Oregon Prescription Drug Affordability Board

Manufacturer feedback submission

Drug under review	Ocrevus (ocrelizumab)
Manufacturer	Genentech USA, Inc.

Publication note: The information below was submitted by the manufacturer through the Oregon Prescription Drug Affordability Board manufacturer feedback form. Responses are presented as submitted, with minor formatting changes. Blank survey fields are identified as "No response provided." Contact and other form fields identified as not for public posting have been omitted. Manufacturer-submitted statements have not been independently verified unless otherwise stated in the drug review packet.

Manufacturer Responses

Question 1. Select the name of the drug.
Ocrevus (ocrelizumab)

Question 2. FDA approval pathway (select all that apply)
Standard; Priority review; Breakthrough therapy; Fast track

Question 3. Year of the first FDA approval
2017

Question 4. Is the drug currently marketed in Oregon?
Yes

Question 5. Number of FDA-approved therapeutic alternatives for the primary indication
None

Question 6. Are generic or biosimilar versions FDA-approved?
No

Question 7. Is the drug considered first-in-class for its primary indication?
Yes

Question 8. Does the drug currently have FDA recognized market exclusivity?
Yes

Question 9. Type of exclusivity (select all that apply)

Patent protection

Question 10. Earliest known expiration of exclusivity or patent protection

More than 3 years

Question 11. Does the drug have orphan drug designation from the FDA to prevent, diagnose or treat a rare disease or condition?

No

Question 12. Does the drug have FDA approval to prevent, diagnose or treat diseases or conditions that are not considered rare diseases?

Yes

Question 13. Does the manufacturer provide price concessions (rebates, discounts, etc.) for the drug in the U.S. market?

Yes

Question 14. Types of price concessions offered (select all that apply):

Rebates; Discounts; Administrative or service fees; Value-based arrangements

Question 15. Primary entities that receive price concessions (select all that apply):

Genentech considers the requested information to be trade secret, confidential, and/or proprietary data that is not otherwise available to the public (collectively, "Trade Secret Information"). Genentech takes reasonable efforts, consistent with industry practice, to maintain the confidentiality of this information and as such this sensitive data is subject to Genentech USA, Inc. confidentiality policies and procedures. For this reason, we have declined to provide these data in response to this request for information as the Board cannot protect the confidentiality of the Trade Secret Information. However, Genentech can affirm that we provide price concessions to commercial payers, pharmacy benefit managers and other health care entities across the United States, including a variety of customers that do business in Oregon. These voluntary, discretionary concessions are reflected in our publicly-available product Average Sales Price (ASP) data for J-Code J2350.

Question 16. Does the manufacturer offer patient financial assistance programs related to this drug?

Yes

Question 17. Types of patient assistant offered (select all that apply):

Copay assistance; Patient assistance program (PAP); Independent foundation support

Question 18. Are patients with public coverage (Medicare, Medicaid) eligible for any assistance?

The Genentech Patient Foundation, an independent 501(c)(3) organization, gives free Genentech medicine to people who don't have insurance coverage, have insufficient insurance coverage, or who have financial concerns and meet eligibility criteria. For more information, please visit https://www.gene.com/patients/patient-foundation.

Question 19. Are patients without public or private insurance eligible for any assistance?

Full response included in Question 23 response

Question 20. Is the drug commonly subject to utilization management (e.g., prior authorization or step therapy)?

Yes

Question 21. Which factors most influence the drug's list price over time? (select up to two)

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. These pricing decisions include our approach to contracting across the pharmaceutical supply chain and delivery system. These decisions are made with an eye toward supporting access to Ocrevus where clinically appropriate for the approximately 7,000 Oregonians living with MS.

Question 22. Does the manufacturer believe the drug's current pricing aligns with its clinical value?

Yes

Question 23. Any additional information the manufacturer chooses to provide.

[Question 5] Regarding our response to Question 5, Ocrevus was FDA-approved on March 28, 2017 for two primary indications: relapsing remitting multiple sclerosis and primary progressive multiple sclerosis. Ocrevus remains the only FDA-approved treatment approved for primary progressive multiple sclerosis and therefore has no alternatives for a primary indication.

[Question 14] Regarding our response to Question 14, Genentech considers "administrative or service fees" a separate category from price concessions like discounts and rebates. Although some administrative or service fees may be treated as a price concession for certain purposes, this is done on a case by case basis.

[Question 17] Regarding our response to Question 17, Genentech supports patients who cannot afford their out of pocket costs for medicines through donations to independent co-pay assistance foundations. Genentech does not influence or control the operations or eligibility criteria of any independent co-pay assistance foundation. For more information, please visit

https://www.gene.com/good/giving/corporate-giving/co-pay-foundation-charitable-support.

[Question 19] In 2024, Genentech provided approximately $3M of patient cost sharing financial assistance for eligible people living with MS including both intravenous and subcutaneous ocrelizumab formulations and its associated administration costs to patients in Oregon. However, Ocrevus Zunovo has its own FDA-approved label and unique NDC codes from Ocrevus and it is therefore out of scope of the Board's current drug selection and affordability review processes.. In 2023, prior to the launch of Ocrevus Zunovo, Genentech provided approximately $2.3M in such assistance.

The value of Genentech co-pay programs are intended exclusively for the benefit of eligible commercially insured patients. Genentech designs its co-pay programs to assist patients, not to provide value to payers. The entire amount of the co-pay program benefit is provided to patients to reduce their cost-sharing obligations. Genentech does not provide financial assistance directly to a commercial payer or any other entity. Further, we do not consider co-pay programs as price concessions or rebates.

This quoted co-pay assistance does not include support provided to patients through the Genentech Patient Foundation. The Genentech Patient Foundation, an independent 501(c)(3) organization, gives free Genentech medicine to people who don't have insurance coverage or who have financial concerns and meet eligibility criteria, as described in our response to Question 18.

To ensure clarity for the Board, Genentech notes that, on September 13, 2024, the FDA approved Ocrevus Zunovo™ (ocrelizumab & hyaluronidase-ocsq) for the treatment of relapsing multiple sclerosis (RMS) and primary progressive multiple sclerosis (PPMS). Ocrevus Zunovo has its own FDA-approved label and unique NDC codes from Ocrevus and it is therefore out of scope of the Board's current drug selection and affordability review processes.

Additionally, Genentech is submitting a separate letter to the Board addressing the addition of Rituxan and providing data and rationale for immediate removal of Rituxan as an alternative to Ocrevus. In addition, Genentech is submitting additional information on Ocrevus via email (the Ocrevus "value dossier"), as requested by the Board. under the instructions for this feedback form. Genentech also incorporates into its response and value dossier the data and information submitted to the Board on Ocrevus in four prior comment letters submitted in October 2023, November 2023, February 2024, June 2024, February 2026, and March 2026. Genentech requests the opportunity to meaningfully review and respond to information about Ocrevus submitted by other stakeholders or collected by Board staff prior to the Board's consideration of such information for the purposes of making selection and/or affordability determinations.