

STANDARD MEDICARE PART B 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 relief of acute bronchospasm or status asthmaticus

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request, for all submissions:

- A. For initial requests:
 - 1. Member's chart or medical record showing pretreatment blood eosinophil count, dependence on inhaled corticosteroids if applicable.
 - 2. Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration
- B. For continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.

III. CRITERIA FOR INITIAL APPROVAL

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

- B. Member is 18 years of age or older.
- C. Member has a baseline blood eosinophil count of at least 400 cells per microliter.
- D. Member has a history of severe asthma despite current treatment with both of the following medications at optimized doses, unless the member has a clinical reason to avoid these therapies:
 - 1. Inhaled corticosteroid
 - 2. Additional controller (long-acting beta₂-agonist, leukotriene modifier, or sustained-release theophylline)

IV. CONTINUATION OF THERAPY

Reference number(s)
2065-A

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

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

- A. Member is 18 years of age or older.
- B. The member is currently receiving therapy with Cinqair.
- C. Cinqair is being used to treat an indication enumerated in Section III.
- D. The member is receiving benefit from therapy as defined by a reduction in the frequency and/or severity of symptoms and exacerbations.

V. REFERENCES

1. Cinqair [package insert]. Frazer, PA: Teva Respiratory, LLC; February 2020.
2. Castro M, Zangrilli J, Wechsler ME, et al. Reslizumab for inadequately controlled asthma with elevated blood eosinophil counts: results from two multicentre, parallel, double-blind, randomised, placebo-controlled, phase 3 trials. *Lancet Respir Med*. 2015;3(5):355-366.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2020 update. Available at: <https://ginasthma.org/reports/>. Accessed March 5, 2021.