Oregon Prescription Drug Affordability Board

Manufacturer feedback submission

Drug under review	Xolair (omalizumab)
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.
Xolair (omalizumab)

Question 2. FDA approval pathway (select all that apply)
Standard

Question 3. Year of the first FDA approval
2003

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

Question 5. Number of FDA-approved therapeutic alternatives for the primary indication
1-2

Question 6. Are generic or biosimilar versions FDA-approved?
Yes, approved but not marketed

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?
No

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

For Xolair, while some of Genentech's patents, owned or licensed, have not yet expired, most of Genentech's patents on Xolair expired by 2025, and we currently anticipate that the first biosimilar versions will come to market in the US in 2026.

Question 10. Earliest known expiration of exclusivity or patent protection

No response provided.

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

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. 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 J2357.

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); Free or replacement drug program; 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?

In 2024, Genentech provided approximately $6.9M of patient cost-sharing financial assistance toward Xolair and its associated administration costs to eligible patients in Oregon. The value of Genentech co-pay programs is 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.

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.

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.

[Overall]: The manufacturer feedback form focuses heavily on price concession and financial assistance provided by manufacturers, ignoring key access metrics specified in OAR 925-200-020 that

are essential to assessing a drug's affordability to Oregonians. Further, many of these metrics are not adequately incorporated across all stakeholder feedback forms or the carrier data call. In addition to better alignment with the Board's statutory obligations, inclusion of these metrics in the eventual affordability reviews, with input from varied stakeholders, allows the Board to consider a more holistic view of a drug's value. For these reasons, Genentech is submitting additional information on Xolair via email (the Xolair "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 Xolair in prior comment letters submitted in February and March 2026. Genentech requests the opportunity to meaningfully review and respond to information about Xolair 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. The data included in this response, the additional information submitted in our value dossier dated May 6, 2026, show Xolair is not suitable for review and does not pose an affordability challenge in Oregon.

[Question 5 additional information]: Genentech answered this question by citing the primary FDA-approved indication for allergic asthma. Genentech recognizes that additional therapeutic alternatives may be identified for other indications, as recognized in our appended dossier.

[Question 6 additional information]: While the manufacturer feedback form asks for information from 2024, we provided an up-to-date response regarding Xolair biosimilars. Omlyclo, an interchangeable Xolair biosimilar, was FDA-approved in March 2025.

[Question 7 additional information]: XOLAIR was first FDA-approved in 2003, and is the first FDA-approved anti-immunoglobulin E (IgE) therapy, initially indicated for allergic asthma (primary indication).

[Question 10 additional information]: Genentech left the response for question 10 unanswered as it requires an explanation not afforded by the multiple choice nature of the question. For Xolair, while some of Genentech's patents, owned or licensed, have not yet expired, most of Genentech's patents on Xolair expired by 2025, and we currently anticipate that the first biosimilar versions will come to market in the US in 2026.

[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.