

## Policy and Procedure

<b>DEPARTMENT:</b> Pharmacy, Medical Directors	<b>DOCUMENT NAME:</b> Omalizumab (Xolair)
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<b>APPROVED DATE:</b>	<b>RETIRED:</b>
<b>EFFECTIVE DATE:</b> 10/2/2021	<b>REVIEWED/REVISED:</b>
<b>PRODUCT TYPE:</b> Star, Star Health, Star Kids, Star Plus, Chip, Chip Perinate	<b>REFERENCE NUMBER:</b> TX.PHAR.97

### SCOPE:

Superior HealthPlan Pharmacy Department, Medical Directors

### PURPOSE:

Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan.

While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria, but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical policy and prior authorization requirements.

### BACKGROUND:

*Description:*

Omalizumab (Xolair®) is an anti-IgE antibody

### FDA Approved Indication(s)

Xolair is 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.

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- Nasal polyps in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment.
- Chronic idiopathic urticaria (CIU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.

### PROCEDURE:

*Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.*

### I. Initial Approval Criteria

#### A. Moderate to Severe Persistent Asthma (must meet all):

1. Diagnosis of moderate to severe asthma
2. Age  $\geq$  6 years  
**Note:** Exceptions may be considered for patients younger than the FDA approved age on a case-by-case basis by the SHP medical director.
3. Documentation showing symptoms are inadequately controlled with use of one of the following combination therapies (a or b):
  - a. 12 months of high-dose inhaled corticosteroid (ICS) given in combination with a minimum of 3 months of controller medication (either a long-acting beta2-agonist [LABA], leukotriene receptor antagonist [LTRA], or theophylline), unless the individual is intolerant of, or has a medical contraindication to these agents
  - b. 6 months of ICS with daily oral glucocorticoids given in combination with a minimum of 3 months of controller medication (a LABA, LTRA, or theophylline), unless the individual is intolerant of, or has a medical contraindication to these agents.

**Note:** Exceptions to the criteria above will be considered on a case-by-case basis, which will require a letter from the prescribing provider stating the medical necessity for omalizumab, the member's asthma severity level, and the duration of current and past therapies and lack of asthma control. Consideration for these exceptions will be reviewed by the SHP medical director.

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4. Positive skin test or radioallergosorbent test (RAST) to a perennial (not seasonal) aeroallergen within the past 36 months;
5. Pulmonary function tests must have been performed within a three-month period  
**Note:** Exceptions may be considered with documentation of medical reasons explaining why pulmonary function tests cannot be performed.
6. Total IgE level greater than 30 IU/ml but less than 1300 IU/ml within the past 12 months
7. Documentation member is not currently smoking  
**Approval duration: 6 months**

### **B. Chronic Idiopathic Urticaria (CIU)** (must meet all):

1. Diagnosis of CIU
2. Age  $\geq$  12 years  
**Note:** Exceptions may be considered for patients younger than the FDA approved age on a case-by-case basis by the SHP medical director
3. The provider must provide evidence of an evaluation that excludes other medical diagnoses associated with chronic urticaria
4. Failure of both of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
  - a. An antihistamine;
  - b. A leukotriene inhibitor;**Approval duration: 6 months**

### **C. Nasal Polyps** (must meet all):

1. Diagnosis of bilateral nasal polyposis confirmed by physical examination or nasal endoscopy
2. Age  $\geq$  18 years  
**Note:** Exceptions may be considered for patients younger than the FDA approved age on a case-by-case basis by the SHP medical director

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3. Documentation of failure of or inadequate response to corticosteroid treatments as monotherapy, unless contraindicated or clinically significant adverse effects are experienced

**Approval duration: 6 months**

### **D. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid.

## **II. Continued Therapy**

### **A. Moderate to Severe Persistent Asthma** (must meet all):

1. Documentation of compliance with the medication for 6 continuous months
2. Member has a satisfactory clinical response to therapy (Documentation of clinical improvement must include one or more of the following (a, b, or c):
  - a. Decreased utilization of rescue medications
  - b. Increase in predicted FEV1 (forced expiratory volume) from pretreatment baseline
  - c. Reduction in reported asthma-related symptoms, as evidenced by decreases in frequency or magnitude of one or more of the following symptoms:
    - i. Asthma attacks
    - ii. Chest tightness or heaviness
    - iii. Coughing or clearing throat
    - iv. Difficulty taking deep breath or difficulty breathing out
    - v. Shortness of breath
    - vi. Sleep disturbance, night waking, or symptoms upon awakening
    - vii. Tiredness
    - viii. Wheezing/heavy breathing/fighting for air
3. Documentation stating member has not exhibited symptoms of hypersensitivity or anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema) after administration of omalizumab

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**Note:** Requests for clients who do not meet the above criteria will be reviewed for medical necessity by the SHP medical director. After lapses in treatment of 3 months or greater, prior authorization requests submitted with documentation will be reviewed by a SHP medical director.

**Approval duration:** 6 months

### **B. CIU or Nasal Polyps (must meet all):**

1. Currently receiving medication via Centene benefit or has met all initial approval criteria
2. Documentation supports positive response to therapy
3. Documentation of compliance with the medication for 6 continuous months
4. Documentation stating member has not exhibited symptoms of hypersensitivity or anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema) after administration of omalizumab

**Note:** Requests for clients who do not meet the above criteria will be reviewed for medical necessity by the SHP medical director. After lapses in treatment of 3 months or greater, prior authorization requests submitted with documentation will be reviewed by a SHP medical director.

**Approval duration:** 6 months

### **C. Other diagnoses/indications**

1. Refer to the off-label use policy for the relevant line of business: CP.PMN.53 for Medicaid

## **III. Appendices/General Information**

### *Appendix A: Abbreviation/Acronym Key*

CIU: Chronic Idiopathic Urticaria  
ICS: inhaled corticosteroids  
LABA: long-acting beta-agonist  
LTRA: leukotriene modifier

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### REFERENCES:

1. Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual, Accessed October 2021

### ATTACHMENTS:

### REVISION LOG

REVISION	DATE

### POLICY AND PROCEDURE APPROVAL

Karen Tadlock, V.P., Pharmacy Operations Approval on file

Dr. David Harmon, Sr. V.P., Chief Medical Officer Approval on file

Pharmacy & Therapeutics Committee: Approval on file

*NOTE: The electronic approval retained in RSA Archer, Centene's P&P management software, is considered equivalent to a physical signature.*