09-J0000-44

Original Effective Date: 12/15/04

Reviewed: 01/14/26

Revised: 04/15/26

Subject: Omalizumab (Xolair®, Omlyclo®)

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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, Omlyclo) 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, Omlyclo) **meets the definition of medical necessity** for members diagnosed with any 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. **ONE** of the following:

   i. Member has a history of uncontrolled asthma while on asthma control therapy (e.g., inhaled corticosteroids [ICS], ICS/long-acting beta-2 agonist [LABA], leukotriene receptor antagonist [LTRA], long-acting muscarinic antagonist [LAMA], theophylline) as demonstrated by **ONE** of the following:

      - Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months
      - Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months
      - Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered
      - The member has baseline (prior to therapy with omalizumab) Forced Expiratory Volume (FEV1) that is less than 80% of predicted

   ii. Member's medication history indicates use of a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of asthma within the past 12 months (treatment on samples is not approvable)

d. **ONE** of the following:

   i. Member is **NOT** currently being treated with a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of asthma (including omalizumab) **AND** is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **AND** has been adherent for 90 days within the past 120 days

   ii. Member is currently being treated with a biologic immunomodulator agent that is FDA labeled or supported in compendia for the treatment of asthma (including omalizumab) **AND ONE** of the following:

      - Member is currently treated with an inhaled corticosteroid for at least 3 months **AND** has been adherent for 90 days within the past 120 days that is adequately dosed to control symptoms
      - Member is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **AND** has been adherent for 90 days within the past 120 days

   iii. Member has an intolerance or hypersensitivity to **ONE** inhaled corticosteroid therapy

   iv. Member has an FDA labeled contraindication to **ALL** inhaled corticosteroids

e. **ONE** of the following:

   i. Member is currently being treated for at least 3 months **AND** has been adherent for 90 days within the past 120 days with **ONE** of the following:

      - A long-acting beta-2 agonist (LABA)
      - A leukotriene receptor antagonist (LTRA)
      - Long-acting muscarinic antagonist (LAMA)

- Theophylline

ii. Member has an intolerance or hypersensitivity to therapy to **ONE** LABA, LTRA, LAMA, or theophylline

iii. Member 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), depemokimab (Exdensur), 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) **OR** one 150 mg vial*

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) **OR** four 150 mg vials*

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

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

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

vii. 375 mg every two weeks: two 75 mg syringes (or autoinjectors) plus two 300 mg syringes (or autoinjectors) **OR** six 150 mg vials*

*** NOTE:** 150 mg vials are provider administered only

k. Member is 6 years of age or older

2. Chronic Spontaneous Urticaria (CSU) (otherwise known as Chronic Idiopathic Urticaria [CIU])

a. Member has had hives and itching for more than 6 weeks

b. Prescriber has evaluated the member to determine if the member is currently treated with medications known to cause or worsen urticaria (e.g., NSAIDs) in order to reduce urticaria risk

c. **ONE** of the following:

i. Member's symptoms remained uncontrolled or inadequately controlled despite two weeks of treatment with a second-generation H1-antihistamine (e.g., cetirizine, fexofenadine, desloratadine) at the FDA-labeled maximum dose **AND ONE** of the following:

- Member tried and had an inadequate response to a maximally tolerated dose of one second-generation H1-antihistamine titrated up to 4 times above the FDA labeled maximum dose after at least a two week duration of therapy
- There is support that the member cannot be treated with a second-generation H1-antihistamine at a dose above the FDA labeled maximum dose

ii. Member has an intolerance or hypersensitivity to therapy with **ONE** second-generation H1-antihistamine

iii. Member has an FDA labeled contraindication to **ALL** second-generation H1-antihistamines

d. **ONE** of the following:

i. Member is currently treated with second-generation H1-antihistamine therapy (e.g., cetirizine, fexofenadine, desloratadine) and will continue use in combination with omalizumab

ii. Member has an intolerance, hypersensitivity, or FDA labeled contraindication to **ALL** second-generation H1-antihistamines

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

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

g. 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*

*** NOTE:** 150 mg vials are provider administered only

h. 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

ii. Nasal endoscopy

iii. Computed tomography (CT) of the sinuses

b. Member has had at least **TWO** of the following symptoms consistent with chronic rhinosinusitis (CRS):

i. Nasal discharge (rhinorrhea or post-nasal discharge)

ii. Nasal obstruction or congestion

iii. Loss or decreased sense of smell (hyposmia)

iv. Facial pressure or pain

c. Member has had symptoms consistent with CRS for at least 12 consecutive weeks

d. **ONE** of the following:
    i. Member has tried and had an inadequate response to **ONE** intranasal corticosteroid (e.g., fluticasone, Sinuva) after at least a 4-week duration of therapy
    ii. Member has an intolerance or hypersensitivity to **ONE** intranasal corticosteroid (e.g., fluticasone, Sinuva)
    iii. Member has an FDA labeled contraindication to **ALL** intranasal corticosteroids
e. **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
f. Member's baseline pretreatment serum total IgE is between 30 IU/mL and 1500 IU/mL – laboratory documentation must be provided
g. Omalizumab is prescribed by a board certified (or board eligible) allergist, immunologist, pulmonologist, or otolaryngologist (ear, nose, and throat specialist)
h. Omalizumab is not used in combination with benralizumab (Fasenra), depemokimab (Exdensur), dupilumab (Dupixent), mepolizumab (Nucala), tezepelumab (Tezspire), or reslizumab (Cinqair)
i. Dose does not exceed FDA-approved dose and frequency (See Table 4)
j. 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) **OR** one 150 mg vial*
    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) **OR** four 150 mg vials*
    iv. 225 mg every four weeks: one 75 mg syringe (or autoinjector) plus one 150 mg syringe (or autoinjector) **OR** two 150 mg vials*
    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) **OR** six 150 mg vials*
    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. 450 mg every two weeks: two 150 mg syringes (or autoinjectors) plus two 300 mg syringes (or autoinjectors) **OR** six 150 mg vials*
    x. 525 mg every two weeks: two 75 mg syringes (or autoinjectors) plus two 150 mg syringes (or autoinjectors) plus two 300 mg syringes (or autoinjectors) **OR** eight 150 mg vials*

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

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

*** NOTE:** 150 mg vials are provider administered only

k. Member is 18 years of age or older

4. IgE-Mediated Food Allergy

a. Member is diagnosed with an IgE-mediated food allergy that is confirmed by **BOTH** of the following:

i. Clinical history of a type I allergic reaction (e.g., nausea, vomiting, cramping, diarrhea, flushing, pruritus, urticaria, swelling of the lips, face or throat, wheezing, lightheadedness, syncope) – documentation from the medical record must be provided

ii. One of the following – documentation from the medical record must be provided:

- Positive food specific skin prick test
- Positive serum IgE antibody test
- Positive oral food challenge

b. Member's baseline pretreatment serum total IgE is equal to or greater than 30 IU/mL – laboratory documentation must be provided

c. Member will avoid known food allergens while treated with omalizumab

d. Omalizumab is prescribed by a board certified (or board eligible) allergist or immunologist

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

f. Dose does not exceed FDA-approved dose and frequency (See Table 5)

g. Omalizumab quantity does not exceed the following dose and frequency based limits per 28 days based on weight and baseline IgE level (See Table 5):

i. 75 mg every four weeks: one 75 mg syringe (or autoinjector) **OR** one 150 mg vial*

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) **OR** four 150 mg vials*

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

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) **OR** six 150 mg vials*

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.

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: two 75 mg syringes (or autoinjectors) plus two 150 mg syringes (or autoinjectors) plus two 300 mg syringes (or autoinjectors) **OR** eight 150 mg vials*

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

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

*** NOTE:** 150 mg vials are provider administered only

h. Member is 1 year of age or older

5. 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: 6 months

Continuation of omalizumab (Xolair, Omlyclo) meets the definition of **medical necessity** for members diagnosed with any 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. Increase in percent predicted Forced Expiratory Volume (FEV1)
        ii. Decrease in the dose of inhaled corticosteroids required to control the patient's asthma
        iii. Decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma
        iv. Decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma
    c. The member is currently treated within the past 90 days and is compliant with asthma control therapy (e.g., inhaled corticosteroids [ICS], ICS/long-acting beta-2 agonist [LABA], leukotriene receptor antagonist [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), depemokimab (Exdensur), 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) **OR** one 150 mg vial*

   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) **OR** four 150 mg vials*

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

   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) **OR** six 150 mg vials*

*** NOTE:** 150 mg vials are provider administered only

2. Chronic Spontaneous Urticaria (CSU) (otherwise known as Chronic Idiopathic Urticaria [CIU])

   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 beneficial clinical response to omalizumab as evidenced by a reduction in itch severity and/or hive count

   c. ONE of the following:

      i. Member is currently treated with second-generation H1-antihistamine therapy (e.g., cetirizine, fexofenadine, desloratadine) and will continue use in combination with omalizumab

      ii. Member has an intolerance, hypersensitivity, or FDA labeled contraindication to ALL second-generation H1-antihistamines

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

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

   f. 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*

*** NOTE:** 150 mg vials are provider administered only

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. **BOTH** of the following:
        i. Member is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids)
        ii. Member will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with omalizumab
    d. Omalizumab is prescribed by or in consultation with a board certified (or board eligible) allergist, immunologist, or otolaryngologist (ear, nose, and throat specialist)
    e. Omalizumab is not used in combination with benralizumab (Fasenra), depemokimab (Exdensur), dupilumab (Dupixent), mepolizumab (Nucala), or reslizumab (Cinqair)
    f. Dose does not exceed FDA-approved dose and frequency (See Table 4)
    g. 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) **OR** one 150 mg vial*
        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) **OR** four 150 mg vials*
        iv. 225 mg every four weeks: one 75 mg syringe (or autoinjector) plus one 150 mg syringe (or autoinjector) **OR** two 150 mg vials*
        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) **OR** six 150 mg vials*
        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. 450 mg every two weeks: two 150 mg syringes (or autoinjectors) plus two 300 mg syringes (or autoinjectors) **OR** six 150 mg vials*

x. 525 mg every two weeks: two 75 mg syringes (or autoinjectors) plus two 150 mg syringes (or autoinjectors) plus two 300 mg syringes (or autoinjectors) **OR** eight 150 mg vials*

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

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

*** NOTE:** 150 mg vials are provider administered only

h. Member is 18 years of age or older

4. IgE-Mediated Food Allergy

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

c. Member will avoid known food allergens while treated with omalizumab

d. Omalizumab is prescribed by or in consultation with an allergist or immunologist

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

f. Dose does not exceed FDA-approved dose and frequency (See Table 5)

g. Omalizumab quantity does not exceed the following dose and frequency based limits per 28 days based on weight and baseline IgE level (See Table 5):

i. 75 mg every four weeks: one 75 mg syringe (or autoinjector) **OR** one 150 mg vial*

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) **OR** four 150 mg vials*

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

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) **OR** six 150 mg vials*

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

x. 525 mg every two weeks: two 75 mg syringes (or autoinjectors) plus two 150 mg syringes (or autoinjectors) plus two 300 mg syringes (or autoinjectors) **OR** eight 150 mg vials*

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

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

*** NOTE:** 150 mg vials are provider administered only

h. Member is 1 year of age or older

5. 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 based on serum total IgE level measured before the start of treatment and by body weight

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

See Table 4 for appropriate dose assignment

IgE-Mediated Food Allergy:

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

See Table 5 for appropriate dose assignment

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		300	375	450	450	525	600		
>800-900		300	375	450	525	600			
>900-1000		375	450	525	600				
>1000-1100	Every 2 weeks	375	450	600					
>1100-1200		450	525	600					
>1200-1300		450	525						
>1300-1500		525	600						

Insufficient Data to Recommend a Dose

Table 5

Adult and Pediatric Patients 1 Year of Age and Older with IgE Mediated Food Allergy														
		Body Weight												
Pre-treatment Serum IgE (IU/mL)	Dosing Freq.	≥10-12 kg	>12-15 kg	>15-20 kg	>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	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					
>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							

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
Q5154	Injection, omalizumab-igec (omlyclo), biosimilar, 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
L50.0	Allergic urticaria
L50.1	Idiopathic urticaria
L50.8	Other (chronic, recurrent) urticaria
L50.9	Urticaria, unspecified
Z91.010	Allergy to peanuts
Z91.0110	Allergy to milk products, unspecified
Z91.0111	Allergy to milk products with tolerance to baked milk
Z91.0112	Allergy to milk products with reactivity to baked milk
Z91.0120	Allergy to eggs, unspecified
Z91.0121	Allergy to eggs with tolerance to baked egg
Z91.0122	Allergy to eggs with reactivity to baked egg
Z91.013	Allergy to seafood

Z91.018	Allergy to other foods

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.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request

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:

Dupilumab (Dupixent®) Injection, 09-J2000-80

Interleukin-5 (IL-5) Inhibitors, 09-J5000-35

Tezepelumab (Tezspire), 09-J4000-13

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 01/14/26.

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	Revision to guideline; consisting of position statement.
07/15/16	Revision 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	Revision 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.
02/15/25	Review and revision; consisting of updating position statement and references.
07/01/25	Revision to guideline; updated position statement.
07/15/25	Revision to guideline; updated position statement and coding.
08/15/25	Revision to guideline; updated position statement
10/01/25	Revision: Added HCPCS code Q5154.
02/15/26	Review and revision to guideline; updated position statement, references, and coding.
03/15/26	Revision to guideline; updated position statement, related guidelines.

04/15/26	Revision to guideline; updated position statement.