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Oregon Prescription Drug Affordability Board
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Re: 2026 Preliminary Drug List - Ocrevus®, Perjeta®, & Xolair® Should Not Be Reviewed

Dear Members of the Oregon Prescription Drug Affordability Board:

Genentech appreciates the opportunity to submit comments for your consideration as you deliberate your preliminary drug list for possible selection and review in 2026. As you continue your discussions this month, we ask the Board to strongly consider the suitability of drugs on your preliminary list for an affordability review. Below we summarize the data that supports removal of Ocrevus, Perjeta, and Xolair from the Board's preliminary list of drugs for review in 2026.

1. As demonstrated in various prior Genentech submissions to the Board in 2024 and 2025 and the Board's own analysis included in its June 2024 meeting materials, Ocrevus is accessible and affordable for Oregonians, health systems and payers and should not be selected for an affordability review in 2026.

2. As demonstrated in prior Genentech submissions to the Board in 2025, Perjeta is not suitable for review as a medicine only used in combination with other therapies as part of a full treatment regimen for HER2-positive breast cancer. In addition, Perjeta confers significant clinical benefit and overall affordability to patients and the health care system and should not be selected for an affordability review in 2026.

3. Xolair is the first and only anti-immunoglobulin E (IgE) therapy approved by the FDA and as of its 2024 FDA approval for food allergies, is the only medication proven to reduce the risk of severe reactions (including anaphylaxis) from accidental exposure to multiple food allergens. An FDA-approved biosimilar was licensed in March 2025 (Omlyclo) and is expected to launch later this year. Further, CMS announced on January 26 that Xolair was selected for negotiation of a Medicare Maximum Fair Price (MFP). Finally, with both intravenous (IV) and subcutaneous (SC) formulations billed under pharmacy and medical claims, data from APAC and the PDAB data call may not accurately reflect true costs for payers, providers, or patients.

OCREVUS

As the Board's own draft report on Ocrevus from its June 2024 meeting materials concludes - Ocrevus is not only a critical disease-modifying therapy (DMT) for patients with multiple sclerosis (MS) and the only FDA-approved treatment options for patients with primary progressive MS (PPMS) - it is also an affordable option offering value to the health care system, payers, and society.

1. **Ocrevus is affordable and delivers high value to payers and health care systems:**
    a. In the materials from the June 2024 Board meeting, Ocrevus was identified as having the lowest average health care spend per enrollee per year relative to Board-determined therapeutic alternatives.
    b. Patients using Ocrevus as a first-line treatment had better clinical outcomes and lower health care resource use corresponding to payor savings of approximately $11,500 per year.[1]
    c. Ocrevus is priced lower than 15 other DMTs that represent treatment options for MS patients,[2] and has been consistently priced approximately 27% less than the average annual WAC for MS medications.

2. **Ocrevus delivers high value to Oregon and to society:**
    a. Oregon-specific disease modeling predicts improved access to first-line use of Ocrevus would lead to reduced long-term disability and increased productivity, corresponding to a potential savings of over $14 million to the state of Oregon over a 10-year period.[3]
    b. A separate national-level model predicted that over 10 years, productivity losses were lowest for Ocrevus compared to other DMTs with percent employment among patients treated with Ocrevus being highest compared to other DMTs (53.3% versus 41.7%) in year 10.[4]

3. **Ocrevus delivers high value to patients:**
    a. Ocrevus has established long-term benefits in slowing disease progression.[5]
    b. Patients treated with Ocrevus are highly adherent and persistent with therapy, corresponding to an average savings of $16,000 over two years in non-drug medical cost offsets per patient.[6]

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[1] 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.

[2] Genentech (2025 April). *Ocrevus® (ocrelizumab) Multiple Sclerosis (MS) WAC Flash Card.*

[3] Pineda E, et. al. National and State Population-Level Estimated Economic Impact of Ocrelizumab on Cumulative Disabilities Avoided and Work Productivity Under Different Access Scenarios in the United States. To be presented at ISPOR Annual Meeting. Montreal, QC. May 2025.

[4] 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.

[5] 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.

[6] 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.

PERJETA

1. **Perjeta is a targeted cancer therapy used in combination with other medicines as part of a complete treatment regimen - making it unsuitable for PDAB review.**
    a. Perjeta is a targeted cancer treatment and is FDA-approved for use in combination with trastuzumab and docetaxel in people who have HER2-positive breast cancer. It is important to consider that treatment of HER2-positive breast cancer, and many other cancers, consists of multi-therapy regimens to provide patients with the best possible clinical outcome. Given the complexities of combination treatment regimens and the limitations of the Board to fully collect and interpret patient-specific data, any affordability review of these medicines would be incomplete and inappropriate.

2. **Perjeta confers significant clinical benefit and overall affordability to patients and the health care system.**
    a. **Perjeta is recognized by leading US cancer guidelines with its highest level of recommendation.** Perjeta's indication in the adjuvant setting carries a National Comprehensive Cancer Network (NCCN) Category 1 Preferred recommendation, highlighting its clinical value to patients and the health care system.[7]
    b. **New data presented for the first time on May 15, 2025, show a statistically and clinically meaningful improvement in overall survival.**
        i. After ten years, the risk of death was reduced by 17% for people treated with the combination of Perjeta, trastuzumab and chemotherapy for a year as post-surgery (adjuvant) treatment, compared with individuals who received trastuzumab, chemotherapy and placebo. Further, a subgroup of people with lymph node-positive disease with high risk of recurrence experienced 21% reduction in the risk of death.[8]
    c. **Perjeta leads to approximately $106 million in total health care cost savings between 2013 and 2031 in Oregon based on scaled projections from a 2023 model.**[9,10,11]

XOLAIR

1. **Xolair is a first-and-only in class medicine offering patients a unique treatment option.**[12]

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[7]Gradishar WJ, et al. Breast Cancer, Version 3.2024, NCCN Clinical Practice Guidelines in Oncology. J Natl Compr Canc Netw. 2024;22(5):331-357.
[8] Loibi S, et al. Adjuvant pertuzumab or placebo + trastuzumab + chemotherapy (P or Pla + T + CT) in patients (pts) with early HER2-positive operable breast cancer in APHINITY: Final analysis at 11.3 years' median follow-up. Presented at ESMO Breast Cancer. May 2025.
[9] US Census Bureau Quick Facts. https://www.census.gov/quickfacts/fact/table/US/PST045224. Accessed April 2025
[10] US Census Bureau Quick Facts. https://www.census.gov/quickfacts/fact/table/US,OR/PST045224. Accessed April 2025.
[11] Sussell JA, Sheinson D, Wu N, Shah-Manek B, Seetasith A. HER2-Positive Metastatic Breast Cancer: A Retrospective Cohort Study of Healthcare Costs in the Targeted-Therapy Age. *Adv Ther.* 2020;37(4):1632-1645.10.1007/s12325-020-01283-4
12 U.S. Food and Drug Administration, "FDA Approves First Medication to Help Reduce Allergic Reactions to Multiple Foods After Accidental Exposure," news release, February 16, 2024, https://www.fda.gov/news-events/press-announcements/fda-approves-first-medication-help-reduce-allergic-reactions-multiple-foods-after-accidental.

a. First approved in 2003, Xolair is the first and only anti-immunoglobulin E (IgE) therapy approved by the FDA. Its anti-IgE mechanism of action affects multiple steps in the inflammatory pathway that lead to morbidity and mortality.[13]
b. Xolair is the only FDA-approved broad spectrum food allergy medication.
c. While therapeutic alternatives include other biological drugs that target subsets of XOLAIR's four indications, XOLAIR is the only agent approved for these indications with its unique mechanism.

2. **An FDA-approved biosimilar to Xolair is expected to launch this year, and Xolair was selected by CMS in January 2026 for negotiation of a Medicare Maximum Fair Price (MFP).**
    a. Omlyclo(TM) is a biosimilar to Xolair approved in March 2025 (in 25mg/0.5mL and 150mg/mL solutions) with an extra strength (300mg/2mL solution) approved in December 2025. Omlyclo is the first and only biosimilar designated as interchangeable with XOLAIR and is expected to launch later this year.
    b. On January 26, CMS announced that it had selected Xolair for review under the Medicare Drug Price Negotiation Program.[14]

3. **Complexity of Benefit Design of IV and SC formulations could lead to inaccurate conclusions of affordability challenges.**
    a. Xolair is unique in that it is often billed under either the medical benefit (office injection) or the pharmacy benefit (self-injection). The APAC database has historically struggled to cleanly aggregate these two different silos of data, leading to potential inaccuracies in calculating the true "affordability challenge" for the drug.

Based on these data and prior data shared by Genentech, the Board should remove Ocrevus, Perjeta and Xolair from its 2026 preliminary drug list and from further consideration for drug selection and affordability reviews. If you have any questions or want to discuss these data, 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

13 Genentech USA, Inc. and Novartis Pharmaceuticals Corporation, "XOLAIR® (omalizumab) Prescribing Information," (Reference ID: 5333161, revised February 2024), https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/103976s5262lbl.pdf.

14 Centers for Medicare & Medicaid Services, "Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2028," (Fact Sheet, January 2026), https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2028.pdf.