Effective Date: 9/2017
Reviewed: 9/2017, 12/2018, 12/2019, 08/2020, 4/2021, 4/2022, 01/2023 Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

CINQAIR (reslizumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Cinqair is indicated for the add-on maintenance treatment of patients with severe asthma aged 18 years and older with an eosinophilic phenotype.

Limitations of Use:

- Not for treatment of other eosinophilic conditions
- Not for the relief of acute bronchospasm or status asthmaticus

All other indications are considered experimental/investigational and are not a covered benefit.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

A. Initial requests:
   1. Documentation of baseline blood eosinophil count and components of severity that classify asthma as severe
   2. Baseline documentation of one of the following:
      a. Use of systemic corticosteroids
      b. Use of inhaled corticosteroids
      c. Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to asthma condition
      d. Forced expiratory volume in 1 second (FEV1)

B. Continuation of therapy requests: documentation of improved asthma control

III. CRITERIA FOR INITIAL APPROVAL

Authorization of 6 months may be granted for treatment of asthma when all of the following criteria are met:

A. Member is 18 years of age or older.
B. Cinqair is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist.
C. Member has documentation of severe asthma (see Appendix).

D. Member has asthma with an eosinophilic phenotype with documentation of blood eosinophil count of at least 400 cells per microliter within 4 weeks of starting therapy.
E. Member is adherent to current treatment with both of the following medications at optimized doses for at least 3 months:
    1. Inhaled corticosteroid
    2. Additional controller medication (long-acting beta$_2$-agonist, long-acting muscarinic antagonists, leukotriene modifier), unless contraindicated or not tolerated
F. Member has inadequate asthma control with two or more exacerbations in the previous year requiring additional medical treatment (e.g., oral corticosteroids, emergency department or urgent care visits, or hospitalizations)
G. Member will use Cinqair as add-on maintenance treatment.
H. Member will not use Cinqair concomitantly with other biologics (e.g., Dupixent, Fasenra, Nucala, Xolair).
I. Baseline measurement of at least one of the following for assessment of clinical status:
    1. Use of systemic corticosteroids
    2. Use of inhaled corticosteroids
    3. Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to asthma condition
    4. Forced expiratory volume in 1 second (FEV1); AND
J. Cinqair will not be used for treatment of eosinophilic conditions (e.g., allergic bronchopulmonary aspergillosis/mycosis, Churg-Strauss syndrome, hypereosinophilic syndrome, etc.) or relief of acute bronchospasm, or status asthmaticus

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for treatment of asthma when all of the following criteria are met:

A. Member is 18 years of age or older.
B. Cinqair is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist.
C. Member is tolerating treatment.
D. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: malignancy, parasitic (helminth) infection, and anaphylaxis (e.g., dyspnea, decreased oxygen saturation, wheezing, vomiting, skin and mucosal involvement, urticaria), etc.;
E. Treatment has resulted in clinical benefit:
    1. Documentation that asthma control has improved/stabilized on Cinqair treatment from baseline as demonstrated by a decrease in one of the following:
        a) Use of systemic corticosteroids
        b) ER visits
        c) Hospitalizations
        d) Unscheduled visits to healthcare provider
        e) Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days; OR
    2. Improvement from baseline in forced expiratory volume in 1 second (FEV1)
F. Member will use Cinqair as add-on maintenance treatment.
G. Member will not use Cinqair concomitantly with other biologics (e.g., Dupixent, Fasenra, Nucala, Xolair).

V. QUANTITY LIMIT

Cinqair has a quantity limit of 3 vials (300mg) per 28 days, with post-limit up to 6 vials per 28 days.

VI. APPENDIX

Components of Severity for Classifying Asthma as Severe may include any of the following (not all inclusive):

1. Symptoms throughout the day
2. Nighttime awakenings, often 7x/week
3. Short-acting beta agonist (SABA) use for symptom control occurs several times per day
4. Extremely limited normal activities
5. Lung function (percent predicted FEV1) <60%
6. Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma