Cinqair® (reslizumab)
(Intravenous)

Document Number: IC-273

Last Review Date: 10/02/2018
Date of Origin: 05/31/2016
Dates Reviewed: 05/2016, 06/2017, 09/2017, 12/2017, 03/2018, 06/2018, 10/2018

I. Length of Authorization

Initial authorization is valid for six months and is eligible for renewal.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

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

B. Max Units (per dose and over time) [Medical Benefit]:

- 345 billable units every 4 weeks

III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient must be at least 18 years of age; **AND**
- Must not be used in combination with another monoclonal antibody (e.g., benralizumab mepolizumab, omalizumab, etc.); **AND**

Severe Asthma †

- Patient must have severe* disease; **AND**
- Patient must have asthma with an eosinophilic phenotype indicated by blood eosinophils ≥ 400 cells/µL within 4 weeks of dosing; **AND**
- Must 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, etc.); **AND**
- Patient must have **ONE** of the following:
  - Two or more exacerbations in the previous year; **OR**
  - Require daily oral corticosteroids (for at least 3 days in addition to the regular maintenance therapy defined above)

*Components of severity for classifying asthma as severe 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

† FDA-labeled indication(s)

IV. Renewal Criteria

- Patient continues to meet the criteria identified in Section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: malignancy, parasitic (helminth) infection, and anaphylaxis; **AND**
- Treatment has resulted in clinical benefit:
  - Improvement in asthma symptoms or asthma exacerbations as evidenced by 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 (FEV_1)

V. Dosage/Administration

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

*Store refrigerated at 2°C to 8°C

VI. Billing Code/Availability Information

Jcode:

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

NDC:

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

VII. References

1. Cinqair [package insert]. Frazer, PA; Teva Respiratory, LLC; May 2016. Accessed August 2018.
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
J45.51	Severe persistent asthma with (acute) exacerbation
J45.52	Severe persistent asthma with status asthmaticus
J82	Pulmonary eosinophilia, not elsewhere classified

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

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 Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): 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, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC