

Cinqair® (reslizumab) (Intravenous)

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I. Length of Authorization

Initial coverage will be provided for 6 months and may be renewed annually thereafter.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC unit]:

- Cinqair 100 mg single-use vial: 4 vials every 28 days

B. Max Units (per dose and over time) [HCPCS Unit]:

- 400 billable units every 4 weeks

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria ¹

- Will not be used in combination with other anti-IgE, anti-IL4, anti-IL5, or IgG2 lambda monoclonal antibody agents (e.g., omalizumab, mepolizumab, benralizumab, dupilumab, tezepelumab, etc.); **AND**
- Will NOT be used for either of the following:
 - Treatment of other eosinophilic conditions (e.g., allergic bronchopulmonary aspergillosis/mycosis, Churg-Strauss syndrome, hypereosinophilic syndrome, etc.)
 - Relief of acute bronchospasm or status asthmaticus; **AND**

Severe Asthma † ^{1,2,5-7,9,10-12}

- Patient has severe* disease; **AND**
- Patient has asthma with an eosinophilic phenotype indicated by blood eosinophils ≥ 150 cells/ μ L; **AND**
- Will be used for add-on maintenance treatment in patients regularly receiving BOTH of the following:
 - Medium to high-dose inhaled corticosteroids; **AND**

- An additional controller medication (e.g., long acting beta agonist, long-acting muscarinic agent, leukotriene modifiers, etc.); **AND**
- Patient must have two or more exacerbations in the previous year requiring daily oral corticosteroids for at least 3 days (in addition to the regular maintenance therapy defined above); **AND**
- 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 condition
 - Forced expiratory volume in 1 second (FEV₁)

***Components of severity for classifying asthma as severe may include any of the following (not all inclusive):^{2,7}**

- 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 FEV₁) <60%
- Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ^{1,5,6}

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- 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**
 - Improvement in asthma symptoms or asthma exacerbations as evidenced by a decrease in one or more 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**
 - Improvement from baseline in forced expiratory volume in 1 second (FEV₁)

V. Dosage/Administration ¹

| Indication | Dose |
|--|---|
| Severe Asthma with an eosinophilic phenotype | Administer 3 mg/kg via intravenous infusion every 4 weeks |

VI. Billing Code/Availability Information

HCPCS code:

- J2786 - Injection, reslizumab, 1 mg; 1 billable unit = 1 mg

NDC:

- Cinqair 100 mg/10 mL single-use vial: 59310-0610-xx

VII. References

1. Cinqair [package insert]. West Chester, PA; Teva Respiratory, LLC; June 2020. Accessed August 2024.
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. 2020 Update. Available from: <http://www.ginasthma.org>. Accessed September 2020.
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.
6. Holguin F, Cardet JC, Chung KF, et al. Management of severe asthma: a European Respiratory Society/American Thoracic Society guideline. *Eur Respir J* 2020; 55: 1900588 [<https://doi.org/10.1183/13993003.00588-2019>].
7. National Asthma Education and Prevention Program (NAEPP). 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. Bethesda, MD: National Institutes of Health (NIH), National Heart, Lung, and Blood Institute (NHLBI); December 2020.
8. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2021 Update. Available from: <http://www.ginasthma.org>. Accessed August 2021.
9. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2022 Update. Available from: <http://www.ginasthma.org>. Accessed September 2023.
10. Global Initiative for Asthma (GINA) Report: Global Strategy for Asthma Management and Prevention. 2023 Update. Available from: <http://www.ginasthma.org/2023-gina-main-report>. Accessed September 2023.
11. Global Initiative for Asthma (GINA) Report: Global Strategy for Asthma Management and Prevention. 2024 Update. Available from: <http://www.ginasthma.org>. Accessed August 2024.

12. Chipps BE, Jarjour N, Calhoun WJ, et al. A Comprehensive Analysis of the Stability of Blood Eosinophil Levels. *Ann Am Thorac Soc.* 2021 Dec; 18(12):1978-1987. doi: 10.1513/AnnalsATS.202010-1249OC.

Appendix 1 – Covered Diagnosis Codes

| ICD-10 | ICD-10 Description |
|--------|--|
| J45.50 | Severe persistent asthma, uncomplicated |
| J82.81 | Eosinophilic pneumonia, NOS |
| 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) |

| Medicare Part B Administrative Contractor (MAC) Jurisdictions | | |
|--|--------------------------------------|-------------------------|
| Jurisdiction | Applicable State/US Territory | Contractor |
| 15 | KY, OH | CGS Administrators, LLC |