



PRIOR AUTHORIZATION REQUEST

XOLAIR

Patient Information:

Name:	
Member ID:	
Address:	
City, State, Zip:	
Date of Birth:	

Prescriber Information:

Name:	
NPI:	
Phone Number:	
Fax Number:	
Address:	
City, State, Zip:	

Requested Medication

Rx Name:	
Rx Strength:	
Rx Quantity:	
Rx Frequency:	
Rx Route of Administration:	
Diagnosis and ICD Code:	

Your patient's prescription benefit requires that we review certain requests for coverage with the prescriber. You have prescribed a medication for your patient that requires Prior Authorization before benefit coverage or coverage of additional quantities can be provided. Please complete the following questions then fax this form to the toll-free number listed below. Upon receipt of the completed form, prescription benefit coverage will be determined based on the plan's rules.

SECTION A: Please note that supporting clinical documentation is required for **ALL PA requests**. Pharmacy prior authorization reviews can be subject to trial with additional medications that are not listed within the criteria. The policies are subject to change based on COMAR requirements, MDH transmittals and updates to treatment guidelines.

- | | | | |
|---|---|-----|----|
| 1 | Is this request for initial therapy or for a continuation of therapy? | | |
| | ☐ Initial (If checked, go to 8) | | |
| | ☐ Continuation (If checked, go to 2) | | |
| 2 | Will the patient be concurrently receiving the requested medication in combination with any anti-interleukin (IL)-4, anti-IL-5, thymic stromal lymphopoietin (TSLP) inhibitor therapies such as Dupixent, Nucala, Cinqair, Fasenra, and Tezspire? | Yes | No |

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[If yes, no further questions.]

- | | | | |
|---|--|-----|----|
| 3 | Is the patient currently receiving the requested medication?
[If no, skip to question 8.] | Yes | No |
| 4 | Has the patient been receiving medication samples of the requested medication?
[If yes, skip to question 8.] | Yes | No |
| 5 | Does the patient have a previously approved prior authorization (PA) on file with the current plan?
[Note: If the patient does NOT have a previously approved PA on file for the requested medication with the current plan, the renewal request will be considered under initial therapy.]
[If no, skip to question 8.] | Yes | No |
| 6 | Has the patient been established on therapy for at least 3 months?
[If no, skip to question 8.] | Yes | No |
| 7 | Has documentation been submitted to confirm that the patient has had a significant response to therapy, as determined by the provider? ACTION REQUIRED: Submit supporting documentation.
[No further questions.] | Yes | No |
| 8 | Will the patient be concurrently receiving the requested medication in combination with any anti-interleukin (IL)-4, anti-IL-5, thymic stromal lymphopoietin (TSLP) inhibitor therapies such as Dupixent, Nucala, Cinqair, Fasenra, and Tezspire?
[If yes, no further questions.] | Yes | No |
| 9 | What is the indication or diagnosis?

☐ Asthma (If checked, go to 10)

☐ Atopic dermatitis (If checked, no further questions)

☐ Chronic idiopathic urticaria (Chronic spontaneous urticaria) (If checked, go to 24)

☐ Chronic rhinosinusitis (If checked, no further questions)

☐ Eosinophilic colitis (If checked, no further questions)

☐ Eosinophilic esophagitis (If checked, no further questions)

☐ Eosinophilic gastroenteritis (If checked, no further questions)

☐ Nasal polyps (If checked, go to 29)

☐ Treatment of latex allergy in health care workers with occupational latex allergy (If checked, no further questions) | | |

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☐ Immunoglobulin E (IgE) mediated food allergies (If checked, go to 40)

☐ Other (If checked, no further questions)

- | | | | |
|----|---|-----|----|
| 10 | Is the patient 6 years of age or older?
[If no, no further questions.] | Yes | No |
| 11 | Has documentation been provided to confirm that the patient has a baseline (prior to treatment with Xolair or anti-interleukin-[IL]-4/13 therapy [Dupixent]) immunoglobulin E (IgE) level 30 IU/mL to 1300 IU/mL? ACTION REQUIRED: Submit supporting documentation.
[If no, no further questions.] | Yes | No |
| 12 | Does the patient have a baseline (prior to treatment with Xolair) positive skin test or in vitro test (that is, a blood test) for allergen-specific immunoglobulin E (IgE) for one or more perennial aeroallergens AND/OR for one or more seasonal aeroallergens?
[Note: Examples of perennial aeroallergens are house dust mite, animal dander, cockroach, feathers, and mold spores. Examples of seasonal aeroallergens are grass, pollen, and weeds.]
[If no, no further questions.] | Yes | No |
| 13 | Has the patient received at least 3 consecutive months of combination therapy with BOTH of the following unless contraindicated or intolerant to at least two inhaled corticosteroid containing medications: A) An inhaled corticosteroid, AND B) At least one additional asthma controller/maintenance medication?
[Note: Examples of additional asthma controller/maintenance medications are inhaled long-acting beta2-agonists, inhaled long-acting muscarinic antagonists, leukotriene receptor antagonists, and theophylline. Use of a combination inhaler containing both an inhaled corticosteroid and a long-acting beta2-agonist would fulfill the requirement for both criteria A and B.]
[If yes, skip to question 15.] | Yes | No |
| 14 | Has the patient already received anti-interleukin (IL)-4/13 therapy (Dupixent) used concomitantly with an inhaled corticosteroid for at least 3 consecutive months?
[If no, no further questions.] | Yes | No |
| 15 | Do the patient and prescriber agree to continue asthma therapy with an asthma controller maintenance medication in conjunction with the requested medication: inhaled corticosteroids (ICS) or ICS combination inhaler?
[If no, no further questions.] | Yes | No |
| 16 | Is the patient's asthma uncontrolled or was uncontrolled prior to receiving the requested medication or anti-interleukin (IL)-4/13 therapy (Dupixent) therapy as defined by the following: the patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year? | Yes | No |

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[If yes, skip to question 21.]

- | | | | |
|----|--|-----|----|
| 17 | <p>Is the patient's asthma uncontrolled or was uncontrolled prior to receiving the requested medication or anti-interleukin (IL)-4/13 therapy (Dupixent) therapy as defined by the following: the patient experienced one or more asthma exacerbations requiring hospitalization or an Emergency Department (ED) visit in the previous year?</p> <p>[If yes, skip to question 21.]</p> | Yes | No |
| 18 | <p>Is the patient's asthma uncontrolled or was uncontrolled prior to receiving the requested medication or anti-interleukin (IL)-4/13 therapy (Dupixent) therapy as defined by the following: the patient has a forced expiratory volume in 1 second (FEV1) less than 80% predicted?</p> <p>[If yes, skip to question 21.]</p> | Yes | No |
| 19 | <p>Is the patient's asthma uncontrolled or was uncontrolled prior to receiving the requested medication or anti-interleukin (IL)-4/13 therapy (Dupixent) therapy as defined by the following: the patient has a forced expiratory volume in 1 second/forced vital capacity (FEV1/FVC) less than 0.80?</p> <p>[If yes, skip to question 21.]</p> | Yes | No |
| 20 | <p>Is the patient's asthma uncontrolled or was uncontrolled prior to receiving the requested medication or anti-interleukin (IL)-4/13 therapy (Dupixent) therapy as defined by the following: the patient's asthma worsens upon tapering of oral corticosteroid therapy?</p> <p>[If no, no further questions.]</p> | Yes | No |
| 21 | <p>Is patient's weight 30 kg to 150 kg?</p> <p>[If no, no further questions.]</p> | Yes | No |
| 22 | <p>Is the requested medication prescribed by or in consultation with an allergist, immunologist, or pulmonologist?</p> <p>[If no, no further questions.]</p> | Yes | No |
| 23 | <p>Does the dose of the requested medication exceed the Food and Drug Administration (FDA) approved label dosing for the requested indication?</p> <p>[No further questions.]</p> | Yes | No |
| 24 | <p>Is the patient 12 years of age or greater?</p> <p>[If no, no further questions.]</p> | Yes | No |
| 25 | <p>Has the patient been evaluated for other causes of urticaria (bradykinin-related angioedema, auto-inflammatory disorders, urticarial vasculitis)?</p> <p>[If no, no further questions.]</p> | Yes | No |
| 26 | <p>Does the patient remain symptomatic despite a 4-week trial with at least one H1 antihistamine in combination with a leukotriene receptor antagonist (LTRA), or H2 antihistamine, or another H1 antihistamine with doses that have been titrated up to</p> | Yes | No |

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a maximum of four times the standard Food and Drug Administration (FDA)-approved dose, unless contraindicated or intolerant?

[Note: Examples of H1 antihistamine therapy are cetirizine, desloratadine, fexofenadine, levocetirizine, and loratadine.]

[If no, no further questions.]

27	Is the requested medication prescribed by or in consultation with an allergist, immunologist, or dermatologist? [If no, no further questions.]	Yes	No
28	Does the dose of the requested medication exceed the Food and Drug Administration (FDA) approved label dosing for the requested indication? [No further questions.]	Yes	No
29	Is the patient greater than or equal to 18 years of age? [If no, no further questions.]	Yes	No
30	Does the patient have chronic rhinosinusitis with nasal polyposis as evidenced by direct examination, endoscopy, or sinus computed tomography (CT) scan? [If no, no further questions.]	Yes	No
31	Has the patient experienced TWO or more of the following symptoms for at least 6 months: A) Nasal congestion, B) Nasal obstruction, C) Nasal discharge, and/or D) reduction/loss of smell? [If no, no further questions.]	Yes	No
32	Does the patient have a baseline immunoglobulin E (IgE) level greater than or equal to 30 IU/mL? [Note: "Baseline" is defined as prior to receiving any Xolair or anti-interleukin (IL)-4/13 therapy (that is, Dupixent [dupilumab subcutaneous injection]).] [If no, no further questions.]	Yes	No
33	Has the patient received at least 3 months of therapy with an intranasal corticosteroid, unless contraindicated or intolerant to two products? [If no, no further questions.]	Yes	No
34	Will the patient receive the requested medication as an add on maintenance therapy in combination with an intranasal corticosteroid unless contraindicated or intolerant? [If no, no further questions.]	Yes	No
35	Has the patient received at least one course of treatment with a systemic corticosteroid for 5 days or more within the previous 2 years? [If yes, skip to question 38.]	Yes	No
36	Does the patient have a contraindication to systemic corticosteroid therapy? [If yes, skip to question 38.]	Yes	No

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37	Has the patient had prior surgery for nasal polyps? [If no, no further questions.]	Yes	No
38	Is the requested medication prescribed by or in consultation with an allergist, immunologist, or an otolaryngologist (ear, nose and throat [ENT] physician specialist)? [If no, no further questions.]	Yes	No
39	Does the dose of the requested medication exceed the Food and Drug Administration (FDA) approved label dosing for the requested indication? [No further questions.]	Yes	No
40	Is the patient greater than or equal to 1 year of age? [If no, no further questions.]	Yes	No
41	Does the patient have a baseline immunoglobulin E (IgE) level greater than or equal to 30 IU/mL? [Note: "Baseline" is defined as prior to receiving any Xolair or anti-interleukin (IL)-4/13 therapy (that is, Dupixent [dupilumab subcutaneous injection]).] [If no, no further questions.]	Yes	No
42	Does the patient have a documented diagnosis for Immunoglobulin E (IgE)-mediated food allergy to one or more foods with signs and symptoms of a significant systemic allergic reaction (i.e., hives, swelling, wheezing, hypotension, gastrointestinal symptoms)? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
43	Does the patient have a positive skin-prick test with response to one or more foods? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
44	Does the patient have a positive in vitro test (i.e., blood test) for Immunoglobulin E (IgE) to one or more foods? ACTION REQUIRED: Submit supporting documentation. [If no, no further questions.]	Yes	No
45	Will the requested medication be used in conjunction with food allergen avoidance? [If no, no further questions.]	Yes	No
46	Is the requested medication prescribed by or in consultation with an allergist or immunologist? [If no, no further questions.]	Yes	No
47	Does the dose of the requested medication exceed the Food and Drug Administration (FDA) approved label dosing for the requested indication?	Yes	No

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Please document the diagnoses, symptoms, and/or any other information important to this review:

SECTION B: Physician Signature

PHYSICIAN SIGNATURE

DATE

FAX COMPLETED FORM TO: 1-833-896-0656

Disclaimer: An authorization is not a guarantee of payment. Member must be eligible at the time services are rendered. Services must be a covered Health Plan Benefit and medically necessary with prior authorization as per Plan policy and procedures.

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