

Corporate Medical Policy

Xolair® (Omalizumab)

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Origination:	9/2003
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Next CAP Review:	11/2020
Last Review:	11/2019

Description of Procedure or Service

Asthma is a chronic lung disease that affects an estimated 20 million Americans. Asthma is characterized by inflammation of the airways. The inflammation makes the airways smaller which makes it more difficult for air to move in and out of the lung, creating the symptoms of asthma (cough, chest tightness, shortness of breath and wheezing). The severity of asthma varies from mild intermittent to severe persistent. Asthma is related to a number of factors, including family history, smoking, stress and allergies. In the initial assessment and diagnosis of asthma, the following must be determined:

- History or presence of episodic symptoms of airflow obstruction (i.e., wheezing, shortness of breath, chest tightness, or cough);
- Airflow obstruction is at least partially reversible (demonstration of reversibility, defined as > 12% improvement and 200 mL increase in FEV1, or a 20% increase in PEF following the inhalation of a bronchodilator);
- Alternative diagnoses are excluded (e.g., vocal cord dysfunction, vascular rings, foreign bodies, or other pulmonary diseases).

For some patients, allergies play a significant role in their asthma. Allergic asthma is the most common form of asthma, affecting over 50% of the 20 million asthma sufferers. Many of the symptoms of allergic and non-allergic asthma are the same (coughing, wheezing, shortness of breath or rapid breathing, and chest tightness). However, allergic asthma can be triggered by several factors, including inhaled allergens such as dust mite allergen, pet dander, pollen, mold, etc. resulting in asthma symptoms. Other factors that may trigger asthma symptoms are irritants such as tobacco smoke and strong odors, weather changes, viral or sinus infections, exercise, reflux disease, medication or foods.

Allergens are identified as a key cause of allergic asthma; however, the real culprit in causing allergic asthma is the IgE (immunoglobulin E) antibody. The IgE antibody is produced by the body in response to allergen exposure. The combination of the IgE antibody with allergens results in the release of potent chemicals called mediators. The mediators cause the inflammation and swelling of the airways, resulting in the symptoms of asthma. This makes the antibody IgE an underlying cause of allergic asthma symptoms. Anti-IgE antibody treatments are a new type of preventative drug therapy used to reduce asthma symptoms. Anti-IgE antibody treatments disrupt the sequence of events that cause the allergic reaction.

Xolair® (Omalizumab) is the first asthma treatment that works by blocking IgE (anti-IgE antibody treatment). Xolair® is a recombinant DNA-derived humanized monoclonal antibody that selectively binds to human IgE and inhibits the immune system's response to allergen exposure.

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Thus, inflammation is blocked at the initiation stage. It is indicated for adults and adolescents with moderate to severe persistent asthma. It has been shown to be beneficial as adjunctive therapy in patients whose symptoms are inadequately controlled despite appropriate therapy for moderate to severe asthma. Xolair® is to be prescribed as prophylactic therapy for allergy-induced asthma. It is to be used in conjunction with other agents used in the management of moderate to severe persistent asthma, but never as monotherapy.

Xolair® is effective in the treatment of allergy-induced asthma only. Allergy tests are required to identify patients who may be candidates for Xolair® therapy. The FDA advisory committee defines having allergic asthma as testing positive to at least one perennial aeroallergen according to either a skin test (e.g., prick/puncture test, intracutaneous test) or a blood test (e.g., RAST) and having an IgE level between 30 and 700 IU/mL. The use of Xolair® in adult patients with IgE levels less than 30 and greater than 700 IU/mL and in pediatric patients (6 to less than 12 years of age) with IgE levels less than 30 and greater than 1300 IU/mL has not been adequately studied and should not be used.

Xolair® has not been shown to alleviate asthma exacerbations acutely and should not be used for treatment of acute bronchospasm or status asthmaticus. Patients should have a short-acting beta2-agonist available for rescue therapy.

The FDA has approved Xolair (March, 2014) for the treatment of chronic idiopathic urticaria (CIU), a form of chronic hives. The new use is for patients 12 years of age and older who remain symptomatic despite treatment with H1-antihistamine therapy. Xolair is not used to treat other forms of urticaria (hives) and is not for use in children less than 12 years of age. According to the manufacturer's recent update, CIU is characterized by hives that spontaneously occur without an identifiable cause and reoccur for six weeks or more. CIU symptoms include red, swollen, itchy and sometimes painful hives on the skin that can be burdensome and last for many months and even years. Nearly 50% of these patients remain symptomatic despite treatment with approved doses of H1-antihistamines, the only previously FDA-approved therapy for CIU. In the US, it is estimated that approximately 1.5 million people suffer from CIU. Women are twice as likely as men to experience CIU and most people develop symptoms between the ages of 20 and 40 years.

Related Policies:

Place of Service for Medical Infusion

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Xolair® when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Xolair® (Omalizumab) is covered

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INITIAL COVERAGE REVIEW:

Asthma Treatment criteria

Xolair® is indicated for individuals 6 years of age or older with **ALL** of the following:

1. Moderate to severe **persistent** asthma; **and**
2. Positive skin test or in vitro reactivity to a perennial aeroallergen; **and**
3. Symptoms are inadequately controlled despite use of medium dose of inhaled corticosteroids with combination therapy (long acting inhaled B2 agonist or leukotriene modifier) for at least three months, **OR** there is a requirement for chronic administration of systemic corticosteroids or high dose inhaled corticosteroids to maintain adequate control; **and**
4. For patients 6 to less than 12 years of age, IgE level >30 but < 1300 IU/mL; **or**
5. For patients 12 years of age or older, IgE level >30 but < 700 IU/mL.

Chronic Idiopathic Urticaria treatment criteria

Xolair is indicated for treatment of chronic idiopathic urticaria (CIU) in adults and adolescents (12 years of age and above) who remain symptomatic despite H1 antihistamine treatment.

CONTINUATION OF COVERAGE AFTER 12 MONTHS:

For Asthma, documentation must be provided of symptom improvement, and/or decreased exacerbations, and/or decreased use of chronic controller or rescue medications based on physician re-evaluation every 12 months, as a result of Xolair administration.

For Chronic urticaria, documentation must be provided of symptom improvement, and/or decreased exacerbations, and/or decreased use of chronic controller medications based on physician reevaluation every 12 months, as a result of Xolair administration.

Patients undergoing treatment with Xolair® prior to the effective date of coverage under a BCBSNC health plan, will meet BCBSNC criteria if the treating physician certifies that initial coverage criteria were met prior to initiation of therapy.

When Xolair® (Omalizumab) is not covered

Xolair® (Omalizumab) is considered not medically necessary when the conditions listed above have not been met.

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

Xolair® is considered not medically necessary for allergic rhinitis.

Policy Guidelines

Because the use of Xolair® (Omalizumab) requires allergy testing and assessment of IgE blood levels prior to its use, initial administration or prescription should be given by a consulting specialist (pulmonologist or allergist) with significant training and experience in the diagnosis and treatment of asthma and allergies.

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According to the NHLBI, patients with **moderate persistent asthma** exhibit some of the following characteristics:

- Daily symptoms
- Daily use of inhaled short-acting beta2-agonists
- Exacerbations affect activity
- Exacerbations > 2 times a week; may last days
- Nighttime symptoms >1 time a week
- FEV1 or PEF more than 60% but less than 80% predicted
- PEF variability >30%

Patients with **severe persistent asthma** exhibit some of the following characteristics:

- Continual symptoms
- Limited physical activity
- Frequent exacerbations
- Frequent nighttime symptoms
- FEV1 or PEF ≤ 60% predicted
- PEF variability >30%

Clinical documentation of inadequately controlled symptoms (#3 under "When Covered") includes frequent severe exacerbations that often require emergency room visits, unscheduled office visits and/or hospitalizations, excessive use of rescue medications and/or oral steroids, impairment in activities of daily living, such as work, school, exercise and/or sleep.

Due to an expected delayed onset of action, the efficacy of Xolair® is determined after treatment for a minimum of 12 weeks.

In February 2007, the FDA requested that the product label for omalizumab include a boxed warning emphasizing that Xolair® may cause anaphylaxis. Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, usually occurred within two hours of receiving the subcutaneous injection. However, there have been reports of delayed anaphylaxis with onset two to 24 hours after treatment. Anaphylaxis may occur after any dose of Xolair® (including the first dose), even if the patient had no allergic reaction to the first dose. Health care professionals should observe patients for at least two hours after Xolair® is given and should be prepared to manage life-threatening anaphylaxis.

The FDA issued a black box warning for Xolair® for anaphylaxis. Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, has been reported to occur after Xolair® administration. Anaphylaxis has occurred after the first dose, but has also occurred beyond one year after treatment initiation. Patients should be closely observed for an appropriate period of time after Xolair® administration and healthcare professionals should be prepared to manage anaphylaxis that can be life-threatening. Healthcare professionals should educate patients receiving Xolair® about the risk of anaphylaxis and educate those patients on how to recognize and treat Xolair® induced anaphylaxis. Patients using Xolair® should be educated about, and prescribed, an epinephrine autoinjector device (Epi-pen, or similar device).

In September 2014, the FDA released a review of a 5-year safety study. The review of the safety studies suggests a slightly increased risk of problems involving the heart and blood vessels supplying the brain among patients being treated with Xolair (omalizumab) than those who were not being treated with Xolair. As a result, information has been added to the drug label about these potential risks. Patients taking Xolair should continue to take the medication as prescribed and discuss any questions or concerns with their health care professionals.

Administration of Xolair (omalizumab) - Site of Care Eligibility

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1. Administration of Xolair (omalizumab) may be given in an inpatient setting if the inpatient setting is medically necessary. An inpatient admission for the sole purpose of Xolair (omalizumab) infusion is not medically necessary.
2. Xolair (omalizumab) administration in a hospital outpatient setting is considered medically necessary if the following criteria are met:
 - a. History of mild adverse events that have not been successfully managed through mild pre-medication (diphenhydramine, acetaminophen, steroids, fluids, etc.),
OR
 - b. Inability to physically and cognitively adhere to the treatment schedule and regimen complexity, OR
 - c. First infusion, OR
 - d. Less than 3 months since first Xolair (omalizumab) infusion, OR
 - e. First infusion after six months of no Xolair (omalizumab) infusions, OR
 - f. Requirement of a change in Xolair (omalizumab) product.
3. Members who do not meet the criteria above are appropriate for Xolair (omalizumab) administration in a home-based or physician office setting with or without supervision by a certified healthcare professional. Inpatient and hospital outpatient infusion, in the absence of the criteria in #1 or #2 above is considered not medically necessary.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: J2357, 96372

(96401 is specific to chemotherapy administration and is not applicable to treatment of urticaria or asthma.)

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

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Specialty Matched Consultant Advisory Panel review 11/2019

Policy Implementation/Update Information

- 9/03 Original policy issued.
- 10/03 Source added. Spell check.
- 11/03 Medical Policy Advisory Group review. No change to the policy.
- 3/04 Code S0107 added to the policy.
- 10/14/04 Specialty Matched Consultant Advisory Panel review 7/23/2004. Inadequately controlled asthma defined in "Policy Guidelines". Sources added.
- 1/6/05 First quarter 2005 HCPCS code J2357 added to the Billing/Coding section of policy.
- 8/4/05 Specialty Matched Consultant Advisory Panel review 6/17/05. "Description" section revised. Under "Benefits Application" section, added information re: Member Health Partnership Program for Asthma. "When Covered" section separated into initial coverage review, continuation of coverage review beyond 6 months and after 12 months. Also #5 re: evidence of reversible disease deleted from this section and incorporated into the "Description" section regarding the initial assessment and diagnosis of asthma. Policy Guidelines expanded to list characteristics exhibited with moderate persistent asthma and severe persistent asthma. Notice given 8/4/05. Effective date 10/6/05.
- 10/8/05 HCPCS code S0107 is no longer valid as of 01/01/05. Code S0107 removed from Billing/Coding section. Due to a scheduling change for the 10/6/05 website update, the effective date for the 8/4/05 entry above is 10/8/05.
- 10/2/06 Specialty Matched Consultant Advisory Panel review 7/2006. Reference sources added. No changes to criteria. (pmo)
- 8/25/08 The following was added to the Policy Guidelines section: "In February 2007 the FDA requested that the product label for omalizumab include a boxed warning emphasizing that Xolair® may cause anaphylaxis. Anaphylaxis, presenting as bronchospasm, hypotension, syncope, urticaria, and/or angioedema of the throat or tongue, usually occurred within two hours of receiving the subcutaneous injection. However, there have been reports of delayed anaphylaxis with onset two to 24 hours after treatment. Anaphylaxis may occur after any dose of Xolair® (including the first dose), even if the patient had no allergic reaction to the first dose. Health care professionals should

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observe patients for at least two hours after Xolair® is given and should be prepared to manage life-threatening anaphylaxis. Health care professionals should educate patients using Xolair® about the risk of anaphylaxis and educate those patients on how to recognize and treat Xolair® induced anaphylaxis. Patients using Xolair® should be educated about, and prescribed, an epinephrine autoinjector device (Epi-pen, twin-ject).¹ References updated. Specialty Matched Consultant Advisory Panel review 7/14/08. No change to policy statement. (adn)

- 6/22/10 Policy Number(s) removed (amw)
- 12/21/10 Specialty Matched Consultant Advisory Panel review 11/2010. References updated. (mco)
- 12/20/11 Specialty Matched Consultant Advisory Panel review 11/2011. Revised following statement from “Description” section: “It has been shown to be beneficial as adjunctive therapy in patients whose symptoms are inadequately controlled despite the regular use of maximum dose inhaled corticosteroids.” to “It has been shown to be beneficial as adjunctive therapy in patients whose symptoms are inadequately controlled despite appropriate therapy for moderate to severe asthma.” Removed the following statement from the “When Covered” section: “Depending on the length of time the patient has been receiving Xolair® therapy, documentation may be necessary to verify that criteria for continuing therapy are met (under B. and/or C. above.)” Revised the following statement in the “When not Covered” section: “Xolair® (Omalizumab) is not covered when the conditions listed above have not been met.” to “Xolair® (Omalizumab) is considered **not medically necessary** when the conditions listed above have not been met.” Removed “twin-ject” from Policy Guidelines and replaced with “or similar device.” References updated. (mco)
- 5/15/12 Deleted sections B1 and 2 from “When Covered” section addressing continuation of coverage after 6 months. Continuation of Xolair will be reviewed after 12 month interval. Medical Director review 4/2012. (mco)
- 1/15/13 Specialty Matched Consultant Advisory Panel review 11/2012. References updated. No changes to Policy Statements. (mco)
- 12/10/13 Specialty Matched Consultant Advisory Panel review 11/2013. References updated. Description section updated. Medical Director review 11/2013. (mco)
- 4/15/14 Medical Director review. Description section updated. References updated. The following statement added to the “When Covered” section: “Xolair is indicated for treatment of chronic idiopathic urticaria (CIU) in adults and adolescents (12 years of age and above) who remain symptomatic despite H1 antihistamine treatment.”
- 1/13/15 Reference added. Policy Guidelines section updated to include updated safety study information regarding slightly higher risk of heart and brain adverse events in patients being treated with Xolair for asthma. Specialty Matched Consultant Advisory Panel review 11/2014. Medical Director review 11/2014. No change to Policy statement. (td)
- 12/30/15 When Covered section for continuation of coverage after 12 months updated to state, “For Asthma, documentation must be provided of symptom improvement, and/or decreased exacerbations, and/or decreased use of chronic controller or rescue medications based on physician re-evaluation every 12 months, as a result of Xolair administration. For Chronic urticaria, documentation must be provided of symptom improvement, and/or decreased exacerbations, and/or decreased use of chronic controller medications based on physician reevaluation every 12 months, as a result of Xolair administration”. References updated. Specialty Matched Consultant Advisory

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Panel review 11/18/2015. Medical Director review 11/2015. Policy noticed 12/30/15 for effective date 2/29/16. (td)

- 9/30/16 When Covered section updated to include expanded coverage for asthma treatment to individuals 6 years of age and older. References updated. (jd)
- 12/30/16 Specialty Matched Consultant Advisory Panel review 11/2016. Medical Director review 11/2016. (jd)
- 12/15/17 Specialty Matched Consultant Advisory Panel review 11/2017. Medical Director review 11/2017. (jd)
- 12/29/17 Policy Guidelines updated to include guidelines for “Site of Care Eligibility” related to infusion of Xolair (omalizumab). Policy notification given 12/29/17 for effective date 4/1/18. (jd)
- 5/25/18 Updated “When Covered” section to reflect IgE range for patients 6 to less than 12 years of age. Minor update made to Description section for clarity of pediatric IgE level range. References added. Medical Director review 5/2018. (krc)
- 9/28/18 Updated Billing/Coding section to include code 96372 and the following clarification: “96401 is specific to chemotherapy administration and is not applicable to treatment of urticaria or asthma.” (krc)
- 12/14/18 Specialty Matched Consultant Advisory Panel review 11/28/2018. No change to policy intent. (krc)
- 12/10/19 Updated Policy Guidelines section with further clarity on anaphylaxis black box warning and monitoring requirements. Specialty Matched Consultant Advisory Panel review 11/20/2019. No change to policy intent. (krc)

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