Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 22.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Xolair (Omalizumab)

Applicable line of business:

Commercial	X	Medicaid	
Medicare	X	ACA	X
CHIP	X		

I. Policy:
Xolair (Omalizumab)

II. Purpose/Objective:
To provide a policy of coverage regarding Xolair (Omalizumab)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:
a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Commercial
Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Medicare
Geisinger Gold Medicare Advantage HMO, PPO, and HMO D-SNP plans are offered by Geisinger Health Plan/Geisinger Indemnity Insurance Company, health plans with a Medicare contract. Continued enrollment in Geisinger Gold depends on contract renewal. Geisinger Health Plan/Geisinger Indemnity Insurance Company are part of Geisinger, an integrated health care delivery and coverage organization.

CHIP
Geisinger Health Plan Kids (GHP Kids) is a Children's Health Insurance Program (CHIP) offered by Geisinger Health Plan in conjunction with the Pennsylvania Department of Human Services (DHS). Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

DESCRIPTION:
Xolair (Omalizumab) is a recombinant humanized monoclonal antibody to immunoglobulin E (IgE). Currently, Xolair is available as a subcutaneous injection only.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Xolair (Omalizumab) will be considered medically necessary for the commercial, exchange, and CHIP lines of when all of the following criteria are met:

1. **Asthma:**
   - Must be prescribed by an allergist or pulmonologist **AND**
   - Insured individual must be compliant with current therapeutic regimen **AND**
   - Insured individual is at least 6 years of age **AND**
   - Physician provided documentation of a diagnosis of moderate to severe persistent asthma* with evidence of reversible airway disease [i.e. greater than 12% improvement in forced expiratory volume in one second (FEV_1) with at least 200 ml increase or at least a 20% or greater improvement in peak expiratory flow (PEF) after administration of albuterol] **AND**
   - Physician provided documentation of inadequate control or intolerance, despite a 3 month trial of: medium –high dose inhaled corticosteroids or systemic corticosteroids **and** long-acting beta agonists or leukotriene receptor antagonists **AND**
   - Physician provided documentation of an IgE level of greater than 30 IU/ml and less than 700 IU/ml for individuals age 12 and older OR IgE level of greater than 30 IU/ml and less than 1300 IU/ml for individuals age 6 through 11 **AND**
   - Physician provided documentation of evidence of a specific allergic reactivity to a perennial aeroallergen by positive skin or blood test for a specific IgE **AND**
   - Known environmental triggers within the member's control have been eliminated. **AND**
   - Medical record documentation that Xolair will not be used in combination with another biologic medication indicated for asthma treatment (e.g. Tezspire, Nucala, Fasenra, Dupixent, Cinqair)

*Moderate persistent asthma is defined by the National Heart, Lung and Blood institute (NHLBI) as:
1. Daily symptoms
2. Daily use of inhaled short-acting beta agonist
3. Exacerbations affect activity
4. Exacerbations at least twice a week, which may last days
5. Nighttime symptoms more frequently than one time per week
6. Lung function of FEV1 greater than 60% but less than 80%

*Severe persistent asthma is defined by the NHLBI as:
1. Continual symptoms
2. Limited physical activity
3. Frequent exacerbations
4. Frequent nighttime symptoms
5. Lung function of FEV1 less than or equal to 60% predicted

**The 12% improvement target value is calculated using the following methodology: The target value = baseline FEV_1 x 1.12

The actual clinical calculation is: $\frac{\text{post-treatment } FEV_1 - \text{baseline } FEV_1}{\text{baseline } FEV_1} = \%$ improvement baseline FEV_1

RECOMMENDED DOSING SCHEDULE:

Xolair Dosing and Administration

For individuals 12 year and older:

Pre-treatment Serum IgE (IU/mL)	Body Weight (kg)			
	30-60	> 60-70	>70-90	>90-150
≥ 30-100	150 mg every 4 weeks	150 mg every 4 weeks	150 mg every 4 weeks	300 mg every 4 weeks
> 100-200	300 mg every 4 weeks	300 mg every 4 weeks	300 mg every 4 weeks	225 mg every 2 weeks
> 200-300	300 mg every 4 weeks	225 mg every 2 weeks	225 mg every 2 weeks	300 mg every 2 weeks
> 300-400	225 mg every 2 weeks	225 mg every 2 weeks	300 mg every 2 weeks	
> 400-500	300 mg every 2 weeks	300 mg every 2 weeks	375 mg every 2 weeks	
> 500-600	300 mg every 2 weeks	375 mg every 2 weeks		
> 600-700	375 mg every 2 weeks	**Do Not Dose**		

Adapted from Xolair [package insert]. South San Francisco, CA: Genentech USA Inc; March 2014

For individuals 6 to 11 years old:

Pre-treatment Serum IgE (IU/mL)	Body Weight (kg)									
	20-25	**>25-30**	**>30-40**	**>40-50**	**>50-60**	**>60-70**	**>70-80**	**>80-90**	**>90-125**	**>125-150**
≥ 30-100	75mg every 4 week	75mg every 4 weeks	75mg every 4 weeks	150mg every 4 weeks	150mg every 4 weeks	150mg every 4 weeks	150mg every 4 weeks	150mg every 4 weeks	300mg every 4 weeks	300mg every 4 weeks
>100-200	150mg every 4 weeks	150mg every 4 weeks	150mg every 4 weeks	300mg every 4 weeks	300mg every 4 weeks	300mg every 4 weeks	300mg every 4 weeks	300mg every 4 weeks	225mg every 2 weeks	300mg every 2 weeks
>200-300	150mg every 4 weeks	150mg every 4 weeks	225mg every 4 weeks	300mg every 4 weeks	300mg every 4 weeks	225mg every 2 weeks	225mg every 2 weeks	225mg every 2 weeks	300mg every 2 weeks	375mg every 2 weeks
>300-400	225mg every 4 weeks	225mg every 4 weeks	300mg every 4 weeks	225mg every 2 weeks	225mg every 2 weeks	225mg every 2 weeks	300mg every 2 weeks	300mg every 2 weeks		
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>700-900	225mg every 2 weeks	225mg every 2 weeks	300mg every 2 weeks	375mg every 2 weeks						
>900-1100	225mg every 2 weeks	300mg every 2 weeks	375mg every 2 weeks							
>1100-1200	300mg every 2 weeks	300mg every 2 weeks								
>1200-1300	300mg every 2 weeks	375mg every 2 weeks								

Do Not Dose

Adapted from Xolair [package insert]. South San Francisco, CA: Genentech USA Inc; July 2016

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

2. **For Chronic Idiopathic Urticaria:**
   - Prescription is written by an allergist, immunologist, or dermatologist **AND**
   - Patient is at least 12 years of age **AND**
   - Diagnosis of moderate-to-severe chronic idiopathic urticaria **AND**
   - At least 6 week history of symptoms (e.g., hives associated with itching, angioedema) **AND**
   - Medical record documentation of a therapeutic failure on Xolair 150 mg dose, when Xolair 300 mg dose is requested **AND**
   - Medical record documentation of contraindication to, therapeutic failure on, or intolerance to a four week trial of ALL of the following treatment alternatives:
     - At least two different high dose antihistamines
     - Maximum dose antihistamine(s) used in combination with a leukotriene receptor antagonist (e.g., montelukast)
     - High dose antihistamine used in combination with H_2 receptor antagonist (e.g., ranitidine
     - Dose advancement of potent antihistamine (e.g., hydroxyzine or doxepin)

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

3. **For Nasal Polyps:**
   - Medical record documentation that Nucala is prescribed by or in consultation with an allergist, pulmonologist, immunologist, or otolaryngologist (ENT provider) **AND**
   - Medical record documentation of age greater than or equal to 18 years **AND**
   - Medical record documentation of a diagnosis of nasal polyps **AND**
   - Medical record documentation that Xolair will be used as add-on maintenance treatment **AND**
   - Medical record documentation of therapeutic failure on, intolerance to, or contraindication to (3) intranasal corticosteroids (including but not limited to: beclomethasone, ciclesonide, fluticasone, mometasone, triamcinolone)

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

4. **IgE Mediated Food Allergies**
   - Medical record documentation that Xolair is prescribed by an allergist or immunologist **AND**
   - Medical record documentation that member is 1 year of age or older **AND**
   - Medical record documentation of use for the maintenance reduction of IgE mediated food allergies (type 1) **AND**
   - Medical record documentation of a positive skin prick test response to one or more foods **AND**
   - Medical record documentation of a positive in vitro test for IGE to one or more foods **AND**
   - Prescriber attestation that reaction is significant enough for the member to require and receive a prescription for an epinephrine product **AND**
   - Medical record documentation that medication will be used in conjunction with a food allergen-avoidant diet **AND**
   - Medical record documentation of a dose consistent with FDA approved labeling **AND**
   - Medical record documentation of an IgE level of greater than 30 IU/mL **AND**
   - Medical record documentation that Xolair is not being administered in combination with an additional monoclonal antibody used for the treatment of IgE mediated conditions.

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

LIMITATIONS:
The Plan considers the use of Xolair for conditions other than those listed under Indications to be experimental, investigational or unproven. There is insufficient peer-reviewed, published medical literature to support the use of Xolair for any of the following:

- Other allergic conditions or other forms of urticarial besides chronic idiopathic urticaria.
- Acute bronchospasm or status asthmaticus.
- Pediatric patients less than 6 years of age.

Xolair (Omalizumab) will be considered medically necessary for the Medicare line of business when all of the following criteria are met:

1. Asthma:

- Must be prescribed by an allergist or pulmonologist **AND**
- Insured individual is at least 6 years of age **AND**
- Physician provided documentation of a diagnosis of moderate to severe persistent asthma* with evidence of reversible airway disease [i.e. greater than 12% improvement in forced expiratory volume in one second (FEV1) with at least 200 ml increase or at least a 20% or greater improvement in peak expiratory flow (PEF) after administration of albuterol] **AND**
- Physician provided documentation of inadequate control or intolerance, despite a 3 month trial of: medium–high dose inhaled corticosteroids or systemic corticosteroids AND long-acting beta agonists or leukotriene receptor antagonists **AND**
- Physician provided documentation of an IgE level of greater than 30 IU/ml and less than 700 IU/ml for individuals age 12 and older OR IgE level of greater than 30 IU/ml and less than 1300 IU/ml for individuals age 6 through 11 **AND**
- Physician provided documentation of evidence of a specific allergic reactivity to a perennial aeroallergen by positive skin or blood test for a specific IgE **AND**
- Known environmental triggers within the member's control have been eliminated. **AND**
- Medical record documentation that Xolair will not be used in combination with another biologic medication indicated for asthma treatment (e.g. Tezspire, Nucala, Fasenra, Dupixent, Cinqair)

*Moderate persistent asthma is defined by the National Heart, Lung and Blood institute (NHLBI) as:

1. Daily symptoms
2. Daily use of inhaled short-acting beta agonist
3. Exacerbations affect activity
4. Exacerbations at least twice a week, which may last days
5. Nighttime symptoms more frequently than one time per week
6. Lung function of FEV1 greater than 60% but less than 80%

*Severe persistent asthma is defined by the NHLBI as:

1. Continual symptoms
2. Limited physical activity
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4. Frequent nighttime symptoms
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**The 12% improvement target value is calculated using the following methodology: The target value = baseline FEV_1 x 1.12

The actual clinical calculation is: $\frac{\text{post-treatment } FEV_1 - \text{baseline } FEV_1}{\text{baseline } FEV_1} = \%$ improvement baseline FEV_1

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Adapted from Xolair [package insert]. South San Francisco, CA: Genentech USA Inc; March 2014

For individuals 6 to 11 years old:

Pre-treatment Serum IgE (IU/mL)	Body Weight (kg)									
	20-25	**>25-30**	**>30-40**	**>40-50**	**>50-60**	**>60-70**	**>70-80**	**>80-90**	**>90-125**	**>125-150**
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2. For Chronic Idiopathic Urticaria:

- Prescription is written by an allergist, immunologist, or dermatologist **AND**
- Patient is at least 12 years of age **AND**
- Diagnosis of moderate-to-severe chronic idiopathic urticaria **AND**
- At least 6 week history of symptoms (e.g., hives associated with itching, angioedema) **AND**
- Medical record documentation of contraindication to, therapeutic failure on, or intolerance to a four week trial of maximal dose of one antihistamine used in combination with one of the following:
    - H2 receptor antagonist (e.g., ranitidine)
    - leukotriene receptor antagonist (e.g., montelukast)

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- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of nasal polyps **AND**
- Medical record documentation that Xolair will be used as add-on maintenance treatment **AND**
- Medical record documentation of therapeutic failure on, intolerance to, or contraindication to two (2) intranasal corticosteroids (including but not limited to: beclomethasone, ciclesonide, fluticasone, mometasone, triamcinolone)

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4. IgE Mediated Food Allergies

- Medical record documentation of use for the maintenance reduction of IgE mediated food allergies (type 1) **AND**
- Medical record documentation that Xolair is prescribed by an allergist or immunologist **AND**
- Medical record documentation that member is 1 year of age or older **AND**
- Medical record documentation of a positive skin prick test response to one or more foods **AND**
- Medical record documentation of a positive in vitro test for IGE to one or more foods **AND**
- Prescriber attestation that reaction is significant enough for the member to require and receive a prescription for an epinephrine product **AND**
- Medical record documentation that medication will be used in conjunction with a food allergen-avoidant diet **AND**
- Medical record documentation of a dose consistent with FDA approved labeling **AND**
- Medical record documentation of an IgE level of greater than 30 IU/mL **AND**
- Medical record documentation that Xolair is not being administered in combination with an additional monoclonal antibody used for the treatment of IgE mediated conditions.

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

LIMITATIONS:
The Plan considers the use of Xolair for conditions other than those listed under Indications to be experimental, investigational or unproven. There is insufficient peer-reviewed, published medical literature to support the use of Xolair for any of the following:

- Other allergic conditions or other forms of urticarial besides chronic idiopathic urticaria.
- Acute bronchospasm or status asthmaticus.
- Pediatric patients less than 6 years of age.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Xolair [prescribing information]. South San Francisco, CA: Genentech Inc; March 2023.
2. Global Strategy for Asthma Management and Prevention. Global Initiative for Asthma. 2023 July [cited 2023 Dec 26]. Available from: https://ginasthma.org/2023-gina-main-report/
3. Bernstein JA, Lang DM, Khan DA. The diagnosis and management of acute and chronic urticaria: 2014 update. American Academy of Allergy. Asthma & Immunology; 2014 Feb 12; 133(5):1270-1277 [cited 2023 Dec27]. Available from: https://pubmed.ncbi.nlm.nih.gov/24766875/
4. Rank MA, Chu DK, Bognanni A, et al. The Joint Task Force on Practice Parameters GRADE guidelines for the medical management of chronic rhinosinusitis with nasal polyposis. Joint Task Force on Practice Parameters (JTF-PP). Journal of Allergy and Clinical Immunology; 2023 Feb; 151(2):386-398 [cited 2023 Dec 27]. Available from: https://www.sciencedirect.com/science/article/pii/S0091674922014841?via%3Dihub

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 10/27/03

Revised: 5/05 expanded criteria for coverage; 5/07 added FDA warning; 3/08 criteria change; 11/09 (added formulary alternatives, dosing chart); 2/13, 09/16/14 (added new indication), 3/24/15 changed auth duration, 3/23/17 (updated age criteria, PARP), 5/15/18 (criteria updated), 5/18/21 (nasal polyps), 5/17/22 (asthma biologics verbiage), 5/11/23 (Medicaid business segment, Nasal Polyps prescriber [see 3/2022 P&T]), 12/31/23 (references added), 6/3/24 (LOB carve out, alts for nasal polyps per Dec 2023 P&T), 6/19/24 (Food allergies indication, LOB box, taglines)

Reviewed: 6/06, 12/10; 2/12; 09/16/14, 3/31/16, 1/30/17, 10/31/17, 4/22/19, 2/1/20, 1/19/21

MA UM Committee approval: 12/31/23, 8/30/24