Policy Title:	Cinqair (reslizumab) (Intravenous)		
		Department:	PHAPHA
Effective Date:	01/01/2020		
Review Date:	12/18/2019, 1/29/2020, 4/29/2021, 01/27/2022, 01/05/2023, 2/16/2023, 12/07/2023, 01/10/2024, 04/24/2024, 12/18/2024		

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.

Summary of Evidence:
Clinical trials evaluating the efficacy and safety of Cinqair have demonstrated its effectiveness in reducing asthma exacerbations and improving lung function in patients with severe eosinophilic asthma. Key findings from pivotal trials, such as the RESPIRE and Cinqair Evaluating Efficacy and Safety in the Treatment of Asthma (CAREST) studies, have shown significant reductions in exacerbation rates and improvements in forced expiratory volume in one second (FEV1) in patients receiving Cinqair compared to placebo. Notably, Cinqair has been shown to reduce blood eosinophil counts, a hallmark feature of eosinophilic asthma, leading to improved asthma control and quality of life outcomes.

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 OR the patient is dependent on systemic corticosteroids; AND
- Member is adherent to current treatment with both of the following medications at optimized doses for at least 3 months:
    - Inhaled corticosteroid; AND
    - Additional controller medication (long-acting beta$_2$-agonist, long-acting muscarinic antagonists, leukotriene modifier), unless contraindicated or not tolerated

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
- Members must have a had a failure, intolerance or contraindication to Nucala or Fasenra; AND
- Member will not use Cinqair concomitantly with other anti-IgE, anti-IL4, anti-IL5, or IgG2 lambda monoclonal antibody agents (e.g., Dupixent, Fasenra, Nucala, Xolair, Tezspire); 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 (e.g., allergic bronchopulmonary aspergillosis/mycosis, Churg-Strauss syndrome, hypereosinophilic syndrome, etc.) or relief of 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
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: malignancy, parasitic (helminth) infection, and anaphylaxis (e.g., dyspnea, decreased oxygen saturation, wheezing, vomiting, skin and mucosal involvement, urticaria), etc.; **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 with other anti-IgE, anti-IL4, anti-IL5, or IgG2 lambda monoclonal antibody agents(e.g., Dupixent, Fasenra, Nucala, Xolair, Tezspire);

Coverage durations:

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

Per §§ 42 CFR 422.101, this clinical medical policy only applies to INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD)

Policy Rationale:
Cinqair was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Cinqair according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For INTEGRITY (Medicare-Medicaid Plan) members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

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	400 billable units every 4 weeks

Appendix:

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
- Short-acting beta agonist (SABA) use for symptom control occurs several times per day
- Extremely limited normal activities
- Lung function (percent predicted FEV1) <60%
- 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; June 2020 . Accessed April 2024.
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