Health and Community Services

FLUTICASONE FUROATE/VILANTEROL (BREO ELLIPTA *100mcg/25mcg and 200mcg/25mcg dry powder for inhalation*)

Reversible Obstructive Airway Disease (Asthma) (**100mcg/25mcg, 200mcg/25mcg**):

For treatment of moderate to severe asthma in patients in whom:

- are compliant with inhaled corticosteroids at optimal doses; and
- require additional symptom control, (e.g., cough, awakening at night, missing activities such as school, work or social activities because of asthma symptoms); and
- require increasing amounts of short-acting beta$_2$-agonists, indicative of poor control
- Dosage approved: One inhalation once daily
- 100mcg/25mcg, 200mcg/25mcg dry powder for inhalation

Chronic Obstructive Pulmonary Disease (COPD) (**100mcg/25mcg only**):

For the treatment of COPD, as defined by spirometry[1]:

- When the LABA/ICS is part of **triple therapy** in patients with COPD.

  Triple therapy: Combination therapy with LAAC/LABA/ICS will be considered for the treatment of COPD, as defined by spirometry in patients who have inadequate control[2] while being treated with a LAAC/LABA combination for at least 2 months.

OR

- In patients with **asthma/COPD (ACO) overlap** based on patient history and lung function studies indicating an ACO diagnosis
  - Please provide details to support the ACO diagnosis (patient symptoms, risk factors, spirometry etc).

1. COPD diagnosis is defined by spirometry as a post bronchodilator $FEV_1/FVC < 0.7$. Spirometry from any point in time will be considered.

   In the rare occasion when spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding COPD severity must be provided for consideration (i.e., Medical Research Council (MRC) dyspnea scale score of at least Grade 3. MRC Grade 3 is described as: walks slower than people of the same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level because of COPD.

2. Inadequate control is defined as persistent symptoms or experiencing 2 or more exacerbations of COPD in the previous year requiring treatment with antibiotics

and/or systemic corticosteroids or at least 1 severe exacerbation of COPD requiring hospitalization.

Clinical Notes

Triple therapy COPD:

- Patients should not be started on triple inhaled therapy as initial therapy for COPD.
- LAAC coverage will be provided for the previously used LAAC/LABA combination product unless otherwise indicated on the special authorization request.

Asthma/COPD overlap (ACO):

- Inadequate control is defined as persistent symptoms (ex. cough, sputum, dyspnea) or experiencing 2 or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least 1 exacerbation of COPD requiring hospitalization.
- Please provide details to support the ACO diagnosis (patient symptoms, risk factors, spirometry etc).
- Coverage will be provided for Breo Ellipta 100mcg/25mcg.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Chronic-Obstructive-Pulmonary-Disease-Form.pdf

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