

## Clinical Policy: Fluticasone/Vilanterol (Breo Ellipta)

Reference Number: IL.PMN.229

Effective Date: 3.13.20

Last Review Date: 6.30.21

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Fluticasone/vilanterol (Breo Ellipta<sup>®</sup>) is a combination product containing a corticosteroid and a long acting beta-2 agonist.

### FDA Approved Indication(s)

Breo Ellipta is indicated for the:

- Once-daily treatment of asthma in patients aged 18 years and older
- Long-term, once-daily, maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD)

Limitation(s) of use: Breo Ellipta is not indicated for relief of acute bronchospasm.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Breo Ellipta is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Asthma and Chronic Obstructive Pulmonary Disease (must meet all):

1. Diagnosis of asthma or COPD;
2. Age  $\geq$  18 years;
3. Failure of at least TWO of the following: Symbicort, Wixela, Bevespi or Dulera at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed (a or b):
  - a. Asthma: 1 inhalation of 200 mcg fluticasone/25 mcg vilanterol per day (60 blisters every 30 days);
  - b. COPD: 1 inhalation of 100 mcg fluticasone/25 mcg vilanterol per day (60 blisters every 30 days).

**Approval duration: 12 months**

##### B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

## II. Continued Therapy

### A. Asthma and Chronic Obstructive Pulmonary Disease (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed (a or b):
  - a. Asthma: 1 inhalation of 200 mcg fluticasone/25 mcg vilanterol per day (60 blisters every 30 days);
  - b. COPD: 1 inhalation of 100 mcg fluticasone/25 mcg vilanterol per day (60 blisters every 30 days).

**Approval duration: 12 months**

### B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.  
**Approval duration: Duration of request or 12 months (whichever is less);** or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

## III. Diagnoses/Indications for which coverage is NOT authorized:

- ### A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

## IV. Appendices/General Information

### Appendix A: Abbreviation/Acronym Key

COPD: chronic obstructive pulmonary disease

FDA: Food and Drug Administration

### Appendix B: Therapeutic Alternatives

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
fluticasone/ salmeterol (Wixela)	Asthma: 1 inhalation BID (starting dosage is based on asthma severity)	Asthma: 500/50 mcg BID
	COPD: 1 inhalation of 250/50 mcg BID	COPD: 250/50 mcg BID

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): primary treatment of status asthmaticus or acute episodes of asthma or COPD requiring intensive measures, hypersensitivity to milk proteins or any ingredient
- Boxed warning(s): none reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Asthma	1 inhalation of 100/25 or 200/25 mcg QD	200/25 mcg/day
COPD	1 inhalation of 100/25 mcg QD	100/25 mcg/day

**VI. Product Availability**

Foil blister strips with inhalation powder containing fluticasone/vilanterol: 100/25 mcg, 200/25 mcg

**VII. References**

1. Breo Ellipta Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; January 2019. Available at <http://www.mybreo.com>. Accessed June 30, 2021.
2. National Heart, Lung, and Blood Institute. Expert panel report 3: guidelines for the diagnosis and management of asthma. National Asthma Education and Prevention Program. Published August 28, 2007. Available from: <http://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines/full-report/>. Accessed October 29, 2020.
3. Global Initiative for Asthma (GINA): Global strategy for asthma management and prevention (2020 report). Available from: [www.ginasthma.org](http://www.ginasthma.org). Accessed October 29, 2020.
4. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2020 report). Published November 2019. Available at: <http://www.goldcopd.org>. Accessed October 29, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created, adapted from CP.PMN.229 Fluticasone-vilanterol (Breo Ellipta) for HFS PDL.	3.13.20	
2Q 2021 Annual Review; Removed generic Advair and added Wixela; Reviewed and updated reference	6.30.21	

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical

practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note:**

**For Medicaid members,** when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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