Respiratory Monoclonal Antibody Drug Therapy

**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 Respiratory Monoclonal Antibody Drug Therapy policy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines, and clinical studies. Xolair® (omalizumab) is a recombinant DNA-derived humanized IgG1κ monoclonal antibody that selectively binds to human immunoglobulin E (IgE). IgE is the antibody responsible for activation of allergic reactions and is important to the pathogenesis of allergic diseases and the development and persistence of inflammation. Nucala® (mepolizumab) and Cinqair® (reslizumab) are humanized interleukin 5 (IL-5) antagonist monoclonal antibodies. They inhibit the bioactivity of IL-5 by preventing its binding to the alpha chain of the IL-5 receptor complex expressed on the eosinophil cell surface, thus reducing the production and survival of eosinophils. While the exact mechanism is not clearly established, they are believed to reduce eosinophilic inflammation of the airways. Both omalizumab and mepolizumab are administered by subcutaneous injection and mepolizumab is administered by intravenous infusion.

Xolair has been approved by the Food and Drug Administration (FDA) for the treatment of moderate to severe persistent asthma in patients 12 years of age or older with a positive skin test or in vitro reactivity to a perennial aeroallergen and symptoms that are inadequately controlled with inhaled corticosteroids (ICS). Xolair is also approval for the treatment of chronic urticaria in patients 12 years of age and older who remain symptomatic despite treatment with H1 antihistamine therapy. Nucala and Cinqair are FDA approved as add-on maintenance treatment of patients with severe asthma with an eosinophilic phenotype. Nucala is approved for use in patients 12 years of age or older and Cinqair is approved for use in patients 18 years of age or older.

**Policy**

I. Xolair (omalizumab) may be considered medically necessary for the treatment of allergic asthma when all of the following criteria are met:
   - The patient is 12 years of age or older
   - Patient has a diagnosis of moderate to severe persistent asthma
   - Patient has a positive skin or in vitro reactivity to at least one perennial aeroallergen
   - Patient has a pre-treatment IgE level greater than or equal to 30 IU/mL
   - Patient has a history of severe asthma attacks/exacerbations despite current treatment with both of the following medications at optimized doses:
     - Inhaled corticosteroid
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- Additional controller (long acting beta₂-agonist, leukotriene modifier, or sustained-release theophylline)
- Xolair is used in combination with other medications for long-term control of asthma
- Patient has a reliever agent (i.e., short acting beta₂-agonist, low-dose combination inhaled corticosteroid/formoterol) available for rescue therapy
- Xolair is administered in a controlled healthcare setting with access to emergency medication

**Initial approval** will be for a period of **12 months**. Continued treatment with Xolair for **subsequent 12 month periods** is considered **medically necessary** when the following criteria are met:

- Xolair is used in combination with other medications for long-term control of asthma
- Patient has a reliever agent (i.e., short acting beta₂-agonist, low-dose combination inhaled corticosteroid/formoterol) available for rescue therapy
- The patient has had a documented therapeutic response to omalizumab therapy, demonstrated by at least one of the following:
  - Reduction in the frequency and/or severity of symptoms and exacerbations
  - Improvement in FEV₁ since initiation of therapy
- Xolair continues to be administered in a controlled healthcare setting with access to emergency medication

**II.** Xolair (omalizumab) may be considered **medically necessary** for the treatment of moderate to severe chronic idiopathic urticaria (CIU) when **all** of the following criteria are met:

- The patient is 12 years of age or older
- Must be prescribed by or in consultation with an allergist or dermatologist
- Patient has been evaluated for other causes of urticaria, including bradykinin-related angioedema and IL-1-associated urticarial syndromes (auto-inflammatory disorders, urticarial vasculitis)
- Patient has experienced a spontaneous onset of wheals, angioedema, or both, for at least 6 weeks
- Patient remains symptomatic despite second generation H₁ antihistamine therapy with maximized dosing used continuously for at least two weeks
- Patient remains symptomatic despite a two week continuous trial of at least one of the following:
  - Higher dose (up to four times the recommended dose) of second generation H₁ antihistamine therapy
  - Addition of another second generation antihistamine to existing therapy
  - Addition of a leukotriene receptor antagonist (LTRA) to existing therapy
  - Addition of a H₂-antagonist to existing therapy
  - Addition of a first generation antihistamine taken at bedtime
- Patient remains symptomatic despite the addition of a potent antihistamine (e.g., hydroxyzine or doxepin) used continuously for at least two weeks
- Xolair is administered in a controlled healthcare setting with access to emergency medication

**Initial approval** will be for a period of **6 months**. Continued treatment with Xolair for **subsequent 12 month periods** is considered **medically necessary** for patients who have had a documented therapeutic response (e.g., improved symptoms) to Xolair therapy and it continues to be administered in a controlled healthcare setting with access to emergency medication.

**III.** Nucala (mepolizumab) is considered **medically necessary** for the treatment of eosinophilic asthma when all of the following criteria are met:

- The patient is 12 years of age or older
- Patient has a diagnosis of severe asthma with an eosinophilic phenotype
• Patient has a baseline blood eosinophil count of at least 150 cells per microliter
• Patient has a history of severe asthma attacks/exacerbations despite current treatment with both of the following medications at optimized doses:
  ▪ Inhaled corticosteroid
  ▪ Additional controller (long acting beta2-agonist, leukotriene modifier, or sustained-release theophylline)
• Nucala is used in combination with other medications for long-term control of asthma
• Patient has a reliever agent (i.e., short acting beta2-agonist, low-dose combination inhaled corticosteroid/formoterol) available for rescue therapy

Initial approval will be for a period of 12 months. Continued treatment with Nucala for subsequent 12 month periods is considered medically necessary when the following criteria are met:
• Nucala is used in combination with other medications for long-term control of asthma
• The patient has a rapid acting beta2-agonist available for rescue therapy
• The patient has had a documented therapeutic response to Nucala therapy, demonstrated by at least one of the following:
  ▪ Reduction in the frequency and/or severity of symptoms and exacerbations
  ▪ Improvement in FEV1 since initiation of therapy

IV. Cinqair® (reslizumab) is considered medically necessary for the treatment of eosinophilic asthma when all of the following criteria are met:
• The patient is 18 year of age or older
• Patient has a diagnosis of severe asthma with an eosinophilic phenotype
• Patient has a baseline blood eosinophil count of at least 400 cells per microliter
• Patient has a history of severe asthma attacks/exacerbations despite current treatment with both of the following medications at optimized doses:
  ▪ Inhaled corticosteroid
  ▪ Additional controller (long acting beta2-agonist, leukotriene modifier, or sustained-release theophylline)
• Cinqair is used in combination with other medications for long-term control of asthma
• Patient has a reliever agent (i.e., short acting beta2-agonist, low-dose combination inhaled corticosteroid/formoterol) available for rescue therapy
• Cinqair is administered in a healthcare setting by a healthcare professional prepared to manage anaphylaxis

Initial approval will be for a period of 12 months. Continued treatment with Cinqair for subsequent 12 month periods is considered medically necessary when the following criteria are met:
• The patient is 18 years of age or older
• Cinqair is used in combination with other medications for long-term control of asthma
• Patient has a reliever agent (i.e., short acting beta2-agonist, low-dose combination inhaled corticosteroid/formoterol) available for rescue therapy
• The patient has had a documented therapeutic response to Cinqair therapy, demonstrated by at least one of the following:
  ▪ Reduction in the frequency and/or severity of symptoms and exacerbations
  ▪ Improvement in FEV1 since initiation of therapy
• Cinqair continues to be administered in a healthcare setting by a healthcare professional prepared to manage anaphylaxis

Prior approval is required. Submit a prior approval/treatment request now
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
- C9473 Injection, mepolizumab, 1mg
- J3490 Unclassified drugs [when specified as mepolizumab or reslizumab]
- J3590 Unclassified biologics [when specified as mepolizumab or reslizumab]

REFERENCES

POLICY HISTORY

Policy #: 05.01.07
Original Effective Date: December 2003
Reviewed: February 2016
Revised: May 2016
Current Effective Date: July 18, 2016