BlueCross BlueShield
Federal Employee Program
Federal Employee Program®
1310 G Street, N.W.
Washington, D.C. 20005
202.942.1000
Fax 202.942.1125

5.45.008

Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Respiratory Agents	**Original Policy Date:**	April 22, 2016
Subject:	Cinqair	**Page:**	1 of 5

Last Review Date: December 8, 2023

Cinqair

Description

Cinqair (reslizumab)

Background
Cinqair (reslizumab) is an interleukin-5 antagonist (IgG4 kappa). IL-5 is the major cytokine responsible for the growth and differentiation, recruitment, activation, and survival of eosinophils (a cell type associated with inflammation and an important component in the pathogenesis of asthma). Cinqair, by inhibiting IL-5 signaling, reduces the production and survival of eosinophils; however, the mechanism of Cinqair action in asthma has not been definitively established (1).

Regulatory Status
FDA-approved indication: Cinqair is an interleukin-5 antagonist monoclonal antibody (IgG4 kappa) indicated for add-on maintenance treatment of patients with severe asthma aged 18 years and older, and with an eosinophilic phenotype (2).

Limitations of Use: (2)

1. Cinqair is not indicated for treatment of other eosinophilic conditions
2. Cinqair is not indicated for relief of acute bronchospasm or status asthmaticus

Cinqair has a boxed warning for anaphylaxis. Patients should be observed for an appropriate period of time after Cinqair administration by a healthcare professional prepared to manage anaphylaxis. Discontinue Cinqair immediately if the patient experiences signs or symptoms of anaphylaxis (2).

FEP adherence is defined as ≥50% utilization within the last 180 days.

The safety and effectiveness of Cinqair in pediatric patients less than 18 years of age have not been established (2).

Related policies
Dupixent, IL-5 Antagonists, Tezspire, Xolair

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Cinqair may be considered **medically necessary** if the conditions indicated below are met.

Cinqair may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following **AND** submission of medical records (e.g., chart notes, laboratory values) documenting the following:

Severe Asthma with an eosinophilic phenotype

AND ALL of the following:

1. Eosinophil count greater than or equal to 150 cells/mcL in the past 90 days **OR** greater than or equal to 300 cells/mcL in the past 12 months
2. Inadequate control of asthma symptoms after a minimum of 3 months of compliant use with greater than or equal to 50% adherence with **ONE** of the following within the past 6 months:
    a. Inhaled corticosteroids & long acting beta$_2$ agonist
    b. Inhaled corticosteroids & long acting muscarinic antagonist
3. Only administered by a healthcare professional with appropriate medical support to manage anaphylaxis and monitored for an appropriate period of time after infusion

AND NONE of the following:

1. For the treatment of other eosinophilic conditions
2. Used for the relief of acute bronchospasm or status asthmaticus
3. Dual therapy with another monoclonal antibody for the treatment of asthma

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following **AND** submission of medical records (e.g., chart notes, laboratory values) documenting the following:

Asthma with an eosinophilic phenotype

AND ALL of the following:

1. Decreased exacerbations **OR** improvement in symptoms
2. Decreased utilization of rescue medications
3. Patient has been compliant on Cinqair therapy

AND NONE of the following:

1. For the treatment of other eosinophilic conditions
2. Used for the relief of acute bronchospasm or status asthmaticus
3. Dual therapy with another monoclonal antibody for the treatment of asthma

All approved requests are subject to review by a clinical specialist for final validation and coverage determination once all required documentation has been received. Current utilization, including samples, does not guarantee approval of coverage.

Policy Guidelines

Pre - PA Allowance
None

Prior - Approval Limits

Duration 6 months

Prior – Approval *Renewal* Limits

Duration 12 months

Rationale

Summary
Cinqair (reslizumab) is an interleukin-5 antagonist monoclonal antibody (IgG4 kappa) indicated for add-on maintenance treatment of adult patients with severe asthma with an eosinophilic phenotype. Cinqair has a boxed warning for anaphylaxis. Patients should be observed for an appropriate period of time after Cinqair administration by a healthcare professional prepared to manage anaphylaxis. The safety and effectiveness of Cinqair in pediatric patients less than 18 years of age have not been established (2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Cinqair while maintaining optimal therapeutic outcomes.

References
1. Cinqair. Drug Facts and Comparisons. eFacts [online]. 2021. Available from Wolters Kluwer Health, Inc.
2. Cinqair [package insert]. Frazer, PA: Teva Respiratory, LLC; February 2020.
3. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2019. Available from www.ginasthma.org.

Policy History

Date	Action
April 2016	Addition to PA
June 2016	Addition of the following requirement: Only administered by a healthcare professional with appropriate medical support to manage anaphylaxis and monitored for an appropriate period of time after infusion

September 2016	Annual review
March 2017	Annual review and reference update
March 2018	Annual editorial review
June 2018	Annual editorial review Addition of requirement for asthma: Inadequate control of asthmatic symptoms after a minimum of 3 months of ONE of the following: Inhaled corticosteroids & long acting beta$_2$ agonist or Inhaled corticosteroids & long acting muscarinic antagonist
March 2019	Annual review
August 2019	Addition of the 50% adherence requirement. Removed requirement to use in combination with IBS + LABA and addition of renewal requirement to be compliant on therapy. Addition to managed PA program
September 2019	Annual review and reference update
March 2020	Annual review
March 2021	Annual review and reference update
May 2021	Revision of eosinophil count requirement from 400 cells/mcL in the last 30 days to 150 cells/mcL in the last 90 days or 300 cells/mcL in the last 12 months to align with GINA guidelines. Removal of “Severe” from renewal diagnosis.
June 2021	Annual review
March 2022	Annual review
June 2022	Annual review
September 2022	Annual review
March 2023	Annual review
December 2023	Annual review. Per SME, changed renewal requirement to decreased exacerbations or improvement in symptoms

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.