Policy Title: Cinqair (reslizumab) (Intravenous)

Department: PHA

Effective Date: 01/01/2020

Review Date: 12/18/2019, 1/29/20, 4/29/2021

Revision Date: 12/18/2019, 1/29/20, 4/29/2021

Purpose: To support safe, effective and appropriate use of Cinqair (reslizumab).

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Policy Statement:
Cinqair (reslizumab) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:
Coverage of Cinqair (reslizumab) will be reviewed prospectively via the prior authorization process based on criteria below.

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 (see Appendix); 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; AND
- Member is adherent to current treatment with both of the following medications at optimized doses for at least 2 months:
  - Inhaled corticosteroid; AND
  - Additional controller medication (long acting beta₂-agonist, leukotriene modifier, or sustained-release theophylline); AND
- 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 will not use Cinqair concomitantly with other biologics (e.g., Dupixent, Fasenra, Nucala, Xolair); 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 asthma condition
- Forced expiratory volume in 1 second (FEV1); AND
- Will not be used for treatment of eosinophilic conditions (other than indicated), acute bronchospasm, or status asthmaticus;

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

**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
- 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
  - Improvement from baseline in forced expiratory volume in 1 second (FEV1)
- Member will use Cinqair as add-on maintenance treatment; AND
- Member will not use Cinqair concomitantly with other biologics (e.g., Dupixent, Fasenra, Nucala, Xolair)

**Coverage durations:**

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

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***
Dosage/Administration:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
<th>Maximum dose (1 billable unit = 1 mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe Asthma with an eosinophilic phenotype</td>
<td>3 mg/kg via intravenous infusion every 4 weeks</td>
<td>345 billable units every 4 weeks</td>
</tr>
</tbody>
</table>

Appendix:

Components of Severity for Classifying Asthma as Severe may include any of the following (not all inclusive):

1. Symptoms throughout the day
2. Nighttime awakenings, often 7x/week
3. Short-acting beta agonist (SABA) use for symptom control occurs several times per day
4. Extremely limited normal activities
5. Lung function (percent predicted FEV1) <60%
6. Exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

<table>
<thead>
<tr>
<th>HCPCS/CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J2786</td>
<td>Injection, reslizumab, 1 mg</td>
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References: