Preserving Progress: Why America's Intellectual Property System is Vital to Innovation and Competition

Introduction

The U.S. biopharmaceutical industry is responsible for the development of the vast majority of new medicines each year, delivering innovative treatments for patients with conditions like cancer, heart disease, rare genetic disorders, and other costly and debilitating diseases. This is made possible by America's system of intellectual property (IP) protections. Our carefully crafted IP framework and market-based system also enables robust competition from both innovative medicines within the same therapeutic area as well as lower-cost generics and biosimilars.[1] As a result, U.S. patients have access to more medicines and are able to access those medicines faster than patients in any other country, including those in Europe where governments set prices.[2] The U.S. market's ability to harness competition has helped keep spending on medicines a small and stable share of total health care costs. Notably this share of spending is in line with our global counterparts.[3]

Our IP framework should be celebrated for its distinct ability to balance the important goals of fostering innovation and promoting competition to control overall health care costs. Unfortunately, however, critics often rely on a misguided understanding of the biopharmaceutical innovation model and the dynamics of the marketplace to call for reforms that purport to drive competition in the near-term but could put this longstanding and carefully balanced system at risk over the long term. Efforts to improve generic and biosimilar competition should instead focus on other aspects of the marketplace, such as reducing market distortions caused by middlemen and addressing the root causes of generic drug shortages. Addressing these aspects of our system, without disrupting our carefully balanced IP framework, will help ensure the system can help sustain the development of new medicines in the years ahead.

America's IP Framework: Balancing Incentives for Competition and Innovation

Patents and other forms of IP protection play an essential role in America's IP framework and in encouraging the development of new treatments and cures that improve patients' lives. Over the last four decades, Congress has established this carefully balanced framework, through the Hatch-Waxman Act (1984) (Hatch-Waxman) and the Biologics Price Competition and Innovation Act (2010) (BPCIA), to promote competition by generics and biosimilars, while at the same time providing critical incentives for continued innovation.

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[1] A generic is copy of a brand small molecule drug that is permitted to enter the market under the existing IP framework after a set period of time. Small molecules typically come in pill or tablet form and can be copied exactly. A biosimilar is exactly what its name implies: a medicine that is highly similar and has no clinically meaningful differences to a brand biologic medicine. Biologic medicines are made from living organisms and highly complex. For these reasons they cannot be exactly reproduced (hence the term biosimilars). Like generics, biosimilars are permitted to enter the market under the existing IP framework after a set period of time.

[2] PhRMA, Global Access to New Medicines Report, April 2023.

[3] Altarum Institute. "Projections of the Non-Retail Prescription Drug Share of National Health Expenditures." September 2020. Available at: https://altarum.org/publications/projections-non-retail-prescription-drug-share-national-health-expenditures; IQVIA. Drug Expenditure Dynamics 1995–2020: Understanding medicine spending in context, October 2021. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-expenditure-dynamics.

Hatch-Waxman and the BPCIA encourage the introduction of generics and biosimilars by creating abbreviated regulatory pathways for manufacturers of these products. These pathways allow for substantially shortened development time and cost compared to a traditional marketing application for a new drug by allowing generics and biosimilars to rely on valuable clinical data of the original branded product when obtaining approval from the Food and Drug Administration (FDA). Hatch-Waxman and the BPCIA also set forth patent litigation frameworks with clear processes and predictable timetables through which a generic or biosimilar manufacturer can challenge certain innovator patents in federal court without risking liability for patent infringement damages.

On the other hand, Hatch-Waxman and the BPCIA also foster investment in new medicines by setting periods of time before generic and biosimilar applicants can apply for or gain FDA approval. These periods provide certainty that should a medicine successfully reach the market, its manufacturer will be able to earn revenues on its substantial R&D investment for a period of time before facing generic and biosimilar competition. Though U.S. patent term is 20 years from application at the U.S. Patent and Trademark Office, the amount of time drug manufacturers can rely on patents to protect medicines is often significantly shorter due to the time needed to conduct clinical trials and seek FDA approval before companies can sell their medicines. Other forms of regulatory exclusivity separate from patents also provide critical IP protections by providing for a period of time, generally running on a timeline concurrent with any patents, during which FDA is prohibited from accepting or approving generic or biosimilar drug applications.

The certainty provided by IP protections is necessary for the development of new medicines due to the high costs and the low probabilities of success involved. Unlike products sold by other industries, on average it takes $2.6 billion and 10 to 15 years to develop a single medicine, with no guarantee of success. In fact, just 12% of drug candidates entering clinical trials are ultimately successful in obtaining FDA approval.[4] Patents and other forms of IP protection are designed to ensure that research-intensive biopharmaceutical companies have the necessary incentives to conduct their costly and lengthy R&D activities, particularly given the immense uncertainty inherent in the biopharmaceutical development process.

Importantly, America's IP framework is what fuels cost savings and competition by requiring innovators to publicly disclose information about their inventions in patents. This disclosure aids market entry of generic and biosimilar products after the brand product's patents and other IP protections expire. This swift entry fuels competition and drives down costs, benefiting patients and the healthcare system over the long term. It also encourages innovators to develop competing brand products different from others already on the market, which drives not only improvements in any given class but also brand-to-brand competition that further drives savings to the system and patients.

By many measures, America's IP framework has been a resounding success, promoting incentives for continued innovation and patient access to needed medicines while leveraging our market-based system to drive competition to achieve cost containment. Prior to passage of Hatch-Waxman, just 19% of prescriptions in the U.S. were filled with generics and only 35% of top-selling pharmaceuticals had generic competitors after their

[4] Joseph A. DiMasi, Henry G. Grabowski, Ronald W. Hansen, Innovation in the pharmaceutical industry: New estimates of R&D costs, Journal of Health Economics, Volume 47,2016, Pages 20-33, ISSN 0167-6296.

patents expired.[5] Today 90% of prescriptions filled in the U.S. are filled with generics or biosimilars,[6] offsetting spending on newer brand drugs and keeping spending on medicines a small and stable share of overall healthcare spending. Since Congress enacted the BPCIA in 2010, a robust biosimilars market has emerged in the U.S, with 38 biosimilars launched and competing on the market against 16 brand biologics.[7] The introduction of biosimilar competition into the biologics market has also led to dramatically lower prices not only for biosimilars, but also for brand biologics.[8] Overall, generic and biosimilar competition has resulted in $2.9 trillion in savings over the past ten years.[9]

Our robust IP framework is what has enabled America's decades-long leadership in the discovery and development of new medicines. Since 2000, biopharmaceutical companies have brought more than 750 new medicines to U.S. patients.[10] Last year, novel treatments and vaccines approved by the FDA for U.S. patients reached a five-year record high of 71.[11] This progress is only possible because of the significant R&D investments made by biopharmaceutical companies each year – totaling over $100 billion in 2022 by PhRMA member companies alone. Since 2000, PhRMA's member companies have invested more than $1.2 trillion in the search for new treatments and cures for patients battling serious life-threatening illnesses.[12]

It's also worthwhile to note innovation doesn't stop once a new medicine becomes available to patients. IP protections are critical in encouraging biopharmaceutical manufacturers to continue to conduct R&D to improve upon medicines after initial approval. Post approval R&D increases treatment options for patients by demonstrating, for example, that an existing medicine can treat a different disease or stage of disease, or a new dosage form is safe and effective or can be used in children. This research also leads to improved forms of medicines which can improve patient adherence and improve health outcomes.

IP incentives fuel not only innovation, but also competition among brands. As described above, brand medicines face robust competition from other generic drugs and biosimilars competing in the same therapeutic area, as well as other brand medicines. Big health insurance companies and middlemen in the system known as pharmacy benefit managers (PBMs) have historically leveraged these options to negotiate steep discounts and rebates on medicines to drive down net prices they pay for brand medicines. For example, less than a year after market entry of the first highly effective curative treatments for hepatitis C virus, multiple other competing brand products entered the market, some offering improved cure rates for patients. The resulting competition was so

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[5] Congressional Budget Office, How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry, July 1998; Michael A. O'Shea and Christopher M. Mikson, "The Hatch-Waxman Act: Still Critical, Still in Flux," The National Law Journal, January 23, 2006.
[6] Association for Accessible Medicines, The U.S. Generic & Biosimilar Medicines Savings Report, September 2023.
[7] https://www.amerisourcebergen.com/-/media/assets/cencora-biosimilars-usmarketlandscape-11mar24.pdf.
[8] Xcenda Issue Brief. Biosimilars are lowering costs in the Medicare Part B and across the healthcare system overall. Available at; https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_biosimilar_trends_issue_one_july2022.pdf.
[9] Association for Accessible Medicines, The U.S. Generic & Biosimilar Medicines Savings Report, September 2023.
[10] US Food and Drug Administration. Summary of NDA Approvals & Receipts, 1938 to the Present; US Food and Drug Administration. New Drugs at FDA: CDER's New Molecular Entities and New Therapeutic Biological Products 2012 – 2014.
[11] FDA, Center for Drug Evaluation and Research, New Drug Therapy Approvals 2023; FDA, Center for Biologics Evaluation and Research, 2024 Biological License Application Approvals.
[12] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Report-PDFs/A-C/PhRMA_membership-survey_single-page_70523_es_digital.pdf.

fierce that the average net cost for this class today is nearly 80% lower than the first product's launch price.[13] Taking a broader look at these dynamics, a recent Health Affairs study found that new brand medicines launched between 2013 and 2017 led to an immediate decrease in the average net price of competitors already on the market, generating more than $10 billion in savings across just 12 therapeutic classes.[14]

The competitive dynamics in the market for prescription medicines have worked successfully to balance innovation, patient access to new medicines and cost containment for decades. As a result of this system, U.S. patients also have broader and faster access to new medicines than patients in other countries, while keeping overall spending on medicines under control. Of all new medicines launched since 2012, 85% are available in the U.S., compared to less than 40%, on average, in Europe where governments set prices. In Europe, patients wait an average of two years longer for new cancer treatments compared to patients in the U.S.[15] And when generics enter the U.S. market, they make up a far greater portion of prescriptions than in other countries. They also tend to be cheaper here than they are abroad, with one recent study finding that generic drugs cost, on average, 33% less in the U.S. than in other countries.[16] Despite common misconceptions, the U.S. market's ability to harness competition has constrained spending on medicines to just 14% of total U.S. health care spending over the past decade – and is projected to remain a stable share of spending through the next decade – despite many new treatments quickly reaching patients with unmet needs. Notably, this is on par with the percentage of overall health care spending on medicines in other countries.[17]

Common Claims Misrepresent America's IP Framework

Despite many indicators that our carefully crafted system supports both innovation and competition, continued calls for short-sighted reforms threaten to throw America's balanced IP framework off-kilter. These reforms are often rooted in a fundamental misunderstanding of America's IP framework and the biopharmaceutical innovation model.

Claims of "product hopping" and "evergreening"

As noted previously, the process of developing a new medicine is long, costly and uncertain, and that path rarely ends with FDA approval. Whether reducing side effects, improving product quality, finding new diseases a medicine can treat, or developing a new way to make it easier for patients to take their medicines, patent protections incentivize innovators to continue working to improve their medicines for patients after FDA approval, which creates new competition in the marketplace.

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[13] S Silseth, H Shaw, Analysis of prescription drugs for the treatment of hepatitis C in the United States, June 2021. https://www.milliman.com/en/insight/analysis-of-prescription-drugs-for-the-treatment-of-hepatitis-c-in-the-united-states.
[14] S Dickson, N Gabriel, I Hernandez, Changes In Net Prices And Spending For Pharmaceuticals After The Introduction Of New Therapeutic Competition, 2011–19, Health Affairs, 2023. https://www.healthaffairs.org/doi/10.1377/hlthaff.2023.00250.
[15] PhRMA, Global Access to New Medicines Report, April 2023.
[16] https://www.rand.org/pubs/research_reports/RRA788-3.html.
[17] Altarum Institute. "Projections of the Non-Retail Prescription Drug Share of National Health Expenditures." September 2020. Available at: https://altarum.org/publications/projections-non-retail-prescription-drug-share-national-health-expenditures; QVIA. Drug Expenditure Dynamics 1995–2020: Understanding medicine spending in context, October 2021. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-expenditure-dynamics.

Allegations of so-called "product hopping" and "evergreening" inaccurately characterize the way America's IP system actually works and exaggerate the extent to which IP protections block competition. Patent law requires that all patented inventions be new, useful and non-obvious; this means a biopharmaceutical company cannot simply add patents to existing products or obtain patents for trivial changes to a medicine.

Moreover, earning a patent is an early step in developing a new medicine for patients. A patent is only protected from the date its application was filed, and it can be several years before a patent is granted. Once an initial patent is granted, innovators still typically spend years in clinical trials proving the safety and effectiveness of their drug before they can bring it to market. Because of the time spent running clinical trials, on average there is generic competition against a patented drug after it has been on the market for around 13 years, which is substantially less than the 20 years afforded to other products by the patent system generally.[18]

Most modern innovations, especially technologically advanced ones like medicines, encompass multiple inventions that may each be covered by an individual patent. Indeed, coverage of products by multiple patents is common across many industries as a patent can only cover a single invention. To put this into context, one of the best-selling golf balls has 60 patents alone, but those patents obviously do not prevent competitors from also making non-identical golf balls. Likewise, patents do not prevent competition from non-identical medicines that treat the same conditions. In fact, as noted previously, brand patented medicines often have many competitors that compete on both price and clinical effects.

Additionally, post-approval advances require supplemental applications (or even new applications) to the FDA, many requiring costly and labor-intensive Phase III clinical trials, which can take four years or more to complete and are held to the same rigorous FDA standards as the initial approval.[19] Patent protections are therefore sought to protect the investments that result in additional, critical benefits to patients. Despite misguided claims that post-approval innovation blocks competition, in reality, new patents protect only the *new* innovations – any earlier patents expire at the end of their term, and do not prevent FDA approval of generic or biosimilar copies of earlier products or uses. Moreover, new brand options will succeed only if they add value for patients because payers also have tools to drive generic and biosimilar use. If not, generic or biosimilar copies of the earlier forms are likely to be used. Moreover, generics are routinely substituted at the pharmacy counter for the prescribed brand drug.[20]

Similarly, patents on certain uses do not block generics or biosimilars from coming to market for any FDA approved uses (indications) not subject to IP protection. The FDA often permits both generic and biosimilar manufacturers to carve out indications protected by patents or other exclusivities from their labeling – a practice referred to as "skinny labeling"[21] – which allows generic drugs and biosimilars to enter the market before a brand drug's patents for other indications expire.

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[18] Grabowski HG, Long G, Mortimer R, Bilginsoy M. Continuing trends in U.S. brand-name and generic drug competition. J Med. Econ. 2021; 24:1, 908–917.
[19] FDA, The Drug Development Process, Step 3: Clinical Research.
[20] *See Bristol-Myers Squibb Co. v. Shalala*, 892 F. Supp. 295, 296 (D.D.C. 1995) (stating that a therapeutic equivalence rating "allows pharmacists to substitute the generic version of [a product] for the original product.).
[21] *See, e.g.*, 21 C.F.R. § 314.94(a)(8)(iv); Biosimilars and Interchangeable Biosimilars Guidance, *supra* note 17, at 3-4.

Patent settlement agreements

Generic companies can seek to market their products prior to patent expiration if they dispute the validity of any patents covering a brand medicine. Such disputes are litigated in federal court. Due to the costly and uncertain nature of patent litigation, competitors often enter into settlement agreements to resolve litigation and allow for generic or biosimilar entry. These settlement agreements do not extend the patent term of an innovator's drug. Even patent settlement agreements with so-called reverse payments, which some misleadingly called "pay-for-delay agreements," generally permit generics and biosimilars to enter the market *before* the branded version's patents expire, generating significant savings for consumers.

Furthermore, the Federal Trade Commission (FTC) has robust authority to review and evaluate individual patent settlement agreements for their potential anticompetitive effects. And the FTC is not shirking its watchdog role in this area: the FTC has aggressively investigated and litigated settlements that it believed violated the antitrust laws and continues to do so in the wake of a pivotal Supreme Court decision that provided a framework to challenge settlements on a case-by-case basis.[22] Since that decision, a 2019 FTC review of data on the frequency of pharmaceutical patent settlements indicated a decline in the number of settlements it considered to raise potential issues due to "changes in the prevailing legal standard."[23] As explained above, patent settlement agreements help both brand and generic/biosimilar manufacturers to avoid the costs and uncertainty of litigation. Therefore, proposals that make it harder for companies to enter into these agreements may harm generic and biosimilar manufacturers by reducing their incentive to challenge patents, as they would have fewer options to resolve a patent challenge in litigation.[24] These proposals may in turn discourage settlements that would have otherwise brought a generic or biosimilar to market sooner.

Authorized generics

An authorized generic is a generic version of a brand drug manufactured by the innovator or a third-party licensee under the innovator's original marketing application. Authorized generics have been shown to increase competition and save consumers money – without reducing incentives for generic competition or development of new products, contrary to claims that innovators use authorized generics for anticompetitive purposes. In fact, an analysis by the FTC found that "there is little evidence of authorized generic competition affecting the number of patent challenges."[25]

Citizen petitions

The citizen petition process, through which any individual can petition the FDA, is an important avenue for raising safety and public policy issues to the FDA through a transparent public process and is the required pathway for

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[22] *Fed. Trade Comm'n v. Actavis, Inc.*, 570 U.S. 136 (2013).
[23] FTC, Bureau of Competition, Then, now, and down the road: Trends in pharmaceutical patent settlements after FTC v. Actavis, May 2019. https://www.ftc.gov/enforcement/competition-matters/2019/05/then-now-down-road-trends-pharmaceutical-patent-settlements-after-ftc-v-actavis.
[24] *Asahi Glass Co.*, 289 F. Supp. 2d at 994; *see also In re Ciprofloxacin Hydrochloride Antitrust Litigation*, 261 F. Supp. 2d at 256 (to maximize incentives for generic entry in Hatch-Waxman, the generic company should be permitted not only to choose when to initiate a patent challenge, but also when to terminate patent litigation).
[25] FTC, "Authorized Generics: Short-Term Effects and Long- Term Impact," August 2011. http://www.ftc.gov/os/2011/08/2011genericdrugreport.pdf.

raising certain concerns with the FDA regarding abbreviated applications for generics or biosimilars.[26] The public nature of the citizen petition process affords all interested stakeholders an opportunity to provide input on issues raised in a petition, which contributes to both an informed FDA and an informed and engaged public.

Critics claim that innovative brand manufacturers misuse the citizen petition process to delay the entry of generics and biosimilars into the market. However, the FDA is authorized to summarily deny any citizen petition if it "determines that a petition or a supplement to the petition was submitted with the primary purpose of delaying the approval of an application and the petition does not on its face raise valid scientific or regulatory issues."[27] To date, the FDA has never invoked its authority to summarily deny a petition based on intent to delay. In fact, recent data suggests that concerns that citizen petitions are delaying approval of generics or biosimilars are overstated; FDA's most recent annual report to Congress on citizen petitions for abbreviated applications states that during fiscal year (FY) 2019, the agency received only 11 such petitions, but during this same period, FDA approved 935 generic applications and 11 biosimilar applications.[28]

Market Distortions and Drug Shortages Impede Generic and Biosimilar Competition

Critics commonly misrepresent and inaccurately characterize the biopharmaceutical innovation model and the dynamics of the marketplace to suggest America's IP framework impedes generic and biosimilar competition. However, evidence shows perverse incentives exist in the biopharmaceutical marketplace that distort the market and impede access to generics and biosimilars.

PBMs impede generic and biosimilar uptake

PBMs exercise an enormous amount of influence in the prescription drug market, from negotiating rebates with manufacturers, setting up pharmacy networks, administering the pharmacy benefit on behalf of health plan sponsors, crafting utilization management protocols, setting up formularies, and operating mail order, specialty, and/or retail pharmacies. PBMs use their clout to demand rebates and fees tied to the list price of a medicine,[29] which experts say create perverse incentives that can lead PBMs to prefer medicines with higher prices.[30]

Evidence suggests that the largest PBMs routinely deny access to lower-cost products, including generics and biosimilars that would save patients money. Indeed, despite the availability of lower cost generic versions of many brand medicines, PBMs do not uniformly include these medicines on preferred formulary tiers. For example, in Medicare Part D, 57% of generic medicines were placed on non-generic tiers in 2022 (which are generally coverage tiers associated with higher patient cost-sharing and/or greater access restrictions), up from 36% in 2016.[31] Not only are these lower-cost products often placed at a disadvantage on formularies, but coverage of newly launched generic products has been slow moving. In 2021, just 21% of generic medicines

[26] *See* FDCA § 505(q)(1)(A); FDA, Guidance for Industry: Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act (Nov. 2014).
[27] Section 505(q)(1)(E) of the Food, Drug, and Cosmetic Act.
[28] https://www.fda.gov/media/143518/download.
[29] https://mailchi.mp/nephronresearch.com/pbmcompensation.
[30] https://phrma.org/Blog/ICYMI-in-WSJ-Same-Drug-Two-Prices-Why-the-Higher-Price-Prevails.
[31] Avalere (2022). 57% of Generic Drugs Are Not on 2022 Part D Generic Tiers. Avalere. https://avalere.com/insights/57-of-generic-drugs-are-not-on-2022-part-d-generic-tiers.

newly launched in 2020 were covered on Part D formularies and only 66% were covered on commercial formularies.[32] Similarly, starting in 2018, the three largest PBMs began excluding biosimilars from their formularies for patients with commercial insurance.[33] The prevalence of this practice has skyrocketed since then: as of 2022, 14 biosimilars were excluded from the formulary of at least one of the three largest PBMs.[34]

For example, newly available Humira (adalimumab) biosimilars have struggled to gain market share as PBMs have continued to prefer the brand, even though the brand was more costly to plans and patients. According to a recent report from IQVIA, biosimilar versions of Humira account for just 1% of the market.[35] Just 1 in 3 patients who were prescribed biosimilar versions were able to fill the prescription due to PBM and health plan access restrictions. Notably, if all adalimumab prescriptions were filled with biosimilars, patient costs would be reduced by 68% and employer costs would be reduced 58%. But PBM profits on the market for Humira and its biosimilars would be reduced by 84%.

The 340B program impedes uptake of biosimilars

Growth of the 340B Drug Pricing Program may also be interfering with the uptake of biosimilars and reducing patient access. The program was designed to help improve access to medicines for vulnerable, low-income patients through price reductions on outpatient medicines acquired by specific qualifying hospitals and federally funded clinics. However, the program has strayed far from its intended purpose with more and more hospitals keeping for themselves the significant "spread" between the total payments they receive from insurers and patients on 340B medicines and the low price at which they acquire those medicines. Research shows that market distortions driven by hospitals' pursuit of 340B profits on the "spread" are encouraging the prescribing of medicines with higher list prices and discouraging uptake of biosimilars in 340B hospital settings.[36]

As biosimilars generally enter the market with lower list prices compared to their corresponding brand biologic, they may offer smaller margins to hospitals than higher list price alternatives. In fact, a Milliman analysis found that 340B hospitals have lower utilization of biosimilars than non-340B hospitals among their commercially insured patients, potentially leading to higher patient out-of-pocket costs.[37] The study found that among commercially insured patients who paid cost sharing, those who received biosimilar products at 340B hospitals

[32] Medicines, A. f. A. (2021). New Generics Are Less Available in Medicare Than Commercial Plans. Association for Accessible Medicines. https://accessiblemeds.org/sites/default/files/2021-07/AAM-New-Generics-Are-Less-Available-in-Medicare-2021.pdf.
[33] https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf.
[34] https://www.xcenda.com/-/media/assets/xcenda/english/content-assets/white-papers-issue-briefs-studies-pdf/xcenda_pbm_exclusion_may_2022.pdf.
[35] https://biosimilarscouncil.org/wp-content/uploads/2024/04/04022024_IQVIA-Humira-Tracking-Executive-Summary.pdf?utm_source=costcurve.beehiiv.com&utm_medium=newsletter&utm_campaign=iqvia-makes-clear-where-the-blame-should-fall-for-the-broken-humira-biosims-market.
[36] https://mycoa.communityoncology.org/education-publications/studies/examining-hospital-price-transparency-drug-profits-and-the-340b-program-2022; T Hagan, "Biosimilars Advance in the Oncology Space," AJMC, April 2021; T Hagan, "COA's Okon Takes Aim at Biosimilar Misconceptions," AJMC, April 2021; R Gal, Moto Advisors, "Examining Hospital Price Transparency, Drug Profits, & the 340B Program," September 2021. https://communityoncology.org/wp-content/uploads/2021/09/Moto-COA-340B_Hospital_Markups_Report.pdf; P Kolchinsky. "When drug prices are a Trojan Horse for other costs, we all lose," July 14, 2021. Rapport. https://rapport.bio/all-stories/when-drug-prices-are-a-trojan-horse.
[37] https://www.milliman.com/en/insight/2020-outpatient-drug-spend-at-340b-hospitals.

in 2020 had 16% lower out of-pocket costs compared to patients who received the brand biologic at such hospitals that year. In other words, if 340B hospitals had biosimilar utilization rates that were in line with non-340B hospitals, patient out-of-pocket costs at 340B hospitals would generally have been lower.

Drug shortages can impede access to generics

Another challenge to a competitive biopharmaceutical marketplace is the growing incidence of generic drug shortages. While brand medicines are not immune from shortages, shortages tend to occur significantly more frequently among generic drugs.[38] Drug shortages can occur for many reasons, with manufacturing quality issues being a primary driver; other causes include production or supply chain delays and discontinuations of products or components.[39] Low profit margins for generic drugs have also driven consolidation among manufacturers to just a few players, resulting in a highly concentrated generic drug market that can exacerbate these issues.[40]

Policy Reforms Should Seek to Address Market Distortions and Drug Shortages

The evidence is clear that America's IP framework and patent system support a competitive market where more than 90% of prescriptions for medicines are filled with generics and biosimilars. This framework is critical to driving patient access and affordability, as well as health system sustainability, and maintaining strong incentives for continued investment in innovation. Heavy-handed reforms to our current IP framework will do little to bolster competition and may only reduce incentives for innovation. Efforts to drive greater competition and savings in the health system should look beyond patents and seek to address the underlying causes of misaligned incentives in our health care system such as the distortive effects of PBMs and generic drug shortages.

For example, addressing the underlying misaligned incentives that can lead PBMs to favor medicines with high list prices and large rebates over lower cost generics and biosimilars is critical to enabling a competitive biopharmaceutical marketplace. Additionally, policymakers could pursue a number of approaches, including policies to spur increased infrastructure investments by generic manufacturers, tax and other investment incentives for new manufacturing facilities and the expansion and enhancement of existing facilities to prevent generic drug shortages.

Addressing these market distortions can help support a more competitive marketplace for generics and biosimilars while preserving America's IP framework which has proven a remarkable success in incentivizing the development of new medicines in the United States over the years.

[38] IQVIA. Drug Shortages in the U.S. 2023. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/instutereports/drug-shortages-in-the-us-2023/drug-shortages-in-the-us-2023.pdf.
[39] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Fact-Sheets/S-U/Understanding-Prescription-Drug-Shortages_Apr-2024.pdf.
[40] https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Refresh/Fact-Sheets/S-U/Understanding-Prescription-Drug-Shortages_Apr-2024.pdf.

May 14, 2024

Oregon Prescription Drug Affordability Board (PDAB)
Re: April 17, 2024, board meeting
Submitted via email

Chair Bailey, Vice-Chair Burns and members of the board,

I am writing to express concern over remarks made by PDAB's Executive Director Ralph Magrish during the April 17, 2024, board meeting. During an update on upper payment limits, Mr. Magrish addressed a recent report by PhRMA, categorizing it as "inflammatory" and "fear mongering." Through the course of the update, the tenor of his comments came across as inflammatory and unprofessional, particularly his comment calling Pharmacy Benefit Managers "drug dealers."

We are not under the illusion that Mr. Magrish is neutral in the policy issues before PDAB, nor do we question the ability of PDAB staff to respond to comments provided by interested parties. We do, however, expect department and program directors to adhere to a level of professionalism as they facilitate important policy debates for Oregonians. So blatantly inserting personal bias into discussions—particularly when comments are directed at those who have not been afforded an opportunity to engage directly with the PDAB—does nothing but fuel harmful rhetoric and divisive approaches to critical conversations.

OBI's statement here is not about any particular policy proposal or item on the table for debate. It is about good government and process. Our foremost interest is in ensuring that Oregonians can rely on boards such as yours to foster healthy, productive and respectful debate.

Thank you for your consideration.

Best,

Katie Koenig

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PIPC Partnership to Improve Patient Care

May 14, 2024

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

Dear Chair Bailey and Mr. Magrish:

I am writing on behalf of the Partnership to Improve Patient Care (PIPC) to comment on the Oregon Prescription Drug Affordability Board's ongoing affordability review activities. Our comments follow letters sent to the Board urging it to avoid policies that would potentially discriminate by relying on discriminatory metrics such as the Quality-Adjusted Life Year (QALY) that have detrimental implications for access to needed care and treatment, as well as encouraging the Board to include patients and people with disabilities throughout its decision-making process.[1] I am writing to update the Board on recent federal policy developments that increase clarity on the state's obligations and limitations related to its use of discriminatory value assessments and to request robust engagement of patients and people with disabilities.

The State of Oregon has a long history related to the use of QALYs in developing its prioritized list of services under Medicaid. Over the last few years, PIPC was engaged in advocacy with the Health Evidence Review Commission (HERC) to shift away from the use of quality-adjusted life years (QALYs) and similar measures that discriminate. Recently, the legislature passed Senate Bill 1508 barring the use of generalized quality of life measures by statute.[2] We have been very concerned that the legislative provisions governing the use of QALYs and similar measures in legislation creating the Prescription Drug Affordability Board may be interpreted narrowly. Entities supporting the use of QALYs as the gold standard for value assessment, such as the Program on Regulation, Therapeutics and Law (PORTAL) and the Institute for Clinical and Economic Review (ICER), may be playing a role in the Board's decisions.

On May 9, 2024, the final new regulations governing Section 504 of the Rehabilitation Act were published, protecting the rights of people with disabilities in programs and activities receiving

[1] https://caringambassadors.org/pnw-advocates-confab/
[2] https://www.droregon.org/releases/landmark-legislative-healthcare-wins-for-people-with-disabilities

federal financial assistance.[3] In response to the proposed rule last year, PIPC joined 100 organizations and individuals on a letter supporting agency rulemaking to bar the use of quality-adjusted life years and similar measures in decisions impacting access to care.[4]

The U.S. Department of Health and Human Services' rule represents a critical step forward to protecting patients and people with disabilities and sends a strong message that we need better solutions for U.S. decision-making that don't rely on the biased, outdated standards historically used by payers. As described in the final rule, the new regulations would bar health care decisions made using measures that discount gains in life expectancy, which would include measures such as the quality-adjusted life year (QALYs) and the combined use of QALYs and equal value of life years gained (evLYG). The agency broadly interpreted what constitutes the discriminatory use of value assessment in its description of the rule, stating, "The Department interprets recipient obligations under the current language of § 84.57 to be broader than section 1182 of the Affordable Care Act, because it prohibits practices prohibited by section 1182 (where they are used to deny or afford an unequal opportunity to qualified individuals with disabilities with respect to the eligibility or referral for, or provision or withdrawal of an aid, benefit, or service) and prohibits other instances of discriminatory value assessment." As you may be aware, section 1182 of the ACA bars Medicare's use of QALYs and similar measures that that discount the value of a life because of an individual's disability. PIPC was pleased the final rules governing Section 504 would be interpreted as broader than section 1182.

The agency referenced both § 84.56 and § 84.57 as relevant to entities receiving federal financial assistance, which includes state Medicaid programs. For example, the agency stated, "Methods of utility weight generation are subject to section 504 when they are used in a way that discriminates. They are subject to § 84.57 and other provisions within the rule, such as § 84.56's prohibition of discrimination based on biases or stereotypes about a patient's disability, among others." Therefore, it will be critical for compliance with these rules that the Board understand the methods for generating the utility weights in any clinical and cost effectiveness studies that it may be using to make decisions to ensure they do not devalue people with disabilities. As PIPC and others noted in its comments to HHS, studies have confirmed inherent bias against people with disabilities in the general public, finding much of the public perceives that people with disabilities have a low quality of life.[5] Therefore, the potential for discrimination is significant when value assessments rely on public surveys, for example.

[3] https://www.govinfo.gov/content/pkg/FR-2024-05-09/pdf/2024-09237.pdf?utm_campaign=subscription+mailing+list&utm_medium=email&utm_source=federalregister.gov
[4] https://www.pipcpatients.org/uploads/1/2/9/0/12902828/pipc_504_comment_final.pdf
[5] Ne'eman Et. Al, "Identifying and Exploring Bias in Public Opinion on Scarce Resource Allocation During the COVID-19 Pandemic," October 2022, https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00504.

In summary, the new rules clarify that recipients of federal financial assistance, including Medicaid programs, may not rely on measures like QALYs.

Alternatively, PIPC recommends:

- The Board should engage directly with patients and people with disabilities to learn about their real-world experiences, consistent with recommendations from experts in the patient and disability communities.[6,7,8,9]
- The Board should collaborate directly with the patient and disability communities to solicit information. To date, we have seen very little participation from patients in the Board's meetings and listening sessions. We are also concerned that the Board did not develop its survey for patients in collaboration with patients. We have learned from other states how survey data may be misleading or fail to solicit the kind of information that is most useful to Board decisions.[10,11]
- The Board should respond to new federal regulations by making its process and decisions transparent related to its use of value assessments. We hope that the evidentiary basis for its decisions will be made public in a manner that is accessible and clear.

Thank you for your consideration of our comments.

Sincerely,

Tony Coelho
Chairman
Partnership to Improve Patient Care

[6] https://nationalhealthcouncil.org/wp-content/uploads/2024/03/Amplifying-the-Patient-Voice-Roundtable-and-Recommendations-on-CMS-Patient-Engagement.pdf
[7] https://www.pharmacy.umaryland.edu/media/SOP/wwwpharmacyumarylandedu/programs/PATIENTS/pdf/Patient-driven-recommendations-for-the-Medicare-Drug-Price-Negotiation-Program.pdf
[8] https://www.pcori.org/sites/default/files/PCORI-Engagement-in-Research-Foundational-Expectations-for-Partnerships.pdf
[9] https://thevalueinitiative.org/ivi-partners-with-academyhealth-to-address-economic-impacts-on-patients-and-caregivers/
[10] https://drive.google.com/file/d/1oYGIPVVLrXL7ZXeu-eZ2vLZEunPhzN3u/view
[11] https://drive.google.com/file/d/1hF5-4Lxf5IHNNHMunRVm-fBaDt6QF-M3/view

From: Michelle Cole
Tuesday, May 14, 2024
To: PDAB * DCBS <pdab@dcbs.oregon.gov>
Topic: Drug costs

I'm married to a soon-to-be 76 year old man with health problems. It's amazing to learn about the possible medications that would bring him relief and then we learn about the costs. Why create and market these drugs if nobody can afford them? I also, as part of my work, often hear from people (usually senior citizens) who are forced to choose between medication and rent or food. That's just not right.

Michelle Cole, Tualatin
Voices for Affordable Health

June 7, 2024

To the Members of the PDAB board:

My name is Ann Kitchen and I am a caregiver for my daughter who was lives with Ulcerative Colitis. I am writing today to provide feedback and comments for this prescription drug review and to let the board know how difficult it is for my daughter to live with this condition every day. She is reliant on her medications to live a quality life.

Living with UC is difficult not only for my daughter but for the extended family. My daughter works full time and has a very demanding job which at times, can be stressful which in turn, impacts her health. Her first experience with UC was 12 years ago. Flares and hospital stays were our new norm. She had to take medical leave from her job as did I in order to care for her as she was bedridden several times. After years of trying various medications and alternative medicines, a medication was found that put her into remission. The fact is however, that she is dependent on this medication to keep her in remission. She still has occasional flares. Over the past year, she has gone into a flare which requires me, as her caregiver, to either live with her or have her live with me while she balances the demands of the disease and daily life. Without her vigilance to keep the condition under control through medication, diet and life skills, she would have an even more difficult life experience.

Having access to her medications allows her to keep flares at bay and her general health in check. She is able to work and lead an active life. Although my daughter has health insurance, the co pays are high – as a single income household and the high inflation rates, she has, at times, had to have financial assistance to make her co-pay. That alone adds undo stress to an already tenable situation. As you consider and review these drugs, it is my hope that access to these drugs by people with chronic diseases is not hindered due to cost.

Thank you for reading my letter and considering not only the physical but financial hardships that patients and their family members who rely on these expensive drugs must manage.

Regards,

Ann M. Kitchen

Dear members of the PDAB board,

My name is Andrew Kitchen and I am a caregiver for a loved one that lives with ulcerative colitis. I am writing today to provide comments for this prescription drug review and to let the board know how difficult it is for my loved one, who lives with this condition every day, and how important these medications are to the quality of their life.

Living with ulcerative colitis is difficult. On a daily basis it is generally manageable but can require frequent bathroom visits. However, the condition does produce "flares" that can prove incapacitating, cause severe gastric distress, lack of energy and pain. When these flares occur, caregiving necessitates changes to diet, home assistance and emotional support.

Having access to these medications helps my loved one to be able to live as close to a normal life as possible. Perhaps most importantly the medicine allows my daughter to eat whatever food she wants – strict dietary rules were traditionally a means to deal with UC and that was extremely difficult to live with and very distressing for her. She is also able to travel freely and not remain tethered to home, this is a big psychological boost for her.

Luckily, my loved one has insurance, but the co-pays are still very high and it's important for the board to consider these costs, even for patients that have insurance.

Thank you for considering the real-lived experiences of patients and their caregivers during your deliberations.

Sincerely,
Andrew Kitchen

National
Multiple Sclerosis
Society

June 11, 2024

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

RE: National Multiple Sclerosis Society Comments on Ocrevus® Review

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

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

Background

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

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

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

National
Multiple Sclerosis
Society

Costs of Living with MS

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

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

MS DMT Commentary

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

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

National
Multiple Sclerosis
Society

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

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

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

Public Input and Meeting Processes

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

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

National
Multiple Sclerosis
Society

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

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

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

Sincerely,

Bari Talente

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

ICER
INSTITUTE FOR CLINICAL AND ECONOMIC REVIEW

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

June 14, 2024

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

Re: Comments on Ocrevus

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

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

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

ICER's findings on Ocrevus for Multiple Sclerosis 2023

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

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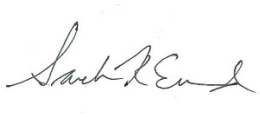
contextual considerations and potential other benefits, the potential budget impact and policy recommendations.

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

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

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

Sincerely,



Sarah K. Emond, MPP
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Attachments:

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

Genentech
A Member of the Roche Group

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

June 13, 2024

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

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

Dear Members of the Oregon Prescription Drug Affordability Board:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Ocrevus' price history highlights a focus on affordability.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

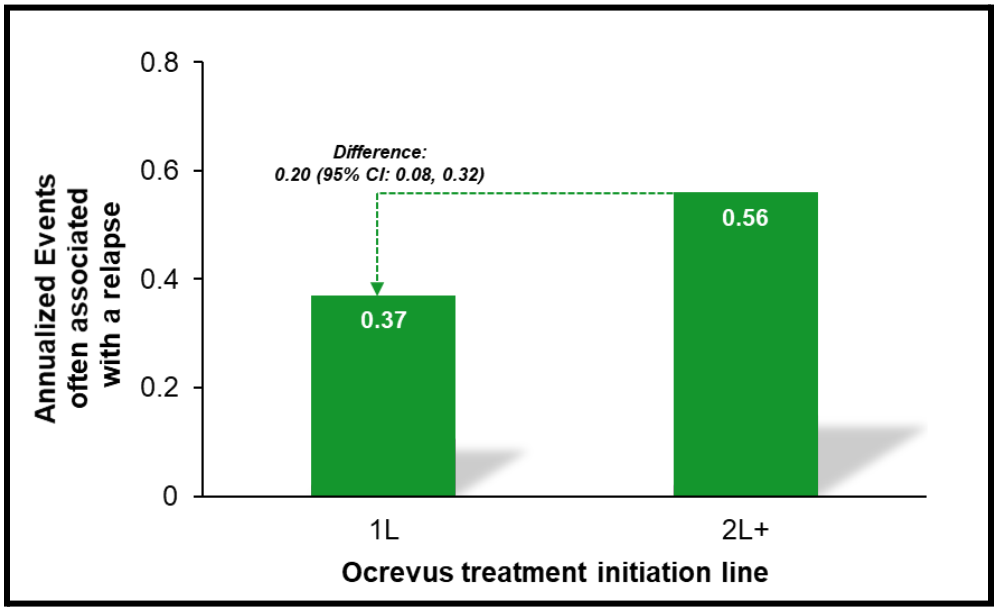
[26] Chen, Jing, et al. "Effects of multiple sclerosis disease-modifying therapies on employment measures using patient-reported data." *Journal of Neurology, Neurosurgery & Psychiatry* 89.11 (2018): 1200-1207.

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

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

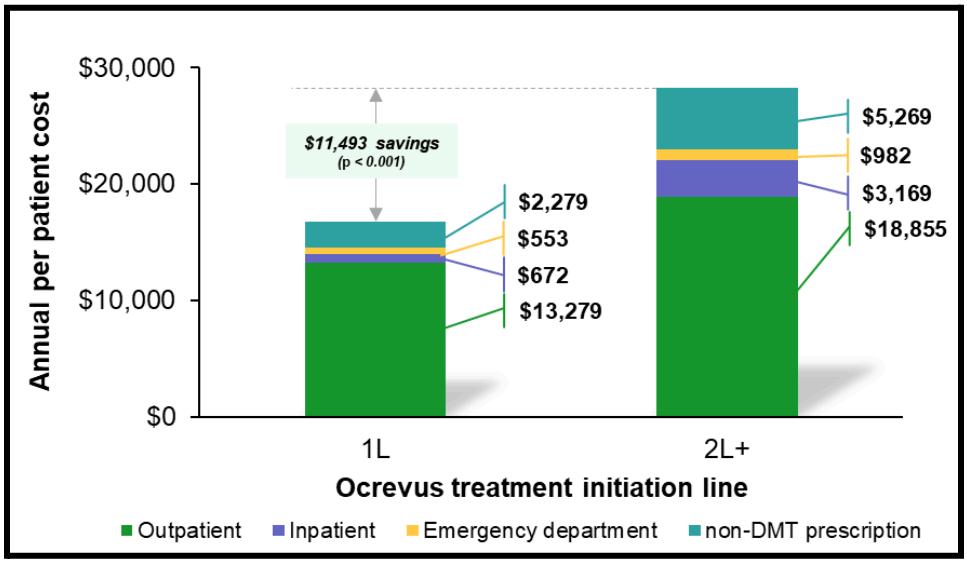
[29] Geiger CK et al. Real-World Clinical and Economic Outcomes Among Persons With Multiple Sclerosis Initiating First- Versus Second- or Later-Line Treatment With Ocrelizumab. Neurol Ther. 2023 Oct;12(5):1709-1728.

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



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

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



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

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

Ocrevus' Available Patient Assistance Supports Patient Affordability

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

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

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

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

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

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

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

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

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

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

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

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

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

Sincerely,

Mary Wachter, RN
Executive Director
State & Local Government Affairs

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

June 14, 2024

VIA ELECTRONIC FILING

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

Dear Members of the Oregon Prescription Drug Affordability Board:

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

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

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

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

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

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

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

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

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

2) Shingrix improves patient outcomes and reduces treatment costs

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

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

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

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

3) The CDC found Shingrix to be cost-effective

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

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

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

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

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

Sincerely,

Harmeet Dhillon
Head, Public Policy
GSK

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

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

SAFE COMMUNITIES COALITION

June 14th, 2024

Dear Members of the Oregon Prescription Drug Affordability Board:

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

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

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

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

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

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

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

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

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

February 26, 2024

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

Re: March 20, 2024 Ocrevus® Review

Dear Board members:

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

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

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

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

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

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

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

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

Sincerely,

Natalie Blake
Executive Director

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

msaa Improving Lives Today!®
Multiple Sclerosis Association of America

February 26, 2024

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

Re: March 20, 2024 Ocrevus® Review

Dear Board members:

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

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

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

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

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

Phone: (800) 532-7667 · Fax: (856) 661-9797
msaa@mymsaa.org · mymsaa.org

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

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

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

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

Sincerely,

Gina Ross Murdoch

Gina Ross Murdoch
President and CEO
Multiple Sclerosis Association of America

MULTIPLE SCLEROSIS ASSOCIATION OF AMERICA
NATIONAL HEADQUARTERS
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NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

June 14, 2024

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

Submitted via pdab@dcbs.oregon.gov

Re: Vaccine Eligibility

Dear Chair Bailey,

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

Vaccine Eligibility for PDAB Review

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

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

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

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

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

Sincerely,

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

cc: Oregon Prescription Drug Affordability Board Members

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

June 10, 2024

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

Re: June 26, 2024 Ocrevus® Review

Dear members of the Oregon Prescription Drug Affordability Board:

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

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

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

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

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

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

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

Sincerely,

June Halper

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

Kathleen Costello, MS, ANP-BC, MSCN
COO
Can Do Multiple Sclerosis

June 17, 2024

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

Dear Prescription Drug Affordability Board members,

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

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

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

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

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

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

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

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

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

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

Sincerely,

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

June 19, 2024

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

Dear Prescription Drug Affordability Board members,

My name is Katie Parker and I have lived with multiple sclerosis for the past 22 years. I am writing to let you know how important drugs like Ocrevus are to my quality of life, as well as the financial challenges those living with chronic conditions face in managing the cost of treatment.

Multiple sclerosis is a physically and mentally exhausting condition. In addition to chronic fatigue, nearly every day includes headaches and balance issues, as well as impaired memory. Living with MS is a constant day-to-day struggle with difficulty predicting when recurring and new symptoms will manifest.

Prior to beginning Ocrevus therapy, seven previous disease-modifying drugs taken over 15 years did not seem to slow down the progress of MS in my body. I regularly received steroid infusions to treat recurring flareups and began to feel discouraged.

I took Ocrevus for more than four years from 2017-21 before a life-threatening side effect forced me to discontinue its use. During the time I took Ocrevus, I faced far fewer MS relapses (flareups), and none required immediate immuno-suppressive intervention.

I have since been treated with another expensive disease-modifying therapy. Like many others suffering MS and other chronic diseases who are unable to work and have employer-based health insurance, I must rely on financial assistance to afford the drugs.

I worked full-time while managing MS for nearly 20 years, including the last 7 as a college professor, before becoming disabled. Even with social security disability insurance, my income and ability to survive financially is very difficult.

For Ocrevus and other prohibitively expensive drugs, I have had to complete a long and exhausting application process that has not always been approved. In one case, I spent nearly a year trying to get financial relief for a co-pay of nearly $6,000 for an MS therapy that had already been on the market for several years.

It is my hope that the board represent Oregonians like me in urging the legislature to enact laws that guarantee immediate access to innovative drugs like Ocrevus without the anxiety that comes with financial distress or uncertainty.

Thank you very much for anything the board can do to garner legislative support.

Sincerely,

Katie Parker
Hillsboro, OR
lilybelle.kp@gmail.com
971-506-5339

Kathleen Gardipee
2912 SW 153rd Drive
Beaverton, OR 97003
kmg052565@gmail.com

Dear members of the PDAB Board,

My name is Kathleen Gardipee, and I am a patient that lives with Psoriasis. I am writing today to provide comments for this prescription drug review and to let the board know how difficult it is to live with this condition every day and how important these medications are to the quality of my life.

Living with Psoriasis is very difficult. When I am unmedicated, my flares cover most of my body. It is itchy and painful. In addition, it has a profound impact on my psychological health. Prior to being on Tremfaya, I isolated myself from going out in public as I searched for help.

Having access to Tremfaya helps me to be able to live my life in normal ways. I am not covering my skin when I am around other people. I am not waking up to blood on my sheets. And, I feel a greater sense of confidence and happiness,

I have been lucky enough to have good insurance and help from the company that produces Tremfaya to make this affordable for me. I am an Executive Assistant, and my income would not even come close to being able to pay for the drug without this help. My life would be very different and painful.

As you consider and review these drugs, it is my hope that access to these drugs by not just me, but other people with chronic diseases, is not hindered due to cost.

Thank you for taking the time to read my letter and considering not only the physical but the financial hardships that patients and their family members who rely on these expensive drugs must manage.

Regards,

Kathleen Gardipee

Subject: Global Coalition on Aging concerns about Oregon Prescription Drug Affordability Board (PDAB)

June 26, 2024

Oregon Prescription Drug Affordability Board,

The Global Coalition on Aging (GCOA) is the leading business voice on aging-related policy. GCOA aims to reshape how global leaders approach and prepare for the 21st century's profound shift in population aging, uniquely bringing together global companies across industry sectors with common strategic interests in aging populations, a comprehensive and systemic understanding of aging, and an optimistic view of its impact.

We write to share our deep concerns about your inclusion of vaccines as a category for state-level affordability review. While we commend your commitment to finding solutions to address drug affordability and access challenges for Oregonians, the reexamination of vaccines through this process, while well-intentioned, is an inefficient use of Oregon's resources. More importantly, it fundamentally misunderstands the concept and value of immunization and threatens to undermine public health, healthy aging, and Oregon's fiscal sustainability goals.

The U.S. government already has a well-established and well-functioning system in place to evaluate the economic value and cost-effectiveness of vaccines. Through this process, every single FDA-approved vaccine undergoes rigorous review by the U.S. Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) before it can be accessed by the public or covered by public and private insurance. If the ACIP finds a vaccine to meet cost-effectiveness and economic value standards, as well as demonstrating clear public health value, it is approved for recommendation by the ACIP.

In addition, the Affordable Care Act and the Inflation Reduction Act mandate that all CDC-recommended vaccines are covered without cost-sharing for all publicly and privately insured individuals. This means that out-of-pocket costs are largely non-existent for Oregonians. Additionally, federal safety net programs provide access to vaccines without cost-sharing for uninsured and underinsured individuals.

Collectively, these federal initiatives ensure that vaccines – one of the most successful and celebrated preventive health tools available to us – are widely accessible and contribute to health equity goals throughout the United States. The establishment of an additional affordability review process for vaccines at the state level is both duplicative and redundant - ultimately, an inefficient use of public funds. Further, it can undermine confidence in and public understanding of the very premise of immunization, which is most effective and valuable to individuals and society when implemented at the largest possible scale.

Robust vaccine programs are a direct interest for Oregon's health system capacity, healthy aging, and fiscal sustainability goals. Countless studies have found that immunization is

consistently cost-saving at the population level, and the body of research supporting immunization for older adults continues to grow, underscoring its importance for 21st-century demographics.

Childhood vaccines are widely recognized as one of the greatest public health achievements of the 20th century and are in large part responsible for the healthier longevity we now enjoy. Amid the demographic transformation of the 21st century, with more and more of us living longer – in Oregon and globally – vaccines, especially those for adults, offer the promise of more years spent in good health and reduced spending by our healthcare systems.

This latter point is particularly critical for Oregon, whose population aged 65 and older is growing at a faster than the nation as a whole. Oregon's average age exceeds that of the national average, and the number of Oregonians 65 and older has increased by 32% since 2010.

Amid increasing pressures on government to spend smarter and invest in prevention, all must now prioritize widespread vaccination for all ages and particularly for older adults, where the largest gaps exist. Placing vaccines in a category for additional scrutiny directly conflicts with this growing imperative, a particularly urgent challenge for a rapidly aging state like Oregon.

Thank you for allowing us to share our concerns and for your commitment to finding solutions to Oregon patients' affordability and access challenges. We would be happy to discuss these concerns further or answer any questions you might have.

Sincerely,

Olivia Canie

Senior Associate, Global Coalition on Aging