Xolair

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*

Site of Service Questions (SOS):

A. Indicate the site of service requested:
- ❑ On Campus Outpatient Hospital
- ❑ Off Campus Outpatient Hospital
- ❑ Home infusion, *skip to Criteria Questions*
- ❑ Physician office, *skip to Criteria Questions*
- ❑ Ambulatory surgical, *skip to Criteria Questions*
- ❑ Pharmacy, *skip to Criteria Questions*

B. Is this request to continue previously established treatment with the requested medication?
- ❑ Yes – This is a continuation of an existing treatment
- ❑ No – This is a new therapy request (patient has not received requested medication in the last 3 months). *Skip to Clinical Criteria Questions*

C. 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 an infusion? ***ACTION REQUIRED: If Yes, please attach supporting clinical documentation.***
- ❑ Yes, *skip to Clinical Criteria Questions* ❑ No

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

D. 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

E. 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 ❑ No

Criteria Questions:

1. What is the diagnosis?
   ❑ Asthma
   ❑ Chronic spontaneous urticaria (CSU)
   ❑ Nasal polyps
   ❑ Immune checkpoint inhibitor-related toxicity
   ❑ Systemic mastocytosis
   ❑ Other _____

2. What is the ICD-10 code? _____

Complete the following section based on the patient's diagnosis, if applicable.

Section A: Asthma

2. Is the medication prescribed by or in consultation with an allergist, immunologist, or pulmonologist?
   ❑ Yes ❑ No

4. Is the request for continuation of therapy with Xolair? ❑ Yes ❑ No *If No, skip to #10*

5. Is the patient currently receiving Xolair through samples or a manufacturer's patient assistance program?
   ❑ Yes ❑ No ❑ Unknown *If Yes or Unknown, skip to #10*

6. Has the patient's asthma control improved on Xolair therapy as demonstrated by at least one of the following?
   ACTION REQUIRED: If 'Yes', please attach supporting chart notes or medical record documentation of improved asthma control. ACTION REQUIRED: Submit supporting
   Indicate below and no further questions.
   ❑ A reduction in the frequency and/or severity of symptoms and exacerbations
   ❑ A reduction in the daily maintenance oral corticosteroid dose
   ❑ None of the above

7. Will the patient continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Xolair? ❑ Yes ❑ No

8. Will the patient receive Xolair concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, or Tezspire)? ❑ Yes ❑ No *No further questions*

9. 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 submit supporting chart notes, medical records, or claims history of previous corticosteroid use for asthma exacerbations. ACTION REQUIRED: Submit supporting documentation*** *If Yes, skip to # 12* ❑ Yes ❑ No

10. Does the patient have uncontrolled asthma as demonstrated by experiencing one or more asthma exacerbation resulting in hospitalization or emergency medical care visit within the past year? ***ACTION REQUIRED: If 'Yes', please submit supporting chart notes, medical records of previous asthma exacerbations requiring hospitalization or emergency medical visit. ACTION REQUIRED: Submit supporting documentation***
    If Yes, skip to # 12 ❑ Yes ❑ No

11. 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 submit supporting chart notes or medical records.*** ***ACTION REQUIRED: Submit supporting documentation*** ❑ Yes ❑ No

12. Prior to receiving Xolair, did the patient have inadequate asthma despite current treatment with both of the following medications at optimized doses: 1) Medium-to-High dose inhaled corticosteroids AND 2) Additional controller (i.e., long acting beta2-agonist, long acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)? ***ACTION REQUIRED: If "Yes", please attach supporting chart notes, medical records, or claims history of previous medications tried including drug, dose, frequency, and duration. ACTION REQUIRED: Submit supporting documentation*** ❑ Yes ❑ No

13. Does the patient have positive skin test or *in vitro* reactivity to at least 1 perennial aeroallergen? ❑ Yes ❑ No

14. What is the patient's pre-treatment IgE level? ***ACTION REQUIRED: Please attach chart notes or medical record showing pre-treatment IgE level.*** _____IU/mL ❑ No pre-treatment IgE level

15. Will the patient continue to use maintenance asthma treatments (i.e., inhaled corticosteroids, additional controller) in combination with Xolair? ❑ Yes ❑ No

16. Will the patient receive Xolair concomitantly with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, or Tezspire)? ❑ Yes ❑ No

Section B: Chronic Idiopathic Urticaria (CIU)

18. Is the medication prescribed by or in consultation with an allergist/immunologist or dermatologist? ❑ Yes ❑ No

19. Is the request for continuation of therapy with Xolair? ❑ Yes ❑ No *If No, skip to #23*

20. Is the patient currently receiving Xolair through samples or a manufacturer's patient assistance program? *If Yes or Unknown, skip to #23* ❑ Yes ❑ No ❑ Unknown

21. Has the patient experienced a 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 of response to therapy. ACTION REQUIRED: Submit supporting documentation.*** ❑ Yes ❑ No *No further questions.*

23. How long has the patient had a spontaneous onset wheals and/or angioedema? _____weeks

24. 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 supporting chart note(s), medical record documentation, or claims history of previous medications tried showing inadequate response with up-dosing of a second-generation H1 antihistamine. ACTION REQUIRED: Submit supporting documentation.*** ❑ Yes ❑ No

25. 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

Section C: Nasal Polyps

27. Is the medication prescribed by or in consultation with an allergist/immunologist or otolaryngologist? ❑ Yes ❑ No

28. Will the patient receive Xolair concomitantly with other biologics indicated for nasal polyps (e.g., Dupixent, Nucala)? ❑ Yes ❑ No

29. Is the request for continuation of therapy with Xolair? ❑ Yes ❑ No *If No, skip to #33*

30. Is the patient currently receiving Xolair through samples or a manufacturer's patient assistance program? *If Yes or Unknown, skip to #33* ❑ Yes ❑ No ❑ Unknown

31. Has the patient experienced a 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 of response to therapy. ACTION REQUIRED: Submit supporting documentation*** ❑ Yes ❑ No *No further questions.*

33. Does the patient have bilateral nasal polyps and chronic symptoms of sinusitis? ❑ Yes ❑ No

34. 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 of previous medications tried. ACTION REQUIRED: Submit supporting documentation*** *If Yes, skip to #36* ❑ Yes ❑ No

35. 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. ACTION REQUIRED: Submit supporting documentation*** ❑ Yes ❑ No

36. Has the patient had a bilateral nasal endoscopy or anterior rhinoscopy showing polys reaching below the lower border of the middle turbinate or beyond in each nostril? ***ACTION REQUIRED: If Yes, please attach supporting chart note(s) or medical record showing endoscopy, rhinoscopy, or CT details (e.g., polyps location, size) ACTION REQUIRED: Submit supporting documentation*** *If Yes, skip to #39* ❑ Yes ❑ No

37. Has the patient had a Meltzer Clinical Score of 2 or higher in both nostrils? ***ACTION REQUIRED: If 'Yes', please submit chart notes or medical records of Meltzer Clinical score. ACTION REQUIRED: Submit supporting documentation*** *If Yes, skip to #39* ❑ Yes ❑ No

38. Has the patient had 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 submit chart notes or medical records of endoscopic nasal polyps score. ACTION REQUIRED: Submit supporting documentation*** ❑ Yes ❑ No

39. Does the patient have nasal blockage? ❑ Yes ❑ No

40. Does the patient have rhinorrhea (anterior/posterior) or reduction or loss of smell, or facial pain or pressure? ❑ Yes ❑ No

41. Will the patient continue to use a daily intranasal corticosteroid while being treated with Xolair? *If Yes, no further questions* ❑ Yes ❑ No

42. Are intranasal corticosteroids contraindicated or not tolerated? ❑ Yes ❑ No

Section D: Immune Checkpoint Inhibitor-Related Toxicities

44. Does the patient have a refractory case of immune-therapy related severe (G3) pruritus? ❑ Yes ❑ No

45. Does the patient have elevated IgE levels? ***ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation of pre-treatment IgE level. ACTION REQUIRED: Submit supporting documentation*** ❑ Yes ❑ No

Section E: Systemic Mastocytosis

46. Does the patient have the major and at least one minor diagnostic criterion for systemic mastocytosis present? ***ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation supporting diagnosis. ACTION REQUIRED: Submit supporting documentation*** *If Yes, skip to #48* ❑ Yes ❑ No

47. Does the patient have three or more minor diagnostic criteria present for systemic mastocytosis? ***ACTION REQUIRED: If Yes, please attach chart notes or medical record documentation supporting diagnosis. ACTION REQUIRED: Submit supporting documentation*** ❑ Yes ❑ No

48. Is Xolair being prescribed as a step-wise prophylactic treatment for chronic mast cell mediator-related cardiovascular and pulmonary symptoms? ❑ Yes ❑ No *If No, skip to #50*

49. Has the member tried both of the following? ***Indicate below and no further questions.***
    - H1 blockers and H2 blockers
    - Corticosteroids

    ACTION REQUIRED: If Yes, please attach supporting chart notes, medical records, or claims history of previous medications tried. ACTION REQUIRED: Submit supporting documentation ❑ Yes ❑ No

50. Is Xolair being prescribed for prevention of recurrent unprovoked anaphylaxis?
If Yes, no further questions ❑ Yes ❑ No

51. Is Xolair being prescribed for prevention of hymenoptera or food-induced anaphylaxis?
❑ Yes ❑ No *If No, skip to #53*

52. Does the patient have negative specific IgE or a negative skin test? ❑ Yes ❑ No *No further questions*

53. Is Xolair being prescribed to improve tolerability of venom immunotherapy? ❑ Yes ❑ No

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)**

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

 Xolair SOC SGM - 09/2022.