

Clinical Policy: Fluticasone/vilanterol (Breo Ellipta)

Reference Number: ERX.NPA.32

Effective Date: 12.01.15

Last Review Date: 08.17

[Revision Log](#)

See **Important Reminder** at the end of this policy for important regulatory and legal information.

Description

Fluticasone/vilanterol (Breo[®] Ellipta[®]) is a combination of fluticasone furoate, an inhaled corticosteroid (ICS), and vilanterol, a long-acting beta₂-adrenergic agonist (LABA).

FDA approved indication

Breo Ellipta is indicated:

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

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

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Breo Ellipta is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of COPD;
2. Age ≥ 18 years;
3. Failure of one of the following (a or b) at up to maximally indicated doses, unless all are contraindicated or clinically significant adverse effects are experienced:
 - a. One LABA (e.g., Serevent) and one long-acting anticholinergic (LAA) (e.g., Arcapta, Spiriva);
 - b. One ICS in combination with a LABA (e.g., fluticasone/salmeterol [Advair]);
4. An inhaled LABA, ICS/LABA combination, or LAA must have been used in the last 60 days, unless all agents are contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 1 inhalation/day (1 inhaler/month).

Approval duration: 12 months

B. Asthma (must meet all):

1. Diagnosis of asthma;
2. Age ≥ 18 years;
3. Failure of fluticasone/salmeterol (Advair) and mometasone/formoterol (Dulera) at up to maximally indicated doses, unless both are contraindicated or clinically significant adverse effects are experienced;
4. Use of Advair or Dulera in the last 60 days as evidenced by pharmacy claims, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 1 inhalation/day (1 inhaler/month).

Approval duration: 12 months

C. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. All Indications in Section I (must meet all):

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions 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 1 inhalation/day (1 inhaler/month).

Approval duration: 12 months

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.**

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

COPD: chronic obstructive pulmonary disease

FDA: Food and Drug Administration

ICS: inhaled corticosteroid

LAA: long-acting anticholinergic

LABA: long-acting beta agonist

Appendix B: Therapeutic Alternatives

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
Spiriva® (tiotropium)	2 inhalations PO QD	2 inhalations/day
Serevent® (salmeterol)	1 inhalation BID	2 inhalations/day
Arcapta® (indacaterol)	75 mcg (1 capsule) via inhalation QD	1 inhalation (1 capsule)/day
Advair® (fluticasone/salmeterol)	1 inhalation PO BID	2 inhalations/day
Dulera® (mometasone/formoterol)	2 inhalations PO BID	4 inhalations/day

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Asthma, COPD	1 inhalation PO QD	1 inhalation/day

Product Availability

Inhalation powder inhaler: contains 2 foil blister strips of powder formulation for oral inhalation; one strip contains fluticasone furoate 100 or 200 mcg per blister and the other contains vilanterol 25 mcg per blister

VI. References

1. Breo Ellipta Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; May 2017. Available at: www.mybreo.com. Accessed July 2017.

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 July 2017.
3. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease, updated 2017. Available from: <http://goldcopd.org/>. Accessed July 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.15	12.15
Updated to new template (added background and references). Modified ICS/LABA trial duration from 12 weeks to 6 weeks per literature review.	07.16	09.16
<ul style="list-style-type: none"> - Converted to new template. - Updated maximum dosing limits. - Updated required alternatives for COPD to reflect GOLD guidelines. - Removed trial durations and instead required that preferred drugs be trialed at up to maximally indicate doses. 	07.16.17	08.17

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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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