Pharmacy Drug Policy & Procedure

Policy Name:	Xolair (omalizumab)	Policy #:	1059P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Xolair.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Xolair under the specialty medical benefit or Xolair prefilled syringe under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for Asthma

1.1 Member age 6 years or older
1.2 Diagnosis of moderate to severe persistent asthma
1.3 Availability of a rapid-acting beta2 agonist (Ventolin, ProAir, Proventil)
1.4 Prescribed by immunologist (immune system doctor) or pulmonologist (lung doctor)
1.5 Planned use of Xolair with other chronic therapeutic agents for the treatment of asthma
1.6 Positive skin or *in vitro* reactivity to at least 1 perennial aeroallergen
1.7 Pretreatment IgE level 30 IU/mL
1.8 Documented use with one of the following:
- An inhaled corticosteroid (ICS, such as Asmanex, Pulmicort or QVAR) treatment one additional asthma controller medication with lack of asthma control
- A maximally tolerated inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) such as Symbicort or Dulera

2. Coverage Criteria for Chronic Idiopathic Urticaria

2.1 Documented itchy hives for at least 6 weeks
2.2 Member is age 12 and older
2.3 Documented failure on at least two different high-dose H1-antihistamines, unless contraindicated
- High dose defined by the total daily dose
  - Cetirizine 20mg
  - Fexofenadine 360mg
  - Loratidine 20mg daily
  - Hydroxyzine 200mg
  - Diphenhydramine 400mg

2.4 Documented failure, intolerance, or contraindication to ranitidine or famotidine used in combination with a H1-antihistamine
2.5 Documented failure, intolerance, or contraindication to montelukast or zafirlukast
2.6 Prescribed by an immunologist (immune system doctor) or allergist (allergy specialist)

3. Coverage Criteria for Rhinosinusitis Nasal Polyposis

3.1 Documented diagnosis of rhinosinusitis with nasal polyps
3.2 Prescribed by an otolaryngologist (ear, nose and throat doctor), allergist (allergy specialist), or immunologist (immune system doctor)
3.3 Age 18 years or older
3.4 Documented failure, intolerance, or contraindication to intranasal glucocorticoids

4. Coverage Criteria for IgE-mediated Food Allergy

4.1 Documented diagnosis of IgE-mediated food allergy confirmed by history of IgE-mediated allergy to one or more foods

4.2 Patient has one or more demonstrated food allergies through positive skin prick test or positive serum IgE

4.3 Age 1 year or older

4.4 Prescribed by an allergist or immunologist

4.5 Documentation Xolair is medically necessary despite a diet avoiding food allergens

4.6 Xolair will not be used in conjunction with Palforzia

5. Approval Period

5.1 Initial: 12 months

5.2 Reauthorization: 12 months with documented clinical benefit

HCPCS Codes	
J2357	Injection, omalizumab, 5 mg

References

1. Xolair (omalizumab) [prescribing information]. South San Francisco, CA: Genentech Inc; February 2024.
2. Global Initiative for Asthma (GINA), Global Strategy for Asthma Management and Prevention, 2023. https://ginasthma.org/2023-gina-main-report/.
3. Zuberbier T, Abdul Latiff AH, Abuzakouk M, et al. The international EAACI/GA²LEN/EuroGuiDerm/ APAAACI guideline for the definition, classification, diagnosis, and management of urticaria. Allergy. 2022;77(3):734-766.
4. Rank MA, Chu DK, Bognanni A, et al. The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. J Allergy Clin Immunol. 2023 Feb;151(2):386-398.
5. Fleischer DM, Chan ES, Venter Cet al. A Consensus Approach to the Primary Prevention of Food Allergy through Nutrition: Guidance from the American Academy of Allergy, Asthma, and Immunology; American College of Allergy, Asthma, and Immunology; and the Canadian Society for Allergy and Clinical Immunology. J Allergy Clin Immunol Pract. 2021 Jan;9(1):22-43.e4.

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