MOLINA HEALTHCARE
Service Authorization (SA) Form
XOLAIR® (omalizumab)

If the following information is not complete, correct, or legible, the SA process can be delayed.
Please use one form per member.

MEMBER INFORMATION

Last Name:

First Name:

Medicaid ID Number:

Date of Birth: ___ – ___ – ____

Weight in Kilograms: _____

PRESCRIBER INFORMATION

Last Name:

First Name:

NPI Number:

Phone Number: ___ – ___ – ____

Fax Number: ___ – ___ – ____

DRUG INFORMATION

Drug Name/Form: _____

Strength: _____

Dosing Frequency: _____

Length of Therapy: _____

Quantity per Day: _____

(Form continued on next page.)

Revised: 06012024 | Effective: 07012024

VA-ALL-PF-16719-24

Member's Last Name:

Member's First Name:

DIAGNOSIS AND MEDICAL INFORMATION

For severe* asthma initial approval, complete the following questions to receive a 6-month approval:

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

   ☐ Yes ☐ No
6. Will coadministration with another monoclonal antibody be avoided (e.g., mepolizumab, reslizumab, benralizumab, dupilumab, tezepelumab-ekko)? **AND**
   ☐ Yes ☐ No
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)?

   ☐ Yes ☐ No
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**
   ☐ Yes ☐ No

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Member's Last Name:

Member's First Name:

9. Does the member have at least one of the following for assessment of clinical status:
    - Use of systemic corticosteroids
    - Use of inhaled corticosteroids
    - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to condition
    - Forced expiratory volume in 1 second (FEV_1)?

    ☐ Yes ☐ No

For severe* asthma renewal, complete the following questions to receive a 12-month approval:

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

    ☐ Yes ☐ No

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

    ☐ Yes ☐ No

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Member's Last Name: | | | | | | | | | | | | |

Member's First Name: | | | | | | | | | | | | |

For CHRONIC IDIOPATHIC URTICARTIA/CHRONIC SPONTANEOUS URTICARIA initial approval, complete the following questions to receive a 6-month approval:

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

    ☐ Yes ☐ No

13. Is the underlying cause of the patient's condition is NOT considered to be any other allergic condition(s) or other form(s) of urticaria? **AND**

    ☐ Yes ☐ No

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

    ☐ Yes ☐ No

15. 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**

    ☐ Yes ☐ No

16. Has the member had an inadequate response to a one or more-month trial on previous therapy with scheduled dosing of a second-generation H1-antihistamine product; **AND**

    ☐ Yes ☐ No

17. Has the member had an inadequate response to a one or more-month trial on previous therapy with scheduled dosing of at least one of the following:

    - Up-dosing/dose advancement (up to 4-fold) of a second generation H1-antihistamine
    - Add-on therapy with a leukotriene antagonist (e.g., montelukast, zafirlukast, etc.)
    - Add-on therapy with another H1-antihistamine**
    - Add-on therapy with a H2-antagonist (e.g. ranitidine, famotidine, etc.)

    ☐ Yes ☐ No

For CHRONIC IDIOPATHIC URTICARTIA/CHRONIC SPONTANEOUS URTICARIA renewal, complete the following questions to receive a 12-month approval:

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

    ☐ Yes ☐ No

19. 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.)

    ☐ Yes ☐ No

(Form continued on next page.)

Revised: 06012024 | Effective: 07012024

Member's Last Name:

Member's First Name:

For CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSwNP) initial approval, complete the following questions to receive a 6-month approval:

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

☐ Yes ☐ No

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

☐ Yes ☐ No

22. 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]:

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

☐ Yes ☐ No

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

- Antrochoanal polyps
- Nasal septal deviation that would occlude at least one nostril
- Disease with lack of signs of type 2 inflammation
- Cystic fibrosis
- Mucoceles; AND

☐ Yes ☐ No

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24. 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**

☐ Yes ☐ No

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

☐ Yes ☐ No

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

☐ Yes ☐ No

For CRSwNP renewal, complete the following questions to receive a 12-month approval:

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

☐ Yes ☐ No

28. 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**

☐ Yes ☐ No

29. 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?

☐ Yes ☐ No

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Member's Last Name: | | | | | | | | | | | | |

Member's First Name: | | | | | | | | | | | | |

For IgE-Mediated Food Allergy initial approval, complete the following questions to receive a 6-month approval:

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

   ☐ Yes ☐ No

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

   ☐ Yes ☐ No

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**

   ☐ Yes ☐ No

4. Will the member continue to practice allergen avoidance?

   ☐ Yes ☐ No

For IgE-Mediated Food Allergy initial renewal, complete the following questions to receive a 12-month approval:

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

   ☐ Yes ☐ No

2. Is the member experiencing a clinical response and improvement as attested by the prescriber?

   ☐ Yes ☐ No

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

- 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 FEV_1) < 60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

Prescriber Signature (Required) **Date**

By signature, the physician confirms the above information is accurate and verifiable by member records.

Please include ALL requested information; Incomplete forms will delay the SA process.
Submission of documentation does NOT guarantee coverage by Molina Healthcare.

The completed form may be: **FAXED to (844) 278-5731**, or you may call (800) 424-4518 (TTY: 711).

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