Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 11/07/2019

**Fasenra™ (benralizumab)**

**FDA approval:** 11/14/2017  
**HCPCS:** C9466, J0517  
**Benefit:** Medical

**Policy:**

*Requests must be supported by submission of chart notes and patient specific documentation.*

**A. Coverage of the requested drug is provided when all the following are met:**
   a. FDA approved age  
   b. Documentation of a consult with an allergist/immunologist or pulmonologist prior to initiation of Fasenra therapy  
   c. Must be used as add on maintenance treatment with severe uncontrolled eosinophilic asthma  
   d. Patient is currently receiving, and will continue to receive standard of care regimen  
   e. Severe eosinophilic asthma identified by:
      i. Blood eosinophils greater than or equal to 300 cells/microliter in the past 12 months AND  
      ii. Repeated hospital/ED visits AND  
      iii. Chronic administration of systemic corticosteroids or high dose inhaled corticosteroids in combination with long acting inhaled β2 agonist or leukotriene modifier for at least 3 months fails to maintain adequate control  
   f. Trial and failure of the preferred products as specified in the BCBSM/BCN utilization management medical drug list  
   g. It cannot be used in combination with other biologics for asthma  
   h. Administered by a health care professional

**B. Quantity Limitations, Authorization Period and Renewal Criteria**
   a. Quantity Limit: 30 mg monthly for the first 3 doses then every 8 weeks thereafter  
   b. Initial Authorization Period: Up to 1 year  
   c. Renewal Criteria:
      i. Patient has not experienced an adverse reaction to Fasenra therapy  
      ii. Documented improvement in severe eosinophilic asthma. Examples included, but are not limited to:
         1. Reduction in hospitalizations  
         2. Reduction in asthma medication use  
         3. Reduction in asthma exacerbations
4. Improvement in pulmonary tests  
   d. Renewal Authorization Period: Up to 1 year  

C. Fasenra is considered investigational when used for all other conditions, including but not limited to:  
   a. Other asthma conditions  
   b. Acute bronchospasm  
   c. Status asthmaticus  
   d. Eosinophilic esophagitis  

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.  

Therapeutic considerations:  

A. FDA approved indication/Diagnosis  
   a. For the add-on maintenance treatment of patients with severe asthma aged 12 years and older and with an eosinophilic phenotype  

   *Please refer to most recent prescribing information.  
   https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761070s000lbl.pdf  

B. Background Information  
   a. Per the CDC, more than 22 million Americans have asthma and between 5% and 10% of patients with asthma have severe asthma  
   b. Of those with severe asthma, approximately 50% of have an eosinophilic phenotype  
   c. IL-5 is the major cytokine responsible for eosinophilic air way inflammation in patients with asthma  
   d. Fasenra is the third IL-5 receptor antagonist to be approved for severe asthma with an eosinophilic phenotype, after Nucala and Cinqair. All three require administration by a health care professional. Fasenra is dosed less frequently than its competitors (every 8 weeks vs. every 4 weeks)  

C. Efficacy  

   *Please refer to most recent prescribing information.  

D. Medication Safety Considerations  

   Black Box Warning: No  

   *Please refer to most recent prescribing information.  

E. Dosing and administration  
   a. 30 mg subcutaneously every 4 weeks for the first 3 doses, then once every 8 weeks thereafter  

   *Please refer to most recent prescribing information.  

F. How supplied  
   a. 30 mg/mL single-dose prefilled syringe  

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.
References:

18. Xolair® subcutaneous injection [prescribing information]. South San Francisco, CA and East Hanover, NJ: Genentech, Inc. and Novartis Pharmaceuticals Corporation; June 2017.
### Policy History

<table>
<thead>
<tr>
<th>#</th>
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<th>Change Description</th>
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<tr>
<td>1.4</td>
<td>Effective Date: 11/07/2019</td>
<td>Criteria update to authorization period. Also changed language to FDA approved age.</td>
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<tr>
<td>1.3</td>
<td>Effective Date: 08/15/2019</td>
<td>Updated criteria to account for new self-injectable Nucala formulation</td>
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<tr>
<td>1.2</td>
<td>Effective Date: 05/09/2019</td>
<td>Annual Review of Medical Policy</td>
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<tr>
<td>1.1</td>
<td>Effective Date: 08/07/2018</td>
<td>PA added to BCNA and MAPPO</td>
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<tr>
<td>1.0</td>
<td>Effective Date: 05/03/2018</td>
<td>New Drug Review</td>
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#### Line of Business

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*The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or [http://dailymed.nlm.nih.gov/dailymed/index.cfm](http://dailymed.nlm.nih.gov/dailymed/index.cfm).*