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DRUG POLICY

Xolair (omalizumab)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Xolair (omalizumab) drug policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies.

FDA-Approved Indications

1. Allergic Asthma:
 - a. Xolair is indicated for patients 6 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.
 - b. Limitations of use: Xolair is not indicated for the relief of acute bronchospasm or status asthmaticus, or for treatment of other allergic conditions.
2. Chronic Idiopathic Urticaria:
 - a. Xolair is indicated for the treatment of adults and adolescents 12 years of age and older with chronic idiopathic urticaria (CIU) who remain symptomatic despite H1 antihistamine treatment.
 - b. Limitations of use: Xolair is not indicated for treatment of other forms of urticaria.

POLICY

Required Documentation

The following information is necessary to initiate the prior authorization review:

- A. Allergic Asthma (initial therapy):
 1. Baseline (pre-treatment) IgE level
 2. Skin or blood test results confirming reactivity to at least one perennial aeroallergen

Prescriber Specialties

For CIU

- Xolair must be prescribed by or in consultation with an allergist or dermatologist.

Criteria for Initial Approval

A. Allergic Asthma

Authorization of 6 months may be granted for treatment of allergic asthma when ALL of the following criteria are met:

1. Member is 6 years of age or older
2. Xolair is used in combination with other medications for long-term control of asthma
3. Prior to initiating therapy, the severity of the member's asthma is moderate to severe persistent
4. Member has a reliever agent (ie, short-acting beta2-agonist or low-dose combination inhaled corticosteroid/formoterol) available for rescue therapy
5. Member has a positive skin test or in vitro reactivity to at least one perennial aeroallergen
6. Member has a pre-treatment IgE level greater than or equal to 30 IU/mL
7. Member is using optimized doses of inhaled corticosteroid without adequate asthma control (e.g., hospitalization or emergency medical care visit within the past year)
8. Member is using optimized doses of one of the following agents without adequate asthma control:
 - a). Long acting beta2-agonist
 - b). Leukotriene modifier
 - c). Sustained-release theophylline
9. Xolair is administered in a controlled healthcare setting with access to emergency medication
10. Xolair will not be used concomitantly with other biologics (e.g., Cinqair, Dupixent, Fasenna, Nucala).

B. Chronic Idiopathic Urticaria

Authorization of 6 months may be granted for treatment of CIU when ALL of the following criteria are met:

1. Member is 12 years of age or older
2. Prior to initiating therapy, the severity of the member's CIU is moderate to severe
3. Member has been evaluated for other causes of urticaria, including bradykinin-related angioedema and interleukin-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis)
4. Member has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks
5. Member remains symptomatic despite second generation H1 antihistamine therapy with maximized dosing used continuously for at least 2 weeks (see Appendix)
6. Patient remains symptomatic despite a two week continuous trial of at least one of the following:
 - a). Higher dose (up to four times the recommended dose) of second generation H1 antihistamine therapy
 - b). Addition of another second generation antihistamine to existing therapy
 - c). Addition of a leukotriene receptor antagonist (LTRA) to existing therapy
 - d). Addition of a H2-antagonist to existing therapy
 - e). Addition of a first generation antihistamine taken at bedtime
7. Patient remains symptomatic despite the addition of a potent antihistamine (e.g., hydroxyzine or doxepin) used continuously for at least two weeks
8. Xolair is administered in a controlled healthcare setting with access to emergency medication

Continuation of Therapy

A. Allergic Asthma

Authorization of 12 months may be granted for treatment of allergic asthma when ALL of the following criteria are met:

1. Member is 6 years of age or older
2. Xolair is used in combination with other medications for long-term control of asthma
3. Member has a reliever agent (ie, short-acting beta2-agonist or low-dose combination inhaled corticosteroid/formoterol) available for rescue therapy
4. Xolair is administered in a controlled healthcare setting with access to emergency medication
5. Member will not use Xolair concomitantly with other biologics (e.g., Cinqair, Dupixent, Fasenna, Nucala).
6. Asthma control has improved on Xolair treatment as demonstrated by at least ONE of the following:
 - a). A reduction in the frequency or severity of symptoms and exacerbations, OR
 - b). An improvement in FEV1 since initiation of therapy, OR
 - c). A reduction in the daily maintenance oral corticosteroid dose

B. CIU

Authorization of 12 months may be granted for continuation of treatment of CIU when ALL of the following criteria are met:

1. Member is 12 years of age or older
2. Member has experienced a positive response (e.g., improved symptoms, decrease in weekly urticaria activity score [UAS7]) since initiation of therapy
3. Xolair is administered in a controlled healthcare setting with access to emergency medication

Xolair is considered not medically necessary for members who do not meet the criteria set forth above.

Other

Note: If the member is a current smoker, they should be counseled on the harmful effects of smoking on pulmonary conditions and available smoking cessation options.

Quantity Limits Apply

- Xolair 6 vials per 28 days

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- J2357 Injection, omalizumab, 5mg

REFERENCES

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- Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention, 2019. <http://ginasthma.org/gina-reports/>. Accessed March 25, 2019.

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 - Bernstein DI, Blessing-Moore J, Cox L, et al. The diagnosis and management of acute and chronic urticaria: 2014 update. American Academy of Allergy, Asthma & Immunology Practice Parameter. <http://www.aaaai.org/practice-resources/statements-and-practice-parameters/practice-parameter-guidelines.aspx>. Accessed March 25, 2019.
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*Some content reprinted from CVSHealth

APPENDIX

Examples of histamine H1 blockers and standard recommended dosage

Drug	Recommended Dosage
Cetirizine (Zyrtec®)	5-10 mg daily
Desloratadine (Clarinex®)	5 mg daily
Fexofenadine (Allegra®)	180 mg daily
Loratadine (Claritin®)	10 mg daily
Levocetirizine (Xyzal®)	5 mg daily

POLICY HISTORY

Policy #: 05.01.07

Original Effective Date: December 2003

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Current Effective Date: June 1, 2020