July 14, 2025

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

RE: Selection of Sacubitril-Valsartan for Oregon PDAB

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 member 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 provide context for one of the medications being reviewed by the Oregon PDAB.

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 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. Sacubitril-Vasartan provides an excellent example.

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

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July 14, 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 Affordability Review

Dear Members of the Board,

On behalf of the Preventive Cardiovascular Nurses Association, thank you for the opportunity to comment on the July 16th Oregon Prescription Drug Affordability Board 2025 meeting. PCNA writes to reiterate the importance of ensuring patient access to the three crucial cardiovascular medications from the 2025 prescription medication list for the Oregon Prescription Drug Affordability Review Board (PDAB) review.

The Preventive Cardiovascular Nurses Association (PCNA) was founded in 1992 by a group of nurses working in cardiovascular disease management and has since expanded into 41 chapters across the United States, including the Pacific Northwest Chapter, which serves Portland, Oregon and surrounding counties. As PCNA has expanded, we are the leading nursing organization dedicated to preventing and managing cardiovascular disease. Our mission is to support the utilization and dissemination of research and support evidence-based practice in cardiovascular risk reduction and disease management as a means to ensure patient access to treatment and empower nurses as leaders in cardiovascular care.

PCNA acknowledges the barriers to access for many patients that arise from high medication costs, and we align with the Oregon Prescription Drug Affordability Board's intention of ensuring affordable medications for Oregonians. As the board undertakes this effort, PCNA urges a focus not only on top-line cost, but also on patient benefit and healthcare system cost savings from access to these therapies.

According to the Centers for Disease Control and Prevention (CDC), cardiovascular disease remains the second leading cause of death in Oregon[1], and the number one cause of death in the United States.[2] Notably, the cardiovascular disease (CVD) mortality rate in the United States declined by over 20% from 1980 to 2010. However, in the following years, the rate of CVD-related deaths has increased, particularly for adults aged 35 to 64.[3] PCNA believes that ensuring patients have access to preventive cardiovascular care and maintaining healthcare providers' ability to treat their patients with the best available treatment modalities are of utmost importance.

The Oregon PDAB has selected three cardiovascular medications for affordability reviews in 2025. The medications selected represent some of the most effective recent pharmaceutical interventions in cardiovascular medicine, providing immense value not only for patients but for the healthcare system as a whole.

As the Board considers its reviews, PCNA would like to provide comments on the following cardiovascular medications selected for affordability review: Sacubitril-Valsartan (Review Group 1); Apixaban (Review Group 2); and Rivaroxaban (Review Group 2).

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. When compared to angiotensin-converting-enzyme inhibitor (ACEI), also used to treat heart failure, sacubitril-valsartan demonstrated significant reductions in cardiovascular death and heart failure hospitalizations (21%), further emphasizing the value of sacubitril-valsartan for patients living with heart failure.[4] Moreover, a study using the Kansas City Cardiomyopathy Questionnaire (KCCQ), the most well-validated resource in heart failure, to evaluate quality of life revealed that patients being treated with sacubitril-valsartan experienced improvements in all domains, including physical limitations, quality of life, self-efficacy, social limitations, and symptom stability.[5] In a broader context, the efficacy of sacubitril-valsartan in heart failure management helps reduce healthcare costs associated with hospitalizations and patient interactions with the healthcare system.

In summary, recent data shows that sacubitril-valsartan significantly reduces patients' risk of hospitalization, improves overall quality of life, and therefore reduces the burden placed on the healthcare system.

Apixaban:
Apixaban is a factor Xa inhibitor, direct oral anticoagulant (DOAC) used for the treatment of patients with nonvalvular atrial fibrillation (AF), deep vein thrombosis (DVT) and pulmonary embolism (PE).[6] Initially approved by the U.S. Food and Drug Administration (FDA) in 2012, apixaban helps reduce the risk of stroke and blood clots.[7] The drug is also approved for reducing the risk of recurrent DVT and PE after initial therapy.

Efficacy studies on DOACs like apixaban have demonstrated a significant decrease in patients' risk of developing a stroke or systemic embolism, as well as a 15% decreased risk of experiencing a major bleeding episode.[8] Apixaban and other DOACs hold value in minimizing healthcare cost burdens for both patients and the broader healthcare system.

Rivaroxaban:
Rivaroxaban is a factor Xa inhibitor, DOAC used to treat and manage DVT, as well as to prevent blood clots and stroke in patients who have undergone elective orthopedic surgery.[9] In addition to the previously mentioned indications, rivaroxaban has received FDA approval for secondary prevention of acute coronary syndrome (ACS) or peripheral artery disease (PAD).[10] In addition to other DOACs, rivaroxaban has been proven to reduce patients' risk of thromboembolic stroke by 20-29% and decrease risk of death by 19-34% when compared to current generic medications.[11]

By decreasing patients' risk of experiencing adverse events such as strokes, PE, and DVT, rivaroxaban and other DOACs protect patients and help reduce healthcare costs.

Each of the three medications are essential tools for cardiovascular care. PCNA encourages the Board to consider the perspectives of both patients and providers when conducting affordability reviews of the cardiovascular drugs selected.

The cardiovascular treatments being considered by the Board already face access limitations in the form of utilization management[12], which can have devastating consequences for patients – especially for treatments with no other alternative, such as sacubitril-valsartan. Use of utilization management for single-source cardiovascular brand drugs in the commercial market showed increases of over 450% from 2014 to 2020.[13] Excessive use of utilization management tools harms patient access and limits the benefits that medicines have for patients and in controlling overall healthcare costs. A determination of unaffordability could lead to more restricted access while not guaranteeing any patient affordability savings.

PCNA appreciates the Board's work in addressing prescription drug affordability. At this time, we ask that the Board keep in mind the importance of maintaining access to the cardiovascular treatments selected for patient outcomes, as these medications have been proven to help patients and reduce the economic impact on the healthcare system.

Sincerely,

Sue Koob
CEO
Preventive Cardiovascular Nurses Association

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[7] *Id*.

[8] Makam, R. C., Hoaglin, D. C., McManus, D. D., Wang, V., Gore, J. M., Spencer, F. A., Pradhan, R., Tran, H., Yu, H., & Goldberg, R. J. (2018). Efficacy and safety of direct oral anticoagulants approved for cardiovascular indications: Systematic Review and meta-analysis. *PLOS ONE*, *13*(5). https://doi.org/10.1371/journal.pone.0197583.

[9] Singh, R. (2023, April 17). *Rivaroxaban*. StatPearls [Internet]. https://www.ncbi.nlm.nih.gov/books/NBK557502/.

[10] *Id*.

[11] David J. Graham MD, Hernandez, I., Lip, G., Pisters, R., Connolly, S., Patel, M., Granger, C., Giugliano, R., Lip, G., Noseworthy, P., Deitelzweig, S., Adeboyeje, G., … Ray, W. (2019, January 9). *Comparative stroke, bleeding, and mortality risks in older Medicare patients treated with oral anticoagulants for nonvalvular atrial fibrillation*. The American Journal of Medicine. https://www.sciencedirect.com/science/article/abs/pii/S0002934319300518.

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July 14, 2025

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

TO: Members of Oregon Prescription Drug Affordability Board

As a physician with decades of experience caring for patients whose families often struggle to access and afford necessary medications, I am deeply concerned that the Board's process for selecting medications and conducting affordability reviews will leave Oregon patients without access to necessary medications.

I am a board-certified pediatrician and pediatric rheumatologist who has spent my career caring for young people with chronic or disabling conditions. Many of my patients, including those with juvenile idiopathic arthritis and lupus, rely on specialized, innovative, expensive therapies. My primary focus is always ensuring the well-being of my patients, but I fear that the Board's decisions do not reflect this same mandate.

The Board's search for "therapeutic alternatives" is fundamentally misguided and dangerous for patients for whom substitution is not clinically appropriate due to unique medical conditions or treatment needs. The criteria for selecting these so-called "alternatives" often fail to account for the complexities of individual patient care. Unilaterally designating certain medications as "therapeutic alternatives" fundamentally disrupts the physician's ability to exercise their medical expertise in concert with their patient.

Healthcare providers like myself consider therapeutic equivalents when considering medication substitutions as a matter of standard practice, but therapeutic alternatives do not constitute therapeutic equivalents. Even if medications are in the same "therapeutic category", their different modes of action are considered when making individualized therapeutic decisions. It is not unexpected, therefore, that "therapeutic alternatives" within drug categories are not equivalent and result in patients only responding to specific medications and not others within a category. Patients who suffer from complex chronic conditions, such as rheumatoid arthritis and other rheumatologic diseases, require continuity of care to successfully manage their conditions. Policymakers have no business overriding their doctor's prescribing recommendations.

Further, I find the lack of consideration of the real-world consequences of a UPL problematic. We have seen that the creation of the Maximum Fair Price (MFP) within the Inflation Reduction Act has resulted in a 32% increase in out-of-pocket costs to patients.[1] Since a UPL creates a similar situation to the MFP, there is no reason not to expect a similar consequence within Oregon. Similarly, NCPA has reported that many of its member pharmacies will not be carrying the medications with a MFP because they cannot afford to do so. This too is likely to occur in Oregon[1]. We also know that insurers and PBMs will likely adjust their formularies if the UPL reduces their profits by shifting such a medication to a higher tier or excluding it from the formulary; what will be the Board's response to such actions?

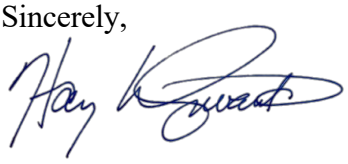
The opaque evaluation process of collected data further undermines confidence in the affordability review process. Without detailed definitions, methodologies or standards for assessing therapeutic alternatives and other critical factors, the Board risks decisions that do not adequately reflect real-world patient experiences or clinical realities. Establishing clear, consistent processes and ensuring transparency in decision-making are essential steps toward improving access to affordable medications for those who depend on them. While you are doing your best to be transparent, more time and extensive public contributions and deliberations will only improve your process.

The proposed list of potential therapies for affordability review is extensive and could significantly impact Oregon patients across a wide range of disease states. I am deeply concerned about the potential predictable and unintended consequences of such evaluations, especially when conducted under short timelines and without sufficient public input.

I share your goal to lower prescription drug costs, but the current process risks limiting access to essential medications. Physicians and patients are eager to collaborate with the Board to ensure affordability decisions reflect real-world patient needs on a more thoughtful, patient-centered approach. As it stands now, the Board's actions could inadvertently restrict access to medications for those who need them most in Oregon.

Thank you for your attention to this critical issue.

Sincerely,



Harry L. Gewanter, MD, FAAP, MACR
Board Member, Let My Doctors Decide Action Network
President, Virginia Society of Rheumatology

[1] https://pioneerinstitute.org/the-inflation-reduction-act-ira-overview/

The Headache & Migraine Policy Forum

July 15, 2025

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

RE: Comments on Patient Access and Migraine Treatments Under Consideration for Affordability Review

Dear Chair Bailey and Members of the Oregon Prescription Drug Affordability Board:

The Headache and Migraine Policy Forum (HMPF) appreciates the opportunity to provide comments regarding the Oregon Prescription Drug Affordability Board's list of drugs selected for affordability review. We understand that four migraine therapies are currently under consideration for review and believe that including these treatments is misguided and ill-advised for several reasons, given the critical role they play in managing a disabling neurological disease.

HMPF is a group of diverse stakeholders seeking to advance public policies and practices that promote access to care for persons living with headache disorders and migraine disease. Migraine is not only one of the most common neurological conditions affecting more than 40 million Americans, with an estimated 640,000 of which are Oregonians. It is also the second leading cause of disability globally. Despite its significant burden, migraine is frequently underdiagnosed, undertreated, and often mischaracterized as a lifestyle issue instead of a serious neurological disease.

Thankfully, after more than 25 years without therapies specifically developed for migraine disease, innovative treatments have finally transformed care for many patients. However, these therapies are only effective if patients can access and can bear these costs. Like other stakeholders in the chronic disease community, we are concerned that affordability policies, if not carefully designed and implemented, could inadvertently limit patient access through restrictive coverage policies or utilization management, such as step therapy, prior authorization, or non-medical switching.

As a community, we share concern that affordability reviews can lead to direct reductions in patient out-of-pocket costs, that such policies may result in narrowed access or the steering of patients to less effective alternatives, and that patients with a heterogenous and complex disease such as migraine may not be afforded sufficient engagement throughout such a process.

Moreover, migraine imposes an enormous economic and social burden. Inadequate access to effective treatment can lead to frequent ER visits, missed work, and long-term disability. Migraine imposes more than $78 billion in annual economic burden in the United States, exceeding those of epilepsy, asthma, and ovarian cancer combined. In fact, individuals with chronic migraine can lose tens of thousands of dollars annually in lost productivity and face up to $300,000 in lost lifetime earnings. Migraine patients are the fourth highest users of the emergency department.

In addition, research shows that coverage barriers — not drug efficacy — are often the limiting factor in treatment access. Formulary exclusions, prior authorization, and step therapy delays prevent patients from obtaining the therapy selected by their provider, increasing the risk of poor outcomes and avoidable costs elsewhere in the healthcare system.

We are also concerned that the current review process lacks a mechanism to protect access for patients who rely on therapies deemed "unaffordable." Without protections in place, affordability reviews could lead to increased utilization management or the removal of therapies from preferred formularies, leaving patients with fewer, often less effective, options.

Migraine treatment is not one-size-fits-all. Patients respond differently to medications depending on their symptom patterns, comorbidities, and past treatment experience. As such, decisions that prioritize cost above clinical appropriateness risk undermining personalized care — especially in an area where therapeutic innovation is still emerging.

We strongly urge the PDAB to incorporate these considerations into your review process and to ensure that Oregon patients with migraine and other disabling conditions are not left behind in efforts to reduce costs.

While we appreciate the Board's work, we do not believe it is appropriate or timely for migraine therapies to be subject to an affordability review. Thank you for your attention to this request.

Sincerely,

Lindsay Videnieks

Executive Director
The Headache & Migraine Policy Forum
lindsay@headachemigraineforum.org

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AWARENESS

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Coalition for Headache and Migraine Patients

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women

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AT SCHOOL

MIGRAINE
AT WORK

Migraine
Meanderings

MIGRAINE WORLD SUMMIT

MILES FOR MIGRAINE

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HEADACHE
FOUNDATION

U.S. PAIN
FOUNDATION

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VIA Electronic Delivery

July 14, 2025

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

Re: July 2025 Oregon Prescription Drug Affordability Board Meeting

Dear Prescription Drug Affordability Board Members and Staff:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide comments for the Oregon Prescription Drug Affordability Board (PDAB)'s July 2025 meeting.

BIO is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech start-ups to some of the world's largest biopharmaceutical companies – all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives. BIO also organizes the BIO International Convention and a series of annual conferences that drive partnerships, investment, and progress within the sector. Learn more at bio.org.

At the June 2025 Oregon PDAB meeting, a board member indicated a desire to recommend to the legislature that the orphan drug exemption be removed from Oregon PDAB's review affordability process. These comments were extremely concerning for the entire patient community and represents a key misunderstanding of the critical role that the orphan drug exemption plays in ensuring patient access to life-saving treatments for individuals with rare diseases. **BIO strongly opposes any recommendation to alter or remove the orphan drug exemption, which would threaten the delicate ecosystem of innovation that makes these therapies possible.**

The EveryLife Foundation's "National Economic Burden of Rare Disease Study" found that rare diseases affect over 30 million Americans and imposed nearly $1 trillion in costs in 2019 alone[1]—highlighting both the scale of the burden and the urgent need for treatment innovation. Many rare disease patients have few or no previously approved medicines for

[1] Yang G., Cintina I., Pariser A., Oehrlein E., Sulliva n J., Kennedy A. (2022). The national economic burden of rare disease in the United States in 2019. Orphanet Journal of Rare Diseases, 17:163.

Biotechnology Innovation Organization
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their conditions. With 95% of the 7,000+ known rare diseases lacking an FDA-approved therapy, continued investment in rare disease research and development is vital. Further, continued investment in post-marketing R&D helps uncover new uses or populations that benefit from existing drugs, expanding their value toward patients.

Applying traditional affordability assessments—designed for broader populations—to rare disease therapies, without accounting for their distinct challenges, can significantly restrict access. These therapies often serve small, medically complex populations and involve high development costs, yet they can deliver life-altering or even curative outcomes. Without a tailored review approach that reflects the realities of rare disease—including disease heterogeneity, long diagnostic journeys, and profound unmet need—Oregon risks discouraging innovation and denying patients access to critical treatments.

We respectfully urge the PDAB and state policymakers maintain the rare disease exemption from affordability review, which provides a critical lifeline for rare disease patients to access these important treatments.

In addition, we urge the OR PDAB to communicate a schedule for their reviews and to promptly provide details on what the process for stakeholder input will be moving forward. In the June 2025 meeting, Board members made comments about wanting to standardize their review criteria and identified a need to establish critical definitions for key terms, like affordability. These concerns are carried over from the OR PDAB's aborted 2024 process, and it seems prudent for the Board to address them in earnest before commencing with reviews in 2025.

Sincerely,

Primo J. Castro

Primo J. Castro
Director, State Government Affairs – Western Region

Chronic Disease Coalition

Oregon Prescription Drug Affordability Board (PDAB)
Department of Consumer and Business Services
350 Winter St. NE Room 410
Salem, OR 97309

July 21, 2025

Chair Bailey and members of the board,

On behalf of the Chronic Disease Coalition, thank you for the opportunity to provide our thoughts and feedback as the PDAB considers supporting legislation that would remove the rare disease exemption from your review process.

Founded in Oregon, the Chronic Disease Coalition is a national nonprofit organization dedicated to raising the patient voice and perspective in healthcare policymaking. Our patient volunteers represent both common diseases like diabetes and kidney disease and rare diseases such as Guillain-Barré, von Willebrand's Disease Type 2N, Partial Trisomy 8q and hypoparathyroidism.

We are especially attuned to the needs of our rare disease patients because they have a unique experience of the healthcare system. It is not an exaggeration to say that just getting to diagnosis is a tortured path. Symptoms are dismissed or misunderstood, and patients are often left to research and diagnose themselves. Then they have to find and connect with national expert providers and build informed local care teams. There is not always a treatment for a rare condition, of course, so many willingly participate in clinical trials, desperate for anything that helps.

They are willing to risk so much for access to care. The reality is that chronic disease patients need more access to better treatments, and any action to address pricing must consider its potential impact on current availability and future development. This Colorado patient's experience and concerns are similar to that of thousands of other families (read here).

To improve affordability for rare disease patients, it's especially important to protect, support and expand discounts at the patient level. By prioritizing reforms that offer immediate and tangible benefits to patients, we can advance the cause of more accessible and effective care.

Sincerely,

Mary Kay Clunies-Ross
Executive Director
marykay@chronicdiseasecoalition.org
(206) 817-4845

From: MacKay Jimeson, Executive Director, Patients Rising
Sent: Tuesday, July 22, 2025
To: PDAB
Subject: Protecting the Rare Disease Patients in Oregon's PDAB Law

Chairwoman Bailey, Senator Patterson, and Representative Nosse,

On behalf of Patients Rising, I urge the Board to preserve the rare disease exemption in Oregon's Prescription Drug Affordability Board (PDAB) statute.

Removing this exemption would endanger access to life-saving therapies for individuals facing some of the most devastating medical challenges. For rare disease patients—many of them children—these treatments are often the only options available, and they arrive only after years of advocacy and scientific perseverance.

At the core of this issue is how we define "value." Health Technology Assessments (HTAs)—like those often used by affordability boards—are intended to guide payers and policymakers by projecting the costs and benefits of new therapies. Unfortunately, these assessments often rely on generic, population-level quality-of-life models that do not reflect the lived experience of patients with rare conditions.

These models fail in three fundamental ways:

1. **They ignore indirect and non-medical costs** such as caregiving burdens, home adaptations, and the economic impact on families who must forgo work or education to care for a loved one.
2. **They overlook societal benefits**, including productivity regained, educational opportunity restored, and caregiver reentry into the workforce—real-world impacts that matter deeply to families and communities.
3. **They are not designed to evaluate rare diseases**, where traditional randomized clinical trials may be impractical or unethical. Small, heterogeneous patient populations, unpredictable disease progression, and rapid degeneration often make placebo-controlled trials impossible.

More than 90 percent of rare diseases currently have no FDA-approved treatment. For the small number that do, the evidence base may come from alternative clinical designs, such as natural history studies, real-world data, or single-arm trials—because it's not feasible or humane to randomize patients to certain decline or death. Yet HTA frameworks often penalize such methods, undervaluing the therapy's true benefit and placing it at risk of being deemed "unaffordable."

The rare disease exemption in Oregon's PDAB law is not a loophole. It is a necessary safeguard that recognizes the limitations of traditional cost-effectiveness frameworks when applied to rare conditions. Eliminating this exemption would allow incomplete, generalized, and sometimes discriminatory valuation models to dictate access decisions for patients with no therapeutic alternatives.

This is not just a technical issue—it is a moral one. Oregon must not become the first state to institutionalize health inequity for people with rare conditions by stripping away the one protection that ensures their needs are judged on their own terms.

On behalf of our community, we respectfully ask that the Board:

1. **Retain the rare disease exemption** in full;
2. **Formally recognize the limitations of current HTA methodologies**, especially for small-population, high-need conditions;
3. **Engage patients and caregivers directly** in any future evaluations or working groups; and
4. **Adopt patient-centered best practices** that account for indirect costs, real-world outcomes, and non-traditional evidence when reviewing access and affordability.

Thank you for your attention and your commitment to making healthcare more equitable and responsive. Patients Rising stands ready to support the Board in its work while defending the rights of those living with rare and life-threatening conditions.

Sincerely,

MacKay Jimeson

Novartis Services, Inc.
801 Pennsylvania Avenue NW
Suite 700
Washington, DC 20004

Courtney Piron
US Country President
Head, US Public Affairs
Telephone +1 202-253-1803

August 12, 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: Cosentyx® 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 comment on the Board's affordability review of Cosentyx® (secukinumab) 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.

Cosentyx is a proven medicine backed by robust clinical evidence. Patients in Oregon have broad affordable access to Cosentyx:

- Eligible patients with commercial health coverage can access Cosentyx 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 via the Novartis Patient Assistance Foundation.
- When adjusted for inflation, the average net price of Cosentyx has declined between January 2018 and December 2023.
- Cosentyx provides value to the broader health care system. This is particularly clear for Cosentyx when compared to therapeutic alternatives.

[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 is a Proven Medicine 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.[2]

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.[3]

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.[4]

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 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.[5]

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

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[2] Data on file. COSENTYX Patient Reach. Novartis Pharmaceuticals Corp; January 2023.
[3] 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.
[4] 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.
[5] 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.

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.[6]

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.

Cosentyx is Affordable for Oregonians and the Health Care System

At its core, the question of whether Cosentyx is “affordable” for Oregonians has a simple answer: it is affordable because eligible Oregon patients with commercial health coverage can access it at a cost as low as zero dollars with the assistance of the Cosentyx Co-pay Card Program.[7] 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.[8]

Furthermore, the health plans that pay a portion of the cost of Cosentyx 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 price of Cosentyx has declined between January 2018 and December 2023. The vast majority of patients, too, receive significant assistance even beyond the net

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[6] Cosentyx Webpage. Accessed April 2025. https://www.cosentyx.com/kids-and-teens/juvenile-idiopathic-arthritis

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

[8] 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.

price of Cosentyx and their insurance coverage through the Cosentyx Co-Pay Programs or the charitable assistance of the Novartis Patient Assistance Foundation (NPAF). These programs further reduce the costs patients pay, in many cases to as little as $0.[9]

Cosentyx is 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. Through our Patient Assistance website[10], we inform patients about programs that may provide savings or resources that can help them access Cosentyx 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.[11] 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-five states, the District of Columbia, and Puerto Rico have enacted laws banning accumulator adjustment programs in state-regulated commercial plans.[12] We commend Oregon for taking similar action to protect patients in

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[9] IQVIA Claim Data FY 2022, 2023.
[10] Novartis.com. Patient Assistance. https://www.novartis.com/us-en/patients-and-caregivers/patient-assistance. Accessed April 10, 2025.
[11] IQVIA Claim Data FY 2023, SP Dispense Data FY 2023.
[12] All Copays Count Coalition. State Legislation Against Copay Accumulators. Accessed July 7, 2025. https://allcopayscount.org/state-legislation-against-copay-accumulators/

2024.[13] However, payers are still using other tactics, such as copay maximizers[14] and alternative funding programs[15], 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.[16]

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.[17]

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.[18]

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

[14] 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.

[15] 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.

[16] 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.

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

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

Oregon Payers Benefit from Significant Discounts on Cosentyx.

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 is *currently* affordable to patients, but also why Cosentyx's net price has 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.

Cosentyx Provides 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."[19] In this regard, Cosentyx should be recognized as effectively treating multiple indications. It treats conditions that would otherwise significantly limit patient health and impose major costs on the state.

The major indications for which Cosentyx is used[20] are associated with significant economic burden. We strongly urge the Board to consider the value Cosentyx provides in reducing the direct and indirect costs of these diseases to the workforce, communities, and overall health care system as described below.

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

[20] 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.

Psoriasis:

Total direct and indirect costs associated with the disease have been estimated at $11.3 billion annually.[21]

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.[22] After multivariate adjustment, psoriasis patients demonstrated significantly higher direct and indirect costs compared to other patients.[23] Approximately 40% of the total cost burden was associated with work loss (i.e., indirect costs).[24]

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.[25]

Psoriatic Arthritis (PsA):

The total direct costs of PsA in the US have been estimated at $1.9 billion annually.[26] 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 indirect costs account for approximately 52% to 72% of total costs.[27] The costs increase with deterioration of disease activity and decline in physical function.[28]

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.[29]

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[21] NPF, National Psoriasis Foundation Statistics [Online]. 2015b. Available: http://www.psoriasis.org/research/science-of-psoriasis/statistics [Accessed November 17, 2015].
[22] 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.
[23] *Id.*
[24] *Id.*
[25] Academy of Managed Care Pharmacy (AMCP) Formulary Dossier. Cosentyx. July 2023.
[26] 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.
[27] *Id.*
[28] *Id.*
[29] Academy of Managed Care Pharmacy (AMCP) Formulary Dossier. Cosentyx. July 2023.

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.[30]

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.[31] 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.[32]

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.[33,34,35] 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 children involving inflammation of the joints. Cosentyx is approved to treat two of those disorders: ERA and JPsA.[36]

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.[37] Even compared with patients with severe psoriasis, rates of inpatient care and emergency department use are higher for patients with HS.[38]

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[30] *Id.*
[31] 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.
[32] Academy of Managed Care Pharmacy (AMCP) Formulary Dossier. Cosentyx. July 2023.
[33] 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.
[34] Kumar N, Ramphul K, Ramphul Y, et al. Children hospitalized for juvenile arthritis in the United States. Reumatologia. 2021;59(4):270-272.
[35] 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.
[36] 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.
[37] 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.
[38] *Id.*

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. [39]

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.[40] Cosentyx can help reduce flares in adults with moderate to severe HS.

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".[41] 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 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

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[39] 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.
[40] 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.
[41] 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

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 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 is 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

Johnson & Johnson

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1125 Bear Tavern Road
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jnj.com

Via Electronic Submission

August 14, 2025

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

Dear Board Chair Bailey:

Johnson & Johnson Innovative Medicine ("J&J") offers comments on XARELTO to the Oregon Prescription Drug Affordability Board ("PDAB" or "Board") in advance of the August 20, 2025 Board meeting. We reiterate the concerns in our comments submitted to the Board on April 14, 2025, April 30, 2025, and June 13, 2025. We respectfully request that the Board **cancel XARELTO's affordability review, or alternatively, find that XARELTO does not create an affordability challenge for Oregon patients or payers for the following reasons:**

- XARELTO should not have been deemed eligible for an affordability review based on Oregon law and the criteria that the PDAB agreed to prioritize.[1]
- XARELTO is affordable for Oregon patients and payers.
- XARELTO is subject to a CMS-regulated "Maximum Fair Price" ("MFP") under the Inflation Reduction Act ("IRA"), which may negatively impact access to the medication.

J&J continues to reiterate our concerns regarding the PDAB's processes and methodologies for affordability reviews, including:

- A lack of clear processes, consensus on how to conduct affordability reviews, and consistent application of criteria for conducting reviews;
- Calculation errors and data that cannot be verified;
- Irrelevant data; and
- Insufficient time to conduct thorough reviews.

A. The Board should cancel XARELTO's affordability review.

1. XARELTO should not have been deemed eligible for an affordability review.

As previous noted, Oregon law requires the PDAB to prioritize drugs appearing on three carrier-reported lists when selecting drugs for affordability reviews—the top 25 most frequently prescribed drugs, the top 25 most costly drugs, and the top 25 drugs contributing to the greatest increase in plan spend.[2] XARELTO appears on only one of these lists. Similarly, the

[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] *Id.*

PDAB is required to prioritize drugs on two Oregon Drug Price Transparency ("DPT") Program Reports—namely, the Manufacturer New Drug Report and Manufacturer Price Increase Report).[3] XARELTO is on neither of these lists. The Board had also agreed to exclude drugs subject to CMS's "MFP negotiations."[4] CMS has set an MFP for XARELTO, which goes into effect January 1, 2026. Therefore, given that XARELTO should not have been included on the PDAB's final list of drugs, the PDAB should cancel its review of XARELTO.

2. XARELTO is affordable for Oregon patients and payers.

J&J offers multiple programs to help support patient access to XARELTO. Through the "XARELTO withMe" program, eligible Oregon patients pay as little as $10 for their medication.[5] Additional affordability support for XARELTO is available for eligible Oregon patients through the Johnson & Johnson Patient Assistance Program.[6] Through this program, J&J medicines, such as XARELTO, "may be provided at no cost to eligible patients who are uninsured or have inadequate coverage through commercial, employer group, or government insurance coverage and are not supported by other offerings from J&J."[7]

Notwithstanding the availability of financial assistance, the PDAB data indicates that XARELTO continues to be cost-effective for patients and payers in Oregon. According to the PDAB's Dashboard, the All Payer All Claims (APAC) data and the Data Call (DC) show that patients face low average out-of-pocket costs per claim:[8]

- Commercial (APAC): $42 copay, $11 coinsurance, $27 deductible
- Commercial (DC): $44-$71 copay, $2-$51 coinsurance, $19-$110 deductible
- Medicaid (APAC): $0 out of pocket
- Medicare (APAC): $43 copay, $60 coinsurance, $24 deductible

Currently, the Board is tasked with identifying nine drugs that "create an affordability challenge" for Oregon patients or the state.[9] Currently, 16 drugs are under review. XARELTO ranks in the bottom quarter of the 16 drugs—not within the top nine—when sorting the list by

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[3] *Id.*
[4] *Prescription Drug Affordability Board (PDAB) Upper Payment Limit (UPL) Report to the Legislature* (Dec. 2024), https://dfr.oregon.gov/pdab/Documents/reports/PDAB-upper-payment-limit-report-2024.pdf (last visited Aug. 12, 2025); OR PDAB, *Agenda* (March 19, 2025), https://dfr.oregon.gov/pdab/Documents/20250319-PDAB-document-package.pdf (last visited Aug. 12, 2025).
[5] *Xarelto withMe*, https://www.xarelto-us.com/xarelto-cost/en/ (last visited Aug. 12, 2025).
[6] Janssen Carepath, *Johnson & Johnson Patient Assistance Program: Quick Reference Guide*, https://www.myjanssencarepath.com/resource/1716902197000/Immunology_Medications_English (last visited Aug. 12, 2025).
[7] *Id.*
[8] Oregon PDAB, Oregon PDAB Subset List Dashboard (July 16, 2025), https://app.powerbigov.us/view?r=eyJrIjoiMzY4NWY3ZmItZTI2Yi00M2EyLThmNjktOWE1MjhlYWI1NjhjIiwidCI6ImFhM2Y2OTMyLWZhN2MtNDdiNC1hMGNlLWE1OThjYWQxNjFjZiJ9 (last visited Aug. 12, 2025) [thereinafter "OR PDAB SUBSET LIST DASHBOARD"]
[9] Or. Rev. Stat. 646A.694 (2025).

key cost categories across all payer types represented in the APAC and DC data.[10] For patients, this includes average copay, coinsurance, or deductible per enrollee and per claim. For payers, this includes average paid per claim and per enrollee and average plan spend per claim and per enrollee.

XARELTO's inclusion on the list appears to be based on volume alone (i.e., 16,810 claims and 3,712 enrollees). Yet, the fact that so many Oregon patients can successfully access XARELTO is a testament to the product's value and affordability.

3. An MFP may negatively impact XARELTO's access.

XARELTO is subject to an "MFP" that takes effect on January 1, 2026.[11] Initial unintended consequences are already starting to emerge for "MFP" drugs, including constraints on pharmacists and reduced patient access. A recent National Community Pharmacists Association (NCPA) survey found over 90% of independent pharmacies are considering or have already decided not to stock MFP drugs due to potential financial losses.[12] Another study estimates that the "MFP" could lead to 71,000-93,000 patients abandoning XARELTO, increasing the risk of major cardiovascular events and deaths nationally.[13] The PDAB should refrain from reviewing products subject to an "MFP," such as XARELTO, until access challenges are addressed.

B. The Board's processes and methodologies are flawed.

J&J remains concerned with the PDAB's processes and methodologies. For example, much of the July 15, 2025 Board meeting was spent discussing how to define "affordability" and prioritize statutory review criteria without reaching consensus. These processes should be finalized before affordability reviews begin to ensure consistency and transparency.

Additionally, the Dashboards contain calculation errors that inflate out-of-pocket costs for patients. For instance, average copays, coinsurance, and deductibles were added together to calculate "average enrollee paid per claim" and "average paid per enrollee." Yet, plans typically require either a copay or coinsurance, and if coinsurance is required, either a deductible or a coinsurance, but not both simultaneously. Moreover, the data cannot be verified, so it is unclear whether additional errors exist in the Dashboard.

The Dashboard also contains irrelevant data. For example, Medicare data, which accounts for

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[10] OR PDAB SUBSET LIST DASHBOARD, *supra* note 8.
[11] CMS, *Medicare Drug Price Negotiation Program: Negotiated Prices for Initial Price Applicability Year 2026*, https://www.cms.gov/files/document/fact-sheet-negotiated-prices-initial-price-applicability-year-2026.pdf (last visited Apr. 22, 2025).
[12] National Community Pharmacists Association, *Report for January 2025 Survey of Independent Pharmacy Owners/Managers*, https://ncpa.org/sites/default/files/2025-01/1.27.2025-FinalExecSummary.NCPA_.MemberSurvey.pdf (last visited July 17, 2025).
[13] Anne M. Sydor, et al., *Could the Inflation Reduction Act Maximum Fair Price Hurt Patients?* J. Health Econ Outcomes Res. (Nov. 27, 2024) https://pubmed.ncbi.nlm.nih.gov/39629268/ (last visited Apr. 22, 2025).

nearly 75% of XARELTO claims and spend, should be excluded because Medicare plans are regulated by CMS, not Oregon.

J&J also shares multiple Board members' concerns about insufficient review time. Currently, the PDAB is scheduled to review five to six drugs per Board meeting. At the July 16 Board meeting, the PDAB spent little time reviewing each drug, and members noted that they would review updated drug data packets on their own time rather than revisiting these drugs at future meetings. Yet, private reviews undermine transparency and consistency. Instead, the Board should pause reviews until it develops a clear, evidence-based process, corrects Dashboard errors, removes irrelevant information, and reschedules reviews to allow proper assessment of each drug.

Lastly, stakeholders lack a predictable timeframe for oral comments and Board engagement. The agenda for the July 16, 2025 Board meeting did not specify estimated start times or durations for each topic. Public comment occurred after each drug was reviewed, but the time spent on each drug was inconsistent. Moreover, an hour will be added to each Board meeting moving forward. This format does not allow stakeholders to adequately predict when they may speak, many of whom may be unable to carve out four hours from their daily commitments. Moving forward, the Board should allocate time at the beginning and end of each meeting to facilitate meaningful stakeholder participation.

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 innovation ecosystem. We know that patients are counting on us to develop and bring medicines to market. 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. To learn more about our efforts, please see Johnson & Johnson's 2024 Transparency Report, available here: https://policyresearch.jnj.com/2024transparencyreport.

Sincerely,

Michael Valenta

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

August 15, 2025

VIA ELECTRONIC FILING

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

Dear Members of the Oregon Prescription Drug Affordability Board:

GSK appreciates the opportunity to submit comments to the Oregon Prescription Drug Affordability Board (PDAB) regarding its affordability review of Trelegy Ellipta (Trelegy). 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 patients. Our goal is to work in the best interests of patients and for the good of our company; we systematically use a value-based framework to look 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.

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, highly effective treatment option for patients with severe asthma and/or COPD. Use of Trelegy results in improved outcomes that drive downstream cost savings such as reduced hospitalizations, and Trelegy may prevent escalation to more expensive biologics for some patients with severe disease.

For the reasons listed below, we respectfully request that the Board find Trelegy affordable for Oregon residents.

1. Trelegy Provides Significant Value to the State of Oregon and to Patients

Trelegy is a once-daily, single inhaler, fixed-dose combination of three highly effective molecules including 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/LAMA/LABA (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.

Clinical benefit in COPD

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) report offers non-biased, peer-reviewed guidance for clinicians treating patients with COPD. It is updated annually and

recognized by experts worldwide as the definitive standard for the management of COPD.[1] These guidelines recommend ICS/LAMA/LABA 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/LABA and LAMA/LABA).

The only other single inhaler triple therapy (SITT) available in the US is Breztri. For this reason, GSK agrees with the PDAB that it is the most appropriate therapeutic alternative to Trelegy. Unlike Trelegy which is administered in one inhalation, once daily, Breztri 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] A network meta-analysis of 23 randomized controlled trials found a 38% reduction in the annual rate of moderate or severe exacerbations in patients using Trelegy compared to those using Breztri at 24 weeks post-initiation.[2] A 2024 real-world cohort study conducted by researchers at Harvard University also compared exacerbation rates in users of Trelegy and Breztri.[4] Compared to Trelegy, initiation of Breztri was associated with a 7% higher risk of moderate COPD exacerbation and a 29% higher risk of severe COPD exacerbation, defined by a COPD-related hospital admission. Both groups had the same incidence of first admission to hospital with pneumonia, suggesting a similar safety profile. Trelegy's one inhalation, once-daily regimen has also been associated with improved adherence and persistence compared with Breztri. In a real-world claims-based study, patients using once-daily Trelegy were 42% more likely than Breztri users to be adherent after 12 months.[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.[2,6,7,8,9] A retrospective claims study found a statistically significant 10% lower annual rate of severe exacerbations in Trelegy users compared to MITT users.[7] This trend is aligned with another real-world retrospective claims study of patients who initiated Trelegy after previously

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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] 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.

[8] Hanania, N.A., et al. "COPD Exacerbations, Costs, and Health Care Resource Utilization Before and After Initiation of Fluticasone Furoate/Umeclidinium/Vilanterol in Routine Care in the USA." International Journal of Chronic Obstructive Pulmonary Disease, 2023. 18: p. 407-418.

[9] 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.

being treated with MITT, which found overall reduced exacerbation rates with Trelegy versus MITT.[8] Multiple studies have also demonstrated that as a one inhaler, once daily regimen, Trelegy is associated with improved adherence and persistence compared to MITT regimens. One retrospective cohort study found Trelegy users were about 2.5 times more likely to be adherent at 12 months compared to MITT users.[9]

Studies show that Trelegy is associated with improved adherence and outcomes whether compared to either Breztri or MITT. These differences in outcomes translate into reduced health care spending. For patients switching from MITT to Trelegy, COPD-related office visit costs, emergency department costs, and pharmacy costs were statistically significantly lower after 12 months.

Clinical benefit in asthma

Trelegy is the only approved single inhaler triple therapy for asthma. Breztri is not approved for asthma. 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.[10] 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.[11,12,13] A retrospective claims analysis evaluating patients switching to Trelegy from other asthma maintenance medications found a 41% reduction in the annual rate of exacerbations one year post-Trelegy initation.[11] Another study found that 12 months after initiating triple therapy, rates of adherence were 31% higher in users of Trelegy compared to those using MITT regimens.[13]

Again, improvements in adherence and outcomes drive reduced health care spending. Asthma patients progressing to Trelegy from dual therapy saw a 26 percent reduction in asthma-related medical costs due to lower rates of outpatient, emergency department, and urgent care visits.[14]

2. Trelegy is Affordable to the State of Oregon and to Patients

Based on a 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.[15]

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[10] 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.

[11] 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.

[12] 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.

[13] Busse, W. W., et al. "Adherence and Persistence to Single-Inhaler Versus Multiple-Inhaler Triple Therapy for Asthma Management." J Allergy Clin Immunol Pract. 2022 Nov;10(11):2904-2913.

[14] 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.

[15] Oregon Prescription Drug Affordability Board. Data for drug reviews. https://dfr.oregon.gov/pdab/pages/data.aspx.

At the federal level, 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 (e.g., those offered to payers/PBMs who operate within Medicare Part D and Medicare Advantage) 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 to payers to ensure access to 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.
    - Additionally, 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.[16] Notably, an IQVIA analysis found that manufacturer coupons help offset high costs and play a role in improving drug affordability.[17]
- 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.

3. Upper Payment Limits Could Create Access Challenges for Patients

While the Oregon 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. Most notably, while UPLs are touted as a policy tool to lower out-of-pocket costs for patients, effectuation will lead to numerous consequences across the supply chain and will pose notable risks to patient access. For example, payers state they expect formulary adjustments, including moving selected drugs and therapeutic alternatives to different tiers, as a result of UPL effectuation, resulting in barriers to access for patients who may have been previously stable on a medicine like Trelegy.[18]

Additionally, UPLs are likely to place additional financial burdens on pharmacies, as they do not establish a minimum threshold, creating the risk that pharmacies could be reimbursed below the acquisition cost for certain drugs.[19] As a result, pharmacies may not be able to keep the medicines that patients need in stock, disrupting care continuity and worsening health outcomes.

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[16] 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/.

[17] IQVIA. Medicine Spending and Affordability in the U.S. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/medicine-spending-and-affordability-in-the-us

[18] Partnership to Fight Chronic Disease, Payer Perspectives Confirm UPLs Will Likely Raise Costs and Hinder Patient Access to Medicines. https://b11210f4-9a71-4e4c-a08f cf43a83bc1df.usrfiles.com/ugd/b11210_1e92735a49744639ac37321c6320e8c8.pdf

[19] The Partnership for Safe Medicines. Prescription Drug Affordability Board Activity. https://www.safemedicines.org/2024/05/colorado-upls.html.

In conclusion, we urge the Board to find Trelegy affordable for patients in Oregon and ensure continued broad access and uptake given:

- The significant value Trelegy delivers to the Oregon health care system and its patients; and
- Its affordability for both the state of Oregon and its residents.

Thank you for the opportunity to provide comments and for considering this data and evidence. Please feel free to contact Christian Omar Cruz at Christian.O.Cruz@gsk.com with any questions.

Sincerely,

Molly Burich
Head of Public Policy
US Government Affairs, Public Policy and Patient Advocacy (GAPPA)

EACH PIC COALITION

August 18, 2025

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

RE: Public Comments on Affordability Review Meeting on August 20

Dear Members and Staff of the Oregon Prescription Drug Affordability Board:

The Ensuring Access through Collaborative Health (EACH) and Patient Inclusion Council (PIC) is a two-part coalition that unites patient organizations and allied groups (EACH), as well as patients and caregivers (PIC), to advocate for drug affordability policies that benefit patients.

We appreciate your continued efforts to strengthen Oregon's drug affordability review process. However, we are concerned that the current affordability review process is moving too quickly and without a clear, patient-centered foundation.

The board is still finalizing its methodology for evaluating affordability, yet the review process is already halfway complete. During the last meeting, several members expressed uncertainty about how affordability is being assessed. This lack of clarity risks inconsistent determinations and undermines public trust in the process.

Equally troubling is the limited time available for meaningful discussion of each drug under review. During the July meeting, only a cursory conversation was held on the first six drugs under review due to time constraints. When a board member asked if more time could be allotted, the answer was that the evaluation could be done individually, outside of public discussion. This approach risks reducing transparency, undermining deliberation, and diminishing the value of public participation.

Further, public surveys to date have had low participation rates, making it unclear how patient perspectives will be incorporated. Findings from our recent Patient Experience Survey underscore why a deliberate, transparent process is critical. Affordability is often shaped less by the drug's price and more by insurance barriers, cumulative health costs, and individual life circumstances. Many patients paying $0–$10 per month still reported unaffordability due to denials, utilization management, or other access challenges.

These realities must be built into the board's criteria before reviews move forward. The board should extend outreach, keep surveys open until robust participation is achieved, and expand beyond three-minute testimony to include patient roundtables or listening sessions for deeper insight. Only by starting with patient input can the board appropriately address patient needs.

Broadly, the process has become rushed and overly complicated. For these reviews to achieve their intended purpose, improving drug affordability for Oregonians, they must be deliberate, transparent, and based on clear, shared criteria. We urge the Board to slow down, revisit its

process, and ensure that both its methodology and meeting structure support thorough, informed evaluation.

Thank you for your continued commitment to improving drug affordability in Oregon. We appreciate the opportunity to provide this feedback and look forward to continuing our engagement with the board.

Sincerely,

Tiffany Westrich-Robertson
tiffany@aiarthritis.org
Ensuring Access through Collaborative Health (EACH) Coalition Lead

Vanessa Lathan
vanessa@aiarthritis.org
Patient Inclusion Council (PIC) Coalition Lead

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VIA Electronic Delivery

August 20, 2025

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

Re: August 2025 Oregon Prescription Drug Affordability Board Meeting

Dear Prescription Drug Affordability Board Members and Staff:

The Biotechnology Innovation Organization (BIO) appreciates the opportunity to provide comments for the Oregon Prescription Drug Affordability Board (PDAB)'s August 2025 meeting. Our comments below focus on the PDAB's Drug Review Scoring Framework and Metrics used in conducting the drug reviews included in the August PDAB Meeting Materials (Drug Review Scoring Framework).

BIO is the premier biotechnology advocacy organization representing biotech companies, industry leaders, and state biotech associations in the United States and more than 35 countries around the globe. BIO members range from biotech start-ups to some of the world's largest biopharmaceutical companies – all united by the same goal: to develop medical and scientific breakthroughs that prevent and fight disease, restore health, and improve patients' lives. BIO also organizes the BIO International Convention and a series of annual conferences that drive partnerships, investment, and progress within the sector. Learn more at bio.org.

General Comments

BIO has long argued that the Board's premise behind establishing a drug review process is flawed. An overt focus on cost savings rather than patient value will harm patient access to lifesaving medication while failing to protect patients from harmful coverage restrictions imposed by plans and PBMs. The Drug Review Scoring Framework augments these concerns by assigning products as "unaffordable" rather than examining the system that determines whether patients can access a given product. Measures of patient access are not functions of manufacturer price. Whether or not a product is covered, the patient's out-of-pocket cost, and benefit design are determined by health plans and PBMs, independent of manufacturer pricing. Problematic coverage and benefit designs such as prior authorization and step therapy require targeted solutions to remove coverage barriers, rather than simply deeming a drug unaffordable. In fact, a designation of unaffordability would only worsen patient access concerns, as research has shown.[1] Given our critical concerns with the Drug Review

[1] Partnership to Fight Chronic Disease, "New Research Shows Prescription Drug Affordability Boards Will Not Benefit Patients." March 31, 2025. Retrieved: ://www.fightchronicdisease.org/post/new-research-shows-prescription-drug-affordability-boards-will-not-benefit-patients

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Scoring Framework and Metrics, BIO urges the Board to make significant changes and carefully consider stakeholder impacts before finalizing any materials.

Please note that our below comments on the Drug Review Scoring Framework should not be interpreted as endorsing the Board's actions, and BIO's positioning remains that the Board should not implement its affordability review process.

Drug Review Scoring Framework

It is evident that the Drug Review Scoring Framework will have negative impacts on patient access for any given therapy. Drugs deemed to be "unaffordable" may shift market-based access incentives and lead payers to reform their benefit designs. This in turn may reduce patient access to those medications. In addition, patient access could be harmed as providers change prescribing patterns for drugs subject to price setting. Patients who visit small provider practices and specialty providers may be disproportionately harmed if those providers cannot, or will not, access these drugs anymore because reimbursement for associated services is limited. Further, penalizing drugs with fewer or no therapeutic alternatives can be consequential, leading to further coverage limits when access is already a challenge. Instead of effectively addressing patient access, the Drug Review Scoring Framework fails to recognize or understand the unique circumstances of specific disease areas and why there may be more or fewer therapies available to treat patients.

BIO is also concerned by the lack of scientific rigor of the Drug Review Scoring Framework, which has never been vetted publicly or validated in any way. As drugs are given a score of 0-3 based on "minimal" to "severe" impact, there is no clear indication of how value is determined and instead relies on subjective interpretation. It is especially problematic that there is no description or explanation for the established cut offs of what would be scored as "minimal" vs. "severe." As it stands, these cutoffs are extremely arbitrary with no indication of any evidence-based evaluation. There is also no consistency across how impact is determined across each "domain." Further, the designation of "somewhat more costly/effective" is also lacking in analysis and rigor necessary for a credible scientific assessment. The designation is unsupported by any quantitative evidence or clear criteria, which creates subjectivity and bias.

On page 11 of the meeting materials, the "key questions" posed are overly general and lack any consideration for the underlying factors or components of each "domain." For instance, under the domain "Enrollee Burden," the question "are enrollees facing high OOP costs with the drug?" does not consider the full range of out-of-pocket (OOP) cost data available to understand the role of high-deductible health plans, benefit designs, and other considerations determined by health plans and PBMs.

Throughout the meeting materials, it is evident that Medicare data is repeatedly referenced, including a comparison of Medicare costs per enrollee. This reference is in direct conflict with prior discussions by the Board, in which several members agreed that Medicare data is

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irrelevant to the Board's work and would create data inaccuracies given that the Medicare benefit design and coverage paradigm is significantly different than commercial and Medicaid coverage. Accordingly, we encourage the Board to exclude all references and uses of Medicare data.

The Drug Review Scoring Framework compares average OOP costs for selected drugs vs. therapeutic alternatives. BIO opposes the use of average OOP costs in this scoring, since average costs are inflated by outliers, which would misrepresent the OOP costs for most patients. Instead, a more accurate measure would be the median OOP cost, which aligns with the Board's existing policy of excluding drugs from review based on small number of patients (e.g., drugs with less than 1,000 enrollees). The Board should similarly apply median costs rather than average costs in the other comparisons of costs per enrollee. It is also unclear whether the OOP analysis accounts for co-pay coupons and patient assistance programs.

Under the section "Input from Specified Stakeholders," BIO is concerned by the significant lack of detail regarding patient perspectives. It is critical that direct patient feedback is highlighted in the report along with appropriate context. At a minimum, we recommend that a summary of patient perspectives should be included in the review summary for each selected drug. We cannot overemphasize the importance of engaging consistently with the patient community, particularly to gain relevant and impactful insight into the unique challenges of different patient groups.

***

BIO appreciates the opportunity to provide feedback to the Board through these August meeting materials. We look forward to continuing to work with the Board to ensure Oregon residents can access medicines in an efficient, affordable, and timely manner.

Sincerely,

Melody Calkins

Director, Health Policy

Biotechnology Innovation Organization

COMMUNITY ACCESS NATIONAL NETWORK

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HIV/HCV Co-Infection Watch

National Groups:

Hepatitis Education, Advocacy & Leadership (HEAL) Group

Industry Advisory Group (IAG)

National ADAP Working Group (NAWG)

August 17, 2025

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

RE: Drug Reviews

Dear Honorable Members of the Oregon Prescription Drug Affordability Board,

The Community Access National Network (CANN) is a 501(c)(3) national nonprofit organization focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and support for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking.

While CANN is primarily focused on policy matters affecting access to care for people living with and affected by HIV, we stand in firm support of all people living with chronic and rare diseases and recognize the very reality of those living with multiple health conditions and the necessity of timely, personalized care for every one of those health conditions. State Prescription Drug Affordability Boards are of profound importance to our community.

Process Remains Unclear

At this point in the Board's deliberations, it was presented that affordability drug review discussions for multiple drugs would occur at each meeting in preparation for final determinations at the end of the year. Numerous stakeholders and board members had previously raised concerns about the number of reviews that were going to be executed, worrying that there would not be sufficient time for thorough affordability analysis.

After the July 2025 meeting, that remains a concern. During the that meeting, there was a robust discussion about the construction of the information packets and how the vast amounts of data included in the packets were not organized in a way that facilitated meaningful analysis. Board members also highlighted discrepancies in the data, including issues with the net and gross spend data, that need to be addressed before conclusions can be drawn appropriately, as the calculations and formulas were incorrect.

Most importantly, several board members highlighted that there is still no established board paradigm for affordability and no agreed-upon metrics to use in making affordability determinations. One example of unresolved deliberation was the question of how to utilize APAC versus Data Call data in determining affordability and impact.

There are a couple more meetings before the Board is slated to vote on nine drugs, plus an insulin product, to be deemed unaffordable in November. In light of the nebulous outcome of the first drug reviews, it is unclear at this juncture how these additional drug reviews will result in a robust affordability analysis of the impact on patients and the system for the drugs from the first meeting and all the remaining drugs on the docket.

We appreciate the time and energy the Board has been putting into attempting to engage in careful discussion, and its desire to "get it right this time". However, presently, the outcome of the current trajectory of deliberations is unclear.

Respectfully submitted,

Ranier Simons
Director of State Policy, PDABs
Community Access National Network (CANN)

On behalf of
Jen Laws
President & CEO
Community Access National Network

DCAN
DERMA CARE ACCESS NETWORK

August 18, 2025

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

RE: Selection of Cosentyx for the Oregon Prescription Drug Affordability Review

Dear Members of the Board,

On behalf of the Derma Care Access Network (DCAN), thank you for the opportunity to comment on the August 20th Oregon Prescription Drug Affordability Board 2025 meeting. DCAN writes to reiterate the importance of ensuring patient access to the dermatological medication, Cosentyx, from the 2025 prescription medication list for the Oregon Prescription Drug Affordability Review Board (PDAB) review.

The Derma Care Access Network is a national coalition of more than two dozen advocacy organizations representing patients, health providers, and other skin health stakeholders working to raise awareness of and inform policies impacting patient-centered care. DCAN sponsors educational initiatives and advocacy programs designed to encourage informed policymaking about the benefits of access to approved therapies and appropriate clinical care. These programs provide the foundational capacity for developing a network of engaged advocates who are trained, organized, and activated in furtherance of DCAN's mission.

DCAN recognizes the importance of lowering health care costs for patients, and we appreciate the Oregon Prescription Drug Affordability Board's intention to ensure affordable medications for Oregonians. As the Board moves forward with affordability reviews, DCAN urges you to consider the potential unintended consequences that an Upper Payment Limit (UPL) can have on patient access to the best available treatment.

The U.S. Food and Drug Administration (FDA) has approved Cosentyx (secukinumab) for six indications, including plaque psoriasis, psoriatic arthritis, and hidradenitis suppurativa (HS).[i] Cosentyx is one of the only FDA-approved medications to treat HS, which is a chronic skin condition that causes painful nodules or boil-like abscesses to develop near hair follicles and affects approximately one in every 100 people.[ii] According to the American Academy of Dermatology, HS typically presents between puberty and before 40 years of age.[iii] Because of the nature of HS, many patients with HS are in chronic pain that impacts their ability to work regularly. In fact, patients with HS lose an average of 34 workdays a year just due to the symptoms of the condition.[iv]

Recent findings from the National Institutes of Health (NIH) position Cosentyx as the primary treatment option for patients with moderate-to-severe HS.[v] Cosentyx has proven to be effective in alleviating the signs and symptoms of HS, regardless of whether patients have had prior exposure to biologic treatments. For patients with debilitating symptoms, policies that are likely to restrict

patient access to advanced therapies like that of Cosentyx risk undermining patient quality of life, physician decision making, and the stated goal of cost containment.

In the Board's affordability review of Cosentyx, it is important to consider potential disparities between real-world patient experiences and the data being used to inform affordability reviews. In a recent report from Ensuring Access through Collaborative Health (EACH) Coalition, patient survey results revealed that affordability, as defined by patients, is not limited to drug price or out-of-pocket costs; rather, it incorporates insurance design, financial assistance, and additional economic burdens associated with chronic illness.[vi] For example, although many patients may report that their medication is unaffordable, much of this labeling can be attributed to the drug's list price and additional out-of-pocket costs that stem from doctor visits, diagnostic testing, and more.[vii]

DCAN urges the Board to consider qualitative factors outside of the monetary cost of the selected medications for patients that impact patient perceptions of affordability in your review. Rather than capping the price of medications and potentially increasing barriers to patient access, focusing on improving patient support programs and insurance design could promote affordability of medications deemed unaffordable. It is critical that patients with chronic conditions like that of HS and plaque psoriasis have consistent access to all FDA approved treatment options to effectively manage their symptoms.

DCAN appreciates the Board's work in addressing prescription drug affordability for all Oregonians. At this time, we ask that the Board keep in mind the importance of protecting access to Cosentyx and other medications undergoing affordability reviews.

Sincerely,

Gabrielle Draper
Director of Advocacy & Policy
Derma Care Access Network

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[i] https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/125504s082lbl.pdf
[ii] https://www.nhs.uk/conditions/hidradenitis-suppurativa/.
[iii] https://www.aad.org/public/diseases/a-z/hidradenitis-suppurativa-causes.
[iv] https://pmc.ncbi.nlm.nih.gov/articles/PMC7379487/#:~:text=What%20does%20this%20study%20add,;%20181:7%E2%80%938.
[v] https://pubmed.ncbi.nlm.nih.gov/38470171/.
[vi] https://eachpic.org/wp-content/uploads/2025/08/FINAL-PIC-Patient-Experience-Survey-Prescription-Drug-Affordability-and-Unaffordability-1.pdf.
[vii] *Id. P. 5.*

August 17, 2025

Oregon Prescription Drug Affordability Board
Department of Consumer and Business Services
350 Winter Street NE
Salem, OR 97301

FROM:

Kim B. Sanders MPAS, PA-C
3303 S Bond Ave
CH16D
Portland, OR 97239

Jordan Praytor, MPAS, PA-C
16699 Boones Ferry Rd, Ste 210
Lake Oswego, OR 97035

RE: Selection of Cosentyx (secukinumab) for Oregon PDAB

Dear Members of the Oregon Prescription Drug Affordability Board,

My name is Kim Sanders, PA-C, and I am a dermatology Physician Associate (PA) of 20 years living and practicing in Oregon. Alongside me is my colleague, Jordan Praytor, PA-C, a dermatology PA with a special focus on hidradenitis suppurativa (HS). In our roles, we work closely with patients to identify the safest and most effective medications to help manage their conditions. Our shared priority is always to ensure patients have access to treatments that allow them to live with less pain and an improved quality of life.

For those with severe dermatologic diseases, such as hidradenitis suppurativa, these medications are not optional—they are essential. HS in particular is a chronic, painful, and debilitating disease that often goes unrecognized. At OHSU, we routinely receive referrals for the most severe cases from across Oregon, southern Washington and even Idaho. These patients come to us after years of suffering, often having exhausted numerous ineffective treatments and having seen many other dermatologists. They are desperate for relief, and when barriers to access exist, the consequences are devastating.

As clinicians, our foremost responsibility is to reduce suffering and improve our patients' quality of life. However, when access to proven, effective therapies is restricted, our ability to provide the best possible care is directly undermined. Barriers to treatment can mean prolonged pain, preventable disease progression, and avoidable emergency room visits and hospitalizations – all of which will increase the cost of care for these patients placing further financial burden on the system. Additionally, inadequately controlled HS can lead to the development of cancer – particularly squamous cell carcinoma (see example below). This type of cancer tends to be very aggressive and life threatening[1]. For HS patients, barriers to treatment mean additional surgeries, recurrent infections, an even greater burden of mental health challenges and could possibly lead to cancer and death.

HS is a chronic skin condition that causes painful nodules or boil-like abscesses to develop commonly in the axillae, groin, buttocks and chest. The condition affects approximately one in every 100 people. Because of the nature of HS, many of our patients are in chronic pain that impacts their ability to walk,

sit or lift their arms. It also causes significant drainage and often a foul odor. Our patients report the need for frequent bandage and clothing changes. Due to these circumstances, patients with HS lose an average of 34 workdays a year.[1][2]

Cosentyx (secukinumab) has six FDA-approved indications, including plaque psoriasis and hidradenitis suppurativa.[3] Cosentyx is one of only three medications with FDA approval to treat moderate to severe HS. As such, limiting access to this medication would have terrible consequences for these patients.

The first FDA-approved treatment for HS was granted in 2015 with the other two approvals coming in 2023 and 2024. Prior to this, treating HS was a frustrating endeavor. For many years, HS was managed using a combination of topical treatments, long-term antibiotics, and a range of surgical procedures—from incision and drainage to intralesional steroid injections and extensive surgical excisions to remove the skin from these areas. For those with severe disease, the therapies available at the time yielded only modest and often temporary improvement. Despite our best efforts, these patients often required multiple visits, repeated interventions, and, in severe cases, hospitalization with intravenous antibiotics just to achieve a minimal level of disease control. This approach is not only burdensome to patients—who endure chronic pain, emotional distress, and significant lifestyle limitations—but also places a considerable strain on the healthcare system due to the high cost of ongoing care.

While TNF-alpha inhibitors have provided meaningful relief for some, a substantial number remain non-responders who continue to suffer despite aggressive management. Additionally, many patients are not candidates for TNF-inhibitor therapy due to contraindications including a history of cancer, multiple sclerosis, nephrotic syndrome, etc. In these patients, our only biologic option for severe disease remains IL-17 inhibitors, such as Cosentyx.

For these patients, alternate biologic therapies offer a critical lifeline. Cosentyx has the potential to transform the lives of patients with HS. It can dramatically reduce disease severity, decrease the need for polypharmacy and invasive procedures, and significantly minimize healthcare utilization. Most importantly, it gives patients a chance to reclaim their quality of life.

Cosentyx is one of the few FDA-approved options for HS and has been shown to improve signs and symptoms regardless of prior biologic use. Recent NIH findings even position it as a first-line choice for moderate-to-severe HS.[4] For many of my patients, it has been the turning point that allowed them to manage pain, maintain employment, and participate more fully in life.

A Strict Upper Payment Limit could lead to non-medical switching, where stable patients are forced to change from an effective therapy to a different and potentially less effective medication solely for cost

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[1] https://pubmed.ncbi.nlm.nih.gov/34075588/

[2] https://pmc.ncbi.nlm.nih.gov/articles/PMC7379487/#:~:text=What%20does%20this%20study%20add,;%20181:7%E2%80%938.

[3] https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/125504s082lbl.pdf.

[4] https://pubmed.ncbi.nlm.nih.gov/38470171/

[5] https://eachpic.org/wp-content/uploads/2025/08/FINAL-PIC-Patient-Experience-Survey-Prescription-Drug-Affordability-and-Unaffordability-1.pdf

savings and not because of a clinical decision. Stability in treatment is critical for disease control, and once lost, it can take months or years to regain.

As you consider an Upper Payment Limit for Cosentyx, I urge you to think about the unintended consequences this may have on patient access. Affordability, as defined by patients, is about much more than just drug price, it includes insurance design, patient support programs, financial assistance, and the hidden economic burdens of chronic illness.[5]

As healthcare providers that see some of the most severe cases in the state, we urge you to look beyond the monetary cost when evaluating patient affordability. Factors including access to robust patient support programs and thoughtful insurance design can play a critical role in ensuring medications remain within reach, without introducing new barriers through strict price limits. For patients with HS, uninterrupted access to Cosentyx is essential to effectively manage their symptoms. We encourage you to consider these broader, real-world challenges when assessing affordability, so that treatment remains consistent and accessible for those who need it most.

Sincerely,

She/her
Associate Professor
Medical Director **I** OHSU Department of Dermatology
Director APP fellowship program
OSDA President

Jordan Praytor
Oregon Health & Science University
Department of Dermatology

To: Oregon Prescription Drug Affordability Board

From: James Grossell

Topic: Eliquis

Date: Aug. 17, 2025

I am a retiree living off a fixed income. My health insurance recently increased by several hundred dollars. Eliquis costs me hundreds of dollars per prescription even with drug insurance.

To: Oregon Prescription Drug Affordability Board

From: Karla Pearcy-Marston, Family caregiver

Topic: Eliquis

Date: Aug. 17, 2025

My mother, who is in her 90s and has a serious heart condition, has been on Eliquis for over a decade. Most of that time, she has been in the “donut hole” with her Medicare only coverage, currently paying approximately $2,000 on this one medication a year. We feel this is unsustainable and unfair to charge so much for Eliquis. We hope that a generic becomes available, so that this lifesaving drug can be available at a reasonable cost so as to avoid the cost burden on vulnerable senior Oregonians.

To: Oregon Prescription Drug Affordability Board

From: Susanna Askins

Topic: High cost of prescription drugs

Date: Aug. 17, 2025

It is despicable that the United States of America has a vast array of drugs/treatments that are only affordable to the wealthy. This is not what our country was founded on. Our country has truly become the United States of Greed.

OCAP OREGON COALITION FOR AFFORDABLE PRESCRIPTIONS

August 15, 2025

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

Dear Chair Bailey, Vice Chair Burns, and PDAB Board Members,

We'd like to thank you for the time and effort you have committed to this important work. **With the projected loss of $11.6 billion in federal funding for Oregon Health Plan (OHP) in the coming years as a result of the passage of H.R.1,[1] your work on prescription drug affordability is even more urgent.**

We are the Oregon Coalition for Affordable Prescriptions or OCAP, a coalition of Oregonians, including health care providers, nonprofit organizations, and community advocates, who believe that prescription drugs should be affordable and accessible to all who need them. Since 2017, we have worked to curb skyrocketing prescription drug prices and hold the pharmaceutical industry accountable for practices that have disproportionately harmed vulnerable Oregonians. **We are focused on lowering prescription drug costs through increasing transparency**, and in that spirit, we proudly reject funding from the pharmaceutical industry.

We would also like to thank the PDAB staff members for their work on the thorough reports included in your agenda packet, particularly the inclusion of health inequities. **Polling has shown that low-income residents and those living in Central and Eastern Oregon reported higher rates of rationing prescription medications due to cost, and Oregonians of color reported doing so at nearly twice the rate of white residents.[2]** As you move forward with affordability reviews, we again urge you to keep these communities at the forefront of your decision-making.

We find the pattern of industry group comments suggesting that the Oregon PDAB sets price caps to be concerning. **Declaring a drug unaffordable does not set a price**

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[1] Vanderhart, D. (2025, August 11). Trump's 'big beautiful bill' will slash $15 billion in federal money to oregon, kotek says. Oregon Public Broadcasting. Retrieved August 13, 2025, from https://www.opb.org/article/2025/08/11/oregon-braces-impacts-trump-budget-cuts-billions-federal-money/.

[2] 2024 Poll of Oregon Adults, Ages 18+, Altarum Healthcare Value Hub's Consumer Healthcare Experience State Survey, Table 1 https://healthcarevaluehub.org/chess-state-survey/oregon/2024/oregon-survey-respondents-worry-about-high-drug-costs-support-a-range-of-government-solutions/

limit; it simply initiates a legislative conversation about whether regulation is needed.

Industry comments, rooted in vague, misleading definitions of PDAB authority rather than the specifics of Oregon law, cause valid feelings of fear and anxiety among Oregonians, particularly for patients with few or no alternatives. **The threat of reducing access to life saving medication for Oregonians, simply because they *might* be subject to regulation is cruel and manipulative.**

Make no mistake, industry groups' primary focus is to improve their bottom line, not patient access or health outcomes.

Take the widely used medication, Eliquis; in 2023 nearly 60,000, or about 1 in every 100, Oregonians filled a prescription for it.[3] The patent for the active ingredient apixaban as used in Eliquis, was originally filed on September 17, 2002 and set to expire 20 years later in September of 2022, at which time a generic medication could have been produced. However, Bristol Myers Squibb and Pfizer, filed for and were granted a patent extension as well as five follow-on patents covering minor modifications. **These moves blocked a generic version of Eliquis from being sold in the United States until at least April 1, 2028, despite a generic version obtaining FDA approval in 2019.[4]**

Since its launch in 2012, the price of Eliquis has skyrocketed 129%, more than triple the amount of inflation. Currently, Bristol Myers Squibb and Pfizer are expected to collect **at least $50 billion in U.S. revenue from sales of Eliquis**, sales that would have had to compete with a generic version if not for their patent extension and follow-ons. Even the Medicare negotiated list price is significantly higher than the list price in other wealthy nations.[5]

We understand that the Oregon Prescription Drug Affordability Board does not have the authority to reform the U. S. patent system, but we share this with you to provide another perspective. One that invites you to question whether pharmaceutical industry groups are *really* doing everything they can to make prescriptions affordable for patients.

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[3]Whitlock, C., Kooyman, S., Choo, P.-C., Stiles, M., & Reddi, P. (2025). Oregon Prescription Drug Affordability Board Agenda Packet (pp. 44–76). Oregon Department of Consumer and Business Services. https://dfr.oregon.gov/pdab/Documents/20250820-PDAB-document-package.pdf

[4] Overpatented. (2025). Overpatented, Overpriced Overpatented, Overpriced . In I-MAK (pp. 4–5). The Initiative for Medicines, Access, & Knowledge (I-MAK). https://www.i-mak.org/wp-content/uploads/2025/06/Database-Brief-2025.pdf

[5] Overpatented. (2025). Overpatented, Overpriced Overpatented, Overpriced . In I-MAK (pp. 5–6). The Initiative for Medicines, Access, & Knowledge (I-MAK). https://www.i-mak.org/wp-content/uploads/2025/06/Database-Brief-2025.pdf

Finally, we would like to note that the Oregon PDAB meetings are held at a time of day that makes it difficult for the most impacted Oregonians to share their experiences. At the same time, the timing is very convenient for industry groups to attend. With this context in mind, we urge you to center the voices of Oregon patients as you continue the affordability review process now and into the future.

Thank you for the opportunity to submit these comments. Our board is available to support your work in any way we can. You can reach us at info@affordablerxnow.org or through BethAnne Darby at Strategies 360 Oregon.

Sincerely,
The Oregon Coalition for Affordable Prescriptions Board

OCAP OREGON COALITION FOR AFFORDABLE PRESCRIPTIONS

August 15, 2025

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

Dear Chair Bailey and Board Members,

Thanks for the hard work you are doing to address the impact of high-cost prescription drugs faced by Oregonians. I am pleased to see that a new rubric is in development for a consistent methodology when reviewing the chosen drugs. However, I am concerned that the accompanying scorecard lacks transparency into its origins, specifically whether the Board has voted to approve the language and scoring. Patient input is crucial in this process, and I want to know whether there will be any opportunity for it. From the packet materials, this is moving forward for this round of reviews, so I hope you will consider the following points.

Therapeutic Alternatives:

In the realm of medicine, **therapeutic alternatives, therapeutic equivalents, and biosimilars are distinct categories, and not all are interchangeable or considered "equal" in the same way; they should not be in the same domain.** Additionally, I don't understand the scoring in this domain. If there are no effective/affordable alternatives, then why would it receive a severe impact score? Is this approach solely focused on saving the state money? It's crucial to consider the patient's perspective -if there is no alternative for a patient, it is not in their interest to have it scored higher. **A patient-centered approach is essential in your evaluations.**

Stakeholder Input:

You have listed minimal stakeholder input as low impact. Are you sure? Was there proper outreach to that patient and provider community to ensure you are hearing from the people prescribing and taking that medication? Why are only concerns about cost evaluated, why aren't other concerns considered? Have you edited your patient survey posted on the website for drugs still under review to reflect the issues raised in the July meeting by Board members regarding the relevance of the data gathered?

Enrollee Burden:

Since APAC includes Medicare (high OOP) and Medicaid (zero OOP) data, it should not be an average. It also does not take into account patient assistance programs. Insurance coverage should be a separate domain. The EACH/PIC Coalition conducted its survey of patients, finding that insurance and financial assistance programs are essential. **100% of patients who said they stopped taking a drug due to affordability cited insurance-related reasons** like denials, prior authorizations, step therapy, or exclusion of copay assistance on Medicare.

Framework Overview:

There is no mention of how the scores will be collated and calculated as a whole. There is no definition for the score interpretation, leaving it very subjective, and each Board member may view these very differently through their lens. **A clear and transparent scoring methodology is crucial for the integrity of the process.**

Access and equity considerations:

The key questions in the rubric for this domain do not align with the scorecard interpretations in that domain. Is this an adequate equity measure? It might make sure for access, but shouldn't equity consider the racial disparities of the condition treated? Also, if a drug is non-preferred, that may be a plan design issue, a PBM issue, or a system issue; it is not necessarily the cost of the drug. Again, this domain in the scorecard is conflating insurance issues with drug pricing.

System and payer costs:

Does this criteria disproportionately impact chronic and rare disease communities?

Thank you for your attention to these comments and concerns.

Sincerely,

Lorren Sandt, Executive Director

724 Columbia St. NW, Ste. 310 • Olympia, WA 98501 • PHRMA.ORG

August 18, 2025

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

Re: Oregon Prescription Drug Affordability Board: July 16, 2025, and August 20, 2025, Agendas and Meeting Materials

Dear Members of the Oregon Prescription Drug Affordability Board:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is writing in response to the Oregon Prescription Drug Affordability Board's (the "PDAB's" or "Board's") agendas and meeting materials for its August 20, 2025, and July 16, 2025, meetings, including the 2025 Affordability Review Roadmap and scoring framework (collectively, the "Meeting Materials").[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. PhRMA member companies have invested more than $850 billion in the search for new treatments and cures over the last decade, supporting nearly five million jobs in the United States.

We provide below select comments and concerns with respect to the Meeting Materials.

I. Lack of Clear, Consistent, and Meaningful Standards in the Draft Scoring Framework

PhRMA has previously expressed concerns with the persistent absence of clear, consistent, and meaningful standards for Board processes.[2] While the aim of developing the draft Scoring Framework may be to provide a consistent method for evaluating drug affordability, we are concerned that additional work is needed to provide consistent and transparent application of the Framework within the Board's affordability review process. The framework relies on vague and inconsistent terminology that needs to be clearly defined in further revisions. PhRMA urges the Board to revise the draft Scoring Framework to also explain the differences between the scores in each domain, clarify how each metric is connected to patient affordability, and provide meaningful opportunity for public comment.

PhRMA highlights the following examples of the lack of clear, consistent, and meaningful standards within the draft Scoring Framework.

- **Vague and Inconsistent Terminology**: Several domains under the draft Framework lack definitions for their terms or use those terms in an unclear or inconsistent manner. For example, in the "Access

[1] August Meeting Materials (Aug. 20, 2025), *available at* https://dfr.oregon.gov/pdab/Documents/20250820-PDAB-document-package.pdf; July Meeting Materials (July 16, 2025), *available at* https://dfr.oregon.gov/pdab/Documents/20250716-PDAB-document-package.pdf. In filing this comment letter, PhRMA reserves all rights to legal arguments with respect to Oregon Senate Bill 844 (2021), as amended by Oregon Senate Bill 192 (2023) (codified at Or. Rev. Stat. § 646A.692 *et seq*.) (collectively, the "PDAB Statute"), and the Board's implementation of the PDAB Statute. PhRMA also incorporates by reference all prior comment letters to the extent applicable.

[2] Board, "Scoring Framework Overview" and "Prescription drug review worksheet," August Meeting Materials at 11-14 (the "draft Scoring Framework" or "draft Framework").

and equity considerations" domain, the Framework does not explain the differences between "minor," "clear," and "significant" disparities, or define the term "disparities" or explain how it applies in this context.[3] Similarly, in the "Specified stakeholder input" domain, Score 1 describes "moderate *financial concerns* noted" while Score 2 describes "significant concerns from providers/patients re: *cost/affordability*" without explaining how concerns in these areas, or their relative level of concern, are to be differentiated.[4] Further, in the "Price evaluation" domain, the average percentage wholesale acquisition cost ("WAC") change is measured over four years in the "Moderate Impact" column, but only three years in the "High Impact" column.[5] PhRMA urges the Board to revise the draft Scoring Framework to clarify these metrics and apply them consistently.

As PhRMA has previously commented, in order for the Board to conduct its work in a manner that is "rational, principled, and fair, rather than ad hoc and arbitrary," it must adopt comprehensive regulations governing each procedural step, factor, and methodology described for its affordability review processes through notice-and-comment rulemaking, consistent with the requirements of the Oregon Administrative Procedures Act ("APA").[6] Accordingly, before it uses the Framework to score any drug affordability reviews, the Board should adopt an APA-compliant process for implementing the Framework, including providing stakeholders an opportunity to comment.

- **"Access and equity considerations"**: PhRMA recognizes the Board's efforts to take both access and equity concerns into account; however, these are distinct factors that should not be conflated in the draft Scoring Framework.[7] The Board should consider revising the framework to evaluate access and equity separately. Additionally, the Board should clarify that pursuant to the requirements of the PDAB Statute, equity factors that the Board considers, including any "[s]ystemic disparities," must specifically relate to the particular drug under review to be factored into its scoring.[8] Additionally, the only metric of access in the draft Scoring Framework refers to formulary placement, a function of plan design.[9] Formulary placement is just one of many factors that impact a patient's access to medicine. The Board should clearly describe how elements of plan design (such as tier status, prior authorization, or step therapy) are being used in the scoring of affordability.

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[3] *Id.*

[4] August Meeting Materials at 13 (emphasis added).

[5] *Id.*

[6] *Gordon v. Bd. of Parole & Post Prison Supervision*, 343 Or. 618, 633 (2007). *See, e.g.,* Letter from PhRMA to Board (May 2, 2025) at 2; Letter from PhRMA to Board (Nov. 1, 2024) at 1 n. 4; Letter from PhRMA to Board (Feb. 17, 2024); Letter from PhRMA to Board (Apr. 16, 2023) at 1-2; Letter from PhRMA to Board (Feb. 11, 2023) at 1-2.; *see also, e.g.*, *Lane Cnty. v. Land Conservation & Dev. Comm'n,* 138 Or. App. 635, 641 (1996) (It is a "fundamental" principle of administrative law that agencies may not act in a manner contrary to their statutory authority); *Realty Grp., Inc. v. Dep't of Revenue*, 299 Or. 377, 383 n.3 (1985) ("The agency is bound to follow ... [a] rule until it replaces the rule, [and] the validity of a rule can always be challenged by one in a procedural posture to do so."); *Johnson v. Dep't of Pub. Safety Standards & Training*, 253 Or. App. 307, 317 (2012) (Agency actions cannot be upheld where they are "inconsistent with agency practice, or violate a statute or constitutional provision.").

[7] August Meeting Materials at 13.

[8] *See* PDAB Statute, Or. Rev. Stat. § 646A.694(1) (authorizing the Board to consider "[w]hether *the prescription drug* has led to health inequities in communities of color" (emphasis added)); Or. Admin. R 925-200-0200(1)(a), (2)(a) (authorizing the Board to consider "Whether the prescription drug has led to health inequities in communities of color" as well as "Whether the pricing of the prescription drug results in or has contributed to health inequities: (A) Under resourced communities; or (B) Regions with limited pharmacy access.").

[9] August Meeting Materials at 13 (listing "25%-49% plans listed drug as non-preferred", "50%-74% plans listed drug as non-preferred", and "75%-100% plans listed drug as non-preferred" as elements of Score 1 (Moderate Impact), Score 2 (High Impact), and Score 3 (Severe Impact) in the "Access and equity considerations" domain).

- **"Price concessions"**: The draft Scoring Framework would assess this domain based on both the percentage of claims for a drug that are discounted and the degree to which net costs are reduced.[10] However, combining these distinct metrics into a single domain would not provide a clear and comparable picture for how price concessions impact the affordability of a particular drug. For instance, a small set of claims with large discounts may provide more reduction in net costs overall than a high percentage of claims with more modest discounts. It is also unclear how the Board intends to distinguish between "net costs modestly reduced" and "moderate payer relief" as described in the Framework, particularly when the latter ostensibly reflects a more serious impact on affordability than the former.[11]

- **"Enrollee burdens"[12]**: PhRMA is concerned by the Framework's reliance on total annual patient out-of-pocket ("OOP") costs as a scoring element.[13] The total annual costs for a drug would not take into account costs per enrollee and would therefore bias affordability determinations against highly utilized drugs. The median OOP cost is a more accurate reflection of the costs faced by most patients because it considers cost at an individual level and, unlike average OOP cost, it is not inflated by outliers.[14] Using the median measure also aligns with the Board's existing policy of excluding drugs from review based on small sample sizes where data are more influenced by outliers.[15] PhRMA asks that the Board review this domain and consider whether there are additional measures that may provide a clearer picture for the patient cost experience with respect to a particular drug.

  Additionally, the Board should consider Medicaid OOP cost data in its assessment of patient burden. The revised Framework used in the August materials omits Medicaid claims from data on patient cost burden "due to the absence of Medicaid OOP costs."[16] Thirty-four percent of Oregonians are enrolled in Medicaid,[17] and the draft Framework would not accurately reflect patient burden—and thus could distort the Board's decision-making—by not considering Medicaid data.

- **Arbitrary Cutoffs**: PhRMA is concerned with the arbitrary cutoffs in the draft Scoring Framework and lack of explanation for the metrics and associated scores. For example, in the "Price concessions" domain, the Board provided no rationale for why "50-75% of claims discounted" is categorized as "moderate impact" and was assigned a score of 1, while "25-50% claims discounted" is categorized as "high impact" and assigned a score of 2. The Board should provide its rationale for setting the quantitative thresholds for these metrics.

- **Connection of Certain Affordability Metrics**: PhRMA is concerned that the draft Scoring Framework does not clearly articulate how each metric in the framework is connected to affordability and ultimately factors into the affordability review process. For example, the draft Scoring Framework should clearly describe how elements of plan design (such as formulary placement, preferred or non-

[10] *See* August Meeting Materials at 13.
[11] *Id.*
[12] Also note that Enrollee Burden, Score 3 references percent of prior authorization denied, but this metric is not included in the August reports. *See* August Meeting Materials, Tables 11.
[13] *Id.* at 11 (scoring the "[e]nrollee burdens" domain based on "[e]stimated *average* enrollee copayment or other cost-sharing") (emphasis added).
[14] *See* August Meeting Materials at 18, 34, 47, 64, 79, 96, 126, 143, 159; July Meeting Materials at 34, 66, 96, 129-30, 165, 199.
[15] *See August Meeting Materials at 19.*
[16] *See* August Meeting Materials at 34, 64, 96, 109, 126-27, 159.
[17] Oregon Health Authority, "The Dashboard: Medicaid Enrollment Report," https://www.oregon.gov/oha/hpa/analytics/pages/medicaid-enrollment.aspx#Dashboard.

preferred tier status, prior authorization requirements, or step therapies) have a bearing on the affordability of that drug and should be factored into the affordability review process. Likewise, the Board should clearly articulate how the presence or absence of a therapeutic alternative is connected to the affordability of a particular drug.[18]

II. Concerns with Data and Inconsistency of Information Considered by the Board

As PhRMA has noted in previous letters, the lack of clarity surrounding the data the Board relies upon to produce affordability review reports raises serious questions about those reports' reliability, and ultimately whether the Board can satisfy its obligation to conduct affordability reviews in a manner required by the PDAB Statute.[19] The Board should adopt procedures for reviewing and evaluating the accuracy and completeness of the information it will consider, and for permitting manufacturers and other stakeholders to provide input where information may be inaccurate or incomplete.

Apparent errors and inconsistencies in how these data are presented in the Board's affordability review reports raise additional questions. PhRMA notes the changes to the reports format in the August drug review materials from the July materials. Notably, all six affordability review reports published in July 2025 have calculations in the Tables titled "Estimated 2023 APAC total gross costs to the healthcare system" and "Estimated 2023 APAC gross cost to the payers" which appear to sum the averages of cost per claim and cost per enrollee, which would misrepresent the cost of these drugs. The same errors were not present in the August 2025 affordability review reports.[20] PhRMA asks whether the Board intends to revise and reissue the July drug review materials to align with the presentation of the August drug review materials prior to the Board voting on affordability reviews for those drugs. Below, PhRMA provides a non-exhaustive list of additional concerns regarding the presentation of data in the Board's affordability review reports.

Report Element	**Concerns**
Data dictionary and methodology	Providing a data dictionary or similar documentation regarding how the Board's data is sourced and compiled is a standard feature of reports that incorporate data from multiple sources. Specifically, "a shared data dictionary provides precise definitions for specific data elements and ensures that the meaning, relevance, and quality of data elements are the same for all users."[21] Documentation of the Board's evolving affordability review methodology, particularly with respect to the data elements it relies on for that methodology,

[18] *Id.*

[19] *See, e.g.*, Letter from PhRMA to Board 3-5 (Jan. 11, 2025); Letter from PhRMA to Board 4 (Nov. 26, 2024); Letter from PhRMA to Board 6-7 (Nov. 1, 2024); Letter from PhRMA to Board 3-4 (June 28, 2024); Letter from PhRMA to Board 1-3 (Oct. 15, 2023); Letter from PhRMA to Board 2-3 (Sept. 16, 2023); Letter from PhRMA to Board 2-3 (Apr. 16, 2023); Letter from PhRMA to Board 3-4 (Feb. 11, 2023); *see also, e.g.*, *Lane Cnty. v. Land Conservation & Dev. Comm'n*, 138 Or. App. 635, 641 (1996) (explaining the "fundamental principle of administrative law" that agencies may not act in a manner contrary to their statutory authority). PhRMA specifically reiterates its prior comments that the Board is required under the PDAB Statute to consider all information outlined in the PDAB Statute. Or. Rev. Stat. § 646A.694(1)(e), (j). PhRMA also remains concerned that the Board does not provide itself sufficient time to comprehensively consider the evaluation criteria and stakeholder input for each drug at its meetings. *See* Letter from PhRMA to Board 2-3 (May 2, 2025).

[20] *See* PDAB, Prescription Drug Affordability Board Meeting, YOUTUBE (July 16, 2025) at 1:55:55, https://youtu.be/wAl1u10eAM4?si=HkF9RHD4txecOSfz&t=6955 (comments of Board member Daniel Hartung, PharmD, MPH).

[21] Harvard Medical School, "What is a Data Dictionary?," https://datamanagement.hms.harvard.edu/collect-analyze/documentation-metadata/data-dictionary.

	would provide greater transparency and allow stakeholders to understand the elements of the Board's affordability reviews.[22] The Board's existing meeting materials, by themselves, do not provide adequate detail to describe how these data elements were compiled, including how specific calculations were performed and analyzed. Methodology documentation is necessary to ensure transparency and allow stakeholders to understand how conclusions were reached and to assess the validity of the findings. The Board should create a standardized data dictionary that provides definitions for each of the variables described in the Board's affordability review reports, as well as publish the methodology used to compile and calculate those variables, in order to provide transparent interpretability of the data the Board publishes its affordability reviews.
Reporting of gross vs net cost data	The affordability review reports state that data provided to the PDAB from the Department of Consumer and Business Services ("DCBS") commercial insurance carriers data call provide information on the "net costs [for a drug] after manufacturer rebates, PBM discounts, and other price concessions."[23] If data from the data call provides information on costs net of rebates then, compared to data from the Oregon All Payer All Claims ("APAC") database, the net cost of shown for drugs should presumably show a lower amount than the gross cost. However, in both the July and August meeting materials, several reports appear to demonstrate a higher net cost of drugs than gross cost prior to rebates and price concessions when comparing data call data to APAC data for the same drug.[24] Even within the carrier-reported data, conflicting prices are reported as net cost of drugs in various tables. The table titled "total net cost" shows a value in Total Annual Spend that does not match the value reported for total net "Cost after price concessions" in Table 2.[25] As PhRMA has previously discussed, the Board should clearly differentiate in its methodology between data showing spend (expenditure) and net costs to plans.[26] PhRMA's is concerned that the carrier data call, which is the data source that the Board's affordability review reports rely upon for certain elements, does not accurately differentiate between certain measures of gross expenditure and

[22] For example, the July and August meeting materials include multiple variable labels that may have ambiguous meanings without further detail as to how those elements were calculated (e.g., "payer paid"; "total payer paid"; "total spend amount"; "total cost/enrollee"; "unit").

[23] *See*, for example, August meeting materials at 19, 48, 80, 110, 144 ("Two primary data sources inform this review: the Oregon All Payers All Claims (APAC) database and the commercial carrier data call. APAC aggregates utilization data across all payer types in Oregon, including Medicaid, Medicare, and commercial plans, and presents gross cost estimates. In contrast, the data call reflects submissions from 11 commercial health insurers, and reports primarily net costs after manufacturer rebates, PBM discounts, and other price concessions.").

[24] *See* PDAB, Prescription Drug Affordability Board Meeting, YOUTUBE (July 16, 2025) at 1:55:45, https://youtu.be/wAl1u10eAM4?si=EdtS85q9AKg9comP&t=6945 (comments of Board member Daniel Hartung, PharmD, MPH) ("Sometimes in the net cost, gross cost … there would be some weird discrepancies where the net cost was higher than the gross cost ….").

[25] July materials tables 4 or 5, August meeting materials tables 9

[26] *See* Letter from PhRMA to Board 2 (Oct. 15, 2023).

	net cost.[27] Specifically, the carrier data call data definitions direct carriers to report: **Total Annual Plan Spending (Allowed Dollar Amount)**: The *total payments made* under the policy *to health care providers* on behalf of covered members, including payments made by issuers and member cost sharing.[28] Note: The total annual plan spending *should reflect the total after all rebates and price concessions have been applied*.[29] The lack of clarity in the data call definition may be related to the apparent inconsistency in gross and net costs in the reports. The Board should clarify these apparent inconsistencies.
Reporting of costs to healthcare system	According to the Oregon Drug Price Transparency Program's 2024 annual report, carrier-reported data comes from eleven carriers from the commercial market representing about 750,000 individuals, "representing about a quarter of all Oregonians."[30] While these data do provide insight on net costs of prescription drugs after rebates and price concessions, the Board should carefully consider whether the carrier-reported data reflects the overall "cost to the healthcare system." The reports similarly appear to use "Plan Spend" to refer to the total of "Payer Paid" and patient OOP costs.[31] For outpatient drugs, member cost sharing for medication is typically paid directly to the dispensing pharmacy and therefore should not be captured under total plan spending.
IQR	The August revised format presents tables with a column labeled "IQR" without definition or explanation. This may refer to the interquartile range ("IQR"), which is a statistical concept that is used to measure the distribution of data and identify outliers.[32] However, without further context, it is difficult to understand the implications of the magnitude of the calculation and its use for the analysis. The Board should consider whether presenting the IQR is the best data point to use to elucidate variability in the underlying data.

[27] Board, March 19, 2025 meeting materials 26-45 (Mar. 12, 2025), https://dfr.oregon.gov/pdab/Documents/20250319-PDAB-document-package.pdf (draft 2025 carrier data call); Board, January 2025 meeting materials 43 (Jan. 8, 2025), https://dfr.oregon.gov/pdab/Documents/20250115-PDAB-document-package.pdf.
[28] See also discussion regarding member cost sharing counting as payer spend, *infra*.
[29] Board, March 19, 2025 meeting materials 29, 31 (Mar. 12, 2025), https://dfr.oregon.gov/pdab/Documents/20250319-PDAB-document-package.pdf (emphasis added).
[30] Or. Dept. of Consumer and Bus. Svcs., "Prescription Drug Price Transparency Program results and recommendations – 2024," 43, https://dfr.oregon.gov/drugtransparency/Documents/20241121-dpt-hearing/Prescription-Drug-Price-Transparency-Annual-Report-2024.pdf.
[31] For example, tables 9 in the August meeting materials.
[32] Jim Frost, Statistics By Jim, "Interquartile Range (IQR): How to Find and Use It," https://statisticsbyjim.com/basics/interquartile-range/.

Oregon AAAC	The meeting materials characterize the Oregon Actual Average Acquisition Cost ("AAAC") as a benchmark for monitoring net price of a drug.[33] However, Average Acquisition Cost ("AAC") is a benchmark for what state Medicaid agencies reimburse pharmacies for the ingredient cost of the drug.[34] States separately invoice manufacturers for rebates (both statutorily required and additional supplemental rebates). AAC therefore should not be considered a measure of a public payer's net cost of drugs.
Medicaid Rebates	The Meeting Materials do not recognize or discuss the mandatory and supplemental rebates negotiated between manufacturers and Oregon Health Plan (OHP), which significantly reduce the amount that state pays for prescription medications. CMS data show that manufacturers rebate about $487 million, or 58% of Oregon's Medicaid drug spending, back to the state and federal government.[35] The Board's consideration of the "annual cost burden to Medicaid" is incomplete without such recognition.[36]
Price history	In Figure 2, CPI and "WAC % change" are graphed as a percentage change over time. The y-axis of the figure should be changed to accurately reflect the units as percent change, not US Dollars.

* * *

On behalf of PhRMA and our member companies, thank you for consideration of our comments. Although PhRMA has concerns about the Meeting Materials, we stand ready to be a constructive partner in this dialogue. Please contact dmcgrew@phrma.org with any questions.

Sincerely,

Dharia McGrew, PhD
Senior Director, State Policy
Sacramento, CA

Merlin Brittenham
Assistant General Counsel, Law
Washington, DC

[33] Board, August meeting materials at 24, 53, 85, 149 ("[T]he AAAC offers a more representative estimate of the net price incurred by Medicaid payers in Oregon, derived from regular pharmacy surveys conducted by the Oregon Health Authority.").
[34] *Compare* Dolan, R. and Tian, M., "Pricing and Payment for Medicaid Prescription Drugs," KFF, https://www.kff.org/medicaid/issue-brief/pricing-and-payment-for-medicaid-prescription-drugs/; *and* MACPAC Issue Brief, "Medicaid Payment for Outpatient Prescription Drugs," May 2018, https://www.macpac.gov/wp-content/uploads/2015/09/Medicaid-Payment-for-Outpatient-Prescription-Drugs.pdf *with* Or. Health Authority, "AAAC Reimbursement for Fee-for-Service Pharmacies," https://www.oregon.gov/OHA/HSD/OHP/Pages/AAAC-Rates.aspx ("AAAC rates are based on the actual cost (invoice) to the pharmacy for the drug dispensed plus a statistically validated dispensing fee.").
[35] Menges Group analysis of FFY2023 CMS Financial Management Reports (FMR) and State Drug Utilization (SDU) data files.
[36] *See* August Meeting Materials at 11.

Bristol Myers Squibb™

August 18, 2025

VIA ELECTRONIC SUBMISSION

Chair Shelley Bailey, MBA
Oregon Prescription Drug Affordability Board
350 Winter Street NE
Salem, OR 97309-0405
cortnee.whitlock@dcbs.oregon.gov

Re: Eliquis Affordability Review

Dear Chair Bailey and 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") regarding the upcoming affordability review of ELIQUIS (apixaban). As the Board's own data and other well-established evidence demonstrate that Eliquis is broadly affordable to patients and delivers substantial clinical, economic, and societal value, we respectfully urge the Board to remove Eliquis from any further review. We offer the following information in support of this request.

Patient Affordability

Affordability is best assessed by examining what patients actually pay out-of-pocket ("OOP") for their medicines. On this measure, Eliquis is affordable for patients across coverage types. For example:

[redacted]

- **Medicare**: According to the Board's data, most Medicare patients pay between $0-$49 per month for Eliquis.

The Board's patient survey, for which Eliquis received the highest response rate among all drugs, also found that the largest group of respondents pay $0-$49 per month. Where patients reported higher OOP costs, responses consistently attributed such costs not to any pricing of Eliquis itself, but to changes in pharmacy benefit design, such as shifts from fixed copays to coinsurance, deductible resets, or changes in formulary tier placement. These findings reinforce that Eliquis remains affordable for patients, and that higher OOP costs in isolated cases are driven primarily by insurance design choices, not the cost of the medicine.

[redacted]

Clinical and Economic Benefit

Eliquis delivers meaningful clinical benefits compared to warfarin, as consistently demonstrated in randomized controlled trials, and demonstrates greater effectiveness than other direct oral anticoagulants (DOACs) as seen in large-scale real-world studies involving U.S. patients. These substantial clinical benefits – lower risk of stroke, systemic embolism, and major bleeding – translate into both measurable and meaningful cost savings for the healthcare system.

[redacted]

By helping to reduce life-altering events such as strokes and major bleeding, Eliquis not only improves patient health and longevity but also reduces the significant personal and financial burdens these events impose on families, caregivers, and communities. [redacted] Reducing these events also helps reduce long-term disability and lowers reliance on long-term care services, which have also shown to be major drivers of increased healthcare costs, particularly with a steadily aging U.S. population.

Conclusion

The evidence before the Board demonstrates that Eliquis is affordable for Oregon patients, delivers proven clinical benefits that reduce the risk of serious and costly medical events, and generates significant economic and societal value. Together, these factors show that Eliquis represents not only an important therapeutic option for patients but also a sound investment for the healthcare system.

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.

[redacted]

Sincerely,

/s/ Anne Murray

Director, State & Local Government Affairs
Bristol Myers Squibb