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XOLAIR DATA SUBMISSION DOSSIER - ATTACHMENT TO OR PDAB FEEDBACK FORM RESPONSE - MAY 6, 2026

Genentech appreciates the opportunity to share additional information relevant to the Board's affordability review process and encourages the Board to fully review this submission in conjunction with Genentech's response to the manufacturer feedback form. The manufacturer feedback form focuses heavily on price concession and financial assistance provided by manufacturers neglecting to address key access metrics specified in OAR 925-200-020 that are essential to assessing a drug's affordability to Oregonians. Further, many of these important access 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, would allow the Board to consider a more holistic, and accurate view of a drug's value. For these reasons, Genentech is submitting additional information on the value and affordability of Xolair as a supplemental response to Question 23 on the Board's manufacturer feedback form.[1]

Xolair, first approved in 2003, is the first FDA-approved anti-immunoglobulin E (IgE) therapy, indicated for allergic asthma, chronic spontaneous urticaria (CSU), IgE-mediated food allergy, and chronic rhinosinusitis with nasal polyps (CRSwNP). **As demonstrated by the data included in our feedback form response and this additional information submitted on May 6, 2026, Xolair is accessible and affordable for Oregonians, health systems, and payers.**

1. **"*Patient treatment preferences*" and patient and caregiver "*perspective on benefits and disadvantages of using the prescription drug*."**

   Xolair remains a preferred therapy among patients and caregivers.

   - Xolair was first approved by the FDA in 2003 to treat moderate to severe persistent allergic asthma.[2] Since then, it has received three additional FDA approvals for other conditions, and earned the ability to be safely administered at home via a pre-filled autoinjector or syringe rather than by a provider in a health care setting (after the initial three doses have proven to be well-tolerated), demonstrating continued scientific investment to meet additional patient needs.[3] Xolair's ease of administration, plus its robust safety profile and extensive track record of effectiveness, address unmet medical needs of significant swaths of the U.S. population across all ages.
   - In addition, while the biologic market has expanded substantially since Xolair's

[1] This complete response supplements drug-specific data provided to the Board on Xolair in two prior comment letters in February and March 2026.
[2] Genentech: The original biotech company [Internet]. South San Francisco: Genentech, Inc., 2026. Highlights of Prescribing Information. 2024 Feb [cited 2026 Feb 24]. Available from: https://www.gene.com/download/pdf/xolair_prescribing.pdf
[3] *I.d.*

initial FDA approval for moderate to severe persistent allergic asthma, Xolair remains a preferred therapy due to its unique mechanism of action and preferred risk-benefit profile.[4,5]

Xolair provides a single, inclusive treatment option for patients presenting with multiple conditions that commonly co-occur.

- Xolair is unique in that patients who present with one of its indications (e.g., moderate to severe allergic asthma) often present with another (e.g., IgE-mediated food allergy); it serves as a single treatment option for patients with multiple comorbid conditions, providing a therapeutic advance while simultaneously addressing an unmet medical need. Xolair therefore provides a significant benefit to patients who might otherwise need to be treated with multiple medications to address each of their various atopic or autoimmune conditions. By addressing multiple indications with one medication, Xolair reduces polypharmacy and patient out-of-pocket costs.

Xolair's flexible administration protocol provides options for patients and caregivers.

- Xolair's flexible administration protocol also allows for home-based self-administration following initial supervision in a healthcare setting for the first three doses.[6] The option to self-administer Xolair has significant benefits for underserved populations, including those in rural areas, due to the fact that the drug can be administered every two or four weeks, as opposed to allergy shots; the latter require more frequent doctor visits initially and may be stressful for many patients and burdensome for those who face difficulties traveling to see their physician for routine injections.

Xolair's approval in IgE-mediated food allergy represents a therapeutic advance addressing an unmet need for patients.

As the first and only biologic approved in 2024 to treat IgE-mediated food allergy, Xolair has an established reputation among health care providers as the preferred treatment option for eligible food allergy patients. No other biologic with this indication has been approved to date. Representing a significant therapeutic advance, Xolair is the sole therapy proven to reduce the risk of allergic reaction after accidental exposure across the full spectrum of food allergens, with great potential to improve the quality of life for patients.

2. **Input on "*the availability of therapeutic alternatives on the formulary.*"**

- In March 2026, the Board published a subset list of prescription drugs and insulin products for affordability reviews, which includes Xolair and the following drugs

[4] *I.d.*
[5] Zuberbier T, Abdul Hameed Ansari Z, Abdul Latiff AH, Abuzakouk MM, Agcaoili-De Jesus MS, Agondi RC, et al. The International Guideline for the Definition, Classification, Diagnosis and Management of Urticaria. Allergy. 2026 Feb 6.
[6] Genentech: The original biotech company [Internet]. South San Francisco: Genentech, Inc., 2026. Highlights of Prescribing Information. 2024 Feb [cited 2026 Feb 24]. Available from: https://www.gene.com/download/pdf/xolair_prescribing.pdf

identified by the Board as therapeutic alternatives across all indications: reslizumab, dupilumab, benralizumab, mepolizumab, and tezepelumb-ekko.[7]

- Each therapy, including Xolair, should also be evaluated in light of its full range of indications, as patients prescribed Xolair often have multiple comorbid conditions for which Xolair is indicated. Note that some therapeutic alternatives identified by the Board may not be applicable in certain circumstances, depending on which Xolair indication is being examined. We clarify this information in question 5 in the manufacturer submission form.
- Based on the gold standard EAACI food allergy guidelines, Xolair has no therapeutic alternative for the reduction of allergic reactions in patients with IgE-mediated food allergy.[8] It is important to note that Xolair is not indicated for the emergency treatment of allergic reactions, including anaphylaxis, that may occur with accidental exposure to one or more food allergens.[9]

- Estimates of national commercial and government payer coverage of Xolair vs. therapeutic alternatives in asthma using Managed Markets Insight & Technology (MMIT) data are provided below.[10]

Asthma

Client Status	Xolair Autoinjector	Xolair PFS	Xolair Vial	Tezspire (Pen)	Tezspire
Covered	13.39%	8.31%	8.01%	6.25%	10.92%
Covered (PA/ST)	80.44%	91.20%	90.97%	80.24%	82.38%
Not Covered	1.96%	0.26%	0.81%	8.51%	6.07%
Unknown	4.22%	0.23%	0.21%	5.00%	0.63%

3. *"Total Cost of the Disease and Drug Price Offset"*

Patients treated with Xolair show a reduction in overall health care resource use and high-cost interventions.

- Across indications, Xolair is associated with substantial improvements in disease-specific health-related quality of life (HRQoL) and a reduction in the overall clinical burden for patients with complex, co-occurring Type 2 inflammatory conditions. Patients with complex, co-occurring allergic, respiratory, and autoimmune conditions with poorly controlled symptoms frequently lead to high HCRU.
- By stabilizing these high-risk patients, Xolair directly reduces the frequency of ED visits, hospitalizations, unscheduled physician consultations, and the need for high-cost interventions, such as revision surgeries in Chronic Rhinosinusitis with Nasal Polyps (CRSwNP) and emergency management of accidental allergen

[7] Other therapeutic alternatives may be identified through separate processes,which use different definitions for therapeutic alternatives.
[8] Santos AF, Riggioni C, Agache I, Akdis CA, Akdis M, Alvarez-Perea A, et al. EAACI guidelines on the management of IgE-mediated food allergy. Allergy. 30 Oct 2024;00(00):1–23
[9] Genentech: The original biotech company [Internet]. South San Francisco: Genentech, Inc., 2026. Highlights of Prescribing Information. 2024 Feb [cited 2026 Feb 24]. Available from: https://www.gene.com/download/pdf/xolair_prescribing.pdf
[10] MMIT Coverage Data and DRG Payer Lives. Data as of April 2026.

exposures in food allergy that drive up the overall cost of care.

- Research shows that Xolair addresses rising health care system costs among patients with moderate to severe asthma by consistently reducing the clinical events that drive health care spending, including asthma exacerbations, asthma-related emergency department (ED) use, and asthma-related hospitalizations.
- In addition, data show that Xolair reduces HCRU costs across indications, as detailed below:
    - **Allergic Asthma:** Xolair addresses rising HRCU costs among patients with moderate to severe asthma by consistently reducing the clinical events that drive health care spending, including asthma exacerbations, asthma-related ED use, and asthma-related hospitalizations. In the INNOVATE trial, patients treated with Xolair had lower rates of total ED use (0.24 versus 0.43), hospitalizations (0.06 versus 0.12), and unscheduled physician visits (0.13 versus 0.24) than the placebo group.[11] These findings are reinforced by the PROSPERO registry, which saw an 81.9% reduction in the percentage of patients requiring hospitalization after 12 months of treatment.[12,13] A Cochrane Systematic Review of 25 trials found that Xolair led to an 83.3% relative reduction in asthma-related hospitalizations.[14] Real-world data mirrors these clinical results, showing significant declines in both the frequency and average number of hospital stays and ED visits following treatment initiation.[15] These improvements translate into broader health care cost savings.
    - **CSU:** HCRU among CSU patients generally takes the form of outpatient visits, which tend to be highest during the first year post-diagnosis, but it also includes ED use, hospitalizations, and urgent care visits; overall, HCRU is higher among patients with uncontrolled CSU.[16,17] Real-world data consistently demonstrate that Xolair provides significant clinical and economic benefits for patients with CSU. A retrospective observational cohort study using U.S. claims data from the HealthCore Integrated Research Database assessed HCRU among CSU patients prior to and

[11] Chu AWL, Oykhman P, Chu X, Rayner DG, Bhangal S, Dam A, Xu J, Sheikh J, Trayes KP, Frazier WT, Lang DM, Beck LA, Mathur SK, Waserman S, Thabane L, Asiniwasis RN, Runyon L, Moellman J, Oliver ET, Chan J, Cole EF, Baker DR, Khan DA, Ben-Shoshan M, Wheeler KE, Eftekhari S, Gardner DD, Winders T, Flindall M, Tattrie J, Bernstein JA, Saini SS, Chu DK. Comparative efficacy and safety of biologics and systemic immunomodulatory treatments for chronic urticaria: Systematic review and network meta-analysis. J Allergy Clin Immunol. 2025 Oct;156(4):1008-1023.
[12] The PROSPERO registry is an international database used to prospectively register systematic reviews on clinical outcomes to ensure transparency and prevent duplicate research efforts.
[13] Casale TB, Luskin AT, Busse W, Zeiger RS, Trzaskoma B, Yang M, Griffin NM, Chipps BE. Omalizumab Effectiveness by Biomarker Status in Patients with Asthma: Evidence From PROSPERO, A Prospective Real-World Study. J Allergy Clin Immunol Pract. 2019 Jan;7(1):156-164.e1.
[14] Akenroye AT, Segal JB, Zhou G, Foer D, Li L, Alexander C, Keet CA, Jackson JW. Comparative effectiveness of omalizumab, mepolizumab, and dupilumab in asthma: A target trial emulation. J Allergy Clin Immunol. 2023 May;151(5):1269-1276.
[15] Al-Shaikhly T, Norris MR, Dennis EH, Liu G, Craig TJ. Comparative Impact of Asthma Biologics: A Nationwide US Claim-Based Analysis. J Allergy Clin Immunol Pract. 2024 June;12(6):1558-1567.
[16] Ke X, Kavati A, Wertz D, Huang Q, Wang L, Willey VJ, Stephenson JJ, Ortiz B, Paknis B, Bernstein JA, Beck LA. Real-World Characteristics and Treatment Patterns in Patients with Urticaria Initiating Omalizumab in the United States. J Manag Care Spec Pharm. 2018 Jul;24(7):598-606.
[17] Seetasith A, Holden M, Hetherington J, Keal A, Salmon P, Bernstein JA, Casale TB. Real-world outcomes in patients with chronic spontaneous urticaria receiving omalizumab: insights from a clinical practice survey. Curr Med Res Opin. 2024 Jun 3:1-8.

following Xolair initiation (index date).[18] ED use dropped from 19.8% at baseline to just 10.7% after one year of treatment, with similar significant reductions specifically related to CSU.[19] While hospitalization rates remained consistently low, the decrease in ED utilization highlights Xolair's role in stabilizing patients and reducing the need for acute, high-cost medical care.

- **IgE Mediated Food Allergy:** A 2025 retrospective analysis of the IQVIA database showed that Xolair was associated with reductions in the prevalence of food allergy-related (12.4% versus 4.8%), asthma/food allergy-related (25.0% versus 15.5%), and all-cause (44.6% versus 30.2%; all P <0.0001) ED visits and hospitalizations (food allergy: 1.5% versus 0.2%; asthma/food allergy: 12.3% versus 7.4%; all-cause: 13.2% versus 7.5%), leading to a decrease in total food allergy-related health care costs per patient ($1600 versus $1502 USD 2023; all P <0.0001).[20]
- **CRSwNP:** On an individual level, adjusting for inflation, the average total health care cost is $23,697 per CRSwNP patient, which increased to $33,394 for those who undergo surgery (2025 USD).[21] When extrapolated to the U.S. population, the annual overall health care cost burden of CRSwNP was $5.7 billion in 2016 and would be $7.1 billion in 2025.[22] Xolair's proven ability to help CRSwNP patients delay or avoid surgery altogether generates substantial cost savings.

4. "***Patient copayment or other cost sharing data, across different health benefit plan designs, including copayment and coinsurance impacts from patient assistance programs and copay coupons; deductible; patient out-of-pocket costs; and any other cost sharing data***."

- Xolair's cost to patients can vary due to a myriad of factors. Insurance type, benefit design, and site of care are a few of these factors outside of Wholesale Acquisition Cost (WAC) (or "list") price that can impact a patient's final out-of-pocket (OOP) 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 that impact costs, ranging from negotiated rebates and discounts to significant markup at the point of care.[23]
- Further, Xolair can be administered by a physician in a health care setting or self-administered at home. Depending on how Xolair is covered by a patient's insurance plan (e.g., medical or pharmacy benefit), patient OOP costs may vary.

"***Changes in the prescription drug's net cost over time***."

[18] Warren C, Whittington MD, Bilaver L, Kratochvil D, Liu R, Seetasith A, Ko S, Garmo V, Kowal S, Gupta S, Gupta R. Estimating the societal economic burden of food allergy in the United States. J Med Econ. 2025 Dec;28(1):1669-1681.
[19] *I.d.*
[20] Ngcobo N. Polypharmacy and deprescribing among geriatric patients. Aging and Health Research. 2025 Sept;5(3):100256.
[21] Fokkens WJ, Lund VJ, Mullol J, Bachert C, Alobid I, Baroody F, et al. European position paper on rhinosinusitis and nasal polyps 2012. Rhinology Suppl. 2012;(23):1-298.
[22] *I.d.*
[23] https://www.gene.com/stories/the-science-of-pricing. Accessed 23 March 2026.

- 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.
- Xolair's pricing has not triggered price increase advance notice or reporting requirements under Oregon's price transparency reporting laws.

Beyond the additional criteria the Board must consider per OAR 925-200-020, Genentech has chosen to provide additional clinical information that we believe the Board should review and include in any affordability review to holistically consider the full value of Xolair.

Across all of its indications, Xolair has a demonstrably positive impact on a number of specific populations, including children, pregnant women, and rural and underserved populations.

Children

- Xolair is uniquely positioned among biologics because it is FDA-approved for multiple IgE-driven conditions that frequently co-exist in children. It is the only treatment approved for use in children as young as one year of age to treat IgE-mediated food allergies and has proven beneficial to pediatric patients across indications with no associated increase in SAEs or discontinuations.[24] Particularly given its ease of administration and the inclusive treatment it provides across allergic, respiratory, and autoimmune conditions, Xolair significantly benefits its youngest patients.[25]
    - Approximately 33% of children with IgE-mediated food allergies also have asthma, and children with both conditions are more likely to experience severe reactions to food allergens.[26,27] Xolair's positive impact on these vulnerable children and their families is particularly significant due not only to its efficacy across multiple allergic conditions, but also its 20-year safety record. Xolair has an established safety profile for children as young as one year old, and children treated with Xolair generally show no new adverse reactions, no experienced anaphylaxis, and no discontinuations due to adverse reactions.[28]
- For patients with asthma, there are significant disparities in asthma prevalence and mortality by race/ethnicity.[29] Black/African American children reported asthma rates 60%

[24] Schoos AM, Bullens D, Chawes BL, Costa J, De Vlieger L, DunnGalvin A, et al. Immunological Outcomes of Allergen-Specific Immunotherapy in Food Allergy. Front Immunol. 2020 Nov 3;11:568598.
[25] Genentech: The original biotech company [Internet]. South San Francisco: Genentech, Inc., 2026. Highlights of Prescribing Information. 2024 Feb [cited 2026 Feb 24]. Available from: https://www.gene.com/download/pdf/xolair_prescribing.pdf
[26] Korn S, Schumann C, Kropf C, Stoiber K, Thielen A, Taube C, Buhl R. Effectiveness of omalizumab in patients 50 years and older with severe persistent allergic asthma. Ann Allergy Asthma Immunol. 2010 Oct;105(4):313-9.
[27] Kolkhir P, Borzova E, Grattan C, Asero R, Pogorelov D, Maurer M. Autoimmune comorbidity in chronic spontaneous urticaria: A systematic review. Autoimmun Rev. 2017 Dec;16(12):1196-1208.
[28] Wood R, Jones S, Dantzer J, Sicherer S, Wang J, Shreffler W, et al. Treatment of Multi-Food Allergy with Omalizumab Compared to Omalizumab-Facilitated Multi-Allergen OIT. J Allergy Clin Immunol. 2025 Feb;155(2):AB444.
[29] Fu Z, Xu Y, Cai C. Efficacy and safety of omalizumab in children with moderate-to-severe asthma: a meta-analysis. J Asthma. 2021 Oct;58(10):1350-1358.

higher than those of all U.S. children.[30] The asthma mortality rate for Black/African American children is more than three times higher than that of all U.S. children (7.7 versus 2.0), and the asthma mortality rate for Black/African American adults is nearly three times that of all U.S. adults (29.7 versus 10.6).[31]

Socioeconomic Status

- Socioeconomic status also has a direct impact on asthma prevalence: current asthma rates are highest among Americans with household incomes below the poverty level (11.3%), and decrease as income increases.[32] These statistics underscore the significance of effective asthma treatment in ensuring optimal health outcomes for all.

Pregnant Patients

- Xolair is the only asthma biologic with a published pregnancy registry analysis in its Prescribing Information. The EXPECT study, which assessed perinatal outcomes among pregnant patients treated with Xolair and their infants, found no increase in the rate of major birth defects or miscarriage when compared to those not treated with Xolair, providing a major benefit to patients with allergic asthma, CSU, and/or other Xolair indications who might otherwise have to forgo treatment during pregnancy.[33]

[30] Namazy JA, Blais L, Andrews EB, Scheuerle AE, Cabana MD, Thorp JM, Umetsu DT, Veith JH, Sun D, Kaufman DG, Covington DL, Mukhopadhyay S, Fogel RB, Lopez-Leon S, Spain CV. Pregnancy outcomes in the omalizumab pregnancy registry and a disease-matched comparator cohort. J Allergy Clin Immunol. 2020 Feb;145(2):528-536.e1.
[31] CDC: Centers for Disease Control & Prevention [Internet]. Atlanta: U.S. Centers for Disease Control & Prevention; 2026. Most Recent National Asthma Data; 2023 May 10 [cited 2026 Feb 24]. Available from: https://www.cdc.gov/asthma/most_recent_national_asthma_data.htm
[32] Fu Z, Xu Y, Cai C. Efficacy and safety of omalizumab in children with moderate-to-severe asthma: a meta-analysis. J Asthma. 2021 Oct;58(10):1350-1358.
[33] Namazy J, Cabana MD, Scheuerle AE, Thorp JM Jr, Chen H, Carrigan G, et al. The Xolair Pregnancy Registry (EXPECT): the safety of omalizumab use during pregnancy. J Allergy Clin Immunol. 2015 Feb;135(2):407-412.