



Effective Date 2/1/2023

Next Review Date 2/1/2024

Drug Quantity Management – Per Days Immunologicals – Xolair® (omalizumab subcutaneous injection)

Table of Contents

National Formulary Medical Necessity	1
Conditions Not Covered.....	5
Background.....	5
References	6
Revision History.....	6

Product Identifier(s)

Effective 1/1/23 to 2/6/23: 109896

Effective 2/7/23: 91127

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

This Drug Quantity Management program has been developed to manage potential dose escalation of Xolair. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year unless otherwise noted below.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per 28 Days	Home Delivery Maximum Quantity per 84 Days
Xolair® (omalizumab subcutaneous injection)	75 mg prefilled syringe	2 syringes [†]	6 syringes [†]
	150 mg prefilled syringe	4 syringes [†]	12 syringes [†]
	150 mg vial	6 vials ^α	18 vials

[†] This provides a quantity sufficient for a dose of up to 375 mg administered once every 2 weeks using a combination of 75 mg and 150 mg syringes as a 28-day supply at retail or an 84-day supply at home delivery; ^α This provides a quantity sufficient for a dose of 450 mg administered once every 2 weeks as a 28-day supply at retail or an 84-day supply at home delivery.

Criteria

Cigna covers quantities as medically necessary when the following criteria are met:

Xolair 75 mg prefilled syringes

No overrides recommended.

Xolair 150 mg prefilled syringes

1. If the individual is requesting Xolair for nasal polyps, approve the quantity listed in the table per 28 days at retail or per 84 days at home delivery.

IgE ^α (IU/mL)	Weight							
	>30-40 kg	>40-50 kg	>50-60 kg	>60-70 kg	>70-80 kg	>80-90 kg	>90-125 kg	>125-150 kg
30 – 100	No Override (75 mg Q4W)	No Override (150 mg Q4W)	No Override (150 mg Q4W)	No Override (150 mg Q4W)	No Override (150 mg Q4W)	No Override (150 mg Q4W)	No Override (300 mg Q4W)	No Override (300 mg Q4W)
>100 – 200	No Override (150 mg Q4W)	No Override (300 mg Q4W)	No Override (300 mg Q4W)	No Override (300 mg Q4W)	No Override (300 mg Q4W)	No Override (300 mg Q4W)	No Override (450 mg Q4W)	No Override (600 mg Q4W)
>200 – 300	No Override (225 mg Q4W)	No Override (300 mg Q4W)	No Override (300 mg Q4W)	No Override (450 mg Q4W)	No Override (450 mg Q4W)	No Override (450 mg Q4W)	No Override (600 mg Q4W)	No Override (375 mg Q2W)
>300 – 400	No Override (300 mg Q4W)	No Override (450 mg Q4W)	No Override (450 mg Q4W)	No Override (450 mg Q4W)	No Override (600 mg Q4W)	No Override (600 mg Q4W)	6 per 28 days or 18 per 84 days (450 mg Q2W)	8 per 28 days or 24 per 84 days (525 mg Q2W)
>400 – 500	No Override (450 mg Q4W)	No Override (450 mg Q4W)	No Override (600 mg Q4W)	No Override (600 mg Q4W)	No Override (375 mg Q2W)	No Override (375 mg Q2W)	8 per 28 days or 24 per 84 days (525 mg Q2W)	8 per 28 days or 24 per 84 days (600 mg Q2W)
>500 – 600	No Override (450 mg Q4W)	No Override (600 mg Q4W)	No Override (600 mg Q4W)	No Override (375 mg Q2W)	6 per 28 days 18 per 84 days (450 mg Q2W)	6 per 28 days or 18 per 84 days (450 mg Q2W)	8 per 28 days or 24 per 84 days (600 mg Q2W)	
>600 – 700	No Override (450 mg Q4W)	No Override (600 mg Q4W)	No Override (375 mg Q2W)	6 per 28 days or 18 per 84 days (450 mg Q2W)	6 per 28 days or 18 per 84 days (450 mg Q2W)	8 per 28 days or 24 per 84 days (525 mg Q2W)		
>700 – 800	No Override (300 mg Q2W)	No Override (375 mg Q2W)	6 per 28 days or 18 per 84 days (450 mg Q2W)	6 per 28 days or 18 per 84 days (450 mg Q2W)	8 per 28 days or 24 per 84 days (525 mg Q2W)	8 per 28 days or 24 per 84 days (600 mg Q2W)		
>800 – 900	No Override (300 mg Q2W)	No Override (375 mg Q2W)	6 per 28 days or 18 per 84 days (450 mg Q2W)	8 per 28 days or 24 per 84 days (525 mg Q2W)	8 per 28 days or 24 per 84 days (600 mg Q2W)			

>900 – 1,000	No Override (375 mg Q2W)	6 per 28 days or 18 per 84 days (450 mg Q2W)	8 per 28 days or 18 per 84 days (525 mg Q2W)	8 per 28 days or 24 per 84 days (600 mg Q2W)	No Override Insufficient Data to Recommend a Dose
>1,000 – 1,100	No Override (375 mg Q2W)	6 per 28 days or 18 per 84 days (450 mg Q2W)	8 per 28 days or 24 per 84 days (600 mg Q2W)		
>1,100 – 1,200	6 per 28 days or 18 per 84 days (450 mg Q2W)	8 per 28 days or 24 per 84 days (525 mg Q2W)	8 per 28 days or 24 per 84 days (600 mg Q2W)		
>1,200 – 1300	6 per 28 days or 18 per 84 days (450 mg Q2W)	8 per 28 days or 24 per 84 days (525 mg Q2W)			
>1,300 – 1,500	8 per 28 days or 24 per 84 days (525 mg Q2W)	8 per 28 days or 24 per 84 days (600 mg Q2W)			

IgE – Immunoglobulin E; * Pre-treatment serum level; ¢ Quantities provided are for 150 mg prefilled syringes, with per 28 day limits at retail and per 84 day limits at home delivery; Q4W – Once every 4 weeks; Q2W – Once every 2 weeks.

Xolair 150 mg vials

1. If the individual is requesting Xolair for nasal polyps, approve the quantity listed in the table per 28 days at retail or per 84 days at home delivery.

IgE[¢] (IU/mL)	Weight							
	>30-40 kg	>40-50 kg	>50-60 kg	>60-70 kg	>70-80 kg	>80-90 kg	>90-125 kg	>125-150 kg
30 - 100	No Override 75 mg Q4W	No Override 150 mg Q4W	No Override 150 mg Q4W	No Override 150 mg Q4W	No Override 150 mg Q4W	No Override 150 mg Q4W	No Override 300 mg Q4W	No Override 300 mg Q4W
>100 - 200	No Override 150 mg Q4W	No Override 300 mg Q4W	No Override (300 mg Q4W	No Override 300 mg Q4W	No Override 300 mg Q4W	No Override 300 mg Q4W	No Override 450 mg Q4W	No Override 600 mg Q4W
>200 - 300	No Override 225 mg Q4W	No Override 300 mg Q4W	No Override 300 mg Q4W	No Override 450 mg Q4W	No Override 450 mg Q4W	No Override 450 mg Q4W	No Override 600 mg Q4W	No Override 375 mg Q2W
>300 - 400	No Override 300 mg Q4W	No Override 450 mg Q4W	No Override 450 mg Q4W	No Override 450 mg Q4W	No Override 600 mg Q4W	No Override 600 mg Q4W	No Override 450 mg Q2W	8 vials per 28 days or 24 per 84 days 525 mg Q2W
>400 - 500	No Override 450 mg Q4W	No Override 450 mg Q4W	No Override 600 mg Q4W	No Override 600 mg Q4W	No Override 375 mg Q2W	No Override 375 mg Q2W	8 per 28 days or 24 per 84 days	8 vials per 28 days or 24 per 84 days

							525 mg Q2W	600 mg Q2W
>500 - 600	No Override 450 mg Q4W	No Override 600 mg Q4W	No Override 600 mg Q4W	No Override 375 mg Q2W	No Override 450 mg Q2W	No Override 450 mg Q2W	8 per 28 days or 24 per 84 days 600 mg Q2W	
>600 - 700	No Override 450 mg Q4W	No Override 600 mg Q4W	No Override 375 mg Q2W	No Override 450 mg Q2W	No Override 450 mg Q2W	8 per 28 days or 24 per 84 days 525 mg Q2W		
>700 - 800	No Override 300 mg Q2W	No Override 375 mg Q2W	No Override 450 mg Q2W	No Override 450 mg Q2W	8 per 28 days or 24 per 84 days 525 mg Q2W	8 per 28 days or 24 per 84 days 600 mg Q2W		
>800 - 900	No Override 300 mg Q2W	No Override 375 mg Q2W	No Override 450 mg Q2W	8 per 28 days or 24 per 84 days 525 mg Q2W	8 per 28 days or 24 per 84 days 600 mg Q2W			
>900 – 1,000	No Override 375 mg Q2W	No Override 450 mg Q2W	8 per 28 days or 24 per 84 days 525 mg Q2W	8 per 28 days or 24 per 84 days 600 mg Q2W				
>1,000 – 1,100	No Override 375 mg Q2W	No Override 450 mg Q2W	8 per 28 days or 24 per 84 days 600 mg Q2W	No Override Insufficient Data to Recommend a Dose				
>1,100 – 1,200	No Override 450 mg Q2W	8 per 28 days or 24 per 84 days 525 mg Q2W	8 per 28 days or 24 per 84 days 600 mg Q2W					
>1,200 – 1,300	No Override450 mg Q2W	8 per 28 days or 24 per 84 days 525 mg Q2W						
>1,300 – 1,500	8 per 28 days or 24 per 84 days 525 mg Q2W	8 per 28 days or 24 per 84 days 600 mg Q2W						

^a Quantities provided are for 150 mg vials, with per 28 day limits at retail and per 84 day limits at home delivery; IgE – Immunoglobulin E; * Pre-treatment serum level; Q4W – Once every 4 weeks; Q2W – Once every 2 weeks.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Xolair, an anti-immunoglobulin E (IgE) monoclonal antibody, is indicated in the following conditions:¹

- **Asthma**, in patients ≥ 6 years of age with moderate to severe persistent disease who have a positive skin test or *in vitro* reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids (ICSs). Xolair has been shown to decrease the incidence of asthma exacerbations in these patients. Limitations of Use: Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus. It is also not indicated for the treatment of other allergic conditions.
- **Chronic idiopathic urticaria (CIU)**, in patients ≥ 12 years of age who remain symptomatic despite H₁ antihistamine treatment. Limitation of Use: Xolair is not indicated for the treatment of other forms of urticaria.
- **Nasal polyps**, as add-on maintenance treatment in patients ≥ 18 years of age with an inadequate response to nasal corticosteroids.

Dosing

Asthma

The recommended dose of Xolair for the treatment of asthma is 75 mg to 375 mg administered as a subcutaneous (SC) injection once every 2 weeks (Q2W) or once every 4 weeks (Q4W) based on serum total IgE level measured before the start of treatment and body weight.

Nasal Polyps

The recommended dose of Xolair for the treatment of nasal polyps is 75 mg to 600 mg administered as a SC injection Q2W or Q4W based on serum total IgE level measured before the start of treatment and by body weight.

Chronic Idiopathic Urticaria

The recommended dose of Xolair for the treatment of CIU is 150 mg or 300 mg administered as a SC injection Q4W. Dosing of Xolair in CIU patients is not dependent on serum IgE level (free or total) or body weight.

Availability

Xolair is available as 75 mg/0.5 mL and 150 mg/mL prefilled syringes.¹ Each carton contains one syringe. It is also available as 150 mg vials of lyophilized powder. Each carton contains one vial. The prefilled syringes are labeled for patient or caregiver administration, while the vials are labeled for healthcare provider administration only.

Tables 2 and 3 provide information on the number of syringes or vials that are needed to achieve each Xolair dose.

Table 2. Number of Xolair Prefilled Syringes Needed Based on Dose.¹

Xolair Dose	75 mg Syringes	150 mg Syringes
75 mg	1	0
150 mg	0	1
225 mg	1	1
300 mg	0	2
375 mg	1	2
450 mg	0	3
525 mg	1	3
600 mg	0	4

Table 3. Number of Xolair Vials Needed Based on Dose.¹

Xolair Dose	150 mg Vials
75 mg	1
150 mg	1
225 mg	2
300 mg	2
375 mg	3
450 mg	3
525 mg	4
600 mg	4

References

1. Xolair® [prescribing information]. South San Francisco, CA: Genentech; July 2021.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	Policy was updated to include the existing quantity limits when the product is obtained via home delivery. No changes to criteria.	12/02/2022

"Cigna Companies" refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc. and HMO or service company subsidiaries of Cigna Health Corporation. The Cigna name, logo, and other Cigna marks are owned by Cigna Intellectual Property, Inc. © 2023 Cigna.