curative

Xolair Prior Authorization Drug List A

Drug Applied:	**Xolair** (omalizumab)

Criteria:
Drug Applied will be approved when the requested medication is being used for a compendia-supported indication and all of the following criteria are met:

I. Initial Therapy Criteria
- **A. Moderate to severe persistent asthma** as indicated by chart notes within past 120 days
  1. ONE of the following:
     a) Patient is 6 to less than 12 years of age and BOTH of the following:
        (1) Pretreatment IgE level is 30 IU/mL to 1300 IU/mL **and**
        (2) Patient's weight is 20 kg to 150 kg **or**
     b) Patient is 12 years of age or over and BOTH of the following:
        (1) Pretreatment IgE level is 30 IU/mL to 700 IU/mL **and**
        (2) Patient's weight is 30 kg to 150 kg **and**
  2. Allergic asthma has been confirmed by a positive skin test or in vitro reactivity test to a perennial aeroallergen **and**
  3. Patient has a history of uncontrolled asthma while on asthma controller therapy as demonstrated by ONE of the following:
     a) Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **or**
     b) Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **or**
     c) Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **or**
     d) Patient has baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **and**
  4. ONE of the following:
     a) Patient is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 consecutive months **or**
     b) Patient has an intolerance or FDA labeled contraindication to ALL inhaled corticosteroids **and**
  5. ONE of the following:

a) Patient is currently being treated for at least 3 consecutive months with ONE of the following: long-acting beta-2 agonist (LABA), long-acting muscarinic antagonist (LAMA), or leukotriene receptor antagonist (LTRA) **or**
b) Patient has an intolerance to therapy with LABA, LAMA, or LTRA **or**
c) Patient has an FDA labeled contraindication to ALL LABA, LAMA, and LTRA **and**

6. ONE of the following:
   a) Patient has tried for a minimum duration of 4 consecutive months and has an inadequate response to BOTH of the following:
      (1) IL-5 (i.e. Nucala (mepolizumab), Fasenra (benralizumab)), **and**
      (2) IL-4 (i.e. Dupixent (dupilumab)) **or**
   b) Patient has an intolerance or FDA labeled contraindication to BOTH of the following:
      (1) IL-5 (i.e. Nucala, Fasenra) **and**
      (2) IL-4 (i.e. Dupixent) **and**
7. Patient will continue asthma control therapy (e.g., ICS, ICS/LABA, LTRA, LAMA) in combination with the requested agent **and**
8. Requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 375 mg every 2 weeks **and**
9. Requested drug is not being used for the relief of acute bronchospasm or status asthmaticus **and**
10. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy & immunology, pulmonology) **and**
11. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 6 months

B. Chronic spontaneous urticaria (CSU) also known as chronic idiopathic urticaria (CIU) as indicated by chart notes within past 120 days

1. Patient is at least 12 years of age **and**
2. Patient has had over 6 weeks of hives and itching **and**
3. If patient is currently being treated with medications known to cause or worsen urticaria, then ONE of the following:

a) Prescriber has reduced the dose or discontinued any medications known to cause or worsen urticaria (e.g., NSAIDs) **or**
b) A reduced dose or discontinuation of any medications known to cause or worsen urticaria is not appropriate **and**

4. ONE of the following:
   a) Patient has tried and had an inadequate response to the FDA labeled maximum dose of a second-generation H-1 antihistamine (e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine) after at least a 2-week duration of therapy and ONE of the following:
      (1) Patient has tried and had an inadequate response to a dose titrated up to 4 times the FDA labeled maximum dose of a second-generation H-1 antihistamine **or**
      (2) Patient cannot be treated with a dose titrated up to 4 times the FDA labeled maximum dose of a second-generation H-1 antihistamine **or**
   b) Patient has an intolerance or FDA labeled contraindication to ALL second-generation H-1 antihistamines **and**
5. ONE of the following:
   a) Patient has tried for a minimum duration of 4 consecutive months and has an inadequate response to IL-4 (i.e. Dupixent (dupilumab)) **or**
   b) Patient has an intolerance to IL-4 **or**
   c) Patient has an FDA labeled contraindication to IL-4 **and**
6. Requested dose does NOT exceed 300 mg every 4 weeks **and**
7. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy & immunology) **and**
8. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 6 months

C. Chronic rhinosinusitis with nasal polyposis (CRSwNP) as indicated by chart notes within past 120 days

1. Patient is at least 18 years of age and BOTH of the following:
   a) Pretreatment Serum IgE level is 30 IU/mL to 1500 IU/mL **and**
   b) Patient is 30-150 kg **and**
2. Patient has at least TWO of the following symptoms consistent with chronic

rhinosinusitis (CRS) for at least 12 consecutive weeks:
   a) Nasal discharge (rhinorrhea or post-nasal drainage)
   b) Nasal obstruction or congestion
   c) Loss or decreased sense of smell (hyposmia)
   d) Facial pressure or pain **and**
3. Patient's diagnosis was confirmed by either anterior rhinoscopy or endoscopy or computed tomography (CT) of the sinuses **and**
4. ONE of the following:
   a) Patient had an inadequate response to sinonasal surgery or is NOT a candidate for sinonasal surgery **or**
   b) ONE of the following:
      (1) Patient has tried and had an inadequate response to oral systemic corticosteroids **or**
      (2) Patient has an intolerance or hypersensitivity to therapy with oral systemic corticosteroids **or**
      (3) Patient has an FDA labeled contraindication to ALL oral systemic corticosteroids **and**
5. ONE of the following:
   a) Patient has tried and had an inadequate response to intranasal corticosteroids (e.g., fluticasone, mometasone, Sinuva) after at least a 4-week duration of therapy **or**
   b) Patient has an intolerance to therapy with intranasal corticosteroids **or**
   c) Patient has an intolerance or FDA labeled contraindication to ALL intranasal corticosteroids **and**
6. ONE of the following:
   a) Patient has tried for a minimum duration of 6 consecutive months and has an inadequate response to BOTH of the following:
      (1) IL-5 (i.e. Nucala (mepolizumab), **and**
      (2) IL-4 (i.e. Dupixent (dupilumab)), **or**
   b) Patient has an intolerance or FDA labeled contraindication to BOTH of the following:
      (1) IL-5 (i.e. Nucala) **and**
      (2) IL-4 (i.e. Dupixent) **and**
7. Patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) **and**
8. Patient will continue standard nasal polyp maintenance therapy in combination with the requested agent **and**
9. Requested dose does NOT exceed 600 mg every 2 weeks **and**
10. Prescriber is a specialist or has consulted with a specialist in the area of the

patient's diagnosis (e.g., otolaryngology) **and**

11. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 6 months

D. Reduction of IgE-mediated food allergy as indicated by chart notes within past 90 days

1. Patient is at least 1 year of age and BOTH of the following:
    a) Pretreatment Serum IgE is 30 IU/mL to 1850 IU/mL
    b) Patient is 10-150 kg **and**
2. Requested agent is not being used for the emergency treatment of allergic reactions, including anaphylaxis **and**
3. Requested dose dose does not exceed 600 mg every 2 weeks **and**
4. Patient is currently practicing food avoidance and will continue in conjunction with requested agent **and**
5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy & immunology, pulmonology) **and**
6. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 6 months

II. Continued Therapy Criteria

A. Moderate to severe persistent asthma as indicated by chart notes within past 12 months

1. Patient meets the initial therapy criteria above **and**
2. Patient has had improvements or stabilization with the requested agent from baseline (prior to therapy with the requested agent) as indicated by ONE of the following:
    a) Increase in percent predicted Forced Expiratory Volume (FEV1) **or**
    b) Decrease in the dose of inhaled corticosteroid required to control the

patient's asthma **or**

c) Decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **or**

d) Decrease in the number of hospitalizations, need for mechanical ventilation, or visits to the emergency room or urgent care due to exacerbations of asthma **and**

3. Patient is currently treated and is compliant with standard therapy [i.e., inhaled corticosteroids (ICS), ICS/long-acting beta-2 agonist (ICS/LABA), leukotriene receptor antagonist (LTRA), oral corticosteroid (OCS), long-acting muscarinic antagonist (LAMA)] **and**
4. Requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling AND does NOT exceed 375 mg every 2 weeks **and**
5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy & immunology, otolaryngology, pulmonology) **and**
6. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 6 months

B. Chronic spontaneous urticaria (CSU) also known as chronic idiopathic urticaria (CIU) as indicated by chart notes within past 12 months

1. Patient meets the initial therapy criteria above **and**
2. Documented clinical benefit since starting the requested agent (i.e., less itching) **and**
3. Requested dose is within FDA labeled dosing for the requested indication AND does NOT exceed 300 mg every 4 weeks **and**
4. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy & immunology, otolaryngology, pulmonology) **and**
5. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full

documentation required])

Approval Duration: 6 months

C. **Chronic rhinosinusitis with nasal polyposis (CRSwNP)** as indicated by chart notes within past 12 months
   1. Patient meets the initial therapy criteria above **and**
   2. Documented clinical benefit since starting the requested agent (i.e., reduction in serum free IgE) **and**
   3. Patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **and**
   4. Requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling and does NOT exceed 600 mg every 2 weeks **and**
   5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy & immunology, otolaryngology, pulmonology) **and**
   6. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

   Approval Duration: 6 months

D. **Reduction of IgE-mediated food allergy** as indicated by chart notes within past 12 months
   1. Patient meets the initial therapy criteria above **and**
   2. Chart notes indicate patient has been treated with the requested agent and is a continuation of therapy (starting on samples is not approvable) **and**
   3. Documented clinical benefit since starting the requested agent (i.e., reduction in serum free IgE levels) **and**
   4. Requested dose is based on the patient's pretreatment serum IgE level and body weight as defined in FDA labeling and does NOT exceed 600 mg every 2 weeks **and**
   5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy & immunology, otolaryngology, pulmonology) **and**
   6. Chart notes and/or prescriber do not provide documentation that patient will be

using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 6 months

Policy Owned by: Curative PBM team