Xolair®

Policy: PHARM-CHIP-079

Origination Date: 07/01/2024

Reviewed/Revised Date:

Next Review Date: 05/22/2025

Current Effective Date: 07/01/2024

Disclaimer:

1. Policies are subject to change in accordance with Federal and State notice requirements.
2. Policies outline coverage determinations for Healthy U CHIP. Refer to the "Policy" and "Lines of Business" section for more information.
3. Services requiring prior-authorization may not be covered, if the prior-authorization is not obtained.
4. This Pharmacy Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Purpose

Xolair® (omalizumab) may be considered as a retail OR medical benefit for the following indications:

1. Moderate to severe persistent asthma
2. Chronic idiopathic urticaria
3. Chronic rhinosinusitis with nasal polyposis

Note: For the treatment of **chronic rhinosinusitis with nasal polyposis (CRSwNP)** see PHARM-HU-146

Policy/Coverage

1. **Prior Authorization Criteria**
    A. Xolair® may be considered medically necessary for moderate to severe persistent asthma if the following criteria are met:
        i. The prescribing physician must be an allergist, dermatologist, immunologist, or a pulmonologist.
        ii. Documentation of a positive skin test or in vitro reactivity to a perennial aeroallergen.
        iii. Documentation that the patient's symptoms are inadequately controlled with a high-dose inhaled corticosteroid used in combination with a long-acting inhaled beta-2 agonist.
            a. The member must be ≥80% compliant for at least 5 months

iv. Clinical documentation of poor asthma control or recurrent exacerbation:
    a. ≥2 acute exacerbations in a 12-month period requiring additional medical treatment including emergency department (ED) visits, hospitalizations, or frequent office visits, **and**
    b. Current Asthma Control Test (ACT) score must be ≤19
v. Documentation of pre-treatment serum Immunoglobulin E (IgE) level of at least 30 IU/mL but not greater than 700 IU/mL.
vi. Documentation of Forced Expiratory Volume in One Second (FEV1) or Peak Expiratory Flow (PEF) < 80% of predicted value

B. Xolair® may be considered medically necessary for chronic idiopathic urticaria if the following criteria are met:
    i. Documentation shows an evaluation has been performed to rule out other possible causes of urticaria
    ii. Documentation shows a trial and failure of or contraindication to an H1-antihistamine used in combination with an H2-antihistamine.
        a. Documentation must show that attempts have been made to increase the H1-antihistamine to the maximum-tolerated, optimized dose, defined per guidelines as up to four-fold standard dosing
    iii. Documentation shows a trial and failure of or contraindication to an H1-antihistamine used in combination with a leukotriene receptor antagonist or cyclosporine.
    iv. For additional criteria regarding dose escalation, see dosage below.

C. Xolair® may be considered medically necessary for IgE-Mediated Food Allergy if ALL of the following is met:
    i. The prescribing physician must be an allergist or immunologist
    ii. Member's age is between 1 and 17 years
    iii. Baseline immunoglobulin (Ig)E level ≥ 30 IU/mL
    iv. Documentation must show the member has experienced dose-limiting symptoms (e.g. moderate to severe skin, respiratory, or GI symptoms) to a single dose of ≤100 mg of peanut protein or ≤300 mg protein for each of 2 of the other 6 foods (milk, egg, wheat, cashew, hazelnut, or walnut)
    v. Documentation of a positive skin test (≥4 mm wheal greater than saline control)
    vi. in vitro reactivity (IgE ≥6 kUA/L) to peanut or at least two of the six other studied foods: milk, egg, wheat, cashew, hazelnut, walnut
    vii. Member must have an active prescription for an EpiPen
    viii. Documentation must show Xolair will be used in conjunction to a diet that avoids food allergens
    ix. Member must not have a history of severe anaphylaxis, eosinophilic esophagitis poorly controlled atopic dermatitis or
    x. Member must not have documentation of poorly controlled asthma defined as at least one of the following:

a. Global Initiative for Asthma (GINA) criteria regarding asthma control latest guidelines,
b. History of two or more systemic corticosteroid courses within six months of Screening or one course of systemic corticosteroids within three months of Screening to treat asthma/wheezing,
c. Prior intubation/mechanical ventilation for asthma/wheezing,
d. One hospitalization or Emergency Department (ED) visit for asthma/wheezing within six months of Screening,
e. Forced expiratory volume in one second (FEV1) <80 percent of predicted or FEV1/forced vital capacity (FVC) <75 percent, with or without controller medications (only for participants who are aged seven years or older and are able to perform spirometry), or
f. Inhaled corticosteroid (ICS) dosing of >500 mcg daily fluticasone (or equivalent ICS based on the National Institutes of Health, National Heart, Lung, and Blood Institute (NHLBI) dosing chart).

xi. Xolair® will be excluded for treatment in combination with other monoclonal antibody therapy, such as dupilumab (Dupixent®), benralizumab (Fasenra™), mepolizumab (Nucala®), and reslizumab (Cinqair®)

2. Re-Authorization Criteria

A. Documentation must show that there continues to be medical necessity and that the therapy has stabilized or improved the patient's condition.

3. Dosage

A. Dosing must be in accordance with US Food and Drug Administration (FDA) approved package insert.
   i. The professional provider must supply supporting documentation (i.e., published peer-reviewed literature) in order to request coverage for any dose outside of the Food and Drug (FDA) package insert listed in this policy. For a list of Health Plan-recognized pharmacology compendia, view our policy on off-label coverage for prescription drugs and biologics.
   ii. In order for Xolair dose escalation to be considered for the treatment of chronic idiopathic urticaria, ALL of the following must be met:
      a. The dose escalation must be done in a conservative, step-wise approach
         1. Dose escalation will only be considered if documentation shows treatment failure after 12-weeks of therapy
      b. Documentation must show that expanded use option have been exhausted
      c. Documentation must show ALL guideline recommended therapies have been tried including Xolair taken at the FDA-approved dose in combination with:
         i. H1-antihistamines taken at the maximum-tolerated, optimized dose, defined per guidelines as up to four-fold

standard dosing AND has **either failed** cyclosporine dosed at 3-5 mg/kg per day after a 6-week trial or **has reached the maximum recommended duration of treatment** with cyclosporine (i.e., 6 months)

Note: cyclosporine requirement is waived if clinical documentation shows a contraindication or intolerance

4. **Exclusions/Contraindications**
   A. The prior use of samples will not be considered in the determination of a member's eligibility for coverage for this medication.
5. **Approval Duration**
   A. Initial Authorization: 6 months
   B. Re-Authorization: 12 months

Lines of Business

1. **University of Utah Health Plans**
   A. CHIP

References:

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2. Humbert M, Beasley R, Ayres J, et al. Benefits of omalizumab as add-on therapy in patients with severe persistant asthma who are inadequately controlled despite best available therapy (GINA 2002 step 4 treatment): INNOVATE. Allergy 2005, 60:309-316.
3. Krause K, Ardelean E, Kebler M, et al. Antihistamine-resistant urticarial factitia successfully treated with anti-immunoglobulin E therapy. Allergy 2010, 65:1494-1495.
4. Maurer M, Rosen K, Hsin-Ju H, et al. Omalizumab for the Treatment of Chronic Idiopathic or Spontaneous Urticaria. N Engl J Med 2013, 368:924-935.
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6. Vignola A, Humbert M, Bousquet J, et al. Efficacy and tolerability of anti-immunoglobulin E therapy with omalizumab in patients with concomitant allergic asthma and persistent allergic rhinitis: SOLAR. Allergy 2004, 59:709-717.
7. Xolair® [package insert] South San Francisco, CA: Genentech Inc.; Revised 07/2021. Accessed 10/2022.
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9. Agache I, Akdis CA, Akdis M, et al. EAACI Biologicals guidelines-omalizumab for the treatment of chronic spontaneous urticaria (CSU) in adults and in the paediatric population 12-17 years old. *Allergy*. 2022;77(1):17-38. doi:10.1111/all.15030[PubMed 34324716]
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Date	Review, Revisions, Approvals
07/01/2024	Healthy U CHIP specific policy created. Separated out from PHARM-HU-079

explanation of benefits, or a contract. Members should consult with appropriate health care providers to obtain needed medical advice, care, and treatment. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the member's individual benefit plan that is in effect at the time services are rendered.

The codes for treatments and procedures applicable to this policy are included for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

U of U Health Plans makes no representations and accepts no liability with respect to the content of any external information cited or relied upon in this policy. U of U Health Plans updates its Coverage Policies regularly, and reserves the right to amend these policies and give notice in accordance with State and Federal requirements.