Reference number(s)
2065-A

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 notes or medical record showing pretreatment blood eosinophil count, dependance 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:
A. Member is 18 years of age or older.
B. Member has a baseline (pretreatment with a biologic indicated for asthma) blood eosinophil count of at least 400 cells per microliter.
C. 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 (i.e., long acting beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
D. Member will not use the requested medication concomitantly with other biologics indicated for asthma (e.g., Dupixent, Fasenra, Nucala, Tezspire, or Xolair).

IV. CONTINUATION OF THERAPY

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

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 the requested medication.
C. The requested medication 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.
E. Member will not use the requested medication concomitantly with other biologics indicated for asthma (e.g., Dupixent, Fasenra, Nucala, Tezspire, or Xolair).

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Cinqair.
2. The available compendium
    a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
    b. Micromedex DrugDex
    c. American Hospital Formulary Service- Drug Information (AHFS-DI)
    d. Lexi-Drugs
    e. Clinical Pharmacology
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2022 update.
4. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Cinqair are covered.

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Cinqair to treat severe asthma can be found in the Global Initiative for Asthma (GINA) guidelines. For adults, add-on interleukin-5 antagonists can be a drug used when either medium dose maintenance inhaled corticosteroids with formoterol or medium to high dose maintenance inhaled corticosteroids with long-acting beta2-agonists are not controlling the patient's asthma.

VII. REFERENCES

1. Cinqair [package insert]. West Chester, 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. 2022 update. Available at: https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf. Accessed March 1, 2023.
4. Cloutier MM, Dixon AE, Krishnan JA, et al. Managing asthma in adolescents and adults: 2020 asthma guideline update from the National Asthma Education and Prevention Program. *JAMA.* 2020;324(22): 2301-2317.