# Medical Policies

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| **Policy Number:** | ME-I-9053 | | |
| **Policy Name:** | Omalizumab (Xolair) | | |
| **Policy Type:** | Medical | **Policy Subtype:** | Injections |
| **Effective Date:** | 10-01-2025 | **Review Date:** | 09-01-2026 |
| **Last Review Date:** | 09-04-2025 | | |

## Description

Omalizumab (Xolair) is a recombinant DNA-derived humanized IgG1k murine monoclonal antibody that selectively binds to human immunoglobulin E (IgE). Omalizumab (Xolair) inhibits the binding of IgE to the high-affinity IgE receptor on the surface of mast cells and basophils, which limits the degree of release of mediators of the allergic response.

Omalizumab-igec (Omlyclo) is a biosimilar to Xolair.

Omalizumab vial may be covered on the medical benefit. Omalizumab prefilled syringe may be covered on the pharmacy benefit.

## Policy Application

All claims submitted for this policy will be processed according to the policy effective date and associated revision effective dates in effect on the date of service.

## Criteria

Coverage is subject to the specific terms of the member's benefit plan.

Omalizumab vial may be approved when the following are met:

Chronic Idiopathic Urticaria

- The use of omalizumab must meet recommendations found in the FDA label or compendia (e.g., diagnosis, age, dosage, frequency, route); and
- Must be prescribed by, or in consult with, an allergist/immunologist; and
- The individual must have failed a 30-day trial of a dose of fourfold normal dosing of second-generation H1 antihistamine (e.g., cetirizine, desloratadine, fexofenadine, levocetirizine, loratadine) in addition to the following, as evidenced by paid claims or pharmacy printouts:
    - Leukotriene receptor antagonist (e.g., montelukast, zafirlukast, zileuton); and
    - Histamine H2-receptor (e.g., ranitidine, famotidine, nizatidine, cimetidine); and
- The individual will only be on one (1) strength of omalizumab at a time; and
- The individual will NOT be using omalizumab in combination with another biologic agent [e.g., injectable IL-5 inhibitor (Cinqair, Fasenra, Nucala), injectable IL-4 inhibitor (Dupixent), thymic stromal lymphopoietic (TSLP) blocker (Tezspire)].

### Reauthorization Criteria

Continuation of therapy with omalizumab vial may be considered medically necessary when the following are met:

- The prescriber must provide documentation showing that the individual has achieved a clinical benefit since treatment initiation with omalizumab; and
- The individual will only be on one (1) strength of omalizumab at a time; and
- The individual will NOT be using omalizumab in combination with another biologic agent [e.g., injectable IL-5 inhibitor (Cinqair, Fasenra, Nucala), injectable IL-4 inhibitor (Dupixent), thymic stromal lymphopoietic (TSLP) blocker (Tezspire)].

### Eosinophilic Asthma

- The use of omalizumab vial must meet recommendations found in the FDA label or compendia (e.g., diagnosis, age, dosage, frequency, route); and
- Must be prescribed by, or in consult with, a pulmonologist or allergist/immunologist; and
- The individual must have had at least one exacerbation requiring use of oral corticosteroids in the previous year despite continued compliant use of a high dose inhaled steroid in combination with a long-acting beta agonist (LABA) and long-acting muscarinic antagonist (LAMA) as evidenced by paid claims or pharmacy printouts; and
- The individual has a serum total IgE level, measured before the start of treatment, of greater than or equal to 30 IU/mL and less than or equal to 700 IU/mL in individuals 12 years of age or older or greater than or equal to 30 IU/mL and less than or equal to 1300 IU/mL in individuals ages six (6) to less than 12 years old; and
- The individual has had a positive skin test or in vitro reactivity to a perennial aeroallergen; and
- The individual will only be on one (1) strength of omalizumab at a time; and
- The individual will NOT be using omalizumab in combination with another biologic agent [e.g., injectable IL-5 inhibitor (Cinqair, Fasenra, Nucala), injectable IL-4 inhibitor (Dupixent), thymic stromal lymphopoietic (TSLP) blocker (Tezspire)].

### Reauthorization Criteria

Continuation of therapy with omalizumab vial may be considered medically necessary when the following is met:

- The prescriber must provide documentation showing that the individual has achieved a significant reduction in asthma exacerbations and utilization of rescue medications since treatment initiation with

omalizumab as evidenced by medical documentation (e.g., chart notes) attached to the request (subject to clinical review); and
- The individual will only be on one (1) strength of omalizumab at a time; and
- The individual will NOT be using omalizumab in combination with another biologic agent [e.g., injectable IL-5 inhibitor (Cinqair, Fasenra, Nucala), injectable IL-4 inhibitor (Dupixent), thymic stromal lymphopoietic (TSLP) blocker (Tezspire)].

### Chronic Rhinosinusitis with Nasal Polyps

- The use of omalizumab v (must meet recommendations found in the FDA label or compendia (e.g., diagnosis, age, dosage, frequency, route); and
- Must be prescribed by, or in consult with, an ear/nose/throat specialist or allergist/immunologist; and
- The individual must have had a 12-week trial of intranasal corticosteroids; and
- The individual must have trialed at least two courses of a 10-day trial of oral glucocorticoids in the past year; and
- The individual must have bilateral polyps confirmed by sinus CT, anterior rhinoscopy, or nasal endoscopy; and
- The individual will only be on one (1) strength of omalizumab at a time; and
- The individual will NOT be using omalizumab in combination with another biologic agent [e.g., injectable IL-5 inhibitor (Cinqair, Fasenra, Nucala), injectable IL-4 inhibitor (Dupixent), thymic stromal lymphopoietic (TSLP) blocker (Tezspire)].

### Reauthorization Criteria

Continuation of therapy with omalizumab vial may be considered medically necessary when ALL of the following are met:

- The prescriber must provide documentation showing that the individual has achieved a significant reduction in nasal polyp size and symptoms since treatment initiation with omalizumab; and
- The individual must be receiving intranasal steroids; and
- The individual will only be on one (1) strength of omalizumab at a time; and
- The individual will NOT be using omalizumab in combination with another biologic agent [e.g., injectable IL-5 inhibitor (Cinqair, Fasenra, Nucala), injectable IL-4 inhibitor (Dupixent), thymic stromal lymphopoietic (TSLP) blocker (Tezspire)].

### Food Allergy

- The use of omalizumab must meet recommendations found in the FDA label or compendia (e.g., diagnosis, age, dosage, frequency, route); and
- Must be prescribed by, or in consult with, an allergist/immunologist; and
- The provider must attest that the individual has access to injectable epinephrine, and that the individual/caregiver has been instructed and trained on its appropriate use; and
- ONE of the following:
    - The individual has a history of severe (type 1) allergic response requiring the use of epinephrine, an ER visit, or hospitalization; or
    - Allergic reaction produced during a provider observed intake of food allergen and attestation that food allergy is likely to produce anaphylaxis as determined by allergist/immunologist; or
    - ALL of the following:
        - History of urticaria, angioedema, or wheeze; and
        - Skin prick wheal of at least three (3) mm or positive IgE test as determined by allergist/immunologist (at least 30 IU/mL for omalizumab); and

- Attestation that food allergy is likely to produce anaphylaxis as determined by allergist/immunologist.

The use of omalizumab vial for all other indications not listed in this policy is considered experimental/investigational and therefore non-covered because the safety and/or effectiveness cannot be established by the available published peer-reviewed literature.

### Procedure Codes

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| J2357 | Q5154 |

NOTE: In addition to the above criteria, product specific dosage and/or frequency limits may apply in accordance with the United States Food and Drug Administration (U.S. FDA)-approved product prescribing information, national compendia, Centers for Medicare and Medicaid Services (CMS) and other peer reviewed resources or evidence-based guidelines.

## Professional Statements and Societal Positions Guidelines

Not Applicable

## Diagnosis Codes

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|---|---|---|---|---|---|---|
| J33.0 | J33.1 | J33.8 | J33.9 | J44.0 | J44.1 | J44.9 |
| J45.40 | J45.41 | J45.42 | J45.50 | J45.51 | J45.52 | J45.901 |
| J45.902 | J45.909 | J45.990 | J45.991 | J45.998 | L50.1 | Z91.010 |
| Z91.011 | Z91.012 | Z91.013 | Z91.018 | | | |

### CURRENT CODING

#### HCPCS:

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|---|---|---|
| J2357 | Omalizumab injection | Medicaid Expansion |

## References
## I-9053

1. Preferred Drug List (PDL) Prior Authorization Criteria. North Dakota Department of Health and Human Services. Medical Services Division. https://ndmedicaid.acentra.com/preferred-drug-list-pdl/#pdl

2. Xolair® (omalizumab), injection, for subcutaneous use [package insert]. Genentech, Inc. South San Francisco, CA. Revised 02/2024.

## ND Committee Review

Internal Medical Policy Committee 11-23-2021- *Effective January 1-01-2022*

- *Adopted* Medicaid Expansion specific policy

Internal Medical Policy Committee 1-20-2022

- *Added* combination therapy criteria

Internal Medical Policy Committee 1-26-2023 *Effective March 01, 2023*

- *Updated* criteria for all indications
- *Added* Tezspire as a combination agent
- *Updated* experimental/investigational statement

Internal Medical Policy Committee 9-12-2023 *Effective September 01, 2023*

- *Updated* criteria for Chronic Idiopathic Urticaria and Nasal Polyps based on the DHHS PDL Version 2023.4

Internal Medical Policy Committee 3-19-2024 *Effective April 01, 2024*

- *Updated* criteria for Nasal Polyps based on the DHHS PDL Version 2024.2

Internal Medical Policy Committee 7-16-2024 *Effective August 01, 2024*

- *Added* criteria for Food Allergy based on the DHHS PDL Version 2024.4

Internal Medical Policy Committee 7-10-2025 *Effective August 01, 2025*

- *Updated* criteria for Chronic Idiopathic Urticaria based on the DHHS PDL Version 2025.4

Internal Medical Policy Committee 9-04-2025 *Effective October 01, 2025*

- *Added* new code, Q5154, to the policy

## Disclaimer

*Current medical policy is to be used in determining a Member's contract benefits on the date that services are rendered. Contract language, including definitions and specific inclusions/exclusions, as well as state and federal law, must be considered in determining eligibility for coverage. Members must consult their applicable benefit plans or contact a Member Services representative for specific coverage information. Likewise, medical policy, which addresses the issue(s) in any specific case, should be considered before utilizing medical opinion in adjudication. Medical technology is constantly evolving, and the Company reserves the right to review and update medical policy periodically.*