EFFECTIVE DATE: 09|01|2004
POLICY LAST UPDATED: 09|06|2016

OVERVIEW

This policy documents coverage guidelines required for the use of Omalizumab (Xolair). Omalizumab is a treatment for moderate to severe persistent allergic asthma and chronic idiopathic urticaria (CIU) in appropriate patients.

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial Products

Allergic Asthma:

Omalizumab may be considered medically necessary when the following criteria are met:

1. Patient has a diagnosis of moderate to severe persistent allergic asthma; AND
2. Patient is 12 years of age or older; AND
3. Patient has evidence of specific allergic sensitivity confirmed by positive skin test (i.e., prick/puncture test) or blood test (i.e., radioallergosorbent test) for a specific anti-immunoglobulin E (IgE) or in vitro reactivity to a perennial aeroallergen; AND
4. Patient has pretreatment serum IgE levels > 30 and < 700 IU/mL; AND
5. Patient's symptoms are not adequately controlled with high-dose inhaled corticosteroid (ICS) plus long-acting beta2-agonist (LABA) for at least 3 months; AND
6. Patient has been adherent within a 12-month period, and is currently adherent, with asthma therapy; AND
7. Xolair is prescribed by or in consultation with an allergist, immunologist, or pulmonologist, AND
8. The patient will not receive the requested agent in combination with an interleukin 5 inhibitor (e.g. Cinqair, Nucala)

For continued use:

Authorization for continued use shall be reviewed at least every 6 months to confirm the following:

1. Patient has experienced an objective response to therapy, defined as one or more of the following:

- Reduction in number of asthma exacerbations from baseline (i.e., asthma exacerbation requiring treatment with systemic corticosteroids or doubling of ICS dose from baseline)
- Improvement in forced expiratory volume in 1 second (FEV1) from baseline
- Decreased use of rescue medications from baseline

Chronic Idiopathic Urticaria:

Omalizumab may be considered medically necessary for when the following criteria are met:

1. Patient has a diagnosis of chronic idiopathic urticaria; AND
2. Patient is 12 years of age or older; AND
3. Patient has a history of itching and hives for at least 4 consecutive weeks despite titrating to an optimal dose with a non-sedating H1 antihistamine (2-4 times normal antihistamine dose); AND
4. Patient has tried at least 4 weeks of the addition of montelukast and had an inadequate response, intolerance, or contraindication; AND
5. Patient has tried and had an inadequate response, intolerance, or contraindication to a short burst of an oral corticosteroid; AND
6. Patient will use Xolair concurrently with H1 antihistamine therapy; AND

7. Xolair is prescribed by or in consultation with an allergist, immunologist, or dermatologist.

For continued use:
Authorization for continued use shall be reviewed at least every 6 months to confirm the following:
1. Patients CIU requires continued treatment AND
2. Patient has experienced an objective response to therapy, defined as reduction in itching severity and/or reduction in the number of hives from baseline

PRIOR AUTHORIZATION

BlueCHiP for Medicare and Commercial Products
Prior authorization review is required for BlueCHiP for Medicare and recommended for Commercial products.

POLICY STATEMENT

Omalizumab therapy is medically necessary for BlueCHiP for Medicare and Commercial products when all of the above medical criteria are met.

COVERAGE

Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable Specialty Pharmacy guidelines.

Specialty Drug Coverage:
For contracts with specialty drug coverage, please refer to the member agreement for benefits and preauthorization guidelines.

BACKGROUND

Omalizumab (Xolair) is a recombinant DNA-derived humanized monoclonal anti-immunoglobulin E (IgE) antibody that selectively binds to human IgE. Omalizumab injection is in a class of medications called monoclonal antibodies. It works by blocking the action of a certain natural substance in the body that causes the symptoms of allergic asthma and hives. Omalizumab injection comes as a powder to be mixed with water and injected subcutaneously. Due to the risk of adverse effects, such as anaphylaxis, it must be given in the physician's office or facility, and patients should be closely observed after administration. Therefore, Omalizumab is not considered a self-administered drug. It may take some time to feel the full benefit of Omalizumab injection.

Omalizumab for subcutaneous use is an injectable prescription medicine used to treat adults and children 12 years of age and older with:

- Moderate to severe persistent asthma whose asthma symptoms are not controlled by asthma medicines called inhaled corticosteroids. A skin or blood test is performed to see if you have allergies to year-round allergies.
- Chronic idiopathic urticaria (CIU; chronic hives without a known cause) who continue to have hives that are not controlled by H1 antihistamine treatment.

Omalizumab (Xolair) is not used to treat other allergic conditions, other forms of urticaria, acute bronchospasm, or status asthmaticus.

Allergic Asthma:
Omalizumab injection is used to decrease the number of asthma attacks (sudden episodes of wheezing, shortness of breath, and trouble breathing) in people with allergic asthma (asthma caused by inhaling substances such as dander, pollen, and dust mites) whose symptoms are not controlled with inhaled steroids. Current asthma guidelines state that Omalizumab may be considered as adjunctive therapy in patients who have allergies and severe persistent asthma that is inadequately controlled with the combination of high-dose

inhaled corticosteroids and long acting beta2-agonists, the preferred treatment for moderate to persistent and severe persistent asthma.

Omalizumab has shown to be effective against allergy-induced asthma only. Allergy tests are required to identify patients who may be candidates for Omalizumab therapy. Allergic asthma is identified as testing positive to at least one perennial aeroallergen according to either a skin test (e.g. prink/puncture test, intracutaneous test) or a blood test (e.g., RAST) and having an IgE level between 30 and 700 IU/ml. When Omalizumab is used to treat allergic asthma, it is usually injected once every 2 or 4 weeks. One or more injections may be given at each visit, depending on the patient's weight and medical condition.

Omalizumab injection is not used to treat a sudden attack of asthma symptoms. Generally, a short-acting inhaler for use during attacks would be prescribed.

Chronic Idiopathic Urticaria:
Omalizumab is also used to treat chronic hives without a known cause that cannot successfully be treated with antihistamine medications such as diphenhydramine (Benadryl), cetirizine (Zyrtec), hydroxyzine (Vistaril), and loratadine (Claritin). Omalizumab has been shown to diminish clinical symptoms and signs of chronic idiopathic urticaria in patients who had remained symptomatic despite the use of approved doses of H1-antihistamines. Omalizumab is not used to treat other forms of hives or allergic conditions. When Omalizumab is used to treat chronic hives, it is usually given once every 4 weeks. The treating physician will determine the length of treatment based on the medical condition and response to the medication.

CODING

BlueCHiP for Medicare and Commercial Products
The following HCPCS code for biological supply is medically necessary the when medical criteria are met:
J2357

RELATED POLICIES

Mepolizumab (Nucala)
Reslizumab (Cinqair)

PUBLISHED

Provider Update, November 2016
Provider Update, December 2015
Provider Update, September 2013
Provider Update, May 2012
Provider Update, September 2011
Provider Update, December 2010
Provider Update, September 2009

REFERENCES

1. National Institutes of Health/U.S. National Library of Medicine. Omalizumab Injection. https://www.nlm.nih.gov/medlineplus/druginfo/meds/a603031.html
2. Xolair Package Insert. Genentech, Inc.; San Francisco, CA. Revised September 2014.
3. National Institutes of Health. *National Asthma Education and Prevention Program Expert Panel Report 3: Guidelines for the Diagnosis and Management of Asthma - Full Report 2007*. Bethesda, MD: National Heart Lung and Blood Institute; August 2007. http://www.nhlbi.nih.gov/guidelines/asthma/asthgdln.pdf.

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