Reference number(s)
2061-A

JURISDICTION SPECIFIC MEDICARE PART B

XOLAIR (omalizumab)

POLICY

I. COVERED USES

The indications below are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. Allergic asthma
B. Chronic idiopathic urticaria
C. Nasal polyps

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions (for the diagnosis of allergic asthma only):

A. History and physical that supports the member has moderate to severe persistent asthma
B. Documentation indicating the member has been on inhaled corticosteroids before the initiation of Xolair and what the response to inhaled corticosteroids has been
C. Member's weight
D. Documentation supporting a positive skin test or in vitro reactivity (RAST test) to a perennial aeroallergen
E. Documentation of a pretreatment IgE level between 30 and 1300 IU/mL (see III.A.6. below)

III. CRITERIA FOR APPROVAL

A. Allergic Asthma[1]

Initial authorization of 16 weeks 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.[3]
2. Member will be monitored for hypersensitivity reactions after Xolair administration.
3. Xolair is prescribed by a specialist in allergy/immunology, pulmonary disease, or by another physician with special expertise in the evaluation and treatment of asthma.
4. Member has moderate persistent or severe persistent allergic asthma.
5. Member has a positive skin test or in vitro reactivity to at least 1 perennial aeroallergen.
6. Member has a pre-treatment IgE level between 30 IU/mL and 700 IU/mL if 12 years of age or older, or between 30 IU/mL and 1300 IU/mL if 6 years of age to less than 12 years of age.

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7. Asthma symptoms are inadequately controlled on inhaled corticosteroids.
8. Member's current weight is 150 kilograms or less.
9. Prescriber will comply with the FDA-recommended weight based dosing.

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

1. Member is 6 years of age or older.[3]
2. Member will be monitored for hypersensitivity reactions after Xolair administration.
3. Xolair is prescribed by a specialist in allergy/immunology, pulmonary disease, or by another physician with special expertise in the evaluation and treatment of asthma.
4. Member has shown a response to Xolair (e.g., the member observed a decrease in the incidence of asthma exacerbations or short-acting beta-agonist use).

B. Chronic Idiopathic Urticaria[1]

Initial authorization of 16 weeks may be granted for treatment of chronic idiopathic urticaria when all of the following criteria are met:

1. Member is 12 years of age or older.[3]
2. Member will be monitored for hypersensitivity reactions after Xolair administration.
3. Xolair will be prescribed by a specialist in allergy/immunology.
4. Other forms of urticaria have been ruled out.
5. Member remains symptomatic despite H1 antihistamine treatment.
6. The dose of Xolair will not exceed 300 mg subcutaneously every four weeks.

Authorization of 12 months may be granted for the continued treatment of chronic idiopathic urticaria when all of the following criteria are met:

1. Member is 12 years of age or older.[3]
2. Member will be monitored for hypersensitivity reactions after Xolair administration.
3. Xolair will be prescribed by a specialist in allergy/immunology.
4. Member has shown a response to Xolair.

C. Nasal Polyps[1]

Initial authorization of 16 weeks may be granted for add-on treatment of nasal polyps when all of the following criteria are met:

1. Member is 18 years of age or older.[3]
2. Member will be monitored for hypersensitivity reactions after Xolair administration.
3. Member has had an inadequate response with intranasal corticosteroid treatment.
4. The dose of Xolair will not exceed 600 mg subcutaneously every 2 weeks.

Authorization of 12 months may be granted for the continued treatment of nasal polyps when all of the following criteria are met:

1. Member is 18 years of age or older.[3]
2. Member will be monitored for hypersensitivity reactions after Xolair administration.
3. Member has shown a response to Xolair.

IV. REFERENCES

1. LCD Omalizumab (Xolair) (L33924) Version R3. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed March 15, 2021.
2. Billing and Coding: Omalizumab (A57658) Version 3. Available at: https://www.cms.gov/medicare-coverage-database/indexes/national-and-local-indexes.aspx. Accessed March 15, 2021.

3. Xolair [package insert]. South San Francisco, CA: Genentech, Inc.; December 2020.