Xolair (omalizumab) Medical Drug Criteria Program Summary

POLICY REVIEW CYCLE

Effective Date 5/1/2023

Date of Origin

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Xolair® (omalizumab) Injection for subcutaneous use	Moderate to severe persistent asthma in patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids Limitation of use: Omalizumab is not indicated for treatment of other allergic conditions, other forms of urticaria, relief of acute bronchospasms, or status asthmaticus. Chronic idiopathic urticaria in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment Add-on maintenance treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids		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.(2,3) It is characterized by variable and recurring clinical symptoms, airflow obstruction, bronchial hyperresponsiveness, and underlying inflammation.(2) Symptoms of asthma include wheezing, coughing, recurrent difficulty breathing, shortness of breath, and chest tightness. Generally, these symptoms will occur or worsen with exposure to allergens and irritants, infections, exercise, changes in weather, stress, or menstrual cycles. Guidelines recommend the use of detailed medical history, physical examination, and spirometry to make a diagnosis of asthma.(2,3) The Global Initiative for Asthma (GINA) guidelines recommend a stepwise approach for managing asthma. Long-term goals for asthma management are to achieve good control of symptoms, maintain normal activity level, and to minimize the future risk of exacerbations, fixed airflow limitation, and side-effects.(3) IgE is the antibody responsible for activation of allergic reactions and is important to the pathogenesis of allergic asthma and the development and persistence of inflammation. GINA guidelines define moderate asthma as that which is well controlled with low dose inhaled corticosteroids (ICS) in combination with a long-acting beta agonist (LABA). Severe

	asthma is defined as asthma that requires Step 4 or 5 treatment (e.g., with high dose ICS plus a LABA) to prevent it from becoming 'uncontrolled' or which remains uncontrolled despite this therapy. Early initiation of low dose ICS in patients with asthma has led to greater improvement in lung function than initiation of ICS after symptoms have been present for more than 2 to 4 years. The 2022 GINA guidelines recommend every adult and adolescent with asthma should receive ICS-containing controller medication to reduce the risk of serious exacerbation, even in patients with infrequent symptoms.(3)
	
	2022 GINA STEP recommendations for adults and adolescents (12 years of age and over) are intended to reduce the risk of serious exacerbations and are broken into two tracks based on reliever therapy.
	
	Track 1 is the preferred approach recommended by GINA, because using low dose ICS-formoterol as reliever reduces the risk of severe exacerbations compared with regimens with SABA as reliever, with similar symptom control:(3)
	
	• Step 1: As-needed low dose ICS-formoterol
	• Step 2: As-needed low dose ICS-formoterol
	  ○ Alternative options: Daily leukotriene receptor antagonist (LTRA), or add house dust mite (HDM) sublingual immunotherapy (SLIT)
	  ○ LTRA are less effective than ICS, particularly for preventing exacerbations
	• Step 3: address and treat modifiable risk factors (e.g., adherence, technique) before considering step up
	  ○ Preferred controller: Low dose maintenance ICS-formoterol
	  ○ Reliever: As-needed low dose ICS-formoterol
	  ○ Alternative options: Medium dose ICS, or add LTRA, or add HDM SLIT
	• Step 4: Medium dose maintenance ICS-formoterol
	  ○ Reliever: As-needed low dose ICS-formoterol
	  ○ Alternative options: Add long-acting muscarinic antagonist (LAMA) or LTRA, or switch to high dose ICS
	• Step 5: Add-on LAMA; refer for phenotypic assessment and consider high dose ICS-formoterol with add on anti-IgE, anti-IL5/5R, anti-IL4R, or anti-TSLP
	  ○ Reliever: As-needed low dose ICS-formoterol
	  ○ Alternative options: Add azithromycin (adults) or LTRA; add low dose oral corticosteroids (OCS) but consider side effects
	
	Track 2 is an alternative approach if Track 1 is not possible or is not preferred by a patient with no exacerbations on their current therapy. Before considering a regimen with SABA reliever, the clinician should consider whether the patient is likely to be adherent with their controller therapy; if not, they will be exposed to the risks of SABA-only treatment:(3)
	
	• Step 1: Take ICS whenever SABA taken
	  ○ Reliever: As-needed short-acting β-2 agonist (SABA)
	• Step 2: Low dose maintenance ICS
	  ○ Reliever: As-needed SABA
	  ○ Alternative options: Low dose ICS whenever SABA taken, or daily LTRA, or add HDM SLIT
	  ○ LTRA are less effective than ICS, particularly for preventing exacerbations
	• Step 3: address and treat modifiable risk factors (e.g., adherence, technique) before considering step up

	○ Preferred controller: Low dose maintenance ICS-LABA ○ Reliever: As-needed SABA ○ Alternative options: Medium dose ICS, or add LTRA, or add HDM SLIT • Step 4: Medium/high dose maintenance ICS-LABA ○ Reliever: As-needed SABA ○ Alternative options: Add LAMA or LTRA, or switch to high dose ICS • Step 5: Add-on LAMA; refer for phenotypic assessment and consider high dose ICS-LABA with add on anti-IgE, anti-IL5/5R, anti-IL4R, or anti-TSLP ○ Reliever: As-needed SABA ○ Alternative options: Add azithromycin (adults) or LTRA; add low dose oral corticosteroids (OCS) but consider side effects 2022 GINA STEP recommendations for children (6 to 11 years of age) are intended to reduce the risk of serious exacerbations:(3) • Step 1: low dose ICS taken whenever SABA taken ○ Reliever: as needed SABA (or ICS-formoterol reliever for maintenance and reliever therapy [MART]) ○ Alternative controller: daily low dose ICS (likelihood of poor adherence should be taken into account) • Step 2: daily low dose ICS ○ Reliever: as needed SABA (or ICS-formoterol reliever for MART) ○ Alternative options: Leukotriene receptor antagonist (LTRA) or as needed ICS taken at the same time as a SABA ○ LTRA are less effective than ICS, particularly for preventing exacerbations • Step 3: address and treat modifiable risk factors (e.g., adherence, technique) before considering step up ○ Preferred controller: low dose ICS-LABA OR medium dose ICS OR very lose dose ICS-formoterol MART ○ Reliever: as needed SABA (or ICS-formoterol reliever for MART) ○ Alternative controller: low dose • Step 4: medium dose ICS-LABA OR low dose ICS-formoterol MART ○ Reliever: as needed SABA (or ICS-formoterol reliever for MART) ○ Alternative options: add-on tiotropium or add-on LTRA ○ Refer for expert advice • Step 5: refer for phenotypic assessment with or without higher dose ICS-LABA or add on therapy with anti-IgE or anti-IL4R ○ Reliever: as needed SABA (or ICS-formoterol reliever for MART) ○ Alternative options: add-on anti-IL5/5R (i.e., mepolizumab), or as a last resort consider add on low dose OCS but consider side effects **Moderate to Severe Allergic (IgE-mediated) Asthma** Allergic asthma is triggered by inhalation of allergens triggering the production of IgE, the antibody responsible for activation of allergic reactions. IgE is important to the pathogenesis of allergic asthma and the development and persistence of inflammation.(3,4) Severe asthma is defined by GINA guidelines as asthma that is uncontrolled despite adherence with maximal optimized GINA Step 4 or Step 5 therapy (e.g., medium or high dose ICS with a second controller; maintenance OCS) and treatment of contributory factors (e.g., inhaler technique, smoking or comorbidities), or that worsens when high dose treatment is decreased. Roughly 3% to 10% of adults with asthma have severe asthma. Guidelines recommend use of omalizumab as add on therapy for patients who have failed to respond to standard therapy and have IgE-mediated allergic asthma.(3,4) The European Respiratory Society (ERS)/American Thoracic Society (ATS) guidelines (2014; updated 2020) and the National Asthma

	Education and Prevention Program Coordinating Committee Expert Panel Working Group mirror the GINA definition of severe asthma, and defined uncontrolled asthma for adult and pediatric patients 5 years of age and over:(2,12)
	
	• 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., FEV1 less than 80% predicted)
	• Asthma that worsens upon tapering of high-dose ICS or systemic corticosteroids
	
	A specialist, preferably in a multidisciplinary severe asthma clinic (if available) performs further assessment, which includes the patient's inflammatory phenotype (i.e., Type 2 or non-Type 2).(3)
	
	Biologic agents should be considered as add-on therapy for patients with refractory Type 2 inflammation with exacerbations or poor symptom control despite taking at least high dose ICS/LABA, and who have allergic or eosinophilic biomarkers or need maintenance OCS.(3) 2022 GINA recommends the biologics below based on patient eligibility factors:
	
	• Anti-IgE (omalizumab):
	  ○ Sensitization on skin prick testing or specific IgE
	  ○ Total serum IgE and weight within dosage range
	  ○ Exacerbations in the last year
	• Anti-IL5/Anti-IL5R (benralizumab, mepolizumab, reslizumab):
	  ○ Exacerbations in the last year
	  ○ Blood eosinophils greater than or equal to 150 cells/microliter (for benralizumab and mepolizumab) or greater than or equal to 300 cells/microliter (for reslizumab)
	• Anti-IL4R (dupilumab):
	  ○ Exacerbations in the last year
	  ○ 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
	• Anti-TSLP (tezepelumab):
	  ○ Exacerbations in the last year
	
	Patient response should be evaluated 4 months after initiating therapy and follow up should occur every 3 to 6 months thereafter. 2022 GINA recommends the following step-down therapy process in patients responding well to targeted biologic therapy:(3)
	
	• Reevaluate the need for each asthma medication every 3 to 6 months, but inhaled therapy should not be completely stopped
	• Oral treatments: gradually decreased starting with OCS due to significant adverse effects.
	• Inhaled treatments: consider reducing ICS dose after 3 to 6 months, but do not completely stop inhaled therapy. Continue at least medium dose ICS and remind patients of the importance of continued inhaled controller therapy
	• Biologic treatments: trial withdrawal after 12 months of treatment and only if patient's asthma remains well controlled on medium dose ICS, and for allergic asthma, there is no further exposure to a previous allergic trigger

Chronic Idiopathic Urticaria (CIU)	Urticaria is characterized by the development of wheals (hives), angioedema, or both. Chronic urticaria is defined by the presence of urticaria that has been continuously or intermittently present for more than 6 weeks.(5,6) Treatment goals for CIU involves symptom control and improvement in quality of life that is acceptable to the patient.(6) The 2021 EAACI/GA LEN/EDF/WAO guidelines, endorsed by the American Academy of Allergy, Asthma, and Immunology, American Academy of Dermatology, American College of Asthma, and Allergy, and Immunology, recommend the following for the treatment of CIU:(6) • Recommend discontinuing medications suspected to worsen CIU (e.g., NSAIDs) • First line treatment: second-generation H-1 antihistamine (cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine) dosed daily • Second-line treatment: Increase the dose up to 4 times the FDA max if inadequate control after 2-4 weeks of therapy at the FDA max • Third-line treatment: addition of omalizumab

Chronic Rhinosinusitis with Nasal Polyposis	Chronic rhinosinusitis with nasal polyposis (CRSwNP) is an inflammatory condition affecting the paranasal sinuses. The International Consensus Statement on allergy and rhinology: Rhinosinusitis indicates that the diagnostic criteria for chronic rhinosinusitis (CRS) consist of ALL the following:(11)
	
	• Symptoms 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
	• One or more of the following findings:
	  ○ Evidence of inflammation on nasal endoscopy or computed tomography
	  ○ Evidence of purulence coming from paranasal sinuses or ostiomeatal complex
	
	Sinus computed tomography (CT) and/or nasal endoscopy are needed to determine the presence of sinonasal inflammation and nasal polyps. The exact cause of CRSwNP is unknown, but biopsies of nasal polyps have shown elevated levels of eosinophils.(8)
	
	First line therapy for CRSwNP consists of nasal saline irrigation in combination with intranasal corticosteroids.(8-10) The American Academy of Family Physicians notes that no one intranasal corticosteroid is superior to another or that increased dosing provides greater effectiveness. The American Academy of Otolaryngology recommends a short course of oral corticosteroids if no response is seen with intranasal corticosteroids after 3-months of appropriate use.(10) Short courses of oral corticosteroids (up to three weeks) can improve sinonasal symptoms and endoscopic findings. Surgical intervention may be required in patients in which medical therapy is ineffective.(8,9)

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. 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 Xolair or other agents such as foods, drugs, biologics, etc • Patient should receive at least 3 doses of Xolair 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 Xolair prefilled syringe with proper technique according to the prescribed dosing regimen and Instructions for Use Omalizumab is contraindicated in patients with history of hypersensitivity to omalizumab or any ingredients of omalizumab.(1)

REFERENCES

Number	Reference
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3	Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2022. Available at www.ginasthma.org
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12	National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. 2020 Focused updates to the asthma management guidelines. National Heart, Lung, and Blood Institute, 2007. Available at: https://www.nhlbi.nih.gov/health-topics/all-publications-and-resources/2020-focused-updates-asthma-management-guidelines

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Preferred Status	Effective Date
Xolair	omalizumab for inj ; omalizumab subcutaneous soln prefilled syringe	150 MG ; 150 MG/ML ; 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 for inj ; omalizumab subcutaneous soln prefilled syringe	150 MG ; 150 MG/ML ; 75 MG/0.5ML	Commercial ; HIM ; ResultsRx

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. ONE of the following: A. The patient has a diagnosis of moderate to severe persistent asthma AND ALL of the following: 1. ONE of the following: A. The patient is 6 to less than 12 years of age AND BOTH of the following: 1. The pretreatment IgE level is 30 IU/mL to 1300 IU/mL **AND** 2. The patient's weight is 20 kg to 150 kg **OR** B. The patient is 12 years of age or over AND BOTH of the following: 1. The pretreatment IgE level is 30 IU/mL to 700 IU/mL **AND** 2. The patient's weight is 30 kg to 150 kg **AND** 2. Allergic asthma has been confirmed by a positive skin test or in vitro reactivity test (RAST) to a perennial aeroallergen **AND** 3. The patient has a history of uncontrolled asthma while on asthma control therapy as demonstrated by ONE of the following: A. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **OR** B. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **OR** C. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **OR** D. The patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **AND** 4. ONE of the following: A. The patient is NOT currently being treated with the requested agent AND is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR** B. The patient is currently being treated with the requested agent AND ONE of the following:

Module	Clinical Criteria for Approval
	1. Is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms **OR** 2. Is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **OR** C. The patient has an intolerance or hypersensitivity to inhaled corticosteroid therapy **OR** D. The patient has an FDA labeled contraindication to ALL inhaled corticosteroids **AND** 5. ONE of the following: A. The patient is currently being treated for at least 3 months with ONE of the following: 1. A long-acting beta-2 agonist (LABA) **OR** 2. A Leukotriene receptor antagonist (LTRA) **OR** 3. Long-acting muscarinic antagonist (LAMA) **OR** 4. Theophylline **OR** B. The patient has an intolerance or hypersensitivity to therapy with long-acting beta-2 agonists (LABA), leukotriene receptor antagonists (LTRA), long-acting muscarinic antagonists (LAMA), or theophylline **OR** C. The patient has an FDA labeled contraindication to ALL long-acting beta-2 agonists (LABA), leukotriene receptor antagonists (LTRA), long-acting muscarinic antagonists (LAMA), AND theophylline **AND** 6. The patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA, theophylline) in combination with the requested agent **AND** 7. The requested 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 idiopathic urticaria (CIU) AND ALL of the following: 1. The patient has had over 6 weeks of hives and itching **AND** 2. If the patient is currently being treated with medications known to cause or worsen urticaria, then ONE of the following: A. The prescriber has reduced the dose or discontinued any medications known to cause or worsen urticaria (e.g., NSAIDs) **OR** B. The prescriber has provided information indicating that a reduced dose or discontinuation of any medications known to cause or worsen urticaria is not appropriate **AND** 3. ONE of the following: A. The patient has tried and had an inadequate response to the FDA labeled maximum dose of a second-generation H-1 antihistamine (e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine) after at least a 2-week trial AND ONE of the following: 1. The patient has tried and had an inadequate response to a dose titrated up to 4 times the FDA labeled maximum dose of a second-generation H-1 antihistamine **OR** 2. The prescriber has provided information indicating the patient cannot be treated with a dose titrated up to 4 times the FDA labeled maximum dose of a second-generation H-1 antihistamine **OR** B. The patient has an intolerance or hypersensitivity to second-generation H-1 antihistamine therapy **OR** C. The patient has an FDA labeled contraindication to ALL second-generation H-1 antihistamines **AND** 4. The requested dose is within FDA labeled dosing 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 polyposis (CRSwNP) AND ALL of the following:

Module	Clinical Criteria for Approval
	1. There is information indicating the patient's diagnosis was confirmed by ONE of the following: A. Anterior rhinoscopy or endoscopy **OR** B. Computed tomography (CT) of the sinuses **AND** 2. ONE of the following: A. The patient has tried and had an inadequate response to intranasal corticosteroids (e.g., fluticasone) used for at least a 3-month trial **OR** B. The patient has an intolerance or hypersensitivity to therapy with intranasal corticosteroids (e.g., fluticasone) **OR** C. The patient has an FDA labeled contraindication to ALL intranasal corticosteroids **AND** 3. BOTH of the following: A. The patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) **AND** B. The patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **AND** 4. The requested 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 another FDA approved indication for the requested agent AND the requested dose is within FDA labeled dosing for the requested indication **OR** E. The patient has another indication that is supported in compendia for the requested agent AND the requested dose is supported in compendia for the requested indication **AND** 2. ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) 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. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, 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:** 6 months for asthma, chronic idiopathic urticaria, and nasal polyps 12 months for all other indications **Renewal Evaluation**

Module	Clinical Criteria for Approval
	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 Medical Drug Review process **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 improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following: A. Increase in percent predicted Forced Expiratory Volume (FEV1) **OR** B. Decrease in the dose of inhaled corticosteroid required to control the patient's asthma **OR** C. Decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **OR** D. Decrease in the number of hospitalizations, need for mechanical ventilation, or visits to the emergency room or urgent care due to exacerbations of asthma **AND** 2. The patient is currently treated and is compliant with standard therapy [i.e., inhaled corticosteroids (ICS), ICS/long-acting beta-2 agonist (ICS/LABA), leukotriene receptor antagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline] **AND** 3. The requested 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 idiopathic urticaria AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The requested dose is within FDA labeled dosing 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 polyposis (CRSwNP) AND BOTH 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) in combination with the requested agent **AND** 3. The requested 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 another FDA approved indication for the requested agent AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The requested dose is within FDA labeled dosing for the requested indication **OR** E. The patient has another indication that is supported in compendia for the requested agent AND BOTH of the following: 1. The patient has had clinical benefit with the requested agent **AND** 2. The requested dose is supported in compendia for the requested indication **AND** 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., allergist, immunologist, otolaryngologist, pulmonologist) 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**

Module	Clinical Criteria for Approval
	2. The prescriber has provided information in support of combination therapy (submitted copy required, e.g., clinical trials, phase III studies, 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 Adbry (tralokinumab-ldrm) Actemra (tocilizumab) Arcalyst (rilonacept) Avsola (infliximab-axxq) Benlysta (belimumab) Cibinqo (abrocitinib) Cimzia (certolizumab) Cinqair (reslizumab) Cosentyx (secukinumab) Dupixent (dupilumab) Enbrel (etanercept) Entyvio (vedolizumab) Fasenra (benralizumab) Humira (adalimumab) Ilaris (canakinumab) Ilumya (tildrakizumab-asmn)

Contraindicated as Concomitant Therapy
Inflectra (infliximab-dyyb)
Infliximab
Kevzara (sarilumab)
Kineret (anakinra)
Nucala (mepolizumab)
Olumiant (baricitinib)
Opzelura (ruxolitinib)
Orencia (abatacept)
Otezla (apremilast)
Remicade (infliximab)
Renflexis (infliximab-abda)
Riabni (rituximab-arrx)
Rinvoq (upadacitinib)
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human)
Ruxience (rituximab-pvvr)
Siliq (brodalumab)
Simponi (golimumab)
Simponi ARIA (golimumab)
Skyrizi (risankizumab-rzaa)
Sotyktu (deucravacitinib)
Stelara (ustekinumab)
Taltz (ixekizumab)
Tezspire (tezepelumab-ekko)
Tremfya (guselkumab)
Truxima (rituximab-abbs)
Tysabri (natalizumab)

Contraindicated as Concomitant Therapy
Xeljanz (tofacitinib) Xeljanz XR (tofacitinib extended release) Xolair (omalizumab) Zeposia (ozanimod)

