Kaiser Permanente Health Plan of Mid-Atlantic States, Inc.
Xolair (omalizumab) Prior Authorization (PA)
Pharmacy Benefits Prior Authorization Help Desk
Length of Authorizations: Initial- 6 months; Continuation- 12 months

Instructions:

This form is used by Kaiser Permanente and/or participating providers for coverage of **Xolair (omalizumab) .** Please complete and fax this form back to Kaiser Permanente within 24 hours [fax: 1-866-331-2104]. If you have any questions or concerns, please call 1-866-331-2103. **Requests will not be considered unless all sections are complete.**

KP-MAS Formulary can be found at: Pharmacy | Community Provider Portal | Kaiser Permanente

1 – Patient Information

Patient Name: _____ Kaiser Medical ID#: _____ Date of Birth: _____

2 – Prescriber Information

Prescriber Name: _____ Specialty: _____ NPI: _____

Prescriber Address: _____

Prescriber Phone #: _____Prescriber Fax #: _____

3 – Pharmacy Information

Pharmacy Name: _____ Pharmacy NPI: _____

Pharmacy Phone #_____ Pharmacy Fax #: _____

4 – Drug Therapy Requested

Drug 1: Name/Strength/Formulation: _____

Sig: _____

Drug 2: Name/Strength/Formulation: _____

Sig: _____

Note: The Virginia Department of Medical Assistance Services considers the use of concomitant therapy with Cinqair®, Dupixent®, Fasenra®, Nucala®, Tezspire™ and Xolair® to be experimental and investigational. Safety and efficacy of theses combinations have NOT been established and will NOT be permitted.

5– Diagnosis/Clinical Criteria

1. Is this request for initial or continuing therapy?

□ Initial therapy □ Continuing therapy, state start date: _____

2. Indicate the patient's diagnosis for the requested medication: _____

Clinical Criteria for severe* asthma:

1. Member is ≥ 6 years of age
   □ No □ Yes
2. Does the member have a diagnosis of severe asthma? **AND**
   □ No □ Yes
3. Does the member have a positive skin test or in vitro reactivity to a perennial aero-allergen; AND
   □ No □ Yes
4. Does the member weigh between 20 kg (44 lbs.) and 150 kg (330 lbs.); **AND**
   □ No □ Yes
5. Does the member have serum total IgE level, measured before the start of treatment, of either:
   a. ≥ 30 IU/mL and ≤ 700 IU/mL in patients age ≥ 12 years; **OR**
   b. ≥ 30 IU/mL and ≤ 1300 IU/mL in patients age 6 to <12 years; **AND**

   □ No □ Yes
6. Will coadministration with another monoclonal antibody be avoided (e.g., mepolizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko)? **AND**
   □ No □ Yes
7. Will this be used for add-on maintenance treatment in members regularly receiving **both** (unless otherwise contraindicated) of the following:
   - Medium- to high-dose inhaled corticosteroids; **AND**
   - An additional controller medication (e.g., long-acting beta agonist, leukotriene modifiers)?

   □ No □ Yes
8. Has the member had two or more exacerbations in the previous year requiring oral or injectable corticosteroid treatment (in addition to the regular maintenance therapy defined above) **or** one exacerbation resulting in a hospitalization? **AND**
   □ No □ Yes
9. Does the member have at least one of the following:
   - Use of systemic corticosteroids
   - Use of inhaled corticosteroids
   - A number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
   - Forced expiratory volume in 1 second (FEV_1)?

   □ No □ Yes

***Components of severity for classifying asthma as severe may include any of the following (not all-inclusive).**

- Asthma remains uncontrolled despite optimized treatment with high-dose ICS-LABA
- Asthma requires high-dose ICS-LABA to prevent it from being uncontrolled
- Symptoms throughout the day
- Nighttime awakenings, often 7 times/week
- SABA use for symptom control occurs several times per day

- Extremely limited normal activities
- Lung function (percent predicted FEV1) < 60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intensely relative to moderate asthma

Clinical Criteria for CHRONIC IDIOPATHIC URTICARTIA/CHRONIC SPONTANEOUS URTICARIA:

1. Is the member 12 years of age or older? **AND**

   □ No □ Yes

2. Is the underlying cause of the patient's condition NOT due to any other allergic condition(s) or other form(s) of urticaria? **AND**

   □ No □ Yes

3. Is the member avoiding triggers (e.g., NSAIDs, etc.)? **AND**

   □ No □ Yes

4. Documented baseline score from an objective clinical evaluation tool, such as: urticaria activity score (UAS7), angioedema activity score (AAS), Dermatology Life Quality Index (DLQI), Angioedema Quality of Life (AE-QoL), urticaria control test (UCT), angioedema control test (AECT), or Chronic Urticaria Quality of Life Questionnaire (CU-Q2oL)? **AND**

   □ No □ Yes

5. Has the member had a trial and failure or inadequate response to the use for ≥ 1 month of a second-generation H1-antihistamine product; **AND**

   □ No □ Yes

6. Has the member had a trial and failure or inadequate response to the use for ≥ 1 month of at least one of the following:

   a. Up-dosing/dose advancement (up to 4-fold) of a second generation H1-antihistamine

   b. Add-on therapy with a leukotriene antagonist (e.g., montelukast, zafirlukast, etc.)

   c. Add-on therapy with another H1-antihistamine

   d. Add-on therapy with a H2-antagonist (e.g. ranitidine, famotidine, etc.)

   □ No □ Yes

7. Will coadministration with another monoclonal antibody be avoided (e.g., mepolizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko)? **AND**

   □ No □ Yes

Clinical Criteria CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSwNP):

1. Is the member 18 years of age or older? **AND**

   □ No □ Yes

2. Has the member failed on at least 8 weeks of intranasal corticosteroid therapy? **AND**

   □ No □ Yes

3. Does the member have at least 3 of the following indicators for biologic treatment:

   [**Note**: members with a history of sino-nasal surgery are only required to have at least 3 of the indicators]:

a. Patient has evidence of type 2 inflammation (e.g., tissue eosinophils ≥10/hpf, blood eosinophils ≥ 150 cells/µL, or total IgE ≥ 100 IU/mL)
b. Patient has required ≥2 courses of systemic corticosteroids per year or >3 months of low dose corticosteroids, unless contraindicated
c. Disease significantly impairs the patient's quality of life
d. Patient has experienced significant loss of smell
e. Patient has a comorbid diagnosis of asthma; **AND**

□ No □ Yes

4. The member does not have any of the following:

a. Antrochoanal polyps
b. Nasal septal deviation that would occlude at least one nostril
c. Disease with lack of signs of type 2 inflammation
d. Cystic fibrosis
e. Mucoceles; AND

□ No □ Yes

5. Have other causes of nasal congestion/obstruction been ruled out (e.g., acute sinusitis, nasal infection or upper respiratory infection, rhinitis medicamentosa, tumors, infections, granulomatosis)? **AND**

□ No □ Yes

6. Has the physician assessed baseline disease severity utilizing an objective measure/tool? **AND**

□ No □ Yes

7. Will therapy be used in combination with intranasal corticosteroids unless unable to tolerate or is contraindicated?

□ No □ Yes

8. Will coadministration with another monoclonal antibody be avoided (e.g., mepolizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko)? **AND**

□ No □ Yes

Clinical Criteria for IgE-Mediated Food Allergy:

1. Is the member 1 year of age or older? **AND**

□ No □ Yes

2. Is the prescribing physician an allergist or immunologist or has an allergist or immunologist been consulted? **AND**

□ No □ Yes

3. Does the member have a diagnosed food allergy as confirmed by:

a. A positive skin prick test under a drop of allergen extract; **OR**
b. A positive IgE screening (≥ kUA/L) to identified foods? **AND**

□ No □ Yes

4. Will the member continue to practice allergen avoidance?

□ No □ Yes

5. Will coadministration with another monoclonal antibody be avoided (e.g., mepolizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko)? **AND**

   □ No □ Yes

For continuation of therapy for all indications, please respond to the <u>additional questions</u> below:

1. Has the member been assessed for toxicity? **AND**

   □ No □ Yes

For severe asthma renewal

2. Does the member have improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:
   a. Use of systemic corticosteroids
   b. Hospitalizations
   c. ER visits
   d. Unscheduled visits to healthcare provider
   e. Improvement from baseline in forced expiratory volume in 1 second (FEV_1)?

   □ No □ Yes

For CHRONIC IDIOPATHIC URTICARTIA/CHRONIC SPONTANEOUS URTICARIA renewal

2. Does the member have a clinical improvement as documented an objective clinical evaluation tool? (e.g., UAS7, AAS, DLQI, AE-QoL, UCT, AECT, CU-Q2oL, etc.)

   □ No □ Yes

For CRSwNP renewal

2. Does the member have disease response as indicated by improvement in signs and symptoms compared to baseline in one or more of the following: nasal/obstruction symptoms, improvement of sinus opacifications as assessed by CT-scans and/or an improvement on a disease activity scoring tool [e.g., nasal polyposis score (NPS), nasal congestion (NC) symptom severity score, sinonasal outcome test-22 (SNOT-22), etc.]? **OR**

   □ No □ Yes
3. Did the member have improvement in at least one of the following response criteria:
   - Reduction in nasal polyp size
   - Reduction in need for systemic corticosteroids
   - Improvement in quality of life
   - Improvement in sense of smell
   - Reduction of impact of comorbidities?

   □ No □ Yes

For IgE-Mediated Food Allergy renewal

2. Is the member experiencing a clinical response and improvement as attested by the prescriber?
   □ No □ Yes

7 – Prescriber Sign-Off

Additional Information –

1. **Please submit chart notes/medical records for the patient that are applicable to this request.**
2. **If member has not tried preferred agent(s) please provide rationale/explanation and any additional supporting information that should be taken into consideration for the requested medication:**

_____

_____

_____

I certify that the information provided is accurate. Supporting documentation is available for State audits.

Prescriber Signature:	**Date:**