Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

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: 10/12/2023

Fasenra™ (benralizumab)

HCPCS: J0517

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. FDA approved indication
   c. Severe eosinophilic asthma identified by:
      i. Blood eosinophils greater than or equal to 150 cells/microliter at initiation of treatment
   d. Chronic administration of systemic corticosteroids or high dose inhaled corticosteroids (listed in table 1) in combination with
      i. Long acting inhaled β2 agonist for at least 3 months fails to maintain adequate control
      OR
      ii. Leukotriene modifier for at least 3 months fails to maintain adequate control
      OR
      iii. LAMA (long acting muscarininc antagonists) in adults and children ≥ 12 years old for at least 3 months fails to maintain adequate control
   e. Cannot be used in combination with other biologics for asthma
   f. Must be used as add on maintenance treatment with severe uncontrolled eosinophilic asthma
   g. Patient is currently receiving, and will continue to receive standard of care regimen
   h. The member will self-administer Fasenra unless clinically unable to do so
   i. Trial and failure, contraindication, OR intolerance to the preferred products as listed in BCBSM/BCN's utilization management medical drug list and/or BCBSM/BCN's prior authorization and step therapy documents

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: One year at a time.
   c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit.

***Note: Coverage and approval duration 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.

Background Information

- Fasenra is the third interleukin-5 (IL-5) receptor antagonist indicated for add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

- Eosinophilic asthma is a sub phenotype of severe asthma characterized by elevated sputum and blood eosinophil levels as well as increased asthma severity, atopy, late-onset disease, and steroid refractoriness.

- Severe asthma requires treatment with high dose inhaled corticosteroids (ICS) plus a second controller (and/or systemic corticosteroids) to prevent it from becoming uncontrolled or which remains uncontrolled despite therapy. Add-on treatment for severe asthma include LAMA, leukotriene receptor antagonist (LTRA), low dose azithromycin (adults) and biologic agents for severe allergic or severe type 2 asthma. Type 2 inflammation is found in majority of the of people with severe asthma and characterized by production of cytokines such as interleukin. Anti-IL5 monoclonal antibodies (Cinqair®, Nucala®, and Fasenra) specifically target formation of eosinophils and depletes blood eosinophil levels.

- The Global Institute for Asthma (GINA) 2021 guidelines stepwise approach recommend those in STEP 5 to add-on therapy with LAMAs such as tiotropium, anti-IgE therapy (omalizumab), anti-IL5 therapy, or anti-IL4 therapy after phenotypic assessment of asthma subtype.

- A peripheral blood eosinophil count is an indirect way to estimate airway inflammation. A blood eosinophil count ≥ 300 cells/microliter may help to predict asthmatics who are at increased risk for exacerbations in the next year. Furthermore, a count-response relation exists between blood eosinophil counts and asthma-related outcomes. The European Respiratory Society/American Thoracic Society guidelines from 2020 suggest that treatment of severe asthma be guided by clinical criteria and biomarkers such as blood eosinophil levels or fractional exhaled nitric oxide (FeNO), rather than by clinical criteria alone. In addition, it also suggests that a blood eosinophil count cut-off point of ≥ 150 cells/microliter can be used to guide anti-IL5 initiation in adult patients with severe asthma and a history of prior asthma exacerbations.

- Approval was based on results from a total of 3 multicenter, randomized, double-blind trials.

    - Two asthma exacerbation trials, SIROCCO (n = 1,204) and CALIMA (n = 1,306) randomized patients 12 to 75 years old with severe asthma not controlled on high dose (medium – high in CALIMA) ICS/LABA therapy to receive Fasenra 30 mg Q4W, Fasenra 30 mg Q8W, and placebo. The addition of Fasenra 30 mg SC Q8W to current therapy significantly reduced asthma exacerbation rates by 51% in SIROCCO and 28% in CALIMA in patients with baseline blood eosinophil levels ≥ 300 cells/microliter.

    - In the oral corticosteroid (OCS) reduction study (ZONDA), included 220 patients aged 18 years of age or older with severe asthma receiving high-dose ICS/LABA and chronic OCS with a baseline blood eosinophil level of ≥ 150 cells/microliter. Significantly more patients receiving Fasenra 30 mg SC Q8W were able to reduce their OCS dose compared to placebo. Patients using Fasenra saw 75% reduction in median daily OCS vs. 25% in the placebo group.

- Review response to biologic therapy after 3-4 months of treatment. If the patient had a good response, the need for each medication should re-evaluated, but do not completely stop inhaled therapy. Consider gradually decreasing or stopping oral steroids first.

- Clinical reasons a patient may be unable to self-administer Fasenra include:

    - Patient or caregivers are unable to perform subcutaneous injections with proper technique

    - Member requires monthly medical support from the physician

References:

1. Fasenra™ subcutaneous injection [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; February 2021.
2. Bleecker ER, Fitzgerald JM, Chanez P, et al. Efficacy and safety of Fasenra for patients with severe asthma uncontrolled with high-dosage inhaled corticosteroids and long-acting β2-agonists (SIROCCO): a randomized, multicenter, placebo-controlled phase 3 trial. Lancet. 2016;388:2115-2127.
3. FitzGerald JM, Bleecker ER, Nair P, et al. Benralizumab, an anti-interleukin-5 receptor α monoclonal antibody, as add-on treatment for patients with severe, uncontrolled, eosinophilic asthma (CALIMA): a randomized, double-blind, placebo-controlled phase 3 trial. Lancet. 2016;388:2128-2141.
4. Global Initiative for Asthma. Global strategy for asthma management and prevention. Updated 2021. Available at: www.ginasthma.org.
5. Holguin F, Cardet JC, Chung KF, et al. Management of severe asthma: a European Respiratory Society/American Thoracic Society guideline. Eur Respir J 2020; 55.

Table 1: Comparative cumulative daily dosing of inhaled corticosteroids (mcg/day)

Inhaled Corticosteroid	Ages 12 and up			Ages 6-11		
	Low Dose	Medium Dose	High Dose	Low Dose	Medium Dose	High Dose
Beclometasone dipropionate HFA	100 – 200	>200 – 400	>400	50 – 100	>100 – 200	>200
Budesonide DPI	200 – 400	>400 – 800	>800	100 – 200	>200 – 400	>400
Budesonide nebules	NA	NA	NA	250 – 500	>500 – 1,000	>1,000
Ciclesonide HFA	80 – 160	>160 – 320	>320	80	>80 – 160	>160
Fluticasone furoate DPI	100	NA	200	NA	NA	NA
Fluticasone propionate DPI	100 – 250	>250 – 500	>500	100 – 200	>200 – 400	>400
Fluticasone propionate HFA	100 – 250	>250 – 500	>500	100 – 200	>200 – 500	>500
Mometasone furoate	110 – 220	>220 – 440	>440	110	≥220 - <440	≥440
Triamcinolone acetonide	400 – 1,000	>1,000 – 2,000	>2,000	400 – 800	>800 – 1,200	>1,200

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>2.1</td><td>Effective Date: 10/12/2023</td><td>Annual review of policy; no changes were made to the criteria.</td></tr>
<tr><td>2.0</td><td>Effective Date: 10/06/2022</td><td>Updated to require self-administration unless clinically unable to do so</td></tr>
<tr><td>1.9</td><td>Effective Date: 10/07/2021</td><td>Updated LABA and LAMA requirement to LABA or LAMA</td></tr>
<tr><td>1.8</td><td>Effective Date: 06/10/2021</td><td>Criteria document created and criteria aligned between all biologic asthma agents. The criteria for asthma was previously part of the Biologics for Asthma Policy which will be retired</td></tr>
<tr><td>1.7</td><td>Effective Date: 08/13/2020</td><td>Criteria updated for Fasenra</td></tr>
<tr><td>1.6</td><td>Effective Date: 4/16/2020</td><td>Critieria update for step therapy to reference dosing chart for inhaled corticosteroids.</td></tr>
<tr><td>1.5</td><td>Effective Date: 12/05/2019</td><td>Updated to include Fasenra self-administered product</td></tr>
<tr><td>1.4</td><td>Effective Date: 11/07/2019</td><td>Criteria update to authorization period. Also changed languge to FDA approved age.</td></tr>
<tr><td>1.3</td><td>Effective Date: 08/15/2019</td><td>Updated criteria to account for new self-injectable Nucala formulation</td></tr>
<tr><td>1.2</td><td>Effective Date: 05/09/2019</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.1</td><td>Effective Date: 08/07/2018</td><td>UM medical management system update for BCNA and MAPPO
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<tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr>
<tr><td>BCBS</td><td>Yes</td></tr>
<tr><td>BCN</td><td>Yes</td></tr>
<tr><td>MAPPO</td><td>Yes</td></tr>
<tr><td>BCNA</td><td>Yes</td></tr>
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<tr><td>1.0</td><td>Effective Date: 05/03/2018</td><td>New Drug Review
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<tr><td>BCNA</td><td>No</td></tr>
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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.*

Blue Cross Blue Shield/Blue Care Network of Michigan
Medication Authorization Request Form
Fasenra™ (benralizumab) HCPCS CODE: J0517

Blue Cross Blue Shield Blue Care Network of Michigan

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This form is to be used by participating physicians to obtain coverage for Fasenra™. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	**Name**
ID Number	**Specialty**
D.O.B. ☐Male ☐Female	**Address**
Diagnosis	**City /State/Zip**
Drug Name	**Phone/Fax: P**: ( ) - **F**: ( ) -
Dose and Quantity	**NPI**
Directions	**Contact Person**
Date of Service(s)	**Contact Person Phone / Ext.**

STEP 1: DISEASE STATE INFORMATION

1. Is this request for: ☐ Initiation ☐ Continuation ***Date patient started therapy***: _____
2. How is this medication being administered? ☐ Self-administered ***(Please fax this completed form to BCBSM at (866) 601-4425)***
   ☐ Health Care Professional administered ***(Continue to #3)***
3. Please provide reason(s) why the patient needs to receive Fasenra administered by a healthcare professional:
   ☐ Patients or caregivers who are unable to perform subcutaneous injections with proper technique
   ☐ Patient requires monthly medical support from the physician
   ☐ Other: _____
4. Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
   ☐ Hospital outpatient facility (go to #4) *Reason for Hospital Outpatient administration:* _____
5. Please specify location of administration if hospital outpatient infusion: _____
6. Please provide the NPI number for the place of administration: _____

7. **Initiation AND Continuation of therapy:**
   a. Please check the patient's diagnosis**:** ☐ Severe eosinophilic asthma ☐ Other: _____
   b. What is the patient's blood eosinophil level at the initiation of therapy, in cells/microliter? _____cells/microliter Date: _____
   c. Which treatment(s) did not adequately control the patient's severe eosinophilic asthma symptoms after a trial of at least 3 months?
      ☐ Systemic corticosteroid: _____ Date: *Start:* _____ *End:* _____
      ☐ High dose inhaled corticosteroids: _____ Date: *Start:* _____ *End:* _____
      ☐ Long acting beta2-agonist: _____ Date: *Start:* _____ *End:* _____
      ☐ Leukotriene receptor antagonist: _____ Date: *Start:* _____ *End:* _____
      ☐ Combination asthma inhaler with a HIGH dose corticosteroid and a long acting inhaled beta agonist: _____ Date: *Start:* _____ *End:* _____
      ☐ Combination asthma inhaler with a MEDIUM dose corticosteroid and a long acting inhaled beta agonist: _____Date: *Start:* _____ *End:* ___
      ☐ Long acting muscarinic antagonist (LAMA): _____ Date: *Start:* _____ *End:* _____
      ☐ Other: _____
   d. Is the patient currently receiving and will continue to receive a standard of care regimen for their diagnosis with Fasenra?
      ☐ Yes ☐ No Comment: _____
   e. Will the patient be using Fasenra in combination with other biologic medications for asthma (for example: Xolair, Nucala, Cinqair, or Duxipent)?
      ☐ Yes ☐ No Comment: _____

8. **Continuation request:** (please answer above questions as well): **Fasenra start date**: _____
   a. Have the patient's signs and symptoms improved with Fasenra?
      ☐ Yes ☐ No, Comment: _____ ☐ Other: _____

Please add any other supporting medical information necessary for our review

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name	Physician Signature	Date

Step 2: Checklist	☐ Form Completely Filled Out ☐ Attach Chart Notes	☐ Attach Diagnostic Tests
Step 3: Submit	**By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979**	**By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320**

11/30/2017; 10/11/2018,11/28/2018; 3/17/2020;12/27/2021; 10/6/2022