STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

OMALIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
OMALIZUMAB	XOLAIR	25399		GPI-10 (4460306000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have moderate to severe persistent asthma and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in allergy or pulmonary medicine
   - The patient has a positive skin prick or blood test (e.g., ELISA, FEIA) to a perennial aeroallergen
   - The patient has a documented baseline IgE serum level greater than or equal to 30 IU/mL
   - The patient is concurrently treated with a medium, high-dose, or maximally tolerated inhaled corticosteroid (ICS) [e.g., triamcinolone acetonide, beclomethasone, mometasone, budesonide] AND at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], long-acting muscarinic antagonist [e.g., aclidinium bromide, ipratropium, tiotropium, umeclidinium], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline, or oral corticosteroid [e.g., prednisone])
   - Xolair will NOT be used concurrently with Dupixent (dupilumab) or an anti-IL5 biologic (e.g., Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when used for the treatment of asthma

     If yes, continue to #2.
     If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months
   - The patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or emergency room visit within the past 12 months

     If yes, **approve for 4 months by GPID or GPI-14 for the requested product as follows:**
     - **Xolair 150mg vial: #6 vials per 28 days.**
     - **Xolair 75mg/0.5mL syringe: #5mL per 28 days.**
     - **Xolair 150mg/mL syringe: #5mL per 28 days.**

     If no, continue to #3.

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta2-agonist reliever (SABA) [e.g., albuterol] for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, **approve for 4 months by GPID or GPI-14 for the requested product as follows:**
   - **Xolair 150mg vial: #6 vials per 28 days.**
   - **Xolair 75mg/0.5mL syringe: #5mL per 28 days.**
   - **Xolair 150mg/mL syringe: #5mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of nasal polyps and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an otolaryngologist or allergist/immunologist
   - Xolair will be used as add-on maintenance treatment
   - The patient had a previous 90-day trial of ONE intranasal corticosteroid (e.g., nasal mometasone)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #8 per 28 days.**
   If no, continue to #5.

5. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in allergy or pulmonary medicine
   - The patient still experiences hives on most days of the week for at least 6 weeks
   - The patient has tried a high dose H1 antihistamine (e.g., four-fold dosing of Clarinex [desloratadine] or Xyzal [levocetirizine]) **AND** leukotriene antagonist (e.g., montelukast, zafirlukast) for at least 2 weeks

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMALIZUMAB (Xolair)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe persistent asthma (a type of lung condition)
   2. Nasal polyps (small growths in the nose)
   3. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

B. **If you have moderate to severe persistent asthma, approval also requires:**
   1. You are 6 years of age or older
   2. Therapy is prescribed by or in consultation with a physician specializing in allergy or pulmonary (relating to lungs/breathing) medicine
   3. You have a positive skin prick or blood test such as ELISA or FEIA (type of blood test to identify what you're allergic to) to a perennial aeroallergen (airborne particles that cause allergies year-round)
   4. You have a documented baseline IgE (type of antibody that is produced by your immune system if you have an allergy) serum level greater than or equal to 30 IU/mL
   5. You are being treated with a medium, high-dose, or maximally tolerated inhaled corticosteroid (such as triamcinolone acetonide, beclomethasone, mometasone, budesonide) AND at least one other maintenance medication such as a long-acting inhaled beta2-agonist (such as salmeterol, formoterol), long-acting muscarinic antagonist (such as aclidinium bromide, ipratropium, umeclidinium, tiotropium), leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), theophylline, or oral corticosteroid (such as prednisone)
   6. You meet ONE of the following:
      a. You have experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months OR at least ONE serious asthma exacerbation requiring hospitalization or emergency room visit within the past 12 months
      b. You have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
         i. Daytime asthma symptoms more than twice per week
         ii. Any night waking due to asthma
         iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
         iv. Any activity limitation due to asthma
   7. You will NOT use Xolair concurrently (at the same time) with Dupixent (dupilumab) or an anti-IL5 biologic (such as Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when used for treatment of asthma

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OMALIZUMAB

INITIAL CRITERIA (CONTINUED)

C. **If you have nasal polyps, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor) or an allergist/immunologist (a type of allergy or immune system doctor)
   3. Xolair will be used as add-on maintenance treatment
   4. You had a previous 90-day trial of ONE intranasal corticosteroid (such as nasal mometasone)

D. **If you have chronic spontaneous urticaria (chronic idiopathic urticaria), approval also requires:**
   1. You are 12 years of age or older
   2. Therapy is prescribed by or in consultation with a physician specializing in allergy or pulmonary (relating to lungs/breathing) medicine
   3. You still experience hives on most days of the week for at least 6 weeks
   4. You have tried a high dose H1 antihistamine (type of allergy medication such as four-fold dosing of Clarinex [desloratadine] or Xyzal [levocetirizine]) AND leukotriene antagonist (such as montelukast, zafirlukast, zileuton) for at least 2 weeks

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe persistent asthma and meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) [e.g., triamcinolone acetonide, beclomethasone, mometasone, budesonide] AND at least one other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., aclidinium bromide, ipratropium, tiotropium, umeclidinium], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline, or oral corticosteroid [e.g., prednisone])
   - Xolair will NOT be used concurrently with Dupixent (dupilumab) or an anti-IL5 biologic (e.g., Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when used for the treatment of asthma

     If yes, continue to #2.
     If no, continue to #3.

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OMALIZUMAB

RENEWAL CRITERIA (CONTINUED)

2. Has the patient shown a clinical response as evidenced by **ONE** of the following?
   - Reduction in asthma exacerbation from baseline
   - Decreased utilization of rescue medications
   - Increase in percent predicted FEV1 from pretreatment baseline
   - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

   If yes, **approve for 12 months by GPID or GPI-14 for the requested product as follows:**
   - **Xolair 150mg vial: #6 vials per 28 days.**
   - **Xolair 75mg/0.5mL syringe: #5mL per 28 days.**
   - **Xolair 150mg/mL syringe: #5mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of nasal polyps **AND** meet the following criterion?
   - The patient has had clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell, size of polyps)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #8 per 28 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of chronic spontaneous urticaria (CSU; also called chronic idiopathic urticaria [CIU]) **AND** meet the following criterion?
   - Therapy is prescribed by or in consultation with an allergist or immunologist

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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OMALIZUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **OMALIZUMAB (Xolair)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:
   1. Moderate to severe persistent asthma (a type of lung condition)
   2. Nasal polyps (small growths in the nose)
   3. Chronic spontaneous urticaria (also called chronic idiopathic urticaria) [severe itching with unknown cause]

B. **If you have moderate to severe persistent asthma, renewal also requires:**
   1. You will continue to use an inhaled corticosteroid (ICS) [such as triamcinolone acetonide, beclomethasone, mometasone, budesonide] AND at least one other maintenance medication such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as aclidinium bromide, ipratropium, tiotropium, umeclidinium), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), theophylline, or oral corticosteroid (such as prednisone)
   2. You will NOT use Xolair concurrently (at the same time) with Dupixent (dupilumab) or an anti-IL5 biologic (such as Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when used for treatment of asthma
   3. You have shown a clinical response as evidenced by ONE of the following:
      a. Reduction in asthma exacerbation (worsening of symptoms) from baseline
      b. Decreased use of rescue medications (such as albuterol)
      c. Increase in percent predicted FEV1 (amount of air you can forcefully exhale) from baseline before treatment
      d. Reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

C. **If you have nasal polyps, renewal also requires:**
   1. You have had a clinical benefit compared to baseline (before starting Xolair) (such as improvements in nasal congestion, sense of smell, size of polyps)

D. **If you have chronic spontaneous urticaria (chronic idiopathic urticaria), renewal also requires:**
   1. Therapy is prescribed by or in consultation with an allergist or immunologist (immune system doctor)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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OMALIZUMAB

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Xolair.

REFERENCES

- Xolair [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; March 2023.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 06/01/23
Created: 08/03
Client Approval: 05/232
P&T Approval: 04/22