



## Drug Quantity Management – Per Days Omalizumab injection (Xolair®) Duration Limit

### Table of Contents

National Formulary Medical Necessity .....	1
Conditions Not Covered.....	4
Background.....	4
References .....	5
Revision History .....	5

### Product Identifier(s)

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

#### Xolair 150 mg vial

Maximum quantity per 28 days = 6 vials

#### Xolair 75 mg prefilled syringe

Maximum quantity per 28 days = 2 syringes

#### Xolair 150 mg prefilled syringe

Maximum quantity per 28 days = 4 syringes

A quantity of two 75 mg prefilled syringes or four 150 mg prefilled syringes every 28 days will be allowed without coverage review. This will be enough drug for a 28-day supply of doses up to 375 mg every two weeks (using a combination of 75 mg and 150 mg syringes). A quantity of six 150 mg vials every 28 days will be covered without coverage review. This is enough drug for a 28-day supply of 450 mg every 2 weeks and one induction dose regimen per 365 days. Exceptions are allowed for individuals requiring higher doses for the treatment of nasal polyps.

The objective of this program is to manage potential dose escalation of Xolair in the treatment nasal polyps.

#### Criteria

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

**Xolair 150 mg vials**

- For individuals who are using Xolair vials for the treatment of nasal polyps, the quantity vials per 28 days may be authorized based on the following table.

Pretreatment Serum IgE (IU/mL)	Bodyweight							
	>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	no override	no override	no override	no override	no override	no override	no override
>100 - 200	no override	no override	no override	no override	no override	no override	no override	no override
>200 - 300	no override	no override	no override	no override	no override	no override	no override	no override
>300 - 400	no override	no override	no override	no override	no override	no override	no override	8 vials per 28 days
>400 - 500	no override	no override	no override	no override	no override	no override	8 vials per 28 days	8 vials per 28 days
>500 - 600	no override	no override	no override	no override	no override	no override	8 vials per 28 days	no override
>600 - 700	no override	no override	no override	no override	no override	8 vials per 28 days	no override	no override
>700 - 800	no override	no override	no override	no override	8 vials per 28 days	8 vials per 28 days	no override	no override
>800 - 900	no override	no override	no override	8 vials per 28 days	8 vials per 28 days	no override	no override	no override
>900 - 1000	no override	no override	8 vials per 28 days	8 vials per 28 days	no override	no override	no override	no override
>1000 - 1100	no override	no override	8 vials per 28 days	no override	no override	no override	no override	no override
>1100 - 1200	no override	8 vials per 28 days	8 vials per 28 days	no override	no override	no override	no override	no override
>1200 - 1300	no override	8 vials per 28 days	no override	no override	no override	no override	no override	no override
>1300 - 1500	8 vials per 28 days	8 vials per 28 days	no override	no override	no override	no override	no override	no override

**Xolair 150 mg prefilled syringes**

- For individuals who are using Xolair prefilled syringes for the treatment of nasal polyps, the quantity 150 mg prefilled syringes per 28 days may be authorized based on the following table.

Pretreatment Serum IgE (IU/mL)	Bodyweight							
	>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	no override	no override	no override	no override	no override	no override	no override
>100 - 200	no override	no override	no override	no override	no override	no override	no override	no override
>200 - 300	no override	no override	no override	no override	no override	no override	no override	no override
>300 - 400	no override	no override	no override	no override	no override	no override	6 syringes per 28 days	8 syringes per 28 days
>400 - 500	no override	no override	no override	no override	no override	no override	8 syringes per 28 days	8 syringes per 28 days
>500 - 600	no override	no override	no override	no override	6 syringes per 28 days	6 syringes per 28 days	8 syringes per 28 days	no override
>600 - 700	no override	no override	no override	6 syringes per 28 days	6 syringes per 28 days	8 syringes per 28 days	no override	no override
>700 - 800	no override	no override	6 syringes per 28 days	6 syringes per 28 days	8 syringes per 28 days	8 syringes per 28 days	no override	no override
>800 - 900	no override	no override	6 syringes per 28 days	8 syringes per 28 days	8 syringes per 28 days	no override	no override	no override
>900 - 1000	no override	6 syringes per 28 days	8 syringes per 28 days	8 syringes per 28 days	no override	no override	no override	no override
>1000 - 1100	no override	6 syringes per 28 days	8 syringes per 28 days	no override	no override	no override	no override	no override
>1100 - 1200	6 syringes per 28 days	8 syringes per 28 days	8 syringes per 28 days	no override	no override	no override	no override	no override
>1200 - 1300	6 syringes per 28 days	8 syringes per 28 days	no override	no override	no override	no override	no override	no override
>1300 - 1500	8 syringes per 28 days	8 syringes per 28 days	no override	no override	no override	no override	no override	no override

### **Xolair 75 mg prefilled syringe**

1. No quantity overrides are recommended.

## **Conditions Not Covered**

Any other exception is considered not medically necessary.

## **Background**

### **Overview**

Xolair is an anti-IgE antibody indicated 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, nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment, and chronic idiopathic urticarial (CIU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.

### **Dosing**

Xolair is administered by subcutaneous injection. The recommended injection sites are the upper arm and the front and middle of the thighs. Do not inject into moles, scars, bruises, or areas where the skin is tender, red, hard, or if there are breaks in the skin. Choose a different injection site for each new injection at least 1 inch from the area used for the last injection.

#### **Asthma**

The recommended dosage for treatment of asthma is XOLAIR 75 mg to 375 mg by subcutaneous injection every 2 or 4 weeks based on serum total IgE level (IU/mL) measured before the start of treatment and by body weight (kg).

#### **Nasal Polyps**

The recommended dosage for treatment of nasal polyps is 75 mg to 600 mg by subcutaneous injection every 2 or 4 weeks based on serum total IgE level (IU/mL) measure before the start of treatment and by body weight (kg).

#### **Chronic Idiopathic Urticaria (CIU)**

The recommended dosage for treatment of chronic idiopathic urticarial is 150 mg or 300 mg by subcutaneous injection every 4 weeks. Dosing of Xolair in CIU patients is not dependent on serum IgE (free or total) level or body weight.

The following tables provide information on the number of syringes or vials that are need to achieve the various doses of Xolair.

**Number of Prefilled Syringes, Injections and Total Injection Volumes**

XOLAIR Dose*	75 mg Syringes	150 mg Syringes	Total Volume Injected
75 mg	1	0	0.5 mL
150 mg	0	1	1 mL
225 mg	1	1	1.5 mL
300 mg	0	2	2 mL
375 mg	1	2	2.5 mL
450 mg	0	3	3 mL
525 mg	1	3	3.5 mL
600 mg	0	4	4 mL

### Number of Vials, Injections and Total Injection Volumes

XOLAIR Dose*	Number of Vials	Number of Injections	Total Volume Injected
75 mg	1	1	0.6 mL
150 mg	1	1	1.2 mL
225 mg	2	2	1.8 mL
300 mg	2	2	2.4 mL
375 mg	3	3	3.0 mL
450 mg	3	3	3.6 mL
525 mg	4	4	4.2 mL
600mg	4	4	4.8 mL

## References

1. Xolair® [prescribing information]. South San Francisco, CA: Genentech, Inc.; November 2020.

## Revision History

Type of Revision	Summary of Changes	Date
New policy	New policy to address override criteria needed for nasal polyp indication. Reviewed and approved at TAC.	12/16/2020

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