Pharmacy Policy Bulletin: J-1081 Xolair (omalizumab) Syringe and Autoinjector – Commercial and Healthcare Reform	
Number: J-1081	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Miscellaneous Specialty Drugs Injectable = Yes w/ Prior Authorization **Quantity Limits (1., 2., 3., or 4.):** **1.** Rx Mgmt Quantity Limits = Safety/Specialty **2.** Rx Mgmt Quantity Limits = Safety/Specialty + Dose Opt **3.** Rx Mgmt Quantity Limits = Safety/Specialty + Dose Opt + Watchful **4.** Rx Mgmt Performance = MRxC = Yes **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1081-011	**Original Date:** 06/02/2021
Effective Date: 07/18/2025	**Review Date:** 06/25/2025

Drugs Product(s):	• Xolair (omalizumab) prefilled syringe and autoinjector
FDA-Approved Indication(s):	• Moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids • Chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age or older who remain symptomatic despite H1 antihistamine treatment • Chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment • IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance.

Background:	• Xolair is the first monoclonal antibody directed against immunoglobulin E. Xolair binds to human IgE's high affinity Fc receptor, preventing the binding of IgE to

cells associated with the allergic response. Xolair also lowers free serum IgE concentrations.

Asthma

- The Global Initiative for Asthma (GINA) guidelines recommend biologic therapy in patients with uncontrolled, difficult-to-treat and severe asthma when optimized on a medium- or high-dose ICS with a second controller (usually a long-acting beta-2 agonist [LABA]). The GINA guidelines define uncontrolled asthma as 2 or more asthma exacerbations requiring oral corticosteroids or 1 or more asthma exacerbation requiring hospitalization.

Estimated Comparative Daily Inhaled Corticosteroid Dosages for Patients 6 to 11 years old			
Drug	**Low Dose**	**Moderate Dose**	**High Dose**
Beclomethasone dipropionate (pMDI, standard particle, HFA)	100-200 mcg	>200-400 mcg	>400 mcg
Beclomethasone dipropionate (pMDI, extrafine particle, HFA)	50-100 mcg	>100-200 mcg	>200 mcg
Budesonide (DPI, or pMDI, standard particle, HFA)	100-200 mcg	>200-400 mcg	>400 mcg
Budesonide (nebules)	250-500 mcg	>500-1000 mcg	>1000 mcg
Ciclesonide (pMDI, extrafine particle, HFA)	80 mcg	>80-160 mcg	>160 mcg
Fluticasone furoate (DPI)	50 mcg	50 mcg	n.a.
Fluticasone propionate (DPI)	50-100 mcg	>100-200 mcg	>200 mcg
Fluticasone propionate (pMDI, standard particle, HFA)	50-100 mcg	>100-200 mcg	>200 mcg
Mometasone furoate (pMDI, standard particle, HFA)	100 mcg	100 mcg	200 mcg

Abbreviations: DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler

Estimated Comparative Daily Inhaled Corticosteroid Dosages for Patients ≥ 12 years old			
Drug	**Low Dose**	**Moderate Dose**	**High Dose**
Beclomethasone dipropionate (pMDI, standard particle, HFA)	200-500 mcg	>500-1000 mcg	>1000 mcg
Beclomethasone dipropionate (DPI or pMDI, extrafine particle, HFA)	100-200 mcg	>200-400 mcg	>400 mcg

Budesonide (DPI, or pMDI, standard particle, HFA)	200-400 mcg	>400-800 mcg	>800 mcg
Ciclesonide (pMDI, extrafine particle, HFA)	80-160 mcg	>160-320 mcg	>320 mcg
Fluticasone furoate (DPI)	100 mcg	100 mcg	200 mcg
Fluticasone propionate (DPI)	100-250 mcg	>250-500 mcg	>500 mcg
Fluticasone propionate (pMDI, standard particle, HFA)	100-250 mcg	>250-500 mcg	>500 mcg
Mometasone furoate (DPI)	220 mcg	>220-440 mcg	>440-880 mcg
Mometasone furoate (pMDI, standard particle, HFA)	200-400 mcg	200-400 mcg	>400 mcg

Abbreviations: DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler

CRSwNP

- The Nasal Congestion Score is a tool used to measure changes in nasal congestion and obstruction. It ranges from 0 – 3 and is the monthly average of the daily morning AM patient-assessed daily symptom severity (0 = no symptoms to 3 = severe symptoms).
- The Nasal Polyp Score is used to characterize the patient's polyps from 0 = no polyps to 4 = severe disease with large polyps causing complete obstruction of the inferior nasal cavity.

CSU

- The American Academy of Allergy, Asthma & Immunology guidelines recommend Xolair as an alternative therapy for patients with refractory chronic urticaria.

Food Allergy

- Food allergies are broadly categorized into either IgE mediated or non–IgE-mediated processes. Type I IgE-mediated food allergic reactions have rapid onset, typically beginning within minutes to 2 hours from the time of ingestion. Signs and symptoms can involve the skin, respiratory and gastrointestinal (GI) tracts, and cardiovascular system (e.g., urticaria and angioedema, oropharyngeal symptoms, respiratory tract symptoms, GI symptoms, or life-threatening anaphylaxis. Non IgE-mediated food reactions are delayed reactions (hours to several days).
- Common food allergies include peanuts, cow's milk, shellfish, tree nuts, egg, fish, soy, and wheat.
- Prescribing Considerations:
    - Xolair is not indicated for acute bronchospasm, status asthmaticus, other forms of urticaria, or emergency treatment of allergic reactions (including anaphylaxis).
    - Xolair has a black box warning for anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue). Anaphylaxis has occurred after the first dose of Xolair but also has occurred beyond 1 year after beginning treatment.

	○ Xolair prefilled syringe and autoinjector can be administered by patients 12 years of age and older under adult supervision. Only Xolair prefilled syringe should be used in pediatric patients 1 to 11 years of age and administered by a caregiver. Xolair autoinjectors (all doses) are not intended for use in pediatric patients under 12 years of age. ○ Due to the risk of anaphylaxis, patients eligible for self-administration should be determined by the healthcare providers in consultation with the patient. • Asthma, CRSwNP, and CSU: Patient should have no prior history of anaphylaxis to Xolair or other agents, such as foods, drugs, biologics, etc. • IgE-Mediated Food Allergy: Patient should have no prior history of anaphylaxis to Xolair or other agents (except foods), such as drugs, biologics, etc. • Patients 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 and able to treat anaphylaxis appropriately, and able to perform the subcutaneous injections with Xolair. ○ For CSU, Xolair may be dosed 150 or 300 mg SC every 4 weeks. Dosing in CSU is not dependent on serum IgE level or body weight. Xolair CSU reauthorization enforces dose de-escalation if clinically appropriate. ○ The 75 mg, 150 mg, 225 mg, 300 mg, and 375 mg Xolair doses are approved for use in asthma patients. All doses (75 mg – 600 mg) are approved for use in CRSwNP and IgE-mediated food allergy patients. The 150 mg and 300 mg XOLAIR doses are also approved for use in CSU patients.

Approval Criteria

I. Moderate To Severe Persistent Asthma

A. Initial Authorization

When a benefit, coverage of Xolair syringe/autoinjector may be approved when all of the following criteria are met **(1. through 9.)**:

1. The member meets one (1) of the following criteria **(a. or b.)**:
   a. If the request is for Xolair prefilled syringe, the member is 6 years of age or older.
   b. If the request is for Xolair autoinjector, the member is 12 years of age or older.

2. The member has a diagnosis of moderate to severe persistent asthma (ICD-10: J45.40, J45.50).

3. The member has documentation of a positive skin test or in vitro reactivity to a perennial aeroallergen.

4. The member has a baseline IgE titer greater than or equal to 30 IU/mL.

5. The member meets one (1) of the following criteria **(a. or b.):**
   a. The member has a history of ≥ 2 asthma exacerbations requiring oral or injectable corticosteroid treatment in the previous 12 months.
   b. The member has a history of ≥ 1 asthma exacerbation requiring hospitalization in the previous 12 months.

6. The member has inadequate symptom control despite regular treatment with medium- or high-dose inhaled corticosteroids (ICS) and at least one (1) additional asthma controller (for example, long-acting beta-2 agonist [LABA], leukotriene receptor antagonist [LTRA], or theophylline), with or without oral corticosteroids (OCS), unless intolerant of, or has contraindications to all of these agents.

7. The member will continue treatment with medium- or high-dose ICS and at least one (1) additional asthma controller (for example, LABA, LTRA, or theophylline), with or without OCS, while using Xolair.
8. The prescriber attests that the member is an appropriate candidate for self-administration by the member or caregiver according to all of the following criteria **(a. and b.)**:
   a. The member does not have a history of anaphylaxis.
   b. The member will receive at least 3 doses of Xolair (either syringe or vial) under the guidance of a healthcare provider, with no hypersensitivity reactions.
9. The prescriber submits documentation substantiating all of the following **(a. and b.)**:
   a. Current weight
   b. Pretreatment serum IgE

B. Reauthorization

When a benefit, reauthorization of Xolair syringe/autoinjector may be approved when all of the following criteria are met **(1., 2., and 3.)**:

1. The member meets one (1) of the following criteria **(a. or b.)**:
   a. If the request is for Xolair prefilled syringe, the member is 6 years of age or older.
   b. If the request is for Xolair autoinjector, the member is 12 years of age or older.
2. The prescriber submits documentation substantiating all of the following **(a. and b.):**
   a. Current weight
   b. Pretreatment serum IgE
3. The member meets one (1) of the following criteria **(a. through d.)**:
   a. The prescriber attests that the member has decreased rescue medication or oral corticosteroid use.
   b. The prescriber attests that the member has had a decrease in frequency of severe asthma exacerbations.
   c. The prescriber attests that the member experienced an increase in pulmonary function from baseline (e.g. FEV1).
   d. The prescriber attests that the member has experienced a reduction in reported asthma-related symptoms (e.g. asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing).

C. Quantity Limitations

When prior authorization is approved, Xolair syringe/autoinjector may be authorized in quantities as follows:

Table 1. Subcutaneous Xolair Syringe/Autoinjector Doses Every 2 or 4 Weeks for Patients 12 Years of Age and Older with Asthma

Pretreatment serum IgE (IU/mL)	Dosing Frequency	Dose	PLA	Dose	PLA	Dose	PLA	Dose	PLA
		30 – 60 kg		> 60-70 kg		> 70- 90 kg		> 90 – 150 kg	
≥ 30 – 100	Every 4 weeks	150 mg	1 mL per 21 days*	150 mg	1 mL per 21 days*	150 mg	1 mL per 21 days*	300 mg	2 mL per 21 days*
> 100 – 200		300 mg	2 mL per 21 days*	300 mg	2 mL per 21 days*	300 mg	2 mL per 21 days*	225 mg	3 mL per 21 days
> 200 – 300		300 mg	2 mL per 21 days*	225 mg	3 mL per 21 days	225 mg	3 mL per 21 days	300 mg	4 mL per 21 days
> 300 – 400	Every 2 weeks	225 mg	3 mL per 21 days	225 mg	3 mL per 21 days	300 mg	4 mL per 21 days		
> 400 – 500		300 mg	4 mL per 21 days	300 mg	4 mL per 21 days	375 mg	5 mL per 21 days		
> 500 – 600		300 mg	4 mL per 21 days	375 mg	5 mL per 21 days				
> 600 – 700		375 mg	5 mL per 21 days						

*No PLA is necessary since the product is coded at a quantity limit of 2 mL per 21 days.

Table 2. Subcutaneous Xolair Syringe Doses Every 2 or 4 Weeks for Pediatric Patients with Asthma Who Begin Xolair Between the Ages of 6 to <12 Years

Pretreatment serum IgE (IU/mL)	Dosing Frequency	Dose	PLA	Dose	PLA	Dose	PLA	Dose	PLA
		20 – 25 kg		> 25 - 30 kg		> 30 - 40 kg		> 40 – 50 kg	
≥ 30 – 100	Every 4 weeks	75 mg	0.5 mL per 21 days*	75 mg	0.5 mL per 21 days*	75 mg	0.5 mL per 21 days*	150 mg	1 mL per 21 days*
> 100 – 200		150 mg	1 mL per 21 days*	150 mg	1 mL per 21 days*	150 mg	1 mL per 21 days*	300 mg	2 mL per 21 days*
> 200 – 300		150 mg	1 mL per 21 days*	150 mg	1 mL per 21 days*	225 mg	1.5 mL per 21 days*	300 mg	2 mL per 21 days*
> 300 – 400		225 mg	1.5 mL per 21 days*	225 mg	1.5 mL per 21 days*	300 mg	2 mL per 21 days*	225 mg	3 mL per 21 days
> 400 – 500		225 mg	1.5 mL per 21 days*	300 mg	2 mL per 21 days*	225 mg	3 mL per 21 days	225 mg	3 mL per 21 days
> 500 – 600		300 mg	2 mL per 21 days*	300 mg	2 mL per 21 days*	225 mg	3 mL per 21 days	300 mg	4 mL per 21 days
> 600 – 700		300 mg	2 mL per 21 days*	225 mg	3 mL per 21 days	225 mg	3 mL per 21 days	300 mg	4 mL per 21 days
> 700 – 800	Every 2 weeks	225 mg	3 mL per 21 days	225 mg	3 mL per 21 days	300 mg	4 mL per 21 days	375 mg	5 mL per 21 days
> 800 – 900		225 mg	3 mL per 21 days	225 mg	3 mL per 21 days	300 mg	4 mL per 21 days	375 mg	5 mL per 21 days
> 900 – 1,000		225 mg	3 mL per 21 days	300 mg	4 mL per 21 days	375 mg	5 mL per 21 days		
> 1,000 – 1,100		225 mg	3 mL per 21 days	300 mg	4 mL per 21 days	375 mg	5 mL per 21 days		
> 1,100 – 1,200		300 mg	4 mL per 21 days	300 mg	4 mL per 21 days				
> 1,200 – 1,300		300 mg	4 mL per 21 days	375 mg	5 mL per 21 days				

*No PLA is necessary since the product is coded at a quantity limit of 2 mL per 21 days.

Pretreatment serum IgE (IU/mL)	Dosing Frequency	Dose	PLA	Dose	PLA	Dose	PLA	Dose	PLA
		> 50 - 60 kg		> 60 - 70 kg		> 70 – 80 kg		> 80 – 90 kg	
≥ 30 – 100	Every 4 weeks	150 mg	1 mL per 21 days*	150 mg	1 mL per 21 days*	150 mg	1 mL per 21 days*	150 mg	1 mL per 21 days*
> 100 – 200		300 mg	2 mL per 21 days*	300 mg	2 mL per 21 days*	300 mg	2 mL per 21 days*	300 mg	2 mL per 21 days*
> 200 – 300		300 mg	2 mL per 21 days*	225 mg	3 mL per 21 days	225 mg	3 mL per 21 days	225 mg	3 mL per 21 days
> 300 – 400	Every 2 weeks	225 mg	3 mL per 21 days	225 mg	3 mL per 21 days	300 mg	4 mL per 21 days	300 mg	4 mL per 21 days
> 400 – 500		300 mg	4 mL per 21 days	300 mg	4 mL per 21 days	375 mg	5 mL per 21 days	375 mg	5 mL per 21 days
> 500 – 600		300 mg	4 mL per 21 days	375 mg	5 mL per 21 days				
> 600 – 700		375 mg	5 mL per 21 days						

*No PLA is necessary since the product is coded at a quantity limit of 2 mL per 21 days.

Pretreatment serum IgE (IU/mL)	Dosing Frequency	Dose	PLA	Dose	PLA
		> 90 - 125 kg		> 125 - 150 kg	
≥ 30 – 100	Every 4 weeks	300 mg	2 mL per 21 days*	300 mg	2 mL per 21 days*

> 100 – 200	Every 2 weeks	225 mg	3 mL per 21 days	300 mg	4 mL per 21 days
> 200 – 300		300 mg	4 mL per 21 days	375 mg	5 mL per 21 days

*No PLA is necessary since the product is coded at a quantity limit of 2 mL per 21 days.

Note: the black cells indicate that there are no data to recommend a dose. For members that have IgE and weight within these cells, enter PLA per request from the provider as long as the request does not exceed the maximum dose for asthma, which is 5 mL per 21 days.

II. Chronic Spontaneous Urticaria (CSU)

A. Initial Authorization

When a benefit, coverage of Xolair syringe/autoinjector may be approved when all of the following criteria are met **(1. through 4.)**:

1. The member is 12 years of age or older.
2. The member has a diagnosis of urticaria (ICD-10 L50.0, L50.1, L50.8, L50.9), classified as chronic spontaneous urticaria.
3. The member has experienced therapeutic failure, contraindication, or intolerance to a second-generation non-sedating H_1 antihistamine at the maximum recommended doses (e.g., cetirizine, desloratadine, levocetirizine).
4. The prescriber attests that the member is an appropriate candidate for self-administration by the member or caregiver according to all of the following criteria **(a. and b.)**:
   - **a.** The member does not have a history of anaphylaxis.
   - **b.** The member will receive at least 3 doses of Xolair (either syringe or vial) under the guidance of a healthcare provider, with no hypersensitivity reactions.

B. Reauthorization

When a benefit, reauthorization of Xolair syringe/autoinjector may be approved when all of the following criteria are met **(1. and 2.):**

1. The member has improved CSU symptoms.
2. The prescriber has assessed the member for dose de-escalation, and the member meets one (1) of the following **(a., b., or c.):**
   - **a.** Xolair is requested at a dose of 150 mg every 4 weeks.
   - **b.** The prescriber attests that the member has had one (1) or more CSU attacks in the last 6 months and dose de-escalation to 150 mg every 4 weeks would not be appropriate
   - **c.** The prescriber attests that a dose of 150 mg every 4 weeks would not be appropriate (e.g., history of CSU-induced potential or actual airway compromise).

C. Quantity Limitations

When prior authorization is approved, Xolair syringe/autoinjector may be authorized for a quantity of 1 mL or 2 mL per 21 days.

III. CRSwNP

A. Initial Authorization

When a benefit, coverage of Xolair syringe/autoinjector may be approved when all of the following criteria are met **(1. through 5.)**:

1. The member is 18 years of age or older.
2. The member has a diagnosis of nasal polyps (ICD-10: J33.0, J33.1, J33.8, J33.9) with chronic rhinosinusitis.
3. Xolair will be an add-on to nasal corticosteroid maintenance treatment.
4. The prescriber attests that the member is an appropriate candidate for self-administration by the member or caregiver according to all of the following criteria **(a. and b.)**:
   - **a.** The member does not have a history of anaphylaxis.

b. The member will receive at least 3 doses of Xolair (either syringe or vial) under the guidance of a healthcare provider, with no hypersensitivity reactions.

5. The prescriber submits documentation substantiating all of the following **(a. and b.):**
- **a.** Current weight
- **b.** Pretreatment serum IgE

B. Reauthorization

When a benefit, reauthorization of Xolair syringe/autoinjector may be approved when all of the following criteria are met **(1., 2., and 3.)**

1. The prescriber submits documentation substantiating all of the following **(a. and b.):**
- **a.** Current weight
- **b.** Pretreatment serum IgE

2. The prescriber submits attestation of one (1) of the following **(a. or b.):**
- **a.** The member has a decrease in their nasal polyp score.
- **b.** The member has a reduction in their nasal congestion/obstruction severity score.

3. The member is using Xolair in addition to a nasal corticosteroid as add-on maintenance therapy.

C. Quantity Limitations

When prior authorization is approved, Xolair syringe/autoinjector may be authorized in quantities as follows:

Table 3. Subcutaneous Xolair Syringe/Autoinjector Doses Every 2 or 4 Weeks for Adult Patients with CRSwNP

Pretreatment serum IgE (IU/mL)	Dosing Frequency	Dose (mg)	PLA	Dose (mg)	PLA	Dose (mg)	PLA	Dose (mg)	PLA
		> 30 – 40 kg		> 40 - 50 kg		> 50 - 60 kg		> 60 – 70 kg	
30 – 100	Every 4 weeks	75	0.5 mL per 21 days*	150	1 mL per 21 days*	150	1 mL per 21 days*	150	1 mL per 21 days*
> 100 – 200		150	1 mL per 21 days*	300	2 mL per 21 days*	300	2 mL per 21 days*	300	2 mL per 21 days*
> 200 – 300		225	1.5 mL per 21 days*	300	2 mL per 21 days*	300	2 mL per 21 days*	450	3 mL per 21 days
> 300 – 400		300	2 mL per 21 days*	450	3 mL per 21 days	450	3 mL per 21 days	450	3 mL per 21 days
> 400 – 500		450	3 mL per 21 days	450	3 mL per 21 days	600	4 mL per 21 days	600	4 mL per 21 days
> 500 – 600		450	3 mL per 21 days	600	4 mL per 21 days	600	4 mL per 21 days	375	5 mL per 21 days
> 600 – 700		450	3 mL per 21 days	600	4 mL per 21 days	375	5 mL per 21 days	450	6 mL per 21 days
> 700 – 800	Every 2 weeks	300	4 mL per 21 days	375	5 mL per 21 days	450	6 mL per 21 days	450	6 mL per 21 days
> 800 – 900		300	4 mL per 21 days	375	5 mL per 21 days	450	6 mL per 21 days	525	7 mL per 21 days
> 900 – 1,000		375	5 mL per 21 days	450	6 mL per 21 days	525	7 mL per 21 days	600	8 mL per 21 days
> 1,000 – 1,100		375	5 mL per 21 days	450	6 mL per 21 days	600	8 mL per 21 days		
> 1,100 – 1,200		450	6 mL per 21 days	525	7 mL per 21 days	600	8 mL per 21 days		
> 1,200 – 1,300		450	6 mL per 21 days	525	7 mL per 21 days				
> 1,300 – 1,500		525	7 mL per 21 days	600	8 mL per 21 days				

*No PLA is necessary since the product is coded at a quantity limit of 2 mL per 21 days.

Pretreatment serum IgE (IU/mL)	Dosing Frequency	Dose (mg)	PLA	Dose (mg)	PLA	Dose (mg)	PLA	Dose (mg)	PLA
		> 70 – 80 kg		> 80 - 90 kg		> 90 - 125 kg		> 125 – 150 kg	
30 – 100	Every 4 weeks	150	1 mL per 21 days*	150	1 mL per 21 days*	300	2 mL per 21 days*	300	2 mL per 21 days*
> 100 – 200		300	2 mL per 21 days*	300	2 mL per 21 days*	450	3 mL per 21 days	600	4 mL per 21 days
> 200 – 300		450	3 mL per 21 days	450	3 mL per 21 days	600	4 mL per 21 days	375	5 mL per 21 days
> 300 – 400		600	4 mL per 21 days	600	4 mL per 21 days	450	6 mL per 21 days	525	7 mL per 21 days
> 400 – 500	Every 2 weeks	375	5 mL per 21 days	375	5 mL per 21 days	525	7 mL per 21 days	600	8 mL per 21 days
> 500 – 600		450	6 mL per 21 days	450	6 mL per 21 days	600	8 mL per 21 days		
> 600 – 700		450	6 mL per 21 days	525	7 mL per 21 days				
> 700 – 800		525	7 mL per 21 days	600	8 mL per 21 days				
> 800 – 900		600	8 mL per 21 days						

*No PLA is necessary since the product is coded at a quantity limit of 2 mL per 21 days.

Note: the black cells indicate that there are no data to recommend a dose. For members that have IgE and weight within these cells, enter PLA per request from the provider as long as the request does not exceed the maximum dose for nasal polyps, which is 8 mL per 21 days.

IV. Food Allergy

A. Initial Authorization

When a benefit, coverage of Xolair syringe/autoinjector may be approved when all of the following criteria are met **(1. through 8.)**:

1. The member meets one (1) of the following criteria **(a. or b.)**:
   - **a.** If the request is for Xolair prefilled syringe, the member is 1 year of age or older.
   - **b.** If the request is for Xolair autoinjector, the member is 12 years of age or older.
2. Xolair is being prescribed by or in consultation with an allergist or immunologist.
3. The member has a diagnosis of food allergy (ICD-10: Z91.01), classified as IgE mediated confirmed by one (1) of the following **(a. or b.)**:
   - **a.** Skin prick test (SPT)
   - **b.** Food-specific (sIgE) antibodies
4. The prescriber attests the member has had a previous allergic reaction to food.
5. The prescriber attests the member is using Xolair for the reduction of allergic reactions (type 1), including anaphylaxis.
6. The prescriber attests Xolair will be used in conjunction with food allergen avoidance.
7. The prescriber submits documentation substantiating all of the following **(a. and b.)**:
   - **a.** Current weight
   - **b.** Pretreatment serum IgE
8. The prescriber attests that the member is an appropriate candidate for self-administration by the member or caregiver according to all of the following criteria **(a., b., and c.)**:
   - **a.** The member does not have a history of anaphylaxis to Xolair or other agents (except foods), such as drugs, biologics, etc.
   - **b.** The member will receive at least 3 doses of Xolair under the guidance of a healthcare provider, with no hypersensitivity reactions.
   - **c.** The member has a documented prescription for epinephrine.

B. Reauthorization

When a benefit, reauthorization of Xolair syringe/autoinjector may be approved when all of the following criteria are met **(1. through 5.):**

1. The member meets one (1) of the following criteria **(a. or b.)**:

a. If the request is for Xolair prefilled syringe, the member is 1 year of age or older.
b. If the request is for Xolair autoinjector, the member is 12 years of age or older.

2. The prescriber submits documentation substantiating all of the following **(a. and b.)**:
a. Current weight
b. Pretreatment serum IgE

3. The prescriber attests that the member has experienced a positive clinical response to therapy.

4. The prescriber attests the member requires continuation of therapy

5. The prescriber attests the member will continue food allergen avoidance.

C. Quantity Limitations

When prior authorization is approved, Xolair syringe/autoinjector may be authorized in quantities as follows:

Table 4. Subcutaneous Xolair Syringe/Autoinjector Doses Every 2 or 4 Weeks for Adult and Pediatric Patients 1 Year of Age and Older with IgE-Mediated Food Allergy

Pretreatment serum IgE (IU/mL)	Dosing Frequency	Dose (mg)	PLA	Dose (mg)	PLA	Dose (mg)	PLA	Dose (mg)	PLA
		≥ 10-12 kg		> 12-15 kg		> 15-20 kg		>20-25 kg	
≥ 30 - 100	Every 4 weeks	75	0.5 mL per 21 days*	75	0.5 mL per 21 days*	75	0.5 mL per 21 days*	75	0.5 mL per 21 days*
> 100 - 200		75	0.5 mL per 21 days*	75	0.5 mL per 21 days*	75	0.5 mL per 21 days*	150	1 mL per 21 days*
> 200 - 300		75	0.5 mL per 21 days*	75	0.5 mL per 21 days*	150	1 mL per 21 days*	150	1 mL per 21 days*
> 300 - 400		150	1 mL per 21 days*	150	1 mL per 21 days*	150	1 mL per 21 days*	225	1.5 mL per 21 days*
> 400 - 500		150	1 mL per 21 days*	150	1 mL per 21 days*	225	1.5 mL per 21 days*	225	1.5 mL per 21 days*
> 500 - 600		150	1 mL per 21 days*	150	1 mL per 21 days*	225	1.5 mL per 21 days*	300	2 mL per 21 days*
> 600 - 700		150	2 mL per 21 days*	150	2 mL per 21 days*	225	1.5 mL per 21 days*	300	2 mL per 21 days*
> 700 - 800	Every 2 weeks	150	2 mL per 21 days*	150	2 mL per 21 days*	150	2 mL per 21 days*	225	3 mL per 21 days
>800 - 900		150	2 mL per 21 days*	150	2 mL per 21 days*	150	2 mL per 21 days*	225	3 mL per 21 days
>900 - 1000		150	2 mL per 21 days*	150	2 mL per 21 days*	225	3 mL per 21 days	225	3 mL per 21 days
>1000 - 1100		150	2 mL per 21 days*	150	2 mL per 21 days*	225	3 mL per 21 days	225	3 mL per 21 days
>1100 - 1200		150	2 mL per 21 days*	150	2 mL per 21 days*	225	3 mL per 21 days	300	4 mL per 21 days
>1200 - 1300		150	2 mL per 21 days*	225	3 mL per 21 days	225	3 mL per 21 days	300	4 mL per 21 days
>1300 - 1500		150	2 mL per 21 days*	225	3 mL per 21 days	300	4 mL per 21 days	300	4 mL per 21 days

>1500 - 1850		[redacted]		225	3 mL per 21 days	300	4 mL per 21 days	375	5 mL per 21 days

*No PLA is necessary since the product is coded at a quantity limit of 2 mL per 21 days.

Pretreatment serum IgE (IU/mL)	Dosing Frequency	Dose (mg)	PLA	Dose (mg)	PLA	Dose (mg)	PLA	Dose (mg)	PLA
		>25-30 kg		>30-40 kg		>40-50 kg		>50-60 kg	
≥ 30 - 100	Every 4 weeks	75	0.5 mL per 21 days*	75	0.5 mL per 21 days*	150	1 mL per 21 days*	150	1 mL per 21 days*
> 100 - 200		150	1 mL per 21 days*	150	1 mL per 21 days*	300	2 mL per 21 days*	300	2 mL per 21 days*
> 200 - 300		150	1 mL per 21 days*	225	1.5 mL per 21 days*	300	2 mL per 21 days*	300	2 mL per 21 days*
> 300 - 400		225	1.5 mL per 21 days*	300	2 mL per 21 days*	450	3 mL per 21 days	450	3 mL per 21 days
> 400 - 500		300	2 mL per 21 days*	450	3 mL per 21 days	450	3 mL per 21 days	600	4 mL per 21 days
> 500 - 600		300	2 mL per 21 days*	450	3 mL per 21 days	600	4 mL per 21 days	600	4 mL per 21 days
> 600 - 700		225	3 mL per 21 days	450	3 mL per 21 days	600	4 mL per 21 days	375	5 mL per 21 days
> 700 - 800	Every 2 weeks	225	3 mL per 21 days	300	4 mL per 21 days	375	5 mL per 21 days	450	6 mL per 21 days
>800 - 900		225	3 mL per 21 days	300	4 mL per 21 days	375	5 mL per 21 days	450	6 mL per 21 days
>900 - 1000		300	4 mL per 21 days	375	5 mL per 21 days	450	6 mL per 21 days	525	7 mL per 21 days
>1000 - 1100		300	4 mL per 21 days	375	5 mL per 21 days	450	6 mL per 21 days	600	8 mL per 21 days
>1100 - 1200		300	4 mL per 21 days	450	6 mL per 21 days	525	7 mL per 21 days	600	8 mL per 21 days
>1200 - 1300		375	5 mL per 21 days	450	6 mL per 21 days	525	7 mL per 21 days	[redacted]	
>1300 - 1500		375	5 mL per 21 days	525	7 mL per 21 days	600	8 mL per 21 days		
>1500 - 1850		450	6 mL per 21 days	600	8 mL per 21 days	[redacted]			

*No PLA is necessary since the product is coded at a quantity limit of 2 mL per 21 days.

Pretreatment serum IgE (IU/mL)	Dosing Frequency	Dose (mg)	PLA	Dose (mg)	PLA	Dose (mg)	PLA	Dose (mg)	PLA	Dose (mg)	PLA
		>60-70		>70-80		>80-90		>90 -125		>125-150	
≥ 30 - 100	Every 4 weeks	150	1 mL per 21 days*	150	1 mL per 21 days*	150	1 mL per 21 days*	300	2 mL per 21 days*	300	2 mL per 21 days*

> 100 - 200		300	2 mL per 21 days*	300	2 mL per 21 days*	300	2 mL per 21 days*	450	3 mL per 21 days	600	4 mL per 21 days
> 200 - 300		450	3 mL per 21 days	450	3 mL per 21 days	450	3 mL per 21 days	600	4 mL per 21 days	375	5 mL per 21 days
> 300 - 400		450	3 mL per 21 days	600	4 mL per 21 days	600	4 mL per 21 days	450	6 mL per 21 days	525	7 mL per 21 days
> 400 - 500		600	4 mL per 21 days	375	5 mL per 21 days	375	5 mL per 21 days	525	7 mL per 21 days	600	8 mL per 21 days
> 500 - 600		375	5 mL per 21 days	450	6 mL per 21 days	450	6 mL per 21 days	600	8 mL per 21 days		
> 600 - 700		450	6 mL per 21 days	450	6 mL per 21 days	525	7 mL per 21 days				
> 700 - 800	Every 2 weeks	450	6 mL per 21 days	525	7 mL per 21 days	600	8 mL per 21 days				
>800 - 900		525	7 mL per 21 days	600	8 mL per 21 days						
>900 - 1000		600	8 mL per 21 days								

*No PLA is necessary since the product is coded at a quantity limit of 2 mL per 21 days.
Note: the black cells indicate that there are no data to recommend a dose. For members that have IgE and weight within these cells, enter PLA per request from the provider as long as the request does not exceed the maximum dose for IgE-mediated food allergy, which is 8 mL per 21 days.

IV. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization

- Commercial and HCR Plans: If approved, up to a 6 month authorization may be granted.

Reauthorization

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None

References:

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5. Alobid I et al. SEAIC-SEORL. Consensus Document on Nasal Polyposis. POLINA Project. *Journal of Investigational Allergology and Clinical Immunology* 2011;21(Suppl 1):1-58.
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7. Global Initiative for Asthma. Global Strategy for Astha Management and Prevention. Available at: https://ginasthma.org/2024-report/. Accessed October 3, 2024.
8. Bright DM, et al. Food allergies: Diagnosis, treatment, and prevention. *Am Fam Physician*. 2023;108(2):159-165