Pharmacy Management Drug Policy

SUBJECT: Xolair® (Omalizumab)
POLICY NUMBER: PHARMACY-57
EFFECTIVE DATE: 7/2003
LAST REVIEW DATE: 11/19/2025

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☒ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☒ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☒ Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Asthma

Xolair (omalizumab) is indicated for moderate to severe persistent asthma in adults and pediatric patients 6 years of age and older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids.

Asthma is a heterogeneous syndrome that might be better described as a constellation of phenotypes, each with distinct cellular and molecular mechanisms, rather than as a singular disease. One of these phenotypes is allergic asthma, which is associated with allergies to allergens such as pollen or dust mites. Chronic airway inflammation results in symptoms that include wheezing, shortness of breath, chest tightness, and cough.

Immunoglobulin E (IgE) plays a central role in the pathogenesis of allergic asthma. IgE activation of mast cells, and basophils causes the release of inflammatory mediators such as histamine, prostaglandins, cysteinyl-leukotrienes, and cytokines. Xolair (omalizumab) is a recombinant humanized monoclonal antibody that inhibits the binding of IgE to the IgE receptors on the surface of mast cells, basophils, and dendritic cells. This results in receptor down-regulation on these cells and leads to a reduction in blood/tissue eosinophils and other inflammatory mediators.

Chronic Idiopathic Urticaria (CIU)

Xolair (omalizumab) is indicated for chronic spontaneous urticaria (CSU) in adults and adolescents 12 years of age and older who remain symptomatic despite H1 antihistamine treatment.

Chronic idiopathic urticaria is defined by the presence of wheals (hives), angioedema (swelling), or both, most days of the week, for a duration of 6 weeks or longer. The hives may appear at any age, can occur anywhere on the body, and vary in size. They are typically itchy, raised, and appear as reddish areas on the skin. Angioedema may be painful and usually occurs in the face, throat, hands, and feet, though it can occur in other areas of the body as well. Usually, the cause of chronic urticaria cannot be identified.

Xolair (omalizumab) is a recombinant humanized monoclonal antibody that binds to IgE and lowers free IgE levels, resulting in receptor down-regulation on cells. It is unknown how this mechanism improves symptoms in CIU.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Xolair (omalizumab) is indicated for chronic rhinosinusitis with nasal polyps (CRSwNP) in adult patients 18 years of age and older with inadequate response to nasal corticosteroids, as add-on maintenance treatment.

CRSwNP is a subtype of chronic rhinosinusitis (CRS). It is a heterogeneous chronic inflammatory disease of the nasal lining and sinuses, resulting in the development of noncancerous soft tissue growth (polyps) in the sino-nasal cavity. Symptoms include loss of smell, nasal congestion, and nasal drainage. Most patients with CRSwNP show evidence of type 2 inflammation. Nasal polyp tissue is characterized by local eosinophil inflammation in a large majority of patients with this condition. Despite optimized treatment, nasal polyps have a high rate of recurrence.

Xolair (omalizumab) is a recombinant humanized monoclonal antibody that inhibits the binding of IgE to the IgE receptors on the surface of mast cells, basophils, and dendritic cells. This results in receptor down-regulation on these cells and leads to a reduction in blood/tissue eosinophils and other inflammatory mediators.

Food Allergies

Xolair (omalizumab) is indicated for IgE-mediated food allergy in adult and pediatric patients aged 1 year and older for the reduction of allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance.

IgE-mediated food allergic reactions are rapid in onset, typically beginning within minutes to two hours from the time of ingestion. Most patients react to one or two specific foods/food groups, although an increasing number of patients react to multiple foods.

Xolair is a recombinant humanized monoclonal antibody that inhibits the binding of IgE to the high-affinity on the surface of mast cells, basophils, and dendritic cells, which down-regulates the IgE receptors on these cells and reduces allergic reactions.

ASTHMA POLICY:

Based upon our criteria and review of the peer-reviewed literature, treatment with Xolair administered in accordance with FDA guidelines, has been medically proven to be effective and therefore, **medically appropriate** if **ALL** the following criteria are met:

1. Patient must be at least 6 years old **AND**
2. Patient must be followed by, and drug ordered by an allergist/immunologist or pulmonologist **AND**
3. Patient must have moderate to severe persistent asthma **AND**
4. Patient must be a non-smoker. Non-smoker is defined as someone who has not smoked in the past 6 months **AND**
5. Patient must have well documented use of high-dose inhaled corticosteroids (ICS) (see **Tables 6-8**) for **at least3 months**, be compliant with existing therapy, and have followed GINA guidelines for asthma treatment including an adequate trial of a high-dose inhaled steroid in combination with a long-acting beta agonist.

   a. Compliance will be assessed based on pharmacy refill history. If the patient does not have pharmacy benefits through this health plan, a recent pharmacy profile will be requested. Progress notes documenting usage of sample medication may also be requested.
   b. If there is a contraindication to use of a long-acting beta agonist, then an alternative controller drug may be used in combination with a high-dose inhaled steroid such as a leukotriene inhibitor or long-acting muscarinic antagonist.
   c. Patient must have documentation of inadequate control with optimal therapy (above) for a period of at least 3 months **AND**
6. Patient must have documented evidence of at least 1 perennial aeroallergen [e.g., house dust mite (*Dermatophagoides farinae, D. pteronyssinus*), animal dander (dog, cat), cockroach, feathers, mold spores] by:
   a. a skin test (i.e., prick/puncture test) **OR**
   b. in vitro testing (i.e., blood test for allergen-specific IgE antibodies such as the radioallergosorbent test - RAST Class 2 or greater) **AND**
7. Patient must have baseline IgE levels between 30 and 700 IU/mL
   Coverage for IgE levels outside of this range will be considered as follows:
   a. Patients with a baseline IgE level between 700 and 1300 IU/mL will be considered for Xolair therapy if all other criteria is met and as long as the dose required based on IgE and body weight is not > 750mg per month (See **Tables 1-4** for dosing) **OR**
   b. Patients with a baseline IgE level below 30 IU/mL will not be considered for coverage as there is not enough free IgE with which to bind for the drug to exert its effect **AND**
   c. Note: according to drug labeling, for **adult** patients with **both** asthma and nasal polyps, dosing determination should be based on the **primary diagnosis** for which XOLAIR is being prescribed
8. Patient must have experienced **2 or more** asthma exacerbations within the preceding 12 months that required medical management (defined as unscheduled doctor visits, urgent care visits, emergency room visits, hospital admissions, or documented need for acute systemic steroids) despite existing therapy as outlined in Criterion #5 **AND**
9. For **self-administration** (prefilled syringes only) under the **pharmacy benefit,** the provider must attest to **ALL** the following:
   a. The patient has no prior history of anaphylaxis (including to Xolair or other agents)
   b. The patient has or will receive at least 3 doses of Xolair under the supervision of a healthcare provider
   c. The patient/caregiver has been appropriately trained to self-administer Xolair injections
   d. The patient/caregiver has the ability to recognize the symptoms of anaphylaxis
   e. The patient/caregiver has the ability to appropriately treat anaphylaxis
10. Initial approval will be for 6 months. All recertifications are for 2 years and will require an objective assessment of response to therapy with Xolair (decrease in hospitalizations, decrease in ER visits, decrease in rescue medication use) by the provider as well as documentation of compliance history with the inhaled corticosteroid and controller medication. Recertification will not be granted if the patient starts or restarts smoking. See recertification statement and approval time period table in policy guidelines section of this policy.

URTICARIA POLICY:

Omalizumab is currently classified as third-line therapy in the 2017 EAACI/GA²LEN/EDF/WAO guideline for the definition, classification, diagnosis, and management of urticaria, previously endorsed by AAAAI/ACAAI, and updated in 2022. The following criteria are based on FDA labeling and current treatment recommendations.

1. Patient must be followed by, and drug ordered by an allergist/immunologist or dermatologist **AND**
2. Patients must be at least 12 years old with at least a 6-week history of urticaria characterized by the development of wheals (hives), angioedema, or both, despite adequate trials (minimum of four weeks each) of:
    a. A second generation H_1-antihistamine at standard dosing **AND** a second-generation H_1-antihistamine trialed at 2-4 times the standard dose
        i. These criteria may be satisfied by using either the same second generation H_1-antihistamine at standard dosing and 2-4 times standard dosing **OR** using two different second generation H_1-antihistamines with at least one agent being at 2-4 times standard dosing
3. For **self-administration** (prefilled syringes only) under the **pharmacy benefit,** the provider must attest to **ALL** the following:
    a. The patient has no prior history of anaphylaxis (including to Xolair or other agents)
    b. The patient has or will receive at least 3 doses of Xolair under the supervision of a healthcare provider
    c. The patient/caregiver has been appropriately trained to self-administer Xolair injections
    d. The patient/caregiver has the ability to recognize the symptoms of anaphylaxis
    e. The patient/caregiver has the ability to appropriately treat anaphylaxis
4. Initial approval will be for 6 months
    a. FDA-approved dosing is 150 or 300mg subcutaneously every 4 weeks (Total doses should not exceed 300mg per 4-week interval).
5. All recertifications will be for 2 years and will require documentation that the patient has responded to or continues to benefit from therapy (i.e., decreased severity of itching, or size/number of hives). See recertification statement and approval time-period table in policy guidelines section of this policy.

<u>NASAL POLYPS POLICY</u>:

Based upon our assessment and review of the peer-reviewed literature, treatment with **Xolair (Omalizumab)** has been medically proven to be an effective and therefore, **medically appropriate** for chronic rhinosinusitis with nasal polyps (CRSwNP) if **ALL** the following criteria are met:

1. Must be followed by and drug ordered by an allergist, immunologist, or otolaryngologist **AND**
2. Must have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP)
    - Chronic is defined as having lasted for at least 12 weeks **AND**
    - Must currently have nasal polyposis, confirmed by evidence (such as direct examination, nasal endoscopy, imaging studies (such as a sinus CT scan))
3. Must be ≥ 18 years of age **AND**
4. Step therapy applies – Step therapy (a **AND** b) applies to New Starts for all lines of business, **including** Medicare Part B:
    a. Must have documented inadequate response despite at least 3 months of compliant use of mometasone nasal spray at a dose of 2 sprays in each nostril twice daily (compliance will be verified through pharmacy claims history. Note: each inhaler =17g = 120 sprays, therefore claims should reflect **34g/30 days** for the required dosing) **AND**
    b. Must have documented inadequate response despite at least 3 months of compliant use of Xhance nasal spray at a dose of 2 sprays in each nostril twice daily (compliance will be verified through pharmacy claims history. Note: each inhaler =16ml = 120 sprays, therefore claims should reflect **32ml/30 days** for the required dosing) **AND**

5. Must have had either:
    a. Prior nasal surgery **OR**
    b. Prior treatment with a course of systemic corticosteroids
6. Must be used in combination with an intranasal corticosteroid
    a. Xolair as monotherapy for this indication will not be authorized as it is only FDA approved as an add-on maintenance treatment for this indication
7. Must have baseline IgE level between 30 and 1500 IU/ml
    a. Dosing is based on IgE levels and body weight (see **Table 5**)
    b. Patients with a baseline IgE level above 1500 IU/ml will be considered for Xolair therapy if all other criteria are met and as long as the dose required based on IgE and body weight does not exceed 600mg every 2 weeks
    c. Note: according to drug labeling, for **adult** patients with **both** asthma and nasal polyps, dosing determination should be based on the **primary diagnosis** for which XOLAIR is being prescribed
8. For **self-administration** (prefilled syringes only) under the **pharmacy benefit,** the provider must attest to **ALL** the following:
    a. The patient has no prior history of anaphylaxis (including to Xolair or other agents)
    b. The patient has or will receive at least 3 doses of Xolair under the supervision of a healthcare provider
    c. The patient/caregiver has been appropriately trained to self-administer Xolair injections
    d. The patient/caregiver has the ability to recognize the symptoms of anaphylaxis
    e. The patient/caregiver has the ability to appropriately treat anaphylaxis
9. Initial approval will be granted for 6 months. All recertifications will be for 2 years and will require documentation of continued use of an intranasal corticosteroid and clinical benefit from Xolair use (e.g., reduced nasal polyp size, improved nasal congestion, reduced sinus opacification, decreased sino-nasal symptoms, improved sense of smell). See recertification statement and approval time-period table in policy guidelines section of this policy.

FOOD ALLERGIES POLICY:

1. Must be followed by and drug ordered by an allergist, or an immunologist **AND**
2. Must be at least 1 year old **AND**
3. Must have a confirmed diagnosis of an IgE- mediated food allergy
    a. Must have documentation of a positive skin test OR allergen-specific immunoglobulin E (IgE) blood test for each allergy within 12 months of the request **AND**
    b. Must have documentation of occurrence of significant allergic symptoms (e.g., moderate to severe skin, respiratory or gastrointestinal symptoms, etc.) when exposed to applicable allergens **AND**
4. Prescriber must attest to use in conjunction with food allergen avoidance **AND**
5. Pretreatment serum IgE levels (IU/mL) must be provided on initial requests
    a. Coverage will be excluded for patients with an IgE of greater than or equal to 1850 IU/mL. **AND**
6. Patient's weight must be provided on initial, and all recertification requests **AND**
7. Coadministration of Xolair (omalizumab) with a peanut protein desensitization therapy (e.g., Palforzia) or other oral immunotherapy (OIT) has not been studied and will be considered experimental/investigational and will not be authorized.
8. Xolair is not indicated for the emergency treatment of allergic reactions, including anaphylaxis
9. For self-administration (prefilled syringes only) under the pharmacy benefit, the provider must attest to **ALL** the following:
    a. The patient has no prior history of anaphylaxis (including to Xolair or other agents [**except**

foods])
   b. The patient has or will receive at least 3 doses of Xolair under the supervision of a healthcare provider
   c. The patient/caregiver has been appropriately trained to self-administer Xolair injections
   d. The patient/caregiver has the ability to recognize the symptoms of anaphylaxis
   e. The patient/caregiver has the ability to appropriately treat anaphylaxis
10. See Table 6 in Policy Guidelines for appropriate dosing.
11. Initial approval will be for 6 months. All recertifications will be for 2 years and will require progress notes documenting the patient has had no severe allergic symptoms (e.g., moderate to severe skin, respiratory or gastrointestinal symptoms, etc.) to food allergens while on Xolair therapy AND that the patient continues to practice food allergen avoidance.

POLICY GUIDELINES:

1. Utilization Management are contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
2. Xolair vial for injection is administered by a healthcare professional and is covered under the medical benefit; however, select benefits may allow for coverage under the pharmacy benefit. Xolair prefilled syringes and autoinjector may be covered under the medical benefit (administered by a healthcare professional) **OR** the pharmacy benefit (self-administered).
3. Because of the risk of anaphylaxis, patients should be closely observed for an appropriate period after Xolair administration, and healthcare providers administering Xolair should be prepared to manage anaphylaxis, which can be life-threatening. Patients should also be informed of the signs and symptoms of anaphylaxis and instructed to seek immediate medical care should symptoms occur. Xolair for self-administration should only be for select patients based on a careful assessment of risk for anaphylaxis and mitigation strategies.
4. If an authorization for ongoing administration is added under one benefit, it will be terminated under the other. For example: if the member was approved under the medical benefit and now is requesting coverage under the pharmacy benefit, the authorization on the medical benefit will be terminated when the pharmacy authorization is approved.
5. For any diagnosis, if Xolair therapy is initiated with samples and the member does not meet our criteria for coverage (as outlined above) before the start of Xolair therapy, upon completion of the samples, coverage of Xolair will not be granted.
6. Request for the concurrent use of Xolair with other inflammatory agents such as Adbry, Dupixent, Nucala, Fasenra, Cinqair and Tezspire will be evaluated for safety and efficacy and subject to off-label review.
7. Xolair will not be authorized in the following circumstances:
   a. Concurrent use with peanut protein desensitization therapy (e.g., Palforzia) other oral immunotherapy (OIT)
   b. Patients with previous anaphylaxis to Xolair
   c. Use for latex allergies, atopic dermatitis, or seasonal allergic rhinitis (hay fever)
8. Asthma, Food Allergies and Nasal Polyp dosing is based on patient weight and pre-treatment IgE levels as shown below (See **Tables 1-4** for asthma, **Table 5** for nasal polyps and **Table 6** for food allergies).
9. Dosing of Xolair for CIU is not dependent upon serum IgE level (free or total) or body weight.
10. Periodically reassess the need for continued therapy based on disease severity and level of symptom control. The appropriate duration of therapy for CIU has not been evaluated.

Table 1. Subcutaneous Xolair Doses Every 4 Weeks for Patients 12 Years of Age and Older with Asthma

Pre-treatment Serum IgE	Body Weight			
	30–60 kg	> 60–70 kg	> 70–90 kg	> 90–150 kg
≥ 30–100 IU/mL	150 mg	150 mg	150 mg	300 mg
> 100–200 IU/mL	300 mg	300 mg	300 mg	
> 200–300 IU/mL	300 mg			
> 300–400 IU/mL		**SEE TABLE 2**		
> 400–500 IU/mL				
> 500–600 IU/mL				

Table 2. Subcutaneous Xolair Doses Every 2 Weeks for Patients 12 Years of Age and Older with Asthma

Pre-treatment Serum IgE	Body Weight			
	30–60 kg	> 60–70 kg	> 70–90 kg	> 90–150 kg
≥ 30–100 IU/mL		**SEE TABLE 1**		
> 100–200 IU/mL				225 mg
> 200–300 IU/mL		225 mg	225 mg	300 mg
> 300–400 IU/mL	225 mg	225 mg	300 mg	
> 400–500 IU/mL	300 mg	300 mg	375mg	
> 500–600 IU/mL	300 mg	375 mg	**DO NOT DOSE**	
> 600–700 IU/mL	375 mg			

Table 3. Subcutaneous Xolair Doses Every 2 or 4 Weeks for Pediatric Patients with Asthma Who Begin Xolair Between the Ages of 6 to <12 Years

Pre-treatment Serum IgE (IU/mL)	Dosing Freq.	Body Weight									
		20-25 kg	>25-30 kg	>30-40 kg	>40-50 kg	>50-60 kg	>60-70 kg	>70-80 kg	>80-90 kg	>90-125 kg	>125-150 kg
		Dose (mg)									
30-100	Every 4 weeks	75	75	75	150	150	150	150	150	300	300
>100-200		150	150	150	300	300	300	300	300	225	300
>200-300		150	150	225	300	300	225	225	225	300	375
>300-400		225	225	300	225	225	225	300	300	DO NOT DOSE	
>400-500		225	300	225	225	300	300	375	375		
>500-600		300	300	225	300	300	375	DO NOT DOSE			
>600-700		300	225	225	300	375	DO NOT DOSE				
>700-800	Every 2 weeks	225	225	300	375	DO NOT DOSE					
>800-900		225	225	300	375						
>900-1000		225	300	375	DO NOT DOSE						
>1000-1100		225	300	375							
>1100-1200		300	300	DO NOT DOSE							
>1200-1300		300	375								

11. Although not FDA approved, based on current study data we may allow for doses above 750mg per month for asthma on a case-by-case basis. The dosing utilized in this study and found to be safe and effective is listed below for reference.

Table 4. Omalizumab dosage based on body weight and serum total IgE levels at baseline

Body Weight (kg)	Omalizumab 450mg every 2 weeks	Omalizumab 525mg every 2 weeks	Omalizumab 600mg every 2 weeks
>125-150	n/a	>300-400	>400-2000
>90-125	>300-400	>400-500	>500-2000
>80-90	>500-600	>600-700	>700-2000
>70-80	>500-700	>700-800	>800-2000
>60-70	>600-800	>800-900	>900-2000
>50-60	>700-900	>900-1000	>1000-2000
>40-50	>900-1100	>1100-1300	>1300-2000

Table 5. Subcutaneous XOLAIR Doses Every 2 or 4 Weeks* for Adult Patients with Nasal Polyps

Pretreatment Serum IgE (IU/mL)	Dosing Freq.	Bodyweight							
		>30-40 kg	>40-50 kg	>50-60 kg	>60-70 kg	>70-80 kg	>80-90 kg	>90-125 kg	> 125-150 kg
		Dose (mg)							
30 - 100	Every 4 Weeks	75	150	150	150	150	150	300	300
>100 - 200		150	300	300	300	300	300	450	600
>200 - 300		225	300	300	450	450	450	600	375
>300 - 400		300	450	450	450	600	600	450	525
>400 - 500		450	450	600	600	375	375	525	600
>500 - 600		450	600	600	375	450	450	600	
>600 - 700		450	600	375	450	450	525		
>700 - 800	Every 2 Weeks	300	375	450	450	525	600		
>800 - 900		300	375	450	525	600			
>900 - 1000		375	450	525	600				
>1000 - 1100		375	450	600					
>1100 - 1200		450	525	600	Insufficient Data to Recommend a Dose				
>1200 - 1300		450	525						
>1300 - 1500		525	600						

Table 6. Subcutaneous XOLAIR Doses Every 2 or 4 Weeks* for Adult and Pediatric Patients 1 Year of Age and Older with IgE-Mediated Food Allergy

Pretreatment Serum IgE (IU/mL)	Dosing Freq.	Body Weight (kg)												
		≥10-12	>12-15	>15-20	>20-25	>25-30	>30-40	>40-50	>50-60	>60-70	>70-80	>80-90	>90 - 125	>125 - 150
		Dose (mg)												
≥30 - 100	Every 4 Weeks	75	75	75	75	75	75	150	150	150	150	150	300	300
>100 - 200		75	75	75	150	150	150	300	300	300	300	300	450	600
>200 - 300		75	75	150	150	150	225	300	300	450	450	450	600	375
>300 - 400		150	150	150	225	225	300	450	450	450	600	600	450	525
>400 - 500		150	150	225	225	300	450	450	600	600	375	375	525	600
>500 - 600		150	150	225	300	300	450	600	600	375	450	450	600	
>600 - 700		150	150	225	300	225	450	600	375	450	450	525		
>700 - 800	Every 2 Weeks	150	150	150	225	225	300	375	450	450	525	600		
>800 - 900		150	150	150	225	225	300	375	450	525	600			
>900 - 1000		150	150	225	225	300	375	450	525	600				
>1000 - 1100		150	150	225	225	300	375	450	600					
>1100 - 1200		150	150	225	300	300	450	525	600	Insufficient data to Recommend a Dose				
>1200 - 1300		150	225	225	300	375	450	525						
>1300 - 1500		150	225	300	300	375	525	600						
>1500 - 1850			225	300	375	450	600							

*Dosing frequency:

- Subcutaneous doses to be administered every 4 weeks
- Subcutaneous doses to be administered every 2 weeks

12. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and the requesting prescriber provides rationale and documentation for one of the following circumstances, then trial of the preferred drug(s) will not be required.
    - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member
    - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen
    - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event
    - The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities
    - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
    - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
13. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Non-Formulary Medication Exception Review Policy for review guidelines.
14. This policy is subject to frequent revisions as new medications come onto the market. Some drugs will require prior authorization prior to criteria being added to the policy.
15. Supportive documentation of previous drug use must be submitted for any criteria that require a trial of a preferred agent if the preferred drug is not found in claims history.
16. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
17. For members with Medicare Part B, medications with a National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) will be covered pursuant to the criteria outlined by the NCD and/or LCD. NCDs/LCDs for applicable medications can be found on the CMS website at https://www.cms.gov/medicare-coverage-database/search.aspx. Indications that have not been addressed by the applicable medication's LCD/NCD will be covered in accordance with criteria determined by the Health Plan (which may include review per the Health Plan's Off-Label Use of FDA Approved Drugs policy). Step therapy requirements may be imposed in addition to LCD/NCD requirements.
18. Not all contracts cover all Medical Infusible drugs. Refer to specific contract/benefit plan language for exclusions of Injectable Medications.
19. **Unless otherwise stated above within the individual drug criteria**, approval time periods are listed in the table below.
    - Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition.

Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary. Also, ongoing use of the requested product must continue to reflect the current policy's preferred formulary. Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must continue to be consistent with FDA-approved or off-label/guideline-supported dosing recommendations.

20. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32).
21. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.
22. Manufacturers may either discontinue participation in, or may not participate in, the Medicaid Drug Rebate Program (MDRP). Under New York State Medicaid requirements, physician-administered drugs must be produced by manufacturers that participate in the MDRP. Products made by manufacturers that do not participate in the MDRP will not be covered under Medicaid Managed Care/HARP lines of business. Drug coverage will not be available for any product from a non-participating manufacturer. For a complete list of New/Reinstated & Terminated Labelers please visit: https://www.medicaid.gov/medicaid/prescriptiondrugs/medicaid-drug-rebate-program/newreinstated-terminated-labeler-information/index.html

Line of Business	Medical initial approval	Continued approval
Commercial, Exchange, and SafetyNet (Medicaid, HARP, CHP, Essential Plan)	All sites of service – 2 years	All sites of service – 2 years
Medicare	All sites of service – 2 years	All sites of service – 2 years

Table 6

Estimated comparative daily doses for inhaled glucocorticoids in adolescents ≥12 years and adults

Drug	Low dose (total daily dose)	Medium dose (total daily dose)	High dose (total daily dose)*
Beclomethasone HFA (Qvar RediHaler product available in United States) Administer as 2 divided doses	80 to 160 mcg	>160 to 320 mcg	>320 to 640 mcg
40 mcg per actuation	2 or 4 inhalations	¶	¶
80 mcg per actuation	2 inhalations	4 inhalations	6 or 8 inhalations
Beclomethasone HFAΔ (Qvar product available in Canada, Europe, and elsewhere) Administer as 2 divided doses	100 to 200 mcg	>200 to 400 mcg	>400 to 800 mcg
50 mcg per actuation	2 to 4 inhalations	¶	¶
100 mcg per actuation	2 inhalations	4 inhalations	6 or 8 inhalations
Budesonide DPI (Pulmicort Flexhaler product available in United States) Administer as 2 divided doses	180 to 360 mcg	>360 to 720 mcg	>720 to 1440 mcg
90 mcg per actuation	2 or 4 inhalations	¶	¶
180 mcg per actuation	2 inhalations	4 inhalations	6 or 8 inhalations
Budesonide DPIΔ (Pulmicort Turbuhaler or Turbohaler product available in Canada, Europe, and elsewhere) Administer low doses (ie, ≤400 mcg/day) once daily; administer higher doses (ie, >400 mcg/day) as 2 to 4 divided doses	200 to 400 mcg	>400 to 800 mcg	>800 to 2400 mcg
100 mcg per actuation	2 to 4 inhalations	¶	¶
200 mcg per actuation	1 to 2 inhalations	3 to 4 inhalations	¶
400 mcg per actuation	1 inhalation	2 inhalations	3 to 6 inhalations
Ciclesonide HFA (Alvesco product available in United States, Europe, and elsewhere) United States: Administer as 2 divided doses Australia, Europe, and elsewhere: Administer lower doses (ie, 160 to 320 mcg/day) once daily; administer 640 mcg dose as 2 divided doses	160 mcg	320 mcg	640 mcg
80 mcg per actuation	2 inhalations	4 inhalations	¶
160 mcg per actuation	◇	2 inhalations	4 inhalations
Ciclesonide HFAΔ (Alvesco product available in Canada) Administer lower doses (eg, 100 to 400 mcg) once daily; administer 800 mcg dose as 2 divided doses	100 to 200 mcg	>200 to 400 mcg	>400 to 800 mcg
100 mcg per actuation	1 to 2 inhalations	3 to 4 inhalations	¶
200 mcg per acutation	1 inhalation	2 inhalations	3 to 4 inhalations

Fluticasone propionate HFA (Flovent HFA product available in United States) Administer as 2 divided doses	176 to 220 mcg	>220 to 440 mcg	>440 to 1760 mcg
44 mcg per actuation	4 inhalations	¶	¶
110 mcg per actuation	2 inhalations	4 inhalations	¶
220 mcg per actuation	◇	2 inhalations	4 to 8 inhalations
Fluticasone propionate HFAΔ (Flovent HFA product available in Canada; Flixotide Evohaler product available in Europe and elsewhere) Administer as 2 divided doses	100 to 250 mcg	>250 to 500 mcg	>500 to 2000 mcg
50 mcg per actuation	2 to 4 inhalations	¶	¶
125 mcg per actuation	2 inhalations	4 inhalations	¶
250 mcg per actuation	◇	2 inhalations	4 to 8 inhalations
Fluticasone propionate DPI (Flovent Diskus product available in United States and Canada; Flixotide Accuhaler product available in Europe and elsewhere) Administer as 2 divided doses	100 to 250 mcg	>250 to 500 mcg	>500 to 2000 mcg
50 mcg per actuation	2 to 4 inhalations	¶	¶
100 mcg per actuation	2 inhalations	4 inhalations	¶
250 mcg per actuation	◇	2 inhalations	4 to 8 inhalations
500 mcg per actuation (strength not available in United States)	◇	◇	2 or 4 inhalations
Fluticasone propionate DPI (Armonair Digihaler product available in United States; Aermony Respiclick product available in Canada) Administer as 2 divided doses	110 mcg	226 mcg	464 mcg
55 mcg per actuation	2 inhalations	¶	¶
113 mcg per actuation	◇	2 inhalations	¶
232 mcg per actuation	◇	◇	2 inhalations
Fluticasone furoate DPI (Arnuity Ellipta product available in United States, Canada, Australia, and elsewhere, but not available in Europe or UK) Administer once daily **NOTE:** Inhaled fluticasone furoate has a greater anti-inflammatory potency per microgram than fluticasone propionate inhalers. Thus, fluticasone furoate is administered at a lower daily dose and used only once daily.	50 mcg (by use of pediatric DPI, which is off-label in adolescents and adults)	100 mcg	200 mcg
50 mcg per actuation	1 inhalation	¶	¶
100 mcg per actuation	◇	1 inhalation	2 inhalations
200 mcg per actuation	◇	◇	1 inhalation
Mometasone DPI (Asmanex Twisthaler product available in United States) May administer lower doses (ie, 220 to 440 mcg/day) once daily; administer 880 mcg dose as 2 divided doses	220 mcg	>220 to 440 mcg	>440 to 880 mcg
110 mcg per actuation	2 inhalations	¶	¶
220 mcg per actuation	1 inhalation	2 inhalations	4 inhalations

Mometasone DPI (Asmanex Twisthaler product available in United States) May administer lower doses (ie, 220 to 440 mcg/day) once daily; administer 880 mcg dose as 2 divided doses	220 mcg	>220 to 440 mcg	>440 to 880 mcg
110 mcg per actuation	2 inhalations	¶	¶
220 mcg per actuation	1 inhalation	2 inhalations	4 inhalations
Mometasone HFA (Asmanex HFA product available in United States) Administer as 2 divided doses	200 mcg	>200 to 400 mcg	>400 to 800 mcg
100 mcg per actuation	2 inhalations	4 inhalations	¶
200 mcg per actuation	◇	2 inhalations	4 inhalations
Mometasone DPIΔ (Asmanex Twisthaler product available in Canada, Europe, and elsewhere) May administer lower doses (ie, 200 to 400 mcg/day) once daily; administer 800 mcg dose as 2 divided doses	200 mcg	>200 to 400 mcg	>400 to 800 mcg
200 mcg per actuation	1 inhalation	2 inhalations	¶
400 mcg per actuation	◇	1 inhalation	2 inhalations

- **The most important determinant of appropriate dosing is the clinician's judgment of the patient's response to therapy.** The clinician must monitor the patient's response on several clinical parameters and adjust the dose accordingly. The stepwise approach to therapy emphasizes that once control of asthma is achieved, the dose of medication should be carefully titrated to the minimum dose required to maintain control, thus reducing the potential for adverse effects.
- Suggested total daily doses for low, medium, and high dose inhaled glucocorticoid regimens are based on daily doses recommended by Global Initiative for Asthma (GINA), National Asthma Education and Prevention Program (NAEPP), and/or product labeling[1-5]. This is not a table of equivalence.
- Depending on the specific product, total daily doses are administered once or divided and given twice daily. Refer to local product information or a clinical drug reference (eg Lexicomp).
- Some doses are outside the approved product information recommendations.

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant metered dose inhaler.

* Evidence for additional improvement with dose increases >1000 mcg/day is limited.

¶ Select alternate preparation with higher mcg/actuation to improve convenience.

Δ Products shaded in light gray color are not available in the United States but are available widely elsewhere.

◇ Select preparation with fewer mcg/actuation.

Table 7

Usual doses of combined inhaled glucocorticoids and bronchodilators

Medication	Low dose	Medium dose	High dose
ICS-SABA combination			
Budesonide-albuterol HFA (Brand name: Airsupra)*			
NOTE: Not used for maintenance therapy.			
Acute symptom relief: Budesonide-albuterol (80 mcg/90 mcg) 2 inhalations as needed (usual maximum: 12 inhalations/day).			
ICS-LABA combinations			
Beclomethasone [beclometasone]-formoterol DPI or HFA (Not available in United States or Canada, but available elsewhere [sample brand names: Formodual, Fostair, Foster])¶Δ			
100 mcg/6 mcg	1 inhalation twice a day	2 inhalations twice a day	
200 mcg/6 mcg			2 inhalations twice a day
Budesonide-formoterol HFA (Brand name: Symbicort)¶			
80 mcg/4.5 mcg	2 inhalations twice a day		
160 mcg/4.5 mcg		2 inhalations twice a day	
Fluticasone furoate-vilanterol DPI (Brand name: Breo Ellipta)Δ			
NOTE: Inhaled fluticasone furoate has a greater anti-inflammatory potency per microgram than fluticasone propionate inhalers. Thus, fluticasone furoate is administered at a lower daily dose and used only **once** daily.			
50 mcg/25 mcg◇	1 inhalation once daily		
100 mcg/25 mcg		1 inhalation once daily	
200 mcg/25 mcg			1 inhalation once daily
Fluticasone propionate-formoterol MDI (Not available in United States or Canada, but available elsewhere [sample brand name: Flutiform])			
50 mcg/5 mcg	2 inhalations twice daily		
125 mcg/5 mcg		2 inhalations twice daily	
250 mcg/10 mcg			2 inhalations twice daily
Fluticasone propionate-salmeterol DPI (Brand names: Advair Diskus, Wixela Inhub)Δ			
100 mcg/50 mcg	1 inhalation twice a day		
250 mcg/50 mcg		1 inhalation twice a day	
500 mcg/50 mcg			1 inhalation twice a day
Fluticasone propionate-salmeterol HFA (Brand name: Advair HFA)			
45 mcg/21 mcg	2 inhalations twice a day		
115 mcg/21 mcg		2 inhalations twice a day	
230 mcg/21 mcg			2 inhalations twice a day
Fluticasone propionate-salmeterol DPI (Brand names: AirDuo RespiClick, AirDuo Digihaler)Δ§			
55 mcg/14 mcg	1 inhalation twice a day		
113 mcg/14 mcg	1 inhalation twice a day	1 inhalation twice a day	
232 mcg/14 mcg			1 inhalation twice a day
Mometasone-formoterol HFA (Brand name: Dulera)			
100 mcg/5 mcg		2 inhalations twice a day	
200 mcg/5 mcg			2 inhalations twice a day
Mometasone-indacaterol DPI (Brand name: Atectura Breezhaler; available in Canada)Δ			
80 mcg/150 mcg	1 inhalation (capsule) once a day		
160 mcg/150 mcg		1 inhalation (capsule) once a day	
320 mcg/150 mcg			1 inhalation (capsule) once a day
ICS-LAMA-LABA combinations¥			
Fluticasone furoate-umeclidinium-vilanterol DPI (Brand name: Trelegy Ellipta)Δ			
100 mcg/62.5 mcg/25 mcg		1 inhalation once daily	
200 mcg/62.5 mcg/25 mcg			1 inhalation once daily
Mometasone-glycopyrrolate (glycopyrronium)-indacaterol DPI (Brand name: Enerzair Breezhaler; available in Canada)*Δ			
160 mcg/50 mcg/150 mcg			1 inhalation (capsule) once a day

Do not exceed the maximum number of inhalations/puffs per day listed in the table due to the risk of toxicity from an excess dose of long-acting beta-agonist (ie, salmeterol, formoterol, or vilanterol). Brand names and dose per puff or per inhalation of commercially available fixed dose combinations are according to United States prescribing information, unless otherwise noted. Consult local product information before use.

ICS: inhaled glucocorticoid (inhaled corticosteroid); SABA: short-acting beta-agonist; LABA: long-acting beta-agonist; LAMA: long-acting muscarinic antagonist; HFA: metered dose inhaler with hydrofluoroalkane propellant; DPI: dry powder inhaler; SMI: soft mist inhaler.

* Not approved for use in patients <18 years old.

¶ When using ICS-formoterol as reliever, use one to two inhalations as needed. Maximum daily dose of maintenance and rescue is 12 inhalations.

Δ DPI contains lactose which may have small amounts of milk protein.

◇ Fluticasone furoate-vilanterol 50 mcg/25 mcg DPI is approved for use in patients 5 to 11 years old; use in adolescents and adults is off-label.

§ In AirDuo inhalers, the daily dose of salmeterol is approximately one-fourth of the dose in Advair, and the daily dose of fluticasone is approximately one-half that of the comparable low-, medium-, and high-dose strengths of Advair.

¥ Alternatively, tiotropium SMI (Brand name: Spiriva Respimat) can be used with an ICS or ICS-LABA inhaler. The dose in asthma is two inhalations (1.25 mcg/inhalation) once daily.

Reference: Global Initiative for Asthma (GINA). Global strategy for asthma management and prevention. https://ginasthma.org/wp-content/uploads/2023/05/GINA-2023-Full-Report-2023-WMS.pdf. Updated 2023 (Accessed on June 13, 2023).

Table 8

Estimated comparative daily doses for inhaled glucocorticoids in children

Drug	Low daily dose		Medium daily dose		High daily dose	
	Child 0 to 4	Child 5 to 11	Child 0 to 4	Child 5 to 11	Child 0 to 4	Child 5 to 11
Beclomethasone HFA 40 or 80 mcg/puff	NA	40 mcg/puff - 1 to 2 puffs twice per day	NA	40 mcg/puff - 2 to 4 puffs twice per day 80 mcg/puff - 1 to 2 puffs twice per day	NA	80 mcg/puff - 3 to 4 puffs twice per day
Budesonide DPI* (breath activated) 90 or 180 mcg/inhalation	NA	90 mcg/inhalation - 1 to 2 inhalations twice per day	NA	180 mcg/inhalation - 1 to 2 inhalations twice per day	NA	180 mcg/inhalation - 3 to 4 inhalations twice per day
Budesonide nebulization suspension¶ 0.25 mg/2 mL, 0.5 mg/2 mL, or 1 mg/2 mL	0.25 to 0.5 mg once daily or as 2 divided doses	0.5 mg once daily or as 2 divided doses	0.75 to 1 mg once daily or as 2 or 3 divided doses	1 mg once daily or as 2 divided doses	1.25 to 2 mg once daily or as 2 divided doses	2 mg once daily or as 2 divided doses
Ciclesonide HFAΔ 80 or 160 mcg/puff	NA	80 mcg/puff - 1 to 2 puffs once daily	NA	80 mcg/puff - 3 to 4 puffs once daily	NA	80 mcg/puff - 5 to 6 puffs once daily or as 2 divided doses 160 mcg/puff - 3 puffs once daily or as 2 divided doses
Fluticasone HFA◇ 44, 110, or 220 mcg/puff	44 mcg/puff - 2 puffs twice per day◇	44 mcg/puff - 1 to 2 puffs twice per day	44 mcg/puff - 2 to 4 puffs twice per day 110 mcg/puff - 1 puff in AM and 2 puffs in PM	44 mcg/puff - 2 to 4 puffs twice per day 110 mcg/puff - 1 puff in AM and 2 puffs in PM	110 mcg/puff - 2 puffs twice per day 220 mcg/puff - 1 puff twice per day	110 mcg/puff - 2 puffs twice per day 220 mcg/puff - 1 puff twice per day
Fluticasone DPI (breath activated)§ 50, 100, or 250 mcg/inhalation	NA	50 mcg/inhalation - 1 to 2 inhalations twice per day	NA	50 mcg/inhalation - 3 to 4 inhalations twice per day 100 mcg/inhalation - 1 inhalation in AM and 2 inhalations in PM to 2 inhalations twice per day	NA	100 mcg/inhalation - 2 inhalations in AM and 3 inhalations in PM 250 mcg/inhalation - 1 inhalation twice per day
Mometasone aerosol DPI (breath activated)* 110 or 220 mcg/inhalation	NA	110 mcg/inhalation - 1 inhalation once daily	NA	110 mcg/inhalation - 2 to 3 inhalations once daily	NA	110 mcg/inhalation - 4 inhalations once daily or 2 inhalations twice per day 220 mcg/inhalation - 2 inhalations once daily or 1 inhalation twice per day
Mometasone HFA MDI 50, 100, or 200 mcg/puff	NA	50 mcg/puff - 1 puff once or twice per day	NA	50 mcg/puff - 2 to 3 puffs twice per day 100 mcg/puff - 1 puff twice per day	NA	100 mcg/puff - 2 puffs twice per day 200 mcg/puff - 1 inhalation twice per day

Some doses may be outside approved package labeling, especially in the high-dose range. Doses shown and strengths (ie, mcg per puff or inhalation) are based upon product descriptions approved in the United States, which may differ from how strengths are described for products available in other countries. Consult local product information before use.

HFA: hydrofluoroalkane; NA: not approved and no data available for this age group; DPI: dry-powder inhaler; AM: in morning; PM: in evening; US FDA: US Food and Drug Administration; MDI: metered-dose inhaler.

* Contains milk protein.

¶ Budesonide suspension is compatible with albuterol, ipratropium, and levalbuterol nebulizer solutions in the same nebulizer. Use only jet nebulizers as ultrasonic nebulizers are ineffective for suspensions.

Δ Ciclesonide is not approved by the US FDA for use in children under 12. It is approved for use in children 6 years of age and older in Canada, some European countries, and elsewhere.

◇ For fluticasone HFA, the low dose for children <4 years is higher than for children 5 to 11 years of age due to lower dose delivered with facemask and data on efficacy in young children.

§ Contains lactose.

Data from:

1. National Heart, Blood, and Lung Institute Expert Panel Report 3 (EPR 3): Guidelines for the Diagnosis and Management of Asthma. NIH Publication no. 08-4051, 2007.
2. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. Updated 2012. Available at www.ginasthma.org.

RATIONALE:

CODES: Number

Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.
Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.
Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

HCPCS: J2357 Xolair

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10/07/2021	Revised
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01/21	Revised
08/20	Revised
02/20	Revised
01/20	Revised
11/19	Revised
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4/08	Revised

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