs under review) *	Deadline for signing up to give oral testimony at a board meeting	Deadline for written comments specific to drugs under review at the next board meeting**
Jan. 17, 2024, 9:30 am	Jan. 14, 2024 @ 9:30 am	Jan. 16, 2024 @ 9:30 am	Jan. 8, 2024 @ 9:30 am
Feb. 21, 2024, 9:30 am	Feb. 18, 2024 @ 9:30 am	Feb. 20, 2024 @ 9:30 am	Feb. 12, 2024 @ 9:30 am
Mar. 20, 2024, 9:30 am	Mar. 17, 2024 @ 9:30 am	Mar. 19,2024 @ 9:30 am	Mar. 11, 2024 @ 9:30 am
Apr. 17, 2024, 9:30 am	Apr. 14, 2024 @ 9:30 am	Apr. 16, 2024 @ 9:30 am	Apr. 8, 2024 @ 9:30 am
May 15, 2024, 9:30 am	May 12, 2024 @9:30 am	May 14, 2024 @ 9:30 am	May 6, 2024 @ 9:30 am
	* Written general comments submitted later than 72 hours will be addressed at the next board meeting.		* * The board may not consider drug-specific written comments submitted after the applicable deadline.

Oregon Prescription Drug Affordability Board

2023 POLICY RECOMMENDATIONS

Introduction

The Prescription Drug Affordability Board (PDAB) was established under Senate Bill 844 (2021) and is supported by the Department of Consumer and Business Services (DCBS). The PDAB aims to protect residents of the State of Oregon, state and local governments, commercial health plans, health care providers, pharmacies licensed in the state, and other stakeholders within the health care system of Oregon from the high costs of prescription drugs.

At its implementation, the PDAB had five voting members and three alternate members with expertise in healthcare economics and clinical medicine. In September 2023, under Senate Bill 192, alternate members became full voting members. The board now consists of eight members appointed by the governor to conduct affordability reviews to identify drugs that may present affordability challenges to Oregon residents or health systems. At the time of this writing, the board consists of seven members with one vacancy.

Senate Bill 844, Section 5

The board is required by statute to report to the Legislature and the Oregon Health Authority's Health Care Cost Growth Target program price trends of prescription drugs provided to the board from DCBS, a list of nine drugs and at least one insulin product that may create affordability challenges, and any recommendations for legislative changes to make prescription drug products affordable in Oregon.

Section 5(1): price trends

The board is in the process of studying price trends and will submit the findings in June 2024.

Section 5(2): affordability review

Given the depth and breadth of analysis and decision-making involved in the affordability review process, the board will submit the list in June 2024.

Section 5(3): recommendations

The PDAB is submitting four recommendations for legislative changes necessary to make prescription drug products more affordable in this state.

The PDAB solicited concepts for policy recommendations from the public that were solution-based to address prescription drug affordability concerns. The board received policy recommendations from six stakeholders: American Diabetes Association; Chronic Disease Coalition; Strategies360; Johnson & Johnson; and PhRMA. The board also received recommendations from four groups who presented industry information at board meetings in

2023: Oregon State Pharmacy Association (OSPA); Oregon Primary Care Association (OPCA); America's Health Insurance Plans (AHIP); and T1International.

Commented [CW1]: Chair Akil Patterson recommended identifying the four presenting groups.

The board determined some of the policy recommendations would require further study of the issues, along with robust stakeholder engagement. The board selected the following four policy recommendations:

1) **Lower insulin co-pay limit to $35 and/or decouple from inflation index**
   In 2021, Oregon adopted a law (ORS 743A.069) capping patient out-of-pocket cost for insulin for enrollees of state-regulated health plans, with increases annually indexed to inflation as measured by the Consumer Price Index – G (CPI-G). Inflation has generally been higher than expected in 2022-23, leading to faster growth in the CPI-G and faster than anticipated growth in Oregon's insulin cap, which will be $85 during plan year 2024. Concurrently, additional generic insulins were brought to market and prominent manufacturers of brand-name insulins have dropped their list prices. Due to this, the $85 cap in 2024 will be significantly higher than the actual acquisition cost for most insulin prescriptions in Oregon.

   PDAB supports the American Diabetes Association's (ADA) proposal to lower Oregon's statutory insulin copay maximum to $35. This would align Oregon law with the recently adopted federal maximum for Medicare and many other state laws. The ADA and T1International also proposed decoupling Oregon's insulin copay law from the Consumer Price Index.

   Lowering the insulin cap can lower out-of-pocket costs for consumers who rely on more expensive insulin, with little impact on overall payer costs. Given the reduced list price for standard insulins, Oregon's law as currently written, does not apply to most insulin purchases.

2) **Change Oregon's statute language regarding substitution requirements for biological products and biosimilars**
   The board recommends updating ORS 689.522, which addresses substitution of biological products and limits how substitutions can be made, to include biosimilar products and interchangeable biosimilar language. The board supports using the definition for biosimilars that is consistent with 42 USC 262(i)(2). This change could lead to broader adoption of biosimilar substitutions. In addition, since physicians could still direct a pharmacy not to perform substitution for a particular patient, individuals who experience adverse outcomes with a biosimilar would still be able to access branded biological products. Increased adoption of biosimilars and interchangeable biosimilars has the potential to generate significant savings for the whole health system.

   Biosimilars are similar to the FDA-approved reference product and provide more availability for treatment options, have the same safety and effectiveness as the reference product,

and most often lower costs to patients and the health care system. Currently, there are 44 FDA-approved biosimilar products available for 11 reference products.[1] Biosimilars are a growing category in a market where almost all the highest-cost medications are biological products. This is particularly notable for drugs like Humira, which faces biosimilar competition in the United States for the first time this year and has consistently been the most significant driver of increased plan spending in Oregon's data.[2] However, despite the much lower cost, some reports show low adoption of Humira biosimilars, primarily due to the manufacturer's ability to leverage other drugs in its catalog to maintain priority formulary placement for Humira.

The Oregon Coalition for Affordable Prescriptions (OCAP) and America's Health Insurance Plans (AHIP) proposed amending the language in ORS 689.522 to ensure access to substituted biosimilar products where they are available. OCAP and AHIP's proposed amendments to ORS 689.522 specify that the substituted biological product must be licensed by the U.S. Food & Drug Administration (FDA) as a biosimilar. They also proposed removing requirements about notifying patients of substitutions and posting interchangeable products on the Board of Pharmacy website. The board does not support those changes.

3) Expand PBM reporting requirements for more transparency

The Chronic Disease Coalition, Johnson & Johnson, Pharmaceutical Research and Manufacturer's Association (PhRMA), and the International Cancer Advocacy Network all proposed improving transparency of pharmacy benefit managers (PBMs) activity by expanding reporting requirements, pointing to the Oregon Secretary of State's 2023 audit of PBMs serving Medicaid.[3] Oregon will begin collecting PBM data in 2024 following the passage of the Senate Bill 192 (2023), which requires PBMs to report aggregated amounts for rebates, fees, price protection payments, and how those discounts are allocated. However, stakeholders provided additional recommendations to require that rebates, discounts, or any savings negotiated by PBMs be passed to patients at the pharmacy counter and to prohibit the steering of individuals to use PBM owned or affiliated pharmacies.

Transparency laws can impact corporate behavior, but the effect is often attenuated. However, minimal public information about PBM business practices and pricing models makes state regulation of PBMs difficult. Collecting additional data could generate more

[1] "Biosimilar Product Information." U.S. Food & Drug Administration, Nov. 1, 2023. https://www.fda.gov/drugs/biosimilars/biosimilar-product-information. Accessed Nov. 27, 2023.
[2] "Oregon Drug Price Transparency Program Annual Report 2022." Oregon Drug Price Transparency Program, Nov. 30, 2022. https://dfr.oregon.gov/drugtransparency/Documents/Prescription-Drug-Price-Transparency-Annual-Report-2022.pdf. Accessed Nov. 27, 2023.
[3] "Oregon Health Authority, Pharmacy Benefit Managers: Poor Accountability and Transparency Harm Medicaid Patients and Independent Pharmacies." Oregon Secretary of State Audits Division, August 2023. https://sos.oregon.gov/audits/Documents/2023-25.pdf. Accessed Nov. 27, 2023.

insight into the role of PBMs in drug pricing and support the development of more substantive policy recommendations concerning PBMs in the future.

4) (PROVISIONALLY) Require payers to reimburse pharmacies at cost

The Oregon State Pharmacy Association (OSPA) has proposed adopting a cost-plus-fee reimbursement model for pharmacies. This idea is roughly analogous to the provisions of Oregon House Bill 3013 (2023), which did not get enacted. This bill would have required a minimum dispensing fee and reimbursement at the same level as Medicaid fee-for-service in Oregon. These costs are based on survey data reflecting the pharmacy's actual cost to dispense and purchase pharmaceutical products.[4]

The recommendation to adopt a cost-plus-fee reimbursement would provide further transparency of drug costs between payers, pharmacy benefit managers (PBMs), and pharmacies. When pharmacies are reimbursed at cost, it stabilizes pharmacies and prevents significant losses such as store closures, reduced working hours, or access barriers for individuals and communities. This proposal will likely benefit retail pharmacies by increasing reimbursement for filling prescriptions. However, if the Oregon Health Plan is subject to this requirement, it is also likely to increase the cost of administering pharmacy benefits for the state and coordinated care organizations. Consumers with commercial coverage could also see higher premiums and out-of-pocket costs for prescriptions.

The cost of drugs to individual consumers and the health care system is the result of many overlapping factors, making the net impact of such a fundamental change to the PBM reimbursement model challenging to predict.

The Oregon State Pharmacy Association (OSPA) has proposed a cost-plus-fee reimbursement model for pharmacies which would require a minimum dispensing fee and reimbursement at the same level as Medicaid fee-for-service. These costs are based on survey data already collected reflecting the pharmacy's actual cost to dispense and purchase price of pharmaceutical products.

The recommendations to adopt a cost-plus-fee reimbursement would further provide transparency of drug costs between payers, pharmacy benefit managers (PBMs) and pharmacies. When pharmacies are reimbursed at cost, it stabilizes pharmacies and prevents significant losses such as store closures, reduced working hours and access barriers for individuals and communities.

Thirty-two pharmacies closed in Oregon in 2023. The pharmaceutical delivery system in Oregon, especially rural Oregon, is on the verge of collapse. Pharmacy deserts are a reality with large swaths of the state devoid of local, immediate pharmaceutical care. Stabilizing access to the most accessible

Commented [CW2]: John Murray proposed the following redlined language.

[4] "Understanding Pharmacy Reimbursement Trends in Oregon," Three Axis Advisors, October 2022. https://oregonpharmacy.org/wp-content/uploads/2022/10/Oregon_Pharmacy_Pricing_Report_3AA_1022-FINAL.pdf. Accessed Nov. 27, 2023.

healthcare provider in a community, the pharmacist, has been proven to be critical to the health of communities around them. Pharmacy response during the Covid pandemic showed this.

Beyond stabilizing the remaining pharmacy providers, meaningful PBM reform must be enacted. When states pass meaningful PBM reform, the increase in their average health insurance premium costs have been lower than the nationwide average. In fact, some states have seen a decrease in premium costs.

Summary

The Prescription Drug Affordability Board appreciates the policy recommendation concepts submitted from stakeholders to address prescription drug affordability concerns in Oregon. The board considered all the recommendations and carefully selected four to include in the annual report for the Oregon Legislature.

The board brings forward the following four (4) recommendations:

- Lowering insulin copays to align with current market price reductions;
- Enhancing substitution of biologicals product with biosimilar and interchangeable products;
- Expanding pharmacy benefit manager reporting requirements for more transparency; and
- Requiring payers to reimburse pharmacies at costs.

The board urges the Oregon Legislature to consider these recommendations to improve existing policies, reporting transparency, and reimbursement costs to pharmacies.