JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS162
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		Approval Date	01/18/2023
	Subject **Self-administered Xolair (prefilled syringe)**	*Supersedes Date*	N/A
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Xolair syringe

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I. POLICY

Xolair prefilled syringe (omalizumab) will require prior authorization to ensure it is used only when clinically appropriate. The process for initiating a prior authorization request can be found in policy PHARM 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Xolair** may be approved for patients meeting the following:

1. **Moderate to severe persistent asthma:**
   a. Documentation has been submitted showing the following:
      I. Patient is 6 years of age or older
      II. Patient has a positive skin test or in vitro reactivity to at least one perennial aeroallergen
      III. Patient has a pre-treatment IgE level greater than or equal to 30 IU/mL
      IV. Patient has uncontrolled asthma as demonstrated by experiencing at least ONE of the following within the past year:
         i. 2 or more asthma exacerbations requiring oral or injectable corticosteroid treatment
         ii. 1 or more asthma exacerbations resulting in hospitalization or emergency medical care visit
         iii. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma)
      V. Patient has inadequate asthma control despite current treatment with both of the following medications at optimized doses:
         i. Medium-to-high-dose inhaled corticosteroid
         ii. Additional controller (i.e., long acting beta2-agonist, long acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)

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VI. Patient will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Xolair
VII. Patient will not use Xolair concurrently with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Nucala, Tezspire)
VIII. Prescriber is, or has consulted with, an allergist, immunologist, or pulmonologist

2. **Chronic spontaneous urticaria (CSU):**
   a. Documentation has been submitted showing the following:
      I. Patient is 12 years of age or older
      II. Patient remains symptomatic despite treatment with up-dosing of a second-generation H1 antihistamine (e.g., cetirizine, fexofenadine, levocetirizine, loratadine) for at least 2 weeks
      III. Patient has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis)
      IV. Patient has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks
      V. Prescriber is, or has consulted with, an allergist, immunologist, or dermatologist
3. **Add-on maintenance treatment for Nasal Polyps:**
   a. Documentation has been submitted showing the following:
      I. Patient is 18 years of age or older
      II. Patient has bilateral nasal polyps and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated
      III. Patient has one of the following:
         i. A bilateral nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril
         ii. Meltzer Clinical Score of 2 or higher in both nostrils
         iii. A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril
      IV. Patient has nasal blockage plus one of the following additional symptoms:
         i. Rhinorrhea (anterior/posterior)
         ii. Reduction or loss of smell
         iii. Facial pain or pressure
      V. Patient will continue to use a daily intranasal corticosteroid while being treated with Xolair, unless contraindicated or not tolerated
      VI. Patient will not use Xolair concurrently with other biologics indicated for nasal polyps (e.g., Dupixent, Nucala)
      VII. Prescriber is, or has consulted with, an allergies, immunologist, or otolaryngologist
4. **Immune checkpoint inhibitor-related toxicity:**
   a. Documentation has been submitted showing the following:
      I. Patient has a refractory case of immune-therapy related severe (G3) pruritus and elevated IgE levels
5. **Systemic mastocytosis:**
   a. Documentation has been submitted showing the following:
      I. The presence of the major and at least one minor diagnostic criterion for systemic mastocytosis, or three or more minor diagnostic criteria as noted below:
         i. Major Criteria: multifocal, dense infiltrates of mast cells (at least 15 mast cells in aggregates) detected in sections of bone marrow and/or other extracutaneous organs
         ii. Minor Criteria:

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1. In biopsy sections of bone marrow or other extracutaneous organs, greater than 25% of mast cells in the infiltrate are spindle-shaped or have atypical morphology, or greater than 25% of all mast cells in bone marrow aspirate smears are immature or atypical
2. Detection of an activating point mutation at codon 816 of KIT in the bone marrow, blood, or another extracutaneous organ
3. Mast cells in bone marrow, blood, or other extracutaneous organs express CD25, with or without CD2, in addition to normal mast cell markers
4. Serum total tryptase persistently greater than 20 ng/mL (unless there is an associated myeloid neoplasm, in which case this parameter is not valid)

II. Xolair will be used in any of the following treatment settings:
- i. Used as stepwise prophylactic treatment for chronic mast cell mediator-related cardiovascular and pulmonary symptoms when both of the following have been tried:
  1. H1 blockers and H2 blockers
  2. Corticosteroids
- ii. Used for prevention of recurrent unprovoked anaphylaxis
- iii. Used for prevention of hymenoptera or food-induced anaphylaxis, with negative specific IgE or negative skin test
- iv. Used to improve tolerability of venom immunotherapy

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval may be granted as follows:
1. Six months for the treatment of asthma, chronic spontaneous urticaria, or nasal polyps
2. One month for the treatment of immune checkpoint inhibitor-related toxicity
3. 12 months for the treatment of systemic mastocytosis

B. Continuation of therapy may be approved as follows:
1. Asthma: Continuation may be approved in 12-month intervals with documentation of the following:
   a. Asthma control has improved on Xolair treatment as demonstrated by at least one of the following:
      I. A reduction in the frequency and/or severity of symptoms and exacerbations
      II. A reduction in the daily maintenance oral corticosteroid dose
   b. Patient will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Xolair
   c. Patient will not use Xolair concurrently with other biologics indicated for asthma (e.g., Cinqair, Dupixent, Fasenra, Tezspire, Nucala)
2. Chronic spontaneous urticaria: Continuation may be approved in 12-month intervals with documentation of the following:
   a. Patient has experienced a response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy
3. Nasal polyps: Continuation may be approved in 12-month intervals with documentation of the following:
   a. Patient has 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)
   b. Patient will not use Xolair concurrently with other biologics indicated for nasal polyps (e.g., Dupixent, Nucala)
4. Immune checkpoint inhibitor-related toxicities: Continuation may be approved at the initial coverage duration for patients that still meet the initial coverage.

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5. Systemic mastocytosis Continuation may be approved at the initial coverage duration for patients that still meet the initial coverage.

IV. EXCLUSIONS

A. Xolair will not be approved for the following:
   1. Any indications or uses that are not FDA-approved or guidelines-supported

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information for indication-specific dosing details.

VI. REFERENCES

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VII. APPROVALS

Signature on file at JHHC

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