

<b>Policy Title:</b>	Cinqair (reslizumab) (Intravenous )		
		<b>Department:</b>	PHA
<b>Effective Date:</b>	01/01/2020		
<b>Review Date:</b>	12/18/2019, 1/29/20		
<b>Revision Date:</b>	12/18/2019, 1/29/20		

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

**Scope:** Medicaid, Exchange, 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.
- 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 beta<sub>2</sub>-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);
- 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.
- Member is tolerating treatment; AND
- Documentation that asthma control has improved/stabilized on Cinqair treatment from baseline as demonstrated by at least one of the following:
  - A reduction in the frequency and/or severity of symptoms and exacerbations (e.g. decrease in hospitalizations, emergency department or urgent care visits); OR
  - A reduction in the daily maintenance oral corticosteroid dose; 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)

**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:**

Indication	Dose	Maximum dose (1 billable unit = 1 mg)
Severe Asthma with an eosinophilic phenotype	3 mg/kg via intravenous infusion every 4 weeks	345 billable units every 4 weeks

***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:

HCPCS/CPT Code	Description
J2786	Injection, reslizumab, 1 mg

#### **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

