Fasenra (benralizumab)

**Definition**

Fasenra (benralizumab) is a humanized monoclonal antibody that directly binds to human interleukin-5 receptor. The IL-5 receptor is expressed on the surface of eosinophils and basophils which are involved in inflammation, an important component in the pathogenesis of asthma. By binding to the IL-5Rα chain, benralizumab reduces eosinophils through antibody-dependent cell-mediated cytotoxicity.

Fasenra is indicated for the add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

**Dosage/Administration**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma</td>
<td>– 30 mg administered subcutaneously (SC) once every 4 weeks for the first 3 doses; OR – 30 mg administered subcutaneously (SC) once every 8 weeks.</td>
</tr>
</tbody>
</table>

**Length of Authorization**

- Coverage will be provided for 6 months and may be renewed.
- Renewal Coverage will be provided for 12 months.
Guideline

Asthma

- Patient is ≥ 12 years of age; **AND**
- Fasenra is prescribed by or in consultation with an allergist, immunologist, or pulmonologist; **AND**
- Patient has a blood eosinophil count of ≥ 150 cells per microliter within the previous 6 weeks or within 6 weeks prior to treatment with any anti-interleukin-5 therapy; **AND**
  
  **Note:** Examples of anti-interleukin-5 therapies include Fasenra, Nucala, Cinqair.

- Patient has received at least 3 consecutive months of combination therapy with **BOTH** of the following:
  - An inhaled corticosteroid; **AND**
  - At least one additional asthma controller/maintenance medication; **AND**
  
  **Note:** An exception to the requirement for a trial of one additional asthma controller/maintenance medication (criterion b) can be made if the patient has already received anti-interleukin-5 therapy (e.g., Cinqair, Fasenra, Nucala) used concomitantly with an inhaled corticosteroid for at least 3 consecutive months. Use of a combination inhaler containing both an inhaled corticosteroid and a long-acting beta2-agonist would fulfill the requirement for both criteria a and b. Examples of inhaled corticosteroids include Aerospan, Alvesco, ArmonAir RespiClick, Arnuity Ellipta, Asmanex Twisthaler/HFA, Flovent Diskus/HFA, Pulmicort Flexhaler, Qvar/Qvar RediHaler, and budesonide suspension for inhalation (Pulmicort Respules, generics). Examples of additional asthma controller/maintenance medications include long-acting beta2-agonists (e.g., Serevent Diskus); inhaled long-acting muscarinic antagonists (e.g., Spiriva Respimat); leukotriene receptor antagonists (e.g., montelukast tablets/ granules [Singulair, generics], zafirlukast tablets [Accolate, generics]); theophylline (e.g., Theo 24, TheoChron ER, generics). Examples of combination inhaled corticosteroid/long-acting beta2-agonist inhalers include Advair Diskus (generic Wixela Inhub; authorized generics), Advair HFA, AirDuo RespiClick (authorized generics), Breo Ellipta, Dulera, Symbicort.

- Patient’s asthma is uncontrolled or was uncontrolled prior to starting any anti-interleukin therapy as defined by **ONE** of the following:
  - The patient experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year; **OR**
  - The patient experienced one or more asthma exacerbation requiring hospitalization or an Emergency Department (ED) visit in the previous year; **OR**
  - Patient has a forced expiratory volume in 1 second (FEV₁) < 80% predicted; **OR**
  - Patient has an FEV₁/forced vital capacity (FVC) < 0.80; **OR**
  - The patient’s asthma worsens upon tapering of oral corticosteroid therapy.
  
  **Note:** Examples of anti-interleukin therapies include Fasenra, Cinqair and Nucala.

Coverage for Fasenra may be renewed when the following criteria are met:

- The patient has already received at least 6 months of therapy with Fasenra; **AND**
  
  **Note:** Patients who have received < 6 months of therapy or those who are restarting therapy with Fasenra should be considered new to therapy – see above criteria.
- Patient continues to receive therapy with one inhaled corticosteroid or one inhaled corticosteroid-containing combination inhaler; **AND**

  **Note**: Examples of an inhaled corticosteroid or an inhaled corticosteroid-containing combination inhaler include Flovent Diskus/HFA, ArmonAir RespiClick, Arnuity Ellipta, Asmanex Twisthaler/HFA, Aerospan, Alvesco, Pulmicort Flexhaler, budesonide suspension for inhalation (Pulmicort Respules, generics), Qvar/Qvar RediHaler, Advair Diskus (generic Wixela Inhub; authorized generics), Advair HFA, AirDuo RespiClick (authorized generics), Breo Ellipta, Dulera, and Symbicort.

- The patient has responded to Fasenra therapy as determined by the prescriber.

  **Note**: Examples of a response to Fasenra therapy are decreased asthma exacerbations; decreased asthma symptoms; decreased hospitalizations, emergency department (ED)/urgent care, or medical clinic visits due to asthma; and decreased requirement for oral corticosteroid therapy.

### Limitations and Exclusions

- Chronic Obstructive Pulmonary Disease (COPD)
- Concurrent use of Fasenra with Another Anti-Interleukin (IL) Monoclonal Antibody
- Concurrent use of Fasenra with Xolair® (omalizumab injection for subcutaneous use)
- Hypereosinophilic Syndrome (HES)
- Coverage is not recommended for circumstances not listed in the Guideline. Criteria will be updated as new published data are available.

### Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J0517</td>
<td>Injection, benralizumab, 1 mg</td>
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### Applicable NDC’s

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>0310-173-30</td>
<td>Fasenra 30mg single-dose prefilled syringe for injection</td>
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### Applicable Diagnosis Codes

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J45.50</td>
<td>Severe persistent asthma, uncomplicated</td>
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<tr>
<td>J45.51</td>
<td>Severe persistent asthma with (acute) exacerbation</td>
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### Revision History

<table>
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<tr>
<th>Date</th>
<th>Description</th>
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<tr>
<td>1/1/2021</td>
<td>Criteria apply to Commercial, Medicare, and Medicaid members.</td>
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### References

3. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and

