Medical Policy:

Xolair (omalizumab)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.02	January 2, 2024	December 20, 2016

The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

Definitions

Omalizumab (Xolair®) is a recombinant DNA-derived, humanized, IgG1k monoclonal antibody that is administered by subcutaneous injection. The drug should be used with caution due to risk of severe allergic anaphylaxis.

FEV_1	Forced expiratory volume in 1 second
PEF	Peak expiratory flow
SX	Symptoms
ICS	Inhaled corticosteroids

Dosing Limits [Medical Benefit]

Dosing Guidelines

Allowed Quantities by HCPCS Units

This section provides information about the dosing parameters for omalizumab administered by a medical professional.

Medication Name (Brand/Generic)	Diagnosis	Maximum Dosage per Administration	HCPCS Code	Maximum Allowed
Xolair (omalizumab)	Moderate to Severe Asthma	375mg	J2357	90 HCPCS units (5mg per unit)
Xolair (omalizumab)	Chronic Urticaria	300mg	J2357	60 HCPCS units
Xolair (omalizumab)	Nasal Polyps	600mg	J2357	120 HCPCS units (5mg per unit)

Guideline

I. Initial

Xolair is considered medically necessary for the following conditions:

A. **Nasal Polyps:** Approve if the patient meets the following criteria (i, ii, iii, iv, v, vi, and vii):

i. Patient is ≥ 18 years of age; **AND**

ii. Patient has chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan; **AND**

iii. Patient has experienced two or more of the following symptoms for at least 6 months: nasal congestion, nasal obstruction, nasal discharge, and/or reduction/loss of smell; **AND**

iv. Patient has a baseline immunoglobulin E (IgE) level ≥ 30 IU/mL; **AND**

Note: "Baseline" is defined as prior to receiving any treatment with Xolair or another monoclonal antibody therapy that may lower IgE levels (e.g., Dupixent [dupilumab subcutaneous injection], Tezspire [tezepelumab-ekko subcutaneous injection]).

v. Patient meets **BOTH** of the following (a **and** b):

a. Patient has received at least 3 months of therapy with an intranasal corticosteroid; **AND**

b. Patient will continue to receive therapy with an intranasal corticosteroid concomitantly with Xolair; **AND**

vi. Patient meets **ONE** of the following (a, b, **or** c):

a. Patient has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years; **OR**

b. Patient has a contraindication to systemic corticosteroid therapy; **OR**

c. Patient has had prior surgery for nasal polyps; **AND**

vii. The medication is prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose and throat [ENT] physician specialist).

B **Chronic Idiopathic Urticaria (Chronic Spontaneous Urticaria):** Approve if the patient meets the following criteria (i, ii, and iii):

i. Patient is ≥ 12 years of age; **AND**

ii. Patient has/had urticaria for > 6 weeks (prior to treatment with Xolair), with symptoms present > 3 days per week despite daily non-sedating H_1 antihistamine therapy with doses that have been titrated up to a maximum of four times the standard FDA-approved dose; **AND**

Note: Examples of non-sedating H_1 antihistamine therapy are cetirizine, desloratadine, fexofenadine, levocetirizine, and loratadine.

iii. The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

C. **Asthma**: Approve if the patient meets the following criteria (i, ii, iii, iv, v, and vi):

i. Patient is ≥ 6 years of age; **AND**

ii. Patient has a baseline immunoglobulin E (IgE) level ≥ 30 IU/mL; **AND**

Note: "Baseline" is defined as prior to receiving any treatment with Xolair or another monoclonal antibody therapy that may lower IgE levels (e.g., Dupixent [dupilumab subcutaneous injection], Tezspire [tezepelumab-ekko subcutaneous injection]).

iii. Patient has a baseline positive skin test or *in vitro* test (i.e., a blood test) for allergen-specific immunoglobulin E (IgE) for one or more perennial aeroallergens and/or for one or more seasonal aeroallergens; **AND**

Note: "Baseline" is defined as prior to receiving any Xolair or another monoclonal antibody therapy that may interfere with allergen testing (e.g., Dupixent and Tezspire). Examples of perennial aeroallergens are house dust mite, animal dander, cockroach, feathers, and mold spores. Examples of seasonal aeroallergens are grass, pollen, and weeds.

iv. Patient has received at least 3 consecutive months of combination therapy with **BOTH** of the following (a **and** b):
   a. An inhaled corticosteroid; **AND**
   b. At least one additional asthma controller or asthma maintenance medication; **AND**

   Note: Examples of additional asthma controller or asthma maintenance medications are inhaled long-acting beta$_2$-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, and monoclonal antibody therapies for asthma (e.g., Xolair, Cinqair (reslizumab intravenous infusion), Dupixent, Fasenra (benralizumab subcutaneous injection), Nucala (mepolizumab subcutaneous injection), and Tezspire). Use of a combination inhaler containing both an inhaled corticosteroid and additional asthma controller/maintenance medication(s) would fulfil the requirement for both criteria a and b.

v. Patient has asthma that is uncontrolled or was uncontrolled at baseline as defined by **ONE** of the following (a, b, c, d, or e):

   Note: "Baseline" is defined as prior to receiving Xolair or another monoclonal antibody therapy for asthma. Examples of monoclonal antibody therapies for asthma include Cinqair, Dupixent, Fasenra, Nucala, Tezspire, and Xolair.
   a. Patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; **OR**
   b. Patient experienced one or more asthma exacerbation(s) requiring a hospitalization, an emergency department visit, or an urgent care visit in the previous year; **OR**
   c. Patient has a forced expiratory volume in 1 second (FEV_1) < 80% predicted; **OR**
   d. Patient has an FEV_1/forced vital capacity (FVC) < 0.80; **OR**
   e. Patient has asthma that worsens upon tapering of oral corticosteroid therapy; **AND**

vi. The medication is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

Table 1: Asthma Severity Classifications

Severity	Symptom frequency	Nighttime symptoms	Peak expiratory flow rate or FEV1 of predicted	Variability of peak expiratory flow rate or FEV1
Intermittent	< once a week	≤ twice per month	≥ 80% predicted	< 20%
Mild persistent	> once per week but < once per day	> twice per month	≥ 80% predicted	20–30%
Moderate persistent	Daily	> once per week	60–80% predicted	> 30%
Severe persistent	Daily	Frequent	< 60% predicted	> 30%

Limitations/Exclusions

Xolair is not covered for allergic conditions other than as listed above or for children less than 6 years old, as safety and efficacy have not been established.

Dosing Guidelines by National Drug Code (NDC) Units

The allowed quantities in this section are calculated based upon both the dosing guideline information supplied within this policy as well as the process by which NDC claims are billed. This list may not be inclusive of all available NDC's for each drug product and is subject to change.

Medication Name (Brand/Generic)	Diagnosis	How Supplied	National Drug Code	Maximum Allowed
Xolair (omalizumab)	Moderate to Severe Asthma	150mg vials	50242-0040-62	3 vials
Xolair (omalizumab)	Nasal Polyps	150mg vials	50242-0040-62	4 vials
Xolair (omalizumab)	Chronic Urticaria	150mg vials	50242-0040-62	2 vials

II. Renewal Criteria

Coverage can be renewed in up to 1-year intervals based upon the following criteria:

1. Clinical response and benefit from treatment is evident with continued use**; AND**
2. Absence of unacceptable toxicity from the drug.

Applicable Procedure Codes

Code	Description
J2357	Injection, omalizumab, 5 mg

Applicable NDCs

Code	Description
50242-0040-xx	Omalizumab 150mg
50242-0215-xx	Omalizumab 150mg/1mL
50242-0214-xx	Omalizumab 75mg/0.5mL

ICD-10 Diagnoses

Code	Description
J45.40	Moderate persistent asthma, uncomplicated
J45.41	Moderate persistent asthma with (acute) exacerbation
J45.42	Moderate persistent asthma with status asthmaticus
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
L50.1	Idiopathic urticaria
L50.6	Contact urticaria
L50.8	Other urticaria
L50.9	Urticaria, unspecified
T78.40XA	Allergy, unspecified, initial encounter
T78.40XD	Allergy, unspecified, subsequent encounter
T78.40XS	Allergy, unspecified, sequela
Z91.010	Allergy to peanuts
Z91.040	Latex allergy status

J33.0	Polyp of nasal cavity
J33.1	Polypoid sinus degeneration
J33.8	Other polyp of sinus
J33.9	Nasal polyp, unspecified

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: No Criteria Changes
EmblemHealth & ConnectiCare	3/13/2023	Annual Review: Asthma Criteria: Changed failure to respond to treatment from 6 months to 3 months, updated treatment failure options from: Moderate-dose ICS and long-acting β-agonist OR Low-moderate dose ICS, long-acting inhaled β2-agonist and leukotriene modifiers TO An inhaled corticosteroid; AND At least one additional asthma controller or asthma maintenance medication. Added "uncontrolled asthma" at baseline criteria and prescribed by an allergist, immunologist or pulmonologist. Removed: IgE level ≥ 30 IU/mL to ≤ 1300 IU/mL for pediatric members between age 6 to < 12 or IgE level ≥ 30 IU/mL to ≤ 700 IU/mL for members 12 years and older. AND Evidence of reversible disease (i.e., ≥ 12% improvement in FEV1 following beta2-agonist administration). Chronic Idopathic Uticaria Criteria: Added: Patient has/had urticaria for > 6 weeks (prior to treatment with Xolair), with symptoms present > 3 days per week AND The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist. Nasal Polyps Criteria: Removed: Inadequate response to nasal corticosteroids AND Xolair will be utilized as add-on maintenance treatment ADDED: Patient has chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan; AND Patient has experienced two or more of the following symptoms for at least 6 months: nasal congestion, nasal obstruction, nasal discharge, and/or reduction/loss of smell; AND Patient has a baseline immunoglobulin E (IgE) level ≥ 30 IU/mL; AND Patient meets BOTH of the following (a and b): a. Patient has received at least 3 months of therapy with an intranasal corticosteroid; AND b. Patient will continue to receive therapy with an intranasal corticosteroid concomitantly with Xolair; AND Patient meets ONE of the following (a, b, or c): a. Patient has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years; OR b. Patient has a contraindication to systemic corticosteroid therapy;OR

		c. Patient has had prior surgery for nasal polyps; AND The medication is prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose and throat [ENT] physician specialist).
EmblemHealth & ConnectiCare	1/18/2023	Transfer to New Template, updated NDC codes
EmblemHealth & ConnectiCare	11/11/2021	Updated max dose, max billable units, and max vials allowed to reflect dosing for nasal polyps.
EmblemHealth & ConnectiCare	1/11/2021	Added renewal criteria
EmblemHealth & ConnectiCare	12/30/2020	Added indication for nasal polyps. Updated max dose and max vials allowed to reflect dosing for nasal polyps. Added respective ICD-10 codes for nasal polyps.
EmblemHealth & ConnectiCare	12/02/2019	Added Table for Dosing Guideline for omalizumab administered by a medical professional. Added table for Dosing Guidelines by National Drug Code (NDC) units
EmblemHealth & ConnectiCare	09/24/2019	Under guidelines Section B (subset e) added following beta2-agonist administration for clarity. Updated language in Limitations/Exclusions to reflect drug is not listed for children less than 6 years old.
EmblemHealth & ConnectiCare	12/20/2016	Updated to include pediatric age parameters per indication and amended IgE requirement.

References

1. National Heart Blood Lung and Blood Institute. Guidelines for the Diagnosis and Management of Asthma (EPR-3). 2007. Available at: http://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines. Accessed September 24, 2019.
2. Omalizumab (Xolair): an anti-IgE antibody for asthma. *Med Lett Drugs Ther*. 2003;45(1183):67-68.
3. Specialty-matched clinical peer review.
4. Xolair (omalizumab) [prescribing information]. South San Francisco, CA: Genentech Inc; November 2020