

Medical Policy:

Xolair (omalizumab) subcutaneous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.02	January 2, 2025	December 20, 2016

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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.

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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]

Max Units (per dose and over time) [HCPCS Unit]:

Allergic Asthma

- 75 billable units every 14 days

Nasal Polyps and IgE-Mediated Food Allergy

- 120 billable units every 14 days

All other indications

- 60 billable units every 28 days

Guideline

****For Medicare members – Xolair-please refer to our separate LCD/NCD Medicare criteria**

I. Initial

Xolair is considered medically necessary for the following conditions:

1. **Nasal Polyps:** Approve if the patient meets the following criteria (A, B, C, D, E, F, AND G):
 - A. Patient is ≥ 18 years of age; **AND**
 - B. Patient has chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan; **AND**
 - C. 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**
 - D. 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]).
 - E. Patient meets **BOTH** of the following (i **and** ii):
 - i. Patient has received at least 4 weeks of therapy with an intranasal corticosteroid; **AND**
 - ii. Patient will continue to receive therapy with an intranasal corticosteroid concomitantly with Xolair; **AND**
 - F. Patient meets **ONE** of the following (i, ii, **or** iii):
 - i. Patient has received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years; **OR**
 - ii. Patient has a contraindication to systemic corticosteroid therapy; **OR**
 - iii. Patient has had prior surgery for nasal polyps; **AND**
 - G. The medication is prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose and throat [ENT] physician specialist).
2. **Chronic Idiopathic Urticaria (Chronic Spontaneous Urticaria):** Approve if the patient meets the following criteria (A, B, **and** C):
 - A. Patient is ≥ 12 years of age; **AND**
 - B. Patient has/had urticaria for > 6 weeks (prior to treatment with Xolair), with symptoms present > 3 days per week despite daily non-sedating H₁ 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 H₁ antihistamine therapy are cetirizine, desloratadine, fexofenadine, levocetirizine, and loratadine.
 - C. The medication is prescribed by or in consultation with an allergist, immunologist, or dermatologist.
3. **Asthma:** Approve if the patient meets the following criteria (A, B, C, D, E, **and** F):
 - A. Patient is ≥ 6 years of age; **AND**
 - B. 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]).
 - C. 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.

- D. Patient has received at least 3 consecutive months of combination therapy with **BOTH** of the following (i **and** ii):
- An inhaled corticosteroid; **AND**
 - 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 beta₂-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.
- E. Patient has asthma that is uncontrolled or was uncontrolled at baseline as defined by **ONE** of the following (i, ii,iii, iv, **or** v):
- 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.*
- Patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; **OR**
 - 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**
 - Patient has a forced expiratory volume in 1 second (FEV₁) < 80% predicted; **OR**
 - Patient has an FEV₁/forced vital capacity (FVC) < 0.80; **OR**
 - Patient has asthma that worsens upon tapering of oral corticosteroid therapy; **AND**
- F. The medication is prescribed by or in consultation with an allergist, immunologist, or pulmonologist.

4. **Immunoglobulin (Ig)E-Mediated Food Allergy.** Approve if the patient meets **ALL** of the following (A, B, C, D, E, F, and G):

- A. Patient is ≥ 1 year of age; **AND**
- B. Patient has a baseline immunoglobulin (Ig)E 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]).
- C. Patient meets **BOTH** of the following (i **and** ii):
- Patient has a positive skin prick test (SPT) response to one or more foods; **AND**
 - Patient has a positive *in vitro* test (i.e., a blood test) for IgE to one or more foods; **AND**
- D. According to the prescriber, the patient has a history of an allergic reaction to a food that met each of the following (i, ii, **and** iii):
- Patient demonstrated signs and symptoms of a significant systemic allergic reaction; **AND**
Note: Signs and symptoms of a significant systemic allergic reaction include hives, swelling, wheezing, hypotension, and gastrointestinal symptoms.
 - This reaction occurred within a short period of time following a known ingestion of the food; **AND**
 - The prescriber deemed this reaction significant enough to require a prescription for an epinephrine auto-injector; **AND**
Note: Examples of epinephrine auto-injectors include EpiPen, EpiPen Jr., Auvi-Q, and generic epinephrine auto-injectors.
- E. Patient has been prescribed an epinephrine auto-injector; **AND**
Note: Examples of epinephrine auto-injectors include EpiPen, EpiPen Jr., Auvi-Q, and generic epinephrine auto-injectors.
- F. According the prescriber, Xolair will be used in conjunction with a food allergen-avoidant diet; **AND**
- G. The medication is prescribed by or in consultation with an allergist or immunologist.

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, as safety and efficacy have not been established.

Dosing Please see package insert

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
50242-0227-xx	Xolair 300 mg single-dose prefilled syringe or autoinjector

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
Z91.010	Allergy To Peanuts
Z91.011	Allergy To Milk Products
Z91.012	Allergy To Eggs
Z91.013	Allergy To Seafood
Z91.014	Allergy To Mammalian Meats
Z91.018	Allergy To Other Foods

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	1/2/2025	Annual Review: Updated dosing limits Nasal Polyps: Updated length from “3 months” to “4 weeks” in the following statement: “Patient has received at least 4 weeks of therapy with an intranasal corticosteroid; AND” Removed doing guidance chart, added statement to refer to PI for dosing. Added Medicare NCD/LCD Statement.
EmblemHealth & ConnectiCare	5/24/2024	Added NDC: 50242-0227-xx
EmblemHealth & ConnectiCare	3/15/2024	Added IgE Mediated Food Allergy Indication, removed “or for children less than 6 years old” from limitations and exclusions, added related Jcodes.
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: No Criteria Changes
EmblemHealth & ConnectiCare	3/13/2023	Annual Review: <u>Asthma Criteria</u> : 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 β 2-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 \geq 30 IU/mL to \leq 1300 IU/mL for pediatric members between age 6 to < 12 or IgE level \geq 30 IU/mL to \leq 700 IU/mL for members 12 years and older. AND Evidence of reversible disease (i.e., \geq 12% improvement in FEV1 following beta2-agonist administration). <u>Chronic Idiopathic Urticaria Criteria</u> : 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

		<p>dermatologist. <u>Nasal Polyps Criteria</u>: 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):</p> <p>a. Patient has received at least 3 months of therapy with an intranasal corticosteroid; AND</p> <p>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):</p> <p>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</p> <p>b. Patient has a contraindication to systemic corticosteroid therapy; OR</p> <p>c. Patient has had prior surgery for nasal polyps; AND</p> <p>The medication is prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose and throat [ENT] physician specialist).</p>
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