Oregon Prescription Drug Affordability Board

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Agenda

This is a regular meeting. *Date*: **June 26, 2024** | *Time*: **9:30 a.m.**
This agenda is subject to change.

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

Board Members: Chair Shelley Bailey; Vice Chair Amy Burns; Daniel Hartung; Robert Judge; Christopher Laman; John Murray; Akil Patterson

Staff: Ralph Magrish, executive director; Cortnee Whitlock, policy analyst; Stephen Kooyman, Heather Doyle, data analyst, Lou Savage, outreach coordinator, project manager; Melissa Stiles, administrative specialist; Jake Gill, counsel; Pramela Reddi, counsel

Purpose	Subject	Presenter	Estimated Time Allotted
Informational and vote	Call to order and roll call	Chair Bailey	2 minutes
Discussion and vote	Board discussion and approval of **05/15/2024 minutes**	Chair Bailey	3 minutes
Informational	Board declaration of conflict of interest	Chair Bailey	2 minutes
Informational	Executive director's program update	Ralph Magrish	5 minutes
Discussion and possible vote	Chair proposal regarding changing the timing of Affordability Reviews	Chair Bailey	10 minutes
Discussion	**Affordability review: Shingrix** • Drug-specific public comment • Board discussion	Ralph Magrish and Cortnee Whitlock	40 minutes including 20 minutes of public comment
Discussion	**Affordability review: Ocrevus** • Drug-specific public comment • Board discussion	Ralph Magrish and Cortnee Whitlock	40 minutes including 20 minutes of public comment
	5-minute break	Chair Bailey	5 minutes
Discussion	Senate Bill 192 upper payment limit (UPL) planning update	Ralph Magrish	5 minutes

Informational	Board review and discussion of the **UPL consumer outreach report**	Lou Savage	10 minutes
Informational	July meeting UPL constituent presentations and engagement	Chair Bailey	5 minutes
Informational	Announcements	Chair Bailey	3 minutes
Informational	General public comment *Comments will be limited to 3 minutes per person or organization. Written comments are reviewed by the board prior to the meeting.*	Chair Bailey	10 minutes
Informational	Adjournment	Chair Bailey	2 minutes

Next meeting

July 24, 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 provide testimony to the board

The Prescription Drug Affordability Board welcomes people to provide testimony. Testimony is when a person sends a letter to the board or signs up to speak during a board meeting. There are two types of testimony: general testimony is about any topic not related to the affordability review; affordability review testimony is about the drugs the board will consider during the affordability review process taking place between May and November 2024. There are two ways to provide testimony: oral or written. Oral testimony is speaking to the board during the public comment portion of the agenda. Written testimony is sending comments in writing to the board. Written comments will be posted to the PDAB website.

General testimony

- **Oral:** To speak during a board meeting about any topic not related to the affordability review, please submit the PDAB public comment form no later than 24 hours before the PDAB meeting.
- **Written:** to provide written comments about any topic not related to the affordability review, please submit the PDAB public comment form with attachments no later than 72 hours before the PDAB meeting.

Drug affordability review testimony

- **Oral:** To speak during a board meeting about a drug under reviewed by the board, please submit the PDAB public comment form no later than 24 hours before the PDAB meeting.
- **Written:** to provide written comments about a drug under review by the board, please submit the PDAB public comment form with attachments by the deadlines posted on the affordability review web page. Written comments specific to drugs under review and submitted by the deadlines below will be included in the affordability review drug reports that are posted one week before the meeting. However, written comments specific to drugs under review may be submitted up until 72 hours before the November board meeting.

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, May 15, 2024
Draft Minutes

Web link to the meeting video: https://www.youtube.com/watch?v=s3gOiI3-lfo
Web link to the meeting materials: https://dfr.oregon.gov/pdab/Documents/20240515-PDAB-document-package.pdf

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Call to order and roll call: Chair Shelley Bailey called the meeting to order at 9:30 am and roll was called.
Board members present: Chair Shelley Bailey, Vice Chair Amy Burns, Dan Hartung, Robert Judge, Chris Laman, John Murray, and Akil Patterson
Absent: None

Declaration of potential conflict of interest: John Murray and Dan Hartung disclosed potential conflicts of interest. View in the meeting video at minute 00:00:51.

Board Chair Update: Chair Bailey thanked the public for submitting feedback and said the board has reviewed all comments. She is taking an active role as board chair, participating in meetings, to guide board efforts effectively. She said the board is expanding constituent meetings to include manufacturers, PBMs and advocacy groups in June and July. She talked about the updated calendar for affordability reviews and said the board will vote during the November meeting. View the video at minute 00:02:00.

Approval of board minutes: Chair Bailey asked for a motion and second to approve the board minutes from the April 17 board meeting as shown on Pages 3-4 of the agenda materials, with any amendments. John Murray made a motion to approve the minutes as presented and Amy Burns provided a second. View the video of the chair's update at minute 00:16:11.

MOTION to approve the April 17, 2024, minutes
Board Vote:
Yes: Dan Hartung, Robert Judge, Chris Laman, John Murray, Akil Patterson, Vice Chair Amy Burns, Chair Shelley Bailey
No: None
Motion passed 7-0

Program update by Executive Director Ralph Magrish. Chair Bailey called on Ralph Magrish to provide an update. View the video of the executive director's report at minute 00:17:24.

Board discussion and vote on the OAR 925-200-0010 status of Inflectra and Skyrizi: Chair Bailey called on Cortnee Whitlock, policy analyst, to discuss OAR 925-200-0010 as it relates to Inflectra and Skyrizi. View the video of the board discussion at minute 00:19:54.

Affordability Review of Ozempic: Chair Bailey called on Cortnee Whitlock to provide an overview of the affordability review report about Ozempic shown on Pages 5-41. View the video of the board discussion at minute 00:35:14.

Affordability Review of Trulicity: Chair Bailey called on Cortnee Whitlock to provide an overview of the affordability review report about Trulicity shown on Pages 42-69. View the video of the board discussion at minute 00:49:25.

Board consideration of and vote on generic drug report prepared for the Oregon Legislature: Chair Bailey called on Cortnee Whitlock to discuss the generic drug report shown on Pages 70-86. The chair asked for a motion and second to approve the report. John Murray moved to approve the report and Robert Judge provided a second. View the video of the board discussion at minute 00:53:17.

MOTION to approve the 2024 generic drug report
Board Vote:
Yes: Dan Hartung, Robert Judge, Chris Laman, John Murray, Akil Patterson, Vice Chair Amy Burns, Chair Shelley Bailey
No: None
Motion passed 7-0

Senate Bill 192 upper payment limit planning update: Chair Bailey called on Ralph Magrish to provide an update shown on Pages 87-97. View the video of the board discussion at minute 00:58:50.

Announcements: Chair Bailey said the next board meeting would be June 26, 2024. View the video of announcements at minute 01:07:16.

Public comment: Chair Bailey called on those who signed up to speak to the board. There were four requests to provide oral testimony and 12 written comments, which are posted to the PDAB website. View oral testimony from Bridget Doherty, Johnson & Johnson, John Mullin, Oregon Coalition for OCAP, Dharia McGrew, PhRMA, and Brian Warren, Biotechnology Innovation Organization, in the meeting video at minute 01:07:45.

Adjournment: Chair Bailey adjourned the meeting at 11:10 am with all board members in agreement. View adjournment at minute 01:24:29.

Oregon Prescription Drug
Affordability Board

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

Shingrix

Affordability Review[1]

[1] Image source: https://mms.mckesson.com/product/1080947/Glaxo-Smith-Kline-58160081912. Accessed Jan. 23, 2024.

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Review Summary

Price history

Shingrix initially began marketing in December 2017. Over the past five years, Shingrix's wholesale acquisition cost (WAC) has increased by **5.6% YoY**[2] on average. This increase outpaced inflation in 2019, 2020, and 2023.[3]

Therapeutic alternatives

A clinical review did not find any therapeutic alternatives for Shingrix.

Cost to the healthcare system

In 2022, total gross spend for Shingrix in Oregon was **$13.5 million** across **55,578 enrollees,** with a gross per patient spend of **$242.89.**[4]

Cost to patients

On average, patient out-of-pocket costs was **$0.50** for Shingrix in 2022 across deductibles, copays and coinsurance charges.[5]

[2] Based on data from Medi-Span.
[3] Inflation rates obtained from the US Bureau of Labor Statistics website. Accessed from page https://www.bls.gov/cpi/tables/supplemental-files/ on 1/11/24.
[4] Based on Oregon's 2022 All Payer All Claims (APAC) data across commercial insurers, Medicaid, and Medicare. APAC cost information are prior to any price concessions such as discounts or coupons. For more information regarding APAC data visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.
[5] Ibid.

Review Background

Senate Bill 844 (2021) created the Prescription Drug Affordability Board (PDAB) to evaluate the cost of prescription drugs and protect residents of this state, state and local governments, commercial health plans, health care providers, pharmacies licensed in Oregon and other stakeholders within the health care system from the high costs of prescription drugs.

In accordance with OAR 925-200-0020, PDAB will conduct an affordability review on the prioritized subset of prescription drugs, selected under OAR 925-200-0010, and 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.

This review addresses the affordability review criteria in OAR 925-200-0020, to the extent practicable. Therefore, due to limitations in scope and resources, some criteria will have minimal or no consideration in this review.

In addition to information provided by the Department of Consumer and Business Services (DCBS) pursuant to ORS 646A.694, this review reflects information from various sources, including Oregon's 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): **Shingrix**

Non-proprietary name: **Zoster recombinant vaccine**

Manufacturer: **GlaxoSmithKline**

Treatment for: **For prevention of herpes zoster virus (HZV) (shingles) in adults 50 years and older.**

FDA approval

Shingrix was first approved by the FDA on 10/20/2017.[6]

The drug qualified for the following expedited forms of approval: None

At the time of the review, the drug had no approved indications with designations under the Orphan Drug Act.

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

Health Inequities

ORS 646A.694(1)(a) and OAR 925-200-0020 (1)(a) & (2)(a)(A-B). Limitations in scope and resources available for this statute requirement. Possible data source through APAC.

A study done by National Center of Health Statistics showed trends with socioeconomics, demographics, and race impacting patients accessing Shingrix.

Socioeconomic and educational factors[7]:
Vaccination coverage was highest for those who were not poor and those who had more than a high school education. Education and socioeconomic status play a role in vaccine uptake.

Regional Variation[8]:
The percentage of adults aged 60 and over who ever had a shingles vaccination ranged from 26.3% in the East South Central region to 42.8% in the West North Central region of the United States.

Racial Disparities[9]:
Non-Hispanic white adults (38.6%) were approximately twice as likely as non-Hispanic black (18.8%) and Hispanic (19.5%) adults to have ever received a shingles vaccine.

Residents prescribed

ORS 646A.694(1)(b) and OAR 925-200-0020(1)(b) & (2)(b). Data source from APAC.

Based on APAC claims, **20,079** Oregonians filled a prescription for Shingrix in 2022.[10]

Price for the Drug

ORS 646A.694(1)(c) and OAR 925-200-0020(1)(c) & (2)(e), (f), & (g). Data source from Medi-Span, APAC, and carrier data call.

Price History

The package wholesale acquisition cost (WAC) for Shingrix (NDC 58160082311 that contains ten single-dose vials) was **$1,834.06**[11] making WAC per dose $184 as of 12/31/2023.

The WAC for the drug was reviewed using Medi-Span's price history tables for the package WAC from 2019 to 2023. From 2019-2023 the average year-over-year change to the package WAC was calculated and determined to be **5.6%**. As of January 1, 2024, the WAC price

[7] Terlizzi EP, Black LI. Shingles vaccination among adults aged 60 and over: United States, 2018. NCHS Data Brief, no 370. Hyattsville, MD: National Center for Health Statistics. 2020.
https://www.cdc.gov/nchs/products/databriefs/db370.htm
[8] Ibid.
[9] Ibid.
[10] Number of 2022 enrollees from APAC database. For more information regarding APAC data visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.
[11] To determine which NDC to use for the WAC price history, the available 2022 utilization data and selected the NDC with the highest volume of claims in 2022.

increased another **7.9%** to **$1,978.95**. The historical change in the package WAC is displayed in figure 1 and the year over year change in WAC for Shingrix compared to inflation rates[12] is displayed in figure 2.

Figure 1 Shingrix WAC between 2019-2023

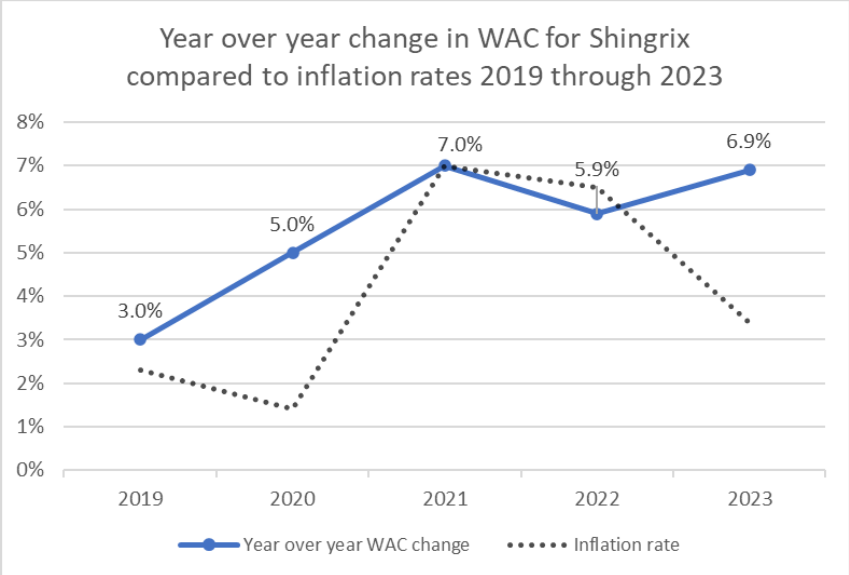

Figure 2 Year over year change in WAC compared to inflation rates[13]

[12] Inflation rates obtained from the US Bureau of Labor Statistics website. Accessed from page https://www.bls.gov/cpi/tables/supplemental-files/ on 1/11/2024.

[13] Inflation rates obtained from the US Bureau of Labor Statistics website. Accessed from page https://www.bls.gov/cpi/tables/supplemental-files/ on 1/11/2024.

Package WAC was reviewed as an indication of historic price trends for the drug. However, WAC does not account for discounts, rebates, or other changes to the drug's cost throughout the supply chain.

Pharmacy acquisition costs

Figure 3 shows the Oregon actual average acquisition cost (AAAC) for Shingrix (NDC 58160082311) from January 2020 to December 2023. The AAAC for Shingrix rose from **$148** in January 2023, to **$180** in January 2023, with a minor reduction to **$178** in December 2023.[14]

AAAC is updated weekly by the Oregon Health Authority (OHA) using pharmacy survey data. The survey reflects the actual cost for pharmacies to purchase a given drug across all Medicaid enrolled pharmacies on a rolling basis. AAAC is used to calculate reimbursement to pharmacies for fee-for-service (or "open card") Medicaid claims.[15]

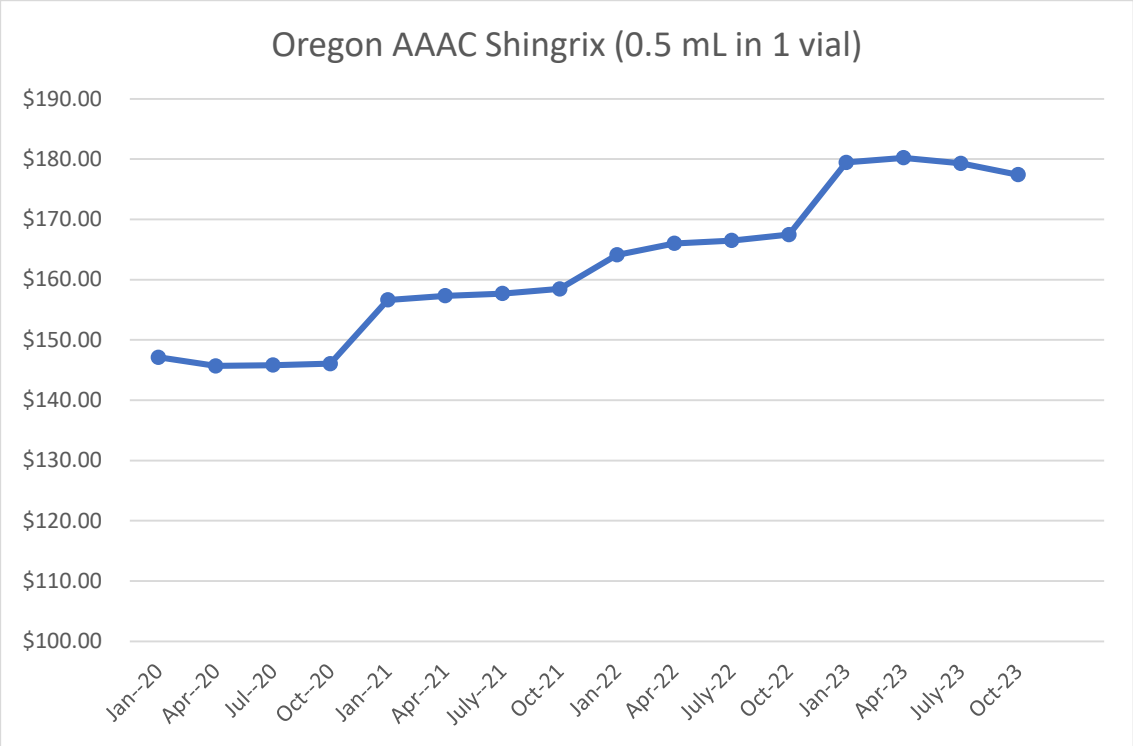

Figure 3 AAAC for Shingrix from Q1 2020 to Q4 2023

[14] This data was compiled using the first weekly AAAC chart of each month from January 2020 to December 2023, available at https://myersandstauffer.com/client-portal/oregon/ as of April 18, 2024.
[15] Average Actual Acquisition Cost (AAAC) Questions and Answers. Oregon Health Authority, Health Systems Division, Medicaid Programs, Jan. 19, 2023. https://www.oregon.gov/oha/HSD/OHP/Tools/aaac-qa.pdf. Accessed April 18 2024.

Estimated average monetary price concession

ORS 646A.694(1)(d) and OAR 925-200-0020(1)(d) & (2)(d) & (2)(L)(A-B). Data source information provided from data call.

No information was provided by the manufacturer or found in the data review for the average monetary price concession, discount, or rebate in this state for Shingrix.

Estimated total amount of the price concession

ORS 646A.694(1)(e) and OAR 925-200-0020(1)(e) & (2)(d) & (2)(L)(A-B). Limitations in scope and resources available for this statute requirement. Possible data source carrier data call.

No information was provided by the manufacturer or found in the data review for total amount of price concession, discount or rebate the manufacturer in this state for Shingrix.

Estimated price for therapeutic alternatives[16]

ORS 646A.694(1)(f) and OAR 925-200-0020(1)(f), (2)(c) & (2)(m). Data source information provided from APAC.

Shingrix has no therapeutic alternatives.

Estimated average price concession for therapeutic alternatives

ORS 646A.694(1)(g) and OAR 925-200-0020(1)(g) & (2)(d) & (2)(L)(A-B). Limitations in scope and resources available for this statute requirement.

No information was provided by manufacturers or found in the data review for the average price concession, discount or rebate for therapeutic alternatives.

Estimated costs to health insurance plans

ORS 646A.694(1)(h) and OAR 925-200-0020(1)(h) & (2)(h) & (m). Data source information provided from APAC and data call.

In 2022, Shingrix had **84,225** claims across **55,578** enrollees. Total gross spend on the drug was **$13,499,199** or **$243** per enrollee per year, and **$160** per claim per year.

[16] Therapeutic alternative means a drug product that contains a different therapeutic agent than the drug in question, but is FDA-approved, compendia-recognized as off-label use for the same indication, or has been recommended as consistent with standard medical practice by medical professional association guidelines to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose. ORS 925-200-0020(2)(c). https://dfr.oregon.gov/pdab/Documents/OAR-925-200-0020.pdf. Accessed Jan. 9, 2024.

Table 1 Gross cost estimates based on APAC data[17]

Payer line of business	Total enrollees	Total claims	Total spend amount	Average spend amount per enrollee	Average spend amount per claim
Commercial	20,081	29,548	$5,287,237	$263	$179
Medicaid	5,455	7,280	$1,360,250	$249	$187
Medicare	30,042	47,397	$6,851,713	$228	$145
Total	**55,578**	**84,225**	**$13,499,199**	**$243**	**$160**

Net cost estimates for Shingrix are not available.

Label and off-label indications and budget impact

Label

In 2021, the Food and Drug Administration (FDA) placed a black-box warning for Shingrix about Guillain-Barre Syndrome (GBS) observed during the 42 days following vaccination with Shingrix.[18]

Off label

There are no off label uses for Shingrix.

Budget impact

For the 2022 Oregon insurer reported data **100%** of health insurances carriers reported a budget impact with Shingrix identifying it as one of their top 25 most costly and greatest increase for prescription drugs. According to the submitted information provided by the carriers the average costs per prescription was **$194**, with **35,123** prescriptions for **27,538** enrollees. It was estimated that the total annual spend was **$6,822,359** with a total annual spend per enrollee of **$248**.[19]

Additional label and off label indication information is provided under the Information from manufacturer sections.

[17] Based on 2022 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information are prior to any price concessions such as discounts or coupons.

[18] FDA black label warning. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-requires-warning-about-guillain-barre-syndrome-gbs-be-included-prescribing-information. Accessed June 14, 2024.

[19] Revised Prescription Drug Subset List. Data for board review on Nov. 15, 2023. Prescription Drug Data, Prescription Drug Affordability Board website. https://dfr.oregon.gov/pdab/Documents/2023-PDAB-Top-Drug-List-v2.0.xlsx. Accessed May 8, 2024.

Impact on patient access to the drug

ORS 646A.694(1)(i) and OAR 925-200-0020(1)(i). Data source information provided from carrier data call.

No information was obtained by Oregon commercial health plans for rejected claims or drug benefit design for Shingrix.

Relative financial impacts to health, medical or social services costs

ORS 646A.694(1)(j) and OAR 925-200-0020(1)(j) & (2)(i)(A-B). Limitations in scope and resources available for this statute requirement.

The research suggests that financial obstacles linked to reimbursement of the recombinant zoster vaccine (RZV) could hinder the vaccine's adoption. A study analyzing RZV reimbursement from private insurers found that the average reimbursement was $149 in 2018, exceeding the private sector price ($140) listed by the CDC vaccine price list.[20] Reimbursement levels varied considerably across different states. The Inflation Reduction Act (IRA) included provisions that eliminated cost-sharing for recommended vaccinations among Medicare Part D beneficiaries starting in 2023, aligning Medicare with vaccine cost-sharing policies for commercially insured individuals. Eliminating out-of-pocket costs was associated with a significant increase in shingles vaccines dispensed to Medicare enrollees (46%) compared with a decrease of 21% among commercially insured individuals.[21] Furthermore, a review of the usage, total costs, and out-of-pocket spending for vaccines covered under Medicare Part D in 2021 showed that the shingles vaccine was utilized by approximately 2.7 million Medicare Part D enrollees and accounted for 92% of total costs (over $680 million).[22] The average out-of-pocket cost for the shingles vaccine was $76.94, with significantly lower costs for enrollees receiving low-income subsidies (LIS) compared to those without LIS.[23]

[20] Leidner AJ, Tang Z, Guo A, Anderson TC, Tsai Y. Insurance reimbursements for recombinant zoster vaccine in the private sector. *Vaccine*. 2021;39(36):5091-5094. doi:10.1016/j.vaccine.2021.07.050

[21] Qato DM, Romley JA, Myerson R, Goldman D, Fendrick AM. Shingles Vaccination in Medicare Part D After Inflation Reduction Act Elimination of Cost Sharing. *JAMA*. Published online May 23, 2024. doi:10.1001/jama.2024.7348

[22] US Assistant Secretary for Planning and Evaluation. Medicare Part D Enrollee Savings from Elimination of Vaccine Cost-Sharing. Issue Brief HP-2023-05. Published March 15, 2023. https://aspe.hhs.gov/sites/default/files/documents/407d41b6534e7af6702eb280b3945d00/aspe-ira-vaccine-part-d.pdf

[23] Ibid.

Estimated average patient copayment or other cost-sharing

ORS 646A.694(1)(k) and OAR 925-200-0020(1)(k) & (2)(j)(A-D). Data source information provided from APAC and carrier data call. Data limitations with patient assistance programs

The APAC database[24] was analyzed to determine the average patient copayment or other cost-sharing for the prescription drug.

Table 2 Out of pocket costs

2022 Average annual patient out of pocket costs[25]		
Value	**APAC**	**Data Call**
Average Co-Pay	$0.16	Not on data call
Average Deductible	$0.11	Not on data call
Average Coinsurance	$0.23	Not on data call
Other Cost Sharing	$0.00	Not on data call
Total Out-of-Pocket Costs for Patients[26]	**$0.50**	Not on data call

Information from manufacturers

ORS 646A.694(1)(L) and OAR 925-200-0020(1)(L). Information provided from manufacturers and information with sources from contractor(s).

Refer to Appendix A for manufacturers' information.

Drug indications[27]

- FDA Approved:
  - For prevention of herpes zoster virus (HZV) (shingles) in:
    - Adults 50 years and older.
    - Adults 18 years and older who are or will be at increased risk of HZV due to immunodeficiency or immunosuppression caused by known disease or therapy.

[24] APAC total cost may include a dispensing fee and physician administration fees.
[25] Costs from the APAC database are prior to any price concessions such as discounts or coupons. Cost information from the data call is the cost of the drug after price concessions. Medicaid and Medicare were excluded from cost information.
[26] For patients who used the drug at least once in the 2022 calendar year.
[27] Shingrix Prescribing Information. GlaxoSmithKline. Rixensart, Belgium: 5/2023

Clinical efficacy

- Shingrix is a recombinant, non-live, adjuvanted vaccine given in two doses to prevent herpes zoster virus (HZV), or shingles. A first dose is administered intramuscularly at month zero followed by a second dose administered two to six months later.

- HZV is a localized, painful, cutaneous eruption resulting from reactivation of latent varicella zoster virus. Postherpetic neuralgia is the most common complication of HZV.

- A person's risk for HZV increases after 50 years of age and from immunosuppressive medications and/or conditions.

- Shingrix was FDA approved in 2017 for use in adults 50 years of age and older based on two phase 3, placebo-controlled, randomized controlled trials (RCTs).[28,29] One RCT compared Shingrix to placebo in immunocompetent adults 50 years of age or older (n=15,411) and the other RCT compared Shingrix to placebo in immunocompetent adults 70 years of age or older (n=13,900).

- In the study of those 50 years of age and older, Shingrix significantly reduced the incidence of confirmed HZV from six cases in the vaccine group (incidence rate 0.3 per 1000 person-years) compared to 210 cases in the placebo group (incidence rate 9.1 per 1000 person-years) with an overall vaccine efficacy of 97.2% (95% confidence interval [CI] 93.7% to 99%; p< 0.001) over a mean follow up of 3.2 years.[30] The mean age of the population was 62.3 years and most participants were white (71.8%) and female (61.2%). There was no significant difference in vaccine efficacy among the different age groups and efficacy was durable up to four years post-vaccination.[31]

- In subjects 70 years of age and older, Shingrix reduced HZV from 9.2 cases per 1000 person-years to 0.9 cases per 1000 person-years, for an overall efficacy of 89.8% (95% CI 84.2% to 93.7%; p<0.001).[32]

- Pooling data from both studies, vaccine efficacy in older adults 70 years and older was 91.3% (95% CI 86.8% to 94.5%).[33,34] The incidence of postherpetic neuralgia was low overall, but was reduced in the Shingrix group compared to placebo (0.1 per 1000

[28] Cunningham AL, Lal H, Kovac M, Chlibek R, et al. Efficacy of the Herpes Zoster Subunit Vaccine in Adults 70 Years of Age or Older. N Engl J Med. 2016 Sep 15;375(11):1019-32. doi: 10.1056/NEJMoa1603800. PMID: 27626517.
[29] Lal H, Cunningham AL, Godeaux O, Chlibek R, Diez-Domingo J, et al.. Efficacy of an adjuvanted herpes zoster subunit vaccine in older adults. N Engl J Med. 2015 May 28;372(22):2087-96. doi: 10.1056/NEJMoa1501184.
[30] Ibid.
[31] Lal H, Cunningham AL, Godeaux O, Chlibek R, Diez-Domingo J, et al.. Efficacy of an adjuvanted herpes zoster subunit vaccine in older adults. N Engl J Med. 2015 May 28;372(22):2087-96. doi: 10.1056/NEJMoa1501184.
[32] Cunningham AL, Lal H, Kovac M, Chlibek R, et al. Efficacy of the Herpes Zoster Subunit Vaccine in Adults 70 Years of Age or Older. N Engl J Med. 2016 Sep 15;375(11):1019-32. doi: 10.1056/NEJMoa1603800. PMID: 27626517.
[33] Ibid.
[34] Lal H, Cunningham AL, Godeaux O, Chlibek R, Diez-Domingo J, et al.. Efficacy of an adjuvanted herpes zoster subunit vaccine in older adults. N Engl J Med. 2015 May 28;372(22):2087-96. doi: 10.1056/NEJMoa1501184.

person-years vs. 0.9 per 1000 person-years; efficacy of 91.2%; 95% CI 75.9% to 97.7%; p<0.001).[35,36]

- In 2021, Shingrix's label was expanded to include adults 18 years and older who are immunosuppressed. Shingrix demonstrated vaccine efficacy of 68.2% (95% CI 55.6% to 77.5%) in autologous hematopoietic cell transplant recipients.[37]

Clinical safety[38]

- FDA safety warnings:
  - Guillain-Barre syndrome
  - Syncope

- Contraindications:
  - History of severe allergic reaction to the vaccine
  - During an acute episode of HZV

- Common side effects:
  - Injection site pain (78%), redness (38%), and swelling (26%)
  - Systematic reactions including myalgia (45%), fatigue (45%), headache (38%), fever (21%), and gastrointestinal symptoms (17%).

- Due to higher reactogenicity with the adjuvanted vaccine, rates of local or systemic reactions are high in the first seven days after vaccination. These are generally of short duration and self-limiting. This could impact adherence to the second dose.

Therapeutic alternatives

- There are no therapeutic alternatives to the Shingrix vaccine.

- When Shingrix was FDA approved in 2017, it was given preference over Zostavax, which was a live, attenuated HZ vaccine. Preference was given due to higher and longer lasting efficacy against HZ and postherpetic neuralgia. Zostavax was only considered 51% effective for preventing shingles, compared to approximately 97% with Shingrix and efficacy of Zostavax diminished with increasing age. As of November 18, 2020, Zostavax is no longer available for use in the United States.

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[35] Cunningham AL, Lal H, Kovac M, Chlibek R, et al. Efficacy of the Herpes Zoster Subunit Vaccine in Adults 70 Years of Age or Older. N Engl J Med. 2016 Sep 15;375(11):1019-32. doi: 10.1056/NEJMoa1603800. PMID: 27626517.
[36] Lal H, Cunningham AL, Godeaux O, Chlibek R, Diez-Domingo J, et al.. Efficacy of an adjuvanted herpes zoster subunit vaccine in older adults. N Engl J Med. 2015 May 28;372(22):2087-96. doi: 10.1056/NEJMoa1501184.
[37] Anderson TC, Masters NB, Guo A, et al. Use of Recombinant Zoster Vaccine in Immunocompromised Adults Aged ≥ 19 years: Recommendations of the Advisory Committee on Immunization Practices – United States, 2022. MMWR Morb Mortal Wkly Rep 2022;71:80-84.
[38] Shingrix Prescribing Information. GlaxoSmithKline. Rixensart, Belgium: 5/2023.

- Shingrix is the first HZV vaccine approved for use in immunocompromised persons. As Zostavax was a live vaccine, immunosuppression and immunodeficiency were contraindications to its use.

Additional information

- Oregon Health Authority: https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Documents/NewCPTcodes.pdf
- Health Evidence Review Commission data: https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/VFC/Documents/BillPriceListJan-Jun.pdf

Input from Specified Stakeholders

ORS 646A.694(3) and OAR 925-200-0020(2)(k)(A-D)

Additional information for Shingrix can be submitted until November 11, 2024.

Refer to the appendix section for specific stakeholder feedback.

Appendix A: Patients and caregivers

- No information was provided by patients and caregivers.

Appendix B: Individuals with scientific or medical training

- No information was provided by safety net providers.

Appendix C: Safety net providers

- No information was provided by safety net providers.

Appendix D: Payers

- No information was provided by payers.

Appendix E: Manufacturer

The board received letters from the following people on these dates:

- Harmeet Dhillon, head of public policy, GSK, submitted information on June 14, 2024.

Appendix F: Advocacy Groups

The board received letters from the following people on these dates:

- Northe Saunders, Executive Director, with SAFE Communities Coalition & Action Fund, submitted information on June 14, 2024.

Appendix G: Other

The board received letters from the following people on these dates:

- Steven C. Anderson, president and chief executive officer, National Association of Chain Drug Stores, submitted information on June 14, 2024.

Appendix E

June 14, 2024

VIA ELECTRONIC FILING

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, Oregon 97309-0405
pdab@dcbs.oregon.gov

Dear Members of the Oregon Prescription Drug Affordability Board:

GSK appreciates the opportunity to resubmit written comments regarding the affordability review of Shingrix following the previous opportunity in February 2024. Shingrix is a vaccine indicated for prevention of herpes zoster (also known as shingles) in adults aged 50 years and older and in adults aged 18 years and older who are or will be at increased risk due to immunodeficiency or immunosuppression caused by known disease or therapy. There is currently no alternative vaccine to Shingrix licensed in the United States to prevent shingles.

For the reasons listed below, **we respectfully request that the Board once again find Shingrix affordable for Oregon residents.**

1) Shingrix is widely available with no patient cost-sharing

GSK would like to reiterate its concerns that the methodology, data sources, and criteria used by the Board to identify drugs for affordability review do not accurately prioritize drugs that may pose affordability challenges for patients. The data as presented does not fully consider that all Center for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) recommended vaccines, including Shingrix, are covered without cost-sharing for the majority of publicly and privately insured individuals, meaning out-of-pocket costs for these patients are $0.

After conducting a clinical and economic assessment, the CDC recommended that immunocompetent adults aged 50 years and older as well as adults aged ≥19 years who are or will be immunodeficient or immunosuppressed because of disease or therapy receive Shingrix.[1,2] The economic and clinical support provided across multiple studies contributed to the CDC issuing this routine policy recommendation.[3,4]

Coverage for all CDC recommended vaccines without cost-sharing is mandated by the following statutes and regulations:

- Commercial plans: 42 U.S.C. §30gg-13(a)(2)
- Medicare Part B: 42 U.S.C. §1395x(s)(10) and 42 C.F.R. 410.57
- Medicare Part D: 42 U.S.C. §1395w-102(e)
- Medicaid/Children's Health Insurance Program (CHIP): 42 U.S.C. §300gg-13(a)(2) (Medicaid Expansion) and 42 U.S.C. §1396o-1 (Traditional Medicaid)

Additionally, federal safety net programs provide access to vaccines without cost-sharing for uninsured and under-insured individuals (i.e., adults enrolled in non-Affordable Care Act [ACA]-compliant plans, including

grandfathered and short-term limited-duration plans for individuals). These statutory provisions ensure out-of-pocket patient costs are not a barrier to accessing Shingrix or any other recommended vaccines.

2) Shingrix improves patient outcomes and reduces treatment costs

Supporting vaccine access and uptake is one of the most cost-effective ways to improve public health.[5] Adult vaccination for four common diseases in older adults, including shingles, is estimated to prevent 64 million cases and $185 billion in treatment costs over the next 30 years in the United States.[6]

An estimated 1 million people develop shingles annually in the United States, with risk increasing with age.[7] CDC recommendations intend to improve the recognized burden associated with shingles.[8] There is no alternative prophylactic or effective prevention option for shingles, which makes unencumbered access to Shingrix critical.

Widespread utilization of a vaccine such as Shingrix is the goal of any state vaccination program and serves to prevent associated medical conditions resulting from the underlying disease.[9] Specifically, the Oregon Immunization Program (OIP) "is committed to ensuring and increasing access to vaccines for people of all ages."[10] Shingles cases have been tied to an estimated $2.4 billion in annual direct medical costs and productivity losses, with incremental direct medical costs ranging from $1,210-$3,804 for individuals with shingles (compared to matched controls) and increasing with age.[11,12] Prevention of shingles also reduces incidence of certain downstream health conditions and their associated costs.[13]

A model estimating the cost-effectiveness of Shingrix compared to no vaccination for one million US adults aged ≥60 years found that Shingrix can be expected to prevent approximately 104,000 shingles cases at an incremental cost of $11,863 per quality adjusted life year (QALY) saved.[14] An updated model estimated that increasing Shingrix coverage in US adults aged 50-59 years from 7.3% to 14.6% can be expected to avoid approximately 504,000 shingles cases and save $143 million from a societal perspective.[15]

3) The CDC found Shingrix to be cost-effective

All vaccines undergo a cost-effectiveness and economic value assessment process by the ACIP after Food and Drug Administration (FDA) approval. Vaccines are reviewed and recommended by the ACIP before they can be accessed by the public or covered by insurance. When reviewing a vaccine, the ACIP considers "disease epidemiology and burden of disease, vaccine safety, vaccine efficacy and effectiveness, the quality of evidence reviewed, economic analyses, and implementation issues," as specified in its charter.[16] The ACIP also assesses a product's cost-effectiveness to determine if "the intervention is a reasonable and efficient allocation of resources."[17]

In its analysis of Shingrix, the ACIP found the vaccine cost-effective compared to no vaccination. In fact, the analysis concluded that the cost-effectiveness of Shingrix was greater than the cost-effectiveness of many other recommended adult vaccines.[18] Additionally, in more recent analyses, the ACIP determined the economic value of Shingrix was generally favorable among immunocompromised adults; consequently, the ACIP determined that Shingrix was a reasonable and efficient allocation of resources for the prevention of shingles in immunocompromised adults 19 years and older.[19]

In conclusion, we respectfully request that the Board once again find Shingrix affordable for patients in Oregon and ensure continued broad access and uptake given:

- The public health implications of vaccination as a critical disease prevention tool;
- The lack of alternatives to Shingrix for shingles vaccination in the US;
- The current CDC recommendations for immunocompetent adults aged 50 years and older as well as adults aged ≥19 years who are or will be immunodeficient or immunosuppressed because of disease or therapy to receive Shingrix;
- The non-existent out-of-pocket costs for nearly all insured patients; and
- The value Shingrix delivers to the Oregon health care system and its patients.

Thank you again for your consideration and for the opportunity to engage with the Board. Please feel free to contact Christian Omar Cruz at Christian.O.Cruz@gsk.com with any questions.

Sincerely,

Harmeet Dhillon
Head, Public Policy
GSK

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[1] National Institute of Health. Shingles vaccination of adults 50–59 and ≥60 years, U.S. (2020). Available here.
[2] ACIP. Evidence to Recommendations Framework for Use of Recombinant Zoster Vaccine in Immunocompromised Adults Aged ≥19 Years (2022). Available here.
[3] Centers for Disease Control and Prevention. Considerations for the use of herpes zoster vaccines. October 25, 2017. Available here.
[4] Dooling KL, Guo A, Patel M, et al. Recommendations of the Advisory Committee on Immunization Practices for Use of Herpes Zoster Vaccines. 2018. Available here.
[5] Centers for Disease Control and Prevention. Why CDC Is Involved in Global Immunization. 2023. Available here.
[6] Carrico, J. Cost-benefit analysis of vaccination against four preventable diseases in older adults: Impact of an aging population. 2021. Available here.
[7] Centers for Disease Control and Prevention. Shingles (herpes zoster): clinical overview. Available here.
[8] Ibid.
[9] Vaccines and Immunization. Oregon Immunization Program. Available here.
[10] Vaccine Access Program (VAP) Overview. Available here.
[11] Harvey M, Prosser LA, Rose AM, Ortega-Sanchez IR, Harpaz R. Aggregate health and economic burden of herpes zoster in the United States: illustrative example of a pain condition. 2020. Available here.
[12] Meyers JL, Madhwani S, Rausch D, Candrilli SD, Krishnarajah G, Yan S. Analysis of real-world health care costs among immunocompetent patients aged 50 years or older with herpes zoster in the United States. 2017. Available here.
[13] Liu X, Guan Y, Hou L, et al. The Short- and Long-Term Risk of Stroke after Herpes Zoster: A Meta-Analysis. 2016. Available here.
[14] Curran D, Patterson B. Cost-effectiveness of an Adjuvanted Recombinant Zoster Vaccine in older adults in the United States. 2018. Available here.
[15] Singer D, Salem A, Stempniewicz N, et al. The potential impact of increased recombinant zoster vaccine coverage on the burden of herpes zoster among adults aged 50-59 years. 2023. Available here.
[16] US Department of Health and Human Services. Charter of the ACIP. Available here.
[17] Centers for Disease Control and Prevention. Guidance for Health Economics Studies Presented to ACIP. 2019. Available here.
[18] Prosser LA, Harpaz R, Rose AM, et al. A Cost-Effectiveness Analysis of Vaccination for Prevention of Herpes Zoster and Related Complications: Input for National Recommendations. 2019. Available here.
[19] Centers for Disease Control and Prevention. Meeting of the Advisory Committee on Immunization Practices (ACIP), October 20-21, 2021. Available here.

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
pdab@dcbs.oregon.gov

SAFE COMMUNITIES COALITION

June 14th, 2024

Dear Members of the Oregon Prescription Drug Affordability Board:

We write today on behalf of SAFE Communities Coalition & Action Fund, a non-profit organization whose purpose is to support pro-vaccine policies and legislation. We appreciate your consideration of our comments for your upcoming meeting on June 26th, 2024. We believe that vaccines are a critical component of public health infrastructure and ask that the board not consider any vaccine as part of their review process.

We ask that vaccines not be subject to an affordability review based on high utilization, as this conflicts with the goal of decreasing overall healthcare costs through immunization. The high utilization of immunizations is, by design, a goal and necessary outcome of a successful inoculation program. High utilization of immunizations has been proven to reduce healthcare costs in the long term. Additionally, the prevention of infectious disease through immunization will have a direct impact, in line with the stated goal of the OR PDAB, of the use (and costs) of prescription drugs to treat diseases that could have been prevented.

The process of reviewing and recommending vaccines for the American public, including cost-effectiveness, has already been given great consideration at the federal level by the Advisory Committee on Immunization Practices (ACIP) and the Centers for Disease Control and Prevention (CDC). ACIP's Evidence to Recommendation Framework, used when vaccines are reviewed for recommendation, already considers many of the economic factors that may be considered by OR PDAB.

Vaccines are one of the most important pillars of public health in Oregon and across the nation. We must ensure, as has already been done by ACIP, that vaccines remain affordable, accessible, and widely utilized. Anything less undermines the public's health

and puts our communities, schools, and those most susceptible to vaccine-preventable diseases at risk.

Finally, subjecting any vaccine to affordability measures beyond what has already been established by ACIP could have a chilling effect on the entire vaccine development process, slowing and possibly limiting the future development of lifesaving vaccines. The impact of a decision of the OR PDAB to add any vaccine, which is a unique and critical classification of products, to the list of reviewed prescription drugs, could have a knock-on effect, threatening vaccine access across the nation.

We ask that the board not consider any vaccine as part of their review process.

Thank you for your consideration and the work that you do to make sure that all Oregonians have access to affordable healthcare.

Northe Saunders
Executive Director
SAFE Communities Coalition & Action Fund
info@safecommunitiescoalition.org

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

June 14, 2024

Shelley Bailey
Chair
Oregon Prescription Drug Affordability Board
350 Winter St. NE, Room 410
Salem, OR 97309

Submitted via pdab@dcbs.oregon.gov

Re: Vaccine Eligibility

Dear Chair Bailey,

On behalf of our members operating in Oregon, the National Association of Chain Drug Stores (NACDS) is writing to comment on the Prescription Drug Affordability Board's June 26th meeting regarding the affordability review of Shingrix. We are concerned with the inclusion of vaccines in PDAB affordability reviews.

Vaccine Eligibility for PDAB Review

Community pharmacies provide many vital preventive services, including administering vaccines. To date, over 307 million COVID-19 vaccinations alone have been provided by pharmacies.[1] NACDS strongly believes that vaccines should not be subject to affordability review. Vaccines currently undergo a cost effectiveness and economic value assessment process through the CDC's Advisory Committee on Immunization Practices (ACIP) after FDA approval. They are reviewed and recommended by the ACIP before they can be accessed by the public or covered by public and private insurance. Both the Affordable Care Act and the Inflation Reduction Act mandate that all CDC-recommended vaccines are covered without cost-sharing for all publicly and privately insured individuals. For patients, this means that out-of-pocket costs are largely nonexistent. Additionally, federal safety net programs provide access to vaccines without cost-sharing for uninsured and underinsured individuals.

Finally, high utilization of vaccines and preventing associated medical costs is the goal of the Oregon Immunization Program and helps address healthcare inequities. Vaccines should not be subject to an affordability review based on high or increasing utilization, as this conflicts with public health goals to increase immunization rates as an important prevention tool.

NACDS appreciates the board's endeavors to reduce prescription drug costs and enhance affordability for Oregonians. However, we strongly encourage removing vaccines as eligible for

[1] https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html#closing-out

review by the board based on the above rationale to help ensure continuity of care in Oregon. For questions or further discussion, please get in touch with Sandra Guckian, Vice President of State Pharmacy and Advocacy, at SGuckian@nacds.org.

Sincerely,

Steven C. Anderson, FASAE, CAE, IOM
President and Chief Executive Officer
National Association of Chain Drug Stores

cc: Oregon Prescription Drug Affordability Board Members

###

NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 155,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit NACDS.org.

Oregon Prescription Drug
Affordability Board

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

Ocrevus[1]
Affordability Review

[1] Image source: https://pmlive.com/pharma_news/

Table of Contents

Review Summary

Price history

Ocrevus (Ocrelizumab) initially began marketing on **3/28/2017.** Over the past five years, Ocrevus's wholesale acquisition cost (WAC) has increased by **2.9%**[2] on average.

Therapeutic alternatives

A clinical review found four therapeutic alternatives for Ocrevus. The average gross spend per enrollee per year for Ocrevus was **$45,133** vs. an average of **$58,747** across this drug and all identified therapeutic alternatives. Average out of pocket costs for patients was **$2,381** per patient per year, vs. an average of **$2,267** across this drug and all identified therapeutic alternatives.

Cost to the healthcare system

In 2022, total gross spend for Ocrevus in Oregon was **$37.36 million** across **757 enrollees,** with a gross per patient spend of **$49,348** across Medicare, Medicaid, and commercial plans**.** Net spend for private insurers was estimated to be **$61,292** per enrollee per year.[3]

Cost to patients

On average, patient out-of-pocket costs was **$3,665**[4] for Ocrevus in 2022 across deductibles, copays, and coinsurance.

[2] Based on data from Medi-Span.
[3] Based on data submitted to the Department of Consumer and Business Services (DCBS) by Oregon's commercial insurance carriers. Cost information from the data call is the cost of the drug after price concessions.
[4] Ibid

Review Background

Senate Bill 844 (2021) created the Prescription Drug Affordability Board (PDAB) to evaluate the cost of prescription drugs and protect residents of this state, state and local governments, commercial health plans, health care providers, pharmacies licensed in Oregon and other stakeholders within the health care system from the high costs of prescription drugs.

In accordance with OAR 925-200-0020, PDAB will conduct an affordability review on the prioritized subset of prescription drugs, selected under OAR 925-200-0010, and 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.

This review addresses the affordability review criteria in OAR 925-200-0020, to the extent practicable. Therefore, due to limitations in scope and resources, some criteria will have minimal or no consideration in this review.

In addition to information provided by the Department of Consumer and Business Services (DCBS) pursuant to ORS 646A.694, this review reflects information from various sources, including Oregon's 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): **Ocrevus**

Non-proprietary name: **Ocrelizumab**

Manufacturer: **Genentech**

Treatment: **Adult with relapsing forms of multiple sclerosis (MS) and primary progressive multiple sclerosis (PPMS)**.

FDA approval

Ocrevus was first approved by the FDA on **3/28/2017**.[5]

The drug qualified for the following expedited forms of approval: **Fast track approval, breakthrough therapy, priority review.**

At time of the review, the drug had no approved indications with designations under the Orphan Drug Act.

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

Health Inequities

ORS 646A.694(1)(a) and OAR 925-200-0020 (1)(a) & (2)(a)(A-B). Limitations in scope and resources available for this statute requirement. Possible data source through APAC.

The impact of social determinants of health (SDOH) on health outcomes, specifically among Black and Hispanic/Latinx individuals with Multiple Sclerosis (MS) in the United States, was highlighted in a recent review published in JAMA Neurology. The review stressed the critical need for increased research to gain a deeper understanding of how SDOH contributes to racial and ethnic health disparities and inequities in MS, as well as in other autoimmune disorders.[6]

The relationship between the severity of disease and socioeconomic status in Black and White Americans with MS has been a topic of research. Studies have discovered that Black Americans with MS often exhibit more severe disease symptoms and greater disability compared to White Americans.[7] The study indicated that black patients have been noted to present with more pronounced disability at their initial visit, lower scores on neurological health measures, and a higher likelihood of disease progression.[8] These disparities persist even when adjusting for differences in socioeconomic status, suggesting that additional factors, such as healthcare access and quality, may play a role in the observed differences.

Residents prescribed

ORS 646A.694(1)(b) and OAR 925-200-0020(1)(b) & (2)(b). Data source from APAC.

Based on APAC claims, **1,506** Oregonians filled a prescription for Ocrevus in 2022.[9]

Price for the Drug

ORS 646A.694(1)(c) and OAR 925-200-0020(1)(c) & (2)(e), (f), & (g). Data source from Medi-Span, APAC, and carrier data call.

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[6] Amezcua L, Rivera VM, Vazquez TC, Baezconde-Garbanati L, Langer-Gould A**.** Health Disparities, Inequities, and Social Determinants of Health in Multiple Sclerosis and Related Disorders in the US: A Review. *JAMA Neurol*. 2021 Dec 1;78(12):1515-1524. http://doi.org/10.1001/jamaneurol.2021.3416

[7] Gray-Roncal K, Fitzgerald KC, Ryerson LZ, Charvet L, Cassard SD, Naismith R, Ontaneda D, Mahajan K, Castro-Borrero W, Mowry EM. **Association of Disease Severity and Socioeconomic Status in Black and White Americans With Multiple Sclerosis**. *Neurology*. 2021 Aug 31;97(9):e881-e889. http://doi.org/10.1212/WNL.0000000000012362

[8] Ibid.

[9] Number of 2022 enrollees in APAC database across commercial insurers, Medicaid, and Medicare. For more information regarding APAC data visit: https://www.oregon.gov/oha/HPA/ANALYTICS/Pages/All-Payer-All-Claims.aspx.

Price History

The package wholesale acquisition cost (WAC) for Ocrevus (NDC 50242015001, (1 VIAL, SINGLE-USE in 1 CARTON / 10 mL in 1 VIAL, SINGLE-USE)) was **$18,775.6** as of 12/31/2023.[10]

The WAC for the drug was evaluated using Medi-Span's price history tables for the package WAC from 2019 to 2023. From 2020-2023 the average year-over-year change to the package WAC was calculated to have an average **4.93%** year over year increase. The historical change in the package WAC is displayed in Figure 1 and the year over year change in WAC for Ocrevus compared to inflation rates[11] is displayed in Figure 2.

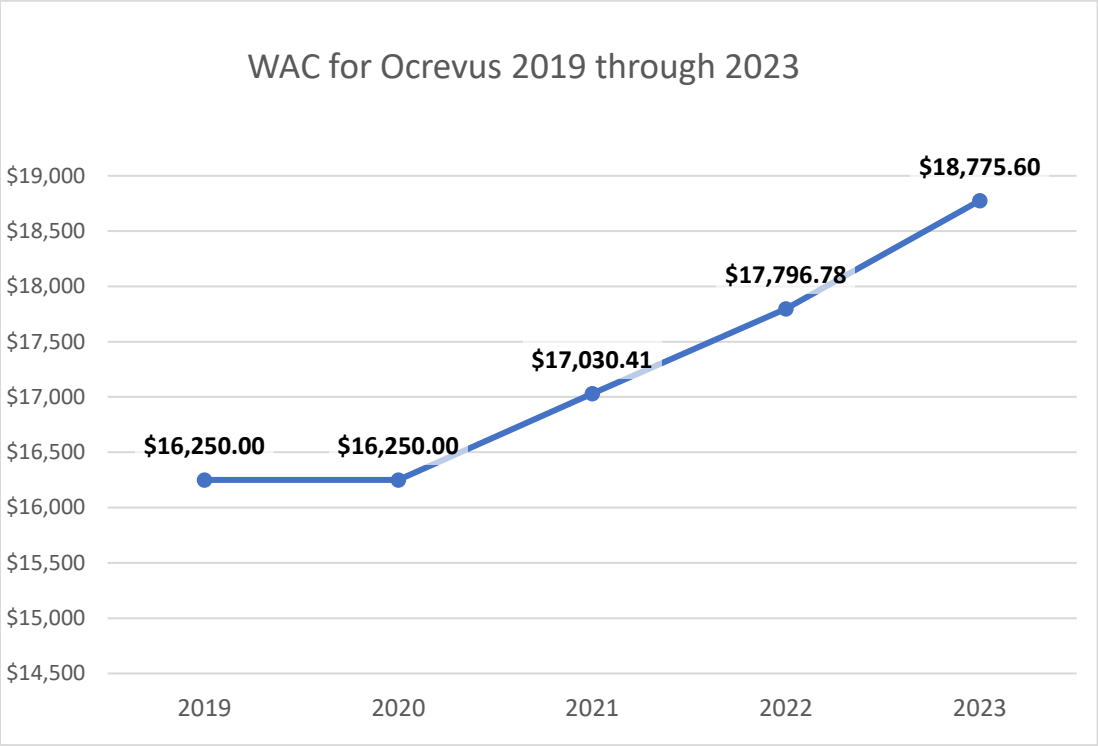


Figure 1 Ocrevus WAC from 2019-2023

[10] To determine which NDC to use for the WAC price history, the available 2022 utilization data was analyzed and the NDC with the highest volume of claims in 2022 was used.

[11] Inflation rates obtained from the US Bureau of Labor Statistics website. Accessed from page https://www.bls.gov/cpi/tables/supplemental-files/ on 1/11/24.

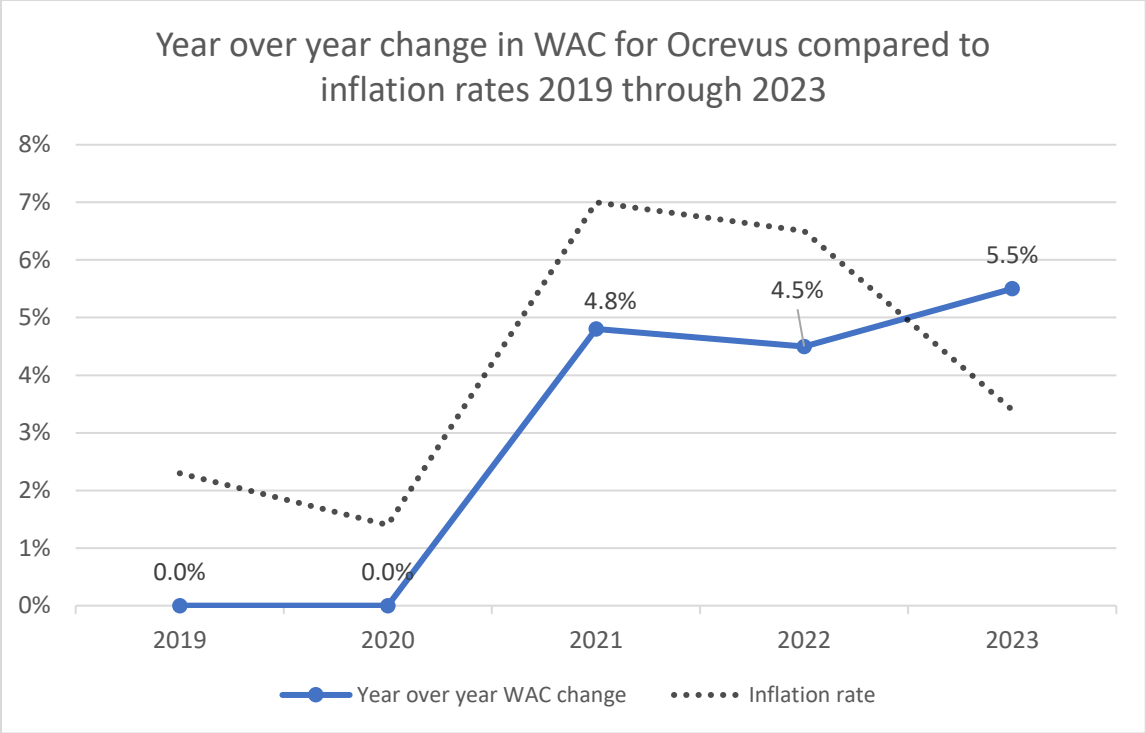


Figure 2 Year over year change in WAC compared to inflation rates[12]

Package WAC was reviewed as an indication of historic price trends for the drug. However, WAC does not account for discounts, rebates, or other changes to the drug's cost throughout the supply chain.

Pharmacy acquisition costs

The Oregon actual average acquisition cost (AAAC) for Ocrevus was not reported from January 2020 to December 2023. AAAC is updated weekly by the Oregon Health Authority (OHA) using pharmacy survey data. The survey reflects the actual cost for pharmacies to purchase a given drug across all Medicaid enrolled pharmacies on a rolling basis. AAAC is used to calculate reimbursement to pharmacies for fee-for-service (or "open card") Medicaid claims.[13]

[12] Inflation rates obtained from the US Bureau of Labor Statistics website. Accessed from page https://www.bls.gov/cpi/tables/supplemental-files/ on 1/11/24.

[13] Average Actual Acquisition Cost (AAAC) Questions and Answers. Oregon Health Authority, Health Systems Division, Medicaid Programs, Jan. 19, 2023. https://www.oregon.gov/oha/HSD/OHP/Tools/aaac-qa.pdf. Accessed April 18 2024.

Estimated average monetary price concession

ORS 646A.694(1)(d) and OAR 925-200-0020(1)(d) & (2)(d) & (2)(L)(A-B). Data source information provided from data call.

The carrier data call[14] submissions were analyzed to determine the total gross annual spend, total number of claims and enrollees, the average amount paid for claim and per enrollee, and out-of-pocket (OoP) costs for enrollees.

The total gross drug cost reported from the carrier data call prior to price concessions for Ocrevus in 2022 was **$17,745,079** for **620** claims. The average net cost per enrollee discounts, rebates, and other price concessions was **$61,292.28**. Post concessions discounts represented **0.52%** applied to **115** claims, with **0%** from PBMs, and **0.46%** from manufacturers, and 0.06% not yet received.

Table 1 Percent of claims from data call with price concessions applied

Payer line of business	Total claims	Number of claims with price concessions applied	% of claims with price concessions applied	% of price concessions
Commercial	620	115	18.55%	0.52%

Estimated total amount of the price concession

ORS 646A.694(1)(e) and OAR 925-200-0020(1)(e) & (2)(d) & (2)(L)(A-B). Limitations in scope and resources available for this statute requirement. Possible data source carrier data call.

No information was provided by the manufacturer or found in data review for the total amount of price concession, discount or rebate in this state for Ocrevus.

Estimated price for therapeutic alternatives[15]

ORS 646A.694(1)(f) and OAR 925-200-0020(1)(f), (2)(c) & (2)(m). Data source information provided from APAC.

- The estimated net price is not included due to lack of information on discounts, rebates, and other price adjustments. Pharmaceutical companies negotiate prices with pharmacies, insurance companies and other stakeholders, but the price negotiations of

[14] Cost information from the data call is the cost of the drug after price concessions.

[15] Therapeutic alternative means a drug product that contains a different therapeutic agent than the drug in question, but is FDA-approved, compendia-recognized as off-label use for the same indication, or has been recommended as consistent with standard medical practice by medical professional association guidelines to have similar therapeutic effects, safety profile, and expected outcome when administered to patients in a therapeutically equivalent dose. ORS 925-200-0020(2)(c). https://dfr.oregon.gov/pdab/Documents/OAR-925-200-0020.pdf. Accessed Jan. 9, 2024.

drugs are not disclosed to the public. The lack of transparency and regulation in pricing of prescription drugs makes it difficult to know the true cost and value of the drug.

- Cost and availability:
  - Data regarding costs, expenditures, and utilization are listed below and shown in Tables 2 and 3.
  - According to the FDA, there is no shortage status for Ocrevus.[16]

Comparative effectiveness to therapeutic alternatives:

Table 2 Alternative Monoclonal Antibodies Indicated for Multiple Sclerosis

Non-proprietary name	Proprietary Name	FDA Approved Indications	Route	Maintenance Dosing Frequency	Approved Biosimilars	Safety Concerns
Subject drug **Ocrelizumab**	Ocrevus	**CIS, RRMS, SPMS, PPMS**	IV	Every 6 months	None	Infusion reactions, infection, malignancies, PML
Therapeutic Alternatives for Relapsing forms of MS						
Alemtuzumab	Lemtrada	RRMS, SPMS	IV	Daily x 5 days every 12 months	None	Autoimmunity, infusion reactions, infections, stroke, malignancies, PML
Natalizumab	Tysabri	CIS, RRMS, SPMS	IV	Every 4 weeks	Tyruko	PML, hepatotoxicity, teratogenicity
Ofatumumab	Kesimpta	CIS, RRMS	SC	Every 4 weeks	None	Infusion reactions and infections
Ublituximab	Briumvi	CIS, RRMS, SPMS	IV	Every 24 weeks	None	Infusion reactions, Infections
Therapeutic Alternatives for Primary Progressive MS						
None						

Abbreviations: CIS: clinically isolated syndrome; IV: intravenous; PML: progressive multifocal leukoencephalopathy; PPMS: primary progressive multiple sclerosis; RRMS: relapsing remitting multiple sclerosis; SC: subcutaneous; SPMS: secondary progressive multiple sclerosis

- Generally, all disease modifying treatments decrease the annualized relapse rate compared to placebo, with monoclonal antibodies having a greater effect than other oral and injectable medications.[17]

[16] FDA Drug Shortages: Current and Resolved Drug Shortages and Discontinuations Reported to FDA. Federal Drug Administration, Dec. 15, 2022. https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Dulaglutide%20Injection&st=c. Accessed May 8, 2024.

[17] Lin GA, Whittington MD, Nikitin D, Agboola F, McKenna A, Herron-Smith S, Pearson SD, Campbell J. Treatments for Relapsing Forms of Multiple Sclerosis; Final Evidence Report. Institute for Clinical and Economic Review, February 21, 2023.

- There are no randomized head-to-head trials comparing ocrelizumab to its therapeutic alternatives and insufficient evidence of clinically meaningful differences in efficacy between different monoclonal antibodies.
- Indirect evidence suggests ocrelizumab has similar effects on annualized relapse rate and disability progression to its therapeutic alternatives, including natalizumab and alemtuzumab.[14]

Table 3 Average healthcare and average patient OoP costs for Ocrevus vs therapeutic alternatives

Drug	Average gross healthcare spend per enrollee per year[18]	Average patient out-of-pocket cost per year[19]
Subject drug Ocrevus	$45,133	$2,381
Kesimpta	$63,514	$1,625
Tysabri	$67,594	$2,795
Average	**$58,747**	**$2,267**

Table 3 shows the average gross spend per enrollee per year for Ocrevus was **$45,133** vs. an average of **$58,747** across this drug and all identified therapeutic alternatives. Average out of pocket costs for patients was **$2,381** per patient per year, vs. an average of **$2,267** across this drug and all identified therapeutic alternatives.

Estimated average price concession for therapeutic alternatives

ORS 646A.694(1)(g) and OAR 925-200-0020(1)(g) & (2)(d) & (2)(L)(A-B). Limitations in scope and resources available for this statute requirement.

No information was provided by manufacturers or found in data review for price concession, discount or rebate manufacturers provide to health insurance plans and pharmacy benefit managers in this state for therapeutic alternatives.

Estimated costs to health insurance plans

ORS 646A.694(1)(h) and OAR 925-200-0020(1)(h) & (2)(h) & (m). Data source information provided from APAC and data call.

[18] APAC total gross spend for drug and total unique enrollees for drug. . Averages across commercial, Medicaid, and Medicare plans.

[19] APAC total copay, deductible, and coinsurance spend for drug and total unique enrollees for drug. Averages across commercial, Medicaid, and Medicare plans

In 2022, Ocrevus had **1,506** claims across **757** enrollees. Total gross cost of the drug was **$37,356,952** or **$45,133**per enrollee per year, and **$24,805** per claim per year.

Table 4 2022 Gross cost estimates based on APAC data[20]

Payer line of business	Total enrollees	Total claims	Total spend amount	Average spend amount per enrollee	Average spend amount per claim
Commercial	374	782	$24,539,601	$65,614	$31,3801
Medicaid	233	448	$6,596,382	$28,311	$14,724
Medicare	150	276	$6,220,968	$41,473	$22,540
Total	**757**	**1,506**	**$37,356,952**	**$45,133**	**$24,805**

Figure 3 illustrates the percent breakdown of the estimated 2022 gross costs of each business type identified in APAC. Commercial carriers held **65%** of the gross cost with Medicaid at **18%** and Medicare at **17%**.

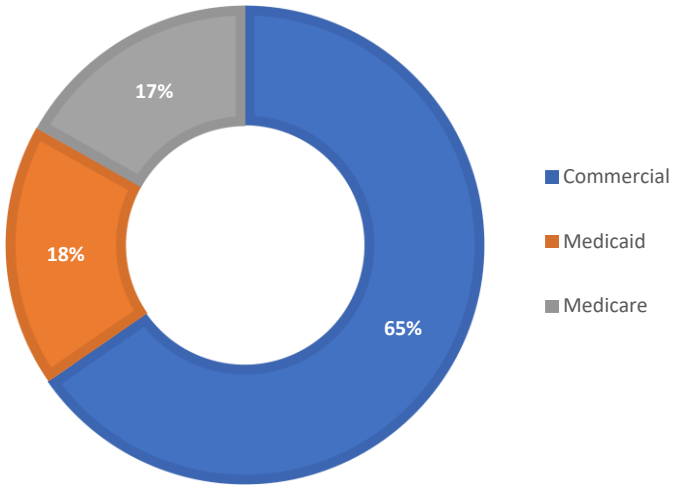


Figure 3 Percent of estimated gross cost based on 2022 APAC data[21]

The carrier data call[22] submissions were analyzed to determine the total gross annual spend, total number of claims and enrollees, the average amount paid for claim and per enrollee, and out-of-pocket (OoP) costs for enrollees. Table 5 indicates costs to Oregon payers and enrollees. Additional OoP information can be found in Tables 10 and 11 below.

[20] Based on 2022 Oregon APAC data across commercial insurers, Medicaid, and Medicare. APAC cost information are prior to any price concessions such as discounts or coupons.
[21] Ibid.
[22] Cost information from the data call is the cost of the drug after price concessions.

Table 5 2022 data call reported costs to Oregon payers and enrollees

Market	Total enrollees	Total claims	Total of paid claims	Total payer cost	Average paid claim	Average paid per enrollee	Total annual out-of-pocket cost for enrollees	Out-of-pocket cost per enrollee
Individual	58	174	112	$3,728,561	$33,291	$64,286	$352,289	$6,074
Small Group	57	143	111	$3,630,011	$32,703	$63,684	$306,568	$5,378
Large Group	75	190	166	$5,104,892	$30,752	$68,065	$262,607	$3,501
OEBB	44	246	91	$2,426,422	$26,664	$55,146	$93,586	$2,127
PEBB	54	170	106	$3,705,192	$34,955	$68,615	$40,386	$748
TOTAL	**288**	**923**	**586**	**$18,595,078**			**$1,055,436**	

Figure 4 represents the percentage of annual spend by market type reported in the carrier data call by commercial carriers. The large group represents the largest annual spend of **27%** of the Oregon market. Individual, small group, and PEBB contribute to **20%** each towards the market spend.

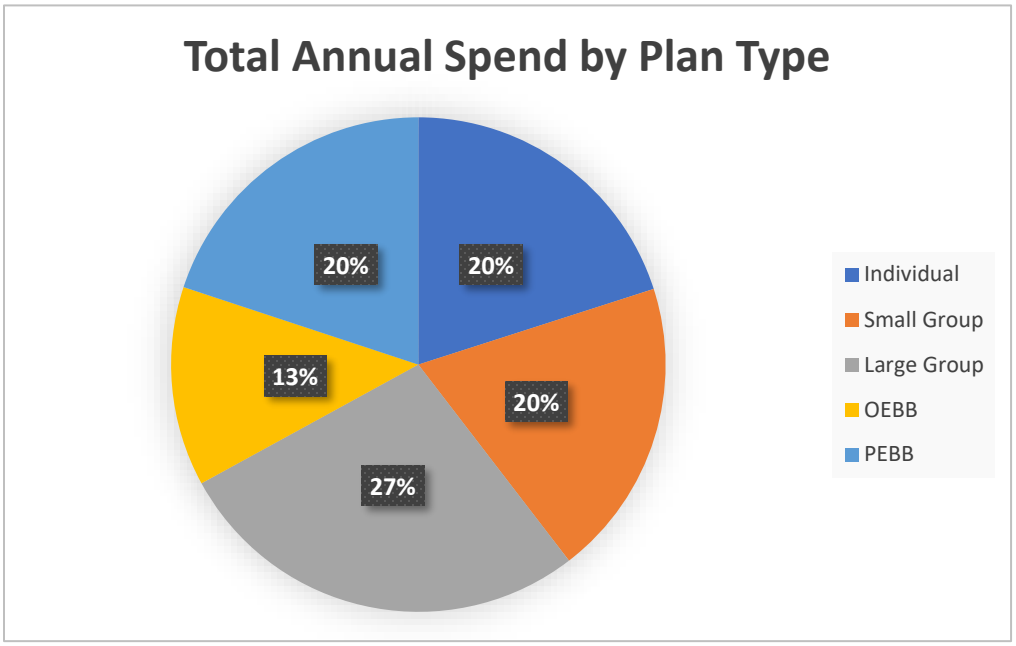


Figure 4 Data call total annual spend (payer paid)

Cost to the state medical assistance showed that the fee-for-service program had a gross annual average of **$84,190.50** for approximately **6.5** Ocrevus claims. The drug was listed as a

preferred drug and required prior authorization**.** No data was obtained from Oregon's coordinated care organizations (CCOs) for paid claims or per paid claim averages.

Table 6 2022 Gross amount paid for Medicaid/Oregon Health Plan fee for service

Fee for Service[23]							
2022 Quarter	**Drug name on report**	**Amount paid**	**% Total fee for service costs**	**Claim count**	**Average paid per claim**	**Preferred drug list (PDL)**	**Prior auth**
Q1	Injection, Ocrelizumab, 1 Mg	$76,426.00	0.80%	6	$12,737.67	Non-PDL class	No
Q2	Injection, Ocrelizumab, 1 Mg	$65,931.00	0.70%	7	$9,418.71	Non-PDL class	No
Q3	Injection, Ocrelizumab, 1 Mg	$127,082.00	1.40%	7	$18,154.57	Non-PDL class	No
Q4	Injection, Ocrelizumab, 1 Mg	$67,323.00	0.70%	6	$11,220.50	Non-PDL class	No
Annual Average:		**$84,190.50**	**0.90%**	**6.50**	**$12,882.86**		

Drug indicated on top 40 quarterly reports of the pharmacy utilization summary report provided by Oregon State University drug use research and management program.

Table 7 2022 Gross amount paid for Medicaid CCOs

Medicaid CCOs			
Drug	**Amount paid**	**Claim count**	**Average paid per claim**
Ocrevus	No data	No data	No data

Label and off-label indications and budget impact

Label

Ocrevus does not have a black box label warning.

Off label

There are no off label uses for Ocrevus.

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

Budget impact

For the 2022 Oregon insurer reported data **89%** of health insurances carriers reported a budget impact with Ocrevus identifying it as one of their top 25 most prescribed, most costly, and greatest increase for prescription drugs in 2022. According to the submitted information provided by Oregon commercial health plans the average costs per prescription was **$31,057** with **352** prescriptions for **164** enrollees. It was estimated that the total annual spend was **$10,932,003** with a total annual spend per enrollee of **$66,659**.[24]

Additional label and off label indication information is provided under the Information from manufacturer sections.

Impact on patient access to the drug

ORS 646A.694(1)(i) and OAR 925-200-0020(1)(i). Data source information provided from carrier data call.

Review of rejected claims and drug benefit designs

Carriers reported **923** claims for Ocrevus in 2022. Of those claims **586** were paid and **337** were rejected.[25] Based on this information, on average, **37%** of Ocrevus claims 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, information was collected regarding prior authorizations and approval for the drug. Insurers reported a wide variety of plan designs for Ocrevus. 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.

Information on how many carrier and market combinations were evaluated that had at least one plan that represented the following for Ocrevus:

Table 8 Plan design analysis

Percent of carrier/market combinations that had one or more plans that:[26]	
Required prior authorization	50%
Did not require prior authorizations	50%

[24] Revised Prescription Drug Subset List. Data for board review on Nov. 15, 2023. Prescription Drug Data, Prescription Drug Affordability Board website. https://dfr.oregon.gov/pdab/Documents/2023-PDAB-Top-Drug-List-v2.0.xlsx. Accessed May 8, 2024.
[25] For the purpose of this review the terms "denied" and "rejected" for claims are used interchangeable.
[26] Less than 5% of all total Rx claims was omitted from carrier entries that were considered unusable.

Percent of carrier/market combinations that had one or more plans that:[26]	
Drug was excluded on the plan formulary	9%
Drug was non-preferred on the plan formulary	82%
Drug was preferred on the plan formulary	9%
Required step therapy	14%
Did not require step therapy	86%

Note: percentages can equal over 100% as some carrier and market combos may have multiple plans that fall under different designs. For example: Carrier A may have three plans in the small group market that require prior authorization but two other plans in the small group market that do not require prior authorization.

Relative financial impacts to health, medical or social services costs

ORS 646A.694(1)(j) and OAR 925-200-0020(1)(j) & (2)(i)(A-B). Limitations in scope and resources available for this statute requirement.

Indication: Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults

Report	Treatment	Price (WAC)	Time Horizon	Total Cost (USD)	evLYs	Cost per evLY gained	Conclusion
ICER[27,28] (2023)	**Ocrelizumab**	**$71,187[29]**	**Lifetime**	**$1,829,000**	**14.13**	**$267,000**	Each listed therapy exceeds standard cost-effectiveness levels. To achieve a cost per evLY between $100,000-150,000, these treatments would need to be priced between $17,500-$34,900. This would require a discount in WAC ranging from 41-84%.
	Ublituximab	$59,000-$68,833		$1,683,000	12.81	$403,000	
	Natalizumab	$102,128		$2,636,000	13.56	$687,000	
	Ofatumumab	$89,760-119,686		$1,960,000	12.73	$616,000	
	Dimethyl fumarate	$2,739-$2,762		$1,065,000	11.27	*Comparator*	

ICER did not conduct an evLY-based cost-effectiveness analysis for ocrelizumab in the treatment of primary, progressive MS.

[27] https://icer.org/news-insights/press-releases/icer-publishes-final-evidence-report-on-treatments-for-multiple-sclerosis/
[28] Cost-effectiveness data presented from the ICER report are from the base case analysis.
[29] Price listed for ICER reports is the annualized wholesale acquisition cost (WAC).

Estimated average patient copayment or other cost-sharing

ORS 646A.694(1)(k) and OAR 925-200-0020(1)(k) & (2)(j)(A-D). Data source information provided from APAC and carrier data call. Data limitations with patient assistance programs

The APAC database[30] and the carrier data call were analyzed to determine the average patient copayment for commercially insured enrollees or other cost-sharing for the prescription drug.

Table 9 Breakdown of Out-of-Pocket Costs

2022 Average annual patient out of pocket costs		
Value	**APAC (commercial plans only)[31]**	**Data Call[32]**
Average Co-Pay	$367	$116
Average Deductible	$835	$990
Average Coinsurance	$1,623	$2,558
Potential Out-of-Pocket Costs for Patients[33]	**$2,826**	**$3,665**

Table 10 shows the breakdown of out-of-pocket costs for Ocrevus. A majority of patients taking Ocrevus could spend up to **$3,665** in out-of-pocket costs. Figure 4 illustrates the distribution of patient out-of-pocket costs, indicating many patients pay **$0**, but patients are shown to pay costs ranging from **$1,500** to **$2,500**, depending on insurance coverage and plan. Table 11 represents the central tendency of Ocrevus data, with patients potentially spending an average of **$2,826,** with a maximum spend of **$15,025**.

[30] Costs from the APAC database are prior to any price concessions such as discounts or coupons. Cost information from the data call is the cost of the drug after price concessions.
[31] Medicaid and Medicare were excluded from cost information.
[32] Data call refers to cost information collected from the health insurance plans by DCBS on prescription drugs under both pharmacy and medical benefits after price concessions.
[33] For patients who used the drug at least once in the 2022 calendar year.

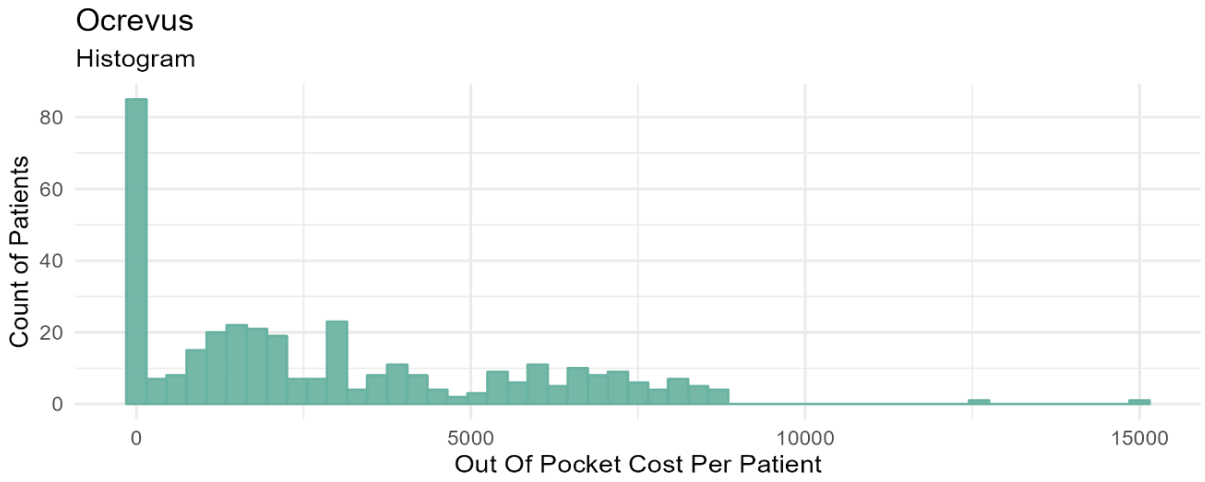


Figure 5 OoP costs central tendency histogram of Ocrevus costs in 2022

Table 10 OoP costs central tendency of Ocrevus costs in 2022

Out of Pocket costs per patient per year[34]		
Min	*This is the least any one patient paid*	$0.00
Average	*Patients pay this much on average*	$2,826
Median	*Half of patients pay more than this amount and half pay less*	$1,971
Mode	*The largest number of patients pay this amount*	$0.00
Max	*This is the most any one patient paid*	$15,025

For plan designs reported in the carrier data call, when a co-pay was greater than $0, the co-pay ranged from $5.00 up to $250.00. If the coinsurance was greater than 0%, the coinsurance ranged from 10% up to 50%.

The average patient out-of-pocket costs for the APAC data may be impacted by mandatory state reporting requirements, the exclusion of data from health plans with fewer than 5,000 covered lives and is prior to price concessions. The carrier data call out-of-pocket costs are from reports collected by DCBS from commercial carriers and may be affected by price concessions.

Additional information

The Colorado Prescription Drug Affordability Board reviewed Ocrevus 300 mg/10 mL Vial ML, resulting in the drug being ranked 45th out of 604 eligible drugs reviewed by the state. See Appendix A for the report.

[34] For patients who used the drug at least once in the 2022 calendar year.

Information from manufacturers

ORS 646A.694(1)(L) and OAR 925-200-0020(1)(L). Information provided from manufacturers and information with sources from contractor(s).

Refer to Appendix F for manufacturers' information.

Drug indications

- FDA Approved:
    - Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
    - Primary progressive MS, in adults

Clinical efficacy

- Multiple sclerosis is a chronic, immune-mediated disease of the central nervous system (CNS) characterized by inflammation, demyelination, and neuronal destruction which results in progressive, irreversible disability.[35] There are four distinct clinical courses of MS. Most patients have relapsing MS, including clinically isolated syndrome (first MS event), relapsing-remitting MS (RRMS), and active secondary progressive MS (SPMS). Only 10 to 15% of patients have primary progressive MS (PPMS), characterized by a steady decline in neurologic function and progressive accumulation of disability without acute attacks or relapses.[4] Patients with RRMS have relapses lasting 3 to 6 months with full recovery and minimal disease progression between episodes. Most of the clinical evidence in MS comes from RRMS and ocrelizumab is the only FDA approved medication for PPMS.

- In addition to symptom management, disease-modifying therapies are recommended to reduce relapses, slow progression of disability, and reduce new MRI lesion activity.[4] FDA approved disease modifying treatments include injectable agents (interferons, glatiramer acetate), oral medications (sphingosine 1-phosphate modulators, fumarates, teriflunomide) and monoclonal antibody infusions (including ocrelizumab).[4] The most common treatment approach is starting with a less potent, first line medication (interferon or glatiramer) with fewer adverse events and escalating to more potent medications as disease progresses.[4] The second approach is to initiate a higher potency medication initially (monoclonal antibody infusion) to delay disability. This approach increases the risk of adverse events and is often limited to those with more active disease and/or a limited treatment window. In relapsing forms of MS, monoclonal antibodies, including ocrelizumab, are generally recommended for those who have not

[35] McGinley MP, Goldschmidt CH, Rae-Grant AD. Diagnosis and Treatment of Multiple Sclerosis: A Review. JAMA. 2021 Feb 23;325(8):765-779.

responded adequately to first line medications. In PPMS, ocrelizumab is recommended if benefits outweigh risks.

- Ocrelizumab is a CD20-directed monoclonal antibody indicated for the treatment of both relapsing forms of MS and primary progressive MS.[36] It selectively depletes CD20-expressing B cells, which are present in meningeal inflammation and may cause neurodegenerative pathologic features of MS. Ocrelizumab is the only disease-modifying treatment approved for PPMS.

- FDA approval for relapsing forms of MS was based on moderate quality evidence from two identical, double-blind, active comparator, randomized controlled trials (RCTs) in patients with relapsing MS (n=1656).[37] In these trials, ocrelizumab 300 mg intravenously (IV) every 2 weeks for 2 doses followed by 600 mg every 24 weeks was compared to interferon beta-1a in patients with RRMS and SPMS over 96 weeks. The primary outcome was annualized relapse rate, defined as new or worsening neurological symptoms persisting for at least 24 hours followed by stable or improved disease state for at least 30 days. The annualized relapse rate was significantly lower with ocrelizumab compared to interferon beta-1a in both trials (0.16 vs. 0.29; hazard ratio [HR] 0.53; 95% CI 0.40 to 0.71 in trial 1; 0.16 vs. 0.29; HR 0.54; 95% CI 0.40 to 0.72 in trial 2).[6] Ocrelizumab also significantly decreased the rates of disability progression compared to interferon beta-1a at 12 weeks (absolute risk reduction [ARR] 4.6%).[6]

- Approval in primary progressive MS was based on a single, double-blind, multicenter, RCT comparing ocrelizumab IV infusion to placebo for 120 weeks in adults with PPMS.[38] The primary outcome was the percentage of patients with sustained disability over 12 weeks. Overall, the percentage of patients with sustained disability was lowered with ocrelizumab compared to placebo (32.9% vs. 39.3%; respectively; ARR 6.4%).[7] Although this was statistically significant, the magnitude of impact is low and clinical significance is unknown. Although the FDA reviewers noted several concerns with the design of the trial submitted for approval and no data to confirm benefit, it was approved due to an unmet need and no available disease modifying treatments for PPMS.[39]

Clinical safety

- <u>FDA safety warnings and precautions:</u>
    - Infusion reactions (34% to 40%)
    - Infections (58% to 70%): serious bacterial, viral, parasitic, and fungal infections have been reported.
        - Hepatitis B virus (HBV) reactivation

[36] [36]OCREVUS Prescribing Information. Genentech, Inc. San Francisco, CA. 01/2024

[37] Hauser SL, Bar-Or A, Comi G, Giovannoni G, et al.; OPERA I and OPERA II Clinical Investigators. Ocrelizumab versus Interferon Beta-1a in Relapsing Multiple Sclerosis. N Engl J Med. 2017 Jan 19;376(3):221-234.

[38] Montalban X, Hauser SL, Kappos L, Arnold DL, et al. ORATORIO Clinical Investigators. Ocrelizumab versus Placebo in Primary Progressive Multiple Sclerosis. N Engl J Med. 2017 Jan 19;376(3):209-220.

[39] FDA Center for Drug Evaluation and Research. Ocrelizumab medical review. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/761053Orig1s000MedR.pdf

        - Herpes infection
        - Respiratory tract infections (40%)
        - Vaccinations: Administer at least 4 weeks prior to treatment initiation.
    - Progressive multifocal leukoencephalopathy (PML)
    - Reduction in immunoglobulins
    - Malignancies
    - Immune-mediated colitis

- Contraindications:
    - Active HBV infection
    - History of life-threatening infusion reaction to ocrelizumab

- Common side effects:
    - Upper respiratory tract infections (40%), infusion reactions (34%), decreased neutrophils (13%), depression (8%), lower respiratory tract infections (8%), back pain (6%), herpes virus associated infections (6%), pain in extremity (5%)

- Safety advantages or disadvantages:
    - There are multiple monoclonal antibodies administered as infusions available for the treatment of RRMS. These therapies may be associated with the highest efficacy (compared to injectable therapy with interferon or oral therapy) but are associated with unfavorable adverse effects. There are differences in risk of adverse events between monoclonal antibodies that need to be considered prior to treatment choice.
    - Ocrelizumab is associated with infusion related reactions, malignancies including breast cancer, and depression and these have potential for more serious outcomes. The FDA reviewers noted concern for post-marking risks of infections and malignancies when patients are observed less frequently and uncertainty in use during pregnancy.[40]
    - There is moderate certainty of no difference in adverse events and low certainty of no difference in serious adverse events between ocrelizumab and interferon beta-1a in patients with RRMS.[41]
    - There have been reports of progressive multifocal leukoencephalopathy (PML), a rare but serious opportunistic infection of the brain with ofatumumab, alemtuzumab, and natalizumab. However, it has been most frequently reported with natalizumab treatment which carries a black box warning and requires testing and monitoring every 6 months. There is a potential risk of PML with ocrelizumab, particularly with prior immunosuppressive therapies.[42]

[40] FDA Center for Drug Evaluation and Research. Ocrelizumab medical review. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/761053Orig1s000MedR.pdf
[41] Lin M, Zhang J, Zhang Y, Luo J, Shi S. Ocrelizumab for multiple sclerosis. Cochrane Database Syst Rev. 2022(5).
[42] Rae-Grant A, Day GS, Marrie RA, et al. Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis: Neurology. 2018 Apr 24;90(17):777-788.

- There is limited data on the use of all monoclonal antibodies during pregnancy and it is generally recommended to stop all disease modifying therapies before conception or during pregnancy.[12]
- Due to serious safety concerns, natalizumab and alemtuzumab are monoclonal antibodies with specific risk evaluation and mitigation strategies (REMS) recommended for use by the FDA.[12] The REMS for natalizumab focused on PML and the REMS for alemtuzumab focuses on autoimmunity. There is no REMS program designated for ocrelizumab.

Input from Specified Stakeholders

ORS 646A.694(3) and OAR 925-200-0020(2)(k)(A-D)

Additional information for Ocrevus (Ocrelizumab) can be submitted until November 11, 2024.

Refer to the appendix section for specific stakeholder feedback.

Appendix A

The Colorado Prescription Drug Affordability Board reviewed Ocrevus 300 mg/10 mL Vial ML.

Appendix B: Patients and caregivers

The board received letters from the following people on these dates:

- Joe Lang, caregiver, June 17, 2024

Appendix C: Individuals with scientific or medical training

The board received letters from the following people on these dates:

- Dr. Kyle Smoot, Portland neurologist specializing in multiple sclerosis, Providence Brain and Spine Institute, February 12, 2024
- Sarah Emond, Institute for Clinical and Economic Review (ICER), June 14, 2024
- Kindyl Boyer, National Infusion Center, February 16, 2024

Appendix D: Safety Net Providers

- No information was provided by safety net providers.

Appendix E: Payers

- No information was provided by payers.

Appendix F: Manufacturers

The board received letters from the following people on these dates:

- Mary Wachter, Genentech, June 13, 2024

Appendix G: Advocacy Groups

The board received letters from the following people on these dates:

- Tiffany Robertson, AiArthritis, April 12, 2024
- Bari Talente, National Multiple Sclerosis Society, June 12, 2024
- Natalie Blake, Multiple Sclerosis Foundation, June 14, 2024
- Gina Murdoch, Multiple Sclerosis of America, June 14, 2024
- June Halper, International Organization of MS Nurses, Kathleen Costello, Can Do Multiple Sclerosis, June 17, 2024

Appendix A

Ranked
45th
out of 604 eligible drugs

OCREVUS 300 mg/10 mL VIAL (ML)

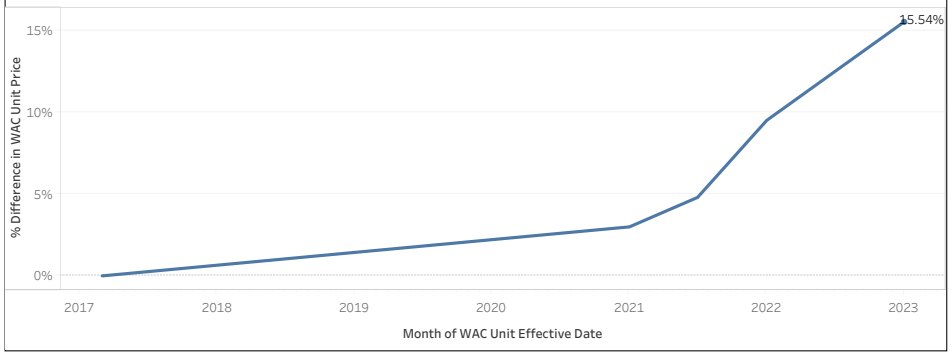
Select Brand/Strength/Dose:
OCREVUS 300 mg/10 mL VIAL (ML)

174 Utilizers	15.54% increase in WAC per unit since January 2018	$2,480 Out of Pocket Cost	$7,141,991 total paid in APCD Claims in 2021	$47,649 average paid per person per year

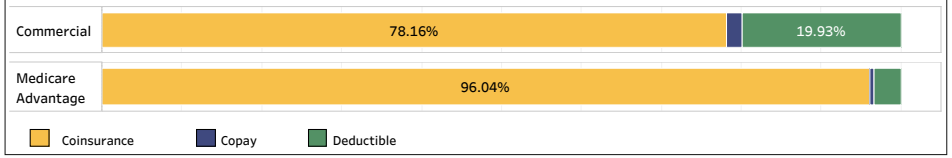
Therapeutic Class: **Multiple Sclerosis Agent - CD20 Specific Monoclonal Antibody**

Therapeutic Equivalent:
None Available

WAC per unit pricing change over time



Patient Out of Pocket Cost Breakdown



FDA Approval Date: **3/28/2017**

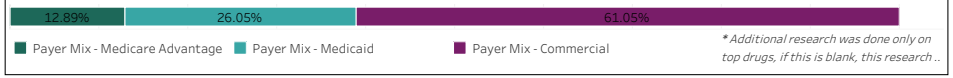
Approved under Expedited Pathway? **YES**
Approval Programs: **FT, PR, BT**

44.59%
of patients live in a county with a social vulnerability index that is higher than the statewide average

****Proprietary****
Estimated Rebate

Current WAC: per unit - ****Proprietary**** per course of treatment: **$50k - $60k**	Current ASP: per unit: **$58.97** per course of treatment: **$1,578**	Current NADAC: per unit: per course of treatment:
Total Plan Paid Amount: **$2,278,559**	Total Patient Paid Amount: **$303,430**	Average Out of Pocket Cost (ALOB): **$1,954**

Payer Mix



*Additional research was done only on top drugs, if this is blank, this research ..

First Quartile
Second Quartile
Third Quartile
Fourth Quartile

COLORADO
Prescription Drug Affordability Board
Division of Insurance

Appendix B

June 17, 2024

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309

Dear Prescription Drug Affordability Board members,

My name is Joe Lang and I am writing to share my perspectives as partner and caregiver of a female who has lived with multiple sclerosis for more than 20 years.

Now 47 years-old, she has been prescribed numerous drugs to halt or slow the progression of MS, including Ocrevus.

The development of drugs and therapies that target auto-immune disorders is critical to extending both quality of life and quantity of years. Equally as important for quality of life, however, is the affordability of drugs like Ocrevus to mitigate anxiety and depression caused by insurmountable financial burden.

After many previous drugs failed to slow the progression of my girlfriend's MS, Ocrevus was most effective at doing so, although the retail cost of each dose exceeded tens of thousands of dollars.

Had it not been for employer-based health insurance during the first three years of Ocrevus treatment, she would have had to request financial assistance, which she eventually needed to do after becoming unable to work because of the disease.

The process to request financial assistance, either through pharmaceutical companies or disease support groups, is painstakingly long and arduous with no guarantee of financial support for cost relief.

Prior to Ocrevus, my girlfriend experienced MS flareups multiple times per year that required expensive steroid infusions to bring the disease under control. During four years of Ocrevus treatments, she needed no steroid infusions to treat MS flareups.

I understand corporations need to recoup costs for developing innovative treatments. For patients who are unable to work and are insured through Medicare, however, the cost for these treatments almost always necessitates financial assistance, stigmatization and anxiety for patients and their families.

I am hopeful the PDAB and the Oregon Legislature can alleviate the anxiety and financial burden to access innovative drugs like Ocrevus.

Please do not hesitate to contact me if you have any questions or need more information. Thank you very much for your time and consideration.

Sincerely,

Joe Lang
Hillsboro, OR
503-707-5957
jlang1515@hotmail.com

Appendix C

Oregon Prescription Drug Affordability Board

350 Winter Street NE

Salem, OR 97309-0405

pdab@dcbs.oregon.gov

Subject Line:

Re: Oregon Prescription Drug Affordability Review of Ocrevus

Salutation:

Dear Members of the Oregon Prescription Drug Affordability Board,

In the past five years, there has been a notable transformation in the treatment approach for multiple sclerosis (MS), particularly emphasizing the early initiation of more potent therapies. As a leading neurologist specializing in MS in Portland, Oregon, I have witnessed this shift firsthand in my extensive practice, which serves as one of the largest MS cohorts in the Pacific Northwest.

Among the arsenal of treatments, ocrelizumab has emerged as a cornerstone therapy due to its remarkable efficacy, safety profile, and patient convenience. With over 200 patients benefiting from ocrelizumab under my care since its approval in 2017, I have seen its profound impact on reducing disease activity and enhancing the stability of MS.

One of the most significant advantages of ocrelizumab is its ability to substantially decrease the frequency of relapses and the formation of new MRI lesions. This translates into a tangible improvement in disease stability for a substantial portion of my patients. The resulting reduction in disease activity not only halts the progression of disability but also promotes a better quality of life for those living with MS.

Furthermore, ocrelizumab is well-tolerated by most patients, with few experiencing any significant side effects post-infusion. This not only fosters patient adherence but also minimizes the burden of treatment-related adverse events, allowing individuals to focus on their daily lives without the added stress of managing debilitating symptoms or medication side effects.

As a healthcare provider, it's imperative that we advocate for our patients' access to the treatments they need to thrive. I urge policymakers and stakeholders to carefully consider the implications of limiting access to ocrelizumab and to work towards solutions that prioritize the well-being of individuals living with MS in Oregon.

Kind Regards,

Kyle Smoot, MD, FAAN

Appendix C

INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

14 Beacon Street
Suite 800
Boston, MA 02108
617-528-4013
www.icer.org

June 14, 2024

The Oregon Prescription Drug Affordability Board
350 Winter St. NE
Room 410
Salem, OR 97309

Re: Comments on Ocrevus

Dear Members and Staff of Oregon's Prescription Drug Affordability Board,

The Institute for Clinical and Economic Review (ICER) is pleased to submit comments on Ocrevus. ICER is an independent non-profit research organization that evaluates medical evidence and convenes public deliberative bodies to help stakeholders improve patient outcomes and improve affordability. Our reports are used by the Veterans Health Administration and by most Medicaid and private insurance plans to help inform their formulary determinations, support drug price negotiation, and improve access for patients. As part of the international community of value assessment organizations (sometimes referred to as health technology assessment), we also participate in many activities related to the development of methods of evidence assessment, cost-effectiveness analysis, and public deliberation that can support efforts to achieve affordable access to high-value care.

As part of our work, we conducted an assessment for multiple sclerosis (MS) which included analyzing Ocrevus. Given our expertise in this field, we believe we can offer valuable insights to help inform your efforts to make prescription drugs more affordable and accessible for Oregonians.

ICER's findings on Ocrevus for Multiple Sclerosis 2023

In 2023, ICER produced an Evidence Report on Multiple Sclerosis focused on multiple interventions, including ocrelizumab (Ocrevus®), for relapsing forms of MS. Each ICER Report consists of multiple sections including: a comparative clinical effectiveness analysis, perspectives from patients and patient advocates, long term cost-effectiveness,

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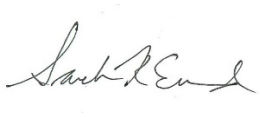
contextual considerations and potential other benefits, the potential budget impact and policy recommendations.

Additionally, as part of all analyses an ICER "health benefit price benchmark" is developed for the intervention, which reflects prices that align with the benefits patients receive. Further information on the ICER Health Benefit Price Benchmark (HBPB) can be found in ICER's Value Assessment Framework. For the 2023 Evidence Report on multiple sclerosis ICER determined the Health Benefit Price Benchmark range for Ocrevus to be $16,500 – $34,900 per year.

Finally, as part of our 2023 analysis, we held a public meeting on January 20, 2023 in which ICER presented evidence from the report, an independent appraisal committee vote was conducted on questions of comparative effectiveness and value, along with policy recommendations regarding pricing, access, and future research. All of these are captured in the final report.

Thank you for the opportunity to comment on Ocrevus for the treatment of multiple sclerosis. We are available to respond to any follow-up questions the Board may have.

Sincerely,



Sarah K. Emond, MPP
President and Chief Executive Officer
Institute for Clinical and Economic Review (ICER)
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Attachments:

1. Lin GA, Whittington MD, Nikitin D, Agboola F, McKenna A, Herron-Smith S, Pearson SD, Campbell J. Treatments for Relapsing Forms of Multiple Sclerosis; Final Evidence Report. Institute for Clinical and Economic Review, February 21, 2023. https://icer.org/assessment/multiple-sclerosis-2023/#timeline

Appendix C

NATIONAL INFUSION CENTER ASSOCIATION

The Nation's Advocacy Voice for In-Office Infusion

3307 Northland Dr, Ste 160 ▪ Austin, TX 78731
www.infusioncenter.org ▪ info@infusioncenter.org

February 16, 2024

Re: Concerns with Prescription Drug Affordability Board

To Whom It May Concern:

On behalf of the infusion providers we represent in your state, thank you for your service and commitment to the people of Oregon. As a nonprofit trade association that provides a national voice for non-hospital, community-based infusion providers; we would like to express our concerns with the potential implementation of an Upper Payment Limit (UPL) for Ocrevus, Entyvio, and Inflectra.

The National Infusion Center Association (NICA) is a nonprofit organization formed to support non-hospital, community-based infusion centers caring for patients in need of infused and injectable medications. To improve access to medical benefit drugs that treat complex, rare, and chronic diseases, we work to ensure that patients can access these drugs in high-quality, non-hospital care settings. NICA supports policies that improve drug affordability for beneficiaries, increase price transparency, reduce disparities in quality of care and safety across care settings, and enable care delivery in the highest-quality, lowest-cost setting.

Our organization writes to express concern regarding the potential implementation of a UPL for the three aforementioned drugs. NICA is concerned with the high costs borne by patients, however, we believe imposing a UPL for drugs with provider billing codes, such as Ocrevus, Entyvio and Inflectra, will cause a systemic lack of access to these drugs.

Applying a UPL to these drugs would disrupt the delicate economics of medical benefit drug delivery, putting smaller community providers—that represent the lowest-cost care setting for these expensive medications—out of business. Infusion providers typically acquire, administer, and bill for drugs through a buy-and-bill model. Providers are reimbursed for the drug and provided a small payment for professional services that does not begin to cover the overhead of their business. To remain in business, infusion centers must rely on their drug payments to offset the incredible cost-reimbursement disparity on the professional services side.

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The Nation's Advocacy Voice for In-Office Infusion

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Drug payments are the economic lynchpin to offset practice expenses, including inventory management, staff salaries, and office space. Establishing a UPL would set a ceiling on reimbursement for these drugs. This would compromise the current payment model for provider administered drugs, which is critical to sustaining the economic viability of these services. In order to sustain access to these drugs under a UPL, acquisition costs would have to drop sufficiently below the UPL to cover our members' overhead and professional services. The UPL mechanism has no means through which to achieve this price spread on the acquisition side. Though well-intended, applying a UPL to these drugs would harm infusion providers, leading to a broad lack of access to care for these drugs.

Thank you for your consideration. If I can provide any additional information, please do not hesitate to contact me.

Sincerely,

Kindyl Boyer

Kindyl Boyer
Director of Advocacy
National Infusion Center Association

Genentech
A Member of the Roche Group

600 Massachusetts Ave. NW, Suite 300
Washington, DC 20001
Phone: (202) 296-7272
Fax: (202) 296-7290

June 13, 2024

Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
pdab@dcbs.oregon.gov

Re: Oregon PDAB Prescription Drug Affordability Review - Ocrevus® Review June 26, 2024

Dear Members of the Oregon Prescription Drug Affordability Board:

Genentech, a Member of the Roche Group, appreciates the opportunity to provide input to support the affordability review of Ocrevus® (ocrelizumab). Ocrevus is the first and only approved disease-modifying therapy (DMT) that is indicated for the treatment of adults with either relapsing forms (RMS) or primary progressive (PPMS) multiple sclerosis.[1,2] Since its approval in 2017, Genentech has remained committed to further advancing scientific knowledge on the safety and efficacy of Ocrevus. Of note, there are more than 30 ongoing Ocrevus clinical trials designed to help us better understand MS and its progression. These studies are designed to address questions in areas such as long-term safety, pregnancy and lactation, disease activity of minority patients and many others. The evidence generated through our research efforts continues to support the value Ocrevus brings to patients and their families, health systems and society.

In our previous letters dated October 13, 2023, November 11, 2023, February 21, 2024, and May 7, 2024 we wrote the Board with concerns and suggestions regarding the affordability review process. Concerning Ocrevus, we previously sent the Board written comments on November 10th with evidence that demonstrated: **(1) how Ocrevus provides significant value to multiple sclerosis (MS) patients, the health care system and society;** and **(2) that Ocrevus is affordable, particularly in the context of other FDA-approved therapeutic alternatives.**

As the Board has chosen to proceed with an affordability review for Ocrevus, we are providing the following information to reaffirm that Ocrevus is indeed an affordable treatment option for patients with MS in Oregon. Within this letter, we share three key points for the Board's consideration during the affordability review of Ocrevus on June 26, 2024:

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[1] Ocrevus (ocrelizumab) Prescribing Information. Genentech, Inc. 2016.
[2] National Multiple Sclerosis Society. Treating PPMS. Available at http://www.nationalmssociety.org/What-is-MS/Types-of-MS/Primary-progressive-MS/Treating-Primary-Progressive-MS. Accessed 21 January 2024.

1) **Ocrevus should not be deemed unaffordable, based on its annualized cost relative to therapeutic alternatives for MS.**

2) **The Board is required to consider data bearing on how disease-modifying therapies - like Ocrevus - positively impact patients, their families, and the broader health system.**

3) **The affordability of Ocrevus must be considered within the context of the broader health care system, as a multitude of factors drive patient costs.**

We expand on these points below to provide additional context and evidence. While the Board has deprioritized data and information submitted by manufacturers in its weighting exercise, we strongly urge the Board to thoughtfully consider the data presented here associated with clinical outcomes, cost offsets, and other data essential to determining affordability. We ask the Board to strongly consider the drug characteristics that drive overall treatment value and shape patient and physician choice of treatment, as outlined here, in the affordability review of Ocrevus. The statute authorizing affordability reviews and the Board's regulations both require consideration of a drug's *affordability*, in light of these factors and the drug's overall value, rather than on a pure cost-per-prescription basis.

1) **Ocrevus should not be deemed unaffordable, based on its annualized cost relative to therapeutic alternatives for MS.**

The Board's chosen methodologies and reliance on limited data from insurers have incorrectly targeted Ocrevus due to flaws in the metric used to compare drug prices.

Ocrevus was included in the Board's "Top Cost" drug subset solely due to the limited methodology employed by the Drug Price Transparency (DPT) Carrier reports, which used an "average price per prescription" as a primary metric. Given Ocrevus is administered every 6 months,[3] the "price per prescription" data point vastly overestimates the drug's perceived affordability concerns. On an annualized basis, Ocrevus is priced lower than 17 other disease-modifying therapies (DMTs) that represent therapeutic alternatives for MS patients. In fact, when comparing like time periods (e.g., on an annual or average monthly basis), the cost of Ocrevus is ~27% below the average wholesale acquisition cost (WAC) of the other approved MS DMTs.[4]

The failure to account for the more frequent dosing (i.e., weekly or monthly) schedules of most of these therapeutic alternatives misleadingly produces a lower resulting "cost per prescription", when in fact the cost of these alternatives and the burden to the health care system and society may actually be higher. As such, the methodologies used for drug selection penalized Ocrevus for having a lower patient treatment burden of twice yearly dosing and did not identify other MS

[3] Ocrevus (ocrelizumab) Prescribing Information. Genentech, Inc. 2016.
[4] Genentech (2024 February). *Ocrevus® (ocrelizumab) Multiple Sclerosis (MS) WAC Flash Card.* https://www.ocrevus.com/content/dam/gene/ocrevus/resources/ocrevus-ms-wac-price-flashcard.pdf. Accessed 26 February 2024.

therapies that might present affordability challenges.[5] By following a methodology that does not compare the cost of treatments in a uniform manner (i.e., the annualized WAC), the Board has chosen to include Ocrevus as the sole MS drug in these affordability reviews even though its annualized WAC is considerably lower than many therapeutic alternatives.

In assessing affordability, OAR 925.200.0020 and the PDAB statute both require consideration of "the estimated price for therapeutic alternatives to the drug." That term necessarily requires the Board to consider the *actual* price of alternative therapies - that is, the cost of actually using those alternative therapies - by comparing apples to apples. Focusing on "average cost per prescription" to determine affordability, without regard for the dosing regimen or association of the medicine's use in reducing other health care costs, is inappropriate and leads to inaccurate assessments of a medicine's affordability and value. Based on these limitations, the Board is underestimating the value of Ocrevus by not accurately and holistically assessing the criteria outlined in OAR 925.200.0020, including the requirement to take into account "all relevant data regarding costs, expenditures, availability, and utilization related to the prescription drug and its therapeutic alternatives."

Ocrevus' price history highlights a focus on affordability.

Genentech has a long-standing pricing philosophy that is designed to strike a balance between ensuring patients have rapid, broad and sustainable access to our medicines, while at the same time preserving our ability to invest in future scientific innovations that drive the important medical breakthroughs that patients depend on us for. Since its launch in 2017, the price of Ocrevus remained at $65,000 and was not increased until 2021.

As of February 1, 2024, the WAC for Ocrevus is $78,858 per year, which remains over 42% below interferon-beta 1a, the comparator in our pivotal RMS studies ($137,354) and ~27% below the annual price of the average MS DMT.[6] We believe our pricing approach, along with the proven clinical profile of Ocrevus, have contributed to positive insurance coverage decisions that have improved access for people living with MS. Of those with medical benefit health insurance - both commercial and government-sponsored - 96% have coverage for Ocrevus, highlighting that insurers recognize the value of Ocrevus, thus making it accessible.[7]

In its nearly seven years on the market, Ocrevus pricing has not triggered price increase advance notice nor reporting requirements under Oregon's transparency laws. Between launch in 2017 and 2024, Ocrevus WAC price increases averaged 2.8% per year (cumulative average growth rate, 2017-2024), which is lower than the annual increases in Consumer Price Index for All Urban Consumers (CPI-U) which averaged 3.51% per year.[8] Additionally, the Ocrevus Average Sales Price (ASP) (annually $66,516 as of Q2 2024), which Medicare and some

[5] Oregon prescription Drug Affordability Board. Drug affordability review. https://dfr.oregon.gov/pdab/Pages/affordability-review.aspx. Accessed 1 February 2024.
https://www.ocrevus.com/content/dam/gene/ocrevus/resources/ocrevus-ms-wac-price-flashcard.pdf
[6]Genentech (February 2024). *Ocrevus® (ocrelizumab) Multiple Sclerosis (MS) WAC Flash Card.*
https://www.ocrevus.com/content/dam/gene/ocrevus/resources/ocrevus-ms-wac-price-flashcard.pdf. Accessed 26 February 2024.
[7] MMIT Coverage Data and DRG Payer Lives. Data as of January 2024
[8] Bureau Labor Statistics, CPI-U, All items, Unadjusted (Jan 2017 - Jan 2024).

commercial health plans use as the basis for patient cost-sharing for physician-administered drugs, has increased only 0.57% per year (cumulative average growth rate).[9]

This low ASP growth rate may support patient affordability with minimal year-over-year change in patient out-of-pocket expenses, depending on payers' insurance plan designs. Additionally, ASP, which serves as the cost basis for Medicare payment, is reflective of voluntary financial concessions that reduce costs for commercial insurers and other health care stakeholders. Genentech also provides additional statutory concessions in Medicaid and 340B, which are not reflected in ASP but further reduce costs for government payers and safety net providers.

2) **The Board is required to consider data bearing on how disease-modifying therapies - like Ocrevus - positively impact patients, their families, and the broader health system**

In selecting Ocrevus for review, the board focused heavily on cost data without sufficient consideration of disease and treatment factors that shape how choice of treatment impacts patients, their families and the health care system more broadly. Patient and physician preferences for treatment choice, as well as health plan coverage decisions, are based on a multitude of factors that determine a treatment's value, ranging from how often a drug is administered to its safety profile to how the use of a drug influences overall health plan spending for a patient's disease over time. Both the statute and the Board's regulations require consideration of Ocrevus's long-term cost savings and health impacts. We recommend that the board carefully consider information on the burden of MS and the proven impacts of Ocrevus treatment alongside cost data and stakeholder commentary. Specifically, we ask the board to consider the following evidence during the affordability review of Ocrevus, which supports the finding that Ocrevus does not pose an affordability challenge and should not be included in the Board's report to the legislature.

The burden of MS on the health care system and patients lives should be considered during the affordability review.

MS is a chronic disorder that can lead to permanent neurological and physical disability and affects an estimated 1 million individuals in the US,[10] including over 7,000 people in Oregon.[11] People with MS are often diagnosed between the age of 20-40 years, and are mostly female (3:1).[12] As MS symptoms most often present during an individual's prime years,[13] there are not only long-term impacts on a patient's quality of life, but also serious economic consequences.[14] When considering the broader costs of MS, the annual cost to the US is estimated at nearly $85

[9] CMS ASP Pricing Files, https://www.cms.gov/medicare/payment/all-fee-service-providers/medicare-part-b-drug-average-sales-price/asp-pricing-files. Accessed 30 May 2024.
[10] Wallin MT, Culpepper WJ, Campbell JD, et al. The prevalence of MS in the United States: A population-based estimate using health claims data. Neurology. 2019;92(10):e1029-e1040.
[11] MS Registry | Providence Oregon, https://pacificnwms.org/. Accessed 30 October 2023.
[12] Ford H. Clinical presentation and diagnosis of multiple sclerosis. Clin Med (Lond). 2020 Jul;20(4):380-383. doi: 0.7861/clinmed.2020-0292.
[13] Ford H. Clinical presentation and diagnosis of multiple sclerosis. Clin Med (Lond). 2020 Jul;20(4):380-383. doi: 0.7861/clinmed.2020-0292.
[14] Bass A, Van Wijmeersch B, Mayer L, et al. Effect of Multiple Sclerosis on Daily Activities, Emotional Well-being, and Relationships The Global vsMS Survey.Int J MS Care. 2020;22:158-164.doi: 10.7224/1537-2073.2018-087

billion.[15,16,17] Major contributors to the high socioeconomic burden of MS are disease progression and disability accumulation, as burden and costs increase with disease severity. DMTs are treatments that can reduce disease activity and slow disease progression, and have thereby transformed the treatment landscape for patients with MS. Research has shown that early treatment of MS with high-efficacy DMTs, like Ocrevus, can reduce the risk of relapse and delay disease progression, which has separately been associated with improved long-term clinical and economic outcomes.[18,19] In the sections below, we provide evidence on the value that Ocrevus has brought to patients and their families and the health system overall. Both the statute and the Board's regulations require consideration of how Ocrevus reduces the disease's impact on these stakeholders.

Ocrevus *has established long-term benefits in slowing disease progression.*

The recent publication of 10-year milestone data from the Ocrevus open-label extensions of the Phase III RMS and PPMS studies demonstrated benefits in slowing long-term disability progression.[20] In a 10 year study of Ocrevus, 77% of patients with RMS were free from disability progression, and 92% were still walking unassisted. In patients with PPMS, 36% were free from disability progression, and 80% of those patients treated with Ocrevus over ten years could still walk unassisted. Importantly, the 10-year pooled safety data across a number of studies from over 6,000 patients continues to reinforce the consistent long-term safety profile of Ocrevus.[21]

Additionally, an analysis from the Roche safety database found that maternal exposure to Ocrevus (ie., *in utero* exposure to Ocrevus) was not associated with increases in the risk of adverse pregnancy or infant outcomes compared with the general population.[22] Given that MS often presents during childbearing years for women, these observations reinforce an extremely important safety outcome.

Patients treated with Ocrevus are highly adherent and persistent with therapy.

Real-world research has shown that people with MS who were adherent and persistent with their DMT had substantially lower medical costs compared with those who were not.[23] Specifically, those who were persistent with medication for 24 months showed a reduction in

[15] Whetten-Goldstein K, Sloan FA, Goldstein LB, Kulas ED. A comprehensive assessment of the cost of multiple sclerosis in the United States. Mul Scler. 1998; 4(5):419–25.
[16] Bebo B, Cintina I, LaRocca N, et al. The economic burden of multiple sclerosis in the United States: estimate of direct and indirect costs. Neurology. 2022; 98(18):e1810–17.
[17]Adelman G, Rane SG, Villa KF. The cost burden of multiple sclerosis in the United States: a systematic review of the literature. J Med Econ. 2013; 16(5):639–47.
[18]Nicholas, J., et al. Annual Cost Burden by Level of Relapse Severity in Patients with Multiple Sclerosis. Adv Ther 38, 758–771 (2021).
[19] Filippi M, et al. Early use of high-efficacy disease-modifying therapies makes the difference in people with multiple sclerosis: an expert opinion. J Neurol. 2022 Oct;269(10):5382-5394.
[20] Weber M, et al. The Patient Impact of 10 Years of Ocrelizumab Treatment in Multiple Sclerosis: Long-Term Data from the Phase III OPERA and ORATORIO Studies.Presented at the 9th Joint ECTRIMS-ACTRIMS Meeting. Milan, Italy. 11–13 October 2023.
[21] Hauser et al. Safety of Ocrelizumab in Multiple Sclerosis: Updated Analysis in Patients with Relapsing and Progressive Multiple Sclerosis Presented at the 9th Joint ECTRIMS-ACTRIMS Meeting. Milan, Italy. 11–13 October 2023.
[22] Hellwig, Kerstin, et al. "Pregnancy and Infant Outcomes in Women Receiving Ocrelizumab for the Treatment of Multiple Sclerosis: Analysis of the Largest Available Outcomes Database." Multiple Sclerosis and Related Disorders 80 (2023): 105306.
[23] Pardo G et al. The Association Between Persistence and Adherence to Disease-Modifying Therapies and Healthcare Resource Utilization and Costs in Patients With Multiple Sclerosis. J Health Econ Outcomes Res. 2022 Apr 26;9(1):111-116.

mean total non-drug medical costs of approximately $19,000 compared with non-persistent patients. A similar pattern was observed for adherent versus non-adherent patients (reduction in costs at 24 months was about $16,000).

Relatedly, when assessing Ocrevus compared with other MS DMTs (based on route of administration), one study found patients treated with Ocrevus had higher adherence rates than other therapeutic alternatives that were FDA-approved in or before 2019. Specifically, Ocrevus patients had an adherence rate of 80% compared to rates of 55%, 35%, and 54% for oral, injectable, and other intravenous (IV) treatments, respectively, over two years.[24] Similarly, at 24 months, 75% of patients initiating Ocrevus were persistent with therapy compared with 54%, 33%, and 55% on oral, injectable, and other IV, respectively. In comparing Ocrevus to other therapies and in assessing its overall costs, the Board must consider the cost offsets enabled by Ocrevus's method of administration and its six-month dosing regimen, which results in improvements in adherence and persistence and significant associated cost savings.

Ocrevus treatment is associated with improved work productivity and reduced work impairments.

As MS onset occurs during an individual's most productive years, a reduction in the ability to do routine activities, including being employed, results in a substantial economic burden.[25,26] In lieu of head to head direct comparisons across DMTs, a network meta-analysis was conducted to compare completed clinical trials and predict the impact of DMTs on work productivity.[27] The model predicted that over 10 years, productivity losses were lowest for Ocrevus compared with other DMTs. In addition, the estimated percent employment among patients treated with Ocrevus was highest compared to other DMTs (53.3% versus 41.7%) in year 10. The economic benefit for patients treated with Ocrevus resulted from an improved ability to work due to delayed progression leading to productivity gains of up to $25 million over 10 years relative to other MS treatments.

Real world evidence shows early use of Ocrevus leads to lower health care utilization and costs.

A recent retrospective claims study demonstrated that patients who initiated Ocrevus as a first-line treatment had better clinical outcomes and lower events often associated with relapse[28] than those who initiated it as a second-line or later treatment option (Figure 1).[29]

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[24] Pardo G et al. Adherence to and Persistence with Disease-Modifying Therapies for Multiple Sclerosis Over 24 Months: A Retrospective Claims Analysis. Neurol Ther. 2022 Mar;11(1):337-351. Note, this study was conducted using claims data from April 2016 through December 2019.

[25] Nicholas JA, Electricwala B, Lee LK, Johnson KM. Burden of relapsing-remitting multiple sclerosis on workers in the US: a cross-sectional analysis of survey data. BMC Neurol. 2019;19(1):258.

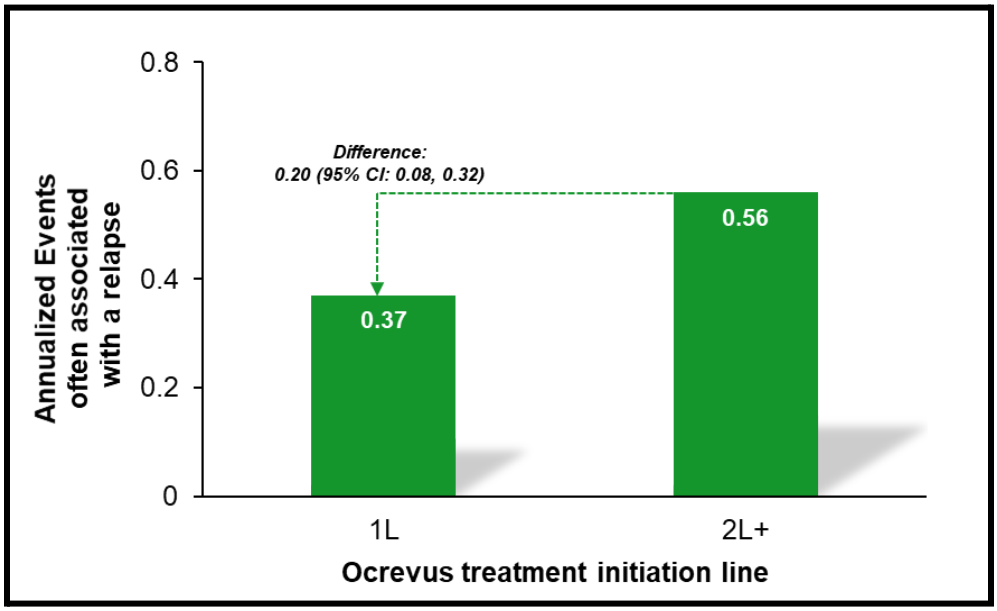
[26] Chen, Jing, et al. "Effects of multiple sclerosis disease-modifying therapies on employment measures using patient-reported data." *Journal of Neurology, Neurosurgery & Psychiatry* 89.11 (2018): 1200-1207.

[27] Geiger C, et al.Productivity Loss Among Persons With Multiple Sclerosis Treated With Ocrelizumab vs Other Disease-Modifying Therapies. Presented at the ISPOR Meeting. Atlanta, GA. May 5 - May 8 2024.

[28] Events often associated with relapse were defined as any inpatient stay with primary diagnosis of MS; or an outpatient visit with an MS diagnosis with evidence of high-dose steroids, IV corticosteroids, adrenocorticotropic hormone, or plasma exchange within 30 days of the outpatient visit. All patient characteristics, use of DMTs, and outcomes were identified using claims data.

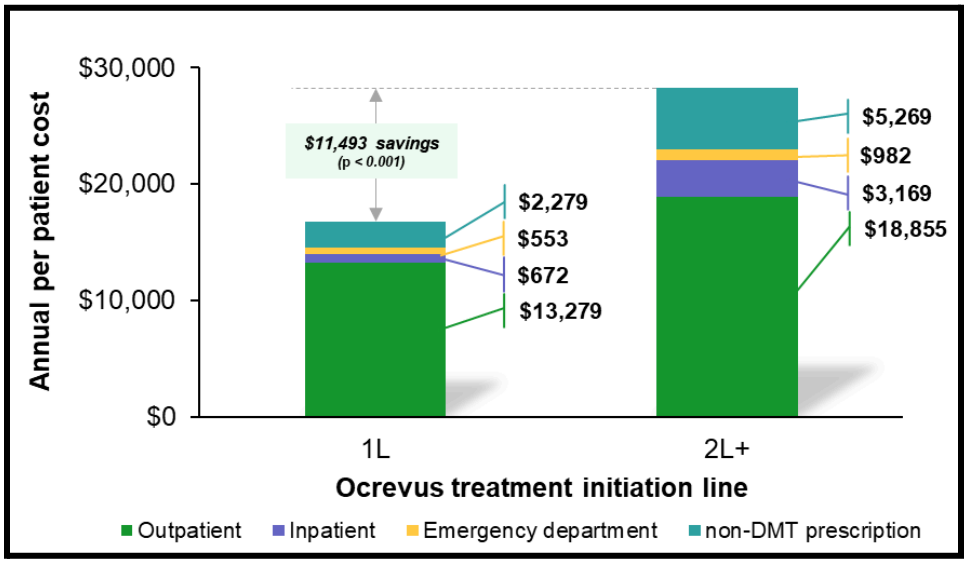
[29] Geiger CK et al. Real-World Clinical and Economic Outcomes Among Persons With Multiple Sclerosis Initiating First- Versus Second- or Later-Line Treatment With Ocrelizumab. Neurol Ther. 2023 Oct;12(5):1709-1728.

Figure 1: Difference in annualized events often associated with a relapse between 1st line and 2nd line initiation of Ocrevus



Patients on first-line Ocrevus also had lower health care resource use, including a lower probability of hospitalization, and longer time to events often associated with relapse compared to those who used Ocrevus as second line treatment or later. Notably, these findings of first-line Ocrevus use correspond to an annual savings of approximately $11,500 per patient, compared to those who were treated second-line or later (Figure 2).

Figure 2: Difference in annualized costs, per patient, between 1st line and 2nd line initiation of Ocrevus



Disease modeling predicts that early use of Ocrevus would lead to reduced long-term disability.

The need for walking aids and wheelchairs highlights the critical stages of disease progression that are associated with not only a decreased quality of life, but also reduced work productivity, and increased health care resource use and costs.[30,31,32,33] In lieu of head to head direct comparisons across DMTs, a network meta analysis was conducted to compare across completed clinical trials and used as the basis for a recently published disability model.[34] This model predicted that over 10 years, treatment with Ocrevus in people with MS would have a lower likelihood of reaching significant disability and the need for walking aids and wheelchairs, based on indirect comparisons to other DMTs.[35] Ocrevus as a first line treatment had the lowest predicted non-DMT direct medical and pharmacy costs compared to all other DMTs. The estimated cumulative non-DMT costs at 10 years for first-line Ocrevus were approximately 20% lower ($140,630 versus $174,203) when compared with other DMTs, such as dimethyl fumarate, natalizumab, ofatumumab, ublituximab, and fingolimod.

Ocrevus' Available Patient Assistance Supports Patient Affordability

Genentech's commitment to patient access for Ocrevus goes beyond responsible launch pricing and limited price increases. Commercially insured patients using Ocrevus, who are covered through their plan's medical benefit, are typically required to pay co-insurance (i.e., patient cost sharing obligation that is a percentage of the reimbursed drug's cost). This co-insurance amount can vary based on an insurance plan's benefit design. However, with Genentech's financial assistance programs, eligible commercially insured patients can pay as little as $0 for their Ocrevus treatment. Genentech also supports patient access to Ocrevus by providing financial assistance (up to $1,500 for the first year and $1,000 per year thereafter) for eligible commercially insured patients' out-of-pocket infusion costs. Genentech also offers programs and resources to support Ocrevus access for patients with other types of health insurance and for patients with no insurance at all.[36]

Genentech is committed to evaluating the safety and efficacy of Ocrevus in minorities and underrepresented populations.

Genentech is committed to advancing health equity by addressing barriers that people face when accessing health care, and inclusive research is at the center of this effort. Black and

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[30] Kwiatkowski A, et al. Social participation in patients with multiple sclerosis: correlations between disability and economic burden. BMC Neurology. 2014;14:1-8.
[31] Rezapour A, et al. The impact of disease characteristics on multiple sclerosis patients' quality of life. Epidemiology and Health. 2017:39.
[32] Geiger C, et al. Declines in Work Productivity in Persons With Multiple Sclerosis by PDDS Score. Presented at the American Academy of Neurology Annual Meeting. Boston, MA. 22-27 April, 2023. Poster #13-3.005.
[33] Simoens S. Societal economic burden of multiple sclerosis and cost-effectiveness of disease-modifying therapies. Frontiers in Neurology. 2022;13:1015256.
[34] Lin, Grace, et al. "Oral and Monoclonal Antibody Treatments for Relapsing Forms of Multiple Sclerosis: Effectiveness and Value - Final Evidence Report." 21 February, 2023.
[35] Geiger C, et al. Disability Outcomes Among Persons With Multiple Sclerosis Treated With First-Line Ocrelizumab vs. Other Disease-Modifying Therapies. Presented at the ACTRIMS Meeting. West Palm Beach, FL. February 29 - March 2 2024
[36] "Financial Assistance Options | OCREVUS® (ocrelizumab)." OCREVUS. https://www.ocrevus.com/patient/financial-support/assistance-options.html. Accessed 3 June 2024. (Assistance under the OCREVUS Co-pay Program is subject to an annual cap per patient.)

Hispanic communities often face socioeconomic and cultural barriers to care that contribute to inequitable differences in health outcomes. Despite making up almost 20% of the MS population, Black and Hispanic people living with MS are vastly underrepresented in clinical research and often experience more severe disease, faster disease progression, and greater disability than white people living with MS.[37,38] [39] Given this disparity, Genentech collaborated to design the CHIMES trial with people living with MS, advocacy groups, and clinical investigators to broaden understanding of MS progression and response to treatment specifically in Black and Hispanic populations.

CHIMES (Characterization of Ocrelizumab in Minorities With Multiple Sclerosis) is a Phase IV study that is ongoing in Black and Hispanic people with MS.[40] The one-year interim analysis found that Ocrevus controlled disease activity and disability progression in these populations, demonstrating a safety and efficacy profile consistent with the established pivotal clinical data. At 48 weeks, about half of the patients enrolled in the CHIMES trial achieved no evidence of disease activity (46% of Black patients and 58% of Hispanic patients), with approximately 95% of patients experiencing no relapses (95% of Black patients and 96% of Hispanic patients). We hope that the Board will recognize Genentech's continued commitment to generating clinical evidence on Ocrevus across underrepresented populations to help ensure that the right treatments are delivered to the right patients at the right time.

3) **The affordability of Ocrevus must be considered within the complexities of the broader health care system, as a multitude of factors drive patient costs.**

As noted above, Genentech shares a commitment to patient affordability, and took that into consideration when initially pricing Ocrevus at a discount versus all other MS therapies approved at the time. When considering the affordability of Ocrevus we ask that the Board consider the many factors that shape the affordability of medicines. Insurance type, benefit design, and site of care are a few of the myriad factors outside of WAC (or "list") price that can impact a patient's final out of pocket costs, as well as cost to the system. As a medicine traverses the delivery supply chain, it can be subject to a variety of factors across several intermediary stakeholders which impact costs, ranging from negotiated rebates and discounts to significant markup at the point of care.[41] For example, the setting in which the patient receives their infusion of Ocrevus may create significant variation in their out-of-pocket cost and overall cost to the health care system. Research published by a health insurer shows a 93% variation in the cost of MS treatments, depending on where the patient received their care.[42] This variation reflects that many complex, interacting factors in the pharmaceutical supply chain and

[37] Hittle M, et al. Population-Based Estimates for the Prevalence of Multiple Sclerosis in the United States by Race, Ethnicity, Age, Sex, and Geographic Region. JAMA Neurol. 2023;80(7):693-701.
[38] Kister I, et al. How Multiple Sclerosis Symptoms Vary by Age, Sex, and Race/Ethnicity. Neurol Clin Pract. 2021 Aug;11(4):335-341. doi: 10.1212/CPJ.0000000000001105.
[39] Williams M, et al. .One-Year Analysis of Efficacy and Safety Data From Black and Hispanic Patients With Relapsing Multiple Sclerosis Receiving Ocrelizumab Treatment in the CHIMES Trial. Presented at the 9th Joint ECTRIMS-ACTRIMS Meeting. Milan, Italy. 11–13 October 2023.
[40] Hauser et al. One-Year Analysis of Efficacy and Safety Data from Black and Hispanic Patients with Relapsing Multiple Sclerosis Receiving Ocrelizumab Treatment in the CHIMES Trial. Presented at the 9th Joint ECTRIMS-ACTRIMS Meeting. Milan, Italy. 11–13 October 2023.
[41] https://www.gene.com/stories/the-science-of-pricing. Accessed 20 February 2024.
[42] https://www.unitedhealthgroup.com/content/dam/UHG/PDF/2019/UHG-Administered-Specialty-Drugs.pdf. Accessed on 1 February 2024.

health care distribution chain play a role in determining the cost of a medicine - to the patient and the health care system at-large.

Similarly, multiple factors influence the final amount that a patient will pay out-of-pocket for their treatment. For example, a patient requiring use of a physician-administered drug on Medicaid may have a nominal copay, while a patient on a Medicare fee-for-service plan without supplemental insurance may be subject to 20% cost-sharing, with no annual limit.[43,44] Relatedly, within employer-sponsored plans, a Kaiser Family Foundation report found that patients who receive insurance through a small firm have higher deductibles than those who work at large firms.[45] Moreover, even within the same insurance type, depending on the benefit design, a patient's out-of-pocket obligations costs may vary. For example, a patient with a $1,000 deductible, $75 copay, and $4,000 out-of-pocket maximum could pay anywhere from $0, $75, $1,000, $4,000 or somewhere in between depending on the timing of their infusion and prior health care utilization within the insurance year. Given the myriad of factors that influence patient cost sharing, changes in list prices for a medicine do not directly translate into changes in cost sharing liability for patients. Indeed, a recent longitudinal study found no association between changes in a drug's list price and out-of-pocket costs for patients for brand-name clinician-administered drugs.[46]

Due to the complexities outlined here regarding cost sensitivities for both patients and the health care system, resulting from a myriad of factors which are disconnected from a medicine's WAC, it is critical the Board carefully considers additional data and supply chain dynamics in making any decision on the affordability of Ocrevus.

Given the evidence and points outlined above, **we ask the Board *not* to include Ocrevus in its list of drugs which may pose an affordability challenge in its forthcoming report to the legislature.** We continue to welcome the opportunity to engage with the Board and its staff on these points. If you have any questions or wish to discuss our comments, please contact Tim Layton, Director of State Government Affairs at layton.timothy@gene.com or (206) 403-8224.

Sincerely,

Mary Wachter, RN
Executive Director
State & Local Government Affairs

[43] https://www.medicaid.gov/medicaid/cost-sharing/index.html. Accessed on 1 February 2024.
[44] https://www.kff.org/medicare/issue-brief/medicare-part-b-drugs-cost-implications-for-beneficiaries-in-traditional-medicare-and-medicare-advantage/- Accessed on 1 February 2024.
[45] https://www.kff.org/report-section/ehbs-2023-summary-of-findings/. Accessed on 1 February 2024.
[46] Lalani, Hussain S., et al. "Association between changes in prices and out-of-pocket costs for brand-name clinician-administered drugs." *Health Services Research* (2024).

AiARTHRITIS
INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS

"We don't represent the patient voice, we *are* the patient voice."

February 28, 2024

Oregon Prescription Drug Affordability Board
Labor & Industry Building
350 Winter Street NE
Salem, OR 97309-0405

RE: Public Comments - Oregon Prescription Drug Affordability Board (PDAB) – Drug Specific Comments for Review of Ocrevus, Entyvio, Inflectra

Dear Members of the Oregon Prescription Drug Affordability Board:

The International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis), a patient organization led by people affected by AiArthritis diseases, is grateful for the opportunity to submit public comments throughout this drug affordability process. We hope the board will consider these statements as you continue forward with your drug affordability program.

About AiArthritis. AiArthritis is a leader in advancing education, advocacy, and research for those impacted by autoimmune and autoinflammatory arthritis (AiArthritis) diseases through peer-led guidance, collaboration, and resources that are driven by patient-identified issues and patient-infused solutions. As we are led by patients we understand how important it is to be able to access safe, efficacious, and affordable treatments. As patients living with heterogeneous conditions, we also understand there is no one-size-fits-all drug - even for those diagnosed with the same disease. Through lived experience, we also know that disrupting continuity of care often leads to uncontrolled disease, comorbidities, and significantly decreased rates of remission.

Focus on Patient Outcomes. For patients with immune conditions, treatments like Ocrevus, Entyvio, and Inflectra can have a significant positive impact. Immune disorders, including multiple sclerosis and Crohn's disease, can be incredibly debilitating and keep those diagnosed from maintaining normal functions and daily routines. Worsened health conditions can result in more frequent doctors visits, the need for invasive medical interventions, and hospitalizations. Patients that identify and maintain effective treatments are able to resume their normal daily lives. It cannot be understated that the medications under review are life-changing for the patients they treat. Therefore, we urge the committee to keep patient impact at the forefront of deliberations of these drugs.

Impeding Patient Access. As the board proceeds with review of drugs that specifically treat immune disorders, we would like to emphasize the importance of maintaining unrestricted access to broad treatment options for patients with complex conditions.

- Patients with complex and chronic conditions often spend years identifying treatments that work for them – it is typical for a patient to try and fail at multiple treatments before finding one that is most effective for them personally.
- Treatments can work for a specific patient for multiple years but then become less effective, forcing a change in therapies.
- Over the course of a lifetime of maintaining a chronic disease, many patients will face switching medications multiple times as their selected treatment becomes less effective to them personally.
- Treatments that are classified as therapeutic alternatives are not guaranteed to work for every patient.

Therefore, it is critical that health policies do not impede access to treatments or lead to fewer options for patients.

AiARTHRITIS
INTERNATIONAL FOUNDATION FOR AUTOIMMUNE & AUTOINFLAMMATORY ARTHRITIS

"We don't represent the patient voice, we *are* the patient voice."

Avoid Unintended Consequences to Patients. Focusing solely on the price of drugs ignores the many complicated factors that ultimately drive costs up for patients and oversimplifies a very complex process. Additionally, reviewing only a handful of medications can create further inequities, picking winners and losers among patients and patient populations. If access is impeded or utilization management for needed drugs increased, patients will suffer from unnecessary delays in connecting patients with highly innovative therapies, fewer treatment options, and more barriers to accessing the life-changing care they need.

Patient and Patient Organization Involvement in the Process. In follow-up to our January letter, we continue to be concerned that the board has not included a mechanism for patient input into the process nor integrated patient perspectives into the affordability assessment in any meaningful way. Those utilizing the drugs in review must be heard and their perspectives counted when analyzing the data. Failure to properly include their input can result in biased and statistically insignificant data, resulting in actions by the state that could impede therapeutic access and stymie innovation.

We appreciate all opportunities to collaborate with the board and invite you to lean on us for additional information or guidance as needed. We appreciate every opportunity given to patients that enables us to have a voice in matters involving our healthcare. Thank you for considering our suggestions and do not hesitate to reach out to me at tiffany@aiarthritis.org with any questions.

Sincerely,

Tiffany Westrich-Robertson

Chief Executive Officer
Person living with non-radiographic axial spondyloarthritis
International Foundation for Autoimmune & Autoinflammatory Arthritis

Appendix G

National
Multiple Sclerosis
Society

June 11, 2024

Oregon Division of Financial Regulation
Oregon Prescription Drug Affordability Board
350 Winter St. SE
Salem, OR 97309

RE: National Multiple Sclerosis Society Comments on Ocrevus® Review

Dear Chair Bailey, Vice Chair Burns, committee members Hartung, Judge, Laman, Murray,

Thank you for the opportunity to submit comments on the Oregon Prescription Drug Affordability Board's review of Ocrevus®. The National Multiple Sclerosis Society (Society) is pleased that the State of Oregon and the Prescription Drug Affordability Board (Board) are seeking public comments and input throughout each step in this process. The Society has been actively involved in the creation and implementation of Prescription Drug Affordability Boards nationwide, as we believe they provide important information about and review of the high cost of prescription medications. The Board and the Society share a common goal in ensuring affordable access to medications for Oregon residents. Our comments focus on the lived experience of people with MS and the patient perspective that we believe is essential for the Board to complete its review of an MS medication.

Background

Multiple sclerosis (MS) is an unpredictable disease of the central nervous system. Currently there is no cure. Symptoms vary from person to person and may include disabling fatigue, mobility challenges, cognitive changes, and vision issues. An estimated 1 million people live with MS in the United States. While there is not yet a cure, we do know that early diagnosis and treatment are critical to minimize disability. Significant progress is being made to achieve a world free of MS.

The Society, founded in 1946, is the global leader of a growing movement dedicated to creating a world free of MS. Oregon has a higher prevalence of MS than many states across the country, with a direct adjusted MS prevalence of 292 to 332 per 100,000 individuals[1]. There is a strong association between latitude and prevalence with higher prevalence estimates in northern latitudes.

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10186207/figure/noi230024f3/ (attn. figure 3)

National
Multiple Sclerosis
Society

Costs of Living with MS

People with MS have a variety of healthcare needs including but not limited to addressing neurological symptoms, emotional and psychological issues, rehabilitation therapies to improve and maintain function and independence, and long-term care. These needs vary dramatically from person to person and can change year to year as the disease progresses.

MS is a highly expensive disease, with the average total cost of living with MS calculated at $88,487 per year[2]. MS may impact one's ability to work and can generate steep out-of-pocket costs related to medical care, rehabilitation, home & auto modifications, and more. For individuals with MS, medical costs are an average of $65,612 more than for individuals who do not live with this disease. Disease-modifying treatments (DMTs) are the single largest component of these medical costs. As of February 2024, the median annual brand price of MS DMTs is more than $107,000. Five out of seven of the DMTs that have been on the market for at least 13 years are priced over $100,000 annually and continue to see regular price increases.

MS DMT Commentary

As the Board undertakes their review, the Society wants to ensure the Board has the appropriate context from both the most up-to-date science and the lived experience of people with MS. As mentioned above, there is consensus that early diagnosis and early treatment with an MS DMT improves long-term health outcomes for people with relapsing forms of MS by reducing the number of relapses, slowing disease progression and delaying irreversible neurological damage. Currently, there are clinical trials underway to evaluate the two approaches for treating relapsing MS, funded by the Patient Centered Outcomes Research Institute (PCORI)[3]. These two approaches are escalation therapy, where treatment is started with a DMT regarded as safe but not as highly effective, and early treatment with highly effective medication, sometimes referred to as induction therapy. This initiative was launched in 2015, and it is still a number of years before the trials will conclude. In the meantime, there is growing scientific consensus that the strategy of early treatment with a high efficacy DMT is best for people with MS.[4]

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9109149/
[3] https://www.pcori.org/research-results/2017/comparing-two-approaches-treat-relapsing-remitting-multiple-sclerosis-deliver-ms-study
[4] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9489547/

National
Multiple Sclerosis
Society

Today there are more than 20 DMTs, both name brand and generic, approved by the FDA for treatment of relapsing forms of MS. Ocrevus® was approved by the FDA in 2017, is considered to be in the category of high efficacy treatments, and was the first medication approved with the specific anti-CD20 mechanism of action. Anti-CD-20 action is beneficial for people living with MS because it specifically reduces nerve damage which can lead to irreversible disability progression. Today there are two additional FDA-approved monoclonal antibodies with an anti-CD20 mechanism of action- one is an infused medication like Ocrevus® and the other is a self-injectable medication.

Along with mechanism of action, there are several other factors which influence the shared decision-making of a patient and doctor's choice of a DMT. Some of the top factors in shared decision-making conversations include efficacy, tolerance of side effects, dosage frequency and route of administration- all of which can affect adherence to treatment. Ocrevus® is administered by infusion every six months. This dosing schedule is often appealing to people with MS, as they may have increased quality of life due to the dosing infrequency. For some individuals, infusions may prove challenging if access to infusion sites is limited.

While there are more than 20 FDA approved medications for relapsing forms of MS, it's important to note that Ocrevus® is the only FDA approved DMT treatment for primary progressive MS (PPMS). Approximately ten to fifteen percent of people with MS have PPMS, and experience gradually worsening neurologic symptoms and an accumulation of disability without relapses.

Public Input and Meeting Processes

The Society appreciates the efforts in public transparency and accountability that the Oregon Board has demonstrated since its establishment. The Board has made their meetings accessible to all Oregonians via online broadcasts and shared materials, as well as by providing multiple forms and points of outreach to interested and concerned stakeholders. These initial efforts should be recognized, applauded, and built upon for continued success.

To further the discussion and public participation in the Oregon Board process, the Society would like to offer some suggestions on how to best improve the overall format and accessibility. While the meetings have been productive, they are at times difficult to follow organizationally with motions and debates becoming muddled in process and procedure questions, necessitating staff intervention to provide guidance when they can. We thank the former Chair Alki Peterson for initiating the organizational work and look forward to the new chair building on these efforts.

National
Multiple Sclerosis
Society

We also suggest the agenda packet and other materials be posted in a more timely manner allowing for proper review by both the general public and interested parties. Providing a full agenda packet at least one week in advance of all meetings would greatly benefit and increase stakeholder engagement and participation. Similarly, it is often unclear, both pre and post meeting, as to what stakeholder input is being solicited or requested by the board from patient organizations and other stakeholders in the process. Stakeholder and public requests for information and comments are mixed in with board requests, thereby making it unclear who should be commenting and on what they should focus. Direct requests for patient, stakeholder, and public comment with a clearer process would be appreciated and beneficial; it would also result in greater participation and more relevant results.

Finally, the lived experience of those who rely on life-changing medications is a crucial component to any evaluation of the medication. We encourage the Board to formalize processes to hear directly from patients.

The National Multiple Sclerosis Society thanks you again for the opportunity to provide comments of the drug selection review process for the Oregon Prescription Drug Affordability Board. The Society welcomes the opportunity to work with the Board on the implementation of their legislative charge to set upper payment limits (UPLs) when appropriate, thereby improving affordability of and access to prescription medications for all Oregonians. Should you have any questions, please contact Seth Greiner, Senior Manager of Advocacy, at seth.greiner@nmss.org.

Sincerely,

Bari Talente

Bari Talente, Esq.
Executive Vice President, Advocacy and Healthcare Access
National Multiple Sclerosis Society

Appendix G

February 26, 2024

Oregon Prescription Drug Affordability Board
350 Winter St. NE
Room 410
Salem, OR 97309

Re: March 20, 2024 Ocrevus® Review

Dear Board members:

The Multiple Sclerosis Foundation is an organization that advocates for access to care for people with MS. We would like to share perspectives on your upcoming review of Ocrevus and two vital factors that must be considered for the safety and well-being of people with MS.

First, the nature of MS and its treatment is important to consider. Multiple sclerosis is a disease that damages the central nervous system – the brain, spinal cord, and optic nerves. This makes rapid access to effective treatments essential. Unlike many other conditions, the damage caused by MS is irreparable if a medication fails to work or a patient is unable to adhere to that medication. If, for example, a cholesterol medication fails to have the desired effect, another medication may successfully lower a person's cholesterol before any long-term consequences occur. If a person with multiple sclerosis receives a medication that is ineffective for them, another medication cannot repair the damage to their nervous system that has occurred while they were without effective treatment. This damage may be apparent immediately in the form of a relapse or disease progression, or its effects may be unseen for years, but research shows the damage is accumulating nonetheless.

For this reason, we believe that people with MS not only deserve but require access to the full range of available, FDA-approved treatments. The stakes are too high when a treatment fails. Asking an Oregonian with MS to risk irreversible damage within their brain on the basis of cost savings is unconscionable. People with MS should have access to any FDA-approved treatment their doctor prescribes through a shared decision-making process that considers the clinical research, indications, and likelihood of adherence.

A second critical factor to consider is that the FDA recognizes relapsing and progressive MS as different treatment indications. While there are many treatments available for relapsing MS, Ocrevus is the only FDA approved treatment for progressive MS. We are very concerned that

should the outcome of an affordability review of this medication in any way lead to diminished access, that people with progressive MS – the more aggressive and debilitating form of the disease – may be left untreated.

As your Board is concerned with equitable access, it's also important to note that Black individuals have been shown to be more likely to have a highly aggressive and progressive form of MS. This particular medication is therefore an invaluable option for Black Oregonians to access.

We urge you to seek out and respect the voices of the MS patient community, MS advocacy organizations, and MS physicians as you advance in this review process, and as you review any further treatments in the future. Without a firm grasp of the stakeholders' needs, true value cannot be assessed.

Our fervent hope is for all Oregonians to have equitable, unhampered access to all FDA-approved medications for multiple sclerosis, as befits the critical nature of these medications in slowing or stopping damage to central nervous system.

Sincerely,

Natalie Blake
Executive Director

Multiple Sclerosis Foundation
National Headquarters: 6520 North Andrews Avenue, Fort Lauderdale, Florida 33309-2130
Toll Free: (800) 225-6495 • (954) 776-6805 • Fax: (954) 351-0630
Website: www.msfocus.org

Appendix G

msaa Improving Lives Today!®
Multiple Sclerosis Association of America

February 26, 2024

Oregon Prescription Drug Affordability Board
350 Winter St. NE, Room 410
Salem, OR 97309

Re: March 20, 2024 Ocrevus® Review

Dear Board members:

On behalf of the Multiple Sclerosis Association of America (MSAA), a patient advocacy organization dedicated to Improving Lives Today for individuals affected by MS, we are writing to provide comments on the upcoming review of ocrelizumab (Ocrevus®) by the Oregon Prescription Drug Affordability Board (PDAB).

We appreciate the need for Oregon to manage the rising costs of managing chronic conditions like multiple sclerosis while ensuring access to necessary treatments for Oregon residents. Your commitment to addressing the challenges of prescription drug affordability is commendable and vital for the health and well-being of the community.

We would like to express our gratitude specifically for the opportunity provided to stakeholders to voice concerns and make recommendations as you plan the review of Ocrevus. As you are aware, Ocrevus plays a crucial role in the treatment of multiple sclerosis, and access and affordability directly impact the lives of many patients who rely on this medication to manage their condition effectively.

Multiple sclerosis is a chronic, incurable disease of the central nervous system with a high likelihood of progressive disability over time. A large body of evidence indicates that early and persistent treatment with an FDA approved MS disease modifying treatment (DMT), reduces the accumulation of damage in the brain and spinal cord thus reducing relapses and disease progression. As the MS disease process is highly individualized, treatments must be carefully chosen for highest efficacy, adherence, and long-term benefit. This requires access to a wide range of MS DMT's, with differing mechanisms of action and modes of administration. While cost is a critical factor, we believe that the PDAB must consider additional factors in the shared decision making process to ensure that Oregonians living with MS have access to the MS DMT's that address their individual needs. Shared decision making must also include the patient voice, MS provider voice, and consideration of the evidence supporting the importance of Ocrevus as an MS treatment option.

NATIONAL HEADQUARTERS
375 KINGS HIGHWAY NORTH, SUITE B
CHERRY HILL, NEW JERSEY 08034

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msaa@mymsaa.org · mymsaa.org

Cost containment is clearly of high importance, however, the voice of those directly impacted by treatment decisions is just as crucial. We are not aware of an established and designated mechanism for the PDAB to hear the voice of those living with MS. We recommend a Patient Council, allowing people living with MS to share their challenges, experiences and needs with the PDAB. This will provide the PDAB with insight into the real-world impact of treatment decisions. People with MS, particularly inclusive of those from diverse backgrounds, can share their unique perspective on access, treatments, adherence, disability, cost of care, and more, that will inform the PDAB's decision making. Inclusion of people with MS fosters transparency and accountability of the decision making process and ensures that the voices of those directly impacted are heard and valued.

The voice of neurology providers, with expertise in MS care, will be critical for PDAB members to hear so that they fully understand the treatment landscape, the need for individualized decision making and access to a wide range of available MS DMT's. There is a growing body of evidence indicating that initiation of a high-efficacy MS DMT, such as Ocrevus, for people diagnosed with a relapsing form of MS provides superior control of the MS disease process through their ability to limit new CNS damage, reduce relapses and reduce disease progression. In MS, "time is brain," and delaying the use of highly effective DMTs will place individuals with MS at high risk for permanent disability.

Ocrevus is the only MS DMT that is FDA approved for the treatment of patients diagnosed with primary progressive MS (those whose symptoms progress from onset of the disease in the absence of well characterized episodes or relapses). No other MS DMT carries the primary progressive MS indication. We strongly recommend consideration of the drug indication and efficacy in the overall decision making process.

MSAA supports the need for Oregon to address the rising costs for Oregonians impacted by multiple sclerosis and appreciates the opportunity to provide comment ahead of the PDAB review of Ocrevus. We believe that consideration of our recommendations will foster a review process that is guided by the principles of equity, affordability, patient perspectives, and patient-centered care.

Sincerely,

Gina Ross Murdoch

Gina Ross Murdoch
President and CEO
Multiple Sclerosis Association of America

MULTIPLE SCLEROSIS ASSOCIATION OF AMERICA
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Appendix G

June 10, 2024

Oregon Prescription Drug Affordability Board
350 Winter St. NE
Room 410
Salem, OR 97309

Re: June 26, 2024 Ocrevus® Review

Dear members of the Oregon Prescription Drug Affordability Board:

The Consortium of Multiple Sclerosis Centers, International Organization of Multiple Sclerosis Nurses and Can Do Multiple Sclerosis, each advocacy organizations dedicated to improving the lives of individuals affected by MS, thank you for the opportunity to provide comments regarding the upcoming review of ocrelizumab (Ocrevus) by the Oregon Prescription Drug Affordability Board (PDAB). We are resubmitting our letter due to the PDAB schedule change.

We applaud the diligent efforts of the Oregon PDAB to manage the rising costs of medications. Your commitment to addressing the challenges of prescription drug affordability is commendable and vital for the health and well-being of the community. We would like to specifically express our gratitude for the opportunity provided to stakeholders to voice concerns and recommendations as you plan the review of Ocrevus. Ocrevus plays a crucial role in the treatment of multiple sclerosis, and access directly impact the lives of many patients who rely on this medication to manage their condition effectively.

Multiple sclerosis is a chronic, incurable disease of the central nervous system with a high likelihood of progressive disability over time. A large body of evidence indicates that early and persistent treatment with an FDA approved MS disease modifying treatment (DMT), reduces the accumulation of damage in the brain and spinal cord thus reducing relapses and disease progression. As the MS disease process is highly individualized, treatments must be carefully chosen for highest efficacy, adherence, and long-term benefit. This requires access to a wide range of MS DMT's, with differing mechanisms of action and modes of administration. While cost is an important factor, it cannot be the only factor and we believe that the PDAB must consider additional factors in the decision making process to ensure that Oregonians living with MS have access to the MS DMT's that address their individual needs. Decision making must also include the patient voice, MS provider voice, and consideration of the evidence supporting the importance of Ocrevus as an MS treatment option.

Cost containment is clearly of high importance, however, the voice of those directly impacted by treatment decisions is crucial. We are not aware of an established and designated mechanism for the Oregon PDAB to hear the voice of those living with MS. We recommend a Patient Council, allowing people living with MS to share their challenges, experiences and needs with the PDAB. This will provide the PDAB with insight into the real world impact of treatment decisions. People with MS, particularly inclusive of those from diverse backgrounds, can share their unique perspective on access, treatments, adherence, disability, cost of care, and more, that will inform the PDAB's decision making. Inclusion of people with MS fosters transparency and accountability of the decision making process and ensures that the voices of those directly impacted are heard and valued.

The voice of neurology providers, with expertise in MS care, will be critical for PDAB members to hear so that they fully understand the treatment landscape, the need for individualized decision making and access to a wide range of available MS DMT's. There is a growing body of evidence indicating that initiation of a high-efficacy MS DMT, such as Ocrevus, for people diagnosed with a relapsing form of MS provides superior control of the MS disease process through their ability to limit new CNS damage, reduce relapses and reduce disease progression. In MS, "time is brain," and delaying the use of highly effective DMTs will place individuals with MS at high risk for permanent disability.

Ocrevus is the only MS DMT that is FDA approved for the treatment of patients diagnosed with primary progressive MS (those whose symptoms progress from onset of the disease in the absence of well characterized episodes or relapses). No other MS DMT carries the primary progressive MS indication. We strongly recommend consideration of the drug indication and efficacy in the overall decision making process.

We support the role of the Oregon PDAB and appreciate the opportunity to provide comment ahead of the PDAB review of Ocrevus. We believe that consideration of our recommendations will foster a review process that is guided by the principles of equity, affordability, and patient-centered care.

Sincerely,

June Halper

June Halper, MSN, APN-C, MSCN, FAAN
President and CEO
Consortium of MS Centers
CEO
International Organization of MS Nurses

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Can Do Multiple Sclerosis

Consumer Outreach Report

Prescription Drug Affordability Board
June 17, 2024

Oregon Prescription Drug
Affordability Board

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Executive summary

The Prescription Drug Affordability Board (PDAB) hosted in-person and online community forums across Oregon to discuss the high cost of prescription drugs and its effect on Oregonians' lives, health, and budgets. The board held events in five cities, along with two online meetings in April and May. about 156 people attended the sessions held in Portland, Lincoln City, Woodburn, Medford, Bend, and online through Zoom. Board and staff members listened to 28 people describe how they skip medications because they cannot afford them, battle insurance companies over prescription coverage, and struggle to find medications that are in short supply.

Event summaries, survey results, video links, and media coverage are included in Appendices A-E of this report. This report is also posted on the PDAB website.

Also, the board invited people to take a survey about medication names and costs, along with insurance coverage. Fifteen people completed the survey. PDAB Chairperson Shelley Bailey and Vice Chairperson Amy Burns attended several events and spoke about the board's goal in wanting to hear from consumers. Bailey and Burns both have pharmacy backgrounds and answered questions and provided resources for consumers throughout the events.

> *"We don't have insurance coverage. My husband and myself are both working. He is sick and needs medicine. It is very expensive because we also need to pay for rent and other bills. He needs his medication every three months. We look for the most economical brands so we can buy them. It's hard for us. Most of us work in the fields for very little money. If we need cholesterol medicine or high blood pressure medicine, even with coverage, copays are high."*
>
> *– Patricia M., Woodburn resident*

Some highlights of the consumer stories included a participant in Woodburn, speaking through an interpreter, who talked about her family's $560 monthly prescription drug costs for her husband's health conditions. The participant said she and her husband both work in the fields for low wages and are unable to afford the medications. Also, a nurse practitioner in Medford and a health care worker in Baker City both described patients skipping unaffordable medications followed by a visit to the emergency room in a health crisis. They said this situation is dangerous for the patient and costly to the health system. A multiple sclerosis patient from Albany said his $7,000 monthly medication cost puts a tremendous financial strain on his family. A Medford woman said her brother cannot get the diabetes medication that works best for his body due to its high cost.

> *"Jardiance is incredibly expense: $42 for 30 pills. It is very effective and keeps my blood sugar under control and helped me lose weight. It is also in short supply. Sometimes I must wait two weeks for my medication."*
>
> *– Susan W., Lincoln City resident*

The stories told at the community forums represent what is happening across the state: Medication costs are burdensome for Oregonians. Consumers experience uncertainty about the cost of their prescription drugs and about the ability to access prescriptions. Consumers are confused about how much they will need to pay for their prescription drugs. They also expressed anxiety about the future.

For its next steps, the board will engage with consumers throughout the year, target its outreach to existing community events, and publicize future events well in advance.

PDAB mission: seek consumer input

The Oregon Legislature established PDAB in 2021 through Senate Bill 844. The board's mission is to protect Oregonians and health systems from the high cost of prescription drugs. There are eight members with backgrounds in clinical medicine or health care economics, appointed by the governor and confirmed by the Oregon Senate. One way the board accomplishes its mission is through affordability reviews, which are rigorous studies of the most costly drugs in the state based on criteria in the Oregon Administrative Rules. The Legislature asked the board to narrow the list of costly drugs down to nine, plus at least one insulin product, and present a list each year. The board's first affordability review process is taking place May through November 2024.

In 2023, the Oregon Legislature expanded the board's mission through Senate Bill 192 to "develop a plan for establishing upper payment limits on drugs sold in this state that are subject to affordability reviews under ORS 646A.694." The Legislature said the plan should include outreach to consumers and others. To fulfill its mandate, the board launched outreach components to hospitals, pharmacies, insurance companies, manufacturers, pharmacy benefit managers, advocacy groups, and consumers.

Community forum structure

For the community forums, the board selected locations around the state in venues that were centrally located and easily accessible to the public. Here was the schedule:

In person:

- Portland – Tuesday, April 2, 6-8 p.m., Portland State Office Building
- Lincoln City – Tuesday, April 9, 6-8 p.m., Cultural Center
- Woodburn – Monday, April 15, 5-7 p.m., Woodburn Public Library
- Medford – Thursday, April 25, 6-8 p.m., Rogue Community College Higher Education Center
- Bend – Tuesday, April 30, 6-8 p.m., East Bend Library

Online:

- Wednesday, May 8, noon to 2 p.m., via Zoom
- Tuesday, May 14, 6-8 p.m., via Zoom

The board provided Spanish interpretation at the Woodburn and online events to encourage more participants from the Spanish-speaking communities. An estimated 9 percent of Oregonians speak Spanish at home, according to the Oregon Office of Economic Analysis.[1] The board also provided American Sign Language interpretation in Medford and at the online meetings to encourage members of the Oregon Deaf community to participate. Three participants at the Medford meeting were from the Deaf community, including one who is a member of the Oregon Disability Commission. There was one participant from the Deaf community at the May 14 online forum.

The board sent a media release providing details about the events to Oregon newspapers, radio stations, and TV newsrooms. In addition, PDAB sent out this information on its social media platforms. In response, the Rogue Valley Times posted an article about the Medford event, and KDRV-TV featured an interview with the PDAB vice chairperson. The Bend Bulletin included the Bend event and the online meetings in its community calendar. See Appendix B.

> *"Rebif is very expensive. It costs about $7,000 a month without any kind of help. And the insurance does not cover that much. So that has been a challenge. As we like to say in my household, we're on a fixed income, and they fixed it good."*
>
> *– Michael T., Albany resident and multiple sclerosis patient*

[1] Hispanic Heritage Month 2019: A Profile of Hispanic Population in Oregon. Oregon Office of Economic Analysis and the U.S. Census Bureau, 2019. https://www.oregon.gov/das/oea/documents/hispanic_heritage_month_2019_oregon.pdf. Accessed May 17, 2024.

> *"I think those prescription drug prices are very hard. It makes a difference in what I can afford and what I cannot. I just think there should be a better way."*
>
> *– Jim H., 77, Portland*

For the meeting format, moderator Lou Savage, a past director of the Department of Consumer and Business Services and a former Oregon insurance commissioner, started the meeting with an overview and PowerPoint presentation. Savage talked about the board's mission and accomplishments, including the board's recommendation to the Legislature that resulted in a $35 monthly cap on insulin medication. He explained that an upper payment limit is a limit on what purchasers in Oregon would pay for specific drugs. He emphasized the board does not have the authority to create upper payment limits, but the board is studying the option at the direction of the Legislature. He also discussed some of the opinions about why prescription drug costs are high, such as co-pay coupons, patents, and pharmacy benefit manager practices.

The PDAB chairperson spoke at the meetings in Portland, Woodburn, and online, telling guests about her work as a co-owner of a Portland pharmacy. She also shared her passion for serving on the board and finding ways to make prescriptions affordable. She encouraged guests to share their stories. The PDAB vice chairperson, a pharmacist in Grants Pass, welcomed participants at the Medford meeting and encouraged people to speak, knowing their stories will likely resonate with others in the room. At the conclusion of the overview, Savage invited participants to share their stories, with the suggestion they consider these three questions:

- How has the cost of your prescription drugs affected you or your household?
- Do you feel you can follow your medical treatment plan for your condition with the cost of your prescription drug(s)?
- Do you, or have you had to, switch your Rx due to insurance coverage?

A total of 28 people shared their stories during the seven events. Their stories are summarized in Appendix A of this report. At each forum, the board chairperson, vice chairperson or staff members provided feedback and ways to help solve immediate needs. For example, the board chairperson provided a local clinic name to a Woodburn family struggling to pay for blood pressure, cholesterol, and diabetes medications. The board vice chairperson encouraged a Medford patient who was having trouble getting the right inhaler to talk to her provider about the prescription.

The meetings ended with Savage sharing a list of prescription drugs the board will be reviewing this year with the participants and inviting them to attend board meetings and submit public comment. The comment can be about the cost of any prescription drugs that are creating financial challenges for people, not just the drugs on the board review list, he said. He also invited people to take the community forum survey about medications and costs.

Takeaways and observations

The consumers and advocates who shared their stories at the forums about their challenges with the cost of prescription drugs had a wide range of experiences; however, some common themes came through. Consumers are experiencing uncertainty, confusion, and anxiety about being able to afford and have access to the prescription drugs needed to maintain their health.

Consumers experience uncertainty with the cost of their prescription drugs. Consumers expressed concern that insurance coverage for certain drugs can change. When the out-of-pocket cost changes, it can have a significant effect. Consumers also expressed uncertainty about what financial assistance programs are available for high-cost drugs.

Uncertainty about the ability to access prescriptions was frequently expressed. Consumers experienced uncertainty about whether their insurance would cover a specific drug that was prescribed by their care provider, as well as the availability of the prescribed drug. Access concerns include delays, because waiting for a prescription can create serious, sometimes life-threatening, health issues.

> *"We were working with a patient who took insulin but couldn't afford it. She quit taking it, and she didn't say anything. She ended up in dialysis with kidney failure. … The health effects are detrimental or even deadly to them at that point."*
>
> *– Jana Parker, community health worker, Baker City*

Consumers expressed confusion about how much they will need to pay for their prescription drugs. Insurance coverage is not clear, both in terms of cost and what specific drugs will be paid for. It is unclear when a brand-name drug will be approved, or only a generic drug. Confusion (or lack of knowledge) about financial assistance programs was also expressed. Several consumers had no knowledge of these programs or were confused about how they worked.

Consumers expressed anxiety about the future. Several consumers have anxiety about being able to continue to afford the drugs prescribed to them. Advocates have identified consumers missing meals to be able to afford their prescription drugs. Anxiety was also expressed about ongoing access to their prescription drugs, either from changes in their insurance coverage, availability, or both.

Recommendations

The attendance at the five in-person and two online forums totaled 156. This turnout was less than hoped for. There are several factors that may have accounted for this.

Due to concerns about completing the consumer forums on a timeline that would meet the initial deadline set for a report to the Legislature, the board and staff thought it was necessary to schedule the forums in April and May. This presented some logistical challenges, particularly for the in-person forums. More time for outreach and publicity could have improved attendance.

While it was important for all Oregonians to be aware of the forums, the board was particularly interested in hearing from consumers who are having challenges with the cost of their prescription drugs. Care providers, medical clinics, and hospitals may be in the best position to provide guidance on how to reach these populations.

Communities of color and marginalized communities were not well represented at the forums. Staff members did outreach to several organizations to encourage participation, and four of the forums had Spanish language and sign language translation available. These efforts were not sufficient. Planning for future consumer engagement should include planning with organizations representing

communities of color and marginalized populations. More resources for publicity in the media serving these communities would also be useful. This would include, but not be limited to, newspapers serving the Hispanic, Black, Asian, and Russian communities.

There is also a significant question as to whether in-person forums are the best vehicle for consumer engagement. It may be more effective to reach people at existing events with high attendance, such as a county fair or a grower's market.

One advantage of in-person forums has been the ability to collect contact information from consumers. The board could send follow-up emails to consumers who attended the in-person forums, inviting them to board meetings and updating them about the board's work.

> *"As a nurse practitioner, I can see the cost of treatment is too high. Patients can't afford medications, don't pick it up at the pharmacy and end up in the emergency room where the cost of the care is tremendous."*
>
> *– Laurie H., La Clinica, Medford*

Conclusion

The board laid a foundation for future public input when it hosted seven community forums around the state in April and May 2024. The board can build on this foundation by engaging with the consumers throughout the year, inviting them to board meetings and informing them of the board's work. The board can also target its outreach to existing community events with high attendance. The board can plan and publicize future events well in advance and hopefully draw more people to come and share their stories about burdensome high-cost medications.

Refer to Appendices A-E for meeting and survey summaries, video links, meeting presentations, and media coverage.

> *"My brother is a diabetic, and they switched him to a generic medication. It didn't work for his body, causing problems for his feet. How can he stay on the medication that helps him and not pay so much for that insulin?"*
>
> *– Joanna Wilson, Medford resident and member of the Oregon Disability Commission*

Appendix A – Event summaries

Here are written summaries of the community forums in each city and also online. The online forums were recorded and posted on the PDAB website: https://dfr.oregon.gov/pdab.

Portland

Prescription Drug Affordability Board (PDAB) Portland Community Forum
Location: Portland State Office Building, Portland
Date: April 2, 2024

Guests in attendance:

Jerry W., Robert N., Michael T., Mark S., Julie L., Mary L., Eric Lohnes of PhRMA, Sara Kofman, of Biogen, Lorren Sandt of Caring Ambassadors, Rebecca McAuliffe of Quinn Thomas, John Mullin of OCAP, and OSPIRG campaign associate Luke Winkler.

Board, staff and legislators in attendance:

PDAB Chairperson Shelley Bailey, Rep. Rob Nosse, Former Department of Consumer and Business Services Director and former Oregon Insurance Commissioner Lou Savage, External Affairs Director Mary Jaeger, Maggie Alvarez of Division of Financial Regulation Outreach, and PDAB Administrative Assistant Melissa Stiles.

Consumer testimony:

Mark S., Portland: Mark said his testimony today is very personal and a matter of life and death. He supports adequate funding for research and development for cure. During the pandemic, routine tests were hard to obtain because beds were used for COVID-19 patients. He missed four years of annual tests. Two years ago he took the routine test and was diagnosed with liver cancer that had spread to other organs and was untreatable and terminal. The doctors said most people at this stage survive six months to a year. He has lasted past the year and, in some ways, feels better than when he was diagnosed. He said his slim chance at life depends on an innovation. Without it, he will eventually deteriorate and die.

He said he benefited from an innovation over a decade ago, which probably allowed him to live another 10-plus years. His annual physical kept coming up with a low platelet count and it finally reached the point where they had to hand count the platelets. He took Interferon and Ribovarin, which had low success rates. Then Harvoni was developed. It was 95 percent effective with few side effects, one pill a day for 12 weeks. After taking Harvoni, he had no more virus and a virtually healthy, normal liver. His medication was paid for by the government. He said medicine needs to advance. Curtailing the innovative process by not adequately funding it serves no one. The government routinely subsidizes these new drugs, so cost is negated on them. He would rather have a cure.

Robert N., Multnomah County: As a result of taking psychiatric drugs for 20 years, Robert developed tardive dyskinesia, which causes involuntary neck movements. He takes Ingrezza once per day. The retail cost is $75,000 for a three-month supply, though his Kaiser Permanente health insurance covers most of the cost. However, it requires a pre-authorization, which is difficult for the doctors. The Ingrezza is slowly helping the tardive dyskinesia symptoms to go away. He recommends anyone with tardive dyskinesia get a case manager to work on securing and paying for the necessary medications to control symptoms, especially to get help with prior authorizations.

Luke Winkler, campaign associate, OSPIRG, of Portland: He thanked PDAB for its work on high medication costs. He said he talks to people who struggle with costly medications. He talked to a person suffering with arthritis because she can't afford the medications to treat it. He knows people living with migraines because they can't afford to treat them.

Lorren Sandt, executive director, Caring Ambassadors: Lorren represents patients who

have lung cancer and hepatitis C. She appreciates what the board is doing and wants to help the board find solutions. She is a proponent of patient engagement, which is different than public comments, where people speak to the board during a meeting. Public engagement is sitting down and talking to patients, finding out the cost drivers. She wants to work with the board to make this happen. Colorado has a patient engagement board and she hopes Oregon will have one too. She wants to make sure cost savings are for the patient and not just the state. If a patient is on a drug paid for by the pharmaceutical company, that helps the patient's medication costs. It helps the patient afford the medication. She hopes the board will have advisory boards to look at the drugs. Her organization works with groups like the Cascade AIDS project and hemophilia groups. Sandt said she is happy Bailey is the chairperson of the PDAB board because she is a patient advocate. When she was a pharmacist and the state said no, Bailey got people cures.

John Mullin, Oregon Coalition for Affordable Prescriptions (OCAP): The stories heard this evening are magnified 1,000 times over, John Mullin said. He thanked DCBS for sponsoring these meetings. He said OCAP supports industry transparency and drug affordability for consumers, but is also cognizant that consumers are paying higher costs. He thanked Rep. Nosse for being present and said Rep. Nosse is a champion in helping form the PDAB. He thanked Bailey for her leadership. He is also a proponent of having an advisory board, though it would probably require legislation. Everyone needs to learn more by hearing from other voices , he said.

Lincoln City

Prescription Drug Affordability Board (PDAB) Community Forum
Location: Lincoln City Cultural Center, Lincoln City
Date: April 9, 2024

Guests in attendance:

John A., Gleneden Beach; Judy H.; Susan W., Lincoln City; Robert C.; Madonna McGuire Smith, executive director of Pacific Northwest Bleeding Disorders; and Lohnes.

Board, legislators, public officials and staff in attendance:

Rep. David Gomberg, Sen. Dick Anderson, County Commissioner Claire Hall, PDAB Executive Director Ralph Magrish, Equity Officer Veronica Murray, Shannon Romero of Division of Financial Regulation Outreach, Savage, and Stiles.

Consumer testimony:

Judy H., Lincoln City: Her husband had osteoporosis and found great relief by taking Forteo (Teriparatide) nightly at a cost of $800 to $1,500 per month. They filled out a form, sent in their tax returns, and got the medication for free through a coupon program. She said it makes no sense why they could get it for free when others couldn't. Her husband also had a heart condition. The cardiologist told them to go to Canada to get the medicines because they were unaffordable in this country. Additionally, her doctor prescribed a medication that cost $113 to treat a skin condition. Her pharmacist found a coupon from GoodRx to bring the price down to $9. She asked these questions: Why is there so much disparity in the price of medications? Wouldn't it be better to have a fair price for everyone instead of having these extremes? Why in Canada do these medications cost half the price? Why are drug companies making such a profit?

Madonna McGuire Smith, executive director of the Pacific Northwest Bleeding Disorders Benton County: Her 16-year-old son, two other sons, and husband have rare bleeding disorders. The treatment involves drugs that cost $1 million per year. Pharmacy benefit managers (PBMs) and insurance companies have formularies that determine which drugs will be covered. Her son went through a pharmacokinetics (PK) process to determine the best hemophilia therapy for him. As a result, the doctor prescribed a specific medication, but the insurance company wouldn't

cover it. Why would doctors go through detailed analysis if the best treatment will not be covered? Additionally, she had thyroid cancer and went through treatments. She takes medicine every day to stay alive. She was prescribed a generic because it was most effective. But the insurance company sent her the brand-name. Every month she fought with them and asked why. They told her they get a great rate, a kick back from the brand-name product.

Her son is a hemophilia patient and treatments cost $50,000 per month for two shots. OHSU said she had to sign on to SaveOnSP, which allows OHSU to collect all the coupons. Her son was in the hospital and nearly died. They were not allowed to leave the hospital because they wouldn't sign up for SaveOnSP. The hospital collected $30,000 in coupons. It is frustrating that the middleman, insurance companies, and others contribute to the problem of the patient's ability to get medicines they need. She said her family is not alone in the struggle to pay for costly medicines for rare diseases.

Susan W.: She takes Jardiance and it frustrates her to see drug advertisements on TV because she realizes consumers are paying for the ads. She said Jardiance is incredibly expensive, $42 for 30 pills, yet it is very effective and keeps her blood sugar under control and helps with weight loss. It is also in short supply. Sometimes, she must wait two weeks for her medication to become available. The insurance company called and asked why she was not taking it every day. She told them sometimes it is because the medication is cost prohibitive and she can't afford it. Other times the medication is unavailable at the pharmacy.

Sen. Dick Anderson, of Lincoln City: He asked about House Bill 4149, the pharmacy benefit manager bill that the Legislature passed in the 2024 session. Magrish said DCBS is beginning the rulemaking process this spring and summer. He said the PBM reporting will include rebates, how much is returned to insurance companies, how much kept in profit, and how much returned to the consumer. Sen. Anderson said that should help with transparency.

Woodburn

Prescription Drug Affordability Board (PDAB) Community Forum
Location: Woodburn Public Library, Woodburn
Date: April 15, 2024

Guests in attendance:

Patricia M. and her three children, Woodburn; Stephanie H., Woodburn; Ramiro R., Woodburn; Lorren Sandt of Caring Ambassadors; Joe Steirer of GSK; and Luke Winkler, OSPIRG, of Portland.

Board and staff in attendance:

Bailey, Savage, Jaeger, Alvarez, Murray, Multicultural Communications Program Manager Ruth Kemmy, Drug Price Transparency Policy Team Assistant Sally Sylvester, and Stiles. Jorge Guzman and Cesar Guzman of Vive Northwest provided Spanish interpretation for the event.

Consumer testimony:

Patricia M., Woodburn: (speaking through interpreter Cesar Guzman). They don't have insurance coverage. She and her husband both work in the fields for very little money. He is sick and needs medicine every three months, which is very expensive. They also need to pay for rent and other bills. It's hard for them but she knows other people are in the same situation. She looks for the most economical brands to buy. If they need cholesterol medicine or high blood pressure medicine, even with coverage, co-pays are high. Many people need this benefit.

Bailey thanked Patricia for telling her story. She said GoodRx.com and Mark Cuban's CostPlus Drug Company provide discount cards that might help. Federally qualified health centers receive drugs at discounted prices and are supposed to pass on the savings to the public. Going to these clinics is a short-term answer to broader solutions. She said she would speak privately with Patricia after this meeting to brainstorm about solutions. **Joe Steirer of GSK** said the federally qualified health

centers in Woodburn that would provide lower-cost prescriptions are Salud Medical Center and Pacific Pediatrics, sponsored by the Yakima Valley Farm Workers Clinic.

Luke Winkler, OSPIRG, of Portland: He thanked PDAB for its work to make medications more affordable for Oregonians. Lowering the cost of prescription drugs is an important part of lowering health care costs.

Medford

Prescription Drug Affordability Board (PDAB) Community Forum
Location: Rogue Community College HEC, Medford
Date: April 25, 2024

Guests in attendance:

Ingri L.; J.R. C.; Janice V.; Joelle M.; Lauri H., nurse practitioner, Medford; Joanne Wilson, Oregon Disability Commission member; and Luke Winkler, campaign associate, OSPIRG, of Portland.

Board and staff in attendance:

PDAB Vice Chairperson Amy Burns, Savage, Karla Martinez of Division of Financial Regulation Outreach, and Stiles. Eric Crook and Belle Tower provided American Sign Language interpretation.

Consumer testimony:

Laurie H., Medford: Laurie is a patient with psoriasis and a nurse practitioner with a federally qualified health center. She has excellent coverage for the medication that treats psoriasis. She had to be on methotrexate for a long time before she was able to get on a biologic. Some of the less expensive treatments for the step requirements were not as effective for a chronic condition and insurance won't cover it. It induces anxiety for the patient. Each biologic works differently and patients don't know how it will impact the condition.

As a nurse practitioner, she can see treatment costs are too high. Patients can't afford medications, don't pick it up at the pharmacy and end up in the emergency room where the cost of the care is tremendous.

Also, as a nurse practitioner, she wishes providers had a way of knowing when a medication is unavailable when prescribing for the patient. Sometimes practitioners can substitute and sometimes they can't. Inhalers are an example of a medication that is very expensive and doesn't work the same for everyone. Dermatology with Medicare is also very high, for example, Metrogel and other antibiotic gels.

Savage echoed Laurie's point about people not taking their medicines, which increases costs for the health system.

Jim C., Medford: He uses two generics, Carvedilol and Atorvastatin, covered by Medicare with a nominal monthly cost. He has had glaucoma most of his life and can no longer drive. He has had several surgeries and used eye drops that cost $400 per month, covered by his insurance through employment. But he has had insurance gaps and been in indigent health care as well, chasing eye drops every month. He takes four different types, twice daily. His sight loss has accumulated over the years, reducing his quality of life. Getting the drops has been a challenge at times, caused by both cost and supply issues. When he had trouble getting Xalatan, for example, he stopped by his ophthalmologist's office and they gave him free pharmacy samples.

Janice V., Medford (speaking through American Sign Language interpreters). She has health insurance through her employer. She has been taking Flovent, 250 milligrams for a co-pay of $35 per month. This year the total changed, and they said Flovent was not available. They gave her a generic that cost only $5 per month. She asked if the quality of the generic was as good as the name brand.

Burns said generics are considered interchangeable. They have to be equivalent.

It doesn't mean a patient responds the same to a generic. She recommended talking to the provider about the medication. The laws for Oregon pharmacies require them to switch to a generic for any medication that has one. Brands have higher out-of-pocket costs than generics for patients.

Wilson, a member of the Oregon Disability Commission, said her brother is diabetic and they switched him to a generic medication. It didn't work for his body, causing problems for his feet. How can he stay on the medication that helps him and not pay so much for that insulin? **Burns** said the cost of insulin is impairing the ability for consumers to afford the medication they need to stay alive. That was one of the first recommendations PDAB made to the Legislature, to institute a cap on insulin of $35. The board is interested in looking at the cost of insulin for Oregonians.

Laurie H. said she works in a school-based health center and sees patients who are having trouble getting medications for ADHD, including Adderall and Vyvanse. Kids don't take their medication because they can't get it. **Burns** said there is a national shortage of methylphenidate. Multiple manufacturers have quality concerns that need to be addressed before they can continue manufacturing. There is an increase in use and demand and a decrease in supply. When there was a shortage of .5 milligrams, people switched to 10 milligrams and now there is a shortage of 10 milligrams. Looking at the system as a whole, how much change can the board afford with its recommendations is challenging. Looking at national issues, it gets harder. She is aware of these shortages affecting kids and adults by switching meds and sometimes it's not in the same therapeutic class. There are also shortages in insulin. She said more regulation or federal support is needed to ensure a sufficient supply.

Laurie H. said there is a shortage of vaccine support in the pharmacy industry. It is preventative care versus life saving care. **Burns** said many pharmacies don't have sufficient staff to provide vaccines. The board has had conversations about how high-cost drugs impact pharmacies. The compensation they receive when buying medication is not sufficient to cover costs. We have had talks about how to increase transparency. There is a correlation between registering the pharmacy benefit managers (PBMs) and additional transparency for downstream users, she said. The board recommended more PBM transparency.

Savage said the margins are thin for pharmacies. If a small pharmacy shuts its doors in rural Oregon, there may not be another option for 100 miles. **Burns** said Bi-Mart pharmacy served more people in rural areas and when it closed, people living in Grants Pass felt it acutely. More recently Rite Aid filed for bankruptcy. From a state and federal perspective, there needs to be scrutiny, making sure patients have these medications and access to the services, she said.

Laurie H. asked if the board had jurisdiction over mail order drugs. **Burns** said forums like this help give board members ideas for future topics and that could be a future topic. **Savage** said there are a lot of questions about the mail-order business in Oregon as it relates to interstate commerce law.

Wilson said her friend almost died from not understanding the medication directions. She asked if American Sign Language could be provided at pharmacy counters. She said American Sign Language is a language that reading and writing do not replace.

Luke Winkler, campaign associate, OSPIRG, of Portland: He said OSPIRG as a public interest group, talks to people who have seen an 18-fold price increase in medications in Portland. He knows a patient in Sweet Home who could afford only one meal a day because of high drug costs.

Bend

Prescription Drug Affordability Board (PDAB) Community Forum
Location: East Bend Library, Bend
Date: April 30, 2024

Guests in attendance:

Joseph Gardner, lobbyist and policy analyst with Gardner & Gardner in Portland; Mary Griffin of Bend, Oregon AARP driver safety and deputy state coordinator community outreach programs; Evelyn Cook of Bend, AARP; Dianne Danowski Smith of Publix Northwest PR in Portland; Bill Robie, state government relations director, National Bleeding Disorders Foundation; and Winkler.

Staff in attendance:

Savage, Karla Martinez, and Stiles.

Consumer testimony:

Mary G. of Bend: She said she pays an annual premium and a co-pay. She learned that people who have the Oregon Health Plan get all prescriptions free. For example, the weight-loss drugs for diabetes, many people can't afford to get them, including those who are obese and doing the healthy things. If the Oregon Health Plan provides prescriptions for free, why do others have to pay so much? **Savage** asked if she has seen the prices of medications go up in the last few years. **Mary** said yes, and she did stop taking one medication because the price went up. She took the opportunity to evaluate her health. She said sometimes doctors prescribe a mediation and never take people off of it; many people are overmedicating themselves.

Winkler thanked PDAB for its work. He has heard from a person in Portland who has arthritis that is progressing because she can't afford to take her medicine. It shouldn't have to be this way, he said.

Karla M. of Salem said recently her whole family was sick and they were prescribed Albuterol inhalers. Her daughter went to the pharmacy to pick it up and the cost was $50. They were very shocked at the price. She said it included an Albuterol pump, which they didn't need. She wondered if there was a generic that could have been provided instead of the brand name.

Bill Robie, state government relations director, National Bleeding Disorders Foundation: He represents a patient group whose medications cost $50,000 to $70,000 per month. If patients don't take their medications, they will die. In Oregon, most people with bleeding disorders are treated at OHSU. He asked about the board's affordability review process. He wants to make sure his organization is engaged, and people are telling their stories to the board. He said there are three gene therapies on the market to treat bleeding disorders.

Diane Smith of Portland asked Winkler about his sense of patients wanting to be involved in the board process. She said there are hundreds of patients impacted by these decisions. **Winkler** said a lot of people feel strongly about this and want to be involved. **Smith** said there needs to be a role for patients and patient advocates. **Savage** said they plan to record the online meetings and post them on the website so board members can view them. The consumer forums were meant to be listening session and not formal board meetings. **Robie** recommended doing one in-person board meeting a year. He likes to see people face to face. He thinks people would be willing to drive to Salem.

Online May 8, 2024

Guests in attendance:, Artia Solutions; Joe Gardner, Arielle & Leif; John Mullin of OPAC; Jana, CHW, of St. Luke's Clinic; Alex Johnson II, mayor of Albany; Mei K.; Richard M.; Jim H.; Michael Q.; Legislative Advocates; Shauna W.; Lorren Sandt of Caring Ambassadors; Tiffany Westrich-Robertson of AiArthritis; Luke Winkler of OSPIRG; Suzanne of Allies for Healthier Oregon/We Can Do Better; Alison G. of Myers and Stauffer; Brian DuVal of AiArthritis; Rebecca McAuliffe of Quinn Thomas; Tim Layton; Kristen O.; Margo P.; Paula W.; Rebecca; Leah Hueser; Katie Chandra; Scott Bertani, director of advocacy at Health HIV; Andy V.; Daniel O.; Alison T.; Trish McDaid-O'Neill of Astra Zeneca; Meaghan C.; Kelsey H.; Sophia G.; Arielle G.; Mike E.; Traci M.; Chloe G.; Laura B.; Elin S.; and Joe Steirer of GSK.

Board and staff in attendance: Megan Wai of Sen. Patterson's office, Bailey, Savage, Jaeger, PDAB Project Manager Stephen Kooyman, and Stiles. Eizaak Jordan, Jorge Guzman, and Cesar Guzman of Vive Northwest provided Spanish interpretation. Bethany Kocmich and Damon Thayer of Willamette Sign Language provided American Sign Language interpretation.

Jim H., 77, has been on Medicare 12 years, has COPD, and takes two inhalers. He also has Atrial fibrillation and takes three medications with high copays. For Xarelto, a blood thinner, his co-pay is $398 for a three-month supply. He is considering going back to a cheaper but inferior medication, Warfarin. If he gets Spiriva at the grocery store pharmacy, he pays $606 for a three-month supply or he pays $333 from Canada. His inhaler Budesonide cost $479 for a three-month supply at the grocery store pharmacy but $369 from Canada. He is considering changing supplemental insurance companies. He said: "I think those prices are very hard. It makes a difference in what I can afford and what I cannot. I just think there should be a better way."

Listen to the testimony at 00:01:13 in the May 8 community forum video on the PDAB website.

Michael Q., Albany: Michael has been diagnosed and living with multiple sclerosis for 20 years. Multiple sclerosis is an unpredictable disease of the central nervous system, including the brain, spinal cord, and optic nerves. It disrupts the flow of information with the brain and between the brain and body. People have different symptoms and flow of the course of their disease. His symptoms include severe foot drop, which impacts his ability to walk, eyesight problems, problems with temperature control, and fatigue. He went on disability retirement from his job at a community college about two years ago and had to change insurance. He went with the Oregon Insurance Marketplace, which added tens of thousands of dollars per year for prescription drugs costs. He takes a disease-modifying therapy called Rebif for multiple sclerosis. Insurers in the Oregon marketplace will provide coverage regardless of pre-existing conditions but they don't cover medication for those pre-existing conditions. Rebif is very expensive. It costs about $7,000 a month without any kind of help. And the insurance does not cover that much. It has been a challenge on a fixed income.

One cost that is perhaps not seen quite as frequently is the cost of time required and the fact that changing insurances may require a delay in treatments because of paperwork needed, needing to schedule with different physicians and neurologists, and going through the system to get approval for the medications needed. Sometimes, it's not the cost that slows down the medical treatment plan but the time to get approvals and work through pharmacy systems. Oregonians, especially those dealing with a disability, the elderly, veterans or those in under representative communities, need reasonably-timed access to reasonably-priced medications. **Bailey** thanked Michael for sharing his story and perspective, especially the comment related to the opportunity cost of time. She said it becomes a job and takes away from other work that could be done.

Listen to the testimony at 00:20:11 in the May 8 community forum video on the PDAB website.

Alex Johnson II, mayor of Albany. For the past 15 years, he has been a broker of insurance for Medicare, helping clients that take expensive medications, such as Eliquis. So many medications are ridiculously overpriced, he said. He tries to help patients get exceptions to the insurance formularies or work with their doctor to find more affordable medications. His concern is that the Eliquis patent expired but the manufacturer got a five-year extension from the U.S. Food and Drug Administration (FDA), delaying the generic drug, Apixaban. Pharmaceutical companies should not be able to extend patents to delay generics, he said. Congress and the FDA need to help with these extremely high drug costs. It's hurting people. He is concerned that doctors prescribe medications that are counterproductive

to medications patients are already taking. One drug may counteract the effects of the other one or reduce its efficacy. There is no communication about prescriptions between doctors. The system needs a check and balance. He said, "I often sit with someone who is in tears because they can't afford their medications."

Listen to the testimony at 00:25:45 in the May 8 community forum video on the PDAB website.

Arielle Goranson, Portland, has worked in primary care transformation for the past decade, focusing on health equity data. She said it is well documented that people of color have worse health outcomes and higher rates of certain conditions that need medication. She read a paper recently about health disparities and outcomes involving medication access and high drug costs being a driver of the inability to access medications, disproportionately affecting communities of color. Those who disproportionately face medication access issues might also benefit by new drugs, and new treatments. She urged the board and decision makers to try to curb health care costs for medication and mitigate any unintended consequences that could further disenfranchise these systematically-disadvantaged, underserved communities. She encouraged the board to engage with diverse stakeholders to ensure they are not advancing one thing at the cost of communities that have been disadvantaged in the past. She provided these links:

- 2023 AHRQ National Healthcare Quality and Disparities Report
- Racial Disparities in Medication Use
- Racial and Ethnic Disparities in Access to Medical Advancements and Technologies

Listen to the testimony at 00:30:01 in the May 8 community forum video on the PDAB website.

Suzanne, Allies for Healthier Oregon/We Can Do Better: She asked how can insurance brokers, such as Alex Johnson, be of service to Oregon consumers in helping find affordable medications.

Listen to the testimony at 00:35:00 in the May 8 community forum video on the PDAB website.

Winkler He thanked PDAB for its work on lowering prescription drug prices. Prescription drug prices are far too high and that hurts everyday Oregonians, he said. OSPIRG hears horror stories from people who have to miss work and deal with migraines because they can't afford the prescriptions that their neurologist prescribes, or people who have to let their arthritis progress because they can't afford treatment. It's saddening and heartbreaking. The board can't fix all of the issues but their work is needed and an appreciated part of improving Oregon's health care.

Listen to the testimony at 00:36:10 in the May 8 community forum video on the PDAB website.

Jana P., CHW, community health worker at St. Luke's in Baker City: She shared stories from her experience working at a clinic and pharmacy with patients who can't afford costly insulin. One of the pharmacy patients couldn't afford their insulin prescription, quit taking it without telling the pharmacy staff, and ended up in dialysis with kidney failure. Elderly patients especially are afraid to speak up or they don't know who to tell and so they just go without, she said. The health effects are detrimental or even deadly. She also works with patients who need Eliquis, which is horribly expensive, even with Medicare or private insurance. She helps patients find financial assistance through manufacturer programs. However, many patients with Medicare or Medicaid don't qualify. She asked if there is a way to help the Medicare population qualify for financial assistance for expensive drugs. Even patients who can afford Eliquis for three to six months of the year will run out of money and the ability to keep taking the medication. **Savage** thanked her and said her comment was echoed in Medford. If someone ends up in the emergency room or urgent care because they haven't been taking their prescription, it impacts their health and it's costing the system as well.

Listen to the testimony at 00:38:21 in the May 8 community forum video on the PDAB website.

Scott Bertani, director of advocacy at Health HIV: He currently works with the Cascade AIDS Project (CAP) that has a 340B program within the HIV ecosystem. He applauded PDAB for having conversations with its partners in Oregon about any upper payment limit considerations and how that will play out for patients. Upper payment limits may impact patients who are taking Biktarvy, for example, if they are forced to switch to a multi-tab regimen. There could also be some additional cost to the systems. He advocates that patients with high acuity should be given special consideration during that switch period, such as more direct and intensive case management involvement to ensure continuity of care. He is glad PDAB is having the conversation with CAP but hopes that conversation gets played out for the rest of the community because there are more HIV individuals than those with Ryan White clinics. There are a lot of people on Medicare and Medicaid. CAP does an amazing job, as do other Oregon community based organizations. Please sure to think about some of those medication pickup logistics and switch needs.Listen to the testimony at 00:41:54 in the May 8 community forum video on the PDAB website.

Tiffany Westrich-Robertson, chief executive officer, AiArthritis: She thanked the board for providing this opportunity for patients and caregivers. She represents people in Oregon. She is also a patient with arthritis and uses biologics. She can afford her medication because of the co-pay assistance plans. She knows there are a lot of patients in Oregon who struggle to pay for their prescriptions. She thanked the board for asking the important question: "What is the name of the drug you are having trouble affording?" That question has been missing in some of the PDAB conversations around the country. Boards need to find out what is expensive before picking drugs that may be expensive for the state, but co-pay assistance programs for patients.

Many patients are struggling with Medicare and unaffordable prescriptions. In most states with PDABs, Medicare isn't something that can be reviewed or talked about in the PDAB. The second component to think about in asking these questions about expensive drugs is the "why." If the reason is Medicare and it can't be addressed, maybe that is a recommendation the board can pass on the Legislature.

Listen to the testimony at 00:44:18 in the May 8 community forum video on the PDAB website.

Lorren Sandt, Caring Ambassadors Program: She thanked the board for having the forum. She said this conversation brought up a question to add into the survey: "What tier is the drug on the patient's insurance plan?" That makes a big difference whether a drug is affordable or not. **Savage** asked her to explain what is meant by tier. **Sandt** said every insurance plan has different levels of paying for the drugs based on a tier of 1 through 5, for example. The most expensive drugs are generally on a tier 5. The co-pay depends on the drug's tier. For instance, she uses a very expensive cream. On Blue Cross Blue Shield, it was a tier 2 and on UnitedHealthcare, it's a tier 5. She now has a 50 percent co-pay for the cream. It makes a big difference to know what tier a drug is on, helps to understand what's covered, and would give PDAB more information about affordability. The person who spoke earlier with multiple sclerosis, his drug is on a high tier and so it was very unaffordable for him. Not all drugs are covered equally.

Listen to the testimony at 00:46:25 in the May 8 community forum video on the PDAB website.

Bailey: To follow up on the conversation about Eliquis, Bailey asked Jana if she is aware of Array RX, which offers drug discounts through a consortium of states, including Oregon.

John Mullin, board president of the Oregon Coalition for Affordable Prescriptions: The chart in the PowerPoint that looks like the back of a television screen shows the complexity of the situation that we're in as a country as it affects providers and consumers. The Oregon Coalition for Affordable Prescriptions works on industry transparency and affordability for purchasers consumers. He encouraged people to visit the OCAP website or Facebook page to learn about their work. He said they don't receive any funds from the pharmaceutical industry and they are not advocating for particular drugs. They are interested in making it better for people who struggle to afford the price of their prescriptions.

He said even though thousands of Oregonians struggle with affordability, the task of getting people to show up and tell their stories is difficult because of time and personal vulnerability people put forward in telling their stories. He appreciates the board chairperson being present here because PDAB doesn't often hear from consumers. The board is doing really important technical work.

Listen to the testimony at 00:50:47 in the May 8 community forum video on the PDAB website.

Online May 14, 2024

Guests in attendance:

Joe Gardner and Lynda Gardner of Gardner & Gardner lobbyists; Rebecca McAuliffe of Quinn Thomas; Bandana Shrestha of AARP; Avi Bakshani of WilmerHale law firm; John Mullin; Frances P.; Jason T.; Arielle Goranson, MPH; Bridge Budbill of Oregon Law Center; Lucy Laube of National Psoriasis Foundation; Sandt; Joanna Wilson of Oregon Disability Commission, and Kay B.

Legislators, board, and staff in attendance:

Rep. Cyrus Javadi, Bailey, Savage, Jaeger, and Stiles. Eizaak Jordan, Jorge Guzman, and Cesar Guzman of Vive Northwest provided Spanish interpretation. Eric Crook and Belle Tower provided American Sign Language interpretation.

Rep. Javadi: He represents House District 32 on the North Oregon Coast and also serves on the Health Care Committee. He just finished his first term. He is looking forward to the comments and feedback tonight. At the capitol, legislators are very concerned about the cost and affordability of health care and that includes prescription drugs. Legislators spent a lot of time last session talking about everything, from insulin to medications for cancer, as well as high blood pressure and all sorts of different conditions; the role the pharmacy benefit managers play, as well as insurance companies; and the immense pressure on Oregonians to continue to meet those needs. Thanks for providing this opportunity and forum.

Listen to the testimony at 00:05:00 in the May 14 community forum video on the PDAB website.

Frances P.: Frances thanked the board for having this forum. Frances moved from North Carolina to Oregon 15 years ago, studied public health in college, finished a business degree, and has been employed at various restaurants. Frances serves on the Zinger Farm board and is very interested in health equity. Frances is recently in between jobs, lost private insurance, and now has access to the Oregon Health Plan. Frances recently learned that prescriptions are tied to providers. Only one of Frances' regular doctors takes OHP, so there is a need to re-establish care. Frances recently learned the pharmacy would not fill the prescriptions because the prescribing provider did not take OHP. Frances had enough money saved to pay out of pocket while job seeking and finding an OHP provider. As someone who is a queer person, trust is really important, Frances said. Health disparities are different for LGBTQ folks, especially LGBTQ folks of color. Frances said this was a learning opportunity to share with the board. **Bailey** wanted to confirm that **Frances** had a valid prescription with refills and simply because that medical provider was not in network for fee-for-service or Medicaid, that prescription did not process properly on the insurance. Frances

confirmed that was the case and that this situation could impact other Oregonians. **Bailey** said this was a new feedback and thanked Frances for sharing. Frances said it is important to think about continuity of care issues that intersect with prescription drug costs. Bailey suggested looking into Array Rx, a state discount card for prescription drugs.

Listen to the testimony at 00:24:00 in the May 14 community forum video on the PDAB website.

Joanna Wilson, member of the Oregon Disability Commission: (speaking through ASL interpreter) Joanna said her son has a chronic illness and it is getting worse. She wondered about his medication for chronic pain. He needs medication that's stronger. She asked if there a law about prescription limitations for people who are low income on the Oregon Health Plan. If the doctor knows the patient is low income, does the doctor prescribe the lower cost medication? Would people with higher incomes be prescribed something different? **Bailey** said what Joanna referenced is part of a discussion related to plan design and how insurers in Oregon and PBMs build formularies of the drugs they cover and drugs they don't cover. She said there are laws that protect access for people on Medicaid versus those who have commercial plans. Formularies are not built off someone's ability to pay. It's a broader plan design discussion between insurers, PBMs and payors. Certain economic groups are not targeted or limited in access. She thanked Joanna for sharing about this challenge and said the PDAB board wants to hear from consumers as it continues its work and provides recommendations to the Legislature. On a personal level, she said she is sorry about the health issues Joanna's family is experiencing. She appreciates her sharing today.

Listen to the testimony at 00:32:11 in the May 14 community forum video on the PDAB website.

John Mullin, board president of the Oregon Coalition for Affordable Prescriptions (OCAP): He thanked Bailey for the good work PDAB is continuing to do. For consumers who have not shared their story, please visit the OCAP website or Facebook page, he said. When consumers tell their stories, it has a real impact. He is pleased that Bailey has been at the presentations because the board has a lot of technical work to do. Unless they hear from consumers, they are really not getting the flavor of what's happen around the state. He thanked DCBS for sponsoring the forums and looks forward to the summary report. For those consumers who spoke, they were speaking on behalf of thousands of Oregonians struggling with paying for their prescription drugs.

Listen to the testimony at 00:41:48 in the May 14 community forum video on the PDAB website.

Wilson (speaking through an interpreter) said she has heard of people stockpiling medication, taking it as little as possible, or taking half a dose because of the cost. Is it dangerous?

Savage thanked Wilson for bringing that up. At the Medford meeting, a nurse practitioner spoke about folks who cut back on medication end up in the emergency room or urgent care center. It does have an impact. It severely impacts their health. And for the cost to the health care system, if someone goes to ER or urgent care, it increases cost of care. It has impact on individual and health care system.

Listen to the testimony at 00:45:04 in the May 14 community forum video on the PDAB website.

Appendix B – Survey and summary

Survey

Age range:

- ☐ 18 – 30
- ☐ 31 – 46
- ☐ 47 – 61
- ☐ 62 – 75
- ☐ 76 and over
- ☐ Prefer not to answer

Annual income

- ☐ $0-$9,999
- ☐ $10,000-$24,999
- ☐ $25,000-$49,999
- ☐ $50,000-$74,999
- ☐ $75,000-$99,999
- ☐ $100,000-$149,999
- ☐ $150,000+
- ☐ Prefer not to answer

County:

_____

Medical conditions

1. _____ **2.** _____ **3.** _____

Prescription drug(s) taken to treat the above medical condition(s):

1. _____ **2.** _____ **3.** _____

How often:

1. _____ **2.** _____ **3.** _____

Monthly costs:

1. _____ **2.** _____ **3.** _____

Please circle which applies to you:

Private health insurance Medicare Medicaid

Survey results April-May 2024

Age: 62-75
Income: $50,000 - $74,999
County: Deschutes
Medical condition:
Prescriptions:
How often:
Monthly costs:
Insurance type: Medicare

Age: 62-75
Income: $10,000 - $24,999
County: Jackson
Medical conditions: Glaucoma with 95 percent vision loss; living with it for 35 years, AFIB
Prescriptions and how often: Carvedilol 12.5 mg 2x/day, Atorvastatin 10 mg/day
Monthly cost: Painless copay of about $20/month
Insurance: Medicare with BCBS Advantage

Age: 62-75
Income: $50,000 - $74,999
County: Jackson
Medical condition: Psoriasis
Medications and how often: Stelara, quarterly
Monthly costs: None, but worry annually that it won't be covered
Insurance: Medicare

Age: 76
County: Jackson
Medical conditions: Heart failure
Prescriptions and how often: Xarelto, 1 daily
Insurance: Medicare

Age: 31-46
Income: $25,000 - $49,999
County: Marion
Medical conditions: High blood pressure and cholesterol, diabetes
Medications and how often: 3 medications but don't recall the names. 2x/month, 3 tablets daily, 3 tablets daily
Monthly cost: $180, $80, and $260
Insurance: Private health insurance

Age: 47-61
Income: $25,000 - $49,999
County: Multnomah
Medical condition: Tardive dyskinesia
Medication and how often: Ingrezza, once per day
Monthly costs: Retails for $75,000 for 3 months supply
Insurance: Private health insurance
Note: got a prior authorization and Tx failure exception

Age: 62-75
Income: $10,000 - $24,999
County: Lincoln
Medical conditions: High blood pressure, diabetes, high cholesterol
Medications and how often: Metformin 2x daily, Jardiance once daily, Verapamil once daily, Pravastatin once daily
Monthly costs: Metformin varies, little; Jardiance varies, expensive; Verapamil varies, medium cost; Pravastatin reasonable
Insurance: Medicare

Age: 47-61
Income: $75,000 - $99,999
County: Benton
Medical conditions: Hemophilia, Von willebrand disease (VWD), other rare bleeding disorders
Medications and how often: Factor products for HEMA weekly, blood products for VWD as needed on demand
Monthly cost: $75,000+
Insurance: Private health insurance

Age: 31-46
Income: $0 - $9999
Medical condition: Chronic complex post-traumatic stress disorder (CPTSD), premenstrual dysphoric disorder (PMDD), Anxiety
Medications and how often: Venlafaxine daily, Propranolol daily, Lorazepam, as needed
Monthly costs: $50, $35, and $35
Insurance: Medicaid

Age: 62-75
Income: $50,000 - $74,999
County: Marion
Medical conditions: Idiopathic distal symmetric polyneuropathy, sleep apnea, chronic pain
Medications and how often: Cyclosporine ophthalmic 2x/day, Belsomra 1x/night, Gabapentin 1x/night
Month cost: $20, $20, and $3.72
Insurance: Private health insurance and Medicare

Age: 62-75
Income: $25,000 - $49,999
County: Washington
Medical conditions: Depression, social anxiety
Medications and how often: Effexor XR 1x/day, Lexapro 1x/day
Monthly cost: $100 co-pay
Insurance: Medicare
Note: I am waiting approval for assistance for both medications otherwise the cost is $1,000

Age: 31-46
Income: $100,000 - $149,999
County: Washington
Medical conditions: ADHD, Anaphylaxis, Asthma
Medications and how often: Epinephrine daily, Strattera, twice daily
Monthly costs: $150, $190, and $22
Insurance: Private health insurance

Age: 62-75
Income: $25,000 - $49,999
County: Douglas
Medical conditions: Heart failure, tumor, back disc issues
Medications and how often: Eliquis 2x day, Bystolic 2x day, Telmisartan, 1x day
Monthly cost: $700, $200, and $100
Insurance: Medicare

Age: 76 and over
Income: $25,000 -$49,999
County: Lane
Medical conditions: AFIB, congestive heart failure, osteoporosis
Medications and how often: Eliquis 2xday, Cartia 2x/day, Atorvastatin, once a day
Monthly costs: $450, $250, and $40
Insurance: Private health insurance, Medicare

Age: 47-61
Income: $100,000 - $149,000
County: Lincoln
Medical condition: Diabetes
Medications and how often: Metformin twice daily, Glipizide once daily, Atorvastatin once daily
Monthly costs: $15, $5, and $5
Insurance: Private health insurance

Appendix C – Media coverage

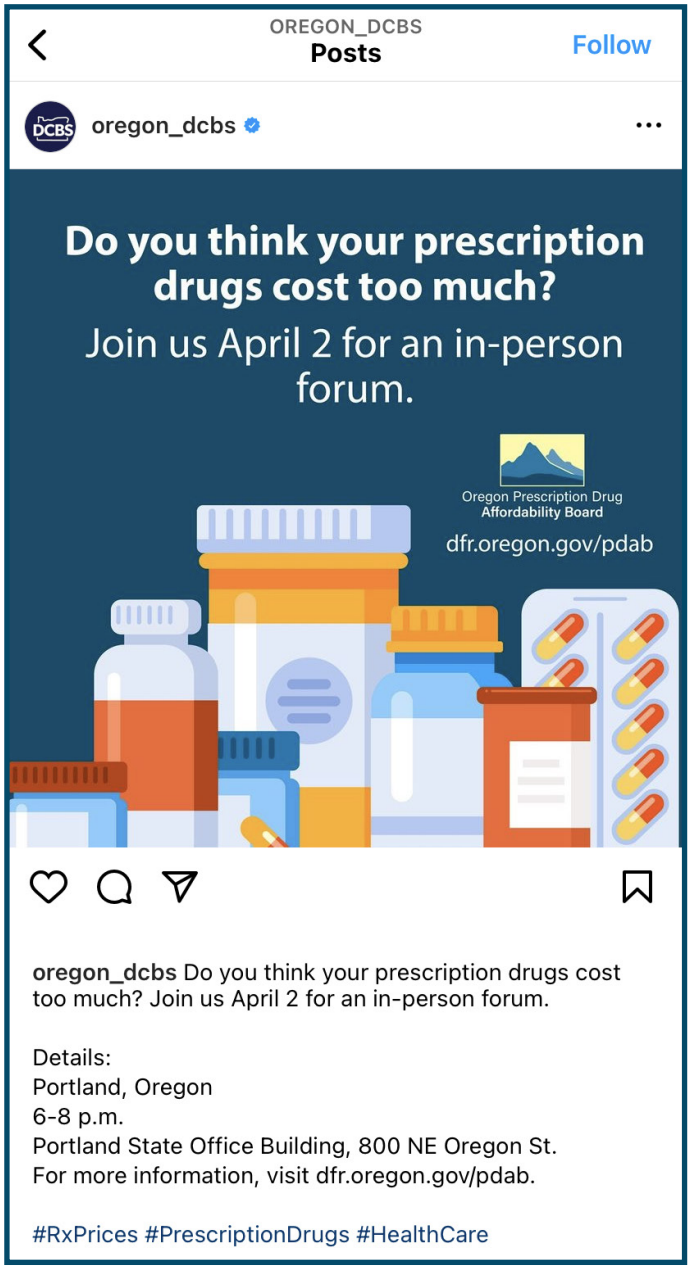
Staff sent press releases to Oregon media outlets and also advertised the event on social media. Here are two examples of media coverage about the community forums.

Rogue Valley Times

View the article at this link: Medford forum on rising prescription drug costs set for RCC Higher Ed Center | Local&State | rv-times.com

KDRV TV station in Southern Oregon

View the video at this link: Oregon Prescription Drug Affordability Board hosting public forum Thursday in Medford | Top Stories | kdrv.com



Appendix D – PowerPoint presentation

The PowerPoint presentation shown at the community events is posted on the PDAB website: https://dfr.oregon.gov/pdab/.

Here is the direct link:

- April-May Community forum PowerPoint presentation

Appendix E – Community forum videos

- The online community forums were recorded with participants' permission. The videos are posted on the PDAB website: https://dfr.oregon.gov/pdab/.

Here are the direct video links:

- May 8, 2024 Community forum about prescription drug costs
- May 14, 2024 Community forum about prescription drug costs