CardinalCare
Virginia's Medicaid Program

COMMONWEALTH OF VIRGINIA DEPARTMENT OF MEDICAL ASSISTANCE SERVICES

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.

Physician Administered Drug: This form is only to be used for members obtaining the medication from a pharmacy through billing the pharmacy benefit at point-of-sale. Please refer to Appendix B: Physician Adminstered Drug Criteria for members/providers who will obtain the medication through the medical benefit.

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: _____

The Virginia Department of Medical Assistance Services considers the use of concomitant therapy with Cinqair®, Dupixent®, Exdensur®, 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.

(Form continued on next page.)

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, depemokimab-ulaa)? **AND**
   ☐ Yes ☐ No
7. Will this medication be used for add-on maintenance treatment in members regularly receiving **both** of the following (unless otherwise contraindicated):
   - 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

(Form continued on next page.)

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. 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

For chronic idiopathic urticartia/chronic spontaneous urticaria initial approval, complete the following questions to receive a 6-month approval:

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

    ☐ Yes ☐ No

12. 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

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

    ☐ Yes ☐ No

14. 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

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

15. 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

16. 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:

17. 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

For chronic rhinosinusitis with nasal polyps (CRSwNP) initial approval, complete the following questions to receive a 6-month approval:

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

☐ Yes ☐ No

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

☐ Yes ☐ No

20. 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

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

21. 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

22. 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

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

    ☐ Yes ☐ No

24. 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:

25. 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

26. 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

(Form continued on next page.)

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:

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

☐ Yes ☐ No

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

☐ Yes ☐ No

29. 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 to identified foods? **AND**

☐ Yes ☐ No

30. 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:

31. 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)
▪ Asthma that remains uncontrolled despite optimized treatment with high-dose ICS-LABA
▪ Asthma that 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 FEV_1) < 60%
▪ Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

(Form continued on next page.)

Member's Last Name: **Member's First Name:**

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 the Department of Medical Assistance Services.

The completed form may be: **FAXED TO 800-932-6651**, phoned to 800-932-6648, or mailed to:
Prime Therapeutics Management LLC
Attn: GV – 4201
P.O. Box 64811
St. Paul, MN 55164-0811