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Section:	Prescription Drugs	**Effective Date:**	April 1, 2021
Subsection:	Respiratory Agents	**Original Policy Date:**	April 22, 2016
Subject:	Cinqair	**Page:**	1 of 5

Last Review Date: March 12, 2021

Cinqair

Description

Cinqair (reslizumab)

Background
Cinqair is used with other asthma medicines for the maintenance treatment of severe asthma. Cinqair is approved for patients who have a history of severe asthma attacks (exacerbations) despite receiving their current asthma medicines. Cinqair reduces severe asthma attacks by reducing the levels of blood eosinophils- a type of white blood cell that contributes to the development of asthma (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 (1).

Limitations of use: (1)

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 (1).

Subjects enrolled in the Cinqair trial were required to have a blood eosinophil count greater than or equal to 400 cells/ mcL (within 3 to 4 weeks of dosing) and at least 1 asthma exacerbation requiring systemic corticosteroid use over the past 12 months (1).

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

Clinical studies with Cinqair in pediatric patients less than 18 years of age have not been conducted (1).

Related policies
Dupixent, IL-5 Antagonists, 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** in patients 18 years of age and older as add-on maintenance treatment of patients with severe asthma with an eosinophilic phenotype and if the conditions indicated below are met.

Cinqair is considered **investigational** in patients less than 18 years of age and 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 400 cells/mcL within past 30 days
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:

Severe asthma with an eosinophilic phenotype

AND ALL of the following:
1. Decreased exacerbations and 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 has been shown to decrease the incidence of asthma exacerbations in adult and adolescent patients 18 years of age and older severe asthma whose symptoms are inadequately controlled with inhaled corticosteroids. Cinqair is approved for patients who have a history of severe asthma attacks (exacerbations) despite receiving their current asthma medicines (1).

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

References
1. Cinqair [package insert]. Frazer, PA: Teva Respiratory, LLC; February 2020.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.