Cinqair® (reslizumab)
Prior Authorization criteria
Drug Protocol Management

Reslizumab is an interleukin-5 antagonist. IL-5 is the major cytokine responsible for the growth and differentiation, recruitment, activation, and survival of eosinophils which can play a role in asthma.

Criteria for Coverage:
• Add-on maintenance treatment of patients aged 18 years and older with severe, uncontrolled asthma with eosinophilic inflammation as defined below:
  o Severe asthma: Documented requirement for one of the following in the 6 months prior to therapy initiation
    ▪ Regular treatment with oral corticosteroid (5 to 35 mg/day prednisone or equivalent)
    ▪ High-dose inhaled corticosteroid (ICS) (at least 880 mcg/day FP ex-actuator or equivalent) plus LABA plus one other daily controller medication; patients should be adherent to these medications (80% of daily doses) for at least 6 months before adding reslizumab and remain on these medications during reslizumab treatment (See Medications below for additional information)
  OR
  o Uncontrolled asthma defined by at least two of the following in the past year:
    ▪ Two or more exacerbations requiring bursts of OCS therapy for at least four days
    ▪ At least one serious exacerbation requiring hospitalization or ED visit
    ▪ Airflow limitation (FEV1 less than 80% predicted)
    ▪ Poor symptom control (ACQ more than 1.5; ACT less than 20)
  o Eosinophilic inflammation:
    ▪ Blood eosinophil level of at least 400 cells/microliters at initiation of therapy
    OR
    ▪ Historical level of at least 400 cells/microliter in the last 15 months if it is documented that the patients is currently on oral steroids

• Treatment should be initiated by allergy or asthma specialist with experience in the diagnosis and treatment of severe refractory eosinophilic asthma

• Reslizumab is NOT indicated for treatment of other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus.

• Patient has at least 1 claim in the last 6 months for a bronchodilator to control acute symptoms (such as albuterol, Alupent®, Maxair®, Proventil®, Ventolin®, Xopenex®, etc.)
• Patient has at least 1 claim of Nucala (mepolizumab) and supporting documentation indicating that they have had an inadequate response or reaction to the medication.

**Medications:**

- Patient must be maintained on and adherent to (taking at least 80% of daily doses) **high dose** inhaled steroids such as the following:

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<tr>
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<th>Budesonide (Pulmicort®)</th>
<th>Flunisolide (AeroBID®)</th>
<th>Fluticasone (Flovent®)</th>
<th>Mometasone (Asmanex®)</th>
<th>Triamcinolon (Azmacort®)</th>
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<tbody>
<tr>
<td>Adults</td>
<td>≥480 mcg/d</td>
<td>&gt;1200 mcg/d</td>
<td>&gt;2000 mcg/d</td>
<td>&gt;660 mcg/d</td>
<td>&gt;400 mcg/d</td>
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- **PLUS**
  - a long-acting bronchodilator (e.g., Serevent®, Foradil®, Arcapta® Neohaler®, etc.)
  - and/or
  - a leukotriene modifier (e.g., Singulair®, Accolate®, or Zyflo®)
  - OR
  - high dose Advair Diskus® (> 500/50; twice daily) or high dose Advair HFA® (≥ 115/21; 2 puffs twice daily) or high dose Symbicort® (≥ 160/4.5; 2 puffs twice daily) or high dose Dulera® (≥ 200/5; 2 puffs twice daily)
  - OR
  - daily systemic steroid therapy

2. **Cautions**

- **Malignancy**: Malignancies were observed in clinical studies.
- **Reduction in Corticosteroid Dosage**: Corticosteroids should not be discontinued abruptly upon initiation of therapy. Corticosteroid doses can be decreased gradually if appropriate.
- **Parasitic (Helminth) Infection**: Treat patients with pre-existing helminth infections before therapy with reslizumab. If patients become infected while receiving treatment with reslizumab and do not respond to anti-helminth treatment, discontinue reslizumab until parasitic infection resolves.

3. **Administration**

- Administration is for intravenous infusion only. Do not administer as an intravenous push or bolus.
- Reslizumab should be administered in a healthcare setting by a healthcare professional prepared to manage anaphylaxis.
• Recommended dosage regimen is 3 mg/kg once every 4 weeks by intravenous infusion over 20-50 minutes.

4. Discontinuation

• Treatment response should be globally assessed by the treating physician taking into consideration any improvement in asthma control, reduction in exacerbations and unscheduled healthcare utilization and improvement in quality of life of the patient.
• Infusion should be discontinued immediately if the patient experiences a severe systemic reaction, including anaphylaxis.

References: