MEDICAL MUTUAL®

Drug Policy

Policy:	**201605_MRx (10 21)**	**Initial Effective Date: 06/02/2016**
Code(s):	**HCPCS J2786**	**Annual Review Date: 10/21/2021**
SUBJECT:	**Cinqair® (reslizumab injection for intravenous use)**	**Last Revised Date: 10/21/2021**

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

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) [NDC unit]:

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

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

- 345 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, or anti-IL5 monoclonal antibody (e.g., omalizumab, mepolizumab, benralizumab, dupilumab, etc.); **AND**
- Must 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 † [1,2,3,5,6]

- 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, 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 (FEV_1)

***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 approved Indication(s)

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 the following: malignancy, parasitic (helminth) infection, and anaphylaxis, etc.; **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[1]

Indication	Dose
Severe Asthma with an eosinophilic phenotype	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:

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

VII. References

1. Cinqair [package insert]. West Chester, PA; Teva Respiratory, LLC; February 2020. Accessed August 2021.
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.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.