

Policy Title:	Cinqair (reslizumab) (Intravenous)		
Policy Number:	000632	Department:	PHA
Effective Date:	12/12/2018		
Review Date:	12/12/2018		
Revision Date:	12/12/2019		

Purpose: To support safe, effective and appropriate use of Cinqair (reslizumab) for the add-on maintenance treatment of patients with severe asthma aged 18 years and older with an eosinophilic phenotype

Scope: Medicaid, Exchange, Integrity

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 Coverage:

- Must be prescribed by a Pulmonologist or Allergist/Immunologist;
- Must be 18 years of age or older;
- Patient has eosinophilic asthma with documentation of a blood eosinophil ≥ 400 cells/ μ L within 4 weeks of starting therapy;
- Evidence of severe asthma in accordance with national asthma guidelines (such as, symptoms throughout the day, nighttime awakenings(often 7 times a week), SABA use for symptom control occurs several times daily, extremely limited in normal activities, lung function (percent predicted FEV1) less than 60% or exacerbations requiring oral systemic corticosteroids are generally more frequent and intense relative to moderate asthma);
- Must be used as add-on maintenance treatment in patients regularly receiving BOTH of the following: High-dose inhaled corticosteroids plus a long-acting beta agonist (LABA) OR high-dose inhaled corticosteroids plus a leukotriene receptor antagonists (LTRA);
- Patients must have ONE of the following:
 - The Patient's symptoms are not well controlled or poorly controlled despite an adherent ≥ 2 month trial of high-dose inhaled corticosteroids (ICS) in combination with a long-acting inhaled beta-2 agonist (LABA) or Serevent

- (tiotropium) or leukotriene modifier or the member is intolerant or has a contraindication to all of these medications; OR
- The Patient has experienced ≥ 2 exacerbations in the previous 12 months requiring additional medical treatment (e.g., oral corticosteroids, emergency department or urgent care visits, or hospitalization) despite an adherent ≥ 2 month trial of high-dose inhaled corticosteroids (ICS) in combination with a long-acting inhaled beta-2 agonist (LABA) or leukotriene modifier prior to the exacerbation or the member is intolerant or has a contraindication to all of these medications
- Patient is not using in combination with omalizumab (Xolair) or Fasentra (benralizumab) or Mepolizumab (Nucala).

Continuation of therapy:

- Patient is tolerating treatment;
- Patient has clinical documentation of disease stabilization or improvement in asthma symptoms or asthma exacerbations as evidenced by decrease in one or more of the following:: Use of systemic corticosteroids, decrease in inhaled corticosteroid use, hospitalizations, ER visits, unscheduled visits to healthcare provider OR Improvement from baseline in forced expiratory volume in 1 second (FEV1);
- Patient is not using in combination with omalizumab (Xolair) or Fasentra (benralizumab) or Mepolizumab (Nucala).

Coverage durations:

- Initial coverage criteria = 6 months
- Continuation of therapy = 12 months

Investigational use: Cinqair (reslizumab) is considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in one of the above listed resources. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Additional information:

Indications:

- Cinqair (reslizumab) is indicated for the add-on maintenance treatment of patients with severe asthma aged 18 years and older with an eosinophilic phenotype

Limitations of Use:

- Cinqair (reslizumab) is not indicated for treatment of other eosinophilic conditions and is not indicated for the relief of acute bronchospasm or status asthmaticus

Dosing:

- 3 mg/kg once every 4 weeks administered by intravenous infusion over 20-50 minutes.

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
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis(specify substance or drug), initial, up to 1 hour
J2786	Injection, reslizumab, 1mg

References:

1. Cinqair Prescribing information. Frazer, PA: Teva Respiratory, LLC, 2018 September.