Fax completed form to Navitus at: 855-668-8553
For questions, please call: 877-908-6023

TEXAS MEDICAID

Drug Prior Authorization
Monoclonal Antibodies: omalizumab (XOLAIR)

Request Information (required)
This request is: ☐ **Expedited* (Urgent)** ☐ **Standard (Non-Urgent)** *Expedited means the standard review time may seriously harm the member's life, health, or ability to regain maximum function.

Member Information (required)			Prescriber Information (required)		
Member Name:			Prescriber Name:		
Member Insurance ID #:			NPI # :	Specialty:	
Date of Birth:			Office Phone:		
Member Phone:			Office Fax:		
Member Street Address:			Office Street Address:		
City:	State:	Zip:	City:	State:	Zip:

Please fill out the following information:

1. Medication Requested (Name):
(Go to #2)

2. Quantity Requested:
(Go to #3)

3. Dose Requested (Strength):
(Go to #4)

4. Dosing Instructions:
(Go to #5)

Required Criteria

5. Provide primary diagnosis including ICD-10 code(s):
(Go to #6)

Clinical Criteria (required)

6. Please indicate which of the following applies for this request:

- ◯ Initial Therapy
(Go to #7)
- ◯ Continuation of Therapy
(Go to #26)

Initial Therapy

7. Is the member greater than or equal to (≥) six (6) years of age?

- ◯ Yes
  (Go to #8)
- ◯ No (Deny)
  (Go to #8)

8. Does the member have a diagnosis of moderate to severe persistent asthma in the last 730 days?

- ◯ Yes
  (Go to #9)
- ◯ No
  (Go to #15)

9. Has the member had a positive skin test or in vitro reactivity to a perennial aeroallergen in the last five (5) years?

- ◯ Yes
  (Go to #10)
- ◯ No
  (Go to #15)

10. Does the member have at least 60 days therapy with an inhaled corticosteroid (ICS) in the last 90 days **OR** does the member have an intolerance, hypersensitivity, or contraindication to inhaled corticosteroids?

    Examples of inhaled corticosteroids include: ALVESCO, ARNUITY ELLIPTA, ASMANEX HFA, ASMANEX TWISTHALER, BREO ELLIPTA, budesonide (PULMICORT), DULERA, FLOVENT DISKUS, FLOVENT HFA, fluticasone-salmeterol (ADVAIR DISKUS/ADVAIR HFA, WIXELA), QVAR REDIHALER, and SYMBICORT.

- ◯ Yes
  (Go to #11)
- ◯ No
  (Go to #15)

11. Does the member have at least 60 days therapy with a long-acting beta agonist (LABA), leukotriene modifier (LTM), long-acting muscarinic antagonist (LAMA) or theophylline (THEO-24) in the last 90 days **OR** does the member have an intolerance or hypersensitivity to all classes listed?

    Examples of long-acting beta agonists include: SEREVENT and TRELEGY ELLIPTA.

    Examples of leukotriene modifiers include: montelukast (SINGULAIR), zafirlukast, and zileuton (ZYFLO).

    Examples of long-acting muscarinic antagonists include: SPIRIVA and TRELEGY ELLIPTA.

    ◯ Yes
    (Go to #12)

    ◯ No
    (Go to #15)

12. Is the member's pretreatment Immunoglobulin E (IgE) level greater than or equal to (≥) 30 IU/mL and less than or equal to (≤) 700 IU/mL (12 years and older) **OR** greater than or equal to (≥) 30 IU/mL and less than or equal to (≤) 1300 IU/mL (six [6] to 12 years of age)? [Manual]

    ◯ Yes
    (Go to #13)

    ◯ No
    (Go to #15)

13. Does the member weigh more than 150kg? [Manual]

    ◯ Yes
    (Go to #15)

    ◯ No
    (Go to #14)

14. Is the requested dose (based on the member's pretreatment serum Immunoglobulin E (IgE) level and body weight) equal to the dose defined in the United States Food and Drug Administration (FDA) labeling, not to exceed 375 mg every two (2) weeks? [Manual]

    ◯ Yes
    (Go to #25)

    ◯ No
    (Go to #15)

15. Does the member have a diagnosis of chronic spontaneous urticaria (CSU) in the last 730 days?

- ◯ Yes
  (Go to #16)
- ◯ No
  (Go to #19)

16. Is the member greater than or equal to (≥) 12 years of age?

- ◯ Yes
  (Go to #17)
- ◯ No (Deny)
  (Go to #17)

17. Does the member have at least 60 days therapy with an H1 antihistamine in the last 90 days **OR** does the member have an intolerance, hypersensitivity, or contraindication to all H1 antihistamines?

    Examples of H1 antihistamines include: cetirizine, clemastine, cyproheptadine, desloratadine (CLARINEX), diphenhydramine (BANOPHEN, SILADRYL), fexofenadine, hydroxyzine (VISTARIL), levocetirizine, and loratadine.

- ◯ Yes
  (Go to #18)
- ◯ No
  (Go to #19)

18. Is the requested dose equal to the dose defined in the United States Food and Drug Administration (FDA) labeling, not to exceed 300 mg every four (4) weeks? [Manual]

- ◯ Yes
  (Go to #25)
- ◯ No
  (Go to #19)

19. Does the member have a diagnosis of nasal polyps in the last 730 days?

- ◯ Yes
  (Go to #20)
- ◯ No (Deny)
  (Go to #20)

20. Is the member greater than or equal to (≥) 18 years of age?

- ◯ Yes
  (Go to #21)
- ◯ No (Deny)
  (Go to #21)

21. Does the member have at least 90 days therapy with an intranasal corticosteroid (INC) in the last 120 days **OR** does the member have an intolerance, hypersensitivity, or contraindication to nasal corticosteroids?

    Examples of intranasal corticosteroids include: azelastine-fluticasone (DYMISTA), BECONASE AQ, budesonide, flunisolide, fluticasone propionate (XHANCE), mometasone furoate (NASONEX), OMNARIS, QNASL, and triamcinolone nasal spray.

- ◯ Yes
  (Go to #22)
- ◯ No (Deny)
  (Go to #22)

22. Is the member's pretreatment Immunoglobulin E (IgE) level greater than or equal to (≥) 30 IU/mL and less than or equal to (≤) 1500 IU/mL? [Manual]

- ◯ Yes
  (Go to #23)
- ◯ No (Deny)
  (Go to #23)

23. Does the member weigh more than 150kg? [Manual]

- ◯ Yes (Deny)
  (Go to #24)
- ◯ No
  (Go to #24)

24. Is the requested dose (based on the member's pretreatment serum Immunoglobulin E (IgE) level and body weight) equal to the dose defined in the United States Food and Drug Administration (FDA) labeling, not to exceed 600 mg every two (2) weeks? [Manual]

- ◯ Yes
  (Go to #25)
- ◯ No (Deny)
  (Go to #25)

25. Will the member have concurrent therapy with another monoclonal antibody agent indicated for the treatment of asthma, chronic spontaneous urticaria or nasal polyps?

    Examples of monoclonal antibody agents include: CINQAIR, DUPIXENT, FASENRA, NUCALA, and TEZSPIRE.

- ◯ Yes (Deny)
  (Go to #37)
- ◯ No (Approve - 365 days)
  (Go to #37)

Continuation of Established Therapy

26. Does the member have a diagnosis of moderate to severe persistent asthma in the last 730 days?

- ◯ Yes
  (Go to #27)
- ◯ No
  (Go to #30)

27. Does the member have current therapy with an inhaled corticosteroid that will continue during therapy with XOLAIR **OR** does the client have an intolerance, hypersensitivity, or contraindication to inhaled corticosteroids?

    Examples of inhaled corticosteroids include: ALVESCO, ARNUITY ELLIPTA, ASMANEX HFA, ASMANEX TWISTHALER, BREO ELLIPTA, budesonide (PULMICORT), DULERA, FLOVENT DISKUS, FLOVENT HFA, fluticasone-salmeterol (ADVAIR DISKUS/ADVAIR HFA, WIXELA), QVAR REDIHALER, and SYMBICORT.

- ◯ Yes
  (Go to #28)
- ◯ No
  (Go to #30)

28. Does the member weigh more than 150 kg? [Manual]

- ◯ Yes
  (Go to #30)
- ◯ No
  (Go to #29)

29. Is the requested dose (based on the member's pretreatment serum Immunoglobulin E (IgE) level and body weight) equal to the dose defined in the United States Food and Drug Administration (FDA) labeling, not to exceed 375 mg every two (2) weeks? [Manual]

- ◯ Yes
  (Go to #36)
- ◯ No
  (Go to #30)

30. Does the member have a diagnosis of chronic spontaneous urticaria (CSU) in the last 730 days?

- ◯ Yes
  (Go to #31)
- ◯ No
  (Go to #32)

31. Is the requested dose equal to the dose defined in the United States Food and Drug Administration (FDA) labeling, not to exceed 300 mg every four (4) weeks? [Manual]

- ◯ Yes
  (Go to #36)
- ◯ No
  (Go to #32)

32. Does the member have a diagnosis of nasal polyps in the last 730 days?

- ◯ Yes
  (Go to #33)
- ◯ No (Deny)
  (Go to #33)

33. Does the member have current therapy with an intranasal corticosteroid that will continue during therapy with XOLAIR **OR** does the member have an intolerance, hypersensitivity, or contraindication to nasal corticosteroids?

Examples of intranasal corticosteroids include: azelastine-fluticasone (DYMISTA), BECONASE AQ, budesonide, flunisolide, fluticasone propionate (XHANCE), mometasone furoate (NASONEX), OMNARIS, QNASL, and triamcinolone nasal spray.

- ◯ Yes
  (Go to #34)
- ◯ No (Deny)
  (Go to #34)

34. Does the member weigh more than 150 kg? [Manual]

- ◯ Yes (Deny)
  (Go to #35)
- ◯ No
  (Go to #35)

35. Is the requested dose (based on the member's pretreatment serum Immunoglobulin E (IgE) level and body weight) equal to the dose defined in the United States Food and Drug Administration (FDA) labeling, not to exceed 600 mg every two (2) weeks? [Manual]

- ◯ Yes
  (Go to #36)
- ◯ No (Deny)
  (Go to #36)

36. Will the member have concurrent therapy with another monoclonal antibody agent indicated for the treatment of asthma, chronic spontaneous urticaria (CSU) or nasal polyps?

Examples of monoclonal antibody agents include: CINQAIR, DUPIXENT, FASENRA, NUCALA, and TEZSPIRE.

- ◯ Yes (Deny)
  (Go to #37)
- ◯ No (Approve - 365 days)
  (Go to #37)

Additional Information

37. Please provide any additional information we should consider (or attach any supporting documents):
(END)

Submission Information (required)

Prescriber Signature: _____ **Date:** _____

**** PLEASE FAX COMPLETED FORM TO: 855-668-8553 ****

If criteria not met, submit chart documentation with form citing complex medical circumstances.
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