Xolair

CareFirst Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518.** For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

Patient's Name: _____ **Date**: _____
Patient's ID: _____ **Patient's Date of Birth:** _____
Physician's Name: _____
Specialty: _____ **NPI#:** _____
Physician Office Telephone: _____ **Physician Office Fax:** _____

Referring Provider Info: ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Rendering Provider Info: ❑ **Same as Referring Provider** ❑ **Same as Requesting Provider**
Name: _____ **NPI#:** _____
Fax: _____ **Phone:** _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____*kg*

Patient Height: _____*cm*

What is the ICD-10 code? _____

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

 CareFirst Xolair 1656-A SGM SOC 5368-A – 09/2024.

CVS Caremark Specialty Pharmacy ● 2211 Sanders Road NBT-6 ● Northbrook, IL 60062
Phone: 1-888-877-0518 ● Fax: 1-855-330-1720 ● www.caremark.com

Site of Service Questions (SOS):

A. Where will this drug be administered?
- ❑ Ambulatory surgical, *skip to Clinical Criteria Questions*
- ❑ Home infusion, *skip to Clinical Criteria Questions*
- ❑ Off-campus Outpatient Hospital, *Continue to B*
- ❑ On-campus Outpatient Hospital, *Continue to B*
- ❑ Physician office, *skip to Clinical Criteria Questions*
- ❑ Pharmacy, *skip to Clinical Criteria Questions*

B. Is the patient less than 14 years of age?
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to C*

C. Is this request to continue previously established treatment with the requested medication? ***ACTION REQUIRED: If No, please attach supporting clinical documentation.***
- ❑ Yes - This is a continuation of an existing treatment., *Continue to D*
- ❑ No - This is a new therapy request (patient has not received requested medication in the last 6 months)*., skip to Clinical Criteria Questions*

D. Has the patient experienced an adverse event with the requested product that has not responded to conventional interventions (eg acetaminophen, steroids, diphenhydramine, fluids or other pre-medications) or a severe adverse event (anaphylaxis, anaphylactoid reactions, myocardial infarction, thromboembolism, or seizures) during or immediately after administration? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.***
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to E*

E. Is the patient medically unstable which may include respiratory, cardiovascular, or renal conditions that may limit the member's ability to tolerate a large volume or load or predispose the member to a severe adverse event that cannot be managed in an alternate setting without appropriate medical personnel and equipment?
ACTION REQUIRED: If Yes, please attach supporting clinical documentation.
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to F*

F. Does the patient have significant behavioral issues and/or physical or cognitive impairment that would impact the safety of the infusion therapy AND the patient does not have access to a caregiver? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.***
- ❑ Yes, *skip to Clinical Criteria Questions*
- ❑ No, *Continue to G*

G. Are ***all*** alternative infusion sites (pharmacy, physician office, ambulatory care, etc.) **greater than** 30 miles from the patient's home? ***ACTION REQUIRED: If Yes, please attach supporting documentation.***
- ❑ Yes, *continue to Clinical Criteria Questions*
- ❑ No, *continue to Clinical Criteria Questions*

Criteria Questions:

1. Will the requested drug be used concomitantly with any other biologic or targeted synthetic drug for the same indication?

❒ Yes, *Continue to 2*
❒ No, *Continue to 2*

2. What is the diagnosis?

❒ Asthma, *Continue to 3*
❒ Chronic spontaneous urticaria (CSU), *Continue to 20*
❒ Chronic rhinosinusitis with nasal polyps (CRSwNP), *Continue to 28*
❒ IgE-mediated food allergy, *Continue to 46*
❒ Immune checkpoint inhibitor-related toxicity, *Continue to 60*
❒ Systemic mastocytosis, *Continue to 62*
❒ Other, please specify. _____, *No further questions*

3. Is the requested drug being prescribed by or in consultation with an allergist, immunologist, or pulmonologist?

❒ Yes, *Continue to 4*
❒ No, *Continue to 4*

4. Is the patient 6 years of age or older?

❒ Yes, *Continue to 5*
❒ No, *Continue to 5*

5. Is the request for continuation of therapy with the requested drug?

❒ Yes, *Continue to 6*
❒ No, *Continue to 11*

6. Is the patient currently receiving Xolair through samples or a manufacturer's patient assistance program?

❒ Yes, *Continue to 11*
❒ No, *Continue to 7*
❒ Unknown, *Continue to 11*

7. Will the requested drug be used for the treatment of moderate-to-severe asthma?

❒ Yes, *Continue to 8*
❒ No, *Continue to 8*

8. Has the patient's asthma control improved on Xolair treatment as demonstrated by a reduction in the frequency and/or severity of symptoms and exacerbations? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation supporting improvement in asthma control.

❒ Yes, *Continue to 10*
❒ No, *Continue to 9*

9. Has the patient's asthma control improved on Xolair treatment as demonstrated by a reduction in the daily maintenance oral corticosteroid dose? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation supporting improvement in asthma control.

❒ Yes, *Continue to 10*
❒ No, *Continue to 10*

10. Will the patient continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Xolair?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

11. Has the patient received in the past year or is currently receiving a biologic drug (e.g., Nucala, Cinqair) indicated for treatment of asthma (excluding receiving the drug via samples or a manufacturer's patient assistance program)? ***ACTION REQUIRED***: If Yes, please attach chart notes, medical record documentation, or claims history of previous medications tried including drug, dose, frequency and duration.
❒ Yes, *No Further Questions*
❒ No, *Continue to 12*

12. Will the requested drug be used for the treatment of moderate-to-severe asthma?
❒ Yes, *Continue to 13*
❒ No, *Continue to 13*

13. Does the patient have uncontrolled asthma as demonstrated by experiencing two or more asthma exacerbations requiring oral or injectable corticosteroid treatment within the past year? ***ACTION REQUIRED***: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous corticosteroid use for asthma exacerbations including drug, dose, frequency and duration.
❒ Yes, *Continue to 16*
❒ No, *Continue to 14*

14. Does the patient have uncontrolled asthma as demonstrated by experiencing one or more asthma exacerbation(s) resulting in hospitalization or emergency medical care visit(s) within the past year? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation of previous asthma exacerbation(s) requiring hospitalization or emergency medical visit(s).
❒ Yes, *Continue to 16*
❒ No, *Continue to 15*

15. Does the patient have uncontrolled asthma as demonstrated by experiencing poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma) within the past year? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation of poor symptom control.
❒ Yes, *Continue to 16*
❒ No, *Continue to 16*

16. Prior to requesting Xolair, did the patient have inadequate asthma control despite current treatment with both of the following drugs at optimized doses: A) Medium-to-high-dose inhaled corticosteroid, AND B) Additional controller (i.e., long-acting beta2-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)? ***ACTION REQUIRED***: If Yes, please attach chart notes, medical record documentation, or claims history of previous medications tried including drug, dose, frequency and duration.
❒ Yes, *Continue to 17*
❒ No, *Continue to 17*

17. Does the patient have a positive skin test or in vitro reactivity to at least one perennial aeroallergen?
❒ Yes, *Continue to 18*
❒ No, *Continue to 18*
18. Prior to requesting Xolair, what is the patient's pre-treatment IgE level (IU/mL)? Please enter pre-treatment IgE level in IU/mL. Indicate pre-treatment IgE level in IU/mL. ***ACTION REQUIRED***: Please attach chart notes or medical record documentation with the patient's pre-treatment IgE level.
❒ _____ IU/mL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 19*
❒ Unknown, *Continue to 19*

19. Will the patient continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Xolair?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

20. Is the medication being prescribed by or in consultation with an allergist, immunologist or dermatologist?
❒ Yes, *Continue to 21*
❒ No, *Continue to 21*

21. Is the patient 12 years of age or older?
❒ Yes, *Continue to 22*
❒ No, *Continue to 22*

22. Is the request for continuation of therapy with the requested drug?
❒ Yes, *Continue to 23*
❒ No, *Continue to 25*

23. Is the patient currently receiving Xolair through samples or a manufacturer's patient assistance program?
❒ Yes, *Continue to 25*
❒ No, *Continue to 24*
❒ Unknown, *Continue to 25*

24. Has the patient experienced a positive response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation supporting positive response to therapy.
❒ Yes, *No Further Questions*
❒ No, *Continue to 25*

25. For how long has the patient had a spontaneous onset of wheals (hives), angioedema, or both?
_____ weeks, *Continue to 26*

26. Does the patient remain symptomatic despite treatment with up-dosing (in accordance with EAACI/GA2LEN/EDF/WAO guidelines) of a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks? ***ACTION REQUIRED***: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried showing inadequate response to up-dosing of a second-generation H1 antihistamine.

❒ Yes, *Continue to 27*
❒ No, *Continue to 27*

27. Has the patient been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis)?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

28. Is the medication being prescribed by or in consultation with an allergist, immunologist or otolaryngologist?
❒ Yes, *Continue to 29*
❒ No, *Continue to 29*

29. Is the patient an adult (18 years of age or older)?
❒ Yes, *Continue to 30*
❒ No, *Continue to 30*

30. Is the request for continuation of therapy with the requested drug?
❒ Yes, *Continue to 31*
❒ No, *Continue to 35*

31. Is the patient currently receiving Xolair through samples or a manufacturer's patient assistance program?
❒ Yes, *Continue to 35*
❒ No, *Continue to 32*
❒ Unknown, *Continue to 35*

32. Has the patient experienced a positive response as evidenced by improvement in signs and symptoms (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain, or reduction in corticosteroid use)? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation supporting positive response to therapy.
❒ Yes, *Continue to 33*
❒ No, *Continue to 33*

33. Will the patient continue to use a daily intranasal corticosteroid while being treated with the requested medication?
❒ Yes, *No Further Questions*
❒ No, *Continue to 34*

34. Are intranasal corticosteroids contraindicated or not tolerated?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

35. Has the patient received in the past year or is currently receiving a biologic drug (e.g., Dupixent, Nucala) indicated for treatment of chronic rhinosinusitis with nasal polyps (CRSwNP) (excluding receiving the drug via samples or a manufacturer's patient assistance program? ***ACTION REQUIRED***: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency and duration.

❒ Yes, *No Further Questions*
❒ No, *Continue to 36*

36. Does the patient have bilateral nasal polyps and chronic symptoms of sinusitis?
❒ Yes, *Continue to 37*
❒ No, *Continue to 37*

37. Has the patient had intranasal corticosteroid treatment for at least 2 months? ***ACTION REQUIRED***: If Yes, please attach chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency and duration.
❒ Yes, *Continue to 39*
❒ No, *Continue to 38*

38. Are intranasal corticosteroids contraindicated or not tolerated? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation of clinical reason to avoid therapy.
❒ Yes, *Continue to 39*
❒ No, *Continue to 39*

39. Has the patient had a bilateral nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation showing endoscopy, rhinoscopy, or CT details (e.g., polyps location, size).
❒ Yes, *Continue to 42*
❒ No, *Continue to 40*

40. Does the patient have a Meltzer Clinical Score of 2 or higher in both nostrils? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation of Meltzer Clinical score.
❒ Yes, *Continue to 42*
❒ No, *Continue to 41*

41. Does the patient have a total endoscopic nasal polyps score (NPS) of at least 5 with a minimum score of 2 for each nostril? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation of endoscopic nasal polyps score.
❒ Yes, *Continue to 42*
❒ No, *Continue to 42*

42. Does the patient have symptoms of nasal blockage, congestion, or obstruction?
❒ Yes, *Continue to 43*
❒ No, *Continue to 43*

43. Does the patient have rhinorrhea (anterior/posterior), reduction or loss of smell, or facial pain or pressure?
❒ Yes, *Continue to 44*
❒ No, *Continue to 44*

44. Will the patient continue to use a daily intranasal corticosteroid while being treated with Xolair?
❒ Yes, *No Further Questions*
❒ No, *Continue to 45*

45. Are intranasal corticosteroids contraindicated or not tolerated?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

46. Is the medication being prescribed by or in consultation with an allergist or immunologist?
❒ Yes, *Continue to 47*
❒ No, *Continue to 47*

47. Is the patient 1 year of age or older?
❒ Yes, *Continue to 48*
❒ No, *Continue to 48*

48. Is the request for continuation of therapy with the requested drug?
❒ Yes, *Continue to 49*
❒ No, *Continue to 52*

49. Is the patient currently receiving Xolair through samples or a manufacturer's patient assistance program?
❒ Yes, *Continue to 52*
❒ No, *Continue to 50*
❒ Unknown, *Continue to 52*

50. Has the patient achieved or maintained a positive clinical response as evidenced by a decrease in hypersensitivity (e.g., moderate to severe skin, respiratory or gastrointestinal [GI] symptoms) to food-allergen? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation supporting positive response to therapy.
❒ Yes, *Continue to 51*
❒ No, *Continue to 51*

51. Will the patient continue to maintain a food-allergen avoidance diet?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

52. Has the patient's IgE-mediated food allergy been confirmed by a pre-treatment allergen-specific IgE level?
❒ Yes, *Continue to 53*
❒ No, *Continue to 54*

53. What is the patient's pre-treatment allergen-specific serum IgE level in IU/mL? ***ACTION REQUIRED***: Please attach chart notes, medical record documentation, or laboratory tests showing the patient's pre-treatment allergen-specific IgE level.
❒ Greater than or equal to 6 IU/mL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 56*
❒ Less than 6 IU/mL ***ACTION REQUIRED****: Submit supporting documentation, Continue to 54*

54. Has the patient's IgE-mediated food allergy been confirmed by a skin-prick test (SPC)?
❒ Yes, *Continue to 55*
❒ No, *Continue to 55*

55. What is the patient's skin-prick test (SPC) wheal diameter? ***ACTION REQUIRED***: Please attach chart notes, medical record documentation, or laboratory tests showing the skin-prick test wheal diameter.

_____ mm ***ACTION REQUIRED****: Submit supporting documentation, Continue to 56*

56. Has the patient had a positive physician controlled oral food challenge (e.g., moderate to severe skin, respiratory, or gastrointestinal [GI] symptoms)? ***ACTION REQUIRED***: Please attach chart notes or medical record documentation showing positive result of a physician controlled oral food challenge.

❒ Yes, *Continue to 58*
❒ No, *Continue to 57*

57. Does the patient have a history of a systemic reaction to a food? ***ACTION REQUIRED***: If yes, please attach chart notes or medical record documentation showing a history of a systemic reaction to a food.

❒ Yes, *Continue to 58*
❒ No, *Continue to 58*

58. What is the patient's pre-treatment serum IgE level in IU/mL? Indicate pre-treatment serum IgE level in IU/mL. ***ACTION REQUIRED***: Please attach chart notes, medical record documentation, or laboratory tests showing pre-treatment serum IgE level.

_____ IU/mL, ***ACTION REQUIRED****: Submit supporting documentation, Continue to 59*

59. Will the patient continue to maintain a food-allergen avoidance diet?

❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

60. Does the patient have a refractory case of immune-therapy related severe (G3) pruritus?

❒ Yes, *Continue to 61*
❒ No, *Continue to 61*

61. Does the patient have elevated IgE levels? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation showing pre-treatment IgE level.

❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

62. Does the patient have the major and at least one minor diagnostic criterion for systemic mastocytosis present (see Appendix)? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation supporting diagnosis.

❒ Yes, *Continue to 64*
❒ No, *Continue to 63*

63. Does the patient have three or more minor diagnostic criteria present for systemic mastocytosis (see Appendix)? ***ACTION REQUIRED***: If Yes, please attach chart notes or medical record documentation supporting diagnosis.

❒ Yes, *Continue to 64*
❒ No, *Continue to 64*

64. Is Xolair being prescribed as a step-wise prophylactic treatment for chronic mast cell mediator-related cardiovascular and pulmonary symptoms?

❒ Yes, *Continue to 65*
❒ No, *Continue to 66*

65. Has the member tried both of the following: A) H1 blockers and H2 blockers, and B) Corticosteroids?
ACTION REQUIRED: If Yes, please attach chart notes, medical records, or claims history of previous medications tried.
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

66. Is Xolair being prescribed for prevention of recurrent unprovoked anaphylaxis?
❒ Yes, *No Further Questions*
❒ No, *Continue to 67*

67. Is Xolair being prescribed for prevention of hymenoptera or food-induced anaphylaxis?
❒ Yes, *Continue to 68*
❒ No, *Continue to 69*

68. Does the patient have negative specific IgE or a negative skin test?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

69. Is Xolair being prescribed to improve tolerability of venom immunotherapy?
❒ Yes, *No Further Questions*
❒ No, *No Further Questions*

APPENDIX

2022 WHO Diagnostic Criteria for Systemic Mastocytosis

A. Major Criteria: multifocal, dense infiltrates of mast cells (at least 15 mast cells in aggregates) detected in sections of bone marrow and/or other extracutaneous organs
B. Minor Criteria
    1. Greater than 25% of all mast cells are atypical cells (type 1 or type II) on bone marrow smears or are spindle-shaped in dense and diffuse mast cell infiltrates in bone marrow or other extracutaneous organ(s)
    2. Activating *KIT* point mutation(s) at codon 816 or in other critical regions of *KIT* in the bone marrow or other extracutaneous organ(s)
    3. Mast cells in bone marrow, blood, or other extracutaneous organs aberrantly express one or more of the following antigens: CD2, CD25, CD30
    4. Baseline serum tryptase concentration greater than 20 ng/mL in the absence of a myeloid associated hematologic neoplasm (AHN). In the case of a known hereditary alpha-tryptasemia (HαT), the tryptase level should be adjusted.

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____
Prescriber or Authorized Signature **Date (mm/dd/yy)**