Cinqair® (reslizumab)
(Intravenous)

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 had at least 1 asthma exacerbation requiring systemic corticosteroid use over the past 12 months

*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**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tbody>
<tr>
<td>Severe Asthma with an eosinophilic phenotype</td>
<td>3 mg/kg via intravenous infusion every 4 weeks</td>
</tr>
</tbody>
</table>

*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**
### Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J45.50</td>
<td>Severe persistent asthma, uncomplicated</td>
</tr>
<tr>
<td>J45.51</td>
<td>Severe persistent asthma with (acute) exacerbation</td>
</tr>
<tr>
<td>J45.52</td>
<td>Severe persistent asthma with status asthmaticus</td>
</tr>
<tr>
<td>J82</td>
<td>Pulmonary eosinophilia, not elsewhere classified</td>
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</table>

### 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](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

<table>
<thead>
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<tr>
<td>E (1)</td>
<td>CA, HI, NV, AS, GU, CNMI</td>
<td>Noridian Healthcare Solutions, LLC</td>
</tr>
<tr>
<td>F (2 &amp; 3)</td>
<td>AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ</td>
<td>Noridian Healthcare Solutions, LLC</td>
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<tr>
<td>5</td>
<td>KS, NE, IA, MO</td>
<td>Wisconsin Physicians Service Insurance Corp (WPS)</td>
</tr>
<tr>
<td>6</td>
<td>MN, WI, IL</td>
<td>National Government Services, Inc. (NGS)</td>
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<td>H (4 &amp; 7)</td>
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<td>Novitas Solutions, Inc.</td>
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<tr>
<td>8</td>
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<td>First Coast Service Options, Inc.</td>
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<td>M (11)</td>
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<td>Novitas Solutions, Inc.</td>
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<td>CGS Administrators, LLC</td>
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