Omalizumab (Xolair)

Severe Asthma

Coverage Criteria:

1. Prescribed by an asthma specialist, allergist or pulmonologist; and,
2. Patient is ≥ 6 years of age; and,
3. Medical chart documentation of patient's age, weight & IgE levels within 4 weeks of prescribing is provided; and,
4. A positive skin test or in vitro (test tube) reactivity to a perennial aeroallergen (air born substance that causes allergies, such as pollen); and,
5. Xolair is reserved for patients with poor asthma control (see criteria #4) and significant symptoms despite the following standard therapies:
    a. Regular use of inhaled steroids (such as Flovent); and,
    b. Regular use of a long-acting beta-agonist (such as Serevent); and,
    c. Regular use or a trial of a leukotriene antagonist (such as Singulair); and,
    d. Regular or periodic use of oral steroids; and,
6. Poor asthma control despite standard therapies is defined as one of the following:
    a. At least 2 exacerbations requiring oral systemic corticosteroids in the last 12 months; or,
    b. At least 1 exacerbation treated in hospital or requiring mechanical ventilation in the last 12 months; and,
7. Patient is not currently using another biologic therapy for the treatment of asthma such as Cinqair, Dupixent, Fasenra or Nucala; and,
8. Prescribed within FDA approved dosing regimen according to patient's age, weight and initial IgE levels.

Renewal Criteria:

1. Patient has been seen by provider within the past 12 months; and,
2. Patient has been adherent to therapy; and,
3. Patient has not experienced unacceptable toxicity from the drug such as parasitic (helminth) infection or herpes zoster infection; and,
4. Patient has a clinically meaningful response to the medication as defined:
    a. Decreased frequency of exacerbations defined as:
        i. Improvement of asthma control, demonstrated by decreased use of oral or systemic corticosteroids; or,
        ii. Less frequent hospitalizations; or,
        iii. Reduced frequency of emergency department visits; or,
    b. Improvement in lung function measured in FEV1; and,
5. Xolair is prescribed within the FDA-approved dosing regimen.

Coverage Duration:
Initial authorizations and reauthorizations will be provided for 12 months.

P&T Date: 4/5/2021
Updated: 4/23/2021, 03/09/2024

Chronic Urticaria

Coverage Criteria:

1. Patient is followed by an allergist or dermatologist; and,
2. Patient ≥ 12 years old has hives/ urticaria longer than 6 weeks; and,
3. Patient has tried and failed all standard therapies including:
    a. H1 antihistamines; and,
    b. H2 antihistamines; and,
    c. Leukotriene inhibitors; and,
    d. Multiple courses of or dependent on a steroids (e.g., prednisone); and,
4. Prescribed within FDA approved dosing regimen.

Renewal Criteria:

1. Patient has been seen by provider within the past 12 months; and,
2. Patient has been adherent to therapy; and,
3. Patient is not currently prescribed another biologic therapy for the treatment of nasal polyps; and,
4. Xolair is prescribed within the FDA-approved dosing regimen.

Coverage Duration:
Initial authorizations and reauthorizations will be provided for 12 months.

Nasal Polyps

Coverage Criteria:

1. Patient is diagnosed with bilateral nasal polyposis and chronic symptoms of sinusitis; and,
2. Prescribed by or in consultation with an allergist, otolaryngologist or pulmonologist; and,
3. Patient has tried and failed intranasal corticosteroids for at least 3 months; and,
4. Patient has a documented reoccurrence of nasal polyps within 12 months of surgery to treat nasal polyps or a contraindication to surgical intervention; and,
5. Patient has moderate to severe symptoms defined as one of the following lasting greater than 12 weeks:
    a. Anterior or posterior rhinorrhea; or,
    b. Nasal congestion; or,
    c. Reduction or loss of smell; or,
    d. Nasal obstruction; and,
6. The member will use a daily intranasal corticosteroid concomitantly with Xolair; and,
7. Patient is not currently prescribed another biologic therapy for the treatment of nasal polyposis; and,
8. Prescribed within FDA approved dosing regimen according to patient's age, weight, and initial IgE levels.

Renewal Criteria:

1. Patient has been seen by provider within the past 12 months; and,
2. Provider attests patient has achieved clinical benefit from use of Xolair for symptoms of chronic rhinosinusitis with nasal polyps; and,

3. Xolair continues to be prescribed within the FDA approved dosing regimen.

Coverage Duration:
Initial authorizations will be provided for 6 months.
Reauthorizations will be provided for 12 months

IgE-Mediated Food Allergy

Coverage Criteria:
1. Prescribed by an allergist; and,
2. Patient is diagnosed with an IgE-mediated food allergy; and,
3. Patient has a food allergy to peanut and at least two of the following allergens:
    a. Milk; or,
    b. Egg; or,
    c. Wheat; or,
    d. Cashew; or,
    e. Hazelnut; or,
    f. Walnut; and,
4. Patient has a food allergy documented by one of the following:
    a. Positive immunoglobulin E (IgE) to peanuts greater than or equal to 6 kUA/L within prior three months; or,
    b. Positive allergy skin prick test (SPT), defined as a wheal of at least 4 mm in the peanut allergen compared to the negative control; or,
    c. Positive double-blind placebo-controlled food challenge (DBPCFC), defined as experiencing dose-limiting symptoms at a single dose of one of the following:
        i. 100 mg or less of peanut protein; or,
        ii. 300 mg or less of food protein (e.g., milk, egg, wheat, nut); and,
5. Patient has demonstrated ALL of the following:
    a. History of significant allergic reaction including but not limited to hives, hypotension, swelling or wheezing; and,
    b. Allergic reaction occurred during or after exposure to allergen or a product containing allergen byproducts; and,
    c. Patient has been prescribed epinephrine as an emergent medication for allergen exposure; and,
    d. Patient does not have a history of severe anaphylaxis to food allergens, defined as neurological compromise or requiring intubation; and,
6. Patient is not currently prescribed another therapy or biologic for the treatment of IgE-mediated food allergies (e.g., Palforzia, Dupixent, Fasenra, Nucala, Cinqair); and,
7. Prescriber attests patient has been counseled on the need to maintain a food allergen-avoidant diet; and,
8. Prescribed within FDA approved dosing regimen according to patient's age, weight, and initial IgE levels.

Renewal Criteria:
1. Patient has been seen by provider within the past 12 months; and,

2. Documentation patient remains adherent to therapy and continues to have clinical benefit, such as reduced frequency in allergic reactions; and,
3. Prescribed within FDA approved dosing regimen according to patient's age, weight, and initial IgE levels.

Coverage Duration:
Initial authorizations will be provided for 6 months.
Reauthorizations will be provided for 12 months