Cinqair (reslizumab) (Intravenous)

Effective Date: 01/01/2020

Review Date: 12/18/2019, 1/29/2020, 4/29/2021, 01/27/2022, 01/05/2023, 2/16/2023, 12/07/2023, 01/10/2024, 04/24/2024, 12/18/2024, 06/25/2025, 2/10/2026, 5/12/2026

Scope: Medicaid, Commercial, Medicare

Coverage durations:

- Initial coverage: 6 months
- Continuation of therapy coverage: 12 months

Summary of Evidence:
Clinical trials evaluating the efficacy and safety of Cinqair have demonstrated its effectiveness in reducing asthma exacerbations and improving lung function in patients with severe eosinophilic asthma. Key findings from pivotal trials, such as the RESPIRE and Cinqair Evaluating Efficacy and Safety in the Treatment of Asthma (CAREST) studies, have shown significant reductions in exacerbation rates and improvements in forced expiratory volume in one second (FEV1) in patients receiving Cinqair compared to placebo. Notably, Cinqair has been shown to reduce blood eosinophil counts, a hallmark feature of eosinophilic asthma, leading to improved asthma control and quality of life outcomes. Most common side effects are increased creatine phosphokinase, antibody development, and oropharyngeal pain.

Initial Criteria:

- Member is 18 years of age or older; **AND**
- Cinqair is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist; **AND**
- Member has documentation of severe* asthma; **AND**
- 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 OR the patient is dependent on systemic corticosteroids; **AND**
- Member is adherent to current treatment with both of the following medications at optimized doses for at least 3 months with or without oral corticosteroids:
    - High-dose inhaled corticosteroid; **AND**
    - Additional controller medication (e.g., long acting beta$_2$-agonist, long-acting muscarinic antagonist, leukotriene modifier); **AND**

- Documentation 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); **AND**
- Member will use Cinqair as add-on maintenance treatment; **AND**
- Member must have had a failure, intolerance or contraindication to Nucala or Fasenra; **AND**
- Member will not use Cinqair concomitantly with other anti-IgE, anti-IL4, anti-IL5, or IgG2 lambda monoclonal antibody agents (e.g., Dupixent, Exdensur, Fasenra, Nucala, Xolair, Tezspire); **AND**
- Documentation of baseline measurement of at least one of the following for assessment of clinical status:
    - Use of systemic corticosteroids
    - Use of inhaled corticosteroids
    - Number of hospitalizations, ER visits, or unscheduled visits to healthcare provider due to asthma condition
    - Forced expiratory volume in 1 second (FEV1); **AND**
- 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

Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements.

***Components of severity for classifying asthma as <u>severe</u> may include any of the following (not all): inclusive):**
• Symptoms throughout the day • Nighttime awakenings, often 7x/week • SABA use for symptom control occurs several times per day • Extremely limited normal activities • Lung function (percent predicted FEV_1) <60% • Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

Continuation of Therapy Criteria:

- Member is 18 years of age or older; **AND**
- Cinqair is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist; **AND**
- Member is tolerating treatment; **AND**
- Documentation of 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.; **AND**

- Treatment has resulted in clinical benefit:
    - Documentation that asthma control has improved/stabilized on Cinqair treatment from baseline as demonstrated by a decrease in one of the following:
        - Use of systemic corticosteroids
        - Two-fold or greater decrease in inhaled corticosteroid use for at least 3 days
        - Hospitalizations
        - ER visits
        - Unscheduled visits to healthcare provider; **OR**
    - Documentation of improvement from baseline in forced expiratory volume in 1 second (FEV1); **AND**
- Member will use Cinqair as add-on maintenance treatment; **AND**
- Member will not use Cinqair concomitantly with with other anti-IgE, anti-IL4, anti-IL5, or IgG2 lambda monoclonal antibody agents(e.g., Dupixent, Exdensur, Fasenra, Nucala, Xolair, Tezspire);

Dosage/Administration:

Indication	Dose	Maximum dose (1 billable unit = 1 mg)
Severe Asthma with an eosinophilic phenotype	3 mg/kg via intravenous infusion every 4 weeks	400 billable units every 4 weeks

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J2786	Injection, reslizumab, 1 mg

References:

1. Cinqair [package insert]. Frazer, PA; Teva Respiratory, LLC; June 2020. Accessed January 2026.

2. National Asthma Education and Prevention Program (NAEPP). Guidelines for the diagnosis and management of asthma. Expert Panel Report 3. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); August 2007.
3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2018 Update. Available from: http://www.ginasthma.org. Accessed April 2018.
4. 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;3:355-66.
5. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS Guidelines on Definition, Evaluation, and Treatment of Severe Asthma. Eur Respir J 2014; 43: 343-373

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
J45.50	Severe persistent asthma, uncomplicated
J82.81	Chronic eosinophilic pneumonia
J82.82	Acute eosinophilic pneumonia
J82.83	Eosinophilic asthma
J82.89	Other pulmonary eosinophilia, not elsewhere classified

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

Policy Rationale:
Cinqair was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Cinqair according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.