POLICY AND PROCEDURE

POLICY NAME: Omalizumab (Xolair)	**POLICY ID:** TX.PHAR.97
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy, Medical Directors, Claims
EFFECTIVE DATE: 10/2/2021	**PRODUCT(S):** CHIP, STAR, STAR PLUS, STAR HEALTH, STAR KIDS
REVIEWED/REVISED DATE: 11/30/2021, 2/16/2022, 8/10/2022, 11/14/2022	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

POLICY STATEMENT:
The purpose of this Clinical Policy is to provide a guide to medical necessity reviews for omalizumab (Xolair).

PURPOSE:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review omalizumab (Xolair).

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.

SCOPE:
This policy applies to Superior HealthPlan Pharmacy Department, Medical Directors, Claims.

DEFINITIONS:
N/A

POLICY:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review omalizumab (Xolair).

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.
• 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 (as defined by the National Heart, Lung and Blood Institute's Guidelines for the Diagnosis and management of Asthma) (diagnosis codes J4540 and J4550)
2. Age ≥ 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.
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.
8. Xolair is not prescribed concurrently with Cinqair, Fasenra, or Nucala or any other interleukin-5 antagonist.

Approval duration: 6 months

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

1. Diagnosis of CIU with symptoms despite H1 antihistamine treatment (diagnosis code L501)
2. Age ≥ 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 an antihistamine, unless clinically significant adverse effects are experienced, or contraindicated.
5. Xolair is not prescribed concurrently with Cinqair, Fasenra, Nucala or any other interleukin-5 antagonist.

Approval duration: 6 months

C. Nasal Polyps (must meet all):

1. Diagnosis of bilateral nasal polyposis (diagnosis codes J330, J331, J338, J339) with inadequate response to nasal corticosteroids
2. Confirmed diagnosis by physical examination or nasal endoscopy
3. Age ≥ 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
4. Documentation of failure of or inadequate response to corticosteroid treatments as monotherapy, unless contraindicated or clinically significant adverse effects are experienced
5. Xolair is not prescribed concurrently with Cinqair, Fasenra, Nucala or any other interleukin-5 antagonist.

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/CHIP.

II. Continued Therapy

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

1. 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:
      - Asthma attacks
      - Chest tightness or heaviness
      - Coughing or clearing throat
      - Difficulty taking deep breath or difficulty breathing out
      - Shortness of breath
      - Sleep disturbance, night wakening, or symptoms upon awakening
      - Tiredness
      - Wheezing/heavy breathing/fighting for air
2. 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.
3. Xolair is not prescribed concurrently with Cinqair, Fasenra, Nucala or any other interleukin-5 antagonist.
4. Member must be compliant with their Xolair regimen in order to qualify for additional prior authorizations. The provider must submit a statement documenting compliance with the requests for each renewal.

Approval duration: 12 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.
5. Xolair is not prescribed concurrently with Cinqair, Fasenra, Nucala or any other interleukin-5 antagonist.

Approval duration: 12 months

C. Other diagnoses/indications

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

REFERENCES:

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS:

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Ad Hoc	Added diagnosis codes	11/30/2021
Ad Hoc	Removed requirement of leukotriene inhibitor therapy	2/16/2022

	Chronic Idiopathic Urticaria (CIU) to match TMHP criteria change that is effective 3/1/22	
Ad Hoc	Added criteria to all diagnoses that Xolair should not be prescribed concurrently with Cinqair, Fasenra, or Nucala	3/11/2022
Ad Hoc	Formatted to new template Added compliance statement requirement for continued approval for asthma Added that treatment must not be used with any other IL-5 antagonist	8/10/2022
Ad Hoc	Extended Approval Duration for continuation of therapy to 12 months	11/14/2022

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company's P&P management software, is considered equivalent to a signature.