Xolair (omalizumab) for injection, for subcutaneous use

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Instructions for Use

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Related Policies

- N/A

Coverage Rationale

This policy is applicable to Xolair (omalizumab) for injection, for subcutaneous use only.

Allergic Asthma

For initial coverage of Xolair (omalizumab) injection for allergic asthma the following will be required:

- Diagnosis of moderate to severe persistent allergic asthma **and**
- Positive skin test or in vitro reactivity to a perennial aeroallergen **and**
- One of the following:
  - All of the following:
    - Patient is 6 years of age or older but less than 12 years of age **and**
    - Pre-treatment serum immunoglobulin (Ig)E level between 30 to 1300 IU/mL **and**
    - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:
      - Both of the following:
        - Medium-dose inhaled corticosteroid (ICS) (e.g., greater than 100–200 mcg fluticasone propionate equivalent/day)
        - Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) **or**
      - One medium dosed combination ICS/LABA product (e.g., Advair Diskus [fluticasone propionate 100 mcg/salmeterol 50 mcg], Symbicort [budesonide 80 mcg/formoterol 4.5 mcg], Breo Ellipta [fluticasone furoate 50 mcg/vilanterol 25 mcg]) **or**
  - All of the following:
    - Patient is 12 years of age or older **and**
    - Pre-treatment serum immunoglobulin (Ig)E level between 30 to 700 IU/mL **and**

        - Patient is currently being treated with one of the following unless there is a contraindication or intolerance to these medications:
            - Both of the following:
                - High-dose inhaled corticosteroid (ICS) (e.g., greater than 500 mcg fluticasone propionate equivalent/day)
                - Additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) **or**
            - One maximally-dosed combination ICS/LABA product (e.g., Advair [fluticasone propionate 500 mcg/salmeterol 50 mcg], Symbicort [budesonide 160 mcg/formoterol 4.5 mcg], Breo Ellipta [fluticasone 200 mcg/vilanterol 25 mcg]) **and**
- Prescribed by or in consultation with one of the following:
    - Pulmonologist
    - Allergist/Immunologist

For reauthorization coverage of Xolair (omalizumab) injection for allergic asthma, the following will be required:

- Patient demonstrates positive clinical response to therapy (e.g., reduction in exacerbations, improvement in forced expiratory volume in 1 second [FEV_1], decreased use of rescue medications) **and**
- Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [LTRA] [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], long-acting muscarinic antagonist [LAMA] [e.g., tiotropium]) unless there is a contraindication or intolerance to these medications **and**
- Prescribed by or in consultation with one of the following:
    - Pulmonologist
    - Allergist/Immunologist

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

For initial coverage of Xolair (omalizumab) injection for chronic rhinosinusitis with nasal polyps (CRSwNP), the following will be required:

- Diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) **and**
- Patient is 18 years of age or older **and**
- Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone) **and**
- Used in combination with another agent for chronic rhinosinusitis with nasal polyps (CRSwNP) **and**
- Prescribed by or in consultation with one of the following:
    - Allergist/Immunologist
    - Otolaryngologist
    - Pulmonologist

For reauthorization coverage of Xolair (omalizumab) injection for chronic rhinosinusitis with nasal polyps (CRSwNP), the following will be required:

- Patient demonstrates a positive clinical response to therapy (e.g., reduction in nasal polyps score [NPS; 0-8 scale], improvement in nasal congestion/obstruction score [NCS; 0-3 scale]) **and**
- Used in combination with another agent for chronic rhinosinusitis with nasal polyps (CRSwNP) **and**
- Prescribed by or in consultation with one of the following:
    - Allergist/Immunologist
    - Otolaryngologist
    - Pulmonologist

Chronic Spontaneous Urticaria (CSU)

For initial coverage of Xolair (omalizumab) injection for chronic spontaneous urticaria (CSU), the following will be required:

- Diagnosis of chronic spontaneous urticaria **and**
- Both of the following:
    - Persistent symptoms (itching and hives) for at least 6 consecutive weeks despite concurrent use of a second generation H1 antihistamine (e.g., cetirizine, fexofenadine), unless there is a contraindication or intolerance to H1 antihistamines **and**
    - Minimum 2-week trial of up-dosing (e.g., up to 4x dose) of the second generation H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines **and**
- Patient is 12 years of age or older **and**
- Will be used concurrently with a second generation H1 antihistamine, unless there is a contraindication or intolerance to H1 antihistamines **and**
- Prescribed by or in consultation with one of the following:
    - Allergist/Immunologist
    - Dermatologist **and**
- Medication will not be used in combination with another immunologic therapy (e.g., Dupixent, Rhapsido) for the treatment of CSU

For reauthorization coverage of Xolair (omalizumab) injection for chronic spontaneous urticaria (CSU), the following will be required:

- Patient's disease status has been re-evaluated since the last authorization to confirm the patient's condition warrants continued treatment **and**
- Patient demonstrates positive clinical response to therapy as evidenced by a reduction from baseline in itching severity or the number of hives **and**
- Medication will not be used in combination with another immunologic therapy (e.g., Dupixent, Rhapsido) for the treatment of CSU

IgE-Mediated Food Allergy

For initial coverage of Xolair (omalizumab) injection for IgE-Mediated Food Allergy, the following will be required:

- One of the following:
    - Both of the following:
        - Diagnosis of IgE-Mediated Food Allergy as evidenced by one of the following:
            - Positive skin prick test (defined as greater than or equal to 4 mm wheal greater than saline control) to food
            - Positive food specific IgE (greater than or equal to 6 kUA/L)
            - Positive oral food challenge, defined as experiencing dose-limiting symptoms at a single dose of less than or equal to 300 mg of food protein **and**
        - Clinical history of IgE-Mediated Food Allergy **or**
    - Provider attestation that patient has a history of severe allergic response, including anaphylaxis, following exposure to one or more foods **and**
- Patient is 1 year of age or older **and**
- Used in conjunction with food allergen avoidance **and**
- Both of the following:
    - Baseline (pre-Xolair treatment) serum total IgE level is greater than or equal to 30 IU/mL and less than or equal to 1850 IU/mL
    - Dosing is according to serum total IgE levels and body weight **and**
- Prescribed by or in consultation with one of the following:

- Allergist
- Immunologist

For reauthorization coverage of Xolair (omalizumab) injection for IgE-Mediated Food Allergy, the following will be required:

- Patient demonstrates positive clinical response to therapy (e.g., reduction of type 1 allergic reactions, including anaphylaxis, following accidental exposure to one or more foods) **and**
- Used in conjunction with food allergen avoidance **and**
- Dosing will continue to be based on body weight and pretreatment total IgE serum levels **and**
- Prescribed by or in consultation with one of the following:
  - Allergist
  - Immunologist

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J2357	Injection, omalizumab, 5 mg

ICD-10 Code	Description
J33.0	Polyp of nasal cavity
J45.40	Moderate persistent asthma, uncomplicated
J45.41	Moderate persistent asthma with (acute) exacerbation
J45.42	Moderate persistent asthma with status asthmaticus
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
L50.1	Idiopathic urticaria
L50.6	Contact urticaria
L50.8	Other urticaria
L50.9	Urticaria, unspecified
T78.40XA	Allergy, unspecified, initial encounter
T78.40XD	Allergy, unspecified, subsequent encounter
T78.40XS	Allergy, unspecified, sequela
Z91.010	Allergy to peanuts
Z91.011	Allergy to milk products
Z91.012	Allergy to eggs
Z91.013	Allergy to seafood
Z91.014	Allergy to mammalian meats
Z91.018	Allergy to other foods

Background

Respiratory and allergy biologics are a mainstay of treatment for severe asthma; in addition, various agents in this class are also indicated for use in chronic spontaneous urticaria (CSU), eosinophilic granulomatosis with polyangiitis (EGPA), chronic rhinosinusitis with nasal polyposis (CRSwNP), allergic fungal rhinosinusitis, hypereosinophilic syndromes (HES), eosinophilic esophagitis (EoE), IgE-mediated food allergy, chronic obstructive pulmonary disease (COPD), bullous pemphigoid, atopic dermatitis, and prurigo nodularis.

Asthma is a chronic lung disease that inflames and narrows the airways, making it difficult to breathe. Asthma causes recurring periods of wheezing, chest tightness, shortness of breath, and coughing. Asthma affects people of all ages but most often starts during childhood. In 2022, asthma affected an estimated 22 million adults and 4.5 million children in the United States (U.S.). The exact causes of asthma are unknown. A combination of factors such as genetics, certain respiratory infections during childhood, and contact with airborne allergens can contribute to its development. Most patients with asthma also have allergies (Centers for Disease Control and Prevention [CDC] Web site 2024, National Heart, Lung, and Blood Institute [NHLBI] Web site 2024).

Approximately 17% of patients have difficult-to-treat asthma and 3.7% have severe disease. Difficult-to-treat asthma is asthma that is uncontrolled despite prescribing of medium- or high-dose ICS with a second controller (usually a LABA) or with maintenance OCS, or that requires high-dose treatment to maintain good symptom control and reduce exacerbations. Severe asthma is a subset of difficult-to-treat asthma; it is defined as asthma that is uncontrolled despite adherence with maximal optimized high-dose ICS/LABA treatment and management of contributory factors, or that worsens when high-dose treatment is decreased (GINA 2025).

Chronic rhinosinusitis with nasal polyps (CRSwNP) has a prevalence of approximately 2.7% in adults, and peaks in the sixth decade of life. Symptoms include nasal obstruction, reduced sense of smell, and sleep disturbance, all of which can substantially impact the quality of life. The majority of cases are idiopathic but may be due to genetic, metabolic, or immunologic causes, resulting in inflammation characterized by eosinophilia and elevated levels of IL-4, IL-5, and interleukin-13 (IL-13) (Hopkins 2019). Common treatment options for CRSwNP include saline irrigation and intranasal glucocorticoids in patients with mild symptoms, and short-term systemic glucocorticoids, surgery, and biologic agents in patients with severe symptoms (Hopkins 2019). Biologic agents that are FDA-approved for CRSwNP include dupilumab, mepolizumab, and omalizumab, omalizumab-igec, and tezepelumab-ekko.

Chronic spontaneous urticaria (CSU) is defined by the presence of hives on most days of the week for 6 weeks or longer, with or without angioedema. The hives are circumscribed, raised, erythematous plaques, often with central pallor and variable in size. No external allergic cause or contributing disease process can be identified in 80 to 90% of adults and children with CSU (Khan 2025, Saini 2025). CSU affects up to 1% of the general population in the U.S. and is more common in adults than children and typically begins in the third to fifth decades of life. Non-sedating H1-antihistamines are the cornerstone of therapy for CSU and limited courses of oral glucocorticoids are often used in combination with antihistamines for refractory symptoms. Other pharmacologic options for patients who do not respond to H1-antihistamines include the use of H2-antihistamines, leukotriene modifiers, cyclosporine, tacrolimus, mycophenolate, hydroxychloroquine, sulfasalazine, dapsone, and omalizumab (Bernstein et al 2014, Khan 2025, Maurer et al 2013, Zuberbier et al 2022).

IgE-mediated food-allergic disease differs from non-IgE-mediated disease because the pathophysiology results from activation of the immune system, causing a T helper 2 response which results in IgE binding to Fc ε receptors on effector cells like mast cells and basophils (Anvari et al 2019). The activation of these cells causes release of histamine and other preformed mediators, and rapid symptom onset, in contrast with non-IgE-mediated food allergy which is more delayed in onset. Symptoms of IgE-mediated food allergies range from mild to severe. The severity of symptoms is not predicted by the level of specific IgE or skin test wheal size, but the likelihood of symptom onset is directly related.

Anaphylaxis is the most severe form of the clinical manifestation of IgE-mediated food allergy, and injectable epinephrine is the first-line treatment. Management of food allergies requires strict avoidance measures, counseling of the family about constant vigilance, and prompt treatment of allergic reactions with emergency medications.

Xolair (omalizumab) is an anti-IgE antibody which prevents binding of IgE to FcεRI (high-affinity IgE receptor) on basophils and mast cells, thereby reducing the amount of free IgE that is available to trigger the allergic cascade. Treatment of atopic subjects with omalizumab resulted in a marked down-regulation of FcεRI receptors on basophils. Treatment with Xolair inhibits IgE-mediated inflammation, as evidenced by reduced blood and tissue eosinophils and reduced inflammatory mediators, including IL-4, IL-5, and IL-13 by innate, adaptive and non-immune.

Clinical Evidence

Asthma

The original FDA approval of omalizumab was based on the results of 3 randomized, double-blind, placebo-controlled, multicenter trials conducted in patients ≥ 12 years of age with moderate to severe asthma for ≥ 1 year and a positive skin test reaction to a perennial aeroallergen. All patients were required to have a baseline IgE between 30 and 700 international unit (IU)/mL and body weight not more than 150 kg. Patients were treated according to a dosing table to administer at least 0.016 mg/kg/IU (IgE/mL) of omalizumab or placebo over each 4-week period.

- Each study was comprised of a run-in period to achieve a stable conversion to a common ICS, followed by randomization to omalizumab or placebo. Patients received omalizumab for 16 weeks with an unchanged ICS dose unless an acute exacerbation necessitated an increase. Patients then entered an ICS reduction phase of 12 (Busse et al 2001, Solèr et al 2001) and 16 weeks (Holgate et al 2004) during which ICS dose reduction was attempted in a stepwise manner.
- In the 28-week study by Busse et al (N = 525), during the steroid stable phase, patients treated with omalizumab had fewer mean exacerbations/subject (0.28 vs 0.54; p = 0.006) and decreased mean duration of exacerbations (7.8 vs 12.7 days; p < 0.001) compared with placebo-treated patients. Similarly, during the steroid reduction phase, omalizumab was associated with fewer exacerbations/subject (0.39 vs 0.66; p = 0.003), and a shorter mean duration of exacerbations (9.4 vs 12.6 days; p = 0.021) (Busse et al 2001).
- In the 28-week study by Solèr et al (N = 546), asthma exacerbations/patient, the primary endpoint, decreased more in the omalizumab group compared to placebo during both the stable steroid (0.28 vs 0.66; p < 0.001) and steroid reduction phases (0.36 vs 0.75; p < 0.001) (Solèr et al 2001).
- In the 32-week study by Holgate et al (N = 246), the percentage reduction in ICS dose, the primary endpoint, was greater among patients treated with omalizumab than among patients treated with placebo (median, 60% vs 50%; p = 0.003). The percentages of patients with ≥ 1 asthma exacerbation were similar between omalizumab and placebo groups during both the stable steroid and steroid reduction phases (p-value not reported). The absence of an observed treatment effect may be related to differences in the patient population compared with the first 2 studies, study sample size, or other factors (Holgate et al 2004).

A Cochrane Review conducted in 2014 evaluated the efficacy of omalizumab in patients with allergic asthma. Treatment with omalizumab was associated with a significant reduction in the odds of a patient having an asthma exacerbation (OR, 0.55; 95% CI, 0.42 to 0.6; 10 studies; n = 3261). This represents an absolute reduction from 26% for patients suffering an exacerbation on placebo to 16% on omalizumab, over 16 to 60 weeks. Additionally, in patients with moderate-to-severe asthma and in those who were receiving background ICS therapy, treatment with omalizumab resulted in a significant reduction in the odds of having an asthma exacerbation (OR, 0.50; 95% CI, 0.42 to 0.6; 7 studies; n = 1889). A significant benefit was noted for SC omalizumab vs placebo with regard to reducing hospitalizations (OR, 0.16; 95% CI, 0.06 to 0.42; 4 studies; n = 1824), representing an absolute reduction in risk from 3% with placebo to 0.5% with omalizumab over 28 to 60 weeks. The authors concluded that omalizumab was effective in reducing asthma exacerbations and hospitalizations as an adjunctive therapy to ICS and significantly more effective than placebo in increasing the number of patients who were able to reduce or withdraw their ICS. Omalizumab was generally well tolerated, although there were more injection site reactions with omalizumab. However, the clinical value of the reduction in steroid consumption must be considered in light of the high cost of omalizumab (Normansell et al 2014).

A systematic review of 8 randomized, placebo-controlled trials (N = 3429) evaluated the efficacy and safety of SC omalizumab as add-on therapy to corticosteroids in children and adults with moderate-to-severe allergic asthma. At the end of the steroid reduction phase, patients taking omalizumab were more likely to be able to withdraw corticosteroids completely compared with placebo (RR, 1.8; 95% CI, 1.42 to 2.28; p = 0.00001). Omalizumab patients showed a decreased risk for asthma exacerbations at the end of the stable (RR, 0.57; 95% CI, 0.48 to 0.66; p = 0.0001) and adjustable-steroid phases (RR, 0.55; 95% CI, 0.47 to 0.64; p = 0.0001); post-hoc analysis suggests this effect was independent of duration of treatment, age, severity of asthma, and risk of bias. The frequency of serious adverse events was similar between omalizumab (3.8%) and placebo (5.3%). However, injection site reactions were more frequent in the omalizumab patients (19.9% vs 13.2%). Omalizumab was not associated with an increased risk of hypersensitivity reactions, cardiovascular effects, or malignant neoplasms (Rodrigo et al 2011).

A meta-analysis of 3 of the previously mentioned trials (Busse et al 2001, Holgate et al 2004, Solèr et al 2001) and their extension studies assessed the efficacy of omalizumab in a subgroup of 254 patients at high risk of serious asthma-related mortality and morbidity. The primary outcome was an annualized rate of acute exacerbation episodes based on data from the initial 16-week stable steroid phase for high-risk patients. Two kinds of acute exacerbation episodes were considered as endpoints: significant acute exacerbation episodes and all acute exacerbation episodes (i.e., all episodes recorded by the investigator). Significant acute exacerbation episodes were defined as those requiring a doubling of baseline ICS dose (Busse et al 2001, Solèr et al 2001) or use of systemic steroids (all 3 studies). During the stable steroid phase, mean significant acute exacerbation episode rates were 1.56 and 0.69/patient-year, respectively, a reduction of 56% with omalizumab (p = 0.007). Similar reductions in exacerbations in favor of omalizumab were observed for the whole study period and for all acute exacerbation episodes. The authors concluded that 113 significant acute exacerbation episodes were prevented for every 100 patients treated with omalizumab for 1 year (Holgate et al 2001).

In July 2016, the FDA expanded the indication of omalizumab to patients 6 to 11 years of age with moderate to severe persistent asthma. The approval was based primarily on a 52-week, randomized, double-blind, placebo-controlled, multicenter trial. The study evaluated the safety and efficacy of omalizumab as add-on therapy in 628 pediatric patients 6 to < 12 years of age with moderate to severe asthma inadequately controlled despite the use of an ICS (Lanier et al 2009).

- Over the 24-week fixed-steroid phase, omalizumab reduced the rate of clinically significant asthma exacerbations (worsening symptoms requiring doubling of baseline ICS dose and/or systemic steroids) by 31% vs placebo (0.45 vs 0.64; RR, 0.69; p = 0.007). Over a period of 52 weeks, the exacerbation rate was reduced by 43% (p < 0.001).

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)
The efficacy and safety of omalizumab for the treatment of CRSwNP in adult patients with an inadequate response to intranasal corticosteroids were based on results from 2 randomized, multicenter, double-blind, placebo-controlled, Phase 3 studies, POLYP 1 (n = 138) and POLYP 2 (n = 127) (Gevaert et al 2020).

- Patients were randomly assigned to omalizumab 75 to 600 mg SC every 2 or 4 weeks (based upon pretreatment serum total IgE level and body weight) or placebo for 24 weeks. All patients received background intranasal mometasone therapy. Results from both studies revealed that omalizumab was associated with a significantly greater improvement from baseline at week 24 in Nasal Polyp Score (NPS) and weekly average Nasal Congestion Score (NCS) as compared to placebo.
- In POLYP 1 and POLYP 2, the mean changes in NPS from baseline to week 24 for omalizumab compared to placebo were -1.08 vs 0.06 (p < 0.0001) and -0.9 vs -0.31 (p = 0.014), respectively, and mean changes in NCS from baseline were -0.89 vs -0.35 (p = 0.0004) and -0.7 vs -0.2 (p = 0.0017), respectively. Adverse events were similar between treatment groups.

Chronic spontaneous urticaria (CSU)
The safety and efficacy of omalizumab for the treatment of CSU was assessed in 2 placebo-controlled, multiple-dose clinical studies. Patients received omalizumab 75, 150, or 300 mg or placebo by SC injection every 4 weeks in addition to their baseline level of H1 antihistamine therapy for 24 or 12 weeks, followed by a 16-week washout observation period.

In both studies, patients who received omalizumab 150 mg or 300 mg had greater decreases from baseline in weekly itch severity scores and weekly hive count scores than placebo at week 12 (Kaplan et al 2013, Maurer et al 2013).

Another randomized, double-blind, placebo-controlled study evaluated omalizumab as add-on therapy for 24 weeks in patients with CSU who remained symptomatic despite H1 antihistamine therapy. Similar to previous studies, patients treated with omalizumab had significantly greater reductions in weekly itch severity score from baseline to week 12 compared to placebo ($p \leq 0.001$) (Saini et al 2015).

A meta-analysis of randomized clinical trials evaluating omalizumab for the treatment of CSU was published in 2016. The analysis included 7 randomized, placebo-controlled studies with 1312 patients with CSU. Patients treated with omalizumab (75 to 600 mg every 4 weeks) had significantly reduced weekly itch and weekly wheal scores compared with the placebo group. The effects of omalizumab were dose-dependent, with the strongest reduction in weekly itch and weekly wheal scores observed with 300 mg. Rates of complete response were significantly higher in the omalizumab group ($p < 0.00001$) and dose-dependent, with the highest rates in the 300 mg group. Rates of patients with adverse events were similar in the omalizumab and placebo groups (Zhao et al 2016). Similar results were identified in a 2019 meta-analysis of 6 trials and a 2020 meta-analysis of 9 trials, both comparing omalizumab with placebo (Jia and He 2020, Rubini et al 2019).

IgE-Mediated Food Allergy

Omalizumab was FDA-approved for IgE-mediated food allergy in adults and children ≥ 1 year of age based on the results of a randomized, multicenter, double-blind, placebo-controlled trial in 180 patients with allergies to peanut and at least 2 other foods, including milk, egg, wheat, cashew, hazelnut, or walnut. Patients with a history of severe anaphylaxis (defined as neurological compromise or requiring intubation) were excluded from the study. Results demonstrated a significantly higher response with omalizumab vs placebo (67% vs 7%, respectively; $p < 0.001$) for the primary outcome (ie, the percentage of patients who were able to tolerate a single dose of ≥ 600 mg of peanut protein without experiencing dose-limiting symptoms [ie, moderate-to-severe skin, respiratory, or gastrointestinal symptoms]) (Wood et al 2024).

Clinical Guidelines

Asthma

The National Asthma Education and Prevention Program (NAEPP) guideline from the NHLBI states that the initial treatment of asthma should correspond to the appropriate asthma severity category, and it provides a stepwise approach to asthma management. Long-term control medications such as ICSs, long-acting bronchodilators, leukotriene modifiers, cromolyn, and immunomodulators should be taken daily on a long-term basis to achieve and maintain control of persistent asthma. ICSs are the most potent and consistently effective long-term asthma control medication. Quick-relief medications such as SABAs and anticholinergics are used to provide prompt relief of bronchoconstriction and accompanying acute symptoms such as cough, chest tightness, and wheezing. Systemic corticosteroids are important in the treatment of moderate or severe exacerbations because these medications prevent progression of the exacerbation, speed recovery, and prevent relapses (NHLBI 2007). A 2020 focused update of the 2007 NAEPP guideline has provided additional updated recommendations on the use of intermittent ICSs and the use of LAMAs as add-on therapy (Cloutier et al 2020).

The 2025 GINA report also provides a stepwise approach to asthma management (GINA 2025). Treatment recommendations are based on patient age, and stepping down should be considered when asthma symptoms have been well-controlled and lung function has been stable for ≥ 2 to 3 months. ICS/beta2-agonist combination products are recommended for both controller (i.e., maintenance treatment) and reliever use in patients ≥ 6 years of age, while the preferred controller option in patients ≤ 5 years of age consists of low-dose ICS for Step 2 and double low-dose ICS for Step 3, with a specialist assessment recommended for Step 4 if a patient's asthma is not well-controlled on double low-dose ICS. In patients ≥ 6 years of age diagnosed with severe asthma and uncontrolled on Step 4 treatment, phenotyping for Type 2 inflammation into categories such as severe allergic, aspirin-exacerbated, allergic bronchopulmonary

aspergillosis, chronic rhinosinusitis, nasal polyposis, atopic dermatitis, or eosinophilic asthma is recommended. Add-on treatment with a biologic agent should be considered as follows:

- Severe allergic asthma: Anti-IgE treatment with omalizumab is recommended for patients ≥ 6 years of age.
- Severe eosinophilic asthma: Add-on anti-IL-5 therapy is recommended for patients ≥ 6 years of age (mepolizumab and benralizumab), or ≥ 18 years of age (reslizumab).
- Severe eosinophilic/Type 2 asthma: Anti-IL4 therapy (dupilumab) is recommended for patients ≥ 6 years of age.
- Adults or adolescents requiring oral corticosteroids for maintenance therapy: Anti-IL4 therapy (dupilumab) is recommended.
- Severe asthma: Anti-TSLP therapy (tezepelumab-ekko) is recommended for patients ≥ 12 years of age.
- Prior to initiation of a biologic agent, several factors should be considered including cost, insurance eligibility criteria, evaluation of predictors of response, delivery route, dosing frequency, and patient preference.

The European Respiratory Society/American Thoracic Society guideline on the management of severe asthma suggests the use of anti-IL-5 therapy as an add-on in adults with severe uncontrolled eosinophilic asthma or severe corticosteroid-dependent asthma. A blood eosinophil count of ≥ 150 cells/µL is suggested as a cut-point to guide initiation of anti-IL-5 therapy in adults with severe asthma and prior exacerbations. A blood eosinophil count of ≥ 260 cells/µL or an exhaled nitric oxide level of 19.5 parts per billion or greater may be used to identify adolescents and adults with severe allergic asthma who are likely to benefit from anti-IgE treatment (Holguin et al 2020).

The American College of Chest Physicians (ACCP) also developed a guideline addressing biologic management in adults with severe asthma. For adults with moderate to severe allergic asthma and ≥ 1 exacerbation per year requiring OCS, the panel recommends treatment with either omalizumab or dupilumab, using individual clinical characteristics to guide selection. For severe, steroid-dependent asthma, the panel recommends either anti-IL-5/IL-5 receptor alpha (IL-R α) therapy or dupilumab and recommends dupilumab over tezepelumab-ekko. For moderate to severe asthma that does not demonstrate a clinical response to omalizumab after 4 to 6 months, the panel recommends switching to either anti-IL-5/IL-5R α therapy or dupilumab. For severe asthma that does not respond to anti-IL-5/IL-5R α therapy after 4 to 6 months, the panel recommends either dupilumab or tezepelumab-ekko, with dupilumab preferred in those who are steroid dependent. For those who do not respond to dupilumab after 4 to 6 months, the panel recommends either anti-IL-5/IL-5R α therapy or tezepelumab-ekko, with anti-IL-5/IL-5R α therapy preferred in steroid-dependent patients. Finally, for those with severe asthma receiving anti-IL-5/IL-5R α therapy who have not demonstrated a clinical response by 4 to 6 months, the panel recommends using a post-treatment FeNO ≥25 ppb to guide switching to dupilumab. All recommendations carry a conditional strength of recommendation and are based primarily on very low-certainty evidence (Oberle et al 2026).

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

- Treatment of CRSwNP is addressed in guidelines from the American Academy of Otolaryngology-Head and Neck Surgery; American Academy of Allergy, Asthma & Immunology, the American College of Allergy, Asthma & Immunology, and the Joint Council of Allergy, Asthma & Immunology; the International Forum of Allergy & Rhinology; and the European Forum for Research and Education in Allergy and Airway Diseases (EUFOREA); and the International Consensus Statement on Allergy and Rhinology: Rhinosinusitis (ICAR-RS) (Orlandi et al 2021, Peters et al 2014, Payne et al 2025, Rank et al 2023).
- Routine treatment recommendations include saline irrigation and/or intranasal glucocorticoids in patients with mild symptoms, and short-term systemic glucocorticoids and surgery in patients with severe or refractory symptoms. Biologics rather than no biologics are recommended for patients with CRSwNP and dupilumab is specifically recommended by ICAR-RS (Orlandi et al 2021, Rank et al 2023). The American Academy of Otolaryngology-Head and Neck Surgery guideline states that biologics (including, but not limited to, monoclonal antibodies such as dupilumab, mepolizumab, or omalizumab) should not be used for the treatment of adults with CRS without polyps (Payne et al 2025).
- In 2023, EUFOREA published an updated expert consensus focused on the use of biologics for CRSwNP. Biologics are indicated in patients with bilateral nasal polyps and previous sinus surgery who also meet 3 of the following

criteria: evidence of Type 2 inflammation (biological biomarkers); the need for systemic corticosteroids (≥ 2 courses per year or > 3 months of low dose steroids) or contraindications to systemic corticosteroids, significant quality-of-life impairment, significant loss of smell, and diagnosis of comorbid asthma. Once eligibility according to the EUFOREA 2023 criteria has been determined, a patient's preference for a surgical or non-surgical approach should be considered if funding within the healthcare system allows. In patients who have never had surgery, 4 of the aforementioned criteria need to be met before a biologic is indicated. Patients with previous sinus surgery plus severe asthma may also qualify for treatment in consultation with their pulmonologist. Lastly, biologics should not be initiated in the following situations: CRSwNP and lack of signs of Type 2 inflammation, cystic fibrosis, unilateral nasal polyps, mucoceles, general contraindications for biological treatments (e.g., immunodeficiencies), and patient-related factors such as noncompliance to therapy (Fokkens et al 2023).

Chronic spontaneous urticaria

- Guidelines developed by the American Academy of Allergy, Asthma & Immunology, the American College of Allergy, Asthma & Immunology, and the Joint Council of Allergy, Asthma & Immunology recommend a stepwise treatment approach for CSU. Treatment with omalizumab is recommended in patients inadequately controlled with antihistamines and a LTRA (Bernstein et al 2014).
- Joint guidelines by the European Academy of Allergy and Clinical Immunology, the Global Allergy and Asthma European Network, the European Dermatology Forum, and the World Allergy Organization recommend treatment with omalizumab in patients with symptoms despite treatment with a 4-fold dose of modern second-generation antihistamines. Due to adverse effects and the lack of an approved indication, cyclosporine should only be considered if omalizumab does not provide an adequate response (Zuberbier et al 2022).

IgE-mediated food allergy

- A 2025 guideline from the AAAAI provides several statements regarding the use of omalizumab in patients with food allergy. Notably, candidates for omalizumab therapy for food allergy should have (1) a qualifying total IgE level to assist with dosing along the nomogram (> 30 to < 1850 IU/mL), as well as (2) evidence of sensitization determined via either (or both) a positive result of food-specific skin prick test or measurement of serum-specific IgE level to a food that would indicate a high likelihood of having an IgE-mediated reaction within the context of the patient's history. It is suggested that testing be obtained within 12 to 18 months of starting therapy. While an oral food challenge is not required prior to omalizumab therapy, candidates for omalizumab should have a clear reaction history in the setting of evidence of IgE sensitization to the food (Anagnostou et al 2025).

- Older national guidelines for food allergies focus on nutritional interventions (Fleischer et al 2021, Sampson et al 2014).
- A 2025 guideline from the European Academy of Allergy and Clinical Immunology provides recommendations for the management of IgE-mediated food allergy. In children ≥ 1 year of age and adults with IgE-mediated food allergy, omalizumab is suggested to achieve desensitization (Santos et al 2025).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Xolair is an anti-IgE antibody indicated for:

- Moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that 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

- 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.

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Policy History/Revision Information

Date	Summary of Changes
11/16/2023	Approved by OptumRx P&T Committee
04/17/2024	New indication added. Updates to all sections
05/16/2024	Annual Review. Updated criteria language in coverage rationale section in line with other drugs in same class. Updated references.
05/15/2025	Annual Review. Added age criterion for CRSwNP in Coverage Rationale section. Updates to Background & Clinical Guidelines sections. Updated references.
06/17/2026	Annual Review. Update to coverage rationale for CSU indication. Updates to background, clinical guidelines and references.

Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. The insurance reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

OptumRx may also use tools developed by third parties to assist us in administering health benefits. OptumRx Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

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- Written information in other formats (large print, audio, accessible electronic formats, other formats).

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PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If *you* need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help *you*.

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

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