

# Criteria-Based Consultation Prescribing Program

## CRITERIA FOR DRUG COVERAGE

### Omalizumab (Xolair)

**Initiation (new start) criteria:** Non-formulary **omalizumab (Xolair)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

#### Moderate-to-Severe Persistent Asthma

- Prescriber is an allergist or pulmonologist
- Patient is at least 6 years of age
- Patient has a diagnosis of asthma
- Patient has a positive skin prick or RAST test to a perennial aeroallergen.
- Patient has a documented baseline serum IgE of at least 30 IU/mL.
- Patient is currently treated with a high-dose, or maximally tolerated inhaled corticosteroid AND at least one other maintenance medication, including: a long-acting inhaled beta2-agonist, long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid
- Within the past 12 months the patient experienced at least two asthma exacerbations requiring systemic corticosteroids for at least 3 days; or least one asthma exacerbation requiring hospitalization or emergency room visit.
- Patient is not planned to concurrently receive treatment with dupilumab (Dupixent), mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire)
- If prescribed for self-injection: Patient has received at least 3 doses of omalizumab under the guidance of a healthcare provider with no hypersensitivity reactions.

#### Chronic Idiopathic Urticaria (CIU)

- Prescriber is an allergist or pulmonologist
- Patient is at least 12 years of age
- Diagnosis of chronic idiopathic urticaria
- Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to two H1-antihistamines [e.g., fexofenadine (Allegra), loratadine (Claritin), cetirizine (Zyrtec) diphenhydramine (Benadryl), chlorpheniramine (Chlor-Trimeton), hydroxyzine (Vistaril)]
- If prescribed for self-injection: Patient has received at least 3 doses of omalizumab under the guidance of a healthcare provider with no hypersensitivity reactions

#### Chronic Rhinosinusitis with Nasal Polyps

- Prescriber is an allergist or otolaryngologist
- Patient is at least 18 years of age

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## CRITERIA FOR DRUG COVERAGE

### Omalizumab (Xolair)

- Patient has diagnosis of bilateral sino-nasal polyposis; with polyps filling the middle meatuses
- Patient has persistent rhinosinusitis (swelling of the sinuses and nasal cavity) symptoms with nasal blockage that includes at least two of the following symptoms for at least 12 weeks:
  - i. Rhinorrhea (runny nose)
  - ii. Facial pain, pressure, or fullness
  - iii. Nasal blockage, obstruction, or congestion
  - iv. Partial or complete loss of smell
- Patient has had a previous full endoscopic sinus surgery
- Patient remains symptomatic despite at least a 12-week trial of a nasal corticosteroid [e.g., fluticasone (Flonase), mometasone (Nasonex), budesonide (Rhinocort)], or patient has a history of contraindication or intolerance to nasal corticosteroids.
- Patient has a documented baseline serum IgE of at least 30 IU/mL.
- Patient will continue to receive therapy with a nasal corticosteroid concomitantly with omalizumab (Xolair); unless contraindication or intolerance to nasal corticosteroids.
- Patient is not planned to concurrently receive treatment with dupilumab (Dupixent), benralizumab (Fasenra), mepolizumab (Nucala), tezepelumab-ekko (Tezspire).
- If prescribed for self-injection: Patient has received at least 3 doses of omalizumab under the guidance of a healthcare provider with no hypersensitivity reactions.

# Criteria-Based Consultation Prescribing Program

## CRITERIA FOR DRUG COVERAGE

### Omalizumab (Xolair)

**Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously:** Non-formulary **omalizumab (Xolair)** will be covered on the prescription drug benefit 12 months when the following criteria are met:

#### Moderate-to-Severe Persistent Asthma

- Prescriber is an allergist or pulmonologist
- Patient is at least 6 years of age
- Patient is currently using omalizumab with an at least one additional asthma controller medication, such as an: inhaled corticosteroid (ICS), or long-acting beta2 agonist (LABA); or leukotriene receptor antagonist (LRTI [e.g., montelukast]); or long-acting muscarinic antagonist (e.g., tiotropium); or daily systemic corticosteroids
- Patient has received at least 3 doses of omalizumab under the guidance of a healthcare provider with no hypersensitivity reactions.

#### Chronic Idiopathic Urticaria (CIU)

- Prescriber is an allergist
- Patient is at least 12 years of age
- Patient has diagnosis of chronic idiopathic urticaria
- Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to two H1-antihistamines [e.g., fexofenadine (Allegra), loratadine (Claritin), cetirizine (Zyrtec) diphenhydramine (Benadryl), chlorpheniramine (Chlor-Trimeton), hydroxyzine (Vistaril)]
- Patient has received at least 3 doses of omalizumab under the guidance of a healthcare provider with no hypersensitivity reactions.

#### Chronic Rhinosinusitis with Nasal Polyps

- Prescriber is an allergist or otolaryngologist
- Patient is at least 18 years of age
- Patient is currently using omalizumab with a nasal corticosteroid; unless history of contraindication or intolerance to nasal corticosteroids.
- Patient has received at least 3 doses of omalizumab under the guidance of a healthcare provider with no hypersensitivity reactions.

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# Criteria-Based Consultation Prescribing Program

## CRITERIA FOR DRUG COVERAGE

### Omalizumab (Xolair)

**Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:** Non-formulary **omalizumab (Xolair)** will be covered on the prescription drug benefit when the following criteria are met:

#### Moderate-to-Severe Persistent Asthma

- Prescriber is an allergist or pulmonologist
- Patient is at least 6 years of age
- Patient is currently using omalizumab with an at least one additional asthma controller medication, such as an: inhaled corticosteroid (ICS), or long-acting beta2 agonist (LABA); or leukotriene receptor antagonist (LRTI [e.g., montelukast]); or long-acting muscarinic antagonist (e.g., tiotropium); or daily systemic corticosteroids
- Patient is not receiving treatment with dupilumab (Dupixent), mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), ~~omalizumab (Xolair)~~, tezepelumab-ekko (Tezspire)

#### Chronic Idiopathic Urticaria (CIU)

- Prescriber is an allergist
- Patient is at least 12 years of age
- Patient has diagnosis of chronic idiopathic urticaria
- Patient remains symptomatic despite at least a 2-week trial of, or history of contraindication or intolerance to two H1-antihistamines [e.g., fexofenadine (Allegra), loratadine (Claritin), cetirizine (Zyrtec) diphenhydramine (Benadryl), chlorpheniramine (Chlor-Trimeton), hydroxyzine (Vistaril)]

#### Chronic Rhinosinusitis with Nasal Polyps

- Prescriber is an allergist or otolaryngologist
- Patient is at least 18 years of age
- Patient has diagnosis of bilateral sino-nasal polyposis
- Patient has had a previous full endoscopic sinus surgery
- Patient is using a nasal corticosteroid [e.g., fluticasone (Flonase), mometasone (Nasonex), budesonide (Rhinocort)], unless contraindication or intolerance to nasal corticosteroids.
- Patient is not receiving treatment with dupilumab (Dupixent), mepolizumab (Nucala), reslizumab (Cinqair), benralizumab (Fasenra), tezepelumab-ekko (Tezspire)

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## CRITERIA FOR DRUG COVERAGE

### Omalizumab (Xolair)

**Continued use criteria (12 months after initiation):** Non-formulary **omalizumab (Xolair)** will continue to be covered on the prescription drug benefit when the following criteria are met:

#### Moderate-to-Severe Persistent Asthma

- Therapy continued to be prescribed by an allergist or pulmonologist
- The patient has shown a clinical response as evidenced by ONE of the following:
  - Reduction in asthma exacerbation from baseline
  - Decreased utilization of rescue medications
  - Increase in percent predicted FEV1 from pretreatment baseline
  - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
- Patient is currently using omalizumab with an at least one additional asthma controller medication, such as an: inhaled corticosteroid (ICS), or long-acting beta2 agonist (LABA); or leukotriene receptor antagonist (LRTI [e.g., montelukast]); or long-acting muscarinic antagonist (e.g., tiotropium); or daily systemic corticosteroids

#### Chronic Idiopathic Urticaria (CIU)

- Therapy continued to be prescribed by an allergist
- Patient has documented response to therapy (e.g., decreased severity of itching, decreased number and/or size of hives)

#### Chronic Rhinosinusitis with Nasal Polyps

- Therapy continued to be prescribed by an allergist or otolaryngologist
- The patient has a documented clinical benefit (e.g., improvement in nasal congestion, improvement in sense of smell, reduction in size of polyps)
- Patient is currently using omalizumab with a nasal corticosteroid; unless history of contraindication or intolerance to nasal corticosteroids.