



Drug Coverage Policy

Effective Date09/01/2026

Coverage Policy Number..... DQM033

Policy Title..... Xolair Drug Quantity

Management Policy – Per Days

Immunologicals – Xolair Drug Quantity Management Policy – Per Days

- Xolair® (omalizumab subcutaneous injection – Genentech/Novartis)

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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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.

Overview

Xolair, an anti-immunoglobulin (Ig)E 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 spontaneous urticaria (CSU)**, 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.
- **Chronic rhinosinusitis with nasal polyps (CRSwNP)**, as add-on maintenance treatment in patients ≥ 18 years of age with an inadequate response to nasal corticosteroids.
- **IgE-mediated food allergy**, in patients ≥ 1 year of age, for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. Xolair is to be used in conjunction with food allergen avoidance.
Limitation of Use: Xolair is not indicated for the emergency treatment of allergic reactions, including anaphylaxis.

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.

CRSwNP

The recommended dose of Xolair for the treatment CRSwNP 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 Spontaneous 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.

IgE-Mediated Food Allergy

The recommended dose of Xolair for the treatment of food allergy 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.

Availability

Xolair is available as 75 mg/0.5 mL, 150 mg/mL, and 300 mg/mL auto-injectors and prefilled syringes.¹ Each carton contains one auto-injector or 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. The auto-injector (all strengths) is labeled for use in patients ≥ 12 years of age only.

Tables 1 and 2 provide information on the number of auto-injectors/syringes or vials that are needed to achieve each Xolair dose.

Table 1. Number of Xolair Auto-Injectors/Prefilled Syringes Needed Based on Dose.¹

Dose	# of Auto-Injectors/Prefilled Syringes per 28 Days Q4W Dosing	# of Auto-Injectors/Prefilled Syringes per 28 Days Q2W Dosing
75 mg	1 x 75 mg	2 x 75 mg
150 mg	1 x 150 mg (preferred) 2 x 75 mg	2 x 150 mg
225 mg	1 x 75 mg and 1 x 150 mg	2 x 75 mg and 2 x 150 mg
300 mg	1 x 300 mg (preferred) 2 x 150 mg	2 x 300 mg
375 mg	1 x 75 mg and 1 x 300 mg (preferred) 1 x 75 mg and 2 x 150 mg	2 x 75 mg and 2 x 300 mg
450 mg	1 x 150 mg and 1 x 300 mg (preferred) 3 x 150 mg	2 x 150 mg and 2 x 300 mg (preferred) 6 x 150 mg
525 mg	525 mg Q4W is not an approved dose.	2 x 75 mg , 2 x 150 mg, and 2 x 300 mg (preferred) 2 x 75 mg and 6 x 150 mg
600 mg	2 x 300 mg	4 x 300 mg

Q4W – Once every 4 weeks; Q2W – Once every 2 weeks.

Table 2. Number of Xolair 150 mg Vials Needed Based on Dose.¹

Xolair Dose	# of Vials per 28 Days Q4W Dosing	# of Vials per 28 Days Q2W Dosing
75 mg	1	2
150 mg	1	2
225 mg	2	4
300 mg	2	4
375 mg	3	6
450 mg	3	6
525 mg	4	8
600 mg	4	8

Q4W – Once every 4 weeks; Q2W – Once every 2 weeks.

Coverage Policy

POLICY STATEMENT

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. Meeting Drug Quantity Management Program Criteria does not satisfy any other prior authorization or medical necessity criteria requirements.

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
	75 mg auto- injector	2 auto-injectors	6 auto-injectors
	150 mg prefilled syringe	2 syringes	6 syringes
	150 mg auto- injector	2 auto-injectors	6 auto-injectors
	300 mg prefilled syringe	2 syringes	6 syringes
	300 mg auto- injector	2 auto-injectors	6 auto-injectors
	150 mg vial	6 vials	18 vials

Exceptions to the quantity limits listed above are covered as medically necessary when ONE of the following criteria are met. Any other exception is considered not medically necessary.

CRITERIA

Xolair 75 mg auto-injectors/prefilled syringes

No overrides recommended.

Xolair 150 mg auto-injectors/prefilled syringes

1. If the patient is requesting Xolair for immunoglobulin E-mediated food allergy or chronic rhinosinusitis with nasal polyps, approve the quantity listed in the table in [Appendix A](#) per 28 days at retail or per 84 days at home delivery.

Note: The override quantities in the table refer only to the quantity of the 150 mg auto-injectors/prefilled syringes needed to provide the appropriate dose. Certain doses require the use of two different strengths of Xolair. Therefore, the patient may also have a claim for another strength.

Xolair 150 mg vials

1. If the patient is requesting Xolair for immunoglobulin E-mediated food allergy or chronic rhinosinusitis with nasal polyps, approve the quantity listed in the table in [Appendix B](#) per 28 days at retail or per 84 days at home delivery.

Xolair 300 mg auto-injectors/prefilled syringes

1. If the patient is requesting Xolair for immunoglobulin E-mediated food allergy or chronic rhinosinusitis with nasal polyps, approve the quantity listed in the table in [Appendix C](#) per 28 days at retail or per 84 days at home delivery.

Note: The override quantities in the table refer only to the quantity of the 300 mg auto-injectors/prefilled syringes needed to provide the appropriate dose. Certain doses require the use of two different strengths of Xolair. Therefore, the patient may also have a claim for another strength.

References

1. Xolair® [prescribing information]. South San Francisco, CA: Genentech; February 2024.

Revision Details

Summary of Changes	Review Date	Effective Date
New policy.	07/30/2026	09/01/2026

The policy effective date is in force until updated or retired.

APPENDIX A

Table 1. Override Quantities for Xolair 150 mg Auto-Injectors/Prefilled Syringes for Immunoglobulin E-Mediated Food Allergy or Chronic Rhinosinusitis with Nasal Polyps.

Immunoglobulin E with Rabat Polypeptide									
IgE (IU/mL)	Weight								
	≥ 10-30 kg	>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	Food allergy dosing only. NO OVERRIDES	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)	3 per 28 days or 9 per 84 days (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)	3 per 28 days or 9 per 84 days (450 mg Q4W)	3 per 28 days or 9 per 84 days (450 mg Q4W)	3 per 28 days or 9 per 84 days (450 mg Q4W)	No Override (600 mg Q4W)	No Override (375 mg Q2W)
>300 – 400		No Override (300 mg Q4W)	3 per 28 days or 9 per 84 days (450 mg Q4W)	3 per 28 days or 9 per 84 days (450 mg Q4W)	3 per 28 days or 9 per 84 days (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)	6 per 28 days or 18 per 84 days (525 mg Q2W)
>400 – 500		3 per 28 days or 9 per 84 days (450 mg Q4W)	3 per 28 days or 9 per 84 days (450 mg Q4W)	No Override (600 mg Q4W)	No Override (600 mg Q4W)	No Override (375 mg Q2W)	No Override (375 mg Q2W)	6 per 28 days or 18 per 84 days (525 mg Q2W)	No Override (600 mg Q2W)
>500 – 600		3 per 28 days or 9 per 84 days (450 mg Q4W)	No Override (600 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)	No Override (600 mg Q2W)	
>600 – 700		3 per 28 days or 9 per 84 days (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)	6 per 28 days or 18 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))	6 per 28 days or 18 per 84 days (525 mg Q2W)	No Override (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)	6 per 28 days or 18 per 84 days (525 mg Q2W)	No Override (600 mg Q2W)			

>900 – 1,000		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 (525 mg Q2W)	No Override (600 mg Q2W)	Insufficient Data to Recommend a Dose NO OVERRIDES
>1,000 – 1,100		No Override (375 mg Q2W)	6 per 28 days or 18 per 84 days (450 mg Q2W)	No Override (600 mg Q2W)		
>1,100 – 1,200		6 per 28 days or 18 per 84 days (450 mg Q2W)	6 per 28 days or 18 per 84 days (525 mg Q2W)	No Override (600 mg Q2W)		
>1,200 – 1300		6 per 28 days or 18 per 84 days (450 mg Q2W)	6 per 28 days or 18 per 84 days (525 mg Q2W)			
>1,300 – 1,500		6 per 28 days or 18 per 84 days (525 mg Q2W)	No Override (600 mg Q2W)			
>1,500 – 1,850		No Override				

APPENDIX B

Table 1. Override Quantities for Xolair 150 mg Vials for Food Allergy or Chronic Rhinosinusitis with Nasal Polyps.

IgE (IU/mL)	Weight								
	≥ 10-30 kg	>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	Food allergy dosing only. NO OVERRIDES	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 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)	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)		Insufficient Data to Recommend a Dose NO OVERRIDES			
>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 – 1300		No Override (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)						

>1,500 - 1,850		8 per 28 days or 24 per 84 days (600 mg Q2W)	
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APPENDIX C

Table 1. Override Quantities for Xolair 300 mg Auto-Injectors/Prefilled Syringes for Food Allergy or Chronic Rhinosinusitis with Nasal Polyps.

IgE (IU/mL)	Weight								
	≥ 10-30 kg	>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	Food allergy dosing only. NO OVERRIDES	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)	No Override (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)	No Override (525 mg Q2W)	4 per 28 days or 12 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)	No Override (450 mg Q2W)	No Override (450 mg Q2W)	4 per 28 days or 12 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)	No Override (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)	No Override (525 mg Q2W)	4 per 28 days or 12 per 84 days (600 mg Q2W)		
>800 – 900		No Override (300 mg Q2W)	No Override (375 mg Q2W)	No Override (450 mg Q2W)	No Override (525 mg Q2W)	4 per 28 days or 12 per 84 days (600 mg Q2W)			

>900 – 1,000		No Override (375 mg Q2W)	No Override (450 mg Q2W)	No Override (525 mg Q2W)	4 per 28 days or 12 per 84 days (600 mg Q2W)	Insufficient Data to Recommend a Dose NO OVERRIDES
>1,000 – 1,100		No Override (375 mg Q2W)	No Override (450 mg Q2W)	4 per 28 days or 12 per 84 days (600 mg Q2W)		
>1,100 – 1,200		No Override (450 mg Q2W)	No Override (525 mg Q2W)	4 per 28 days or 12 per 84 days (600 mg Q2W)		
>1,200 – 1300		No Override (450 mg Q2W)	No Override (525 mg Q2W))			
>1,300 – 1,500		No Override (525 mg Q2W)	4 per 28 days or 12 per 84 days (600 mg Q2W)			
>1,500 – 1,850		4 per 28 days or 12 per 84 days (600 mg Q2W)				

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