Xolair® (omalizumab)

Policy Number:	M031002487
Effective Date:	10/2/2003
Sponsoring Department:	Pharmacy
Impacted Department(s):	N/A

Type of Policy: ☐ Internal ☒ External

Data Classification: ☐Confidential ☒Restricted ☐Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒MediSource Connect; ☒Child Health Plus; ☒Essential Plan
☐Medicare, if yes, which plan(s): ☐MAPD; ☐PDP; ☐ISNP; ☐CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To provide Independent Health members with consistent access to Xolair as medically necessary for the treatment of chronic idiopathic urticaria, asthma, and nasal polyps, to optimize treatment of such patients, and to require proper utilization of these medications.

Xolair® is indicated for the treatment of patients 6 years and older with moderate to severe persistent asthma with a documented allergic component whose symptoms are inadequately controlled with inhaled corticosteroids. Because Xolair® is indicated for use in only a specific subset of patients diagnosed with asthma, authorization is required. Xolair® is also indicated for the treatment of chronic idiopathic urticaria in adults and adolescents 12 years of age and above, who remain symptomatic despite H1 antihistamine treatment and for the treatment of nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids. Prior authorization is required to assure safe and appropriate use of this medication.

Policy:

Medication must be obtained through Specialty Pharmacy.

The following criteria are used within the Pharmacy Services Department to authorize Xolair® administration:

Inclusion Criteria:

Documentation of each of the following must be provided:

- Patient is 12 years of age or older; and
- Patient has a diagnosis of chronic idiopathic urticaria defined as:
- The presence of urticaria (hives) on most days of the week, for a duration of longer than six weeks who remain symptomatic despite intensive H1 antihistamine treatment; OR
- Patient is 6 years of age or older; and
- Diagnosis of moderate to severe asthma; and
- Patient body weight is between 20kg-150kg; and
- Evidence of reversible obstructive airway disease exists (demonstrated by improvement of 12% or more in FEV1 with at least a 200ml increase or improvement of 20% or more in PEFR following beta-agonist administration and/or other asthma medication therapy (i.e., inhaled or systemic steroids) in the past 12 months, the reversibility could be demonstrated at one sitting or can be the difference between two readings of the FEV1 recorded on different dates to prove that the patient has reversible airflow obstruction); and
- Authorization request must come from an allergist or pulmonologist (or under the recommendation of an allergist or pulmonologist); and
- Patient is atopic as defined by:
    - Serum IgE level obtained within the past 12 months with values between 30IU (KU) and 1300IU (KU) depending on patient's age; and
- Positive prick skin test (reaction of 2+ or more) to any perennial allergen; or
- Positive RAST test (class 2 or higher); and
- Patient must be followed by an allergist or pulmonologist for at least three months prior to request to evaluate and optimize patient therapy (consistent with NHLBI guidelines) and compliance and to identify (and treat if indicated) concurrent disease states which may be contributing to asthma symptoms; and
- Patient is poorly controlled on optimal doses of standard therapy (high dose inhaled corticosteroid (ICS) with long acting beta agonist) as defined by:

- Sleep loss
- Age appropriate activity limitation
- Increased albuterol usage
- Exacerbations requiring systemic steroid administration
- Intolerance of ICS
- Poor patient compliance with ICS therapy
- Objective pulmonary measures showing poor control; and
- Patient completion of baseline quality of life (QOL) survey; OR

- Patient is 18 years of age or older: and
- Patient has a diagnosis of nasal polyps; and
- Patient is inadequately controlled on intranasal corticosteroids; and
- Xolair will be used as add-on maintenance treatment; and
- Baseline serum IgE level (IU/mL) and current body weight must be submitted.

In light of the black box warning added to the prescribing information, documentation is submitted stating that:

- The risk of anaphylaxis has been discussed with the patient and documented in the patient record; and
- The patient received a prescription for an epinephrine injection device and instructions concerning the administration of this medication; and
- The patient is observed in the office for at least two hours following the first Xolair injection.

Authorization for self-administration of Xolair may be provided once therapy has been safely established in the healthcare setting, the healthcare provider determines self-administration is appropriate, and documentation of the following is submitted:

- Patient has no prior history of anaphylaxis, including to Xolair or other agents, such as foods, drugs, biologics, etc.; and
- Patient has received at least 3 doses of Xolair under the guidance of a healthcare provider with no hypersensitivity reactions: and
- Patient or caregiver is able to recognize symptoms of anaphylaxis; and
- Patient or caregiver is able to treat anaphylaxis appropriately; and
- Patient or caregiver is able to perform subcutaneous injections with Xolair prefilled syringe with proper technique according to the prescribed dosing regimen and Instructions for Use.

Dosing:

Chronic Idiopathic Urticaria:

- Recommended dosage is 150mg or 300mg by subcutaneous injection every 4 weeks. Dosage is not dependent on serum IgE level or body weight.

Allergic Asthma:

- Recommended dosage is 75mg to 375mg SC every two or four weeks. Dose (mg) and dosing frequency are determined by serum total IgE level (IU/ml), measured before the start of treatment, and body weight (kg) (see dosing charts below).
- Doses greater than 150mg should be divided among more than one injection site with a maximum of 150mg per site.
- Doses should be adjusted for significant changes in body weight.

Xolair Dosing Guide for pediatric patients 6 to <12 years of age:

Pediatric patients 6 to <12 years of age: Initiate dosing according to Table 3.

Table 3. Subcutaneous Xolair Doses Every 2 or 4 Weeks* for Pediatric Patients with Asthma Who Begin Xolair Between the Ages of 6 to <12 Years

Pre-treatment Serum IgE (IU/mL)	Dosing Freq.	Body Weight									
		20-25 kg	>25-30 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
		Dose (mg)									
30-100	Every 4 weeks	75	75	75	150	150	150	150	150	300	300
>100-200		150	150	150	300	300	300	300	300	225	300
>200-300		150	150	225	300	300	225	225	225	300	375
>300-400		225	225	300	225	225	225	300	300		
>400-500		225	300	225	225	300	300	375	375		
>500-600		300	300	225	300	300	375				
>600-700		300	225	225	300	375					
>700-800	Every 2 weeks	225	225	300	375						
>800-900		225	225	300	375						
>900-1000		225	300	375							
>1100-1200		225	300	375							
>1100-1200		300	300								
>1200-1300		300	375								

DO NOT DOSE

*Dosing frequency:

- Subcutaneous doses to be administered every 4 weeks
- Subcutaneous doses to be administered every 2 weeks

Xolair® Dosing Guide for patients 12 years of age and older:

Xolair doses (mg) administered every four weeks dosing table

Pre-treatment Serum IgE (IU/mL)	Body Weight (kg)			
	30-60	>60-70	>70-90	>90-150
≥30-100	150mg	150mg	150mg	300mg
>100-200	300mg	300mg	300mg	
>200-300	300mg			
>300-400	See Table Below			
>400-500				
>500-600				
>600-700				

Xolair doses (mg) administered every two weeks dosing table:

Pre-treatment Serum IgE (IU/mL)	Body Weight (kg)			
	30-60	>60-70	>70-90	>90-150
≥30-100	See Table Above			
>100-200				225mg

>200-300		225mg	225mg	300mg
>300-400	225mg	225mg	300mg	DOSE
>400-500	300mg	300mg	375mg	
>500-600	300mg	375mg	DO NOT	
>600-700	375mg			

Patients whose pretreatment serum IgE level or body weight is outside the limits of the dosing tables should not be dosed.

Because of the complexities of the procedure for preparing the drug for administration and necessity to monitor asthma clinical status, it is only appropriate for office administration. Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration of Xolair®. Anaphylaxis has occurred as early as after the first dose of Xolair®, but also has occurred beyond one year after beginning regularly administered treatment. Because of the risk of anaphylaxis, patients should be closely observed for an appropriate period of time after Xolair® administration, and health care providers administering Xolair® must be prepared to manage anaphylaxis that can be life-threatening. Patients should also be informed of the signs and symptoms of anaphylaxis and instructed to seek immediate medical care should symptoms occur.

Nasal Polyps:

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

Table 3. Subcutaneous XOLAIR Doses Every 2 or 4 Weeks* for Adult Patients with Nasal Polyps

Pretreatment Serum IgE (IU/mL)	Dosing Freq.	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
		Dose (mg)							
30 - 100	Every 4 Weeks	75	150	150	150	150	150	300	300
>100 - 200		150	300	300	300	300	300	450	600
>200 - 300		225	300	300	450	450	450	600	375
>300 - 400		300	450	450	450	600	600	450	525
>400 - 500		450	450	600	600	375	375	525	600
>500 - 600		450	600	600	375	450	450	600	
>600 - 700		450	600	375	450	450	525		
>700 - 800	Every 2 Weeks	300	375	450	450	525	600		
>800 - 900		300	375	450	525	600			
>900 - 1000		375	450	525	600				
>1000 - 1100		375	450	600					
>1100 - 1200		450	525	600	Insufficient Data to Recommend a Dose				
>1200 - 1300		450	525						
>1300 - 1500		525	600						

*Dosing frequency:

- Subcutaneous doses to be administered every 4 weeks
- Subcutaneous doses to be administered every 2 weeks

Duration of Approval:

Allergic Asthma:

- Initial authorization is granted for six months. After six months, patient must be evaluated for therapy continuation including:
  - Evaluation of patient compliance; and
  - Documentation of history, lung function and assessment criteria for period four weeks to 24 weeks; and
  - QOL survey review showing patient perceived positive response to Xolair®; and
  - Pharmacy assessment showing decrease in albuterol and/or steroid usage; and

- Evaluation of other objective clinical measures (i.e., PFR).

If the ordering provider submits a written statement documenting how Xolair® therapy has made a difference in the treatment of this patient's asthma and why continuation is warranted, authorization may be granted for one year. After each year of therapy, the ordering provider must submit a written assessment documenting the continued clinical benefit of this therapy. Authorization may be granted for one year at a time provided the patient continues to be compliant with therapeutic regimen.

Chronic idiopathic urticaria:

- Initial authorization is granted for six months. After six months, documentation must be provided describing patient's response to therapy. If effective and well tolerated, authorization is provided for one year. Periodic consideration should be given to stepping down the dose for patients receiving 300mg every four weeks to 150mg every four weeks when clinically appropriate.

Nasal Polyps:

- Initial authorization is granted for six months. After six months, documentation must be provided describing patient's response to therapy. If effective and well tolerated, authorization is provided for one year at a time. Patients should be periodically reassessed for the need for continued therapy based upon the patient's disease severity and level of symptom control.

The Office of the Medical Director is responsible for all adverse determinations. Denied authorization requests can be appealed through the Complaint and Appeals process.

Pre-Authorization Required? Yes ☒ No ☐

Definitions

N/A

References

Related Policies, Processes and Other Documents

N/A

Non-Regulatory references

Genentech, Inc. and Novartis Pharmaceuticals Corporation. Xolair® Prescribing information. Revised July 2021 .

Regulatory References

List all regulatory references used within this policy.

Version Control

Sponsored By:
Name sponsor: Dr. Anthony J. Billittier, IV
Title of sponsor: Chief Medical Officer
Signature of sponsor:

Revision Date	Owner	Notes
11/3/2004	Pharmacy	Revised
1/1/2006	Pharmacy	Revised
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10/1/2008	Pharmacy	Reviewed
12/1/2009	Pharmacy	Revised
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7/1/2011	Pharmacy	Revised
5/2/2012	Pharmacy	Reviewed
5/1/2013	Pharmacy	Reviewed
10/1/2014	Pharmacy	Revised
8/5/2015	Pharmacy	Reviewed
9/1/2016	Pharmacy	Revised
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