Policy Title: Fasenra (benralizumab) Subcutaneous

Department: PHA

Effective Date: 01/01/2020

Review Date: 11/27/2019, 12/18/19, 1/29/20, 4/1/20, 3/25/2021

Revision Date: 11/27/2019, 1/29/20, 4/1/20, 3/25/2021

**Purpose:** To support safe, effective and appropriate use of Fasenra (benralizumab).

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

*For Medicaid, Fasenra is only available on the Pharmacy Benefit*

**Policy Statement:**

Fasenra (benralizumab) 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 Fasenra (benralizumab) will be reviewed prospectively via the prior authorization process based on criteria below.

**Initial Criteria:**

- Patient is 12 years of age or older; AND
- Fasenra is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist; AND
- Patient has clinically documented 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; AND
- Patient must have asthma with an eosinophilic phenotype defined as blood eosinophils ≥150 cells/µL within 6 weeks of dosing; AND
- Patient is adherent to current treatment with both of the following medications at optimized doses for at least 2 months: (1) Inhaled corticosteroid AND (2) Additional controller
medication (long acting beta\textsubscript{2}-agonist, leukotriene modifier, or sustained-release theophylline); AND

- Must NOT be used for either of the following:
  - Treatment of other eosinophilic conditions (e.g., allergic bronchopulmonary aspergillosis/mycosis, Churg-Strauss syndrome, hypereosinophilic syndrome, etc.)
  - Relief of acute bronchospasm or status asthmaticus; AND

- Patient 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) Member will use Fasenra as add-on maintenance treatment; AND

- Baseline measurements 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 condition
  - Forced expiratory volume in 1 second (FEV\textsubscript{1})

- Patient is not using in combination with omalizumab (Xolair) or reslizumab (Cinqair) or Mepolizumab (Nucala) or dupilumab (Dupixent); AND

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

**Continuation of Therapy Criteria:**

- Patient is 12 years of age or older; AND
- Fasenra is prescribed by, or in consultation with, a pulmonologist or allergist/immunologist; AND
- Patient is tolerating treatment; AND
- Improvement in asthma symptoms or asthma exacerbations as evidenced by a decrease in one or more 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 (FEV\textsubscript{1}); AND
- Patient will use Fasenra as add-on maintenance treatment; AND
- Patient is not using in combination with omalizumab (Xolair) or reslizumab (Cinqair) or Mepolizumab (Nucala) or dupilumab (Dupixent)
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 eosinophilic phenotype</td>
<td>30 mg administered subcutaneously, by a healthcare professional, every 4 weeks for the first three doses and then once every 8 weeks thereafter</td>
<td>Loading: 30 mg (30 units) every 28 days x 3 doses</td>
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<tr>
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<td></td>
<td>Maintenance: 30 mg (30 units) every 56 days</td>
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</tbody>
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**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>J0517</td>
<td>Injection, benralizumab, 1mg</td>
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References:


