Xolair *(omalizumab)*

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Xolair is a monoclonal antibody that specifically targets immunoglobulin E (IgE) indicated for the treatment of moderate to severe asthma inadequately controlled by inhaled corticosteroids and presence of a positive skin test or in vitro reactivity to a perennial aeroallergen, chronic urticaria (CU) refractory to H1 antihistamine treatment, chronic rhinosinusitis with nasal polyps (CRSwNP) inadequately controlled with nasal corticosteroids as add-on maintenance treatment, and IgE-mediated food allergy.
Exclusion Criteria	Must not be used in combination with other biologic drugs (e.g., Dupixent, Nucala, Fasenra).
Required Medical Information	**For initial coverage of asthma:** 1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided. 2. Must have tried and failed 1 ICS/LABA inhaler in combination with one other asthma controller drug in the past six months (failed is defined as an intolerance or inability to improve the condition on required therapy for at least four weeks). 3. Must provide patient's current weight and baseline IgE level. 4. A baseline IgE level of at least 30 IU/mL (baseline is defined as before treatment with Xolair or another therapy that lowers IgE levels). 5. A baseline (defined above) positive skin test or in vitro reactivity to a perennial aeroallergen. **For reauthorization requests for asthma:** 1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided. 2. Must provide patient's current weight and baseline IgE level. 3. (2) Must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms). **For initial coverage of chronic urticaria:** 1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided. 2. Patient has a confirmed diagnosis of chronic urticaria defined as urticaria occurring for more than six weeks. 3. Must try and fail (defined as inability to improve symptoms) with at least two H1 antihistamines (e.g., levocetirizine, desloratadine) - OR - one H1 antihistamine and at least one of the following: H2 antihistamine (e.g., famotidine), oral steroid, or leukotriene modifier. **For reauthorization requests for chronic urticaria:** 1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided. 2. Must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in steroid use).

	For initial coverage of nasal polyps: 1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided. 2. Patient has a baseline IgE level of at least 30 IU/mL (baseline is defined as before treatment with Xolair or another therapy that lowers IgE levels). 3. Must try and fail (defined as an inability to improve symptoms for least four weeks) intranasal steroids. 4. Must be used in combination with an intranasal steroid. 5. Must provide patient's current weight and baseline IgE level. **For reauthorization requests for nasal polyps:** 1. Medical records supporting the request must be provided, including documentation of prior therapies and responses to treatment must be provided. 2. Must have documented clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in steroid use). 3. Must provide patient's current weight and baseline IgE level. 4. Must continue to be used in combination with an intranasal steroid. **For initial coverage of food allergy:** 1. Medical records supporting the request must be provided. 2. Patient has a diagnosis of an IgE-mediated food allergy confirmed by both a positive in vitro test for IgE to the specified foods AND a positive skin prick test to the specified foods. 3. Patient has a clinical history of a significant allergic reaction to the specified foods. 4. Patient has a baseline IgE level of at least 30 IU/mL. 5. Xolair must be used in conjunction with a food allergen-avoidant diet. 6. Patient's current weight and baseline IgE level have been provided. 7. Patient is at least 1 year of age. **For reauthorization requests for food allergy:** 1. Medical records supporting the request must be provided. 2. Xolair must continue to be used in conjunction with a food allergen-avoidant diet. 3. The patient's current weight and baseline IgE level must be provided.
Age Restriction	None.
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	One year initial and reauthorization for food allergy; one year initial and two years reauthorization for all others. Dose will be approved according to the FDA-approved labeling or within accepted standards of medical practice.

GOLD COAST HEALTH PLAN TOTAL Care ADVANTAGE℠

Other Criteria/Information	Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.

HCPCS	Description	Billing Units/How Supplied
J2357	Xolair (omalizumab) Vial/Prefilled syringe	**Billing unit: 5 mg** 150 mg SDV; 75 mg, 150 mg SD syringe

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	8/21/2025	Pharmacy & Therapeutics (P&T) Committee	8/21/2025