



RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Xolair (omalizumab) is a monoclonal antibody that prevents binding of IgE to the high-affinity receptors on basophils and mast cells by forming complexes with circulating free IgE (1-2). Xolair is a treatment option for asthmatic patients with a pre-treatment IgE level of ≥ 30 IU/mL with a positive skin test or *in vitro* reactivity to a perennial aeroallergen such as pollen, mold spores, dust mites, or animal allergens (2).

Current asthma guidelines state that Xolair may be considered as adjunctive therapy in patients who have allergies and severe persistent asthma that is inadequately controlled with the combination of high-dose inhaled corticosteroids and long acting beta₂ agonists, the preferred treatment for moderate persistent and severe persistent asthma. Alternative options include either a leukotriene modifier or theophylline in combination with inhaled corticosteroids for moderate persistent asthma (2).

Xolair has shown to be effective against allergy-induced asthma only. Allergy tests are required to identify patients who may be candidates for Xolair therapy. Allergic asthma is identified as testing positive to at least one perennial aeroallergen according to either a skin test (e.g., prick/puncture test, intracutaneous test) or a blood test (e.g., RAST) and having an IgE level between 30 and 700 IU/ml in patients 12 years of age and older and between 30 and 1300 IU/ml in patients between 6 and 11 years of age (1).

Xolair was evaluated in several clinical studies for safety and efficacy. Dosing for asthma, chronic rhinosinusitis with nasal polyps (CRSwNP), and IgE-mediated food allergy was based on body weight and baseline serum IgE concentration (1).

Regulatory Status

FDA-approved indications: Xolair (omalizumab) is an anti-IgE antibody indicated for: (1)

- Moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids.
- Chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment.



**XOLAIR
(omalizumab)**

- IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance.
- Chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.

Limitations of Use: (1)

- Not indicated for acute bronchospasm or status asthmaticus.
- Not indicated for the emergency treatment of allergic reactions, including anaphylaxis.
- Not indicated for other forms of urticaria.

Xolair has a boxed warning citing the risk of anaphylaxis after administration. Anaphylaxis has occurred as early as after the first dose of Xolair, but also has occurred beyond 1 year after beginning regularly administered treatment. Due to the risk of anaphylaxis, patients should be observed closely for an appropriate period of time after Xolair administration. Health care providers administering Xolair should be prepared to manage anaphylaxis that can be life-threatening. Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of Xolair. Management of anaphylaxis may include administration of subcutaneous epinephrine (1).

Malignant neoplasms were observed in 20 of 4127 (0.5%) Xolair-treated patients compared with 5 of 2236 (0.2%) control patients in clinical studies of adults and adolescents 12 years of age and older with asthma and other allergic disorders. The observed malignancies in Xolair-treated patients were a variety of types, with breast, non-melanoma skin, prostate, melanoma, and parotid occurring more than once, and five other types occurring once each. The majority of patients were observed for less than 1 year. The impact of longer exposure to Xolair or use in patients at higher risk for malignancy (e.g., elderly, current smokers) is not known (1).

FEP adherence is defined as $\geq 50\%$ utilization within the last 180 days.

Prescribers are advised to follow the recommended dosing charts provided in the package insert (see Appendix 1) (1).



XOLAIR (omalizumab)

The safety and effectiveness of Xolair in pediatric patients less than 1 year of age with IgE-mediated food allergy have not been established. The safety and effectiveness of Xolair in pediatric patients less than 6 years of age with asthma have not been established. The safety and effectiveness of Xolair in pediatric patients less than 12 years of age with urticaria have not been established. The safety and effectiveness of Xolair in pediatric patients less than 18 years of age with CRSwNP have not been established (1).

Summary

Xolair (omalizumab) is a monoclonal antibody that prevents binding of IgE to the high-affinity receptors on basophils and mast cells by forming complexes with circulating free IgE. Dosing for asthma, CRSwNP, and IgE-mediated food allergy was based on body weight and baseline serum IgE concentration. Xolair has a boxed warning citing the risk of anaphylaxis after administration. Due to the risk of anaphylaxis, patients should be observed closely for an appropriate period of time after Xolair administration. The safety and effectiveness of Xolair in pediatric patients less than 1 year of age with IgE-mediated food allergy have not been established. The safety and effectiveness of Xolair in pediatric patients less than 6 years of age with asthma have not been established. The safety and effectiveness of Xolair in pediatric patients less than 12 years of age with urticaria have not been established. The safety and effectiveness of Xolair in pediatric patients less than 18 years of age with CRSwNP have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Xolair while maintaining optimal therapeutic outcomes.

References

1. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; February 2024.
2. National Institutes of Health. *National Asthma Education and Prevention Program Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma - Full Report 2007*. Bethesda, MD: National Heart Lung and Blood Institute; August 2007.
3. Global Initiative for Asthma. *Global Strategy for Asthma Management and Prevention*, 2019. Available from www.ginasthma.org.