

DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Immunologicals – Xolair Drug Quantity Management Policy – Per Days

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

REVIEW DATE: 12/02/2022

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 1. 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 2. 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

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.

Automation: None.

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 ^a	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; ^a 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

Xolair 75 mg prefilled syringes

No overrides recommended.

Xolair 150 mg prefilled syringes

- If the patient 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 ^{*a} (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 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 (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)				
>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)		No Override Insufficient Data to Recommend a Dose			
>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 – 1,300	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; ^a 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 patient 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 ^{*a} (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 525 mg Q2W	8 vials 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					
>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 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						

No Override
Insufficient Data to Recommend a Dose

^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.

REFERENCES

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

