

# Antiasthmatic Monoclonal Antibodies – Anti-IgE Antibodies

Medical policy no. 44.60.30.AA-3  
Year

Effective Date: Month, 1,

## Related medical policies:

Policy Name	Indications
IL-5 Antagonists	Severe asthma Eosinophilic granulomatosis with polyangiitis (EGPA) Hypereosinophilic Syndrome Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

*Note: New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: <https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx>

## Medical necessity

Drug	Medical Necessity
omalizumab (XOLAIR®)	<b>omalizumab (XOLAIR®)</b> may be considered medically necessary in patients who meet the criteria described in the clinical policy below.  If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.

## Clinical policy:

Clinical Criteria	
<b>Moderate to severe persistent allergic asthma</b> omalizumab (XOLAIR®)	Omalizumab (XOLAIR) may be approved when all the following criteria are met: <ol style="list-style-type: none"> <li>1. Patient is 6 years of age or older, <b>AND</b></li> <li>2. Prescribed by, or in consultation with, a physician specializing in allergy, pulmonology, immunology, or ENT (ear, nose, throat); <b>AND</b></li> </ol>

3. Not used in combination with another monoclonal antibody indicated for the treatment of asthma (e.g., benralizumab, dupilumab, mepolizumab, reslizumab, etc.); **AND**
4. Patient has a confirmed allergy showing reactivity to a perennial aeroallergen; **AND**
5. Patient has a serum total IgE level, measured before the start of treatment, of either:
  - a.  $\geq 30$  IU/mL and  $\leq 700$  IU/mL in patients age  $\geq 12$  years; **OR**
  - b.  $\geq 30$  IU/mL and  $\leq 1300$  IU/mL in patients aged 6 to  $<12$  years; **AND**
6. Patient has **MODERATE** asthma as defined by one of the following:
  - a. Documentation of functional impairment due to poor asthma control or exacerbations (e.g. limitation of activities of daily living, nighttime awakenings  $> 1x/week$  but not nightly); **OR**
  - b. SABA (e.g. albuterol, levalbuterol) use for symptom control occurs daily; **OR**
  - c. Lung function (percent predicted FEV1)  $>60\%$ , but  $<80\%$ ; **OR**
7. Patient has **SEVERE** asthma as defined by one of the following:
  - a. Documentation of functional impairment due to poor asthma control or exacerbations (e.g. limitation of activities of daily living, nighttime awakenings often  $7x/week$ ); **OR**
  - b. SABA (e.g. albuterol, levalbuterol) use for symptom control occurs several times per day; **OR**
  - c. Lung function (percent predicted FEV1)  $<60\%$ ; **AND**
8. Patient remains uncontrolled with either of the following medications used separately or simultaneously within the last year:
  - a. A maximally tolerated inhaled corticosteroid (ICS) **AND** long-acting beta agonist (LABA) (used as separate or combination products) [e.g., budesonide, fluticasone, mometasone, salmeterol, fluticasone/salmeterol, fluticasone/vilanterol, mometasone/formoterol, budesonide/formoterol]; **OR**
  - b. ICS **AND** long-acting muscarinic antagonist [LAMA] {e.g. tiotropium}; **OR**
  - c. ICS **AND** leukotriene receptor antagonist [e.g. montelukast, theophylline]

If ALL criteria are met, the request will be authorized for **12 months**.

#### Criteria (Reauthorization)

Omalizumab (XOLAIR) may be approved when all the following criteria are met:

	<ol style="list-style-type: none"> <li>1. Initial authorization criteria #3 continues to be met; <b>AND</b></li> <li>2. Patient will continue maintenance asthma therapy [e.g. ICS + LABA, ICS + LAMA, ICS + leukotriene receptor antagonist]</li> <li>3. Documentation is submitted showing improvement or stability of disease symptoms (e.g., reduced asthma exacerbations, FEV1, reduced hospitalizations)</li> </ol> <p>If ALL criteria are met, the request will be authorized for <b>12 months</b>.</p>
<p><b>Chronic spontaneous urticaria (CSU)</b> omalizumab (XOLAIR®)</p>	<p>Omalizumab (XOLAIR) may be approved when all the following criteria are met:</p> <ol style="list-style-type: none"> <li>1. Patient is 12 years of age or older, <b>AND</b></li> <li>2. Prescribed by, or in consultation with, a dermatologist or a physician specializing in allergy, pulmonology, immunology, or ENT (ear, nose, throat); <b>AND</b></li> <li>3. Not used in combination with another monoclonal antibody indicated for the treatment of urticaria; <b>AND</b></li> <li>4. Underlying cause of the patient’s condition is <u>NOT</u> considered to be any other allergic condition(s) or other form(s) of urticaria; <b>AND</b></li> <li>5. Provider attests that the patient has been evaluated for triggers and is being managed to avoid triggers (e.g., NSAIDs, psychological stress, dietary habits.); <b>AND</b></li> <li>6. Baseline assessments using <u>one</u> of the following assessment tools are completed:             <ol style="list-style-type: none"> <li>a. Urticaria activity score (UAS7); <b>OR</b></li> <li>b. Angioedema activity score (AAS); <b>OR</b></li> <li>c. Dermatology Life Quality Index (DLQI); <b>OR</b></li> <li>d. Angioedema Quality of Life (AE-QoL); <b>OR</b></li> <li>e. Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL); <b>AND</b></li> </ol> </li> <li>7. Patient had an inadequate response to a second-generation H1-antihistamine product (two -week minimum trial, see appendix below for list of agents) ; <b>AND</b></li> <li>8. Patient had an inadequate response to at least <u>one</u> of the following, unless contraindicated (one-month minimum trial):             <ol style="list-style-type: none"> <li>a. Dose increase of second-generation H1-antihistamine at the maximally tolerated dose*; <b>OR</b></li> <li>b. Add-on therapy with a leukotriene antagonist (e.g., montelukast, zafirlukast, etc.); <b>OR</b></li> <li>c. Add-on therapy with another H1-antihistamine*; <b>OR</b></li> <li>d. Add-on therapy with a H2-antagonist (e.g. ranitidine, etc.)</li> </ol> </li> </ol> <p>If ALL criteria are met, the request will be authorized for <b>12 months</b>.</p>

	<p><b>Criteria (Reauthorization)</b></p> <p>Omalizumab (XOLAIR) may be approved when all the following criteria are met:</p> <ol style="list-style-type: none"> <li>1. Initial authorization criteria #3 continues to be met; <b>AND</b></li> <li>2. Documentation is submitted showing reassessment of baseline measurements demonstrating disease stability or a positive clinical response</li> </ol> <p>If ALL criteria are met, the request will be authorized for <b>12 months</b>.</p>
<p><b>Chronic rhinosinusitis with nasal polyposis (CRSwNP)</b> omalizumab (XOLAIR®)</p>	<p>Omalizumab (XOLAIR) may be approved when all of the following criteria are met:</p> <ol style="list-style-type: none"> <li>1. Patient is 18 years of age or older, <b>AND</b></li> <li>2. Prescribed by, or in consultation with, a physician specializing in allergy, pulmonology, immunology, or ENT (ear, nose, throat); <b>AND</b></li> <li>3. Not used in combination with another monoclonal antibody indicated for the treatment of rhinosinusitis with nasal polyposis (e.g., dupilumab, mepolizumab, etc.); <b>AND</b></li> <li>4. Diagnosis of bilateral sinonasal polyposis as evidenced by an endoscopy, rhinoscopy or computed tomography (CT); <b>AND</b></li> <li>5. Patient has at least <b>two</b> of the following symptoms:             <ol style="list-style-type: none"> <li>a. Nasal blockage, obstruction, or congestion</li> <li>b. Purulent nasal discharge</li> <li>c. Facial pain or pressure</li> <li>d. Reduction or loss of smell; <b>AND</b></li> </ol> </li> <li>6. Documentation of current persistent symptomatic nasal polyps despite maximal treatment with <u>ALL</u> the following within the last year unless ineffective, not tolerated, or contraindicated:             <ol style="list-style-type: none"> <li>a. Intranasal corticosteroid; <b>AND</b></li> <li>b. Oral systemic corticosteroid; <b>AND</b></li> </ol> </li> <li>7. Intranasal corticosteroid will be continued with the use of omalizumab (Xolair), unless contraindicated.</li> </ol> <p>If ALL criteria are met, the request will be authorized for <b>12 months</b>.</p>
	<p><b>Criteria (Reauthorization)</b></p> <p>Omalizumab (XOLAIR) may be approved when all the following criteria are met:</p> <ol style="list-style-type: none"> <li>1. Initial authorization criteria #3 and #7 continues to be met; <b>AND</b></li> <li>2. Documentation is submitted showing improvement or stability of disease symptoms (e.g., improvement in nasal congestion/obstruction severity, reduction in nasal polyps)</li> </ol> <p>If ALL criteria are met, the request will be authorized for <b>12 months</b>.</p>

## Dosage and quantity limits

Drug	Indication	FDA Approved Dosing	Dosage Form and Quantity Limit
Xolair	Allergic asthma	75 to 375 mg administered subcutaneously by a health care provider every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). See tables below.	<ul style="list-style-type: none"> <li>75 mg/0.5mL prefilled syringe</li> <li>150 mg/mL prefilled syringe</li> <li>150 mg vial</li> </ul>
	Chronic spontaneous urticaria (CSU)	150 or 300 mg administered subcutaneously by a health care provider every 4 weeks. Dosing is not dependent on serum IgE (free or total) level or body weight.	<ul style="list-style-type: none"> <li>150 mg/mL prefilled syringe</li> <li>150 mg vial</li> </ul>
	Chronic rhinosinusitis with nasal polyposis (CRSwNP)	75 to 600 mg SC administered subcutaneously by a health care provider every 2 or 4 weeks. Determine dose (mg) and dosing frequency by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). See tables below.	<ul style="list-style-type: none"> <li>75 mg/0.5mL prefilled syringe</li> <li>150 mg/mL prefilled syringe</li> <li>150 mg vial</li> </ul>

## Coding:

HCPCS Code	Description
J2357	Injection, omalizumab, 5 mg

## Background:

### Moderate to severe persistent allergic asthma

Asthma is a chronic respiratory condition caused by inflammation of the airways, where inflammation triggers airway narrowing and subsequent difficulty breathing. The etiology of asthma is unclear though epidemiology has attributed genetic susceptibility, race, host factors (i.e., obesity, nutrition, infection, allergic sensitization), and environmental exposures to increased disease burden. Of the approximately 339 million individuals with asthma globally (25 million in the United States), up to 10% have severe asthma. Per the [Global Initiative for Asthma \(GINA\) guidelines](#) first line treatment includes ICS-formoterol inhalers. In those with poor control, such as moderate to severe asthma, patients may require high dose inhaled corticosteroids (ICS), or continuous to near continuous oral glucocorticoids to maintain asthma control. Biologic therapies have been developed to target pathways involved with asthma phenotypes (i.e., allergic asthma and eosinophilic asthma). Allergic asthma is associated with allergic rhinitis, atrophy, and elevated immunoglobulin E (IgE) levels and impacts nearly-half of all asthma patients. Biologics to target these mediators include IL-5, anti-IL-5R, anti-IL-4R anti-IL-13, and anti-IgE therapies.

The safety and efficacy of omalizumab were evaluated in three randomized, double-blind, placebo-controlled, multicenter trials. The trials enrolled patients 12-76 years old with moderate to severe persistent asthma for at least a year and a positive allergy skin test to a perennial aeroallergen. At screening, patients in studies 1 and 2 had a FEV1 between 40% and 80% predicted whereas in study 3 there was no restriction on screening FEV1 and

LABAs were allowed. All patients were symptomatic and currently treated with ICS and SABAs. Each study had a run-in period to achieve a stable conversion to a common ICS (for studies 1 and 2 the ICS was beclomethasone dipropionate and study 3 the ICS was fluticasone propionate), followed by randomization to omalizumab or placebo. In study 3, patients were stratified by use of ICS only or ICS with concomitant oral corticosteroids. All patients were required to have a baseline IgE between 30 and 700 IU/mL and a body weight not more than 150 kg. The maximum omalizumab dose per 4 weeks was 750 mg. Exacerbations in all three studies were defined as a worsening of asthma that required treatment with systemic corticosteroids or a doubling of the baseline ICS dose. The primary endpoint for studies 1 and 2 were the number of exacerbations. In studies 1 and 2, omalizumab was shown to have up to a 75% decrease in exacerbations versus placebo in the ICS-stable phase and up to a 50% decrease in exacerbations vs placebo in the ICS-reduction phase. In study 3, the number of exacerbations in the omalizumab group was similar to that of the control group. In the ICS-stable phase, 15.9% of patients in the omalizumab + ICS group experienced  $\geq 1$  exacerbation vs 15% of those in the placebo + ICS. In the ICS-reduction phase, 22.2% of patients taking omalizumab + ICS group experienced  $\geq 1$  exacerbation vs. 26.7% of patients in the placebo + ICS group.

### **Chronic spontaneous urticaria (CSU)**

CSU is defined by the presence of recurrent urticaria (also called hives or wheals), angioedema, or both, for a period of six weeks or longer. Urticaria needs to be differentiated from other medical conditions where wheals, angioedema or both can occur, for example anaphylaxis, auto-inflammatory syndromes, urticarial vasculitis, or bradykinin-mediated angioedema including hereditary angioedema (HAE). There are several theories regarding the pathogenesis of CSU, none of which have been conclusively established. [EAACI/GA<sup>2</sup>LEN/EDF/WAO guidelines](#) recommend various therapies for the management of CSU including H1-antihistamines, leukotriene receptor antagonists, cyclosporin, and omalizumab.

The safety and efficacy of omalizumab for the treatment of CSU was determined in two placebo-controlled, multiple dose clinical trials of 24 weeks duration and 12 weeks duration. Patients received omalizumab 75 mg, 150 mg, or 300 mg or placebo by subcutaneous injection every 4 weeks in addition to baseline H1 antihistamine therapy for 24 or 12 weeks, followed by a 16-week washout observation period. Disease severity was measured by weekly urticaria activity score (UAS7). All patients were required to have a UAS7 of  $\geq 16$ , and a weekly itch severity score of  $\geq 8$  for a week prior to randomization, despite having used an H1 antihistamine for at least 2 weeks. At baseline, the mean weekly itch severity scores ranged between 13.7 and 14.5. In both trials, patients who received omalizumab 150 or 300 mg had greater decreases from baseline in weekly itch severity scores and weekly hive count scores than placebo at week 12. The 75 mg dose did not demonstrate evidence of efficacy.

### **Chronic rhinosinusitis with nasal polyposis (CRSwNP)**

Chronic rhinosinusitis (CRS) is broadly defined as an inflammatory disorder of the paranasal sinuses and linings of the nasal passages that lasts 12 weeks or longer. CRS may present abruptly, begin as a nonspecific upper respiratory infection or acute sinusitis that fails to resolve, or develop slowly and insidiously over months or years. CRS with nasal polyps (CRSwNP) is characterized by the presence of bilateral nasal polyps in the middle meatus. Nasal polyps are translucent, yellowish-gray to white, glistening masses composed of gelatinous inflammatory material, which may form in the nasal cavity or paranasal sinuses. [The American Academy of Allergy, Asthma, and Immunology \(AAAAI\), American College of Allergy, Asthma, and Immunology \(ACAAI\), and Joint Council of Allergy, Asthma, and Immunology \(JCAAI\) 2014 guidelines](#) recommend short-term treatment with oral steroids in patients with CRSwNP “because it decreases nasal polyp size and symptoms”. Additionally, guidelines recommend both intranasal corticosteroids and omalizumab for treatment of CRSwNP.

The safety and efficacy of omalizumab was evaluated in two, randomized, multicenter, double-blind, placebo-controlled clinical trials that enrolled patients with CRSwNP with inadequate response to nasal corticosteroids. Patients received omalizumab or placebo subcutaneous every two or four weeks for 24 weeks followed by a four-week follow-up period. All patients received background nasal mometasone during both the treatment period and during the five week run-in period. Patients were required to have evidence of bilateral polyps as determined by a nasal polyp score (NPS)  $\geq 5$  with NPS  $\geq 2$  in each nostril, despite use of nasal mometasone during the run-in period. Patients were also required to have a weekly average of nasal congestion score (NSC)  $> 1$ . The co-primary endpoints in both trials were NPS and average daily NCS at week 24. Individuals who received omalizumab had a statistically significant greater improvement from baseline at week 24 in NPS and weekly average NCS than patients who received placebo.

## References

1. Xolair. Package insert. Genentech, Inc; March 2023.
2. National Asthma Education and Prevention Program (NAEPP). Guidelines for the diagnosis and management of asthma. Expert Panel Report 3. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); August 2007.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2023 Update. Available from: <http://www.ginasthma.org>. Accessed August 2023.
4. Gevaert P, Omachi TA, Corren J et al. Efficacy and safety of omalizumab in nasal polyposis: 2 randomized phase 3 trials. *J Allergy Clin Immunol* 2020;146(3):595-605. Available at: <https://pubmed.ncbi.nlm.nih.gov/32524991/>. Accessed January 27, 2021.
5. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter Update. *Ann Allergy Asthma Immunol* 2014 (113):347-385. Available at: [http://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20and%20Parameters/2014-October\\_Rhinosinusitis\\_Update.pdf](http://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20and%20Parameters/2014-October_Rhinosinusitis_Update.pdf). Accessed January 27, 2021.
6. Zuberbier T, Aberer W, Asero R, et al. The EAACI/GA2LEN/EDF/WAO guideline for the definition, classification, diagnosis and management of urticaria. *Allergy*. 2018;73(7):1393-1414.
7. UptoDate. Anti-IgE Therapy, Updated November 18, 2021. Accessed August 17, 2023.
8. Busse W, Corren J, Lanier BQ, et al. Omalizumab, anti-IgE recombinant humanized monoclonal antibody, for the treatment of severe allergic asthma. *J Allergy Clin Immunol*. 2001;108(2):184-190. doi:10.1067/mai.2001.117880

## History

Approved Date	Effective Date	Version	Action and Summary of Changes
MM/DD/YYYY	MM/DD/YYYY	44.60.30.AA-3	Pending Approval (draft/unpublished version) - Policy renumbered to new nomenclature - CRSwNP indication added
10/16/2019	05/01/2020	44.60.30-2	Approved by DUR Board General formatting updates were made from 09/24/2019-01/27/2020
02/21/2018	07/01/2018	44.60.30-1	New policy created

## Appendix

*H1 Antihistamine Products (not all inclusive)		
<ul style="list-style-type: none"> <li>• desloratadine</li> </ul>	<ul style="list-style-type: none"> <li>• clemastine</li> <li>• diphenhydramine</li> </ul>	<ul style="list-style-type: none"> <li>• brompheniramine</li> <li>• dexchlorpheniramine</li> </ul>

<ul style="list-style-type: none"> <li>• cetirizine</li> <li>• levocetirizine</li> <li>• loratadine</li> </ul>	<ul style="list-style-type: none"> <li>• chlorpheniramine</li> <li>• hydroxyzine</li> <li>• cyproheptadine</li> </ul>	<ul style="list-style-type: none"> <li>• carbinoxamine</li> </ul>
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### Asthma Dose Recommendations

#### Omalizumab Doses Administered Every 2 or 4 Weeks (mg) for Pediatric Patients Ages of 6 to <12 Years

Pre-treatment IgE (IU/mL)	Dosing Freq.	Body Weight (kg)									
		20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
30-100	Every 4 Weeks	75	75	75	150	150	150	150	150	300	300
>100-200		150	150	150	300	300	300	300	300	225	300
>200-300		150	150	225	300	300	300	225	225	300	375
>300-400		225	225	300	225	225	225	300	300		
>400-500		225	300	225	225	225	225	375	375		
>500-600		300	300	225	300	300	300				
>600-700	300	225	225	300	300						
>700-900	Every 2 Weeks	225	225	300	375						Do Not Dose
>900-1100		225	300	375							
>1100-1200		300	300								
>1200-1300		300	375								

#### Omalizumab Doses Administered Every 2 or 4 Weeks (mg) for Patients 12 Years of Age and Older

Pre-treatment IgE (IU/mL)	Dosing Freq.	Body Weight (kg)			
		30 to 60	> 60 to 70	> 70 to 90	> 90 to 150
30-100	Every 4 Weeks	150	150	150	300
>100-200		300	300	300	225
>200-300		300	225	225	300
>300-400	Every 2 weeks	225	225	300	
>400-500		300	300	375	
>500-600		300	375		
>600-700		375			

### Chronic Rhinosinusitis with Nasal Polyposis Dosing Recommendations (CRSwNP)

#### Omalizumab Doses Every 2 or 4 Weeks\* for Adult Patients with CRSwNP

Pre-treatment IgE (IU/mL)	Dosing Freq.	Body Weight (kg)							
		>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90-125	>125-150
30-100	Every 4 Weeks	75	150	150	150	150	150	300	300
>100-200		150	300	300	300	300	300	450	600
>200-300		225	300	300	450	450	450	600	375
>300-400		300	450	450	450	600	600	450	525
>400-500		450	450	600	600	375	375	525	600
>500-600		450	600	600	375	450	450	600	
>600-700	Every 2 Weeks	450	600	375	450	450	525		
>700-800		300	375	450	450	525	600		
>800-900		300	375	450	525	600			

>900-1000		375	450	525	600	Do Not Dose
>1000-1100		375	450	600		
>1100-1200		450	525	600		
>1200-1300		450	525			
>1300-1500		525	600			

DRAFT

## Asthma and COPD Agents: Monoclonal Antibodies - Anti-IgE Antibodies

Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible to expedite this request. **Without this information, we may deny the request in seven (7) working days.**

Date of request:	Reference #:	MAS:	
Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number
Medication and strength		Directions for use	Qty/Days supply

1. Is this request for a continuation of existing therapy?  Yes  No

If yes, Is there clinical documentation of disease stability or improvement compared to baseline measures?

Yes  No

2. Indicate patient's diagnosis:

Chronic rhinosinusitis with nasal polyposis

Chronic spontaneous urticaria

Moderate to severe persistent allergic asthma

Other, specify: \_\_\_\_\_

3. Was this prescribed by, or in consultation with, a specialist in allergy, dermatology, pulmonology, immunology, or ENT (ear, nose, throat)?

Yes  No

4. Will this be used in combination with other monoclonal antibodies indicated for the treatment of asthma? (e.g., benralizumab, dupilumab, mepolizumab, reslizumab, etc.)

Yes  No

5. What is patient's pre-treatment serum IgE level? \_\_\_\_\_ IU/mL Date taken: \_\_\_\_\_

### Moderate to severe persistent allergic asthma

6. Has patient had reactivity to a perennial aeroallergen?  Yes  No

7. What is the patient's FEV1% predicted? \_\_\_\_\_ Date taken: \_\_\_\_\_

8. Does patient have documentation of functional impairment due to poor asthma control or exacerbations (e.g. limitation of activities of daily living, nighttime awakenings)  Yes  No

If yes, how many times per week? \_\_\_\_\_/week

9. How many times does patient use a SABA (e.g. albuterol, levalbuterol) for symptom control? \_\_\_\_\_/day

10. Has patient remained uncontrolled with either of the following medications (used separately or simultaneously) within the last year? Check all that apply:

- Inhaled corticosteroid (ICS)
- Long-acting beta agonist (LABA)
- Long-acting muscarinic agonist (LAMA)
- Leukotriene receptor antagonist
- Other, specify: \_\_\_\_\_

### Chronic spontaneous urticaria (CSU)

1. Will this be used in combination with other monoclonal antibodies indicated for the treatment of urticaria?  
 Yes  No
2. Has provider confirmed that the underlying cause of patient's condition is NOT considered to be any other allergic condition(s) or other forms of urticaria?  Yes  No
3. Has the patient been evaluated for triggers and is being managed to avoid triggers (e.g., NSAIDS, psychological stress, dietary habits)?  Yes  No
4. Has patient had baseline assessment using any of the following assessment tools? Check all that apply:
  - Urticaria activity score (UAS7)
  - Angioedema activity score (AAS)
  - Dermatology Life Quality Index (DLQI)
  - Angioedema Quality of Life (AE-QoL)
  - Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL)

Has patient had an inadequate response to a second-generation H1 antihistamine (two-week minimum trial)

5. AND one of the following (one-month minimum trial)? Check all that apply:

- Increase in dose of second-generation H1 antihistamine at maximum tolerated dose
- leukotriene antagonist
- H1-antihistamine
- H2-antihistamine
- Other, specify: \_\_\_\_\_

### Chronic rhinosinusitis with nasal polyposis (CRSwNP)

6. Will this be used in combination with other monoclonal antibodies indicated for the treatment of rhinosinusitis with nasal polyposis? (e.g., dupilumab, mepolizumab)  
 Yes  No
7. Has patient had diagnosis of bilateral sinonasal polyposis confirmed by an endoscopy, rhinoscopy or computed tomography (CT)?  Yes  No
8. Has patient had at least two of the following symptoms? Check all the apply:
  - Nasal blockage, obstruction, or congestion
  - Purulent nasal discharge
  - Facial pain or pressure
  - Reduction or loss of smell

9. Does patient have current persistent symptomatic nasal polyps despite maximal treatment (within the last year) with any of the following? Check all that apply:
- Oral systemic corticosteroid
  - Intranasal corticosteroid
10. Will patient continue use of an intranasal corticosteroid with the use of omalizumab (Xolair)?  Yes  No

**CHART NOTES, LABS AND TEST RESULTS ARE REQUIRED WITH THIS REQUEST**

Prescriber signature

Prescriber specialty

Date

DRAFT