

Policy Type: PA/SP

Pharmacy Coverage Policy: EOCCO176

Description

Omaliuzumab (Xolair) is a subcutaneously administered monoclonal antibody that binds to IgE causing the IgE receptors to downregulate and limit the degree of release of the mediators of allergic response.

Length of Authorization

- Initial: Six months
- Renewal: 12 months

Quantity Limits

Product Name	Indication	Dosage Form	Quantity Limit
omalizumab (Xolair)	Allergic asthma*	75 mg/0.5mL prefilled syringe	1 syringe per 28 days
	Systemic mastocytosis		
	Chronic rhinosinusitis with nasal polyposis (CRSwNP)*		
	Allergic asthma*	150 mg/mL prefilled syringe	1 syringe per 28 days
	Systemic mastocytosis		
	Chronic rhinosinusitis with nasal polyposis (CRSwNP)*		
	Chronic idiopathic urticaria (CIU)	150 mg/mL prefilled syringe	2 syringes per 28 days
	Allergic asthma*	150 mg vial [‡]	N/A
	Systemic mastocytosis		
	Chronic rhinosinusitis with nasal polyposis (CRSwNP)*		
	Chronic idiopathic urticaria (CIU)		

[‡]Medical drug that requires administration by a healthcare professional and is not available for self-administration by the member, considered one of the excluded classes under the prescription benefit.

*Quantity limit can vary by IgE level and body weight. **Higher quantities may be appropriate or allowed in specific scenarios depending on IgE and weight.** Reviewing clinician should refer to the dosing listed in Appendix at the end of this policy.

Initial Evaluation

- I. **Omalizumab (Xolair)** may be considered medically necessary when the following criteria below are met:
 - A. Medication is prescribed by, or in consultation with, a dermatologist or a physician specializing in allergy, pulmonology, immunology, or ENT (ear, nose, throat); **AND**
 - B. Must not be used in combination with another monoclonal antibody (e.g., benralizumab, dupilumab, mepolizumab, reslizumab, etc.); **AND**
 - C. A diagnosis of one of the following:
 1. **Moderate to severe persistent allergic asthma; AND**
 - i. Member is six years of age or older; **AND**
 - ii. Member has a positive skin test or in vitro reactivity to a perennial aeroallergen; **AND**
 - iii. Member must weigh between 20 kg (44 lbs.) and 150 kg (330 lbs.); **AND**
 - iv. Member has a serum total IgE level, measured before the start of treatment, of either:
 - a. ≥ 30 IU/mL and ≤ 700 IU/mL in members age ≥ 12 years; **OR**
 - b. ≥ 30 IU/mL and ≤ 1300 IU/mL in members age 6 to <12 years; **AND**
 - v. Member has **MODERATE** asthma as defined by one of the following:
 - a. Daily symptoms
 - b. Nighttime awakenings $> 1x/week$ but not nightly
 - c. SABA (e.g. albuterol, levalbuterol) use for symptom control occurs daily
 - d. Some limitation to normal activities
 - e. Lung function (percent predicted FEV1) $>60\%$, but $<80\%$
 - f. Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to mild asthma; **OR**
 - vi. Member has **SEVERE** asthma as defined by one of the following:
 - a. Symptoms throughout the day
 - b. Nighttime awakenings, often $7x/week$
 - c. SABA (e.g. albuterol, levalbuterol) use for symptom control occurs several times per day
 - d. Extremely limited normal activities
 - e. Lung function (percent predicted FEV1) $<60\%$
 - f. Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma; **AND**
 - vii. Member is currently being treated with:

omalizumab (Xolair®)

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- a. A medium- to high-dose, or maximally tolerated inhaled corticosteroid (ICS) [e.g., budesonide, fluticasone, mometasone]; **AND**
 - i. One additional asthma controller medication (e.g., long-acting beta-2 agonist [LABA] {e.g., Serevent Diskus}, long-acting muscarinic antagonist [LAMA] {e.g., Spiriva Respimat}, leukotriene receptor antagonist [e.g., Singular], or theophylline); **OR**
 - b. A maximally tolerated ICS/LABA combination product (e.g., Advair, Airduo, Breo, Dulera, Symbicort); **OR**
- 2. Chronic idiopathic urticaria (CIU); AND**
- i. Member is 12 years of age or older; **AND**
 - ii. Underlying cause of the member's condition is NOT considered to be any other allergic condition(s) or other form(s) of urticaria; **AND**
 - iii. Member is avoiding triggers (e.g., NSAIDs, etc.); **AND**
 - iv. Documented baseline score from an objective clinical evaluation tool, such as: urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), or Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL); **AND**
 - v. Member had an inadequate response to a minimum (1) month trial on previous therapy of a second-generation H1-antihistamine product*; **AND**
 - vi. Member had an inadequate response to a minimum (1) month trial on previous therapy of at least one of the following:
 - a. Updosing/dose advancement (up to 4-fold) of a second generation H1-antihistamine*
 - b. Add-on therapy with a leukotriene antagonist (e.g., montelukast, zafirlukast, etc.)
 - c. Add-on therapy with another H1-antihistamine*
 - d. Add-on therapy with a H2-antagonist (e.g. ranitidine, etc.)
 - e. Add-on therapy with cyclosporine; **OR**
- 3. Systemic mastocytosis; AND**
- i. Member is 18 years of age or older; **AND**
 - ii. Used for the prevention of one of the following:
 - a. Chronic mast-cell-mediator-related cardiovascular (e.g., pre-syncope, tachycardia, etc.) or pulmonary (e.g., wheezing, throat-swelling, etc.) symptoms insufficiently controlled by conventional therapy (e.g., H1 or H2 blockers or corticosteroids); **OR**
 - b. Unprovoked anaphylaxis; **OR**
 - c. Hymenoptera or food-induced anaphylaxis in members with a negative test for specific IgE antibodies or a negative skin test; **OR**

- iii. Used to improve tolerance while on immunotherapy (i.e., venom immunotherapy [VIT]); **OR**
- 4. **Chronic rhinosinusitis with nasal polyposis (CRSwNP); AND**
 - i. Member is 18 years of age or older; **AND**
 - ii. Member must weigh between 30 kg (66 lbs.) and 150 kg (330 lbs.); **AND**
 - iii. Member has a serum total IgE level ≥ 30 IU/mL and ≤ 1500 IU/mL measured before the start of treatment; **AND**
 - iv. Provider attests that the member has ALL of the following:
 - a. Diagnosis of bilateral sinonasal polyposis as evidenced by an endoscopy or computed tomography (CT); **AND**
 - b. Member has impaired Health-Related Quality of Life due to ongoing nasal congestion, blockage, or obstruction with moderate to severe symptom severity; **AND**
 - c. Member has at least **one** of the following symptoms:
 - i. Nasal discharge
 - ii. Facial pain or pressure
 - iii. Reduction or loss of smell; **AND**
 - v. Documentation of current persistent symptomatic nasal polyps despite maximal treatment with ALL of the following, unless ineffective, not tolerated, or contraindicated:
 - a. Intranasal corticosteroid; **AND**
 - b. Oral systemic corticosteroid therapy within the last 12 months; **AND**
 - vi. Background intranasal corticosteroid will be continued with the use of omalizumab (Xolair), unless contraindicated.
- II. Omalizumab (Xolair) is considered investigational when used for all other conditions, including but not limited to:
 - A. Management of Immune Checkpoint Inhibitor related toxicity
 - B. Esophagitis
 - C. Interstitial cystitis
 - D. Painful bladder syndrome
 - E. Eosinophilic bronchitis
 - F. Multi-food oral immunotherapy
 - G. Bullous pemphigoid
 - H. Peanut allergy
 - I. Chronic spontaneous urticaria
 - J. Solar urticaria
 - K. Chronic urticaria

- L. Cholinergic urticaria
- M. Seasonal allergic rhinitis

Renewal Evaluation

- I. Member has received a previous prior authorization approval for this agent through this health plan or has been established on therapy from a previous health plan; **AND**
- II. Member is not continuing therapy based off being established on therapy through samples, manufacturer coupons, or otherwise. If they have, initial policy criteria must be met for the member to qualify for renewal evaluation through this health plan; **AND**
- III. Must not be used in combination with another monoclonal antibody (e.g., benralizumab, dupilumab, mepolizumab, reslizumab, etc.); **AND**
- IV. A diagnosis of one of the following:
 - i. **Moderate to severe persistent allergic asthma; AND**
 - 1. Member must weigh between 20 kg (44 lbs.) and 150 kg (330 lbs.); **AND**
 - 2. Member has exhibited improvement or stability of disease symptoms (e.g., reduced asthma exacerbations, FEV1, reduced systemic corticosteroid requirements, reduced hospitalizations); **OR**
 - ii. **Chronic idiopathic urticaria (CIU); AND**
 - 1. Member has exhibited improvement or stability of disease symptoms from baseline using objective clinical evaluation tools (e.g., urticaria activity score [UAS7], angioedema activity score [AAS], Dermatology Life Quality Index [DLQI], Angioedema Quality of Life [AE-QoL], or Chronic Urticaria Quality of Life Questionnaire [CU-Q2oL]); **AND**
 - 2. Submitted current UAS7, AAS, DLQI, AE-QoL, or Cu-Q2oL was recorded within the past 30 days; **OR**
 - iii. **Systemic mastocytosis; AND**
 - 1. Member has exhibited improvement or stability of disease symptoms compared to baseline (e.g., decreased frequency of exacerbations); **OR**
 - iv. **Chronic rhinosinusitis with nasal polyposis (CRSwNP); AND**
 - 1. Member must weigh between 30 kg (66 lbs.) and 150 kg (330 lbs.); **AND**
 - 2. Member has exhibited improvement or stability of disease symptoms (e.g., improvement in nasal congestion/obstruction severity, reduction in nasal polyps); **AND**
 - 3. Background intranasal corticosteroid (e.g., beclomethasone [Qnasl], budesonide [Rhinocort], ciclesonide [Omnaris; Zetonna], flunisolide, fluticasone [Flonase], mometasone [Nasonex], triamcinolone [Nasacort]) will be continued with the use of omalizumab (Xolair), unless contraindicated.

Supporting Evidence

- I. There is a lack of evidence supporting treatment with dual use of biologic therapies and a potential for increased risk of side effects.
- II. Omalizumab (Xolair) is FDA approved for 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 (ICS), as add-on maintenance treatment for patients 18 years of age with chronic rhinosinusitis with nasal polyps (CRSwNP), and as chronic idiopathic urticaria in patients 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.
 - Omalizumab (Xolair) is not FDA approved for use in the setting of systemic mastocytosis; however, it is compendia recommended.
- III. Omalizumab (Xolair) **prefilled syringes** have been FDA approved for self-administration for the treatment of asthma in patients 6 years and older, chronic idiopathic urticaria (CIU) in patients 12 years and older, and nasal polyps in patients age 18 years and older. According to the package insert, therapy should be initiated in a healthcare setting. Once therapy has been safely established, the healthcare provider may determine whether self-administration of Xolair prefilled syringe is appropriate, based on careful assessment of risk for anaphylaxis and risk reduction strategies. Patient-specific factors considered when selecting patients for self-administration include the following criteria:
 - Patient should have no prior history of anaphylaxis, including to XOLAIR or other agents, such as latex, 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
- IV. **Moderate to severe persistent allergic asthma**
 - For patients 12 years of age and older, omalizumab (Xolair) was studied in 3 randomized, double-blind, placebo-controlled, multicenter trials. The patients enrolled in these trials were 12 to 76 years of age, with moderate to severe persistent asthma for at least one year, and a positive skin test reaction to a perennial aeroallergen. All patients were required to have a baseline IgE level between 30 and 700 IU/mL and body weight \leq 150 kg. Patients with IgE levels less than 30 IU/mL, greater than 700 IU/mL, or a weight greater than 150 kg have not been studied and efficacy has not been demonstrated in a randomized controlled clinical trial.

- i. Trials 1 and 2: All patients were symptomatic and were treated with ICS/SABA. The primary endpoint was mean number asthma exacerbations per patient during steroid stable phase versus steroid reduction phase in comparison to placebo. In the stable steroid phase, the mean number of exacerbations per patient was 0.2 in the active arm compared to 0.3 in the placebo arm, p-value=0.005 (Trial 1) and 0.1 in the active arm compared to 0.4 in the placebo arm, p-value<0.001 (Trial 2). In the steroid reduction phase, the mean number of exacerbations per patient was 0.2 in the active arm compared to 0.4 in the placebo arm, p-value=0.004 (Trial 1) and 0.2 in the active arm compared to 0.3 in the placebo arm, p-value<0.001 (Trial 2).
 - ii. Trial 3: Long-acting beta2-agonists were allowed. Patients received at least 1000 mcg/day fluticasone propionate and a subset also received oral corticosteroids (OCS). The primary endpoint was percentage of patients with at least 1 exacerbation during steroid stable phase versus steroid reduction phase in comparison to placebo. In the stable steroid phase, the treatment difference in percentage of patients with at least one exacerbation was 0.9 (95% CI -9.7, 13.7) in the ICS only arm compared to 9.8 (95% CI -10.5, 31.4) in the OCS/ICS arm. In the steroid reduction phase, the treatment difference in percentage of patients with at least one exacerbation was -4.4 (95% CI -17.6, 7.4) in the ICS only arm compared to -0.2 (95% CI -22.4, 20.1) in the OCS/ICS arm.
- For patients 6 to <12 years of age, omalizumab (Xolair) was studied in one double-blind, placebo controlled, multi-center trial. All patients were required to have a baseline IgE level between 30 and 1300 IU/mL and body weight between 20 to 150 kg. The primary endpoint was the rate of asthma exacerbations during the 24-week, fixed steroid treatment phase, which was 0.45 in the active arm compared to 0.64 in the placebo arm (RR 0.69, 95% CI 0.53, 0.9).
 - The Global Initiative for Asthma (GINA) 2020 update recommends the addition of respiratory biologics, with respect to their allergic biomarkers, after inadequate asthma control despite good adherence and inhaler technique on maximized Step 4 (medium dose ICS-LABA) or Step 5 (high dose ICS-LABA) therapy. Other controller options for Step 4 include high dose ICS-LABA or add-on tiotropium, or add-on LTRA. Other controller options for Step 5 include add-on anti-IL5, or add-on low dose OCS, though guidelines note to consider side effects.
 - Dose adjustments should be considered for drastic changes in body weight. Dosing should not be adjust based off IgE levels unless therapy has been interrupted for greater than one year. A minimum of three to six months of treatment is suggested to reach maximum efficacy.

V. Chronic idiopathic urticaria (CIU)

- Omalizumab (Xolair) was studied in two placebo-controlled, multiple-dose clinical trials. Patients received omalizumab (Xolair) 75 mg, 150 mg, or 300 mg or placebo by subcutaneous injection every 4 weeks in addition to their baseline level of H1 antihistamine therapy for 24 or 12 weeks, followed by a 16-week washout observation period. Per the prescribing label, the 75-mg dose did not demonstrate consistent evidence of efficacy and is not approved for use in CIU. Clinical trials required a UAS7 score of greater than or equal to 16 with weekly reassessments to objectively measure treatment benefit. The primary endpoints were mean weekly itch severity score and weekly hive count.

	XOLAIR 75mg	XOLAIR 150mg	XOLAIR 300mg	Placebo
n	77	80	81	80
Weekly Itch Severity Score				
Mean Baseline Score (SD)	14.5 (3.6)	14.1 (3.8)	14.2 (3.3)	14.4 (3.5)
Mean Change Week 12 (SD)	-6.46 (6.14)	-6.66 (6.28)	-9.40 (5.73)	-3.63 (5.22)
Difference in LS means vs. placebo	-2.96	-2.95	-5.80	
95% CI for difference	-4.71, -1.21	-4.72, -1.18	-7.49, -4.10	-
Weekly Hive Count Score †				
Mean Baseline Score (SD)	17.2 (4.2)	16.2 (4.6)	17.1 (3.8)	16.7 (4.4)
Mean Change Week 12 (SD)	-7.36 (7.52)	-7.78 (7.08)	-11.35 (7.25)	-4.37 (6.60)
Difference in LS means vs. placebo	-2.75	-3.44	-6.93	
95% CI for difference	-4.95, -0.54	-5.57, -1.32	-9.10, -4.76	-

- Per the EAACI/GA²LEN/EDF/WAO guidelines for the definition, classification, diagnosis, and management of urticaria the recommended starting dose of Omalizumab (Xolair) for CIU is 300 mg every 4 weeks.
- Per clinical trials of patients with CIU taking Omalizumab (Xolair), 36% of patients treated with 300 mg reported no itch or hives at week 12 compared to 15% treated with 150 mg, 12% with 75mg, and 9% with placebo.
- There is limited data regarding the continuation of Omalizumab (Xolair) and the need for dose reductions. Preliminary studies discuss the potential for dose reductions or increased dosing intervals, although there is currently no consensus on the best method.

VI. Systemic mastocytosis

- Omalizumab (Xolair) is recommended per NCCN guidelines for Systemic Mastocytosis for the treatment of mast-cell-mediator-related cardiovascular or pulmonary symptoms after prior trial of an H1 blocker, H2 blocker, and corticosteroids. Use of omalizumab (Xolair) for the management of Systemic Mastocytosis is supported by case studies and prospective reviews, though no clinical trials have been completed. Omalizumab (Xolair) has been found to prevent mast-cell-mediator-related cardiovascular or pulmonary symptoms despite use of

conventional therapies and has been shown to improve tolerance while on immunotherapy.

VII. Chronic rhinosinusitis with nasal polyposis (CRSwNP)

- Omalizumab (Xolair) was studied as an add-on therapy with background intranasal corticosteroid in adult patients with CRSwNP with inadequate response to intranasal corticosteroids. Omalizumab (Xolair) was evaluated in two identical phase 3, randomized, double-blind, placebo-controlled, parallel-group, multicenter trials. Trials enrolled patients aged 18 through 75 years with persistent bilateral nasal polyps, nasal congestion, impaired HRQoL, and weight 30-150 kg and serum IgE level 30- 1500 IU/mL. The primary endpoints were change from baseline to week 24 in endoscopic nasal polyp score (NPS) and mean daily nasal congestion score (NCS). Key secondary endpoints were change from baseline at week 24 in Sino-Nasal Outcome Test-22 (SNOT-22) score, University of Pennsylvania Smell Identification Test (UPSIT) score, and Asthma Quality of Life Questionnaire (AQLQ).

	POLYP 1			POLYP 2		
	PBO N=66	OMA N=72	Treatment Difference (95% CI), p-value	PBO N=65	OMA N=62	Treatment Difference (95% CI), p-value
Primary Endpoint						
NPS (range, 0-8)	0.06 (0.16)	-1.08 (0.16)	-1.14 (-1.59 to - 0.69) p<0.0001	-0.31 (0.16)	-0.9 (0.19)	-0.59 (-1.05 to - 0.12) p<0.14
NCS (range, 0-3)	-0.35 (0.11)	-0.89 (0.1)	-0.55 (-0.84 to - 0.25) p<0.0004	-0.20 (0.11)	-0.70 (0.11)	-0.50 (-0.80 to - 0.19) p<0.0017
Secondary Endpoint						
SNOT-22 score (range, 0-110)	-8.58 (2.08)	-24.70 (2.01)	-16.12 (-21.86 to -10.38) p<0.0001	-6.55 (2.19)	-21.59 (2.25)	-15.04 (-21.26 to - 8.82) p<0.0001
UPSIT score (range, 0-40)	0.63 (0.90)	4.44 (0.84)	3.81 (1.38-6.24) p<0.0024	0.44 (0.81)	4.31 (0.83)	3.86 (1.57-6.15) p<0.0011
AQLQ score, OR of MCID (≥0.5-point improvement)	OR 3.71 (95% CI 1-13.71, p=0.0492)			OR 4.04 (95% CI 1.07-15.25, p=0.0396)		

MCID: minimal clinically important difference

- 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.

VIII. Abbreviated list of H1 antihistamine products:

*H1 Antihistamine Products (not all inclusive)

- fexofenadine
- loratadine
- desloratadine
- cetirizine
- levocetirizine
- clemastine
- diphenhydramine
- chlorpheniramine
- hydroxyzine
- cyproheptadine
- brompheniramine
- triprolidine
- dexchlorpheniramine
- carbinoxamine

Investigational or Not Medically Necessary Uses

- I. Omalizumab (Xolair) has not been adequately studied for the following conditions and does not have established safety and efficacy in these populations:
 - A. Management of Immune Checkpoint Inhibitor related toxicity
 - i. Though use is supported by NCCN guidelines for Management of Immunotherapy-related toxicities, there are no clinical trials demonstrating clinical efficacy or safety of the use of omalizumab (Xolair) in the treatment of Immune Checkpoint Inhibitor related toxicity.
 - B. Ongoing clinical trials for the following conditions without outcomes demonstrating efficacy of treatment:
 - i. Esophagitis
 - ii. Interstitial cystitis
 - iii. Painful bladder syndrome
 - iv. Eosinophilic bronchitis
 - v. Multi-food oral immunotherapy
 - vi. Bullous pemphigoid
 - vii. Peanut allergy
 - viii. Chronic spontaneous urticaria
 - ix. Solar urticaria
 - x. Chronic urticaria
 - xi. Cholinergic urticaria
 - xii. Seasonal allergic rhinitis

Appendix

I. Table 1: Indication and dosing

Indication	Dose
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.
Chronic idiopathic urticaria	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.
Chronic rhinosinusitis with nasal polyposis	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.
All other indications	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.

II. Table 2: Weight based dosing every 4 weeks in members ≥ 12 years

Omaliuzumab Doses Administered Every 4 Weeks (mg) in members ≥ 12 years				
Pre-treatment serum IgE (IU/mL)	Body weight (kg)			
	30 to 60	> 60 to 70	> 70 to 90	> 90 to 150
≥ 30 to 100	150	150	150	300
> 100 to 200	300	300	300	See the following table.
> 200 to 300	300	See the following table.	See the following table.	See the following table.

III. Table 3: Weight based dosing every 2 weeks in members ≥ 12 years

Omaliuzumab Doses Administered Every 2 Weeks (mg) in members ≥ 12 years	
Pre-treatment	Body weight (kg)

serum IgE (IU/mL)	30 to 60	> 60 to 70	> 70 to 90	> 90 to 150
> 100 to 200	See previous table.	See previous table.	See previous table.	225
> 200 to 300	See previous table.	225	225	300
> 300 to 400	225	225	300	Do not dose.
> 400 to 500	300	300	375	Do not dose.
> 500 to 600	300	375	Do not dose.	Do not dose.
> 600 to 700	375	Do not dose.	Do not dose.	Do not dose

IV. Table 4: Weight based dosing every 2 or 4 weeks for in members who begin Xolair between the ages of 6 to <12 years

Omaliuzumab Doses Administered Every 2 or 4 Weeks (mg) for Pediatric Members with Asthma Who Begin Xolair Between the Ages of 6 to <12 Years											
Pre-treatment IgE (IU/mL)	Dosing Freq. (weeks)	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	4	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	225	225	225	300	375
>300-400		225	225	300	225	225	225	300	300		
>400-500		225	300	225	225	300	300	375	375		
>500-600		300	300	225	300	300	375				
>600-700		300	225	225	300	375					
>700-900		225	225	300	375						
>900-1100		225	300	375							
>1100-1200		300	300							Do Not Dose	

>1200-1300	2	300	375	
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References

1. Xolair [package insert]. South San Francisco, CA; Genentech, Inc.; Updated April 2021.
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. 2020 Update. Available from: <http://www.ginasthma.org>.
4. Baiardini I, Braido F, Bindslev-Jensen C, et al. Recommendations for assessing member- reported outcomes and health-related quality of life in members with urticaria: a GA(2)
5. National Comprehensive Cancer Network clinical practice guidelines, systemic mastocytosis. Version 1.2020. Updated May 21, 2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mastocytosis.pdf.
6. [Broesby-Olsen S1](#), [Vestergaard H2](#), [Mortz CG](#), et al. Omalizumab prevents anaphylaxis and improves symptoms in systemic mastocytosis: Efficacy and safety observations. *Allergy*. 2018 Jan;73(1):230-238. doi: 10.1111/all.13237. Epub 2017 Jul 27.
7. National Comprehensive Cancer Network clinical practice guidelines, management of immunotherapy-related toxicities. Version 1.2020. Updated December 16, 2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/immunotherapy.pdf. Accessed February 6, 2020.
8. 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/>.
9. 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.
10. 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.
11. UptoDate. Anti-IgE Therapy, Updated November 18, 2021.

Policy Implementation/Update:

Action and Summary of Changes	Date
New EOCCO policy for self-administered formulation	10/2022