Clinical Policy: Fluticasone/Vilanterol (Breo Ellipta)

Reference Number: IL.ERX.PMN.229
Effective Date: 06.01.21
Last Review Date: 05.21
Line of Business: Illinois Medicaid

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 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 Envolve Pharmacy Solutions 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 ≥ 18 years;
3. Failure of at least TWO of the following: fluticasone/salmeterol (generic Advair Diskus®), Symbicort, 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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Asthma and Chronic Obstructive Pulmonary Disease (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 (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 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

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 (Advair Diskus)	Asthma: 1 inhalation BID (starting dosage is based on asthma severity COPD: 1 inhalation of 250/50 mcg BID	Asthma: 500/50 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/salmeterol: 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 December 10, 2019.
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 December 10, 2019.
3. Global Initiative for Asthma (GINA): Global strategy for asthma management and prevention (2019 report). Available from: www.ginasthma.org. Accessed December 10, 2019.
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 December 10, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04.15.21	05.21

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.

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.