09-J0000-44

Original Effective Date: 12/15/04

Reviewed: 01/09/19

Revised: 09/15/19

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:

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's symptoms remain uncontrolled or inadequately controlled despite three months of treatment with at least **ONE** of the following:
        i. Combination moderate- or high-dose inhaled corticosteroids (Table 4 and 5) **AND** long-acting beta agonist (e.g., formoterol fumarate (Foradil), salmeterol xinafoate (Serevent))
        ii. Combination moderate- or high-dose inhaled corticosteroids (Table 4 and 5) **AND** leukotriene modifier (e.g., montelukast, zafirlukast)
        iii. Combination moderate- or high-dose inhaled corticosteroids (Table 4 and 5) **AND** theophylline
        iv. Combination inhaled corticosteroid/long-acting beta 2 agonist (e.g., fluticasone propionate/salmeterol (Advair), mometasone/formoterol (Dulera), budesonide/formoterol (Symbicort))
    d. Omalizumab is prescribed by a board certified (or board eligible) allergist, immunologist, or pulmonologist
    e. Omalizumab is not used in combination with benralizumab (Fasenra), mepolizumab (Nucala), 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
    g. 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
        ii. 150 mg every four weeks: one 150 mg syringe **OR** one 150 mg vial
        iii. 225 mg every two weeks: two 75 mg syringes plus two 150 mg syringes
        iv. 225 mg every four weeks: one 75 mg syringe plus one 150 mg syringe
        v. 300 mg every two weeks: four 150 mg syringes **OR** four 150 mg vials
        vi. 300 mg every four weeks: two 150 mg syringes **OR** two 150 mg vials
        vii. 375 mg every two weeks: two 75 mg syringes plus four 150 mg syringes
    h. 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), 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** one 150 mg vial

    ii. 300 mg every four weeks: two 150 mg syringes **OR** two 150 mg vials

e. Member is 12 years of age or older

Duration of approval: 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 beneficial clinical response to omalizumab as evidenced by one or more of the following:

        i. Decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in inhaled corticosteroid dose or treatment with systemic corticosteroids)

        ii. Increase in predicted FEV1 or peak flow from pretreatment baseline

        iii. Reduction in reported asthma-related symptoms, such as, asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing

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

    d. 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

        ii. 150 mg every four weeks: one 150 mg syringe OR one 150 mg vial

        iii. 225 mg every two weeks: two 75 mg syringes plus two 150 mg syringes

        iv. 225 mg every four weeks: one 75 mg syringe plus one 150 mg syringe

        v. 300 mg every two weeks: four 150 mg syringes OR four 150 mg vials

        vi. 300 mg every four weeks: two 150 mg syringes OR two 150 mg vials

        vii. 375 mg every two weeks: two 75 mg syringes plus four 150 mg syringes

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 not used in combination with benralizumab (Fasenra), mepolizumab (Nucala), or reslizumab (Cinqair)
    c. 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 one 150 mg vial
        ii. 300 mg every four weeks: two 150 mg syringes OR two 150 mg vials

Duration of approval: 1 year

The safety and efficacy of Xolair® in other allergic conditions and non-allergic asthma has not been established and therefore is considered **experimental or investigational** when administered for all other indications as there is insufficient clinical evidence to support its use, and specifically for the following:

1. Treatment of Mild Persistent or Mild Intermittent Asthma (see under **DEFINITIONS**).
2. Treatment of non-allergic asthma, allergic rhinitis, seasonal allergies, food allergies, other allergic conditions without asthma or initial first line treatment of allergic asthma.

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

Must be administered in a healthcare setting by healthcare providers that are prepared to manage anaphylaxis

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

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	DO NOT DOSE	
>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								

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 and 150 mg/mL solution in a single-dose prefilled syringe
- 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:

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
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

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 4

ESTIMATED COMPARATIVE DAILY DOSAGES FOR INHALED CORTICOSTEROIDS IN CHILDREN			
Drug	**Low Daily Dose** **Child 0 – 4** **Child 5 – 11**	**Medium Daily Dose** **Child 0 – 4** **Child 5 – 11**	**High Daily Dose** **Child 0 – 4** **Child 5 – 11**
Beclomethasone HFA 40 or 80 mcg/puff	NA 80 – 16 mcg	NA >160-120mcg	NA >320mcg
Budesonide DPI 90, 180 or 200 mcg/inhalation	NA 180 – 400mcg	NA >400 – 800mcg	NA >800mcg
Budesonide Inhaled Inhalation suspension for nebulization (child dose)	0.25 – 0.5mg 0.5mg	>0.5 – 1.0mg 1.0mg	>1.0mg 2.0mg
Flunisolide 250mcg/puff	NA 500 – 750mcg	NA 1000 – 1250mcg	NA >1250mcg
Flunisolide HFA 80mcg/puff	NA 160mcg	NA 320mcg	NA ≥640mcg
Fluticasone HFA/MDI 44, 110 or 220mcg/puff	176mcg 88 – 176mcg	>176 – 352 >176 – 352	>352mcg >352mcg

		Mcg mcg	
Fluticasone DPI 250mcg/inhalation	NA 100 – 200mcg	NA >200 – 400mcg	NA >400mcg
Mometasone DPI 200mcg/inhalation	NA NA	NA NA	NA NA
Triamcinoline acetonide 75mcg/puff	NA 300 – 600mcg	NA >600 – 900mcg	NA >900mcg

Table 5

ESTIMATED COMPARATIVE DAILY DOSAGES FOR INHALED CORTICOSTEROIDS FOR YOUTHS ≥12 YEARS OF AGE AND ADULTS			
Drug	**Low Daily Dose Adult**	**Medium Daily Dose Adult**	**High Daily Dose Adult**
Beclomethasone HFA 40 or 80mcg/puff	80 – 240mcg	>240 – 480mcg	>480mcg
Budesonide DPI 90, 180 or 200mcg/inhalation	180 – 600mcg	>600 – 1200mcg	>1200mcg
Flunisolide 250mcg/puff	500 – 1000mcg	>1000 – 2000mcg	>2000mcg
Flunisolide HFA 80mcg/puff	320mcg	>320 – 640mcg	>640mcg
Fluticasone HFA/MDI 44, 110 or 220mcg/inhalation	88 – 264mcg	>264 – 440mcg	>440mcg
Fluticasone DPI 50, 100 or 250mcg/inhalation	100 – 300mcg	>300 – 500mcg	>500mcg
Mometasone DPI 200mcg/inhalation	200mcg	400mcg	>400mcg
Triamcinolone acetanide 75mcg/puff	300 – 750mcg	>750 – 1500mcg	>1500mcg

REFERENCES:

1. American College of Allergy, Asthma & Immunology. Editorial background. Anti-IgE. Accessed 10/31/07.
2. American College of Allergy, Asthma & Immunology. Overview of Expert Care for Asthma. Accessed 11/06/07.
3. American College of Allergy, Asthma & Immunology. Position Statement on the Administration of Immunotherapy Outside of the Prescribing Allergist Facility. Accessed 11/06/07.
4. American Medical Association CPT Coding, 2009professional edition.
5. Asthma. In: Pulmonary (acute & chronic). San Diego (CA): Work Loss Data Institute; 2009. p. 2-18.Accessed January 2012.
6. Bernstein JA, Lang DM, Khan DA, et al. Joint Task Force on Practice Parameters (JTFPP), representing the American Academy of Allergy, Asthma & Immunology (AAAAI); the American

College of Allergy, Asthma & Immunology (ACAAI); and the Joint Council of Allergy, Asthma & Immunology. Practice parameter: The diagnosis and management of acute and chronic urticaria: 2014 update. J Allerg Clin Immunol. 2014; 133(5):1270-1277.

7. Burch J, Griffin S, McKenna C, et al. Omalizumab for the treatment of severe persistent allergic asthma in children aged 6-11 years: a NICE single technology appraisal. Pharmacoeconomics. 2012; 30(11):991-1004.
8. Burch J, Griffin S, McKenna C, Walker S, Paton J, Wright K, Woolacott N. Omalizumab for the treatment of severe persistent allergic asthma in children aged 6-11 years: a NICE single technology appraisal. Pharmacoeconomics. 2012 Nov 1;30(11):991-1004.
9. Canadian Agency for Drugs and Technologies in Health (CADTH), formerly the Canadian Coordinating Office for Health Technology Assessment (CCOHTA). Omalizumab as Add-on Therapy to Inhaled Steroids for Asthma. Issues in Emerging Health Technologies Bulletin, Issue 58. June 2004. Ottawa, ON. Available at: http://www.cadth.ca/media/pdf/282_omalizumab_cetap_e.pdf. Accessed on January 11, 2016.
10. Clinical Pharmacology [Internet]. Tampa (FL): Gold Standard, Inc.; 2019 [cited 1/1/19]. Available from: http://www.clinicalpharmacology.com/.
11. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine; 2000 Feb 29 - [cited 1/1/19]. Available from: http://clinicaltrials.gov/.
12. DRUGDEX® System [Internet]. Greenwood Village (CO): Thomson Micromedex; Updated periodically [cited 1/1/19]. Available from: http://www.thomsonhc.com/.
13.
14. Genentech, Inc. A Study of Xolair (Omalizumab) in Patients with Chronic Idiopathic Urticaria (CIU) who remain Symptomatic with Antihistamine Treatment (H1). NLM Identifier: NCT00866788. Last updated September 16, 2011. Available at: http://clinicaltrials.gov/ct2/show/NCT00866788?term=NCT00866788&rank=1. Accessed on January 11, 2016.
15. Genentech, Inc. A Study of Xolair to Evaluate Effectiveness and Long-Term Safety in Patients With Moderate to Severe Asthma (EXCELS). NLM Identifier: NCT00252135. Last updated November 23, 2011. Available at: http://clinicaltrials.gov/ct2/show/NCT00252135. Accessed on January 11, 2016.
16. Genentech, Inc. XOLAIR Injection. Medication Guide. Reference ID: 3475329. July 2016. Available at: http://www.fda.gov/downloads/Drugs/DrugSafety/UCM089829.pdf.
17. Global Strategy for Asthma Management and Prevention, Global Initiative for Asthma (GINA). Bethesda, MD. Update 2012. Available at: http://www.ginasthma.org/guidelines-gina-report-global-strategy-for-asthma.html. Accessed on January 11, 2016.
18. Joint Task Force on Practice Parameters. The diagnosis and management of urticaria: a practice parameter part I: acute urticaria/angioedema part II: chronic urticaria/angioedema. Joint Task Force on Practice Parameters. Ann Allergy Asthma Immunol. 2000 Dec;85(6 Pt 2):521-44
19. Leech S, Grattan C, Lloyd K, et al.; Science and Research Department, Royal College of Paediatrics and Child Health (RCPCH). The RCPCH care pathway for children with urticaria, angio-oedema or mastocytosis: an evidence and consensus based national approach. Arch Dis Child. 2011; 96(2):34-37.
20. Li JT, Oppenheimer J, Bernstein IL, et al. Attaining optimal asthma control: a practice parameter. Developed by the Joint Task Force on Practice Parameters representing the American Academy of Allergy, Asthma and Immunology; the American College of Allergy, Asthma and Immunology; and the Joint Council of Allergy, Asthma and Immunology. J Allergy Clin Immunol. 2005; 116(5):S3-11. Available at: https://www.aaaai.org/Aaaai/media/MediaLibrary/PDF%20Documents/Practice%20and%20Parameters/attaining-optimal-asthma-control.pdf. Accessed on January 11, 2016.

21. Managing asthma long term in youths >=12 years of age and adults. In: National Asthma Education and Prevention Program (NAEPP). Expert panel report 3: guidelines for the diagnosis and management of asthma. Bethesda (MD): National Heart, Lung, and Blood Institute; 2007 Aug. p. 326-62. [103 references]; National Guideline Clearinghouse. Accessed 01/27/10.
22. National Asthma Education and Prevention Program. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. NIH Publication Number 08-5846. October 2007. Available at: http://www.nhlbi.nih.gov/guidelines/asthma/asthsumm.pdf. Accessed on January 11, 2016.
23. National Heart, Lung, and Blood Institute Guidelines for the Diagnosis and Management of Asthma. 2007. Accessed 01/04/11.
24. National Heart, Lung, and Blood institute. Key Clinical Activities for Quality Asthma Care. Recommendations of the National Asthma Education and Prevention Program in partnership with the Centers for Disease Control and Prevention. Reproduced from the Morbidity and Mortality Weekly Report (MMWR): Recommendations and Reports, Vol. 52/No. RR-6, March 28, 2003.
25. National Heart, Lung, and Blood Institute. National Asthma Education and Prevention Program. Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma. Full Report 2007. NIH Publication No. 07-4051. Originally printed July 1997. Revised June 2002, August 2007.
26. National Heart, Lung, and Blood Institute; Expert Panel Report 3 (EPR-3): Guidelines for the Diagnosis and Management of Asthma – Summary Report 2007. Accessed 01/26/10.
27. National Institute for Health and Clinical Excellence (NICE). Omalizumab for treating severe persistent allergic asthma (review of technology appraisal guidance 133 and 201). Technology Appraisal Guidance No. 278. London, UK: NICE; April 2013. Available at: http://www.nice.org.uk/guidance/ta278. Accessed on January 11, 2016.
28. Walker S, Monteil M, Phelan K, Lasserson TJ, Walters EH. Anti-IgE for chronic asthma in adults and children. Cochrane Database of Systematic Reviews 2003, Issue 3. Art. No.: CD003559. DOI: 10.1002/14651858. CD003559.pub3.
29. Xolair® prescribing information. Accessed 4/23/14.
30. Zuberbier T, Asero R, Bindslev-Jensen C, et al; Dermatology Section of the European Academy of Allergology and Clinical Immunology, Global Allergy and Asthma European Network, European Dermatology Forum, World Allergy Organization. EAACI/GA2LEN/EDF/WAO guideline: management of urticaria. Allergy. 2009 Oct;64(10):1427-43.
31. Zuberbier T, Asero R, Bindslev-Jensen C, et al; Dermatology Section of the European Academy of Allergology and Clinical Immunology, Global Allergy and Asthma European Network, European Dermatology Forum, World Allergy Organization. EAACI/GA2LEN/EDF/WAO guideline: management of urticaria. Allergy. 2009 Oct;64(10):1417-26.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 01/09/19.

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