09-J0000-44

Original Effective Date: 12/15/04

Reviewed: 01/10/24

Revised: 10/15/24

Subject: Omalizumab (Xolair®)

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Xolair® (Omalizumab) is a recombinant DNA-derived humanized IgG1k murine monoclonal antibody that selectively binds to human IgE. Omalizumab inhibits the binding of IgE to the high-affinity IgE receptor on the surface of mast cells and basophils, which limits the degree of release of mediators of the allergic response.

Omalizumab is a treatment option limited to patients with elevated serum levels of IgE. Its current indication is for patients with severe allergic asthma who are uncontrolled on inhaled glucocorticosteroids (ICS), although the dose of concurrent treatment has varied in different studies. Improved asthma control is reflected by fewer symptoms, less need for reliever medications and fewer exacerbations. Additionally, omalizumab is indicated for treatment of chronic idiopathic urticarial who remain symptomatic despite H1 antihistamine treatment.

A 2012 Global Initiative for Asthma (GINA) Global Strategy for Asthma Management and Prevention Report recommends consideration of a trial of omalizumab for allergic patients with an elevated IgE not controlled on high dose inhaled glucocorticosteroids and a long acting B_2 -agonist and who continue to have exacerbations.

Recommendations included in a 2014 practice parameter from the Joint Task Force on Practice Parameters (JTFPP) for the diagnosis and management of acute and chronic urticaria provides a step-based approach to the treatment of chronic urticaria. Omalizumab is included in the Step 4 care approach when chronic urticaria has been refractory to treatment with potent antihistamines and leukotriene receptor antagonists.

POSITION STATEMENT:

Site of Care: If omalizumab (Xolair) is administered in a hospital-affiliated outpatient setting, additional requirements may apply depending on the member's benefit. Refer to 09-J3000-46: Site of Care Policy for Select Specialty Medications.

Initiation of omalizumab (Xolair) **meets the definition of medical necessity** for members diagnosed with either of the following conditions when **ALL** associated criteria are met:

1. Moderate to severe persistent asthma
    a. Member has a positive skin test or in vitro reactivity to a perennial aeroallergen – laboratory documentation must be provided
    b. Member's baseline pretreatment serum total IgE is between 30 IU/mL and 1500 IU/mL – laboratory documentation must be provided
    c. Member has a history of uncontrolled asthma while on asthma control therapy as demonstrated by **ONE** of the following:
        i. Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months
        ii. Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months
        iii. Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered
        iv. The member has baseline (prior to therapy with omalizumab) Forced Expiratory Volume (FEV1) that is less than 80% of predicted
    d. **ONE** of the following:
        i. The member is **NOT** currently being treated with omalizumab **AND** is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months
        ii. The member is currently being treated with the omalizumab **AND ONE** of the following:
            - Is currently treated with an inhaled corticosteroid for at least 3 months that is adequately dosed to control symptoms
            - Is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months
        iii. The member has an intolerance or hypersensitivity to inhaled corticosteroid therapy
        iv. The member has an FDA labeled contraindication to **ALL** inhaledcorticosteroids
    e. **ONE** of the following:
        i. The member is currently being treated for at least 3 months with **ONE** of the following:
            - A long-acting beta-2 agonist (LABA)

- A leukotriene receptor antagonist (LTRA)
- Long-acting muscarinic antagonist (LAMA)
- Theophylline

ii. The member has an intolerance or hypersensitivity to therapy with LABA, LTRA, LAMA, or theophylline

iii. The patient has an FDA labeled contraindication to **ALL** LABA, LTRA, LAMA, **AND** theophylline therapies

f. Member will continue asthma control therapy in combination with omalizumab

g. Omalizumab is prescribed by a board certified (or board eligible) allergist, immunologist, or pulmonologist

h. Omalizumab is not used in combination with benralizumab (Fasenra), dupilumab (Dupixent), mepolizumab (Nucala), tezepelumab (Tezspire), or reslizumab (Cinqair)

i. Dose does not exceed FDA-approved dose and frequency:

i. 12 years of age and older: See Tables 1 and 2

ii. Less than 12 years of age: See Table 3

j. Omalizumab quantity does not exceed the following dose and frequency based limits per 28 days based on weight and baseline IgE level (See Tables 1, 2, and 3):

i. 75 mg every four weeks: one 75 mg syringe (or autoinjector)

ii. 150 mg every four weeks: one 150 mg syringe (or autoinjector) **OR** one 150 mg vial

iii. 225 mg every two weeks: two 75 mg syringes (or autoinjectors) plus two 150 mg syringes (or autoinjectors)

iv. 225 mg every four weeks: one 75 mg syringe (or autoinjector) plus one 150 mg syringe (or autoinjector)

v. 300 mg every two weeks: two 300 mg syringes (or autoinjectors) **OR** four 150 mg vials

vi. 300 mg every four weeks: one 300 mg syringe (or autoinjector) **OR** two 150 mg vials

vii. 375 mg every two weeks: two 75 mg syringes (or autoinjectors) plus two 300 mg syringes (or autoinjectors)

k. Member is 6 years of age or older

2. Chronic idiopathic urticaria

a. Member's symptoms remained uncontrolled or inadequately controlled despite four weeks of treatment with a second-generation antihistamine (e.g., cetirizine, fexofenadine, desloratadine) used in combination with an H2-antihistamine (e.g., ranitidine, famotidine) and a leukotriene modifier (e.g., montelukast, zafirlukast)

b. Omalizumab is prescribed by a board certified (or board eligible) allergist, dermatologist, or immunologist

c. Omalizumab is not used in combination with benralizumab (Fasenra), dupilumab (Dupixent), mepolizumab (Nucala), or reslizumab (Cinqair)

d. Omalizumab quantity does not exceed the following dose and frequency based limits per 28 days:

   i. 150 mg every four weeks: one 150 mg syringe (or autoinjector) **OR** one 150 mg vial

   ii. 300 mg every four weeks: one 300 mg syringe (or autoinjector) **OR** two 150 mg vials

e. Member is 12 years of age or older

3. Chronic rhinosinusitis with nasal polyposis (CRSwNP)

   a. There is information indicating the member's diagnosis was confirmed by **ONE** of the following:

      i. Anterior rhinoscopy or endoscopy

      ii. Computed tomography (CT) of the sinuses

   b. **ONE** of the following:

      i. **ONE** of the following:

         - The member had an inadequate response to sinonasal surgery
         - The member is **NOT** a candidate for sinonasal surgery

      ii. **ONE** of the following:

         - The member has tried and had an inadequate response to ora systemic corticosteroids
         - The member has an intolerance or hypersensitivity to therapy with oral systemic corticosteroids
         - The member has an FDA labeled contraindication to **ALL** oral systemic corticosteroids

   c. **ONE** of the following:

      i. The member has tried and had an inadequate response to intranasal corticosteroids (e.g., fluticasone, Sinuva) used for at least a 3-month trial

      ii. The member has an intolerance or hypersensitivity to therapy with intranasal corticosteroids (e.g., fluticasone, Sinuva)

      iii. The member has an FDA labeled contraindication to **ALL** intranasal corticosteroids

   d. **BOTH** of the following:

      i. The member is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids)

ii. The member will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with omalizumab

e. Member's baseline pretreatment serum total IgE is between 30 IU/mL and 1500 IU/mL – laboratory documentation must be provided

f. Omalizumab is prescribed by a board certified (or board eligible) allergist, immunologist, or otolaryngologist (ear, nose, and throat specialist)

g. Omalizumab is not used in combination with benralizumab (Fasenra), dupilumab (Dupixent), mepolizumab (Nucala), or reslizumab (Cinqair)

h. Dose does not exceed FDA-approved dose and frequency (See Table 4)

i. Omalizumab quantity does not exceed the following dose and frequency based limits per 28 days based on weight and baseline IgE level (See Table 4):

i. 75 mg every four weeks: one 75 mg syringe (or autoinjector)

ii. 150 mg every four weeks: one 150 mg syringe (or autoinjector) **OR** one 150 mg vial

iii. 225 mg every two weeks: two 75 mg syringes (or autoinjectors) plus two 150 mg syringes (or autoinjectors)

iv. 225 mg every four weeks: one 75 mg syringe (or autoinjector) plus one 150 mg syringe (or autoinjector)

v. 300 mg every two weeks: two 300 mg syringes (or autoinjectors) **OR** four 150 mg vials

vi. 300 mg every four weeks: one 300 mg syringe (or autoinjector) **OR** two 150 mg vials

vii. 375 mg every two weeks: two 75 mg syringes (or autoinjectors) plus two 300 mg syringes (or autoinjectors)

viii. 450 mg every four weeks: one 150 mg syringe (or autoinjector) plus one 300 mg syringe (or autoinjector) **OR** three 150 mg vials

ix. 600 mg every four weeks: two 300 mg syringes (or autoinjectors) **OR** four 150 mg vials

x. 450 mg every two weeks: two 150 mg syringes (or autoinjectors) plus two 300 mg syringes (or autoinjectors) **OR** six 150 mg vials

xi. 525 mg every two weeks: eight 150 mg syringes (or autoinjectors) **OR** eight 150 mg vials

xii. 600 mg every two weeks: eight 150 mg syringes **OR** eight 150 mg vials

j. Member is 18 years of age or older

4. Other FDA-approved or NCCN supported diagnosis (not previously listed above)

a. When **ONE** of the following is met:

i. Member is diagnosed with a condition that is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert) **AND** member meets any additional requirements listed in the "Indications and Usage" section of the FDA-approved prescribing information (or package insert)

ii. Indication **AND** usage is recognized in NCCN Drugs and Biologics Compendium as a Category 1 or 2A recommendation

b. Dose does not exceed the maximum FDA-approved dosing

Approval duration: 180 days

Continuation of omalizumab (Xolair) meets the definition of **medical necessity** for members diagnosed with either of the following conditions when **ALL** associated criteria are met:

1. Moderate to severe persistent asthma
    a. Authorization/reauthorization has been previously approved by Florida Blue or another health plan in the past two years, **OR** the member has previously met all indication-specific initiation criteria
    b. Member has a history of improvements or stabilization with omalizumab from baseline (prior to therapy with omalizumab) as evidenced by one or more of the following:
        i. The member has had an increase in percent predicted Forced Expiratory Volume (FEV1)
        ii. The member has had a decrease in the dose of inhaled corticosteroids required to control the patient's asthma
        iii. The member has had a decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma
        iv. The member has had a decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthm
    c. The member is currently treated and is compliant with asthma control therapy [e.g.,inhaled corticosteroids, ICS/long-acting beta-2 agonist (LABA), leukotriene receptorantagonist (LTRA), long-acting muscarinic antagonist (LAMA), theophylline]
    d. Omalizumab is prescribed by or in consultation with a board certified (or board eligible) allergist, immunologist, or pulmonologist
    e. Omalizumab is not used in combination with benralizumab (Fasenra), dupilumab (Dupixent), mepolizumab (Nucala), tezepelumab (Tezspire), or reslizumab (Cinqair)
    f. Dose does not exceed FDA-approved dose and frequency:
        i. 12 years of age and older: See Tables 1 and 2
        ii. Less than 12 years of age: See Table 3
    e. Omalizumab quantity does not exceed the following dose and frequency based limits per 28 days based on weight and baseline IgE level (See Tables 1, 2, and 3):
        i. 75 mg every four weeks: one 75 mg syringe (or autoinjector)

ii. 150 mg every four weeks: one 150 mg syringe (or autoinjector) **OR** one 150 mg vial

iii. 225 mg every two weeks: two 75 mg syringes (or autoinjectors) plus two 150 mg syringes (or autoinjectors)

iv. 225 mg every four weeks: one 75 mg syringe (or autoinjector) plus one 150 mg syringe (or autoinjector)

v. 300 mg every two weeks: two 300 mg syringes (or autoinjectors) **OR** four 150 mg vials

vi. 300 mg every four weeks: one 300 mg syringe (or autoinjector) **OR** two 150 mg vials

vii. 375 mg every two weeks: two 75 mg syringes (or autoinjectors) plus two 300 mg syringes (or autoinjectors)

2. Chronic idiopathic urticaria

   a. Authorization/reauthorization has been previously approved by Florida Blue or another health plan in the past two years, **OR** the member has previously met all indication-specific initiation criteria

   b. Omalizumab is prescribed by or in consultation with a board certified (or board eligible) allergist, dermatologist, or immunologist

   c. Omalizumab is not used in combination with benralizumab (Fasenra), mepolizumab (Nucala), or reslizumab (Cinqair)

   d. Omalizumab quantity does not exceed the following dose and frequency based limits per 28 days:

      i. 150 mg every four weeks: one 150 mg syringe (or autoinjector) **OR** one 150 mg vial

      ii. 300 mg every four weeks: one 300 mg syringe (or autoinjector) **OR** two 150 mg vials

3. Chronic rhinosinusitis with nasal polyposis (CRSwNP)

   a. Authorization/reauthorization has been previously approved by Florida Blue or another health plan in the past two years, **OR** the member has previously met all indication-specific initiation criteria

   b. Member has a history of beneficial clinical response to omalizumab as evidenced by a reduction in disease severity (e.g., reduction in nasal congestion, nasal polyp size, anterior or posterior rhinorrhea, sinonasal inflammation, facial pressure/pain; improved sese of smell; or reduction in corticosteroid use) – documentation from the medical record must be provided

   c. Omalizumab is prescribed by or in consultation with a board certified (or board eligible) allergist, immunologist, or otolaryngologist (ear, nose, and throat specialist)

   d. Omalizumab is not used in combination with benralizumab (Fasenra), dupilumab (Dupixent), mepolizumab (Nucala), or reslizumab (Cinqair)

   e. Dose does not exceed FDA-approved dose and frequency (See Table 4)

   f. Omalizumab quantity does not exceed the following dose and frequency based limits per 28 days based on weight and baseline IgE level (See Table 4):

i. 75 mg every four weeks: one 75 mg syringe (or autoinjector)
ii. 150 mg every four weeks: one 150 mg syringe (or autoinjector) **OR** one 150 mg vial
iii. 225 mg every two weeks: two 75 mg syringes (or autoinjectors) plus two 150 mg syringes (or autoinjectors)
iv. 225 mg every four weeks: one 75 mg syringe (or autoinjector) plus one 150 mg syringe (or autoinjector)
v. 300 mg every two weeks: two 300 mg syringes (or autoinjectors) **OR** four 150 mg vials
vi. 300 mg every four weeks: one 300 mg syringe (or autoinjector) **OR** two 150 mg vials
vii. 375 mg every two weeks: two 75 mg syringes (or autoinjectors) plus two 300 mg syringes (or autoinjectors)
viii. 450 mg every four weeks: one 150 mg syringe (or autoinjector) plus one 300 mg syringe (or autoinjector) **OR** three 150 mg vials
ix. 600 mg every four weeks: two 300 mg syringes (or autoinjectors) **OR** four 150 mg vials
x. 450 mg every two weeks: two 150 mg syringes (or autoinjectors) plus two 300 mg syringes (or autoinjectors) **OR** six 150 mg vials
xi. 525 mg every two weeks: eight 150 mg syringes (or autoinjectors) **OR** eight 150 mg vials
xii. 600 mg every two weeks: eight 150 mg syringes **OR** eight 150 mg vials

g. Member is 18 years of age or older

4. Other FDA-approved or NCCN supported diagnosis (not previously listed above)
   a. When **ONE** of the following is met:
      i. Member is diagnosed with a condition that is consistent with an indication listed in the product's FDA-approved prescribing information (or package insert) **AND** member meets any additional requirements listed in the "Indications and Usage" section of the FDA-approved prescribing information (or package insert)
      ii. Indication **AND** usage is recognized in NCCN Drugs and Biologics Compendium as a Category 1 or 2A recommendation
   b. Dose does not exceed the maximum FDA-approved dosing

Approval duration: 1 year

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

Allergic Asthma:

150 to 375 mg SC every 2 or 4 weeks; do not inject more than 150 mg per injection site

See Tables 1, 2, and 3 for appropriate dose assignment

Chronic Idiopathic Urticaria:

150 or 300 mg SC every 4 weeks

Dosing is not dependent on serum IgE level or body weight

Nasal Polyps:

75 to 600 mg SC every 2 or 4 weeks based on serum total IgE level measured before the start of treatment and by body weight

Dosing is not dependent on serum IgE level or body weight

Table 1

ADMINISTRATION EVERY 4 WEEKS **Adults and Adolescents (12 Years of Age and Older) with Asthma**				
Pre-treatment Serum IgE (IU/mL)	Body Weight			
	30-60 kg	> 60-70 kg	> 70-90 kg	> 90-150 kg
≥30-100	150 mg	150 mg	150 mg	300 mg
> 100-200	300 mg	300 mg	300 mg	
> 200-300	300 mg	SEE TABLE 2		
> 300				

Table 2

ADMINISTRATION EVERY 2 WEEKS **Adults and Adolescents (12 Years of Age and Older) with Asthma**				
Pre-treatment Serum IgE (IU/mL)	Body Weight			
	30-60 kg	> 60-70 kg	> 70-90 kg	> 90-150 kg
≥30-100	SEE TABLE 1			
> 100-200				225 mg
> 200-300		225 mg	225 mg	300 mg
> 300-400	225 mg	225 mg	300 mg	
> 400-500	300 mg	300 mg	375 mg	
> 500-600	300 mg	375 mg		
> 600	375 mg	**SEE NOTE BELOW***		

* **NOTE**: Per FDA label, there is insufficient data to recommend a dose.

Dose is not to exceed FDA labeled maximum dose and frequency

Table 3

Pediatric Patients (6 to < 12 Years of Age) with Asthma											
		Body Weight									
Pre-treatment Serum IgE (IU/mL)	Dosing Freq.	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		
>400-500		225	300	225	225	300	300	375	375		
>500-600		300	300	225	300	300	375				
>600-700		300	225	225	300	375					
>700-800	Every 2 weeks	225	225	300	375						
>800-900		225	225	300	375						
>900-1000		225	300	375							
>1000-1100		225	300	375							
>1100-1200		300	300								
>1200-1300		300	375								

Insufficient Data to Recommend a Dose

Table 4

Adult Patients with Nasal Polyps									
		Body Weight							
Pre-treatment Serum IgE (IU/mL)	Dosing Freq.	>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	300	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					
>1200-1300		450	525						
>1300-1500		525	600						

Insufficient Data to Recommend a Dose

Dosing Adjustments

NOTE: Dosing in CIU is not dependent on IgE levels or body weight; the following information only applies to dosing in allergic asthma.

Total IgE levels are elevated during treatment and remain elevated for up to one year after the discontinuation of treatment. Therefore, re-testing of IgE levels during Xolair® treatment cannot be used as a guide for dose determination. Dose determination after treatment interruptions lasting less than 1 year should be based on serum IgE levels obtained at the initial dose determination. Total serum IgE levels may be re-tested for dose determination if treatment with Xolair® has been interrupted for one year or more.

Doses should be adjusted for significant changes in body weight.

Drug Availability

- Injection: 75 mg/0.5 mL, 150 mg/mL, 300 mg/2 mL solution in a single-dose prefilled syringe
- Injection: 75 mg/0.5 mL, 150 mg/mL, 300 mg/2 mL solution in a single-dose prefilled autoinjector

- Injection: 150 mg lyophilized powder in a single-dose vial for reconstitution

PRECAUTIONS:

Boxed Warning

- Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after administration
- Anaphylaxis has occurred after the first dose but also has occurred beyond 1 year after beginning treatment.

Contraindications

- Severe hypersensitivity reaction

Precautions/Warnings

- Anaphylaxis: Administer only in a healthcare setting prepared to manage anaphylaxis that can be life-threatening and observe patients for an appropriate period of time after administration
- Malignancy: Malignancies have been observed in clinical studies
- Acute Asthma Symptoms: Do not use for the treatment of acute bronchospasm or status asthmaticus
- Corticosteroid Reductions: Do not abruptly discontinue corticosteroids upon initiation
- Fever, Arthralgia, and Rash: Stop if patients develop signs and symptoms similar to serum sickness
- Eosinophilic Conditions: Be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy, especially upon reduction of oral corticosteroids

BILLING/CODING INFORMATION:

HCPCS Coding:

J2357	injection, omalizumab, 5 mg

ICD-10 Diagnosis Codes That Support Medical Necessity:

J33.0-J33.9	Nasal polyp
J45.40	Moderate persistent asthma, uncomplicated
J45.41	Moderate persistent asthma with (acute) exacerbation
J45.42	Moderate persistent asthma with status asthmaticus
J45.50	Severe persistent asthma, uncomplicated
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
J82.83	Eosinophilic asthma

L50.1	Idiopathic urticaria

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: Florida Blue has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage Products:

No National Coverage Determination (NCD) WAS found at the time of the last guideline revised date. The following Local Coverage Determination (LCD) was reviewed on the last guideline revised date: Omalizumab (Xolair), (L33924) located at fcso.com. The Site of Care Policy for Select Specialty Medications does not apply to Medicare Advantage members.

DEFINITIONS:

FEV1: Forced expiratory volume in 1 second.

FVC: Forced vital capacity.

PEF: Peak expiratory flow.

Mild Intermittent Asthma:

Symptoms < or = to 2 times a week
Asymptomatic and normal PEF between exacerbations
Exacerbations brief (from a few hours to a few days); intensity may vary
Nighttime symptoms < or = to 2 times a month
FEV1 or PEF > or = to 80% predicted
PEF variability < 20%.

Mild Persistent Asthma:

Symptoms > 2 times a week but < 1 time a day
Exacerbations may affect activity
Nighttime symptoms > 2 times a month
FEV1 or PEF > or = to 80% predicted
PEF variability 20 to 30 %.

Moderate Persistent Asthma:

Daily symptoms

Nighttime symptoms > one time a week

Daily use of inhaled short-acting beta2-agonist

Exacerbations may affect activity

Exacerbations > or = to 2 times a week; may last days

FEV1 or PEF > 60% but less than 80% predicted

PEF variability > 30%.

Severe Persistent Asthma:

Continual symptoms (i.e., coughing, dyspnea, wheezing)

Limited physical activity

Frequent exacerbations

Frequent nighttime symptoms

FEV1 or PEF < or = 60% predicted

PEF variability > 30%.

RELATED GUIDELINES:

Mepolizumab (Nucala), 09-J2000-54

Benrazlizumab (Fasenra), 09-J2000-92

Reslizumab (Cinqair®) IV infusion, 09-J2000-63

OTHER:

Table 5 - Low, medium and high ICS doses: adults/adolescents (GINA 2020, Box 3-6A)

Inhaled Corticosteroid	Total daily ICS dose (mcg)		
	Low	Medium	High
Beclomethasone dipropionate (pMDI, standard particle, HFA)	200-500	>500-1000	>1000
Beclomethasone dipropionate (pMDI, extrafine particle, HFA)	100-200	>200-400	>400
Budesonide (DPI)	200-400	>400-800	>800
Ciclesonide (pMDI, extrafine particle, HFA)	80-160	>160-320	>320
Fluticasone furoate (DPI)	100	100	200
Fluticasone propionate (DPI)	100-250	>250-500	>500
Fluticasone propionate (pMDI, standard particle, HFA)	100-250	>250-500	>500
Mometasone furoate (DPI)	200	200	400
Mometasone furoate (pMDI, standard particle, HFA)	200-400	200-400	>400

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler (non-CFC)

Table 6 - Low, medium and high ICS doses: children 6-11 years (GINA 2020, Box 3-6B)

Inhaled Corticosteroid	Total daily ICS dose (mcg)		
	Low	Medium	High
Beclomethasone dipropionate (pMDI, standard particle, HFA)	100-200	>200-400	>400
Beclomethasone dipropionate (pMDI, extrafine particle, HFA)	50-100	>100-200	>200
Budesonide (DPI)	100-200	>200-400	>400
Budesonide (nebules)	250-500	>500-1000	>1000
Ciclesonide (pMDI, extrafine particle, HFA)	80	>80-160	>160
Fluticasone furoate (DPI)	50	50	N/A
Fluticasone propionate (DPI)	50-100	>100-200	>200
Fluticasone propionate (pMDI, standard particle, HFA)	50-100	>100-200	>200
Mometasone furoate (pMDI, standard particle, HFA)	100	100	200

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler (non-CFC)

Table 7 - Low, medium and high ICS doses: children 5 years and younger (GINA 2020, Box 3-6B)

Inhaled Corticosteroid	Total daily ICS dose (mcg)		
	Low	Medium	High
Beclomethasone dipropionate (pMDI, standard particle, HFA)	100-200	>200-400	>400
Beclomethasone dipropionate (pMDI, extrafine particle, HFA)	50-100	>100-200	>200
Budesonide (nebules)	250-500	>500-1000	>1000
Ciclesonide (pMDI, extrafine particle, HFA)	N/A	N/A	N/A
Fluticasone furoate (DPI)	N/A	N/A	N/A
Fluticasone propionate (pMDI, standard particle, HFA)	100-200	>200-500	>500
Mometasone furoate (pMDI, standard particle, HFA)	100	100	200

DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler (non-CFC)

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 01/10/24.

GUIDELINE UPDATE INFORMATION:

12/15/04	New Medical Coverage Guideline.
01/01/05	Annual HCPCS code update, consisting of J2357 and C9217. Deleted miscellaneous code J3490.
01/01/06	CPT code update deleted expired code 90782, added new code 90772.

02/15/06	Reviewed. Update description, deleted precautions, deleted expired HCPCS code C9217. Deleted ICD-9 codes: 975.7, 493.82, 493.8, 493.12, 493.1, 493.11, 493.2, 493.21, 493.22, 493.9, 493.91, 493.92. Updated references and related links. Corrected FEV1 and PEF values for moderate to severe asthma definition in when services are covered as per the Heart, Lung and Blood Institute guidance.
01/01/07	MCG revised to include Medicare Part D as a program exception.
02/15/07	Reviewed. Reformatted, edited and updated websites and references.
06/15/07	Reformatted guideline; updated references.
12/15/07	Review and revision to guideline; consisting of maintaining current coverage and limitations, adding black box warning under “Dosage/Administration” section, updating references.
03/15/08	Revision to guideline; consisting of adding “moderate to high dose inhaled corticosteroid” to criteria under POSITION STATEMENT, added note regarding combination therapy trial, added tables comparing inhaled corticosteroid dosages, removed several ICD-9 codes and updated references.
01/01/09	Annual HCPCS coding update: deleted code 90772; added code 96372.
03/15/09	Review and revision; consisting of reformatting and updating references.
03/15/10	Review and revision; consisting of updating the position statement to include requirement of demonstration of asthma symptom persistence despite inhaled corticosteroids AND combination therapy with long acting beta agonists or leukotriene inhibitors and added a baseline pretreatment IgE requirement. Added additional warnings.
02/15/11	Review and revision to guideline; consisting of added additional brand drug name examples of long acting Beta 2 agonist products to the position statement. Added seasonal and food allergies to the experimental or investigational use statement. Removed extrinsic asthma status asthmaticus and acute exacerbation from the ICD-9 codes. Added ICD-10 code for allergic asthma.
02/15/12	Review and revision to guideline; consisting of adding dosage max and chronic urticarial to the exclusion list.
02/15/13	Review and revision to guideline; consisting of adding requirements for initiation of therapy and continuation of therapy.
11/15/13	Revision to guideline; consisting of reformatting position statement, adding approval duration, and updating program exceptions.
02/15/14	Review and revision to guideline; consisting of reformatting and revising position statement, dosing/administration, precautions/warning and references.
06/15/14	Revision to guideline; consisting of position statement, dosing/administration, billing/coding, references.
10/01/15	Revision consisting of update to Program Exceptions section.
11/01/15	Revision: ICD-9 codes deleted.
01/15/16	Revision: ICD10 codes updated.
03/15/16	Review and revision; consisting of position statement, description, references.
06/15/16	Revison to guideline; consisting of position statement.
07/15/16	Revison to guideline; consisting of position statement.

10/15/16	Revision to guideline; consisting of position statement and dosing.
02/15/17	Review and revision to guideline; consisting of updating references.
02/15/18	Revison to guideline; consisting of position statement, references.
02/15/19	Review and revision to guideline; consisting of updating references.
09/15/19	Revision to guidelines; consisting of updating dosing in Position Statement and Dosage/Administration based on FDA label
11/11/19	Revision to guideline consisting of adding a reference to the Site of Care Policy for Select Specialty Medications and updating the Program Exceptions.
02/15/20	Review and revision to guideline; consisting of updating references.
02/15/21	Review and revision to guideline; consisting of updating position statement, dosing, references.
11/15/21	Review and revision; consisting of position statement.
02/15/22	Review and revision; consisting of references.
02/15/23	Review and revision; consisting of position statement, references.
02/15/24	Review and revision; consisting of updating position statement and references.
10/15/24	Revision to guideline; updated position statement with new 300 mg package size.