Breo Ellipta (fluticasone furoate/vilanterol)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Breo Ellipta® prior authorization program is to ensure appropriate selection of patients based on product labeling and/or clinical guidelines and/or clinical studies.

Breo Ellipta® contains both fluticasone furoate and vilanterol. Fluticasone furoate is an inhaled corticosteroid (ICS) that exerts its therapeutic effects by reducing chronic airway inflammation. Vilanterol is a long acting beta agonist (LABA) that works to relax bronchial smooth muscles causing bronchodilation.

FDA-APPROVED INDICATIONS

Maintenance Treatment of Chronic Obstructive Pulmonary Disease

Breo Ellipta 100/25 is a combination inhaled corticosteroid/long-acting beta2-adrenergic agonist (ICS/LABA) indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema. Breo Ellipta 100/25 is also indicated to reduce exacerbations of COPD in patients with a history of exacerbations. Breo Ellipta 100/25 once daily is the only strength indicated for the treatment of COPD.

Important Limitation of Use: Breo Ellipta is NOT indicated for the relief of acute bronchospasm.

Treatment of Asthma

Breo Ellipta is a combination ICS/LABA indicated for the once-daily treatment of asthma in patients aged 18 years and older.

LABA, such as vilanterol, one of the active ingredients in Breo Ellipta, increase the risk of asthma-related death. Available data from controlled clinical trials suggest that LABA increase the risk of asthma-related hospitalization in pediatric and adolescent patients. Therefore, when treating patients with asthma, physicians should only prescribe Breo Ellipta for patients not adequately controlled on a long-term asthma control medication, such as an inhaled corticosteroid, or whose disease severity clearly warrants initiation of treatment with both an inhaled corticosteroid and a LABA. Once asthma control is achieved and maintained, assess the patient at regular intervals and step down therapy (e.g., discontinue Breo Ellipta) if possible without loss of asthma control and maintain the patient on a long-term asthma control medication, such as an inhaled corticosteroid. Do not use Breo Ellipta for patients whose asthma is adequately controlled on low- or medium-dose inhaled corticosteroids.
Important Limitation of Use: Breo Ellipta is NOT indicated for the relief of acute bronchospasm.

**POLICY**

**CRITERIA FOR APPROVAL**

Breo Ellipta will be covered with prior authorization when the following criteria are met:

- Breo Ellipta 100/25 is being prescribed for chronic obstructive pulmonary disease (COPD)
- OR
- Breo Ellipta is being prescribed for asthma in a patient aged 18 years or older
- AND
- The patient has asthma that cannot be adequately controlled on other long-term asthma control medication, such as an inhaled corticosteroid

Prior approval is required. [Submit a prior approval/treatment request now.](#)

**Quantity Limits Apply:** 1 inhaler per 30 days or 3 inhalers per 90 days

**PROCEDURES AND BILLING CODES**

*To report provider services, use appropriate CPT* codes, *Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.*

- No applicable codes

**REFERENCES**


**POLICY HISTORY**

Policy #: 05.01.48  
Policy Creation: September 2011  
Reviewed: September 2016  
Revised: June 2016  
Current Effective Date: July 21, 2016