Bristol Myers Squibb™

April 15, 2025

VIA ELECTRONIC SUBMISSION

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

Re: Oregon Prescription Drug Subset List

Dear Members of the Oregon Prescription Drug Affordability Board:

Bristol Myers Squibb ("BMS") appreciates the opportunity to submit written comments to the Oregon Prescription Drug Affordability Board (the "Board") on its subset of prescription drugs to prioritize for affordability review. **For the reasons below, we respectfully ask that ELIQUIS® (apixaban) be removed from the prioritized subset and not subject to the affordability review process.** Much of this information was shared previously with the Board in 2023, when ELIQUIS was initially identified for potential review and subsequently removed from consideration after the Board voted to remove prescription drugs based on selection for the Medicare Drug Price Negotiation Program under the Inflation Reduction Act (IRA), which continues to be implemented under the new administration.[1]

Bristol Myers Squibb's Commitment to Oregon Patients

At BMS, we are inspired by a single vision—transforming patients' lives through science. We are in the business of breakthroughs—the kind that transform patients' lives through lifesaving, innovative medicines. We combine the agility of a biotech with the reach and resources of an established pharmaceutical company to create a global leading biopharma company. In oncology, hematology, immunology, cardiovascular disease, and neuroscience—with one of the most diverse and promising pipelines in the industry—we focus on innovations that drive meaningful change. BMS supports public policies that promote patient access to new and effective medical treatments and help ensure patients benefit from the innovation that defines the U.S. health care system, and we have long supported efforts in Oregon to meaningfully enhance patient access and improve affordability by lowering out-of-pocket costs for patients.

Driven by our patient-focused mission, we disagree with the potential application of an "affordability review" process to ELIQUIS. Oregon law states that the Board shall identify prescription drugs "that the [B]oard determines may create affordability challenges for health

[1] Please refer to Table 2 of the Meeting Minutes for the PDAB's November 15, 2023, meeting. Accessible here: https://dfr.oregon.gov/pdab/Documents/20231115-PDAB-approved-minutes.pdf

care systems or high out-of-pocket costs for patients in this state" and instructs the Board to consider multiple factors in determining which prescription drugs to prioritize for affordability review.[2] We are concerned that the current methodology, data sources, and criteria used by the Board to identify prescription drugs for affordability review may not accurately prioritize those prescription drugs that may pose affordability challenges for patients, as the listing of ELIQUIS reflects. We believe that ELIQUIS should be removed from the prioritized subset of prescription drugs as its inclusion is inappropriately based on its volume of use by clinicians and patients in Oregon, rather than its costs to health care systems and patients. Indeed, the statutory affordability review process contemplates many factors beyond volume alone, focusing on products presenting actual affordability issues for patients. Currently, Eliquis is widely available to patients, with over 90% open access among commercial plans and low out-of-pocket costs. On average, non-valvular atrial fibrillation patients with commercial insurance pay only $38 per month for Eliquis, and 5 out of 10 paying $20 per month or less.[3] We also wish to emphasize the clinical attributes of ELIQUIS and evidence of its benefits to patients, the healthcare system, and society.

Background on ELIQUIS

ELIQUIS is a best-in-class direct oral anticoagulant ("DOAC") indicated to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation ("NVAF"), for the treatment and prevention of Deep Vein Thrombosis ("DVT") and pulmonary embolism (PE), and to decrease the risk of DVT blood clots after hip or knee replacement surgery.[4] Atrial fibrillation ("AFib") is the most common type of irregular heartbeat that often causes the heart to beat too quickly and can lead to blood clots, stroke, heart failure and other heart-related complications if left untreated.[5]

As the U.S. population ages, the number of people with AFib is projected to increase to more than 12 million by the year 2030.[6] AFib is associated with an approximately fivefold increased risk of ischemic stroke. The risk of having a stroke is nearly twice as high for non-Hispanic Black adults as for White adults and non-Hispanic Black adults and Pacific Islander adults have the highest rates of death due to stroke.[3] Stroke-related costs in the U.S. came to nearly $56.2 billion between 2019 and 2020 which included the cost of health care services, medicines to treat stroke, and missed days of work.[7] In Oregon, hospitalization costs for adults with stroke totaled $277 million in 2022.[8] Effective treatments to reduce the risk of stroke are important to Oregon's health care system and patients, as stroke-related care commonly leads to costly hospitalizations and extended rehabilitation needs.

[2] Or. Rev. Stat. Ann. § 646A.694(1); Or. Admin. R. 925-200-0010.
[3] Pricing information. AFib Pricing Information for Rx ELIQUIS® (apixaban) | Safety Info (December 2024). https://www.eliquis.bmscustomerconnect.com/afib/price.
[4] ELIQUIS® (apixaban) Package Insert. Bristol-Myers Squibb Company, Princeton, NJ and Pfizer Inc, New York, NY https://packageinserts.bms.com/pi/pi_eliquis.pdf.
[5] Why Atrial Fibrillation Matters. https://www.heart.org/en/health-topics/atrial-fibrillation/why-atrial-fibrillation-af-or-afib-matters.
[6] Centers for Disease Control and Prevention. (2022, October 14). Atrial fibrillation. Centers for Disease Control and Prevention. https://www.cdc.gov/heartdisease/atrial_fibrillation.htm.
[7] Centers for Disease Control and Prevention. (2024, October 24). Stroke Facts. Centers for Disease Control and Prevention. https://www.cdc.gov/stroke/data-research/facts-stats/?CDC_AAref_Val=https://www.cdc.gov/stroke/facts.htm,
[8] 2024 The Oregon Stroke Care Committee Report to the Legislature (2024). State Library of Oregon Digital Collections, accessed 15/04/2025, https://digitalcollections.library.oregon.gov/nodes/view/287173

ELIQUIS's benefits to patients, the healthcare system, and society.

The Board's methodology for selecting prescription drugs to prioritize for affordability review does not reflect the substantial clinical and economic benefits of ELIQUIS. The clinical benefits of ELIQUIS have been demonstrated in both the clinical trial and real-world clinical practice settings. In several U.S. real-world data analyses, ELIQUIS use was associated with a similar or lower risk of stroke-related hospitalizations, as well as a consistently lower risk of bleeding-related hospitalizations, when compared to other oral anticoagulants.[9,10,11,12,13] These findings were consistent across different populations and data sources, including Medicare, Commercial, Veterans Affairs, and Department of Defense.[7-11]

In addition to the clinical benefits of ELIQUIS, the economic benefits were found to be associated with reduced healthcare resource utilization and costs across various populations with NVAF and VTE studied in U.S. real-world data analyses. Specifically, these analyses demonstrated that ELIQUIS was associated with similar or lower all-cause healthcare costs and consistently lower all-cause medical costs—particularly those associated with major bleeding events—when compared to other oral anticoagulants.[14,15,16] Considering the economic burden of NVAF in the U.S. has been predicted to approach $30 billion annually by 2050[17] and is largely driven by costs associated with hospitalization, ELIQUIS provides clinicians and health care systems in Oregon with a less costly approach to reducing the risk of stroke, hospitalizations, and extended rehabilitation needs through treating and preventing blood clots.

Insurer-Reported Data Lacks Transparency and Neglects Patient Cost Realities

We understand that the Board gives decisive weight to Drug Price Transparency ("DPT") carrier data and the so-called "CCO list." We are concerned with this approach given the limitations of the DPT carrier data, the lack of transparency into the Board's methodology for

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[9] Ray WA, Chung CP, Stein CM, et al. Association of Rivaroxaban vs Apixaban With Major Ischemic or Hemorrhagic Events in Patients With Atrial Fibrillation. *JAMA*. 2021;326(23):2395–2404. doi:10.1001/jama.2021.21222

[10] Graham DJ, Baro E, Zhang R, Liao J, Wernecke M, Reichman ME, Hu M, Illoh O, Wei Y, Goulding MR, Chillarige Y, Southworth MR, MaCurdy TE, Kelman JA. Comparative Stroke, Bleeding, and Mortality Risks in Older Medicare Patients Treated with Oral Anticoagulants for Nonvalvular Atrial Fibrillation. Am J Med. 2019 May;132(5):596-604.e11. doi: 10.1016/j.amjmed.2018.12.023. Epub 2019 Jan 9. PMID: 30639551.

[11] Deitelzweig, S, Keshishian, A, Li, X. et al. COMPARISON OF EFFECTIVENESS, SAFETY, AND THE NET CLINICAL OUTCOME BETWEEN DIFFERENT DIRECT ORAL ANTICOAGULANTS IN 162,707 NON-VALVULAR ATRIAL FIBRILLATION PATIENTS TREATED IN US CLINICAL PRACTICE. JACC. 2018 Mar, 71 (11_Supplement) A275.
https://doi.org/10.1016/S0735-1097(18)30816-7

[12] Deitelzweig S, Sah J, Kang A, Russ C, Preib M, Dhamane AD, Ratiu A, Cato M, Alfred T, Levi E, Di Fusco M. Effectiveness and Safety of Apixaban Versus Warfarin in Obese Patients with Nonvalvular Atrial Fibrillation Enrolled in Medicare and Veteran Affairs. Am J Cardiol. 2022 Jan 15;163:43-49. doi: 10.1016/j.amjcard.2021.09.047. PMID: 34930532.

[13] Gupta K, Trocio J, Keshishian A, Zhang Q, Dina O, Mardekian J, Rosenblatt L, Liu X, Hede S, Nadkarni A, Shank T. Real-World Comparative Effectiveness, Safety, and Health Care Costs of Oral Anticoagulants in Nonvalvular Atrial Fibrillation Patients in the U.S. Department of Defense Population. J Manag Care Spec Pharm. 2018 Nov;24(11):1116-1127. doi: 10.18553/jmcp.2018.17488. Epub 2018 Sep 13. PMID: 30212268; PMCID: PMC10398049.

[14] Amin A, Keshishian A, Trocio J, Dina O, Le H, Rosenblatt L, Liu X, Mardekian J, Zhang Q, Baser O, Nadkarni A, Vo L. A real-world observational study of hospitalization and health care costs among nonvalvular atrial fibrillation patients prescribed oral anticoagulants in the U.S. Medicare population. J Manag Care Spec Pharm. 2020 May;26(5):639-51.

[15] Deitelzweig S, Luo X, Gupta K, Trocio J, Mardekian J, Curtice T, Hlavacek P, Lingohr-Smith M, Menges B, Lin J. All-cause, stroke/systemic embolism-, and major bleeding-related health-care costs among elderly patients with nonvalvular atrial fibrillation treated with oral anticoagulants. Clin Appl Thromb Hemost. 2018;24(4):602-11.

[16] Hlavacek P, Guo JD, Rosenblatt L, Keshishian A, Russ C, Mardekian J, Ferri M, Poretta T, Yuce H, McBane R. Safety, effectiveness, and health care cost comparisons among elderly patients with venous thromboembolism prescribed warfarin or apixaban in the United States Medicare population. Curr Med Res Opin. 2019 Dec;35(12):2043-51.

[17] Kim MH, Lin J, Hussein M, et al. Cost of atrial fibrillation in United States managed care organizations. Adv Therapy. 2009;26(9):847–857.

compiling and weighing the data, and manufacturers' inability to independently verify or dispute the accuracy of the data. The Board also has not specified how it has weighed the seven regulatory factors articulated in Or. Admin. R. 925-200-0010.

Continued Implementation of the Medicare Drug Price Negotiation Program

In August 2023, ELIQUIS was included as one of the first ten prescription drugs selected for the Medicare Drug Price Negotiation Program under the Inflation Reduction Act (IRA), with the Maximum Fair Prices (MFPs) for these products set to take effect on January 1, 2026. Within the new presidential administration, both the Centers for Medicare and Medicaid Services (CMS) and key appointees have publicly reaffirmed their commitment to the program:

- On January 29, 2025, CMS stated that it "remains committed to achieving value for beneficiaries and taxpayers" through the program.[18]
- Dr. Mehmet Oz, newly confirmed CMS Administrator, has said of the program: *"It's the law. I'm going to defend it and use it."*[19]
- CMS is hosting a series of public engagement events in April 2025 to "provide an opportunity for patients, beneficiaries, caregivers, consumer and patient organizations, and other interested parties, such as clinicians and researchers, to share input relevant to prescription drugs selected for the second cycle of negotiations."[20]
- CMS has communicated a timeline beginning in June 2025 to pharmacies and other drug dispensing entities to help them prepare for implementation of the program.[21]

These public comments confirm the federal government's intent to continue implementing the Medicare Drug Price Negotiation Program and impose MFPs on selected prescription drugs. Of note, since the IRA's inception, we have expressed serious concerns about the impact government price-setting will have on the development of future medicines that can help patients prevail over serious disease.

ELIQUIS's Limited Remaining Market Exclusivity.

ELIQUIS's patent exclusivity is estimated to expire on April 1, 2028, after which generic competitors are expected to enter the market. This creates a narrow window—just over two years—between the implementation of Medicare's Maximum Fair Price and the arrival of generic alternatives. This substantially limits any potential impacts of the affordability review process, even assuming affordability review was appropriate and could result in positive impacts, which we do not believe to be true.

[18] Centers for Medicare & Medicaid Services. (2025, January 29). *CMS statement on lowering the cost of prescription prescription drugs*. https://www.cms.gov/newsroom/press-releases/cms-statement-lowering-cost-prescription-prescription drugs
[19] Senate Committee on Finance. (2025, March 14). *Hearing to consider the nomination of Mehmet Oz, of Pennsylvania, to be Administrator of the Centers for Medicare and Medicaid Services, vice Chiquita Brooks-LaSure, resigned*. https://www.finance.senate.gov/hearings/hearing-to-consider-the-nomination-of-mehmet-oz-of-pennsylvania-to-be-administrator-of-the-centers-for-medicare-and-medicaid-services-vice-chiquita-brooks-lasure-resigned
[20] Centers for Medicare & Medicaid Services. (2025). 2027 public engagement events. Retrieved from https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation/2027-public-engagement-events
[21] Centers for Medicare & Medicaid Services. *Resources for pharmacies and dispensing entities*. Retrieved from https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation/resources-pharmacies-and-dispensing-entities

Conclusion

BMS is committed to promoting policies that protect Oregonian patients and enable them to better afford their medicines. We encourage meaningful reforms that will help lower the price patients pay for medicines at the pharmacy, such as requiring PBMs to share negotiated savings on medicines with patients. Considering the preceding arguments, **we strongly urge the Board to remove ELIQUIS from the prioritized subset of prescription drugs**.

Thank you for the opportunity to provide comments and for considering our concerns. Should you have any questions or concerns, please contact Richard Meyers, Director, State & Federal Policy at richard.meyers@bms.com and Anne Murray, Director, State & Local Government Affairs, U.S. Policy & Government Affairs at anne.murray@bms.com.

Sincerely,

/s/ Anne Murray

Director, State & Local Government Affairs
Bristol Myers Squibb

April 30, 2025

VIA ELECTRONIC FILING

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

Dear Members of the Oregon Prescription Drug Affordability Board,

GSK appreciates the opportunity to provide information on Trelegy Ellipta ("Trelegy") as part of the state's affordability review process. GSK has completed the voluntary online survey and included information regarding Trelegy that is in the public domain not proprietary or confidential in nature. GSK did not respond to the data elements requested by Oregon that are confidential, commercially sensitive or otherwise proprietary.

GSK is a science-led global healthcare company with a special purpose to unite science, technology, and talent to get ahead of disease together. We focus on science of the immune system, human genetics, and advanced technologies to impact health at scale. We prevent and treat disease with vaccines, as well as specialty and general medicines.

GSK remains committed to ensuring that innovation and affordability can coexist. We extend this spirit of innovation to the way we responsibly do business. When establishing our prices in the US, we strive for a fair and appropriate balance that rewards innovation while affording access for appropriate patients. Our goal is to work in the best interests of patients and for the good of our company; we systematically apply a value-based framework that looks at the benefits of our medicines compared to alternatives, and we focus on improving health outcomes for patients. We conduct extensive research both internally and externally to ensure we understand the patient, payer, and physician perspectives on a potential drug's value to the system and its appropriate price.

As outlined below, GSK believes Trelegy is appropriately priced for the value it brings to patients and the State of Oregon, and it should not be considered for a full affordability review.

Trelegy Provides Significant Clinical Value

Trelegy is a fixed-dose single inhaler combination of fluticasone furoate (FF), an inhaled corticosteroid (ICS); umeclidinium (UMEC), a long-acting muscarinic antagonist (LAMA); and vilanterol (VI), a long-acting β2-agonist (LABA). It is the only single inhaler ICS/LABA/LAMA (or "triple therapy") administered via one inhalation once daily. Trelegy is delivered in a dry powder inhaler (DPI) device called Ellipta and is indicated for maintenance treatment of chronic obstructive pulmonary disease (COPD) and asthma in patients aged 18 years and older. As noted below, Trelegy is guideline-recommended and multiple studies show that it improves outcomes and reduces health care spending compared to other available triple therapies.

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) report is a set of COPD clinical guidelines revised annually and accepted by clinicians and experts internationally for the management of

COPD.[1] These guidelines recommend ICS/LABA/LAMA triple therapies as a preferred option for patients at high risk of future exacerbations and for those patients who are uncontrolled on dual therapies (e.g., ICS/LABAs).

The only other single inhaler triple therapy available in the US is Breztri, which is administered via two inhalations, twice daily (i.e., four total daily inhalations). Breztri is indicated for COPD but not for asthma. In studies comparing Trelegy to Breztri, Trelegy has been associated with significantly improved adherence, reduced exacerbation rates, improved lung function, and reduced mortality in patients with COPD with a similar safety profile.[2,3,4,5]

Patients may also receive triple therapy via multiple inhalers (e.g., an ICS/LABA in one inhaler, plus a LAMA in a second inhaler), although GOLD guidelines note that "single inhaler therapy may be more convenient and effective than multiple inhalers."[1] Across studies comparing Trelegy to multi-inhaler triple therapies (MITT) in COPD, Trelegy has been associated with improved lung function, reduced exacerbation rates, and better adherence while maintaining a similar safety profile.[2,6,7]

In asthma, leading clinical guidelines from the Global Initiative for Asthma (GINA) recommend triple therapies like Trelegy for use in patients that remain symptomatic on dual therapy ICS/LABAs.[8] Trelegy is the only approved single inhaler triple therapy for asthma, and GINA guidelines recommend single inhalers over multiple inhalers, stating "where more than one medication is needed, a single (combination) inhaler is preferable to multiple inhalers."

Trelegy is associated with improved adherence, reduced exacerbation rates, and improved asthma control compared with other treatments, including MITTs and ICS/LABAs.[9,10] Additionally, use of Trelegy in asthma is associated with lower health care spending. Asthma patients progressing to Trelegy from ICS/LABA saw a 26 percent reduction in asthma-related medical costs due to lower rates of outpatient, emergency department, and urgent care visits.[11]

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[1]Global Initiative for Chronic Obstructive Lung Disease (GOLD). "Global Strategy for Prevention, Diagnosis, and Management of COPD (2025 Report)". Available from: https://goldcopd.org/2025-gold-report/.
[2] Ismaila, A.S., et al. "Fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI) triple therapy compared with other therapies for the treatment of COPD: a network meta-analysis." Advances in Therapy, 2022. 39(9): p. 3957-3978.
[3] Mannino, D., Weng, S., Germain, G., Boudreau, J., Tardif-Samson, A., Forero-Schwanhaeuser, S., Laliberté, F., Gravelle, P., Compton, C.H., Noorduyn, S.G. and Paczkowski, R. "Comparative Effectiveness of Fluticasone Furoate/Umeclidinium/Vilanterol and Budesonide/Glycopyrrolate/Formoterol Fumarate among US Patients with Chronic Obstructive Pulmonary Disease." Advances in Therapy, 2024. 42(2): p. 1131-1146.
[4] Feldman, W.B., et al. "Comparative effectiveness and safety of single inhaler triple therapies for chronic obstructive pulmonary disease: new user cohort study." bmj, 2024. 387.
[5] Young, C., Lee, L.Y., DiRocco, K.K., Germain, G., Klimek, J., Laliberté, F., Lejeune, D., Noorduyn, S.G. and Paczkowski, R. "Adherence and Persistence with Single-Inhaler Triple Therapy Among Patients with COPD Using Commercial and Medicare Advantage US Health Plan Claims Data." Advances in Therapy, 2024.
[6] Ferguson, G.T., et al. "Once-daily single-inhaler versus twice-daily multiple-inhaler triple therapy in patients with COPD: lung function and health status results from two replicate randomized controlled trials." Respiratory Research, 2020. 21(1): p. 1-15.
[7] Mannino, D., et al. "Adherence and persistence to once-daily single-inhaler versus multiple-inhaler triple therapy among patients with chronic obstructive pulmonary disease in the USA: a real-world study." Respiratory Medicine, 2022. 197: p. 106807.
[8] Global Initiative for Asthma (GINA). "Global Strategy for Asthma Management and Prevention (2024 Report)". Available from: https://ginasthma.org/wp-content/uploads/2024/05/GINA-2024-Strategy-Report-24_05_22_WMS.pdf.
[9] Bogart, M., et al. "Real-World Study of Single-Inhaler Triple Therapy with Fluticasone Furoate/Umeclidinium/Vilanterol on Asthma Control in the US." Journal of Asthma and Allergy, 2023: p. 1309-1322.
[10] Lee, L.A., et al. "Efficacy and safety of once-daily single-inhaler triple therapy (FF/UMEC/VI) versus FF/VI in patients with inadequately controlled asthma (CAPTAIN): a double-blind, randomised, phase 3A trial." The Lancet Respiratory Medicine, 2021. 9(1): p. 69-84.
[11] Baptist, A.P., Germain, G., Klimek, J., Laliberté, F., Schell, R.C., Forero-Schwanhaeuser, S., Moore, A., Noorduyn, S.G. and Paczkowski, R. "Medicare Advantage Population in the United States: Outcomes of Patients with Asthma Treated with ICS/LABA Before and After Initiation with Fluticasone Furoate/Umeclidinium/Vilanterol (FF/UMEC/VI)." Advances in Therapy, 2024. 42(2): p. 1061-1074.

Trelegy Provides Significant Economic Value

In addition to these clinical outcomes, Trelegy is associated with lower overall health care spending compared to MITT. Total COPD-related costs, which include pharmacy costs (including inhalers), inpatient, outpatient, emergency department (ED), office visit, and other medical costs, were about 19 percent lower in Medicare patients using Trelegy compared to those using MITT.[12]

Trelegy is Affordable to the State of Oregon and to Patients

Based on review of Oregon's data, GSK believes that Trelegy does not represent an affordability challenge to the state. The Oregon PDAB's Preliminary Aggregated Carrier Data, which utilizes claims from 2023, shows that Oregon's 2023 total annual net spend of Trelegy was $627,285.81, which ranks 125th out of the 158 drugs reported in this list. Oregon's Carrier Data also shows Trelegy's total 2023 annual net spend per Oregon enrollee was $2,133.63, which ranks 90 out of 158.

Trelegy was selected by the Centers for Medicare and Medicaid Services (CMS) this year for IPAY 2027 Medicare Negotiations. CMS selects drugs based on how much Medicare spends on them overall and, in Trelegy's case, this appears to be driven mostly by Medicare enrollee utilization (1.25 million people) given its market leader status rather than its price per unit. Importantly, CMS' selection criteria did not account for discounts already in the market in their selection process. In contrast, Oregon's drug pricing dashboard looks at net spending (after discounts), and it indicates Trelegy does not pose a high affordability concern relative to other widely used drugs in the state.

GSK is committed to increasing patient access to Trelegy. In addition to the significant rebates and discounts we provide for our products, GSK has multiple patient support programs for eligible patients that can reduce their out-of-pocket (OOP) spend to or below $35 per month.

- GSK offers a coupon for Trelegy where eligible commercially insured and cash paying patients may pay as little as $0.
- GSK offers a coupon for our entire portfolio of inhalers, including Trelegy, which caps patient OOP costs at $35-per-month for eligible commercially insured and cash paying patients.[13]
- Patients who are unable to afford the cost of their GSK medicines may be eligible to receive certain medicines, including Trelegy, at no cost through the GSK Access Programs Foundation, an independent, 501(c) (3) charitable foundation.

Potential for Access Challenges

While the OR PDAB currently does not have UPL authority, GSK is concerned over access issues that may be created if UPLs are set for drugs in the future. In addition, changes to formularies and patient drug benefits resulting from upper payment limits (UPLs) could create market disincentives, forcing providers to adjust referral, prescribing, and acquisition patterns for UPL-selected drugs. Such disincentives and market disruptions could create provider pressure to choose specific medications over the clinically appropriate product a provider deems best for the patient based on their individual and unique diagnosis. Research demonstrates that payers will likely change their formularies to account for UPLs, with 27% of survey

[12] Bogart, M., et al. "Outcomes Following Initiation of Triple Therapy with Fluticasone Furoate/Umeclidinium/Vilanterol versus Multiple-Inhaler Triple Therapy Among Medicare Advantage with Part D Beneficiaries and Those Commercially Enrolled for Health Care Insurance in the United States." International Journal of Chronic Obstructive Pulmonary Disease, 2024. 19: p. 97-110.

[13] GSK. GSK Announces Cap of $35 Per Month on U.S. Patient Out-of-Pocket Costs for its Entire Portfolio of Asthma and COPD Inhalers. https://us.gsk.com/en-us/media/press-releases/gsk-announces-cap-of-35-per-month-on-us-patient-out-of-pocket-costs-for-its-entire-portfolio-of-asthma-and-copd-inhalers/.

respondents noting that they will place a UPL-affected drug on a “less preferred tier”.[14] UPLs could negatively influence provider treatment choices and patient therapy access as plan formulary changes driven by the UPL, may alter autonomous provider decision making of clinically appropriate treatment pathways and prevent patients from getting access to a high value treatment.

Conclusion

In summary, we believe Trelegy is appropriately priced for the significant value it brings to patients and does not pose an affordability challenge. Trelegy is an affordable, high-value option for severe asthma or COPD before patients escalate to more expensive biologics. As such, Trelegy does not pose an affordability challenge and should not qualify for the OR PDAB affordability review.

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
VP, Government Affairs, Public Policy, Patient Advocacy
GSK

[14] Partnership to Fight Chronic Disease. Payer Perspectives Confirm UPLs Will Likely Raise Costs and Hinder Patient Access to Medicines. https://www.fightchronicdisease.org/post/new-research-shows-prescription-drug-affordability-boards-will-not-benefit-patients.

Eli Lilly and Company

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April 25, 2025

By Email (*PDAB@DCBS.oregon.gov*)

Oregon Department of Consumer and Business Services
ATTN: Oregon Prescription Drug Affordability Board (the "Board")
P.O. Box 14480
Salem, OR 97309

Re: Prescription Drug Affordability Review of Lilly Products

Dear Board,

I write on behalf of Eli Lilly and Company ("Lilly"), the manufacturer of Emgality®, Mounjaro®, Taltz®, Trulicity®, Verzenio®, Basaglar KwikPen®, Basaglar Tempo Pen® and Rezvoglar KwikPen™. According to the subset lists of products selected for affordability reviews published on the public website for the Oregon Prescription Drug Affordability Board, the Board intends to review these drugs listed above to determine whether the selected products "may create affordability challenges for the health care systems or high out-of-pocket costs for patients"[1]. We appreciate the opportunity to provide our perspective and insights on this critical issue and also provide our perspective on the Request for Information: Manufacturers ("Manufacturer's RFI") posted on the Board's website due April 30, 2025.

Lilly is Committed to Patient Affordability.

Throughout our nearly 150-year history, Lilly has worked to address some of the most pressing health challenges facing humanity, including infections, diabetes, depression, cancer and obesity. Today, more than 55 million people are estimated to use Lilly medicines. We know that our commitment to patients and society goes beyond the medicines we make. We are committed to equitable and affordable access to our medicines so that our breakthroughs can transform more people's lives. This includes our approach to pricing in the U.S.

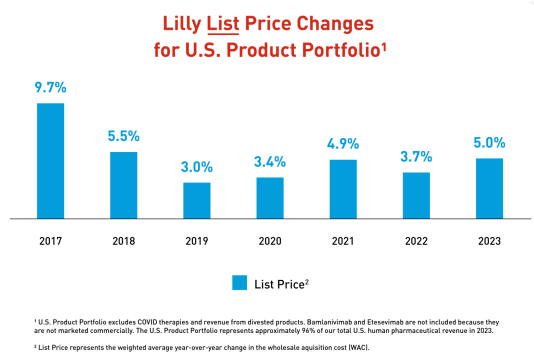
Pricing medicines to achieve the optimal balance between patient access and sustained investment in innovative treatments is complex. At Lilly, we know that pricing our medicines is one of the most important decisions we make as a company. We use a value-based approach to pricing, taking into account customer perspective, company considerations, competitive landscape and other contributing factors like health system changes and policy guidelines. Lilly also makes price adjustments over a product's lifecycle

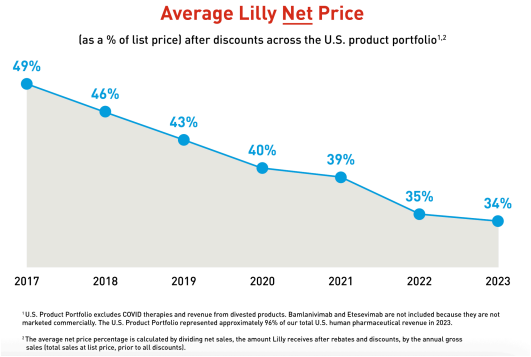
[1] ORS 646A.694.

that are based on the factors above as well as post-approval clinical data. We are committed to educating stakeholders about the value of our medicines and ensuring transparency about our prices. List prices for many of our medicines, as well as average out-of-pocket costs and financial assistance information, are published online[2].

A list price for each of our medicines is set using the considerations noted above. We pay rebates and other discounts and fees to payers, pharmacy benefit managers (PBMs), the U.S. government and other supply chain entities such as wholesalers and distributors. After paying these rebates, discounts and channel costs, the final dollar amount that Lilly ultimately receives is called the net price.

These rebates and discounts have continued to grow over the years for Lilly's U.S. portfolio while net prices for many of our medicines have continued to decrease.





Lilly Patient Support Programs Offer Affordability Solutions.

We're a medicine company turning science into healing to make life better for as many people as possible. We work to improve access to our treatments and increase equity throughout the health care system. We actively advocate for and participate in the process of driving systemic positive changes. We support the realignment of financial incentives for the entire pharmaceutical supply chain so that patients directly benefit from the net pricing we provide. We are also taking important steps within our own control to increase access to Lilly medicines today.

Lilly offers a variety of affordability solutions through patient support programs and copay assistance across the major products in our portfolio. For many of our migraine, immunology, diabetes and obesity medicines, we have copay assistance programs to bring eligible patients' monthly out-of-pocket costs to as little as $25 or lower. For cancer, the Lilly Oncology Support Center assists eligible patients in

[2] https://pricinginfo.lilly.com

identifying affordability options related to their Lilly treatment. The Lilly Diabetes Solution Center is a resource for patients to learn about our different insulin affordability solutions, which are outlined below.

For millions of people with diabetes, insulin is a life-saving medicine. Over the last century, this medicine has improved and extended countless lives around the world. Lilly understands the importance of our role as a leading diabetes company – and that includes supporting affordable access to insulin therapies. While many people in the U.S. have insurance coverage with affordable copays, some have large deductibles they must satisfy before insurance will cover their medicines and others have no insurance at all. And, for many people, insulin is just one of several interventions used to control diabetes, such as blood glucose monitoring devices and other medicines.

Over the past several years, Lilly has introduced multiple insulin affordability solutions, including our Lilly Insulin Value Program. As a result of our efforts, anyone – whether they are uninsured or use commercial insurance – is eligible to buy their monthly prescription of Lilly insulin for $35 or less, regardless of the number of pens or vials they use. To make it even easier for people to access Lilly insulin, we took additional steps in 2023, including:

- Reducing the list price of our most commonly prescribed insulins by 70%.
- Automating the $35 out-of-pocket monthly cap for people with commercial insurance at participating retail pharmacies.
- Cutting the price of our non-branded insulin, Insulin Lispro, which is the same molecule as Humalog, to $25 per vial, making it the lowest list-priced mealtime insulin available.
- Launching a biosimilar basal insulin, Rezvoglar, at a lower list price.

Under the Inflation Reduction Act (IRA), more than 3 million Medicare beneficiaries who take insulin will pay $35 per month or less on their insulin. Lilly was a strong supporter of this provision as it aligns with the affordability solutions we've had in-place years before the IRA became law.

All of these initiatives have made a real impact, helping 100,000 people save $20 million each month. Importantly, despite rising insurance deductibles, Lilly was the first and still only company to cap what people pay at $35 per month for all of our insulins, we cut insulin prices by 70%, and in 2023 the average monthly out-of-pocket cost for Lilly insulin was just $17.16.

The Board's Affordability Review Should Focus on Patient Affordability.

While we share the Board's goal of improving access to medicines and drug affordability for patients, we have concerns regarding the ambiguity of the Board's focus on affordability. It is unclear whether the primary focus of the Board's affordability review is on cost-sharing for patients, specifically

patient out-of-pocket costs, or for the healthcare system as a whole. We believe it is crucial to prioritize patient affordability and the patient out-of-pocket experience to ensure that Oregon patients can access the medications they need without undue financial burden. Clarifying this focus on affordability for patients through the Board's drug affordability process will align efforts for access and affordability of medicines for the intended beneficiaries—patients in Oregon.

The Manufacturer's RFI Requests Speculative and Unavailable Data and Lacks Adequate Protections of Confidential Information.

Lilly highlights that the data collection process employed by the Board requests data that is not available, speculative, and/or highly confidential. Much of the information listed in the Manufacturer's RFI is non-public confidential information and/or information that is not collected, calculated, or allocated by manufacturers on a product or state-level basis. Notably, the Manufacturer's RFI also asks manufacturers to submit pricing and cost information on competitors' therapeutic alternatives, information which manufacturers neither have access to nor can provide.

In addition, we are concerned with the proposed collection of data requested by the Manufacturer's RFI through a Microsoft survey tool – a method that is unprotected and lacks sufficient controls for receiving confidential, proprietary and trade secret information. It is essential to ensure that any confidential data that is collected is protected as required by federal and state law to maintain the integrity of proprietary and trade secret data and information. We urge the Board to consider implementing measures to safeguard any proprietary, confidential, and/or trade secret information that it receives. Ensuring secure data handling practices is crucial for maintaining the integrity and effectiveness of an affordability review process as well as guarding information that is entitled to statutory protections.

We are also concerned with the Board's affordability review process in connection with the lack of notice and submission timing requirements of the Manufacturer's RFI. The Board's request for information to manufacturers was published on the public website for the PDAB on or around March 31, 2025, without direct notification to manufacturers with a response deadline for the Manufacturer's RFI within a month on April 30, 2025. The Manufacturer's RFI timing does not sufficiently allow for complete and meaningful responses (and in some cases for a manufacturer, responses for multiple drugs), and we request that the Board implement a transparent and reasonable process to help the Board determine a drug's therapeutic benefit, cost value, and affordability for patients.

We appreciate that the Board shares our commitment to prescription drug access and patient affordability. We are proud of the impact that our efforts have had on making prescription drugs more

affordable for patients and believe Lilly medicines like those selected by the Board help make the lives of Oregon patients healthier and better.

Sincerely,

Cynthia Ransom
Sr. Director, US Government Pricing & Payer

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May 1, 2025

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

Care of: pdab@dcbs.oregon.gov

Re: Selection of Cosentyx® and Entresto® for Affordability Review

Dear Oregon Prescription Drug Affordability Board ("Board"):

Novartis Services, Inc. submits this letter on behalf of Novartis Pharmaceuticals Corporation and its affiliates referred to collectively herein as "Novartis." We appreciate the opportunity to respond to comment on the Board's selection of Cosentyx® (secukinumab) and Entresto® (sacubitril/valsartan) for affordability review pursuant to *OR. Rev. Stat. § 646A.693 - 646A.697*.[1]

Novartis is an innovative medicines company concentrated on the core therapeutic areas of cardiovascular, immunology, neuroscience, and oncology. At Novartis, we are united by a single purpose to reimagine medicine to improve and extend lives. We believe everyone should have access to the medicines they need. When we determine the prices for our medicines, we consider the value that these medicines provide to patients as well as health care systems and society at large.

Entresto and Cosentyx are both proven medicines backed by robust clinical evidence. Patients in Oregon have broad affordable access to these medicines:

- Eligible patients with commercial health coverage can access Cosentyx and Entresto at a cost as low as zero dollars with the Novartis co-pay support program.
- Eligible patients who are uninsured or underinsured pay nothing for Cosentyx and Entresto via the Novartis Patient Assistance Foundation.
- When adjusted for inflation, the average net prices of Cosentyx and Entresto have declined between January 2018 and December 2023.

[1] By making this submission, Novartis does not waive its rights with regard to any legal challenge to ORS § 646A.694 and OAR 925-200-0020 and the Board's implementing regulations.

- Cosentyx and Entresto provide value to the broader health care system. This is particularly clear for Cosentyx when compared to therapeutic alternatives. It is also clear for Entresto when compared to the former standard of care, enalapril, since Entresto is a first-in-class heart failure therapy without a current therapeutic alternative.[2]

Additionally, for forecasting purposes, Novartis currently assumes Entresto loss of exclusivity in mid-2025.[3]

Cosentyx and Entresto Are Proven Medicines Backed by Robust Evidence.

Cosentyx has been studied clinically for more than 17 years and used to treat more than 1 million patients globally since its approval by the FDA in 2015.[4]

Cosentyx is indicated for the treatment of moderate to severe plaque psoriasis in patients 6 years of age and older who are candidates for systemic therapy or phototherapy. Cosentyx is also indicated for the treatment of active psoriatic arthritis in patients 2 years of age and older.

Affecting 7.5 million Americans, psoriasis is a chronic autoimmune inflammatory disease characterized by thick and oftentimes extensive skin plaques that cause itching, scaling, and pain. Psoriasis can negatively impact patients' quality of life, both psychosocially and physically.[5]

However, psoriasis is not simply a skin disease. Up to 41% of patients with certain types of psoriasis may also have psoriatic arthritis, which - through destructive inflammation - can lead to irreversible joint damage if not properly treated.[6]

In clinical trials, Cosentyx has been shown to help achieve clear skin in plaque psoriasis and help stop progressive joint damage and improve physical function

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[2] McMurray JJ et al. (2014). Angiotensin–Neprilysin Inhibition versus Enalapril in Heart Failure. NEJM**.** https://www.nejm.org/doi/full/10.1056/nejmoa1409077; Solomon SD et al. (2019). Angiotensin–Neprilysin Inhibition in Heart Failure with Preserved Ejection Fraction. NEJM. https://www.nejm.org/doi/full/10.1056/NEJMoa1908655

[3] Novartis Q4 2024 Results Investor Presentation, Slide 6. https//www.novartis.com/sites/novartis_com/files/q4-2024-investor-presentation.pdf

[4] Data on file. COSENTYX Patient Reach. Novartis Pharmaceuticals Corp; January 2023.

[5] Armstrong A, Mehta M, et al. Psoriasis Prevalence in Adults in the United States. JAMA Dermatol. 2021 Aug; 157(8): 1–7. doi: 10.1001/jamadermatol.2021.2007.
National Psoriasis Foundation. About Psoriasis. https://www.psoriasis.org/about-psoriasis/. Accessed September 27, 2023.

[6] Rech J, Sticherling M, et al. Psoriatic arthritis epidemiology, comorbid disease profiles and risk factors: results from a claims database analysis. Rheumatol Adv Pract. 2020; 4(2): rkaa033. doi: 10.1093/rap/rkaa033.

in patients with psoriatic arthritis. Cosentyx generally starts working in as little as 3 to 4 weeks with positive results observed up through 5 years.[7]

Cosentyx is also approved for active ankylosing spondylitis and active non-radiographic axial spondyloarthritis – two inflammatory arthritis conditions that affect the spine - as well as active enthesitis-related arthritis (ERA). Additionally, in 2023, Cosentyx was approved as the first new biologic treatment in nearly a decade for adults with moderate to severe hidradenitis suppurativa (HS), a painful and often debilitating inflammatory skin condition.

Further, Cosentyx is the only medicine FDA approved to treat 2 types of juvenile idiopathic arthritis (JIA), the most common form of juvenile arthritis: Enthesitis-Related Arthritis (ERA) and Juvenile Psoriatic Arthritis (JPsA). ERA is a type of JIA that affects the tissue where the muscles, ligaments, or tendons meet the bone (entheses). Symptoms may include swelling, joint pain, and stiffness at the hips, knees, and feet. The fingers, elbows, pelvis, chest, and lower back can also be affected. JPsA is a type of JIA that may include symptoms of both arthritis and plaque psoriasis. Arthritis symptoms can show up before skin symptoms and may affect 1 or more joints, often in the wrists, ankles, fingers, or toes. Psoriasis can appear as a scaly rash behind the ears, on the eyelids, elbows, knees, belly button, or scalp. In a clinical trial of kids and teens with ERA or JPsA taking Cosentx, those with ERA had a 53% reduced risk of flares and those with JPsA had an 85% reduced risk of flares.[8]

We have ongoing development programs for Cosentyx in other areas of high unmet need such as giant cell arteritis (GCA) a condition that can cause pain and swelling in blood vessels.

Entresto

Entresto is the first and only angiotensin receptor-neprilysin inhibitor (ARNi) approved for the treatment of heart failure in the United States that helps patients stay alive longer and out of the hospital.[9] Entresto is the #1 heart failure brand prescribed by cardiologists and has helped over 2 million people with heart failure.[10]

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[7] Cosentyx Prescribing Information. East Handover, NJ: Novartis Pharmaceuticals Corp; July 2023. Cosentyx.com. Results with Cosentyx. https://www.cosentyx.com/psoriatic-arthritis/treatment-results. Accessed September 27, 2023.
[8] Cosentyx Webpage. Accessed April 2025. https://www.cosentyx.com/kids-and-teens/juvenile-idiopathic-arthritis
[9] McMurray JJ et al. (2014). Angiotensin–Neprilysin Inhibition versus Enalapril in Heart Failure. NEJM. https://www.nejm.org/doi/full/10.1056/nejmoa1409077
[10] Entresto Webpage. Accessed April 10, 2025. https://www.entresto.com/

Entresto targets two complementary pathways to help the heart's ability to pump blood to the body. [11] It has a Class I recommendation by the American Heart Association / American College of Cardiology / Heart Failure Society of America (AHA/ACC/HFSA) treatment guidelines for people with heart failure with reduced ejection fraction (HFrEF).[12]

Cosentyx and Entresto Are Affordable for Oregonians and the Health Care System

At its core, the question of whether Cosentyx and Entresto are "affordable" for Oregonians has a simple answer: they are affordable because eligible Oregon patients with commercial health coverage can access them at a cost as low as zero dollars with the assistance of the Cosentyx and Entresto Co-pay Card Programs.[13,14] Additionally, pursuant to state and federal regulations, patients who access prescription drugs through Oregon's Medicaid program do not pay anything out-of-pocket for covered drugs.[15]

Furthermore, the health plans that pay a portion of the cost of Cosentyx and Entresto benefit from heavily discounted prices. The complicated interplay of drug pricing and rebates throughout the supply chain and the selective use of pricing data can misleadingly complicate what should be a straight-forward analysis of affordability.

Chief among these complicating factors is a reliance on "list" prices as a proxy for patient costs and affordability. A patient or health plan rarely if ever pays the list price of a drug. In Oregon, as in the rest of the United States, where third-party payers and government health care programs negotiate the price of drugs they buy, Novartis works with third parties to negotiate significant rebates and other price concessions on our medicines. When adjusted for inflation, the average net prices of Cosentyx and Entresto have declined between January 2018 and December 2023. The vast majority of patients, too, receive significant assistance even beyond the net price of Cosentyx and their insurance coverage through the Cosentyx Co-Pay Programs or the charitable assistance of the Novartis Patient

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[11] ENTRESTO NDA Approval Letter, https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/207620orig1s000ltr.pdf

[12] Heidenreich PA, et al. on behalf of the American Heart Association Advocacy Coordinating Committee; Council on Arteriosclerosis, Thrombosis and Vascular Biology; Council on Cardiovascular Radiology and Intervention; Council on Clinical Cardiology; Council on Epidemiology and Prevention; Stroke Council (2013). Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. Circ Heart Fail. https://pubmed.ncbi.nlm.nih.gov/23616602/

[13] Novartis.com, Paying for Cosentyx, https://www.cosentyx.com/all/treatment-cost

[14] Entresto.com, Savings and Support. https://www.entresto.com/financial-support

[15] Oregon Health Plan, What to Do If You Are Asked to Pay for a Prescription, https://www.oregon.gov/oha/hsd/ohp/pages/prescriptions.aspx#:~:text=The%20Oregon%20Health%20Plan%20(OHP,they%20give%20them%20to%20you.., Accessed February 25, 2024.

Assistance Foundation (NPAF). These programs further reduce the costs patients pay, in many cases to as little as $0[16].

Cosentyx and Entresto Are Affordable for Oregon Patients.

For patients, the most significant hallmark of "affordability" is the price they pay out-of-pocket. Patients judge the cost of a medicine not by reference to complicated gross or net price formulas, but by how much they must pay out-of-pocket to access their medication.

Novartis negotiates with third-party payers for affordable coverage for patients and provides programs to help address residual affordability challenges once coverage is determined by payers. Over 70% of commercial lives in Oregon have coverage for Entresto on the preferred brand tier or lowest branded copay tier.[17] Further, through our Patient Assistance website[18], we inform patients about programs that may provide savings or resources that can help them access Cosentyx, Entresto, or any other Novartis prescription medication. We do this because Novartis believes that medicines should be available to all who need them.

Novartis has a co-pay assistance program in the US that helps thousands of patients with commercial health coverage access our medicines for as little as zero cost to them. In 2024, 72% of Oregon patients accessing Cosentyx through their commercial coverage used a Cosentyx co-pay card.[19] Manufacturer co-pay card programs play a critical role in helping eligible commercially-insured patients satisfy the cost-sharing requirements dictated by their health insurance coverage. Alarmingly, insurers and pharmacy benefit managers are increasingly subjecting this assistance to accumulator adjustment programs, which prevent co-pay card amounts from counting toward a patient's deductible and out-of-pocket maximum. This can lead to surprise increases in out-of-pocket costs for patients once the pharmacy benefit manager has exhausted the total value of the co-pay card.

Twenty-one states, the District of Columbia, and Puerto Rico have enacted laws banning accumulator adjustment programs in state-regulated commercial plans.[20] We commend Oregon for taking similar action to protect patients in

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[16] IQVIA Claim Data FY 2022, 2023.
[17] Internal Analysis of MMIT Data. February 2025.
[18] Novartis.com. Patient Assistance. https://www.novartis.com/us-en/patients-and-caregivers/patient-assistance. Accessed April 10, 2025.
[19] IQVIA Claim Data FY 2023, SP Dispense Data FY 2023.
[20] All Copays Count Coalition. State Legislation Against Copay Accumulators. Accessed April 10, 2025. https://allcopayscount.org/state-legislation-against-copay-accumulators/

2024.[21] However, payers are still using other tactics, such as copay maximizers[22] and alternative funding programs[23], that disrupt the value of copay cards for patients. Any affordability determination by the Oregon PDAB must consider these health insurer tactics that result in Oregonians paying more out-of-pocket for a necessary medication than they should.

Additionally, our “Covered Until You're Covered Program” is available for eligible patients taking Cosentyx in subcutaneous form who have commercial insurance, a valid prescription for Cosentyx, and a denial of insurance coverage based on a prior authorization request. The program provides Cosentyx for free to eligible patients for up to two years, or until they receive insurance coverage approval, whichever occurs first.[24]

Patients who cannot afford the cost of their Novartis medication, do not have private insurance, and meet income guidelines and other relevant criteria may be eligible to receive the medication at no cost from the Novartis Patient Assistance Foundation (NPAF), an independent, 501(c)(3) non-profit, non-commercial entity. Income and affordability guidelines vary by drug but are generally well above federal poverty levels.[25]

In 2024, NPAF provided approximately $6.0 billion in free medicines to approximately 146,000 patients, covering 42 medicines from our portfolio. Over the last five years, medication has been made available to over 300,000 patients valued at more than $23.0 billion.[26]

We caution the Board against relying on data from third-party sources, including the state’s All Payer All Claims Reporting program, that purports to indicate a patient out-of-pocket cost for Cosentyx and Entresto. That cost may well have been borne by Novartis or the NPAF for the benefit of patients through the mechanisms described above.

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[21] Oregon House Bill 4113. https://olis.oregonlegislature.gov/liz/2024R1/Measures/Overview/HB4113

[22] Copay maximizers allow plans to “maximize” the value extracted from copay assistance programs by adjusting a patient’s cost-sharing to the maximum amount of available assistance and not allowing the funds to count toward the patient’s deductible or out-of-pocket maximum.

[23] Alternative funding programs are strategies used by employer-sponsored health plans to exclude certain medications from coverage, redirecting patients to external assistance programs which can be result in significant burden and delays for patients trying to obtain the medications they need.

[24] The Covered Until You're Covered Program requires the submission of an appeal of a coverage denial within the first 90 days of enrollment in order to remain eligible. A valid prescription consistent with FDA-approved labeling is required. Program is not available to patients whose medications are reimbursed in whole or in part by Medicare, Medicaid, TRICARE, or any other federal or state program. Novartis.com Cosentyx Connect. https://www.cosentyx.com/psoriatic-arthritis/cosentyx-connect-personal-support-program. Accessed March 7, 2024.

[25] Novartis Patient Assistance Foundation. https://pap.novartis.com/ Accessed April 29, 2025.

[26] Novartis Internal Data Analysis. April 10, 2025.

Oregon Payers Benefit from Significant Discounts on Cosentyx and Entresto.

Payers such as commercial insurers routinely negotiate rebates and other price concessions from the Novartis list price. These rebates and price concessions lower the final "net" price of the drug significantly below the initial list price. Payers and employers in turn can pass these rebates and price concessions on to patients by reducing their out-of-pocket costs, or use them in other ways, such as lowering premiums, applying the discount to administrative costs, or other uses.

The continuing gap between list and net prices generated by this practice fuels increasing confusion and misperceptions about the real price paid for drugs by the health care system. While industry critics focus on the rise in wholesale acquisition cost (WAC), also known as the list or gross price, the reality is that price increases are often outpaced by rebates and price concessions to third-party payers and other channel intermediaries (e.g., wholesalers, pharmacies). Oregon, unlike some states, does not require payers and intermediaries to share these rebates and price concessions with patients.

Novartis rebates and price concessions to payers are important not just to understanding why Cosentyx and Entresto are *currently* affordable to patients, but also why Cosentyx's and Entresto's net prices have declined when adjusted for inflation, despite WAC price increases over the same period. It is critical that the Board base its affordability determination on the net price. The Board must take account of these rebates and price concessions, which are a significant component of the affordability of Cosentyx and Entresto.

Notably, between January 2018 and January 2023, inflation, measured by the CPI, was 22.9%. By our estimate this means the Cosentyx and Entresto net prices declined over this timeframe when adjusted for inflation.

Cosentyx and Entresto Provide Value to the Broader Health Care System.

In evaluating a drug's affordability, the Board must take account of its "relative financial effects on health, medical, or social services costs."[27] In this regard, Cosentyx should be recognized as effectively treating multiple indications and Entresto is recognized as the standard of care for treatment of heart failure. [28] Both drugs treat conditions that would otherwise significantly limit patient health and impose major costs on the state.

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[27] OAR 925-200-0020-(1)-(j)

[28] Novartis. The 2024 ACC Expert Consensus Decision Pathway for the treatment of HFrEF recommends ARNi as the only first-line RASi. Accessed April 2025. https://www.entrestohcp.com/sites/entrestohcp_com/files/documents/entresto-acc-ecdp-digital-flashcard.pdf

The major indications for which Cosentyx and Entresto are used[29] are associated with significant economic burden. We strongly urge the Board to consider the value Cosentyx and Entresto provide in reducing the direct and indirect costs of these diseases to the workforce, communities, and overall health care system as described below.

Cosentyx

Psoriasis:

Total direct and indirect costs associated with the disease have been estimated at $11.3 billion annually.[30]

A claims database from 31 self-insured employers (representing 5.1 million employees, their spouses, and dependents) during the period from 1998 to 2005 was used to evaluate both the direct medical and indirect work-loss costs associated with psoriasis.[31] After multivariate adjustment, psoriasis patients demonstrated significantly higher direct and indirect costs compared to other patients.[32] Approximately 40% of the total cost burden was associated with work loss (i.e., indirect costs).[33]

Cosentyx is effective in relieving this burden. A health economic model was developed to demonstrate the cost-effectiveness of Cosentyx for patients with plaque psoriasis. The patient population of interest included adults diagnosed with moderate-to-severe plaque psoriasis who are candidates for systemic or biologic therapy. The model demonstrated that the cost per responder was lower for Cosentyx 150 mg and 300 mg than some leading therapeutic alternatives.[34]

Psoriatic Arthritis (PsA):

The total direct costs of PsA in the US have been estimated at $1.9 billion annually.[35] There are limited data on the indirect costs (e.g., lost productivity and absenteeism) attributable to PsA in the US; however, it was reported that total

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[29] For this analysis, Novartis focuses on Cosentyx's approved indications for treatment of psoriasis, psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, non-radiographic axial spondyloarthritis, and hidradenitis suppurativa, and Entresto's approved indication for chronic heart failure.
[30] NPF, National Psoriasis Foundation Statistics [Online]. 2015b. Available: http://www.psoriasis.org/research/science-of-psoriasis/statistics [Accessed November 17, 2015].
[31] Fowler, J.F., Duh, M.S., Rovba, L., Buteau, S., et al. 2008. The impact of psoriasis on health care costs and patient work loss. *J Am Acad Dermatol.* 59(5), 772-780.
[32] *Id*.
[33] *Id*.
[34] Academy of Managed Care Pharmacy (AMCP) Formulary Dossier. Cosentyx. July 2023.
[35] Lee, S., Mendelsohn, A. & Sarnes, E. 2010. The burden of psoriatic arthritis: a literature review from a global health systems perspective. P T. 35(12), 680-689.

indirect costs account for approximately 52% to 72% of total costs.[36] The costs increase with deterioration of disease activity and decline in physical function.[37]

A health economic model explored the cost-effectiveness of Cosentyx for patients with psoriatic arthritis (PsA). The patient population of interest included adults diagnosed with PsA who are candidates for biologic therapy or apremilast. Cosentyx 150 mg and 300 mg had a lower cost per responder than some leading therapeutic alternatives.[38]

Ankylosing Spondylitis (AS):

A health economic model explored the cost-effectiveness of Cosentyx for patients. The patient population of interest included adults with active AS treated with a biologic. The cost per responder was lower for Cosentyx 150 mg than another leading therapeutic alternative.[39]

Non-radiographic axial Spondyloarthritis (nr-axSpA):

The economic impact of work limitations related to *nr-axSpA* is substantial and compounded by the typically young age at diagnosis.[40] Patients treated with Cosentyx showed substantial reduction in work-related impairment, measured through mean change in the Work Productivity and Activity Impairment (WPAI) from baseline to Week 52.[41]

Juvenile Idiopathic Arthritis (JIA):

Several studies have found that patients with JIA of all types have higher health care resource utilization and health care costs than patients without JIA.[42,43,44] As one of the most common chronic conditions in children, JIA places a sizable burden on the pediatric healthcare system and can result in a substantial economic burden for patients and their families. JIA includes several disorders in

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[36] *Id*.
[37] *Id*.
[38] Academy of Managed Care Pharmacy (AMCP) Formulary Dossier. Cosentyx. July 2023.
[39] *Id.*
[40] Strand, V. and Singh, J. A. 2017a. Patient Burden of Axial Spondyloarthritis. *Journal Of Clinical Rheumatology : Practical Reports On Rheumatic & Musculoskeletal Diseases*. 23(7): 383-391.
[41] Academy of Managed Care Pharmacy (AMCP) Formulary Dossier. Cosentyx. July 2023.
[42] Krause ML, Zamora-Legoff JA, Crowson CS, Muskardin TW, Mason T, Matteson EL. Population-based study of outcomes of patients with juvenile idiopathic arthritis (JIA) compared to non-JIA subjects. *Semin Arthritis Rheum*. 2017;46(4):439-443.
[43] Kumar N, Ramphul K, Ramphul Y, et al. Children hospitalized for juvenile arthritis in the United States. Reumatologia. 2021;59(4):270-272.
[44] Marshall A, Gupta K, Pazirandeh M, Bonafede M, McMorrow D. Treatment patterns and economic outcomes in patients with juvenile idiopathic arthritis. Clinicoecon Outcomes Res. 2019;11:361-371.

children involving inflammation of the joints. Cosentyx is approved to treat two of those disorders: ERA and JPsA.[45]

Hidradenitis suppurativa (HS)

Patients with HS have higher rates of hospital emergency department use and higher mean emergency department costs than healthy individuals and patients with psoriasis.[46] Even compared with patients with severe psoriasis, rates of inpatient care and emergency department use are higher for patients with HS.[47] In a retrospective cohort study analyzing indirect costs, patients with HS were found to have more days of work loss (184 vs 77), higher annual total indirect costs ($2925 vs $1483) and lower annual income ($54,925 vs $62,357) than healthy controls. [48]

Cosentyx helps adults with moderate to severe HS find relief at 16 weeks, including at least a 50% reduction in the number of inflammatory bumps and abscesses and no increase in the number of abscesses or draining tunnels.[49] Cosentyx can help reduce flares in adults with moderate to severe HS.

Entresto

Chronic Heart Failure

Almost 7 million Americans are currently living with chronic heart failure, a progressive chronic condition that can lead to hospitalization or shortened life expectancy.[50] Heart failure prevalence is on the rise and is expected to increase

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[45] Angeles-Han ST, Ringold S, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Screening, Monitoring, and Treatment of Juvenile Idiopathic Arthritis-Associated Uveitis. *Arthritis Care Res (Hoboken)*. 2019;71(6):703-716.

[46] Khalsa, A., Liu, G., & Kirby, J.S. 2015. Increased utilization of emergency department and inpatient care by patients with hidradenitis suppurativa. J Am Acad Dermatol. 73(4), 609-614.

[47] *Id*.

[48] Tzellos, T., Yang, H., Mu, F., Calimlim, B., & Signorovitch, J. 2019. Impact of hidradenitis suppurativa on work loss, indirect costs and income. Br J Dermatol. 181(1), 147-154.

[49] Cosentyx 300mg every 4 weeks (after 5 initial weekly doses). In the 2 clinical trials, 41% and 43% of adults taking COSENTYX 300 mg every 4 weeks (after 5 initial weekly doses) achieved at least a 50% reduction in the number of inflammatory bumps and abscesses, with no increase in the number of abscesses and/or draining tunnels at 16 weeks vs 29% and 26% taking placebo.

[50] Centers for Disease Control and Prevention and National Center for Health Statistics. National Health and Nutrition Examination Survey (NHANES) public use data files. https://www.cdc.gov/nchs/nhanes/

by 46% by 2030.[51,52,53] It is projected that the total costs of heart failure will reach nearly $70 billion by 2030.[54]

According to benchmarks adopted by the AHA/ACC/HFSA, the heart failure guidelines determined that Entresto delivers a high economic value when compared to ACE inhibitors for patients with chronic symptomatic HFrEF. Entresto delivers value for patients, reducing risk of hospitalization, emergency visits, and premature death[55,56,57] and this is backed up by real-world data.[58,59] It was estimated in a model that use of Entresto compared with enalapril in HFrEF patients was associated with averting over 50,000 hospitalizations in the US, saving $92.3 million annually.[60] As a result, Entresto has set a new standard of care for the treatment of chronic heart failure patients per the 2022 AHA/ACC/HFSA guidelines, and its clinical value was reiterated in the 2024 ACC Expert Consensus Decision Pathway guidelines.[61]

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[51] Oktay AA, Rich JD and Shah SJ (2013). The emerging epidemic of heart failure with preserved ejection fraction. Curr Heart Fail Rep. https://pubmed.ncbi.nlm.nih.gov/24078336/

[52] Heidenreich PA, et al. on behalf of the American Heart Association Advocacy Coordinating Committee; Council on Arteriosclerosis, Thrombosis and Vascular Biology; Council on Cardiovascular Radiology and Intervention; Council on Clinical Cardiology; Council on Epidemiology and Prevention; Stroke Council (2013). Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. Circ Heart Fail. https://pubmed.ncbi.nlm.nih.gov/23616602/

[53] CMS Office of Minority Health (2020). Heart Failure Disparities In Medicare Fee-For-Service Beneficiaries. https://www.cms.gov/about-cms/agency-information/omh/downloads/data-snapshot-heart-failure.pdf

[54] Heidenreich PA, et al. on behalf of the American Heart Association Advocacy Coordinating Committee; Council on Arteriosclerosis, Thrombosis and Vascular Biology; Council on Cardiovascular Radiology and Intervention; Council on Clinical Cardiology; Council on Epidemiology and Prevention; Stroke Council (2013). Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. Circ Heart Fail. https://pubmed.ncbi.nlm.nih.gov/23616602/

[55] McMurray JJ et al. (2014). Angiotensin–Neprilysin Inhibition versus Enalapril in Heart Failure. NEJM. https://www.nejm.org/doi/full/10.1056/nejmoa1409077

[56] Solomon SD et al. (2019). Angiotensin–Neprilysin Inhibition in Heart Failure with Preserved Ejection Fraction. NEJM. https://www.nejm.org/doi/full/10.1056/NEJMoa1908655

[57] Packer M et al. (2015). Angiotensin receptor neprilysin inhibition compared with enalapril on the risk of clinical progression in surviving patients with heart failure. Circulation: https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.114.013748?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed

[58] Albert NM et al. (2019). Lower Hospitalization and Healthcare Costs With Sacubitril/Valsartan Versus Angiotensin-Converting Enzyme Inhibitor or Angiotensin-Receptor Blocker in a Retrospective Analysis of Patients With Heart Failure
JAHA:
https://www.ahajournals.org/doi/full/10.1161/JAHA.118.011089?rfr_dat=cr_pub++0pubmed&url_ver=Z39.88-2003&rfr_id=ori%3Arid%3Acrossref.org

[59] Tan NY et al. (2020). Comparative Effectiveness of Sacubitril-Valsartan Versus ACE/ARB Therapy in Heart Failure With Reduced Ejection Fraction. JACC**:**
https://www.sciencedirect.com/science/article/pii/S2213177919306766?via%3Dihub

[60] Gaziano TA et al (2020). Cost-effectiveness of Sacubitril-Valsartan in Hospitalized Patients Who Have Heart Failure With Reduced Ejection Fraction. JAMA Cardiol:
https://jamanetwork.com/journals/jamacardiology/fullarticle/2769180

[61] Novartis. The 2024 ACC Expert Consensus Decision Pathway for the treatment of HFrEF recommends ARNi as the only first-line RASi. Accessed April 2025.
https://www.entrestohcp.com/sites/entrestohcp_com/files/documents/entresto-acc-ecdp-digital-flashcard.pdf

The Board Should Address the Methodological and Implementation Issues with its Processes.

When the Board voted to postpone its affordability reviews during its June 26, 2024, meeting, it did so to, "review, assess and possibly improve both the criteria and methods used to assess and select drugs for potential affordability reviews in 2025".[62] Board members acknowledged data errors, a lack of a clear definition for when a drug "may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon," and an incomplete picture of the drug pricing environment as key factors in their decision to postpone affordability reviews.

Unfortunately, the Board's second attempt at selecting drugs for affordability reviews has so far been hampered by many of the same issues. In particular, Novartis would like to bring the Board's attention to the following gaps:

The Board Selected Entresto for Review Based on Incorrect Information.

As explained above, for forecasting purposes, Novartis currently assumes Entresto loss of exclusivity in mid-2025.[63] This is important because the availability of generic alternatives was a key factor in the Board's selection of drugs for affordability reviews. The Board should reconsider its selection of Entresto.

The Board Has Not Defined What Constitutes "Affordability Challenges to the Health Care System" or "High Out-of-Pocket Costs for Patients."

The Board is required in its affordability analysis to determine if a drug "may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon." When the Board elected to postpone its affordability reviews during its meeting on June 26, 2024, one of the key reasons was the Board's desire to better define what "affordability challenges to the health care system" or "high out-of-pocket costs for patients" mean, but this has still not been done.

The Board still has not defined what it means for a drug to present "affordability challenges to the health care system" or "high out-of-pocket costs for patients" nor has it developed thresholds that would guide the Board in making such a determination. This striking gap leaves Novartis and the public with no

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[62] Oregon Prescription Drug Affordability Board. June 26, 2024 Meeting Minutes. Minutes approved by the Board on July 24, 2024. https://dfr.oregon.gov/pdab/Documents/20240626-PDAB-approved-minutes.pdf
[63] Novartis Q4 2024 Results Investor Presentation, slide 4. https//www.novartis.com/sites/novartis_com/files/q4-2024-investor-presentation.pdf

understanding of what principles the Board is applying to reach its ultimate conclusions, and no means of verifying that the Board's analysis has been conducted correctly.

While the Board has released additional documentation about the affordability review process and factors that it will consider during the affordability reviews, the relative importance of these factors in determining whether a drug may present "affordability challenges to the health care system" or "high out-of-pocket costs for patients" is unclear. This negatively impacts the ability of Novartis and the public to provide meaningful input.

Ultimately, the Board appears to be making an *ad hoc* determination of whether a drug may create affordability challenges for health care systems or high out-of-pocket costs for patients in Oregon without clearly articulating what those thresholds would look like.

The Board has not instituted protections for commercially sensitive data, limiting its ability to understand the drug pricing environment.

Despite repeated requests by stakeholders, the Board's efforts to gather information for affordability reviews continue to be hamstrung by the lack of a mechanism for manufacturers to submit commercially sensitive information. The Board has not developed a process or provided guidance in its Public Comment Policy on how manufacturers can confidentially submit such data. This refusal by the Board makes it impossible for manufacturers to provide data on net pricing of their products. Several Board members acknowledged net pricing data to be a crucial, but missing, component of affordability reviews during the June 26, 2024, meeting when the Board elected to postpone its affordability reviews. Additionally, there is not an opportunity for the Board to discuss commercially sensitive data or meet with manufacturers in executive session, which could have been another opportunity for manufacturers to provide important data for affordability reviews.

Conclusion

For the reasons detailed above, Cosentyx and Entresto are affordable to patients and the health care system. We welcome the opportunity to answer any questions you may have about the information provided above. Please contact me at courtney.piron@novartis.com.

Sincerely,

Courtney Piron
US Country President
Head, US Public Affairs

CYSTIC FIBROSIS FOUNDATION®

April 30, 2025

Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter St. NE
Salem, Oregon 97309-0405

Dear Members of the Oregon Prescription Drug Affordability Board:

On behalf of people living with cystic fibrosis in Oregon, the Cystic Fibrosis Foundation thanks you for the opportunity to provide written testimony for the affordability review of CREON®. Pancreatic insufficiency remains a significant and lifelong complication of cystic fibrosis, and pancreatic enzyme replacement therapy (PERT) is a cornerstone of CF care. CREON®, a commonly prescribed PERT for people with CF, plays a critical role in supporting nutritional status for people living with this disease. We understand the importance of addressing financial barriers to care and commend efforts to increase transparency around drug pricing, improve affordability, and address sustainability of the healthcare system. Throughout this review, we urge the Board to keep the patient voice at the center of the discussion. We provide the following comments on CREON®'s use among people with CF and the Board's affordability review goals and process.

About Cystic Fibrosis & the Cystic Fibrosis Foundation
Cystic fibrosis is a progressive, genetic disease that affects the lungs, pancreas, and other organs. There are close to 40,000 children and adults living with cystic fibrosis in the United States, including nearly 470 people in Oregon, and CF can affect people of every racial and ethnic group. CF causes the body to produce thick, sticky mucus that clogs the lungs and digestive system, which can lead to lung damage, life-threatening infections, malnutrition, and other complications. Cystic fibrosis is both serious and progressive; lung damage caused by infection is often irreversible and can have a lasting impact on length and quality of life, resulting in extended hospitalizations, transplant, or premature death. The gastrointestinal effects, including pancreatic insufficiency, can lead to malnutrition and intestinal blockage. As a complex, multi-system condition, CF requires targeted, specialized treatment and medications. There is no cure.

As the world's leader in the search for a cure for CF and an organization dedicated to ensuring access to high-quality, specialized CF care, the Cystic Fibrosis Foundation supports the development of CF clinical practice guidelines and accredits more than 130 care centers nationally—including two in Oregon. The Foundation also gathers data on the health of people with CF who receive care at CF Foundation accredited care centers through our patient registry. This data helps inform the development of CF care guidelines, supports care teams in providing care to people with CF, and drives quality improvement initiatives at care centers. Researchers also use the patient registry to study CF treatments and outcomes and to design CF clinical trials.

Pancreatic Enzyme Replacement Therapy in CF Care
PERT is a life-sustaining treatment for individuals living with CF. As a multi-system disease, cystic fibrosis causes the ducts in the pancreas to become clogged with thick, sticky mucus that blocks natural digestive enzymes from reaching food in the small intestine. As a result, the vast majority of people with

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CF have exocrine pancreatic insufficiency (EPI), and 86% of people with CF living in Oregon are prescribed a PERT.[1] These therapies play a critical role in managing nutritional status, which is closely tied to pulmonary health, growth, and long-term survival. Pancreatic insufficiency is associated with a faster rate of pulmonary decline, and people with CF who have a higher weight-for-age percentile at a young age have fewer complications from CF and better survival through age 18.[2,3] If pancreatic insufficiency is left untreated, people with CF face severe consequences including malnutrition, weight loss, poor growth, gastrointestinal distress, and a significant decline in overall health.[4,5]

PERTs, including CREON®, contain pancrelipase—a combination of amylase, lipase, and protease—that replaces the enzymes normally produced by the pancreas . These therapies help individuals with EPI digest food properly and absorb nutrients by providing the enzymes needed to break down fats, proteins, and carbohydrates. These enzymes are released in the small intestine, where they work to digest food more effectively. PERTs must be taken with every meal and snack throughout the day to enable proper digestion and nutrient absorption. CREON® is the most commonly prescribed PERT for people with CF, taken by more than two-thirds of people with CF living in Oregon who are on PERT.[6] Research has shown that CREON® improves fat and protein absorption, reduces steatorrhea, improves stool frequency and consistency, and enhances body weight in individuals with EPI.[7,8]

Alternatives to CREON®

Although there are other FDA-approved PERTs such as Zenpep®, Viokace®, Pancreaze®, and Pertzye®, CREON® is not necessarily interchangeable with these alternatives. While the active ingredient is the same across PERTs, patients experience clinically significant differences in how they respond to individual products. Variations in formulation—including enzyme content, particle size, delivery, and enteric coating—can lead to differences in how well patients absorb nutrients. The degree of acidification of the GI tract in each CF patient also varies, causing some patients to have a better clinical response to one product over another. For some patients, CREON® may be the only product that consistently manages their symptoms and supports nutritional stability.

Given the impacts of CF on the pancreas, people with CF require a higher dosage of enzymes than other disease states that utilize PERT. This dosage is carefully determined to reduce overall pill burden for people with CF. PERTs currently tracked in the CF Foundation Patient Registry have a wide range of strengths available, ranging from two to seven different dosage options (Appendix 1). CREON® specifically has five different dosages listed in the registry. The significant number of strengths available indicates the specificity required by care teams when determining the appropriate PERT and dosing strategy for any given individual with CF; dosing depends on body weight, fat content in meals, and pancreatic lipase output. The process of identifying the right PERT and dose can take time, with care teams factoring in all the above while also seeking to minimize the number of pills a person takes. The

---

[1] Cystic Fibrosis Foundation Patient Registry 2023 Annual Data Report. Available at: https://www.cff.org/medical-professionals/patient-registry

[2] Yen, E. H., Quinton, H., & Borowitz, D. (2013). Better nutritional status in early childhood is associated with improved clinical outcomes and survival in patients with cystic fibrosis. *The Journal of pediatrics*, *162*(3), 530-535.

[3] Corey, M., Edwards, L., Levison, H., & Knowles, M. (1997). Longitudinal analysis of pulmonary function decline in patients with cystic fibrosis. *The Journal of pediatrics*, *131*(6), 809-814.

[4] Baker, S. S., Borowitz, D., & Baker, R. D. (2005). Pancreatic exocrine function in patients with cystic fibrosis. *Current gastroenterology reports*, *7*(3), 227-233.

[5] Borowitz, D., Baker, R. D., & Stallings, V. (2002). Consensus report on nutrition for pediatric patients with cystic fibrosis. *Journal of pediatric gastroenterology and nutrition*, *35*(3), 246-259.

[6] Cystic Fibrosis Foundation Patient Registry 2023 Annual Data Report. Available at: https://www.cff.org/medical-professionals/patient-registry

[7] Safdi, M., Bekal, P. K., Martin, S., Saeed, Z. A., Burton, F., & Toskes, P. P. (2006). The effects of oral pancreatic enzymes (Creon 10 capsule) on steatorrhea: a multicenter, placebo-controlled, parallel group trial in subjects with chronic pancreatitis. Pancreas, 33(2), 156-162.

[8] Trapnell, B. C., Maguiness, K., Graff, G. R., Boyd, D., Beckmann, K., & Caras, S. (2009). Efficacy and safety of Creon® 24,000 in subjects with exocrine pancreatic insufficiency due to cystic fibrosis. *Journal of cystic fibrosis*, *8*(6), 370-377.

vast majority of people with CF stay on the same PERT once they have found a treatment they are stable on; less than 2% of people with CF switched enzyme types from one year to another over the past several years (Appendix 2). Once a patient's enzyme regimen is established and effective, changes to that therapy should only be made when medically necessary as any changes made could have adverse clinical consequences.

Access Challenges

Despite the well-documented benefits of PERTs like CREON®, individuals with CF can encounter barriers accessing these life-sustaining medications. Insurance plans often impose formulary exclusions, prior authorization protocols, or step therapy policies that require patients to try and fail alternative treatments before approving the prescribed PERT. For people with CF who take upwards of 20 therapies throughout the day,[9] coverage restrictions or out-of-pocket costs can pose additional hurdles. These administrative hurdles can lead to delays in treatment initiation or disruptions in ongoing therapy, adversely affecting nutritional status and overall health. Consistent access to whichever PERT is most effective for that patient is essential to preventing these complications.

Concerns with the PDAB's Processes

Goals of the PDAB

We caution that the Oregon PDAB may be working towards two separate aims that require separate consideration and policy solutions: evaluating affordability for consumers and evaluating affordability to the state's healthcare system. Any ambiguity about whether the PDAB is reviewing affordability for health care systems or for consumers can create confusion about how the Board should review drugs and recommend appropriate policy remedies to the legislature.

Due to the complexity of the U.S. health care system, there are many factors and entities involved in determining what patients pay for their drugs. For instance, while people with CF rely on expensive specialty drugs, their out-of-pocket costs for these medications are often more affordable because of manufacturer or non-profit copay assistance programs. Navigating intricacies of health plans and assistance programs can be burdensome and time consuming, but often means that people may be able to afford the cost-sharing for their most expensive therapies. Far too many people with CF still struggle to afford all of their care—which includes an extensive treatment and care regimen—but their affordability challenges are not always driven by the cost of one specialty drug. We recognize that copay assistance programs can mask bigger cost and affordability issues; however, we share this information to highlight that affordability challenges for the system do not always align with affordability challenges for consumers. We ask that the PDAB keep these nuances in mind as the Board moves forward with conducting affordability reviews.

Statutory Requirement to Identify a Fixed Number of Unaffordable Drugs

We support the PDAB's request for a statutory amendment to allow for the identification of *up to* nine drugs and one insulin product each year through SB 289. We are concerned that the current statutory requirement that the PDAB identify nine drugs and one insulin product each year that may create affordability challenges creates bias in the affordability review process by requiring the Board to find a specific number of unaffordable drugs. We understand requiring the Board to evaluate a certain number of drugs every year, but pre-determining the outcome of these reviews undermines the credibility and objectivity of the process. This legislation will give the Board the authority to make the best decision

[9] Sawicki, G. S., Sellers, D. E., & Robinson, W. M. (2009). High treatment burden in adults with cystic fibrosis: challenges to disease self-management. Journal of cystic fibrosis, 8(2), 91-96.

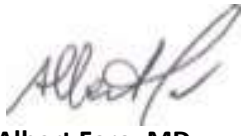
based on the data shared during the affordability review and better reflect the true affordability challenges faced by patients and the healthcare system.

****

Thank you again for the opportunity to provide comments on the PDAB's review of CREON®. The Cystic Fibrosis Foundation believes the price of drugs must not pose a barrier to access but solutions to improve affordability must also safeguard patient access. We urge the Board to ensure that any recommendations related to CREON® do not limit access to this therapy, particularly for those who have found CREON® to be the most effective treatment option.

We are committed to making sure the Oregon PDAB understands the critical role that PERTs like CREON® play in improving the health and quality of life of many individuals with CF. If you have any questions or need additional information, please contact Amanda Attiya, State Policy Specialist, at aattiya@cff.org.

Sincerely,



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Appendix 1

2023 Cystic Fibrosis Foundation Patient Registry Questionnaire

GI/Nutrition/Endrocrine Medications

This Patient is on enzyme medications: ○ Yes ○ No

For all enzymes, "capsules per largest meal" options are:
○ .5 ○ 1 ○ 2 ○ 3 ○ 4 ○ 5 ○ 6 ○ 7 ○ 8 ○ 9
○ 10 ○ 10+
"Total capsules per day" is a numeric free text field.

Enzymes

Creon

Creon 1203: ☐
Number of capsules per largest meal of the day:____
Total capsules per day:____

Creon 1206: ☐
Number of capsules per largest meal of the day:____
Total capsules per day:____

Creon 1212: ☐
Number of capsules per largest meal of the day:____
Total capsules per day:____

Creon 1224: ☐
Number of capsules per largest meal of the day:____
Total capsules per day:____

Creon 1236: ☐
Number of capsules per largest meal of the day:____
Total capsules per day:____

Pancreaze

Pancreaze MT4: ☐
Number of capsules per largest meal of the day:____
Total capsules per day:____

Pancreaze MT10: ☐
Number of capsules per largest meal of the day:____
Total capsules per day:____

Pancreaze MT16: ☐
Number of capsules per largest meal of the day:____
Total capsules per day:____

Pancreaze MT20: ☐
Number of capsules per largest meal of the day:____
Total capsules per day:____

Pancreaze MT37: ☐
Number of capsules per largest meal of the day:____
Total capsules per day:____

Ultresa

Ultresa 14: ☐
Number of capsules per largest meal of the day:____
Total capsules per day:____

Ultresa 20: ☐
Number of capsules per largest meal of the day:____
Total capsules per day:____

Ultresa 23: ☐
Number of capsules per largest meal of the day: ____
Total capsules per day: ____

Pertzye (Pancrecarb)

Pertzye 4000: ☐
Number of capsules per largest meal of the day: ____
Total capsules per day: ____

Pertzye 8000: ☐
Number of capsules per largest meal of the day: ____
Total capsules per day: ____

Pertzye 16000: ☐
Number of capsules per largest meal of the day: ____
Total capsules per day: ____

Pertzye 24000: ☐
Number of capsules per largest meal of the day: ____
Total capsules per day: ____

Zenpep

Zenpep 3: ☐
Number of capsules per largest meal of the day: ____
Total capsules per day: ____

Zenpep 5: ☐
Number of capsules per largest meal of the day: ____
Total capsules per day: ____

Zenpep 10: ☐
Number of capsules per largest meal of the day: ____
Total capsules per day: ____

Zenpep 15: ☐
Number of capsules per largest meal of the day: ____
Total capsules per day: ____

Zenpep 20: ☐
Number of capsules per largest meal of the day: ____
Total capsules per day: ____

Zenpep 25: ☐
Number of capsules per largest meal of the day: ____
Total capsules per day: ____

Zenpep 40: ☐
Number of capsules per largest meal of the day: ____
Total capsules per day: ____

Viokace

Viokace 10: ☐
Number of capsules per largest meal of the day: ____
Total capsules per day: ____

Viokace 20: ☐
Number of capsules per largest meal of the day:____
Total capsules per day: ____

Key:

FORM NAME

○ radio buttons (select one option only)
☐ check box (multiple selections allowed)

*repeated entries can be recorded
[ ] indicates values calculated by the registry

Appendix 2

	Oregon-Specific Data				**United States**			
Year	Number of people with CF with medication data in the CFF Patient Registry	Number (%) of people with CF on any PERT	Number (%*) of people with CF on Creon	Change in Creon use year-over-year (% not prescribed Creon compared to the previous year)	Number of people with CF with medication data in the CFF Patient Registry	Number (%) of people with CF on any PERT	Number (%*) of people with CF on Creon	Change in Creon use year-over-year (% not prescribed Creon compared to the previous year)
2013	391	351 (89.8%)	197 (56.1%)	--	27211	23831 (87.6%)	16361 (68.7%)	--
2014	394	354 (89.8%)	202 (57.1%)	8 (2.3%)	27843	24349 (87.5%)	16497 (67.8%)	547 (2.2%)
2015	407	359 (88.2%)	208 (57.9%)	6 (1.7%)	28341	24687 (87.1%)	16375 (66.3%)	598 (2.4%)
2016	433	377 (87.1%)	221 (58.6%)	5 (1.3%)	28920	25083 (86.7%)	16543 (66.0%)	562 (2.2%)
2017	433	380 (87.8%)	229 (60.3%)	5 (1.3%)	29548	25439 (86.1%)	16610 (65.3%)	493 (1.9%)
2018	461	404 (87.6%)	251 (62.1%)	6 (1.5%)	30326	25907 (85.4%)	16791 (64.8%)	490 (1.9%)
2019	474	420 (88.6%)	259 (61.7%)	<5	30807	26168 (84.9%)	16872 (64.5%)	464 (1.8%)
2020	443	394 (88.9%)	239 (60.7%)	6 (1.5%)	30770	25995 (84.5%)	16729 (64.4%)	412 (1.6%)
2021	444	391 (88.1%)	246 (62.9%)	<5	31439	26338 (83.8%)	16921 (64.2%)	403 (1.5%)
2022	452	399 (88.3%)	272 (68.2%)	0 (0.0%)	32026	26525 (82.8%)	17019 (64.2%)	415 (1.6%)
2023	463	399 (86.2%)	277 (69.4%)	5 (1.3%)	32599	26697 (81.9%)	17206 (64.4%)	350 (1.3%)

*Denominator only includes people with CF on PERT

COMMUNITY LIVER ALLIANCE ™
GLOBAL AWARENESS. LOCAL IMPACT.
100 W. Station Square Drive, Suite 212
Pittsburgh, PA 15219
412.501.3CLA
www.communityliveralliance.org

May 12, 2025

Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97309-0405

Oregon Prescription Drug Affordability Board Members,

Thank you for the opportunity to submit comments as part of Oregon's drug affordability review process. On behalf of the Community Liver Alliance and the many individuals and families we serve, I urge the Board to fully consider the importance of the medications currently under review especially for patients living with liver disease and other chronic health conditions.

Many of the drugs on the list, such as Ozempic, Mounjaro, Rybelsus, and Trulicity play a vital role in treating or managing Metabolic Dysfunction Associated Steatotic Liver Disease (MASLD) and Metabolic Dysfunction Associated Steatohepatitis (MASH). These are among the most common and fastest-growing liver diseases in the country, and these medications can help slow progression and prevent complications such as liver failure and the need for transplant.

Other therapies under review, including Humira and Rinvoq, are used in the treatment of autoimmune liver diseases like autoimmune hepatitis and primary sclerosing cholangitis. These conditions require specialized, ongoing treatment and access to the right medication often makes the difference between stability and disease progression.

While we fully support the goal of reducing healthcare costs and improving drug pricing transparency, we respectfully ask the Board to ensure that this process does not unintentionally restrict access to essential therapies or create new barriers for those managing complex conditions like liver disease.

We urge you to center the lived experiences of patients and the clinical expertise of providers when assessing affordability. Many patients already struggle with access due to insurance hurdles, out-of-pocket costs, and social determinants of health. Limiting access further, particularly for those with liver disease and other chronic illnesses could increase suffering, complications, and long-term healthcare costs.

Thank you for dedicating time to listen to the community and for your efforts to bring affordability and accountability to the forefront. I respectfully ask that the voices of patients and providers be central in your final decisions, and that access to necessary liver disease treatments remains protected in the process.

Sincerely,

Suzanna Masartis, CEO
Community Liver Alliance
Suzanna@communityliveralliance.org
412-400-9343

To: Oregon Prescription Drug Affordability Board
From: Linda Nelson, OCAP
Re: Trelegy
Date: 5/15/2025

I'm on Trelegy and the cost to me every month right now is $166.13, unacceptable. When I fall into the Donut Hole my cost increases to retail price of $838, unacceptable and unattainable. I also have other prescriptions.

May 19, 2025

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

RE: Selection of Cardiovascular Medications for the Oregon Prescription Drug Subset List

Dear Members of the Board,

The Partnership to Advance Cardiovascular Health (PACH) is a nonprofit cardiovascular stakeholder coalition of patient, provider, and advocacy organizations dedicated to advancing public policies and practices that accelerate innovation and improve cardiovascular health for heart patients. As a platform for the 20 members organizations that collaborate with us, PACH advocates at the federal, state, and health plan levels for reforms that increase access to care for patients with cardiovascular and related conditions.

As we are keenly aware that high medication costs complicate access for many patients, we agree with the Oregon Prescription Drug Review Board's goal of making medications affordable for Oregonians. It is our organizational goal to promote both access and innovation in cardiovascular science and medicine so that we can both save and improve lives. We are writing today to advocate for the removal of three cardiovascular medications from the 2023 prescription drug subset list that are being reconsidered for review.

The Cardiovascular Disease Burden:

Cardiovascular disease remains the second leading cause of death in Oregon, and the number one cause of death nationally. America's progress in decreasing the death rate due to heart disease and stroke has stalled. The death rate for cardiovascular disease, including heart disease and strokes, has fallen just 4% since 2011 after dropping more than 70% over the prior six decades. Particularly alarming, certain age and demographic groups are seeing increases in the rate of cardiovascular-related death. These trends are worse for minority communities, rural communities and those with lower socioeconomic status. Ensuring that patients have access to

cardiovascular primary and secondary preventative treatment, and promoting new innovation and modalities for treatment, are of the utmost importance to PACH and our partners.

Innovation in Cardiovascular Disease Management

The cardiovascular medications being considered again by the Oregon PDAB represent some of the best relatively recent pharmaceutical interventions cardiovascular medicine has to offer. Every cardiovascular medication on the PDAB subset list provides immense value not only for patients but for the healthcare system as a whole. For example:

Apixaban:
Apixaban is a factor Xa inhibitor anticoagulant and is shown to lower the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation. It is a treatment for Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE), reducing the risk of recurrence. Studies highlight that DOACs like apixaban have been associated with a nearly 30% risk reduction for thromboembolic stroke, as much as a 60% reduction in intercranial hemorrhage, and as much as a 34% reduction in mortality, compared with current generic offerings.[1] DOAC usage unquestionably results in lower downstream medical expenditures resulting from decreasing risk for major bleeding and reduced drug monitoring.[2]

Rivaroxaban:
Rivaroxaban is a Factor Xa inhibitor, direct oral anticoagulant (DOAC). It is used to treat and manage deep vein thrombosis (DVT). It is also used postoperatively to prevent blood clots and stroke in patients with atrial fibrillation and is used in secondary prevention of acute coronary syndrome and peripheral artery disease. As mentioned above, DOACs like rivaroxaban are associated with a statistically significant risk reduction in thromboembolic stroke (20-29% reduction) intracranial hemorrhage (35-62% reduction), and mortality (19-34% reduction). Fewer people in America have strokes, pulmonary embolism, and deep vein thrombosis as a result.

Sacubitril-Valsartan:
Sacubitril-Valsartan is a treatment for chronic heart failure and is indeed the only angiotensin receptor-neprilysin inhibitor (ARNi) approved by the FDA for the treatment of heart failure – there are currently no other alternatives. For the 6.2 million Americans impacted by heart failure, many of those who take sacubitril-valsartan see a meaningful risk reduction for death and hospitalization – this is a remarkable feat in cardiology. An important study looking at the cost effectiveness of sacubitril-valsartan showed that inpatient treatment was cost saving to the healthcare system.[3] Not only is this medication effective, but it limits costs associated with heart failure on the entire healthcare system.

Comprehensive Approach to Affordability and Access:

All of the cardiovascular treatments being reconsidered by the Oregon PDAB have already been subject to the Centers for Medicare and Medicaid Services "Maximum Fair Price" drug negotiations that were authorized by the Inflation Reduction Act. During the comment period of those negotiations, PACH, our clinician partners and patient advocacy organizations all supported the broad aim of making medications more affordable *for Medicare recipients.* We expressed concern, however, that patients would not actually realize the lower prices as set by the government, and that, without a comprehensive assessment of the medication pipeline, affordability would not be achieved.

We also expressed concern that utilization management of these negotiated medications would increase, which can have devastating consequences for patients – particularly patients on anticoagulant therapy. Cardiovascular medicine has seen remarkable increases in prior authorization and step therapy protocols in recent years, far outpacing other disease states. Clinicians and patients bear the majority of the burden of these oftentimes unnecessary administrative hurdles.

We believe that these same concerns translate to the state level and that Oregon's PDAB could frustrate both access and affordability for patients.

Actions to Protect Patients and Increase Affordability and Access

A more holistic approach to address affordability should include reviewing health insurer and pharmacy benefit manager practices like step-therapy and prior authorization protocols, prohibiting spread pricing, prohibiting co-pay accumulator or "maximizer" programs so that any dollars spent toward a patient's deductible count toward their out-of-pocket limit, and requiring pass-through savings directly to patients. Until more transparency is brought to bear on the medication pipeline, we believe efforts such as the Oregon PDAB's will not achieve their stated goal.

PACH appreciates the Board's work in addressing prescription drug affordability. At this time, we ask that the board remove the cardiovascular medications from the prescription drug subset list as these medications have all been subject to "Maximum Fair Price" negotiations in the Inflation Reduction Act (IRA) and have proven to reduce the economic impact on the healthcare system. Evidence suggests that further "review" will not achieve the PDAB's stated goal. We submit that the above-mentioned actions would do much more to create transparency in the medication delivery pipeline and more effectively support patient affordability.

Respectfully Submitted,

Sarah Hoffman
Senior Director
Partnership to Advance Cardiovascular Health

1. Graham DJ, Baro E, Zhang R, Liao J, Wernecke M, Reichman ME, Hu M, Illoh O, Wei Y, Goulding MR, Chillarige Y, Southworth MR, MaCurdy TE, Kelman JA. Comparative Stroke, Bleeding, and Mortality Risks in Older Medicare Patients Treated with Oral Anticoagulants for Nonvalvular Atrial Fibrillation. Am J Med. 2019 May;132(5):596-604.e11. doi: 10.1016/j.amjmed.2018.12.023. Epub 2019 Jan 9. PMID: 30639551.
2. Duvalyan, A., Pandey, A., Vaduganathan, M., Essien, U. R., Halm, E. A., Fonarow, G. C., & Sumarsono, A. (2021). Trends in anticoagulation prescription spending among Medicare Part D and Medicaid beneficiaries between 2014 and 2019. *Journal of the American Heart Association*, *10*(24). https://doi.org/10.1161/jaha.121.022644
3. Virani, S. S., Alonso, Á., Benjamin, E. J., Bittencourt, M. S., Callaway, C. W., Carson, A. P., Chamberlain, A. M., Chang, A. R., Cheng, S., Delling, F. N., Djoussé, L., Elkind, M. S., Ferguson, J. F., Fornage, M., Khan, S. S., Kissela, B. M., Knutson, K. L., Kwan, T., Lackland, D. T., . . . Tsao, C. W. (2020). Heart disease and stroke statistics—2020 Update: A report from the American Heart Association. *Circulation*, *141*(9). https://doi.org/10.1161/cir.0000000000000757

To: Oregon Prescription Drug Affordability Board
From: Carol Elkins, Aumsville, OR
Re: Ozempic and Mounjaro
Date: 6/3/2025

Hello. Thank you for letting me speak today. My comments are in reference to the cost of weight loss drug prices.

I've been overweight for 40 years and on many diets and programs for weight loss. None have worked for me until Ozempic. I took Ozempic for 1 year and lost 30 pounds. My doctor prescribed Mounjaro to help me continue to lose weight. Then my insurance decided not to cover it. I couldn't afford it without insurance as it was between $300-349/mo. Since I could not afford that, and have had no meds since, I've gained 20 pounds back. This has caused me extreme anguish and depression. I think about my extra weight everyday. I need these medications as they are the only thing that has worked for me. Please consider reducing the cost of these medications. I was prediabetic before the weight loss meds, and since Ozempic helped me to go off these meds. However, I just had a blood test recently and it appears my prediabetes has returned. Weight loss drugs are key to my health, but I need to be able to afford them.

Thank you.

Via electronic submission

June 11, 2025

Oregon Prescription Drug Affordability Board (PDAB)
ATTN: Shelley Bailey, Chair
350 Winter St. NE
Salem, OR 97309-0405
pdab@dcbs.oregon.gov

RE: Requesting Removal of IBRANCE® (palbociclib) and NURTEC® ODT (rimegepant) from Oregon Prescription Drug Affordability Board Prioritized Affordability Review Subset List

Dear Members of the Oregon Prescription Drug Affordability Board:

Pfizer appreciates the opportunity to submit comments to the Oregon Prescription Drug Affordability Board (the "Board"). As noted in our letter dated February 28, 2024, Pfizer has significant concerns with ORS 646A.693-697 which we believe takes a narrow view of controlling health care costs and lacks a mechanism to improve insurance plan design, a key driver of high out-of-pocket cost for patients. For this reason and others outlined below, we request that the Board remove IBRANCE® (palbociclib) and Nurtec® ODT (rimegepant) from affordability reviews or determine that they do not pose affordability challenges if the Board continues with such evaluations.

Requests for Exclusions from Affordability Review.
Pfizer Inc. ("Pfizer") is a research-based global pharmaceutical company dedicated to the discovery and development of innovative medicines and vaccines that improve the quality of life for people around the world. A top priority for Pfizer is ensuring that patients can access and afford our medicines and vaccines. We negotiate with insurers and pharmacy benefit managers (PBMs) to help ensure robust coverage for our medicines. We also provide financial assistance for many of our products to help both eligible insured patients for whom high insurance cost-sharing requirements may jeopardize affordability and uninsured patients who lack drug coverage altogether.[1]

We maintain significant concerns about the affordability review process including because ORS 646A.693-697 fails to address determinants of patient affordability including insurance plan design, access to insurer and PBM negotiated discounts, and the role of patient assistance programs. Moreover, the potential unintended consequences of affordability reviews may limit patient access to medicines. For these reasons, we request that the Board exclude IBRANCE® and NURTEC® from affordability reviews or determine that they do not pose affordability challenges if the Board continues with such evaluations.

[1] Pfizer assistance programs can be found at PfizerForAll™, https://www.pfizerforall.com/prescription-assistance#select-medication-section.

Patient affordability depends on insurance plan design.
What patients pay for their medicines is determined by their insurance company or pharmacy benefit manager (PBM). Insurers and PBMs develop formularies, which are lists of drugs that will be covered under different insurance plans. Formularies not only determine if a drug will be covered, but they also determine how much patients must pay out-of-pocket for medicines and if there are any administrative actions required to obtaining coverage (e.g., prior authorizations, fail first policies). The federal government recognized that patient affordability depends on robust insurance coverage and capped Medicare Part D enrollees' annual out-of-pocket cost at $2,000.[2] Similarly, several states have enacted laws or promulgated regulations directly addressing cost-sharing requirements set by insurers or PBMs.[3] However, the affordability review process under ORS 646A.693-697 contains no mechanism for the Board to lower cost-sharing requirements set by an insurer or PBM to improve patient affordability for prescription drugs.

Patients should benefit from negotiated discounts.
Along with determining patients' cost-sharing requirements, PBMs and insurers determine whether patients receive the discounts and rebates they negotiate with pharmaceutical manufacturers. Three PBMs control nearly 80 percent of U.S. prescriptions and medication access for about 270 million Americans.[4] As the PBM market has consolidated, their negotiating leverage with manufacturers has increased. For example, in 2023, manufacturers paid an estimated $334 billion in discounts and rebates.[5] However, unlike other medical services where the patient pays *less* when their insurer negotiates a better price, very few, if any, patients pay less at the pharmacy counter despite billions of dollars in discounts and rebates paid to PBMs and insurers by manufacturers.[6] Instead, most manufacturer discounts and rebates are retained by PBMs as profit or are passed to an insurer, rather than the patient obtaining the medicine.[7]

Oregon law requires PBMs to report how much they collect in rebates and the proportion that is passed to patients in Oregon health benefit plans. The first report, published in 2024, found that, of the over $287 million collected by PBMs, less than $2.3 million went to patients, or less than 1 percent (0.78%) of rebates collected.[7] In addition to investigating the impact of insurance design on patient affordability, we encourage the Board to examine the role that rebates play in what patients pay at the pharmacy counter.

Pfizer's assistance programs support patient access and affordability for IBRANCE® and Nurtec® ODT.

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[2] Kaiser Family Foundation, A Current Snapshot of the Medicare Part D Prescription Drug Benefit. Available at: https://www.kff.org/medicare/issue-brief/a-current-snapshot-of-the-medicare-part-d-prescription-drug-benefit/
[3] California Chapter 619 of 2015; Maryland Chapter 422 of 2014; New Jersey AB 2431 (2019).
[4] U.S. Federal Trade Commission, Office of Policy Planning, Interim Staff Report, Pharmacy Benefit Managers: The Powerful Middlemen Inflating Drug Costs and Squeezing Main Street Pharmacies, Page 7. July 2024. Available at: https://www.ftc.gov/system/files/ftc_gov/pdf/pharmacy-benefit-managers-staff-report.pdf
[5] Drug Channels, PBM Power: The Gross-to-Net Bubble Reached $334 Billion in 2023—But Will Soon Start Deflating. July 7, 2024. Available at: https://www.drugchannels.net/2024/07/pbm-power-gross-to-net-bubble-reached.html
[6] Petersen-KFF Health System Tracker, Price transparency and variation in U.S. health services. January 13 ,2021. https://www.healthsystemtracker.org/brief/price-transparency-and-variation-in-u-s-health-services/.
[7]Oregon Department of Consumer and Business Services, Division of Financial Regulation, Drug Price Transparency Program, Pharmacy Benefit Managers 2024 Data. https://dfr.oregon.gov/drugtransparency/Pages/DPT-pbm-data-2024.aspx

Pfizer recognizes the growing burden of rising insurance deductibles, copayments, and co-insurance on patient access and affordability of medicines, and supports policies that reform insurance benefit design and patient access to negotiated discounts.[8] However, we also recognize that many patients continue to face high cost-sharing requirements under their insurance plans. To help such patients, Pfizer offers copay assistance programs to eligible commercially insured patients for a range of products, including IBRANCE® and Nurtec® ODT. In addition, some government insured patients struggle to afford their cost-sharing requirements. We therefore provide eligible financially insecure, government insured patients access to our therapies for free.[9] Lastly, we also recognize that an estimated 26 million people in the United States lack health insurance.[10] Therefore, we also offer patient assistance programs that offer free medicines to qualified individuals who lack insurance.[11]

Additional considerations for removing IBRANCE® and Nurtec® ODT from the affordability reviews. Pursuant to OAR 925-200-0010, the Board must take into consideration various factors when selecting the subset of prescription drugs to prioritize for an affordability review, including, but not limited to, whether the drug appears on insurer-reported top 25 lists.[12] According to the Oregon PDAB Data Dashboard, *Aggregated Carrier Data*, neither IBRANCE® nor Nurtec® ODT were included on the top 25 drug lists and both ranked well below for the lists on which they were included. IBRANCE® was included on only one list ranked at #66 and Nurtec® ODT was included on only two lists ranked at #63 and #73, respectively.[13]

Additionally, we believe the Board should take into consideration IBRANCE®'s data exclusivity expiration, the timing of the basic patent expiration, and its inclusion in the Medicare Drug Price Negotiation (MDPN) program established under the Inflation Reduction Act.

OAR 925-200-0010(6) requires the Board to consider, when selecting prescription drugs for a prioritized subset list for affordability review, whether a prescription drug has a patent expiration or data exclusivity expiration within 18 months.[14] Basic product patent expiration for IBRANCE® is March 2027 and data exclusivity has already expired. Based on the Board's current affordability review timeline[15], which contemplates identifying drugs that may create affordability challenges in November 2025 and publishing

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[8]Kaiser Family Foundation, 2024 Employer Heath Benefit Survey. https://www.kff.org/health-costs/report/2024-employer-health-benefits-survey/.

[9]PfizerForAll Prescription Assistance. https://www.pfizerforall.com/prescription-assistance.

[10]The Commonwealth Fund, The State of Health Insurance Coverage in the U.S., Findings from the Commonwealth Fund 2024 Biennial Health Insurance Survey. https://www.commonwealthfund.org/publications/surveys/2024/nov/state-health-insurance-coverage-us-2024-biennial-survey.

[11]Pfizer RxPathways. https://www.pfizerrxpathways.com/. The Pfizer Patient Assistance Program is a joint program of Pfizer Inc. and the Pfizer Patient Assistance Foundation™. The Pfizer Patient Assistance Foundation is a separate legal entity from Pfizer Inc. with distinct legal restrictions.

[12]OAR 925-200-0010 Selecting Prescription Drugs for Affordability Reviews. Available at: https://dfr.oregon.gov/pdab/Documents/OAR-925-200-0010.pdf

[13]Oregon PDAB Data Dashboard. Available at: https://app.powerbigov.us/view?r=eyJrIjoiOGM2YjhlMWUtNzE2OC00MmU1LTk2MjktYWUzZGMyNTNmZmQ1IiwidCI6ImFhM2Y2OTMyLWZhN2MtNDdiNC1hMGNlLWE1OThjYWQxNjFjZiJ9

[14]925-200-0010 Selecting Prescription Drugs for Affordability Reviews. Available at: https://dfr.oregon.gov/pdab/Documents/OAR-925-200-0010.pdf

[15]Oregon Prescription Drug Affordability Board, May 21, 2025 Agenda Materials. Pages 9-14. Available at: https://dfr.oregon.gov/pdab/Documents/20250521-PDAB-document-package.pdf

a final report in December 2025, IBRANCE® basic patent and data exclusivity expirations will be within the 18-month timeframe.

The Board has repeatedly discussed and, in 2023, voted to exclude prescription drugs subject to the Maximum Fair Price (MFP) established under the MDPN from the affordability review process due to the unique supply chain and stakeholder difficulties of drugs subject to the MFP. In January 2025, the Centers for Medicare and Medicaid Services (CMS) announced the selection of IBRANCE® for an MFP that will go into effect on January 1, 2027. We urge the Board to maintain the precedent of removing drugs subject to MFP from the prioritized subset list for affordability review.

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Once again, Pfizer appreciates the opportunity to provide comments to the Board. We support efforts to help ensure that patients can access life-saving medicines and look forward to working with Oregon policymakers to find solutions that help patients. If you have any questions, please contact Brandy Flores, Director of Government Relations, at Brandy.Flores@Pfizer.com.

Sincerely,

Tom Brownlie
Vice President
State Policy and Government Relations

Johnson & Johnson Health Care Systems, Inc.
1125 Bear Tavern Road
Titusville, NJ 08560

T +1-800-526-7736
jnj.com

Via Electronic Submission

June 16, 2025

Shelley Bailey, Board Chair
Oregon Prescription Drug Affordability Board
pdab@dcbs.oregon.gov

Dear Board Chair Bailey:

Johnson & Johnson Innovative Medicine ("J&J") thanks the Oregon Prescription Drug Affordability Board ("PDAB" or "Board") for its open dialogue and for requesting that staff confirm the accuracy of its prescription drug data in response to our oral testimony at the May 21, 2025 Board meeting. We also thank staff for updating the Prescription Drug Data Spreadsheets ("Spreadsheets") and the Oregon PDAB Data Dashboard ("Dashboard") to include the FDA-approved generics of Xarelto (rivaroxaban). We further respectfully request that the Board **remove TREMFYA and XARELTO from the "Subset List of 2023 Prescription Drugs for Affordability Reviews" ("Subset List") because neither drug meets eligibility criteria required by Oregon law or criteria that the PDAB has prioritized.**[1]

As noted in our previous comment, when selecting drugs for affordability reviews, the Board is required by Oregon law to prioritize drugs appearing on the following lists and reports:[2]

- Three Carrier-Reported Top 25 Lists:
    1. Top 25 most frequently prescribed drugs ("MP")
    2. Top 25 most costly drugs as a portion of total annual spending ("MC")
    3. Top 25 drugs that have caused the greatest increase in total plan spend ("GI")

- Two Oregon Drug Price Transparency ("DPT") Program Reports:
    1. Manufacturer New Drug Report
    2. Manufacturer Price Increase Report

As shown in Image 1, ***TREMFYA is not on any of these Lists or in either Report.*** TREMFYA is listed as #47 on the GI list, #46 on the MC list, and #92 on the MP list—***not within the Top 25***. TREMFYA is #159 on the additional category of "Most Expensive" drugs, a category created and prioritized by the PDAB. Image 1 also shows that TREMFYA does not appear on either of the two DPT reports. Therefore, we believe that TREMFYA does not meet the criteria for the Subset List and request that it be removed.

Likewise, Image 1 below shows that XARELTO is #47 on the GI list, #60 on the MP list, and #321

[1] OR Admin Reg 925-200-0010; OR. Rev. Stat. 646A.689; OR Rev. Stat. 743.025; *OR PDAB Agenda - January 15, 2025 Meeting*, *Agenda* (Jan. 15, 2025), https://dfr.oregon.gov/pdab/Documents/20250115-PDAB-document-package.pdf#Page=44 (last visited June 12, 2025).
[2] OR Admin Reg 925-200-0010; OR Rev. Stat. 743.025; OR. Rev. Stat. 646A.689.

on the Most Expensive list—***not within the Top 25***. XARELTO also does not appear on either of the two DPT reports. While XARELTO is now shown as #23 on the MC list, it is a drug for which CMS has set a "Maximum Fair Price," and it has FDA-approved generics—two additional factors that the Board has prioritized. Therefore, XARELTO does not meet the criteria for the Subset List, and we request that it be removed.

Image 1. "Top 25 List" and "DPT Report" Columns for TREMFYA and XARELTO in the "2023 Subset List Aggregated Information v04" Spreadsheet.

Therapy class	Proprietary name(s)	Non-proprietary name	Number of prescriptions	Number of enrollees	List type	Total lists	GI rank	MC rank	MP rank	ME rank	Drug on 2023 Manufacturer reporting under ORS 646A.6
ANTICOAGULANTS	Xarelto	Rivaroxaban	7746	2160	GI / MC	2	47	23	60	321	No
DERMATOLOGICALS	Tremfya	guselkumab	1092	229	GI / MC	2	47	46	92	159	No

As one of the nation's leading healthcare companies, J&J has a responsibility to engage with stakeholders in constructive dialogue to address gaps in affordability and access as well as protect our nation's leading role in the global biopharmaceutical innovation ecosystem. We know that patients are counting on us to develop, bring to market, and support access to our medicines. We live this mission every day and are humbled by the patients who trust us to help them fight their diseases and live healthier lives. We thank you in advance for taking our recommendations into account.

Sincerely,

Michael J. Valenta

Michael Valenta

Vice President, Value, Access & Pricing, Strategic Customer Group
Johnson & Johnson Healthcare Systems, Inc.

June 17, 2025

Via Electronic Mail
Oregon Prescription Drug Affordability Board
PO Box 14480
Salem, OR 97309
pdab@dcbs.oregon.gov

Re: June 18, 2025 Board review and possible vote for updated data subset list of prescription drugs and insulin products pursuant to OAR 925-200-0010

Dear Members of the Oregon Prescription Drug Affordability Board:

Sanofi appreciates the opportunity to submit comments to the Oregon Prescription Drug Affordability Board ("OR PDAB") regarding the Board's potential selection of certain insulin products for affordability reviews, pursuant to OAR 925-200-0010. We understand that the OR PDAB is considering whether to include one or more of Sanofi's insulin glargine products, including Lantus®, Toujeo®, and unbranded products, Insulin Glargine U-100 and Insulin Glargine U-300, in the subset list of prescription drug and insulin products for review. For the reasons described below, OR PDAB's consideration of Sanofi's insulin products is inappropriate and inconsistent with the goal of ORS 646A.694, which is to identify products that currently create affordability challenges for the health care system or high out-of-pocket costs for patients.

1. **The 2023 data is outdated and does not reflect the significant reductions in list prices and other market trends, which reduce Oregon's cost and spending metrics for Sanofi's insulins.**

To further our commitment to support patients directly at the pharmacy counter and accelerate the transformation of the U.S. insulin market, in January 2024, Sanofi reduced the list price of Lantus®, our most widely prescribed insulin in the United States, by 78%.[1] Additionally, beginning January 1, 2024, all commercially-insured patients who fill their Lantus® prescriptions at participating pharmacies have their out-of-pocket responsibility capped at $35 for a monthly supply. At the same time, Sanofi launched Insulin Glargine Injection U-300, an unbranded version of Toujeo®, at a list price that was 60% less than Toujeo's® list price. For additional information

[1] In conjunction with this pricing action, Sanofi withdrew the lower priced, unbranded version of Lantus, Insulin Glargine U-100, from the market because the new list price for Lantus was below the list price of Insulin Glargine U-100. At that time, Sanofi also reduced the list price of our short-acting Apidra® (insulin glulisine injection) 100 Units/mL by 70%.

regarding the steps Sanofi took in 2024 to drive insulin affordability, please see our 2025 Pricing Principles Report.[2]

Although payers, including PBMs and government and private insurers, ultimately decide which medicines to cover, how much to reimburse dispensing pharmacies, and patients' out-of-pocket responsibility, Sanofi's pricing actions have reduced pharmacy reimbursement and out-of-pocket costs for these products. Unfortunately, although Sanofi continues to provide lower cost options to payers and PBMs, patients often do not realize the full cost savings because incentives within the health system drive health plans and middlemen to favor high list prices and larger rebates over lower priced options.

Taken together, the scope of these changes mean that the OR PDAB's 2023 data simply do not accurately reflect current costs, utilization, and spending. At a minimum, the OR PDAB should not consider including Sanofi's insulin products in an affordability review unless and until it can review current data that reflects these changes.

2. **Sanofi's insulin glargine products are highly utilized and affordable life-saving treatments for Oregon residents with diabetes.**

The inclusion of Sanofi's insulin products, like Lantus®, among the top gross spending products is presumably a result of the number of patients who rely on these insulin products – not their prices. As demonstrated by Oregon's own 2023 data,[3] Sanofi's insulin glargine products are not among the highest cost insulin products on a per prescription or per patient basis across multiple metrics, including overall costs, payer payments, and patient out-of-pocket costs. Indeed, healthcare providers and patients choose Sanofi's insulin glargine products because of their well-established clinical benefits and their affordability.

We are proud of the meaningful ways in which our products have transformed the standard of care for patients, from the introduction of Lantus®, which provided significant improvements in basal insulin levels, to the introduction of Toujeo®, a next generation basal insulin that more closely mimics the body's endogenous insulin secretions, among others. In addition to delivering meaningful innovation in the types of insulin available to patients, we are proud of the role we have played in transforming the patient experience through the development of devices to ease the daily burden of insulin administration, allowing for fewer injections and, in some cases, fewer refills and related patient copays.

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[2] Sanofi 2025 Pricing Principles Report: Action Driving Insulin Affordability, *available at* *https://www.sanofi.us/assets/dot-us/pages/images/our-company/Social-impact/responsible-business-values/pricing-principles/Sanofi-2025-Pricing-Principles-Report_Action-Driving-Insulin-Affordability.pdf*.

[3] *See* Insulin Preliminary Data, Oregon PDAB Data Dashboard, *available at* https://app.powerbigov.us/view?r=eyJrIjoiOGM2YjhlMWUtNzE2OC00MmU1LTk2MjktYWUzZGMyNTNmZmQ1IiwidCI6ImFhM2Y2OTMyLWZhN2MtNDdiNC1hMGNlLWE1OThjYWQxNjFjZiJ9.

We have coupled these clinical innovations with our progressive and industry-leading pricing principles, which reflect our commitment to sustainable pricing and transparency,[4] and a suite of innovative affordability programs to help people reduce their prescription medicine costs, regardless of their insurance status or income level. As a result, no Oregon patient has to pay more than $35 per month for their Sanofi insulin product.[5]

Given these utilization and cost trends – even using 2023 data, Sanofi's insulin glargine products are not an appropriate target for the OR PDAB.

3. **The data the OR PDAB is relying on does not appear to take into account the significant rebates and other price concessions that Sanofi provides to payers.**

The "list price" of a medicine often receives the most attention in public discussions, but it does not reflect the price patients pay at the pharmacy counter, nor does it reflect the amount health insurance companies pay (or that Sanofi receives).

Sanofi provides significant discounts, rebates, and fees to different stakeholders across the healthcare value chain, including to payers and their pharmacy benefit managers ("PBMs"), to ensure our medicines are accessible to patients. Sanofi pays these price concessions to insurers (or their PBMs) after a medicine is dispensed to a patient so it is not captured in the "payer paid" amount. As a result, the "payer paid" and "overall spend" data have no relation to the net amount payers actually pay for Sanofi's insulin products.

OR PDAB clearly recognizes the importance of understanding net spend to its analysis as it has collected this data for non-insulin products.[6] OR PDAB should consider payer spend net of rebates for insulin products as well.
For these reasons, Sanofi respectfully requests that the Board remove Lantus®, Toujeo®, Insulin Glargine U100, and Insulin Glargine U300 from consideration for the subset list of insulin products. Further, any consideration of these products should and at a minimum take into account updated data on insulin products before proceeding with any insulin product review.

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[4] *See* Sanofi 2025 Pricing Principles Report, *available at* https://www.sanofi.us/assets/dot-us/pages/images/our-company/Social-impact/responsible-business-values/pricing-principles/Sanofi-2025-Pricing-Principles-Report.pdf.
[5] Additional details regarding our programs are available at https://www.teamingupfordiabetes.com/sanofidiabetes-savings-program.
[6] *See* Carrier Preliminary Data, including Carrier Spend Net of Rebate and Carrier Spend Net of Rebate per Enrollee, Oregon PDAB Data Dashboard, *available at* https://app.powerbigov.us/view?r=eyJrIjoiOGM2YjhlMWUtNzE2OC00MmU1LTk2MjktYWUzZGMyNTNmZmQ1IiwidCI6ImFhM2Y2OTMyLWZhN2MtNDdiNC1hMGNlLWE1OThjYWQxNjFjZiJ9. The 2023 insulin data from the Oregon All Payer All Claims Database (APAC) is gross and not net of rebates. *See* Insulin Data Process, Oregon Prescription Drug Affordability Board (Jan 2025), *available at* https://dfr.oregon.gov/pdab/Documents/Insulin-Data-Process-Documentation.pdf.

Please feel free to contact me at with any questions at carissa.kemp@sanofi.com or (208) 954-6330.

Sincerely,

Carissa Kemp
Lead, State Government Relations, Sanofi

Enclosure:

2025 Sanofi Pricing Principles Report

sanofi

2025 Pricing Principles Report

Advancing Responsible Leadership

At Sanofi, we work passionately to help prevent, treat, and cure illness and disease, understand and solve healthcare needs of people across the world, and transform the practice of medicine.

We have a longstanding commitment to promoting healthcare systems that make our treatments accessible and affordable to those in need. In May 2017, Sanofi reinforced this commitment with the introduction of our Pricing Principles, which details how we price our medicines and advocates for policy solutions to make the system work better for patients.

Our goal—then and now—is to foster a culture of transparency that helps our stakeholders better understand our pricing decisions and facilitates a more informed discussion related to the pricing of medicines across the U.S. healthcare system.

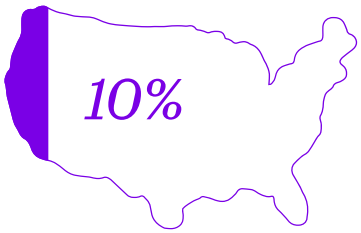
This report outlines our principles, 2024 pricing decisions, and our perspectives on advancing solutions to improve patient outcomes and affordability in the United States.

Our Pricing Principles *& Perspectives*

We share concerns about patients' affordability of medicines while recognizing that we are only one of many stakeholders involved in healthcare delivery.

At Sanofi, we price our medicines according to their value while advancing broader solutions that improve patient outcomes and support affordability within the U.S. healthcare system. Our pricing strategy underscores our commitment to patient access while minimizing our contribution to overall healthcare system spending. We remain transparent in how we price our prescription medicines and limit price increases in the United States.

As of September 2024, prescription medicines accounted for only



of U.S. healthcare spending, marking a reduction of approximately 4% compared to the previous year.[1]

The pricing principles we put forth focus on three pillars:

- **Clear Rationale for Pricing** at the time of launch of a new medicine
- **Reporting of U.S. Pricing Actions** on our medicines over time
- **Continued Transparency in the U.S.** around our pricing decisions

[1] Altarum. Health Sector Economic Indicators. November 2024.

Clear Rationale for Pricing

When we set the price of a new medicine, we follow a rigorous process that includes consultation with external stakeholders and consideration of the following factors:

A holistic value assessment using various internal and external methodologies to define or quantify value, incorporating patient perspectives and priorities. This includes:

- Clinical value and outcomes: the benefit the medicine delivers to patients and its effectiveness compared to the standard of care
- Economic value: how the medicine reduces the need for – and costs of – other healthcare interventions
- Social value: how the medicine contributes to quality of life and productivity

Similar current or future treatment options at launch to understand the landscape within the disease areas where our medicines or vaccines may be used.

System-wide affordability, including steps we must take to promote patient access and contribute to a more sustainable system for payors and healthcare systems.

Unique launch factors specific to a medicine or vaccine at its launch. For example, we may need to support ongoing clinical trials, implement regulatory commitments, or develop sophisticated patient support tools.

Reporting of U.S. Pricing Actions

We acknowledge our role in preserving the sustainability of our healthcare system and limiting our contribution to U.S. healthcare spending growth.

Our approach to pricing actions for existing medicines balances our ambition to chase the miracles of science, patients' access to the medicines they need, government policies, and evolving marketplace trends.

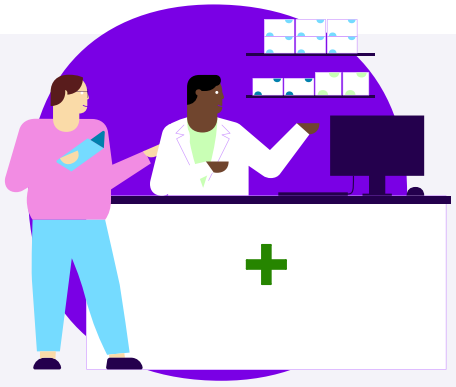
The guiding principle for any list price actions taken during the fiscal year 2024 was to adhere to a level consistent with our approach to responsible pricing.

Sanofi will annually disclose additional background if price actions trigger a prescription drug mandatory supplemental rebate under the Inflation Reduction Act (IRA) of 2022.

Continued Transparency in the U.S.

To maintain an open dialogue and recognize calls for continued transparency in our pricing actions, **we annually disclose our average aggregate U.S. list and net price changes from the prior calendar year**. We believe this information contributes to better-informed discussions to improve patient access and affordability.

It is important to note that patient cost-sharing and coverage decisions are made by public and private payors and employers, not manufacturers. It is most often the case that patients' out-of-pocket costs ultimately depend on how their health plan structures insurance coverage and to what extent it passes through negotiated discounts.



Although list prices often garner the most attention, they often do not represent the price patients pay.

Learn more about misaligned incentives in the drug supply chain impacting patient affordability.

Learn more →

A Look Back
2024 Pricing Actions

Our Pricing Principles reflect our unwavering dedication to providing patients with innovative and life-changing treatments while limiting costs and minimizing our contribution to healthcare spending growth.

Clear Rationale for Pricing

In 2024, Sanofi ushered in scientific breakthroughs by expanding the indications for five of our existing medicines, widening their FDA-authorized labels to treat additional conditions. This achievement was based on extensive and continued research and data, offering new treatment options to different patient populations with unmet needs.

Although post-approval research is less heralded than the investigation and launch of new medicines, continuing research into a medicine's potential to treat multiple different diseases can help unlock its full economic and societal value, allowing more people to benefit from treatments that may improve their conditions.

Specifically, post-approval research is critical for medicines targeting immune system disorders, an area with significant unmet need and severe symptoms, in which the body's immune system mistakenly attacks healthy cells or fails to respond to harmful invaders, causing inflammation and pain.

Our R&D approach, rooted in immunoscience, investigates the underlying causes of inflammation in the body and leverages our deep understanding of biological pathways, often linking seemingly unrelated conditions and broadening the populations of patients that can benefit from our medicines.

These "unsung heroes" of science highlight how fostering an innovative ecosystem that values post-approval research expands these medicines' value to patients and society – an ecosystem at risk due to new government price-setting policies.

Sanofi supports policy solutions that preserve drug discovery while ensuring affordable patient access to life-changing medicines.

Learn more about health care reforms we support.

Learn more →

Unlocking New Potential for Existing Medicines

Our 2024 Milestones in Pediatric, COPD, and Multiple Myeloma Treatments

January 2024

Dupixent® (dupilumab) was approved for pediatric patients aged 1 year and older weighing at least 15 kg with eosinophilic esophagitis, the first and only U.S.-approved medicine indicated for as young as 1 year old. The label was also updated to include efficacy and safety data for patients aged 12 and older with uncontrolled moderate to severe atopic dermatitis affecting the hands and/or feet.

May 2024

Altuviiio's® [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein-ehtl] label was updated with Phase 3 pediatric study results, showing effective bleed protection in children with hemophilia A with once-weekly dosing.

June 2024

Kevzara® (sarilumab) was approved for treating active polyarticular juvenile idiopathic arthritis in patients weighing 63 kg or more.

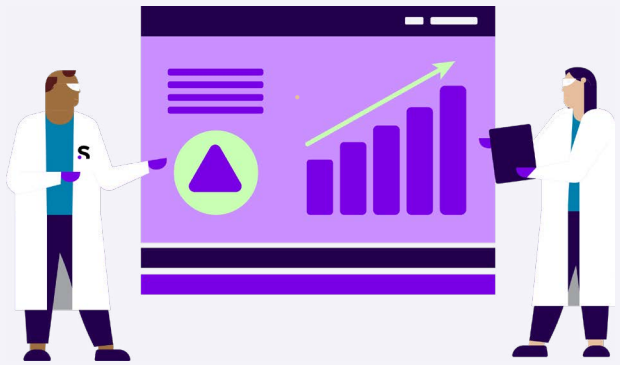
September 2024

Sarclisa® (isatuximab-irfc) was approved in combination with standard-of-care treatment for adults with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant.

Dupixent was approved as an add-on maintenance treatment for adults with inadequately controlled COPD and an eosinophilic phenotype, making it the first-ever biologic for these patients in the U.S. Dupixent is not indicated for the relief of acute bronchospasm in this COPD population. It is also approved as the first and only add-on maintenance treatment for patients as young as 12 years of age with inadequately controlled chronic rhinosinusitis with nasal polyps, expanding on the 2019 approval for adults.

October 2024

The label of Flublok® (Influenza Vaccine) was updated with data from a safety study involving over 48,000 pregnant individuals aged 18 and older.



We keep delivering for patients with the continued momentum of Dupixent, our leading biologic medicine

Approved in

7

indications, driven in part by type 2 inflammation

Treating more than

1 million

patients worldwide[2]

[2]This worldwide number is largely comprised from 10 countries (Canada, China, France, Germany, Italy, Japan, the Netherlands, Spain, the UK, and the US), with the rest of the world comprising ≈10% of this number. This number is comprised of the following US approved indications: AD, asthma, CRSwNP, PN, and EoE. Data through August 2024.

Reporting of U.S. Pricing Actions

In 2024, Sanofi increased the price of *40* of its *80* prescription medicines in line with our Pricing Principles.

Effective January 1, 2024, Sanofi significantly reduced the list price for two insulin products in the U.S.

- The list price of Lantus® (insulin glargine injection) 100 Units/mL, our most prescribed insulin, was reduced by ▼*78%*
- Similarly, the list price of our short-acting insulin, Apidra® (insulin glulisine injection) 100 Units/mL, was lowered by ▼*70%*

Continued Transparency in the U.S.

U.S. Portfolio Annual Aggregate Price Change from Prior Year[3]

Year	Average Aggregate List Price	Average Aggregate Net Price
2016	4.0% Increase	2.1% Decrease
2017	1.6% Increase	8.4% Decrease
2018	4.6% Increase	8.0% Decrease
2019	2.9% Increase	11.1% Decrease
2020	0.2% Increase	7.8% Decrease
2021	1.5% Increase	1.3% Decrease
2022	2.6% Increase	0.4% Decrease
2023	4.3% Increase	15.7% Decrease
2024[4]	1.1% Increase	7.4% Increase

[4]Excluding the unique dynamics of the insulin market, Sanofi saw a 4.5% increase in aggregated gross price and a 3% decrease in net price. This demonstrates the increased demand for rebates and its overwhelming impact on the flow of revenue through the drug supply chain without directly impacting patients' out-of-pocket costs.

[3]As of December 31, 2024

Gross Sales Sanofi Paid as Rebates in 2024

36%
of our gross sales to payors as rebates

$4.3 billion
in mandatory rebates to government payors as required by federal law

$7.4 billion
in rebates negotiated with health plans and pharmacy benefit managers (PBMs) and their related fees

Sanofi's annual net price change is influenced by a number of factors, including the level of discounts, rebates, and fees paid to ensure access to our medicines; the makeup of our product portfolio; the type of health plan or program through which the medicine is dispensed (especially those with both negotiated and government-mandated rebates and discounts); and the extent of patient assistance we provide to improve the affordability of our medications.

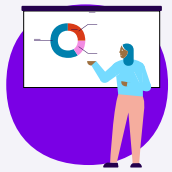
We experienced a 7.4% increase in 2024 in our average aggregated net price across our portfolio, the first increase reported since we began disclosing aggregate data. This increase was influenced by several factors, including dynamics within our insulin portfolio and the broader U.S. insulin market.

In 2024, Sanofi took a significant price reduction for Lantus, our most-prescribed insulin product. As a result of this price reduction within existing regulatory contracts, we saw an increase in net prices due to lower rebates across several channels. The portfolio impact of this net price increase was amplified by an increase in Sanofi market share for Lantus in 2024, which was due in part to a competitor product exiting the insulin market.

It is worth noting that the vast majority of Sanofi medicines still face heightened demand for rebates and fees from health plans and PBMs – which continue to assert control over drug pricing and patient out-of-pocket costs.

Living Out *Our Commitments*

Learn about our perspectives on significant policy issues impacting patient access and affordability and see how we are actively working to lower the out-of-pocket costs of prescription medications for all patients.



The Disconnect Between List Prices & Patient Costs

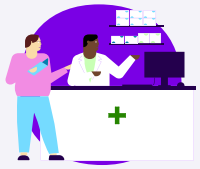
Learn more →

Prioritizing Patient Affordability: Our Patient Support Programs

Learn more →

A Closer Look at 340B

Learn more →



Action Driving Insulin Affordability

Learn more →

Navigating the Complexities of Accessing Specialty Medicine

Learn more →

Health Policy Solutions Protecting Innovation

Learn more →

Boehringer Ingelheim

April 30, 2025

Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
Ridgefield, CT 06877

Dear PDAB Board Members and Staff,

Thank you for the opportunity to provide written comments as a supplement to your Request for Information (RFI). In addition to the survey, we are submitting written comments that provide important context and information as you begin your affordability reviews.

Founded in 1885 and independently owned ever since, Boehringer Ingelheim is a research- driven company with 54,500 employees around the world dedicated to the discovery and development of breakthrough therapies that transform lives, today and for generations to come. As a leading research-driven biopharmaceutical company, we create value through innovation in areas of high unmet medical need focused on breakthrough therapies and first in-class innovations.

Boehringer understands the scrutiny over prescription drug prices. The U.S. healthcare system is complex and often does not work for patients, especially the most vulnerable. In many cases patients face prices at the pharmacy counter that are out of reach. Policy reforms are needed that will address the root of the problem. While we understand that there is a need to find ways to concurrently reduce state budget expenditures and reduce patient out of pocket costs, we believe that alternative approaches may be better suited to meeting your end goal than to conduct affordability reviews.

Healthcare system does not incentivize passing on discounts to patients:
As the Board and Staff are aware, deeming prescription drugs "unaffordable" or even setting an upper payment limit, will not directly help people at the pharmacy counter. Pharmacy counter prices are controlled by the patient's insurance plan.

Boehringer currently provides significant discounts and rebates off the list price of its medicines to insurers, pharmacy benefits managers and other parties. Unfortunately, these discounts are not always passed on to patients. As a result, patients face high out-of- pocket costs at the pharmacy counter.

PBMs and other middlemen seek larger and larger rebates from manufacturers that rarely reach patients while claiming they are providing cost savings to their customers. Their goal is not to ensure the best patient outcome but to continue to extract rebates for formulary access. This perverse incentive means that although Jardiance® has proven its value to patients and health systems, patients may not have access due to PBM decisions or may not see the benefits of discounted pricing at the pharmacy counter. This may account for the difference in the discount rate that is seen on the Oregon PDAB dashboard versus what is, in actuality, more than double.

The healthcare system – including how payors purchase drugs – drives the misaligned incentives. Manufacturers negotiate rebates with PBMs for preferential formulary placement on tiers that provide patients with low-cost sharing. If a PBM/Payor is not satisfied with rebate negotiations, they may choose another prescription drug that is not therapeutically equivalent to the preferred drug for a given condition and put the low-rebate drug on a tier that limits patient access and is more expensive for patients or sometimes remove the drug from their formulary altogether.

Jardiance® Data Proves Its Value:
Boehringer Ingelheim's focus has always been helping to improve outcomes for adults living with a range of cardio-renal-metabolic conditions. We are confident in the value that Jardiance® brings to patients and the healthcare system and believe the value must be considered when evaluating cost to the healthcare system.

Jardiance® is a highly utilized drug since it treats interconnected co-morbid conditions referred to as Cardio-Renal-Metabolic diseases. It is an SGLT2 inhibitor approved for Type II diabetes and three additional indications, including cardiovascular disease associated with Type II diabetes, heart failure, and chronic kidney disease (CKD). Almost 60% of U.S. adults aged 65 years and older – more than 33.5 million Americans - have at least one cardio-renal-metabolic condition, driving significant disease burden, mortality and total overall healthcare spend.

Jardiance® is the number one prescribed SGLT2 inhibitor with 59 million prescriptions. Boehringer is committed to our patients and approximately 88% of Jardiance patients pay no more than $50 for their prescriptions due to our multiple assistance programs.

Peer-reviewed, published economic assessments using real-world data consistently demonstrate that Jardiance® lowers the total cost of care.[1] Studies show Jardiance® is cost- effective in treating CKD. For commercial payors, the increased effectiveness of treating CKD with Jardiance® resulted in a lower cost of approximately $16,363 per patient over their lifetime, for payors.[2]

A study in patients with Type II diabetes and accompanying cardiovascular disease, an annual savings of $13,704 per patient per year (PPPY) was calculated for Jardiance® vs ANY other antidiabetic, INCLUDING about a 50% reduction in medical costs. Specifically, there was a 60% reduction in Emergency Room costs, 37% reduction in Outpatient costs, and 62% reduction in Inpatient costs.[3]

Jardiance's® value is also demonstrated through Outcome Based Agreements with payors. Boehringer entered an Outcomes- Based Agreement with Highmark in Pennsylvania to demonstrate the value of Jardiance®. The results showed that Jardiance® reduced the total cost of care by 20%. Specifically, the cost of care savings was driven by a 30% reduction in the total annual medical spend for adults with Type II diabetes and cardiovascular disease who took Jardiance® compared to other anti-glycemic medications

In 2015, a Jardiance® landmark clinical trial became one of the most significant breakthroughs in the field of diabetes care and the first ever trial for any diabetes medication to show statistically significant reduction of cardiovascular death in people with Type II diabetes and established cardiovascular disease. This trial forever changed the way healthcare providers treat adults with Type II diabetes and led to change in the professional diabetes treatment guidelines in the U.S. and worldwide.

In 2016, the FDA relied on this landmark clinical trial to approve Jardiance® "to reduce the risk of cardiovascular death in adult patients with Type II diabetes mellitus and established cardiovascular disease."[4]

Adding to the evidence supporting the use of Jardiance in this patient population, a study of patients with heart failure, with or without Type II diabetes when treated with Jardiance®, demonstrated an annual savings of $14,271 PPPY for Jardiance® vs ANY other heart failure medication, including a 53% reduction in medical costs.[3]

[1]Peasah SK et al. *J Manag Care Spec Pharm*. 2023;29(2):152-160. doi:10.18553/jmcp.2023.29.2.152
[2]Chatterjee S et al. *J Manag Care Spec Pharm*. 2023;29(10a-Suppl):S110-111. https://doi.org/10.18553/jmcp.2023.29.3-a.s1
[3]Data on File. Boehringer Ingelheim Pharmaceuticals, Inc. 2024
[4]Jardiance® (empagliflozin tablets) Prescribing Information at 1 (Dec. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204629s008lbl.pdf

In 2023, Jardiance was approved to reduce the risk of further worsening of kidney disease, end-stage kidney disease (ESKD), death due to cardiovascular disease, and hospitalization in adults with chronic kidney disease. We have continued to invest significantly in research and development that has extended the impact of Jardiance® to expand its use with additional patient populations. The CKD indication was the result of this continued investment.

This is a critical point because investment in drugs does not end once it is approved for one condition - research and development (R&D) investments continue. Price control policies would negatively impact decisions to continue investing in R&D for such drugs.

Costs and Data Analysis Transparency:
Boehringer has serious concerns over the data being used to establish affordability. We believe that the carrier data reflected in the dashboard grossly underestimates the rebates provided by Boehringer to the payors. This gross miscalculation is reflected in the "total annual net of rebate spend," "total annual net of rebate spend per enrollee," and the "average cost net of rebate per prescription" data columns of the dashboard.

The lack of transparency in the data methodology calls conclusions into question since the analysis and results cannot be independently verified. There could be many reasons for this difference. Likely due to a lack of transparency on the part of the Pharmacy Benefit Manager, they may not be passing along all the rebates to the plan sponsors, or the rebate data received by the plan sponsor is not sufficiently detailed to identify specific Jardiance® rebate amounts.

Conclusion:
Boehringer supports efforts to reduce healthcare costs to patients but believes that such work must include review of the multiple stakeholders and be based on sound data. Unfortunately, the work of this Board falls short in both categories.

We respectfully request you remove Jardiance® from further review.

Regards,

Stacie Phan
Executive Director, State Policy, and Advocacy