Xolair (omalizumab) Prior Authorization Program Summary

Your health benefit plan may not cover certain prescription drug products or drug categories included in this document. Please consult your benefit plan materials for details about your particular benefit. This document may include drugs that are not included on your plan's formulary. For drug coverage status, please consult your plan's formulary.

POLICY REVIEW CYCLE

Effective Date	Date of Origin
04-01-2026	

FDA LABELED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Xolair® (omalizumab) Subcutaneous injection	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 • Limitation of Use: Not indicated for the relief of acute bronchospasms, or status asthmaticus 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 Chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment • Limitation of Use: Not indicated for treatment of other forms of urticaria 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. • Limitation of Use: Not indicated for the emergency treatment of allergic reactions, including anaphylaxis		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Asthma	Asthma is a chronic inflammatory disorder of the airways. It is characterized by a history of respiratory symptoms along with variable expiratory airflow limitation, and is typically associated with bronchial hyperresponsiveness and underlying inflammation. Symptoms are variable and recurrent and include wheezing, coughing, shortness of breath, and chest tightness. Exercise, exposure to allergens and irritants, infections, and changes in the weather can be contributing factors to the variability in symptoms and airflow limitation.(3) Guidelines recommend evaluating respiratory symptoms, medical history, physical examination, and spirometry to determine a diagnosis of asthma.(2,3) Long-term goals for asthma management are to achieve

	control of symptoms, maintain normal activity level, and to minimize the future risk of exacerbations, decline in lung function, and medication side effects.(3) Different types of asthma and levels of severity exist. Moderate asthma is asthma that requires a low- or medium-dose inhaled corticosteroid (ICS) used in combination with a long-acting beta agonist (LABA) to be well controlled. Severe asthma is asthma that remains uncontrolled despite optimized treatment with high-dose ICS-LABA, or that requires high-dose ICS-LABA or biologic therapy to prevent it from becoming uncontrolled (e.g., asthma worsens when high-dose treatment is decreased). Severe asthma needs to be distinguished from difficult-to-treat asthma that remains symptomatic due to poor adherence, poor inhaler technique, comorbidities, and/or continued exposure to environmental agents since treatment and management differs between the two.(3) The European Respiratory Society (ERS)/American Thoracic Society (ATS) guidelines on the definition and evaluation of asthma define uncontrolled asthma for adults and pediatric patients 6 years of age and older as a patient having at least one of the following:(17) • Frequent severe exacerbations (i.e., two or more bursts of systemic corticosteroids within the past 12 months) • Serious exacerbations (i.e., at least one hospitalization, intensive care unit stay, or mechanical ventilation in the past 12 months) • Airflow limitation (i.e., forced expiratory volume in 1 second [FEV1] less than 80% predicted) • Asthma that worsens upon tapering of high-dose ICS or systemic corticosteroids (or additional biologics) The Type 2 inflammatory asthma phenotype is found in the majority of people with severe asthma. Type 2 inflammation involves a systemic allergic response and elevated levels of Type 2 inflammatory cytokines such as interleukin (IL)-4, IL-5, and IL-13. Elevated eosinophils or an increased fractional exhaled nitric oxide (FeNO) are characteristics of the eosinophilic subtype of Type 2 inflammatory asthma, while the allergic asthma subtype is additionally characterized by elevated immunoglobulin E (IgE) levels and positive skin prick testing with common environmental allergens. Type 2 inflammation typically responds well to ICS treatment and rapidly improves. However, in severe asthma, Type 2 inflammation may be relatively refractory to high-dose ICS. Maintenance oral corticosteroids (OCS) may elicit a response, but the risk of serious adverse effects with daily OCS use deters their usefulness and an alternative treatment should be sought.(3) Type 2 inflammation is considered refractory if any of the following are found while the patient is taking high-dose ICS or daily OCS:(3) • Blood eosinophils greater than or equal to 150 cells/microliter • FeNO greater than or equal to 20 ppb • Sputum eosinophils greater than or equal to 2% ○ Note: Sputum eosinophil count is not generally available in clinical practice • Asthma is clinically allergen-driven The Global Initiative for Asthma (GINA) guidelines recommend a stepwise approach for managing asthma. The 2025 GINA guidelines recommend all patients 6 years of age and older with asthma receive ICS-containing medication to reduce the risk of serious exacerbation, even in patients with infrequent symptoms. It is recommended that patients with asthma symptoms most days (e.g., 4+ days per week) be started on low dose ICS-formoterol for maintenance-and-reliever therapy (MART). Patients' response to treatment should be reviewed after 2 to 3 months. If symptoms remain uncontrolled despite good adherence and correct inhaler technique, the next step up (Step 4) involves increasing MART to medium dose ICS-formoterol (ICS-LABA). Other controller options that may be added on to ICS treatment at Step 4 include a long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist (LTRA), or theophylline. Both LTRA and theophylline are considered less efficacious than adding on a LABA or LAMA, and also come with safety concerns. Patients with uncontrolled symptoms and/or exacerbations despite being on Step 4 treatment for 3 to 6 months

	should be assessed for contributory factors, have their treatment optimized, and be referred for expert assessment, phenotyping, and potential add-on therapy. Treatment optimization may include a trial of high dose ICS-LABA or add-on LAMA or LTRA therapy, if not already trialed. Maintenance oral corticosteroids (OCS) should be used only as last resort because short-term and long-term systemic side effects are common and serious.(3)
	
	Biologic agents should be considered as add-on therapy for patients with refractory Type 2 inflammation with exacerbations and/or poor symptom control despite taking at least high dose ICS-LABA, and who have allergic or eosinophilic biomarkers or need maintenance OCS, and only after treatment has been optimized.(3) Tezepelumab is considered a broad-acting biologic and may be considered in patients without a Type 2 inflammatory phenotype due to it binding to circulating thymic stromal lymphopoietin (TSLP), which is upstream on the inflammatory cascade.(3,12) Based on efficacy results from clinical trials, the indication of use for tezepelumab is not restricted to a biomarker-defined phenotype.(12) 2025 GINA guidelines summarize payer eligibility criteria for the use of biologics as follows:(3)
	
	• Anti-IgE (omalizumab) for severe allergic asthma
	  ○ Sensitization to inhaled allergen(s) on skin prick testing for specific IgE
	  ○ Total serum IgE and body weight within dosing range
	  ○ Exacerbations within the last year
	• Anti-IL5 (mepolizumab, reslizumab) /Anti-IL5Ra (benralizumab) for severe eosinophilic asthma
	  ○ Blood eosinophils greater than or equal to 150 cells/microliter (or greater than or equal to 300 cells/microliter, based on locally specified level)
	  ○ Severe exacerbations within the last year
	• Anti-IL4Ra (dupilumab) for severe eosinophilic/Type 2 asthma or patients requiring maintenance OCS
	  ○ Blood eosinophil greater than or equal to 150 cells/microliter but less than or equal to 1500 cells/microliter, or FeNO greater than or equal to 25 ppb, or taking maintenance OCS
	  ○ Severe exacerbations within the last year
	• Anti-TSLP (tezepelumab) for severe asthma
	  ○ Severe exacerbations within the last year
	
	Patient response to biologic therapy should be evaluated 4 months after initiating therapy, and the patient should be re-evaluated every 3 to 6 months. If response is unclear after 4 months, the trial should be extended to 6-12 months.(3)
	
	2025 GINA guidelines recommend the following step-down therapy process in patients responding well to targeted biologic therapy:(3)
	
	• Re-evaluate the need for each asthma medication every 3 to 6 months, but inhaled therapy (e.g., ICS-containing therapy) should not be completely stopped
	• The order of reduction of treatments should be based on observed benefit, potential side-effects, cost, and patient preference. However, minimizing the use of OCS is a very high priority.
	• First, consider decreasing/stopping OCS due to their significant adverse effects. Then consider stopping other add-on asthma medications.
	• Then, if asthma is well controlled for 3-6 months, consider reducing maintenance ICS dose, but do not stop maintenance ICS-containing therapy (e.g., ICS-LABA)
	• Re-evaluate the need for ongoing biologic therapy, but a trial of withdrawal of the biologic should not be considered until after at least 12 months of treatment and only if asthma remains well controlled on medium-dose ICS-containing therapy

	○ For allergic asthma, also confirm there is no further exposure to an allergic trigger
Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)	Chronic rhinosinusitis with nasal polyps (CRSwNP) is an inflammatory condition affecting the paranasal sinuses and nasal cavity.(8,9) The International Consensus Statement on Allergy and Rhinology: Rhinosinusitis (ICAR-RS) indicates that the diagnostic criteria for CRSwNP consist of ALL the following:(11) • Symptoms for greater than or equal to 12 weeks • Two of the following symptoms: ○ Nasal discharge (rhinorrhea or post-nasal drainage) ○ Nasal obstruction or congestion ○ Hyposmia (loss or decreased sense of smell) ○ Facial pressure or pain ○ Cough (in pediatric patients) • One or more of the following objective findings: ○ Evidence of inflammation on nasal endoscopy or computed tomography (CT) ○ Evidence of purulence coming from paranasal sinuses or ostiomeatal complex • Presence of nasal polyps The objective confirmation of CRSwNP through documentation of sinonasal inflammation and nasal polyps can be accomplished via direct visualization by anterior rhinoscopy or nasal endoscopy, or via imaging by CT scanning. Anterior rhinoscopy allows visualization of the anterior one-third of the nasal cavity and is sufficient at detecting large polyps or gross purulence. Nasal endoscopy also allows visualization of the anterior nasal cavity, in addition to the posterior nasal cavity, nasopharynx, and sinus drainage pathway. Anterior rhinoscopy has the least cost and risk associated with it, but nasal endoscopy and CT scanning have a higher diagnostic accuracy. CT scanning also comes with the risk of radiation exposure. Serum biomarkers (e.g., elevated eosinophils, IL-5, IL-5, IgE) are emerging as a potential diagnosis tool, but their role is still not clearly defined. Currently, biomarkers are used to distinguish types of CRS and prognosis.(8) Topical saline irrigation and intranasal corticosteroids (INCS) are recommended as initial treatment for CRSwNP.(7,8,9,11) Nasal saline irrigation, used as adjunct treatment with other therapies, improves symptoms and quality of life (QoL) outcomes and is considered an important aspect of the management of CRSwNP. Saline irrigation can improve nasal mucosa function through the mechanical clearance of thick mucus and inflammatory mediators, including eosinophilic mucin.(7,11) Saline irrigation should not be confused with saline spray since irrigation is more effective in clearing secretions and improving QoL.(8) INCS can improve symptoms, reduce nasal polyp size, and improve sense of smell through their anti-inflammatory properties.(7,8,11) INCS are well tolerated and long term treatment is effective and safe. Many different corticosteroids have been used in the treatment of CRSwNP, including triamcinolone, mometasone, fluticasone, and budesonide, and different dosage forms are also available, including intranasal sprays and steroid-eluding stents. However, no specific corticosteroid or formulation is recommended as being superior to the others.(7,8) Oral systemic corticosteroids (OCS) should be considered in patients with an inadequate response to INCS after 3 months of therapy.(8) A short course (1-3 weeks) can result in a significant reduction in symptoms and nasal polyps for up to three months after the start of treatment. Up to 2 courses per year, taken in addition to INCS, can be useful for patients with partially or uncontrolled disease.(7) Long term use of OCS should be avoided due to the increased risk of adverse effects.(11)

	Endoscopic sinus surgery (ESS) is aimed at improving symptoms and creating better conditions for local treatment. Sinus surgery should be considered when disease is refractory and remains symptomatic despite trial of primary medical therapy (e.g., nasal sinus irrigation, INCS, oral corticosteroids). Based on current evidence, delaying surgical intervention can be detrimental to symptom improvement and outcomes. After surgery, patients need to continue other treatments, such as saline irrigation and INCS, due to the chronic nature of the disease and nasal polyps potentially reoccurring. INCS can help to prevent nasal polyp recurrence post-surgery.(7,11) Biologics can be considered as add-on therapy in patients where their disease remains uncontrolled despite appropriate medical treatment and/or sinus surgery, or when surgery is not a viable option.(8,9,10) For patients that continue to have high disease burden despite using INCS for at least 4 weeks, biologics may be considered and preferred over other medical treatment choices.(9) Biologics vary in their magnitude of benefits, harms, and certainty of evidence across outcomes. Based on network analyses, dupilumab and omalizumab have shown to be the most beneficial for the most patient-important outcomes when compared to other biologics, followed by mepolizumab.(8,9) Response to biologic treatment should initially be evaluated 6 months after initiation of therapy. Response can be defined as reduced nasal polyp size, reduced need for systemic oral corticosteroids, improved QoL, improved sense of smell, and/or reduced impact of comorbidities. Patients with no response should have the current biologic drug discontinued and/or switched, or a revision surgery can be considered. Patients with partial response may continue the current biologic therapy and be re-evaluated at 12 months since some biologics need more than 6 months to reach their full potential. Patients with partial response may also switch to a different biologic, consider salvage surgery, or complete an additional short course of OCS.(10)
Chronic Spontaneous Urticaria (CSU)	Chronic spontaneous urticaria (CSU), also referred to as chronic urticaria (CU) or chronic idiopathic urticaria (CIU), is a mast cell-mediated condition that involves the recurrent spontaneous occurrence of urticaria and/or angioedema.(5) Urticaria is characterized by the development of wheals (hives), angioedema, or both. CSU is defined by the presence of urticaria for more than 6 weeks with no definite eliciting factor involved. Signs and symptoms may occur daily or follow an intermittent/recurrent course.(6) Routine diagnostic tests (e.g., blood tests for complete blood count and inflammatory markers, skin prick test) are mainly used to rule out other potential diseases and not to confirm the diagnosis.(5) Medication that is suspected to worsen the disease (e.g., NSAIDs) should be discontinued or substituted by another class of agents to reduce disease exacerbations. CSU can be a debilitating condition that significantly impairs a patient's quality of life, and treatment goals include symptom control and normalization of quality of life for the patient.(6) The international European Academy of Allergy and Clinical Immunology (EAACI)/Global Allergy and Asthma European Network (GA2LEN)/European Dermatology Forum (EDF)/Asia Pacific Association of Allergy, Asthma and Clinical Immunology (APAAACI) guideline recommends the following algorithm for the treatment of CSU:(6) • First-line treatment: Second-generation H1-antihistamine at standard dosing, dosed daily (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) • Second-line treatment: If inadequate control at standard dosing, increase the daily dose of the second-generation H1-antihistamine to up to 4 times the standard dosing before other treatments are considered • Third-line treatment: If inadequate control after 2-4 weeks of therapy with a high dose second-generation H1-antihistamine, add on omalizumab High dose second-generation H1-antihistamine therapy has been suggested in guidelines since the year 2000, and no serious adverse events or side effects from long-term use or potential accumulation have been reported. Treatment for CSU should be evaluated every 3 to 6 months to assess disease activity, impact, and control. The severity of urticaria can fluctuate, including the possibility of spontaneous remission. In addition, patients should be assessed for any side effects of treatment. If

	an adjustment to treatment is warranted, it may include stepping up therapy, changing medication due to side effects, or stepping down treatment if the patient has been symptom free for 3 to 6 months.(6) Omalizumab was approved for the treatment of CSU in 2014 and has since received placement in treatment guidelines. However, for some patients omalizumab provides partial or no improvement in their signs and symptoms.(13) Current guidelines support using cyclosporine as add-on therapy for patients with severe disease and an incomplete response to omalizumab and an antihistamine used in combination, but it is not recommended as standard treatment due to the risk and incidence of adverse effects.(6) Dupilumab has been shown to be an effective treatment for CSU per the LIBERTY CUPID CSU studies, but its place in treatment guidelines has yet to be established. The LIBERTY CSU CUPID-B trial was designed to determine if dupilumab is an effective alternative in patients with a lack of response to omalizumab, incomplete control of their CSU while taking omalizumab, or an inability to tolerate the use of omalizumab. The dupilumab group in this study did not meet statistical significance for reduction in the primary endpoint of change from baseline in itch severity score over 7 days (ISS7) at Week 24.(13)
IgE-Mediated Food Allergy	Food allergies have been increasing in prevalence in the past few decades affecting about 3-10% of children and up to 10% of adults. Food allergies can be classified based on the underlying mechanism as follows: IgE-mediated (type I hypersensitivity), non-IgE mediated (type III or type IV hypersensitivity), or mixed IgE and non-IgE mediated (combination of IgE and cellular mechanisms). The European Academy of Allergy and Clinical Immunology (EAACI) defines IgE-mediated food allergy as both of the following:(14) • Typical symptoms that usually develop within 2 hours of exposure to the allergen and are reproducible upon re-exposure • Evidence of IgE sensitization and/or effector cell response to the allergen Symptoms of IgE-mediated food allergy can be cutaneous, gastrointestinal, ocular, respiratory, cardiovascular, and/or neurological related. Signs and symptoms may clinically manifest in an isolated or concomitant manner, with the same timing or differing. Reactions can range from being mild and localized to being systemic and fatal, including anaphylaxis.(15) Diagnosing IgE-mediated food allergy typically involves a detailed allergy-focused clinical history as a first step. In patients with a history of suspected IgE-mediated food allergy, the EAACI strongly recommends IgE sensitizations tests, such as a skin prick test (SPT) and/or a serum specific IgE test, as first-line to support the diagnosis. If the results are contradictory or equivocal with the clinical history, additional tests may need to be performed, including an oral food challenge (OFC). The EAACI strongly recommends a supervised OFC as the reference diagnostic procedure to confirm or exclude food allergy in patients with an unclear diagnosis despite IgE sensitization tests.(14) Due to patient and physician fears of severe reactions and logistic considerations, OFC should be reserved for cases that cannot be clarified with IgE sensitization tests.(14,15) Strict avoidance of trigger foods and training in the use of rescue medication for allergic reactions have been the main approach to manage food allergies. Strict avoidance of trigger foods can lead to reduced diet diversity, social restrictions impacting quality of life, potential risk of nutritional deficiencies, and anxiety over the possible accidental random exposure of the trigger food.(15) The Global Allergy and Asthma Excellence Network (GA2LEN) 2022 food allergy guideline suggests that people with a documented food allergy avoid the offending food unless their individual circumstances and risks allow for some consumption, as advised by their healthcare professional.(16) When severe reactions occur, prompt administration of epinephrine should be used, which is the drug of choice for anaphylaxis. Allergen immunotherapy is an option for some food allergies as a disease-modifying therapy. Allergen immunotherapy uses sequential doses of increased amounts of the allergen in an attempt to desensitize the patient to the allergen.(15) Allergen immunotherapy can be

	a treatment option for some specific food allergies (i.e., peanut, hen's egg, cow's milk) for select children and adolescents with substantial risk of severe reactions and/or substantially impaired quality of life. However, no recommendation can be made for using allergen immunotherapy in adults due to limited evidence, even though it may be useful for select adults if potential benefits outweigh the risks.(4,16) Omalizumab has shown efficacy in terms of desensitization to foods commonly implicated in food allergy (e.g., peanut, cashew nut, egg, and milk). Allergen avoidance and access to epinephrine need to be continued while treated with omalizumab.(4)
Efficacy	**Asthma** <u>Adult and Adolescent Patients 12 Years of Age and Older</u> The safety and efficacy of Xolair in adult and adolescent patients 12 years of age and older were evaluated in three randomized, double-blind, placebo-controlled, multicenter trials. All patients were required to have a baseline IgE between 30 and 700 IU/mL and a body weight not more than 150 kg. Dosing information includes weights of at least 30 kg. In Trials 1 and 2, patients had a forced expiratory volume in 1 second (FEV1) between 40% and 80% predicted, and patients had a FEV1 improvement of at least 12% following beta-2-agonist administration. In Trial 3, there was no restriction on screening FEV1. In all three trials, an exacerbation was defined as a worsening of asthma that required treatment with systemic corticosteroids or a doubling of the baseline inhaled corticosteroid dose.(1) In Trials 1 and 2, the number of exacerbations per patient was reduced in patients treated with Xolair compared with placebo. In Trial 3, the number of exacerbations in patients treated with Xolair was similar to that in the placebo-treated patients. The absence of an observed treatment effect in Trial 3 may be related to differences in the patient population compared with the other two trials. In all three trials, a reduction of asthma exacerbations was not observed in the Xolair treated patients who had an FEV1 greater than 80% at the time of randomization. Reductions in exacerbations were not seen in patients who required oral steroids as maintenance therapy.(1) <u>Pediatric Patients 6 to less than 12 Years of Age</u> The safety and efficacy of Xolair in pediatric patients 6 to less than 12 years of age with moderate to severe asthma is based on one randomized, double-blind, placebo controlled, multicenter trial (Trial 4) and an additional supportive study (Trial 5). Dosing information for pediatric patients between the ages of 6 to less than 12 years is based on weight and IgE level with dosing available for weights ranging from 30 to 150 kg and IgE levels between 30 and 1300 IU/mL.(1) Trial 4 evaluated Xolair as add-on therapy in patients with inadequately controlled asthma despite the use of inhaled corticosteroids with or without other controller asthma medications. Patients had a history of clinical features such as daytime and/or night-time symptoms and exacerbations within the year prior to study entry. The primary efficacy variable was the rate of asthma exacerbations during the 24-week, fixed steroid treatment phase. An asthma exacerbation was defined as a worsening of asthma symptoms as judged clinically by the investigator, requiring doubling of the baseline inhaled corticosteroid dose for at least 3 days and/or treatment with rescue systemic (oral or IV) corticosteroids for at least 3 days. At 24 weeks, the Xolair group had a statistically significantly lower rate of asthma exacerbations (0.45 vs 0.64) with an estimated rate ratio of 0.69 (95% CI).(1) **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)** The safety and efficacy of Xolair was evaluated in two randomized, multicenter, double-blind, placebo-controlled clinical trials that enrolled patients with CRSwNP with inadequate response to nasal corticosteroids. All patients received background nasal mometasone therapy during both the treatment period and during a 5-week run-in period. Prior to randomization, patients were required to have evidence of bilateral

	polyps and nasal congestion despite use of nasal mometasone during the run-in period. Prior sino-nasal surgery or prior systemic corticosteroid usage were not required for inclusion in the trials. The co-primary endpoints in both trials were nasal polyp score (NPS) and average daily nasal congestion score (NCS) at Week 24. In both trials, patients who received Xolair had statistically significant greater improvement from baseline at Week 24 in NPS and weekly average NCS than patients who received placebo. The greater improvements in NPS and NCS in the XOLAIR group compared to the placebo group were observed as early as the first assessment at Week 4 in both studies.(1) **Chronic Spontaneous Urticaria (CSU)** The safety and efficacy of Xolair for the treatment of CSU, previously referred to as chronic idiopathic urticaria (CIU), was assessed in two placebo-controlled, multiple-dose clinical trials of 24 and 12 weeks duration. Patients received Xolair in addition to their baseline level of H1 antihistamine therapy. Disease severity was measured by a weekly urticaria activity score (UAS7), which is a composite of the weekly itch severity score and the weekly hive count score. All patients were required to have a UAS7 of greater than or equal to 16 and a weekly itch severity score greater than or equal to 8 for the 7 days prior to randomization, despite having used an H1 antihistamine for at least 2 weeks. In both trials, patients who received Xolair 150 mg or 300 mg had greater decreases from baseline in weekly itch severity score and weekly hive count scores than placebo at Week 12.(1) **IgE-Mediated Food Allergy** The safety and efficacy of Xolair was evaluated in a multi-center, randomized, double-blind, placebo-controlled Food Allergy (FA) trial (NCT03881696) in adult and pediatric patients 1 year of age to less than 56 years who were allergic to peanut and at least two other foods, including milk, egg, wheat, cashew, hazelnut, or walnut (i.e., studied foods). The FA trial enrolled patients who experienced dose-limiting symptoms (e.g., moderate to severe skin, respiratory, or gastrointestinal symptoms) to a single dose of less than or equal to 100 mg of peanut protein and less than or equal to 300 mg protein for each of the other two foods during the screening double-blind placebo-controlled food challenge (DBPCFC). Patients with a history of severe anaphylaxis (defined as neurological compromise or requiring intubation) were excluded from the study. Patients were randomized 2:1 to receive a subcutaneous dosage of Xolair (based on serum IgE level measured before the start of treatment and body weight) or placebo every 2 to 4 weeks for 16 to 20 weeks. After 16 to 20 weeks of treatment, each patient completed a DBPCFC consisting of placebo and each of their 3 studied foods.(1) Efficacy of Xolair was based on 165 pediatric patients who were included in the efficacy analyses. The efficacy of Xolair in adults is supported by the adequate and well-controlled trial of Xolair in pediatric patients, disease similarity in pediatric and adult patients, and pharmacokinetic (PK) similarity. The primary efficacy endpoint was the percentage of patients who were able to consume a single dose of greater than or equal to 600 mg of peanut protein without dose-limiting symptoms during DBPCFC. Xolair treatment led to a statistically higher response rate (68%) than placebo (5%). The secondary efficacy endpoints were the percentage of patients who were able to consume a single dose of greater than or equal to 1000 mg of cashew, milk, or egg protein without dose-limiting symptoms during DBPCFC. The study met the secondary endpoints and demonstrated that Xolair treatment led to statistically higher response rates than placebo for all three foods.(1)
Safety	Omalizumab has a boxed warning due to risk of anaphylaxis. Because of the risk of anaphylaxis, therapy should be initiated in a healthcare setting and the patient closely observed for an appropriate period of time after administration. Inform patients of the signs and symptoms of anaphylaxis and instruct them to seek immediate medical care should symptoms occur. Discontinue omalizumab in patients who experience severe hypersensitivity reaction. Selection of patients for self-administration should be based

	on criteria to mitigate risk from anaphylaxis. Patient-specific factors including the following criteria should be considered:(1) • Patient should have no prior history of anaphylaxis, including to omalizumab, or other agents such as foods, drugs, biologics, etc. ○ *For IgE-Mediated Food Allergy*: Patient should have no prior history of anaphylaxis to omalizumab or other agents (except foods), such as drugs, biologics, etc. • Patient should receive at least 3 doses of omalizumab under the guidance of a healthcare provider with no hypersensitivity reactions • Patient or caregiver is able to recognize symptoms of anaphylaxis • Patient or caregiver is able to treat anaphylaxis appropriately • Patient or caregiver is able to perform subcutaneous injections with omalizumab prefilled syringe or autoinjector with proper technique according to the prescribed dosing regimen and Instructions for Use Omalizumab is contraindicated in patients with severe hypersensitivity reaction to omalizumab or any ingredient of the omalizumab product.(1)

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POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Xolair	omalizumab subcutaneous soln auto-injector	150 MG/ML ; 300 MG/2ML ; 75 MG/0.5ML	M ; N ; O ; Y	N		
Xolair	omalizumab subcutaneous soln prefilled syringe	150 MG/ML ; 300 MG/2ML ; 75 MG/0.5ML	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Xolair	omalizumab subcutaneous soln auto-injector	150 MG/ML ; 300 MG/2ML ; 75 MG/0.5ML	Accord Core ; Accord Enhanced ; Accord Standard ; Choice NetR - A Select ; Choice NetR - F Performance ; Choice NetR-HIM ; Net Results A Core
Xolair	omalizumab subcutaneous soln prefilled syringe	150 MG/ML ; 300 MG/2ML ; 75 MG/0.5ML	Accord Core ; Accord Enhanced ; Accord Standard ; Choice NetR - A Select ; Choice NetR - F Performance ; Choice NetR-HIM ; Net Results A Core

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
PA	**Initial Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The requested agent is eligible for continuation of therapy AND ONE of the following: **Agents Eligible for Continuation of Therapy** All target agents are eligible for continuation of therapy 1. The patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days **OR**

Module	Clinical Criteria for Approval
	2. The prescriber states the patient has been treated with the requested agent (starting on samples is not approvable) within the past 90 days AND is at risk if therapy is changed **OR** B. BOTH of the following: 1. ONE of the following: A. The patient has a diagnosis of moderate to severe persistent asthma AND ALL of the following: 1. If the patient is 6 to less than 12 years of age, then BOTH of the following: A. The patient's pretreatment IgE level is 30 IU/mL to 1300 IU/mL **AND** B. The patient's weight is 20 kg to 150 kg **AND** 2. If the patient is 12 years of age or over, then BOTH of the following: A. The patient's pretreatment IgE level is 30 IU/mL to 700 IU/mL **AND** B. The patient's weight is 30 kg to 150 kg **AND** 3. Allergic asthma has been confirmed by a positive skin test or in vitro reactivity test to a perennial aeroallergen **AND** 4. ONE of the following: A. The patient has a history of uncontrolled asthma while on asthma control therapy (e.g., inhaled corticosteroid [ICS]/long-acting beta-2 agonist [LABA] combination therapy) as demonstrated by ONE of the following: 1. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR** 2. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR** 3. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR** 4. Baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **OR** B. The patient's medication history (excluding sample use) indicates use of a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of asthma within the past 12 months **OR** B. The patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]) AND ALL of the following: 1. The patient has had hives and itching for more than 6 weeks **AND** 2. The prescriber has evaluated the patient to determine if the patient is currently treated with medication known to cause or worsen urticaria (e.g., NSAIDs) in order to reduce urticaria risk **AND** 3. The patient has ONE of the following: A. Tried and had an inadequate response to the FDA labeled maximum dose of ONE second-generation H1-antihistamine (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) AND ONE of the following:

Module	Clinical Criteria for Approval
	1. The patient has tried and had an inadequate response to a maximally tolerated dose of ONE second-generation H1-antihistamine titrated up to 4 times above the FDA labeled maximum dose after at least a 2-week duration of therapy **OR** 2. There is support that the patient cannot be treated with a second-generation H1-antihistamine at a dose above the FDA labeled maximum dose **OR** B. An intolerance or hypersensitivity to ONE second-generation H1-antihistamine **OR** C. An FDA labeled contraindication to ALL second-generation H1-antihistamines **OR** C. The patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) AND ALL of the following: 1. BOTH of the following: A. The patient's pretreatment IgE level is 30 IU/mL to 1500 IU/mL **AND** B. The patient's weight is 30 kg to 150 kg **AND** 2. The patient has at least TWO of the following symptoms consistent with chronic rhinosinusitis (CRS): A. Nasal discharge (rhinorrhea or post-nasal drainage) B. Nasal obstruction or congestion C. Loss or decreased sense of smell (hyposmia) D. Facial pressure or pain **AND** 3. The patient has had symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks **AND** 4. The patient's diagnosis was confirmed by ONE of the following: A. Anterior rhinoscopy **OR** B. Nasal endoscopy **OR** C. Computed tomography (CT) of the sinuses **AND** 5. The patient has ONE of the following: A. Tried and had an inadequate response to ONE intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva) after at least a 4-week duration of therapy **OR** B. An intolerance or hypersensitivity to ONE intranasal corticosteroid (e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva) **OR** C. An FDA labeled contraindication to ALL intranasal corticosteroids **OR** D. The patient has a diagnosis of IgE-mediated food allergy AND ALL of the following: 1. BOTH of the following: A. The patient's pretreatment IgE level is 30 IU/mL to 1850 IU/mL **AND** B. The patient's weight is 10 kg to 150 kg **AND** 2. The patient has an IgE-mediated food allergy confirmed by an allergy diagnostic test (e.g., skin prick test, serum specific IgE test, oral food challenge) **AND** 3. The requested agent will NOT be used for the emergency treatment of allergic reactions, including anaphylaxis **OR** E. The patient has another FDA labeled indication for the requested agent and route of administration **AND** 2. If the patient has an FDA labeled indication, then ONE of the following:

Module	Clinical Criteria for Approval
	A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. There is support for using the requested agent for the patient's age for the requested indication **OR** C. The patient has another indication that is supported in compendia for the requested agent and route of administration **AND** 2. If the patient has a diagnosis of moderate to severe persistent asthma, then ALL of the following: A. ONE of the following: 1. The patient is NOT currently treated with a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of asthma (including the requested agent) AND is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months AND has been adherent for 90 days within the past 120 days **OR** 2. The patient is currently treated with a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of asthma (including the requested agent) AND ONE of the following: A. The patient is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms AND has been adherent for 90 days within the past 120 days **OR** B. The patient is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months AND has been adherent for 90 days within the past 120 days **OR** 3. The patient has an intolerance or hypersensitivity to ONE inhaled corticosteroid **OR** 4. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND** B. ONE of the following: 1. The patient is currently treated for at least 3 months AND has been adherent for 90 days within the past 120 days with ONE of the following: A. A long-acting beta-2 agonist (LABA) **OR** B. A long-acting muscarinic antagonist (LAMA) **OR** C. A leukotriene receptor antagonist (LTRA) **OR** D. Theophylline **OR** 2. The patient has an intolerance or hypersensitivity to ONE long-acting beta-2 agonist (LABA), long-acting muscarinic antagonist (LAMA), leukotriene receptor antagonist (LTRA), or theophylline **OR** 3. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA) AND long-acting muscarinic antagonists (LAMA) **AND** C. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND** D. The requested quantity (dose) is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 375 mg every 2 weeks **AND** 3. If the patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP), then ALL of the following: A. The patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids [e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva]) **AND** B. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids [e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva]) in combination with the requested agent **AND** C. The requested quantity (dose) is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 600 mg every 2 weeks **AND** 4. If the patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]), then BOTH of the following: A. ONE of the following: 1. BOTH of the following:

Module	Clinical Criteria for Approval
	A. The patient is currently treated with second-generation H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) **AND** B. The patient will continue second-generation H1-antihistamine therapy in combination with the requested agent **OR** 2. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL second-generation H1-antihistamines **AND** B. The requested quantity (dose) is within FDA labeling AND does NOT exceed 300 mg every 4 weeks **AND** 5. If the patient has a diagnosis of IgE-mediated food allergy, then ALL of the following: A. The patient will avoid known food allergens while treated with the requested agent **AND** B. The patient has epinephrine on hand for emergency treatment **AND** C. The requested quantity (dose) is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 600 mg every 2 weeks **AND** 6. If the patient has another FDA labeled indication for the requested agent, the requested quantity (dose) is within FDA labeling for the requested indication **AND** 7. If the patient has another indication that is supported in compendia for the requested agent, the requested quantity (dose) is supported in compendia for the requested indication **AND** 8. The prescriber is a specialist in the area of the patient's diagnosis (e.g., asthma: allergist, immunologist, pulmonologist; CRSwNP: otolaryngologist, allergist, immunologist, pulmonologist; CSU: allergist, dermatologist, immunologist; IgE-mediated food allergy: allergist, immunologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 9. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) **AND** 10. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) **AND** 2. ONE of the following: A. The patient has a diagnosis of moderate to severe persistent asthma AND ALL of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The patient is currently treated within the past 90 days and is compliant with asthma control therapy (e.g., inhaled corticosteroids [ICS], ICS/long-acting beta-2 agonist [ICS/LABA], leukotriene receptor antagonist [LTRA], long-acting muscarinic antagonist [LAMA], theophylline) **AND**

Module	Clinical Criteria for Approval
	3. The requested quantity (dose) is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 375 mg every 2 weeks **OR** B. The patient has a diagnosis of chronic spontaneous urticaria (CSU) (otherwise known as chronic idiopathic urticaria [CIU]) AND ALL of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. ONE of the following: A. The patient will continue second-generation H1-antihistamine therapy (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) in combination with the requested agent **OR** B. The patient has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL second-generation H1-antihistamines **AND** 3. The requested quantity (dose) is within FDA labeling for the requested indication AND does NOT exceed 300 mg every 4 weeks **OR** C. The patient has a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) AND ALL of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids [e.g., fluticasone nasal spray, mometasone nasal spray, Sinuva]) in combination with the requested agent **AND** 3. The requested quantity (dose) is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 600 mg every 2 weeks **OR** D. The patient has a diagnosis of IgE-mediated food allergy AND ALL of the following: 1. The patient will avoid known food allergens while treated with the requested agent **AND** 2. The patient has epinephrine on hand for emergency treatment **AND** 3. The requested quantity (dose) is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 600 mg every 2 weeks **OR** E. The patient has a diagnosis other than moderate to severe persistent asthma, CSU/CIU, CRSwNP, or IgE-mediated food allergy AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The requested quantity (dose) is within FDA labeling or supported in compendia for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., asthma: allergist, immunologist, pulmonologist; CRSwNP: otolaryngologist, allergist, immunologist, pulmonologist; CSU: allergist, dermatologist, immunologist; IgE-mediated food allergy: allergist, immunologist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 4. ONE of the following (Please refer to "Agents NOT to be used Concomitantly" table): A. The patient will NOT be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL-4 inhibitors) **OR** B. The patient will be using the requested agent in combination with another immunomodulatory agent AND BOTH of the following: 1. The prescribing information for the requested agent does NOT limit the use with another immunomodulatory agent **AND** 2. There is support for the use of combination therapy (submitted copy of clinical trials, phase III studies, or guidelines required) **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Compendia Allowed:** AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use **Length of Approval:** 12 months

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy
Agents NOT to be used Concomitantly Abrilada (adalimumab-afzb) Actemra (tocilizumab) Adalimumab Adbry (tralokinumab-ldrm) Amjevita (adalimumab-atto) Arcalyst (rilonacept) Avsola (infliximab-axxq) Avtozma (tocilizumab-anoh) Benlysta (belimumab) Bimzelx (bimekizumab-bkzx) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Cyltezo (adalimumab-adbm) Dupixent (dupilumab) Ebglyss (lebrikizumab-lbkz) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Hadlima (adalimumab-bwwd) Hulio (adalimumab-fkjp) Humira (adalimumab) Hyrimoz (adalimumab-adaz) Idacio (adalimumab-aacf) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn) Imuldosa (ustekinumab-srlf) Inflectra (infliximab-dyyb) Infliximab Kevzara (sarilumab) Kineret (anakinra) Leqselvi (deuruxolitinib) Litfulo (ritlecitinib) Nemluvio (nemolizumab-ilto) Nucala (mepolizumab) Olumiant (baricitinib) Omlyclo (omalizumab-igec) Omvoh (mirikizumab-mrkz) Opzelura (ruxolitinib) Orencia (abatacept) Otezla (apremilast) Otezla XR (apremilast extended-release) Otulfi (ustekinumab-aauz) Pyzchiva (ustekinumab-ttwe) Remicade (infliximab) Renflexis (infliximab-abda) Rhapsido (remibrutinib) Riabni (rituximab-arrx) Rinvoq (upadacitinib) Rituxan (rituximab) Rituxan Hycela (rituximab/hyaluronidase human) Ruxience (rituximab-pvvr) Saphnelo (anifrolumab-fnia) Selarsdi (ustekinumab-aekn) Siliq (brodalumab) Simlandi (adalimumab-ryvk)

Contraindicated as Concomitant Therapy
Simponi (golimumab) Simponi ARIA (golimumab) Skyrizi (risankizumab-rzaa) Sotyktu (deucravacitinib) Spevigo (spesolimab-sbzo) subcutaneous injection Starjemza (ustekinumab-hmny) Stelara (ustekinumab) Steqeyma (ustekinumab-stba) Taltz (ixekizumab) Tezspire (tezepelumab-ekko) Tofidence (tocilizumab-bavi) Tremfya (guselkumab) Truxima (rituximab-abbs) Tyenne (tocilizumab-aazg) Tyruko (natalizumab-sztn) Tysabri (natalizumab) Ustekinumab Velsipity (etrasimod) Wezlana (ustekinumab-auub) Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Yesintek (ustekinumab-kfce) Yuflyma (adalimumab-aaty) Yusimry (adalimumab-aqvh) Zeposia (ozanimod) Zymfentra (infliximab-dyyb)

