TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Omalizumab (Xolair®)	**CRITERIA ID:** TX.CC.PHAR.15
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy, Medical Directors, Claims
EFFECTIVE DATE: 10/2/2021	**PRODUCT(S):** STAR, STAR PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 11/30/2021, 2/16/2022, 8/10/2022, 11/14/2022, 8/1/2023, 03/15/2024, 07/02/2024, 6/2/2025	**REGULATOR MOST RECENT APPROVAL DATE(S):** N/A

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for omalizumab (Xolair®).

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 criteria and prior authorization requirements.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
N/A

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review omalizumab (Xolair®); procedure code: J2357.

Description/Mechanism of Action:
Omalizumab (Xolair®) is an anti-IgE antibody.

FDA Approved Indication(s)
Omalizumab (Xolair®) is indicated for treatment of the following:

- Clients who are 6 years of age or older with moderate to severe persistent asthma as defined by the National Heart, Lung and Blood Institute's Guidelines for the Diagnosis and management of Asthma

- Clients who are 12 years of age or older and have chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment
- Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps (CRwNP) in adult clients who are 18 years of age or older with inadequate response to nasal corticosteroids
- IgE-mediated food allergy in adult and pediatric clients who are 1 year of age or older for the reduction of allergic reactions (Type 1), including anaphylaxis, that may occur with accidental exposure to one or more foods.

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. The client has a 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: J45.40 and J45.50)
2. The client is 6 years of age or older.
   Note: Exceptions may be considered for clients younger than the FDA approved age on a case-by-case basis by the Medical Director.
3. Documentation showing symptoms are inadequately controlled with use of a minimum of 3 months of controller medication (which includes but is not limited to a long-acting beta2-agonist [LABA], an inhaled or oral corticosteroid, leukotriene receptor antagonist [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 client'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 CPS medical director.
4. The client has a positive skin test or radioabsorbent test (RAST) to a perennial (not seasonal) aeroallergen within the past 36 months.
5. The client has a total IgE level greater than 30 IU/ml but less than 1300 IU/ml within the past 12 months.
6. Xolair is not prescribed concurrently with Cinqair, Fasenra, or Nucala or any other interleukin-5 antagonist.
7. Any client with a preexisting helminth infection should be treated prior to receiving Xolair therapy. If there is an active helminth infection, the client should be treated with anti-helminth treatment. If there is no response, treatment with Xolair should be discontinued until parasitic infection resolves.

Approval duration: 6 months

B. Chronic Spontaneous Urticaria (CSU) (must meet all):

1. The client has a diagnosis of CSU with symptoms despite H1 antihistamine treatment (diagnosis code L50.1)
2. The client is 12 years of age or older.

   Note: Exceptions may be considered for clients younger than the FDA approved age on a case-by-case basis by the Medical Director.
3. Documentation supporting medical necessity for the treatment of CSU with Xolair must include the following:
   a. Documented failure of, or contraindication to, an antihistamine;
   b. Evidence of an evaluation that excludes other medical diagnoses associated with chronic urticaria.
4. Xolair is not prescribed concurrently with Cinqair, Fasenra, Nucala or any other interleukin-5 antagonist.
5. Any client with a preexisting helminth infection should be treated prior to receiving Xolair therapy.
6. If there is an active helminth infection, the client should be treated with anti-helminth treatment. If there is no response, treatment with Xolair should be discontinued until parasitic infection resolves.

Approval duration: 6 months

C. Chronic Rhinosinusitis with Nasal Polyps (CRwNP) (must meet all):

1. The client has a diagnosis of CRwNP (diagnosis codes J33.0, J33.1, J33.8, J33.9) with inadequate response to nasal corticosteroids.
2. The client is 18 years of age or older.

   Note: Exceptions may be considered for clients younger than the FDA approved age on a case-by-case basis by the Medical Director.
3. Documentation supporting medical necessity for maintenance treatment of nasal polyps with Xolair must include the following:
   a. Client has bilateral nasal polyposis confirmed by physical examination or nasal endoscopy;
   b. Documented failure of or contraindication to prior corticosteroids as monotherapy;
   c. Documented inadequate response to prior corticosteroid treatments
4. Xolair is not prescribed concurrently with Cinqair, Fasenra, Nucala or any other interleukin-5 antagonist.
5. Any client with a preexisting helminth infection should be treated prior to receiving Xolair therapy. If there is an active helminth infection, the client should be treated with anti-helminth treatment. If there is no response, treatment with Xolair should be discontinued until parasitic infection resolves.

Approval duration: 6 months

D. IgE-Mediated Food Allergy to Reduce Allergic Reactions (Type 1) (must meet all):

1. The client has a diagnosis of IgE-mediated food allergy (diagnosis codes Z91.010, Z91.011, Z91.012, Z91.013, Z91.018).
2. The client is 1 year of age or older.
3. Documentation that Xolair will be used in conjunction with food allergen avoidance.
4. Xolair is not prescribed concurrently with Cinqair, Fasenra, Nucala or any other interleukin-5 antagonist.
5. Any client with a preexisting helminth infection should be treated prior to receiving Xolair therapy. If there is an active helminth infection, the client should be treated with anti-helminth treatment. If there is no response, treatment with Xolair should be discontinued until parasitic infection resolves.

Approval duration: 6 months

II. Continued Therapy

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

1. The client 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 that client has not exhibited symptoms of hypersensitivity or anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema) after administration of Xolair.
3. Xolair is not prescribed concurrently with Cinqair, Fasenra, Nucala or any other interleukin-5 antagonist.
4. The client 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.
5. Any client with a preexisting helminth infection should be treated prior to receiving omalizumab therapy. If there is an active helminth infection, the client should be treated with anti-helminth treatment. If there is no response, treatment with omalizumab should be discontinued until parasitic infection resolves.

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

Approval duration: 12 months

B. CSU, CRwNP or IgE- Mediated Food Allergy to Reduce Allergic Reactions (Type 1) (must meet all):

1. Currently receiving medication via Centene benefit or has met all initial approval criteria.
2. Documentation showing that the client has had positive response to therapy.
3. Documentation showing that the client has been compliant with the medication for 6 continuous months.
4. Documentation stating client has not exhibited symptoms of hypersensitivity or anaphylaxis (bronchospasm, hypotension, syncope, urticaria, and/or angioedema) after administration of Xolair.
5. Xolair is not prescribed concurrently with Cinqair, Fasenra, Nucala or any other interleukin-5 antagonist.
6. Any client with a preexisting helminth infection should be treated prior to receiving Xolair therapy. If there is an active helminth infection, the client should be treated with anti-helminth treatment. If there is no response, treatment with Xolair should be discontinued until parasitic infection resolves.

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

Approval duration: 12 months

REFERENCES:

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS:

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 Chronic Idiopathic Urticaria (CIU) to match TMHP criteria change that is effective 3/1/22	2/16/2022
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	8/10/2022

	Added compliance statement requirement for continued approval for asthma Added that treatment must not be used with any other IL-5 antagonist	
Ad Hoc	Extended Approval Duration for continuation of therapy to 12 months	11/14/2022
Ad Hoc	Added additional PA requirement for all indications for initial and continuation criteria: • a client with a preexisting helminth infection should be treated prior to receiving omalizumab therapy • If there is an active helminth infection, the client should be treated with anti-helminth treatment. If there is no response, treatment should be discontinued until parasitic infection resolves Updated criteria step 3 for initial therapy for indication of moderate to severe asthma to: • Documentation showing symptoms are inadequately controlled with use of a minimum of 3 months of controller medication (which includes but is not limited to a long-acting beta2-agonist [LABA], an inhaled or oral corticosteroid, leukotriene receptor antagonist [LTRA], or theophylline, unless the individual is intolerant of, or has a medical contraindication to these agents.	8/1/2023

	Update criteria verbiage to “the client” for consistency throughout document Updated age requirements throughout by removing ≥ symbol. Removed criteria points under asthma indication referencing: smoking and pulmonary function tests. Changed Superior HealthPlan/CPS to Centene Pharmacy Services/CPS throughout policy Added names/titles under Policy and Procedure Approval Section Added CHIP Perinate to Product	
Ad Hoc Review	Updated to TX.CC.PHAR format template Added Centene copyright statement Corrected I.A.7 and I.B.6 criteria from mepolizumab to omalizumab	03/15/2024
Ad Hoc Review	TMHP Criteria changes effective 7/1/24: FDA indications: change from chronic idiopathic urticaria (CIU) to chronic spontaneous urticaria (CSU); change from nasal polyps to chronic rhinosinusitis with nasal polyps (CRwNP); added IgE-Mediated Food Allergy to Reduce Allergic Reactions (Type 1). Updated titles/diagnoses in sections I.B. and I.C. to new FDA indication titles. Combined I.B. criteria steps 3 and 4 into one criteria step to align with verbiage in TMHP manual Combined I.C. criteria steps 2 and 4 into one criteria step to align with verbiage TMHP manual Added section I.D. criteria steps for new FDA indication Updated II.B. title to include new FDA indication titles/new indication	07/02/2024
Annual review	Font and formatting update for 508 remediation	6/2/2025