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**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  $\beta$ 2 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 muscarinic antagonists) in adults and children  $\geq$  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.

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\*\*\*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 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  $\geq 300$  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  $\geq 150$  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  $\geq 300$  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  $\geq 150$  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.

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- 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](http://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 nebulers	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 acetoneide	400 – 1,000	>1,000 – 2,000	>2,000	400 – 800	>800 – 1,200	>1,200

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Policy History												
#	Date	Change Description										
2.1	Effective Date: 10/12/2023	Annual review of policy; no changes were made to the criteria.										
2.0	Effective Date: 10/06/2022	Updated to require self-administration unless clinically unable to do so										
1.9	Effective Date: 10/07/2021	Updated LABA and LAMA requirement to LABA or LAMA										
1.8	Effective Date: 06/10/2021	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										
1.7	Effective Date: 08/13/2020	Criteria updated for Fasenra										
1.6	Effective Date: 4/16/2020	Criteria update for step therapy to reference dosing chart for inhaled corticosteroids.										
1.5	Effective Date: 12/05/2019	Updated to include Fasenra self-administered product										
1.4	Effective Date: 11/07/2019	Criteria update to authorization period. Also changed language to FDA approved age.										
1.3	Effective Date: 08/15/2019	Updated criteria to account for new self-injectable Nucala formulation										
1.2	Effective Date: 05/09/2019	Annual Review of Medical Policy										
1.1	Effective Date: 08/07/2018	UM medical management system update for BCNA and MAPPO <table border="1" data-bbox="496 984 1377 1194"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <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> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
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1.0	Effective Date: 05/03/2018	New Drug Review <table border="1" data-bbox="496 1278 1377 1488"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <tr> <td>BCBS</td> <td>Yes</td> </tr> <tr> <td>BCN</td> <td>Yes</td> </tr> <tr> <td>MAPPO</td> <td>No</td> </tr> <tr> <td>BCNA</td> <td>No</td> </tr> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
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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>.