# Xolair

## HMSACOM - 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 1-866-237-5512**. If you have questions regarding the prior authorization, please contact CVS Caremark at **1-808-254-4414.** 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:** _____
**Patient's Phone Number:** _____
**Physician's Name:** _____
**Specialty:** _____ **NPI#:** _____
**Physician Office Telephone:** _____ **Physician Office Fax:** _____

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

**Additional Demographic Information:**

*Patient Weight:* _____*kg*

*Patient Height:* _____*ft* _____*inches*

***Indicate where the drug is being dispensed:***

❑ Office ❑ Outpatient Hospital ❑ Ambulatory Surgical ❑ Inpatient Hospital
❑ Off Campus Outpatient Hospital ❑ Urgent Care ❑ Emergency Room ❑ Birthing Center
❑ Military Facility ❑ Skilled Nursing Facility ❑ Nursing Facility ❑ Hospice
❑ Inpatient Psychiatric ❑ Psychiatric Residential Treatment ❑ End Stage Renal Facility
❑ Psychiatric Facility ❑ Pharmacy ❑ Other

***Indicate where the drug is being administered:***

❑ Ambulatory surgical ❑ Home ❑ Inpatient Hospital
❑ Office ❑ Outpatient Hospital ❑ Pharmacy

What is the ICD-10 code? _____

**Send completed form to: CVS Caremark Specialty Programs. Fax: 1-866-237-5512**

 

**CVS Caremark Specialty Programs ● 2969 Mapunapuna Place ● Honolulu, HI 96819**
**Phone: 1-808-254-4414 ● Fax: 1-866-237-5512 ● www.caremark.com**

**Criteria Questions:**

1. What is the diagnosis?
❒ Allergic asthma, *Continue to #2*
❒ Chronic spontaneous urticaria (CSU), *Continue to #3*
❒ Nasal polyps, *Continue to #4*
❒ IgE-mediated food allergy, *Continue to #5*
❒ Other, *No Further Questions*

2. What is the patient's age? ***Action Required***: Attach documentation of patient age from the medical record
❒ ≥ 6 years, *Continue to #100*
❒ < 6 years, *Continue to #100*

3. What is the patient's age? ***Action Required***: Attach documentation of patient age from the medical record
❒ ≥ 12 years, *Continue to #200*
❒ < 12 years, *Continue to #200*

4. What is the patient's age? ***Action Required***: Attach documentation of patient age from the medical record
❒ ≥ 18 years, *Continue to #250*
❒ < 18 years, *Continue to #250*

5. What is the patient's age? ***Action Required***: Attach documentation of patient age from the medical record
❒ ≥ 1 years, *Continue to #150*
❒ < 1 years, *Continue to #150*

*ASTHMA: INITIAL REQUEST*

100. Is this request for a new start or continuation of therapy with Xolair?
❒ New start, *Continue to #102*
❒ Continuation of therapy, *Continue to #101*

101. Was Xolair therapy previously authorized by HMSA/CVS for this member?
❒ Yes, *Continue to #300*
❒ No, *Continue to #102*
❒ Unknown, *Continue to #102*

102. What is the specialty of the practitioner who recommended Xolair for this patient?
❒ Allergist, *Continue to #103*
❒ Immunologist, *Continue to #103*
❒ Pulmonologist, *Continue to #103*
❒ Other, *Continue to #103*

103. Prior to initiating therapy, what was the severity of the patient's asthma?

❒ Mild intermittent, *Continue to #104*

❒ Mild persistent, *Continue to #104*
❒ Moderate persistent, *Continue to #104*
❒ Severe persistent, *Continue to #104*

104. Is the patient's asthma inadequately controlled with the use of an inhaled corticosteroid at the optimized dose? ***Action Required***: Attach documentation of current medications (including doses) from the medical record

❒ Yes, *Continue to #105*

❒ No, *Continue to #105*

105. Is the patient's asthma inadequately controlled with the use of a long acting beta agonist at the optimized dose? ***Action Required***: Attach documentation of current medications (including doses) from the medical record

❒ Yes, *Continue to #106*

❒ No, *Continue to #106*

106. What is the patient's current weight? ***Action Required***: Attach documentation of patient's weight from the medical record

❒ > 150 kg, *Continue to #107*

❒ ≤ 150 kg, *Continue to #107*

107. What is the patient's pre-treatment IgE level (IU/mL)? ***Action Required***: Attach documentation of pre-treatment serum IgE (IU/mL) levels

❒ No pre-treatment IgE level, *Continue to #108*

❒ < 30 IU/mL, *Continue to #108*

❒ ≥ 30 IU/mL, *Continue to #108*

108. Does the prescribed dose follow FDA-approved dosing recommendations (for dose and dosing frequency) based on pretreatment serum IgE levels and body weight? (Please refer to the prescribing information at www.xolair.com)

❒ Yes, *Continue to #109*

❒ No, *Continue to #109*

109. Prior to initiating therapy, did the patient have positive skin or in vitro reactivity to at least one perennial aeroallergen? ***Action Required***: Attach documentation from the medical record of either skin or blood test confirming the diagnosis of allergic asthma

❒ Yes, *Continue to #110*

❒ No, *Continue to #110*

110. Has the patient failed environmental controls and standard immune therapy? ***Action Required***: Attach clinical notes documenting failure of environmental controls and immune therapy

❒ Yes, *Continue to #112*

❒ No, *Continue to #111*

111. Is there evidence that immune therapy will trigger a severe allergic reaction?

❒ Yes, *Continue to #112*

❒ No, *Continue to #112*

112. What is the patient's pre-treatment forced expiratory volume (FEV1)? ***Action Required***: Attach documentation of FEV1 results from the medical record

❒ ≥ 80% of predicted value, *Continue to #113*

❒ < 80% of predicted value, *Continue to #113*

113. Have the patient's comorbidities been evaluated and treated? ***Action Required***: Attach clinical notes documenting treatment of comorbidities

❒ Yes, *Continue to #114*

❒ No, *Continue to #114*

114. Does the patient have a rapid-acting beta2-agonist available for rescue therapy?

❒ Yes, *Continue to #115*

❒ No, *Continue to #115*

115. Is this request for a new start or continuation of Xolair therapy?

❒ New start, *No Further Questions*

❒ Continuation, *Continue to #300*

*IgE-Mediated Food Allergy: INITIAL REQUEST*

150. Is this request for a new start or continuation of therapy with Xolair?

❒ New start, *Continue to #152*

❒ Continuation of therapy, *Continue to #151*

151. Was Xolair therapy previously authorized by HMSA/CVS for this member?

❒ Yes, *Continue to #350*

❒ No, *Continue to #152*

❒ Unknown, *Continue to #152*

152. What is the specialty of the practitioner who recommended Xolair use for this patient?

❒ Allergist, *Continue to #153*

❒ Immunologist, *Continue to #153*

❒ Other, *Continue to #153*

153. Has the patient's IgE-mediated food allergy been confirmed by a pre-treatment allergen-specific IgE level?

❒ Yes, *Continue to #154*

❒ No, *Continue to #155*

154. What is the patient's pre-treatment allergen-specific serum IgE level? ***Action Required***: Attach documentation of pre-treatment allergen-specific IgE level

❒ Greater than or equal to 6 IU/mL, *Continue to #157*

❒ Less than 6 IU/mL, *Continue to #155*

155. Has the patient's IgE-mediated food allergy been confirmed by a skin-prick test (SPC)?

❒ Yes, *Continue to #156*

❒ No, *Continue to #156*

156. What is the patient's skin-prick test (SPC) wheal diameter? ***Action Required***: Attach documentation of skin-prick test wheal diameter

❒ Greater than or equal to 4 mm, *Continue to #157*

❒ Less than 4 mm, *Continue to #157*

157. Has the patient had a positive physician controlled oral food challenge (e.g., moderate to severe skin, respiratory, or gastrointestinal [GI] symptoms )? ***Action Required***: If yes, attach documentation of positive result of a physician controlled oral food challenge

❒ Yes, *Continue to #159*

❒ No, *Continue to #158*

158. Does the patient have a history of a systemic reaction to a food? ***Action Required***: If yes, attach documentation of a systemic reaction to a food

❒ Yes, *Continue to #159*

❒ No, *Continue to #159*

159. What is the patient's pre-treatment serum IgE level in IU/mL? ***Action Required***: Attach documentation of pre-treatment serum IgE level

❒ Greater than or equal to 30 IU/mL, *Continue to #160*

❒ Less than 30 IU/mL, *Continue to #160*

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

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

*CSU: INITIAL REQUEST*

200. Is this request for a new start or continuation of therapy with Xolair?

❒ New start, *Continue to #202*

❒ Continuation of therapy, *Continue to #201*

201. Was Xolair therapy previously authorized by HMSA/CVS for this member?

❒ Yes, *Continue to #400*

❒ No, *Continue to #202*

❒ Unknown, *Continue to #202*

202. What is the specialty of the practitioner who recommended Xolair use for this patient?

❒ Allergist, *Continue to #203*

❒ Immunologist, *Continue to #203*

❒ Dermatologist, *Continue to #203*

❒ Other, *Continue to #203*

203. Prior to initiating therapy, what was the severity of the patient's CSU?

❒ Mild, *Continue to #204*

❒ Moderate, *Continue to #204*

❒ Severe, *Continue to #204*

204. How long has the patient been diagnosed with CSU? ***Action Required***: Attach clinical notes supporting a diagnosis of CSU for at least 3 months

❒ Less than 3 months, *Continue to #205*

❒ 3 months or longer, *Continue to #205*

205. Has the patient been evaluated for other causes of urticaria?

❒ Yes, *Continue to #206*

❒ No, *Continue to #206*

206. Has the patient remained symptomatic despite treatment with at least 2 distinct courses of different high-dose second generation H1 antihistamines? ***Action Required***: If 'yes', attach clinical notes supporting trial and failure of antihistamines.Each course must have been continuous use for at least 2 weeks.High-dose is defined as twice daily dosing of standard daily dosing (listed below):

- Cetirizine (Zyrtec®) 10 mg
- Levocetirizine (Xyzal®) 5 mg
- Fexofenadine (Allegra®) 180 mg
- Loratadine (Claritin®) 10 mg
- Desloratadine (Clarinex®) 5 mg

❒ Yes, *Continue to #207*

❒ No, *Continue to #207*

207. Please indicate which type of high-dose second generation H1 antihistamine therapy the patient has received:
❒ Two different second-generation antihistamines at twice daily dosing, each drug for at least 2 weeks, *Continue to #208*
❒ Two courses of 2 second-generation antihistamines used in combination (eg; fexofenadine 180 mg in the morning and cetirizine 10 mg at night), each course at least 2 weeks, *Continue to #208*
❒ One course of one antihistamine at twice daily dosing AND one course of combination therapy, each course at least 2 weeks, *Continue to #208*

❒ None of the above, *Continue to #208*

❒ Above therapies are contraindicated for this patient, *Continue to #208*

208. Has the patient remained symptomatic despite treatment with a first generation H1 antihistamine (eg, hydroxyzine, doxepin) or an H2 antihistamine (eg, ranitidine) in combination with a high-dose second generation H1 antihistamine? ***Action Required***: If 'yes', attach clinical notes supporting trial and failure of antihistamines.The course must have been continuous use for at least 2 weeks

❒ Yes, *Continue to #209*

❒ No, *Continue to #209*

209. Please indicate which type of first-generation H1 antihistamine/H2 antihistamine and high-dose second generation H1 antihistamine combination therapy the patient has received:
❒ First generation H1 antihistamine in combination with a high-dose second generation H1 antihistamine, *Continue to #210*

❒ H2 antihistamine in combination with a high-dose second generation H1 antihistamine, *Continue to #210*

❒ None of the above, *Continue to #210*

❒ Above therapies are contraindicated for this patient, *Continue to #210*

210. Is this request for a new start or continuation of therapy with Xolair?

❒ New start, *No Further Questions*

❒ Continuation of therapy, *Continue to #400*

*NASAL POLYPS: INITIAL REQUEST*

250. Is this request for a new start or continuation of therapy with Xolair?

❒ New start, *Continue to #252*

❒ Continuation of therapy, *Continue to #251*

251. Was Xolair therapy previously authorized by HMSA/CVS for this member?

❒ Yes, *Continue to #450*

❒ No, *Continue to #252*

❒ Unknown, *Continue to #252*

252. What is the specialty of the practitioner who recommended Xolair use for this patient?

❒ Allergist, *Continue to #253*

❒ Immunologist, *Continue to #253*

❒ Otolaryngologist, *Continue to #253*

❒ Other, *Continue to #253*

253. Prior to initiating therapy, what was the member's nasal poly score (NPS)? ***Action Required***: Attach clinical notes showing NPS

❒ Greater than 5, *Continue to #254*

❒ Less than or equal to 5, *Continue to #254*

254. Prior to initiating therapy, what was the member's nasal polyp score (NPS) in each nostril? ***Action Required***: Attach clinical notes showing NPS

❒ Less than or equal to 2, *Continue to #255*

❒ Greater than 2, *Continue to #255*

255. Has the member experienced an inadequate response to nasal corticosteroids as evidenced by a weekly average nasal congestion score (NCS) greater than 1 despite the use of nasal corticosteroids? ***Action Required***: Attach clinical notes showing inadequate response to nasal corticosteroids

❒ Yes, *Continue to #256*

❒ No, *Continue to #256*

256. Will Xolair be used as add-on maintenance therapy?

❒ Yes, *Continue to #257*

❒ No, *Continue to #257*

257. Is the member currently receiving, and will continue to receive, nasal corticosteroid therapy?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

*ASTHMA: REAUTHORIZATION REQUEST*

300. Which of the following measures has the patient shown improvement or sustained improvement in since initiation of Xolair therapy? ***Action Required***: Attach documentation of comparative FEV1

❒ Improvement in forced expiratory volume (FEV1), *Continue to #301*

❒ Decrease in hospitalizations or emergency room visits, *Continue to #301*

❒ No improvement or sustained improvement since initiation of therapy, *Continue to #301*

301. Has the patient continued to use inhaled corticosteroids? ***Action Required***: Attach documentation of current medications (including doses) from the medical record

❒ Yes, *Continue to #302*

❒ No, *Continue to #302*

302. What is this patient's duration of treatment with Xolair?

❒ 0 to < 6 months, *No Further Questions*

❒ ≥ 6 months to < 12 months, *No Further Questions*

❒ 12 months or longer, *No Further Questions*

*IgE-Mediated Food Allergy: CONTINUATION REQUEST*

350. Has the member achieved or maintained a positive clinical response to therapy as evidenced by a decrease in hypersensitivity (e.g., moderate to severe skin, respiratory or GI symptoms) to food-allergen? ***Action Required***: Attach chart notes or medical record documentation supporting positive response to therapy (e.g., decrease in hypersensitivity to food-allergen)

❒ Yes, *Continue to #351*

❒ No, *Continue to #351*

351. Will the member continue to maintain a food-allergen avoidance diet?

❒ Yes, *No Further Questions*

❒ No, *No Further Questions*

*CSU: CONTINUATION REQUEST*

400. Which of the following type of response has the patient demonstrated since initiation of Xolair therapy? ***Action Required***: Attach documentation supporting that the patient has responded to therapy

❒ Complete response to therapy, *Continue to #401*

❒ Partial response to therapy, *Continue to #402*

❒ No response to therapy / unknown, *No Further Questions*

401. Did the symptoms return when the dose was tapered or withheld beyond the next dosing interval? ***Action Required***: Attach documentation that supports tapering of dose and/or withholding of therapy beyond the next dosing interval to see if symptoms return

❒ Yes, *Continue to #402*

❒ No, *Continue to #402*

❒ Dose has not been tapered or withheld, *Continue to #402*

402. What is this patient's duration of treatment with Xolair?

❒ 0 to < 3 months, *No Further Questions*

❒ ≥ 3 months to < 9 months, *No Further Questions*

❒ 9 months or longer, *No Further Questions*

*NASAL POLYPS: REAUTHORIZATION REQUEST*

450. Which of the following measures has the member experienced improvement in since initiation of Xolair therapy? ***Action Required***: Attach documentation of either comparative nasal congestion score or nasal polyp score

❒ Improvement in nasal congestion score (NCS) from baseline, *Continue to #451*

❒ Improvement in nasal polyp score (NPS) from baseline, *Continue to #451*

❒ No improvement since initiation of therapy, *Continue to #451*

451. What is this patient's duration of treatment with Xolair?

❒ 0 to < 6 months, *No Further Questions*

❒ ≥ 6 months to < 12 months, *No Further Questions*

❒ 12 months or longer, *No Further Questions*

***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)**