

LCD for Omalizumab (Xolair®) (L29240)

Contractor Information

Contractor Name

First Coast Service Options, Inc.

Contractor Number

09102

Contractor Type

MAC - Part B

LCD Information

LCD ID Number

L29240

LCD Title

Omalizumab (Xolair®)

Contractor's Determination Number

J2357

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CMS National Coverage Policy

CMS Manual System, Pub 100-2, Medicare Benefit Policy, Chapter 15, Section 50 and 60

CMS Manual System, Pub. 100-8, Program Integrity Manual, Chapter 13, Section 5.1.C

Primary Geographic Jurisdiction

Florida

Oversight Region

Region IV

Original Determination Effective Date

For services performed on or after 02/02/2009

Original Determination Ending Date

Revision Effective Date

Revision Ending Date

Indications and Limitations of Coverage and/or Medical Necessity

Asthma is a chronic inflammatory lung disease. Allergic asthma is the most common form of asthma and symptoms may include coughing, wheezing, shortness of breath and chest tightness. Allergens (dust mites, mold, pollen, pet dander etc.) and IgE antibodies are the main causes of allergic asthma. IgE antibodies are produced by the body in response to being exposed to allergens. This combination results in the release of mediators (histamine, prostaglandins and leukotrienes), which cause the asthma symptoms to manifest.

Xolair (Omalizumab) is a recombinant DNA-derived monoclonal antibody that selectively binds to human immunoglobulin E (IgE). Xolair inhibits the binding of IgE to the high-affinity IgE receptor on the surface of mast cells and basophils.

Indications

Xolair is indicated for adults and children (12 years of age and older) with moderate to severe persistent asthma who have a positive skin test or in vitro reactivity to a perennial aeroallergen and whose symptoms are inadequately controlled with inhaled corticosteroids. Xolair has been shown to decrease the incidence of asthma exacerbations in these patients.

Moderate persistent asthma

Moderate persistent asthma is defined by the National Heart, Lung, and Blood Institute (NHLBI) as:

- Daily symptoms
- Daily use of inhaled short-acting beta2-agonist
- Exacerbations affect activity
- Exacerbations greater than or equal to 2 times a week; may last days
- Nighttime symptoms greater than 1 time a week

Severe persistent asthma

Severe persistent asthma is defined by the National Heart, Lung, and Blood Institute (NHLBI) as:

- Continual symptoms

- Limited physical symptoms
- Frequent exacerbations
- Nighttime symptoms are frequent

The presence of one of these features of severity (moderate or severe) is sufficient to place a patient in that category. These clinical features are based on pre-treatment symptoms and measurements.

Limitations

Anaphylaxis has occurred within 2 hours of the first or subsequent administration of Xolair. Patients should be observed after injection of Xolair, and medications for the treatment of severe hypersensitivity reactions should be available. If severe hypersensitivity reaction to Xolair occurs, then therapy should be discontinued.

Xolair should not be administered to patients who have a body weight greater than 150 kg and who do not have a baseline IgE level between 30 and 700 IU/mL. See dosing charts under Utilization guidelines of this LCD.

Xolair has not been shown to alleviate asthma exacerbations acutely and should not be used for the treatment of acute bronchospasm or status asthmaticus.

Systemic or inhaled corticosteroids should not be abruptly discontinued upon initiation of Xolair therapy.

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

999x Not Applicable

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

99999 Not Applicable

CPT/HCPCS Codes

J2357 INJECTION, OMALIZUMAB, 5 MG

ICD-9 Codes that Support Medical Necessity

493.00 EXTRINSIC ASTHMA UNSPECIFIED
493.10 INTRINSIC ASTHMA UNSPECIFIED
493.20 CHRONIC OBSTRUCTIVE ASTHMA
UNSPECIFIED

Diagnoses that Support Medical Necessity

Any diagnosis not listed under ICD-9 CM codes that support medical necessity

ICD-9 Codes that DO NOT Support Medical Necessity

Any diagnosis code not listed under ICD-9 CM codes that support medical necessity

XX000 Not Applicable

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

Any diagnosis code not listed under ICD-9 CM codes that support medical necessity.

General Information

Documentation Requirements

The medical record documentation should support the indications and limitations outlined in this LCD. The medical record should include: a history and physical that supports the patient has moderate to severe persistent asthma as defined in this LCD; documentation indicating that the patient has been on inhaled corticosteroids for asthma before initiation of Xolair and what the patients response to inhaled corticosteroids has been; patients weight; documentation supporting a positive skin test or in vitro reactivity (RAST test) to a perennial aeroallergen; **documented IgE level prior to treatment that is between 30 and 700 IU/ml.**

If the medical record documents that the patient has not shown any response to Xolair after 16 weeks of therapy, then further use of Xolair will be considered medically unnecessary.

Appendices

Utilization Guidelines

The CMS Manual System, Pub. 100-8, Program Integrity Manual, Chapter 13, Section 5.1.C outlines that “reasonable and necessary” services are “ordered and/or furnished by qualified personnel.” The use of this drug will be limited to specialty 03 (Allergy/Immunology) and Specialty 29 (Pulmonary Disease), or other physicians (MD/DO)/NPPS who have special expertise in evaluation and treatment of asthma.

Dosing

The dosing for Xolair is based on body weight and baseline serum total IgE concentration. Xolair should not be administered to patients who have a body weight greater than 150 kg and who do not have a baseline IgE level between 30 and 700 IU/mL. See dosing charts below.

Xolair 150-375 mg is administered subcutaneously (SC) every two (2) or 4 (four) weeks. Doses (mg) and dosing frequency are determined by serum total IgE level (IU/mL), measured before the start of treatment, and body weight (kg). Doses of more than 150 mg are divided among more than one injection site to limit injections to not more than 150 mg per site.

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.

Every 4 week administration of Xolair

Pretreatment serum IgE (units/mL): 30 to 100

Body weight (kg) 30-60: 150 mg
Body weight (kg) >60 to 70: 150 mg
Body weight (kg) >70-90: 150 mg
Body weight (kg) >90-150: 300 mg

Pretreatment serum IgE (units/mL): >100 to 200

Body weight (kg) 30-60: 300 mg
Body weight (kg) >60 to 70: 300 mg
Body weight (kg) >70-90: 300mg
Body weight (kg) >90-150: see every 2 week administration

Pretreatment serum IgE (units/mL): > 200 to 300

Body weight (kg) 30-60: 300 mg
Body weight (kg) >60 to 70: see every 2 week administration
Body weight (kg) >70-90: see every 2 week administration
Body weight (kg) >90-150: see every 2 week administration

Pretreatment serum IgE (units/mL): >300 to 400

Body weight (kg) 30-60: see every 2 week administration
Body weight (kg) >60 to 70: see every 2 week administration
Body weight (kg) >70-90: see every 2 week administration
Body weight (kg) >90-150: see every 2 week administration

Pretreatment serum IgE (units/mL):>400 to 500
Body weight (kg) 30-60: see every 2 week administration
Body weight (kg) >60 to 70: see every 2 week administration
Body weight (kg) >70-90: see every 2 week administration
Body weight (kg) >90-150: see every 2 week administration

Pretreatment serum IgE (units/mL):> 500 to 600
Body weight (kg) 30-60: see every 2 week administration
Body weight (kg) >60 to 70: see every 2 week administration
Body weight (kg) >70-90: see every 2 week administration
Body weight (kg) >90-150: see every 2 week administration

Every 2 week administration of Xolair

Pretreatment serum IgE (units/mL): >100 to 200
Body weight (kg) 30-60: see every 4 week administration
Body weight (kg) >60 to 70: see every 4 week administration
Body weight (kg) >70-90: see every 4 week administration
Body weight (kg) >90-150: 225 mg

Pretreatment serum IgE (units/mL): >200 to 300
Body weight (kg) 30-60: see every 4 week administration
Body weight (kg) >60 to 70: 225 mg
Body weight (kg) >70-90: 225 mg
Body weight (kg) >90-150: 300 mg

Pretreatment serum IgE (units/mL): >300 to 400
Body weight (kg) 30-60: 225 mg
Body weight (kg) >60 to 70: 225 mg
Body weight (kg) >70-90: 300 mg
Body weight (kg) >90-150:Do not dose

Pretreatment serum IgE (units/mL): >400 to 500
Body weight (kg) 30-60: 300 mg
Body weight (kg) >60 to 70: 300 mg
Body weight (kg) >70-90: 375 mg
Body weight (kg) >90-150: Do not dose

Pretreatment serum IgE (units/mL): >500 to 600
Body weight (kg) 30-60: 300 mg
Body weight (kg) >60 to 70: 375 mg
Body weight (kg) >70-90: Do not dose
Body weight (kg) >90-150:Do not dose

Pretreatment serum IgE (units/mL): >600 to 700
Body weight (kg) 30-60: 375 mg
Body weight (kg) >60 to 70: Do not dose
Body weight (kg) >70-90: Do not dose
Body weight (kg) >90-150: Do not dose

Although the risk of anaphylaxis following administration of Xolair necessitates the need for observation, this is not separately reimbursable and is considered part of the administration of Xolair.

It is expected that this drug is administered according to locally accepted standards of medical practice and the administration of Xolair should be in keeping with the FDA approved package insert.

Sources of Information and Basis for Decision

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Advisory Committee Meeting Notes

This Local Coverage Determination (LCD) does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this LCD was developed in cooperation with advisory groups, which includes representatives from numerous societies.

Start Date of Comment Period

End Date of Comment Period

Start Date of Notice Period

12/04/2008

Revision History Number

Original

Revision History Explanation

Revision Number:Original

Start Date of Comment Period:N/A

Start Date of Notice Period:12/04/2008

Revised Effective Date:02/02/2009

LCR B2009-
December 2008 Bulletin

This LCD consolidates and replaces all previous policies and publications on this subject by the carrier predecessors of First Coast Service Options, Inc. (Triple S and FCSO).

For Florida (00590) this LCD (L29240) replaces LCD L25294 as the policy in notice. This document (L29240) is effective on 02/02/2009.

Reason for Change**Last Reviewed On Date****Related Documents**

This LCD has no Related Documents.

LCD Attachments

There are no attachments for this LCD.

All Versions

Updated on 11/30/2008 with effective dates 02/02/2009 - N/A