

P.E.I. Pharmacare Bulletin

Issue (2019-7)

Effective immediately the criteria for Chronic Obstructive Pulmonary Disease Medications listed below will be as follows:

Chronic Obstructive Pulmonary Disease Medications

- Acclidinium Bromide, aerosol powder for inhalation, 400ug/dose (Tudorza Genuair-ALM)**
- Fluticasone Furoate/Vilanterol, blister with inhalation device, 100mcg-25mcg/dose (Breo Ellipta-GSK)**
- Formoterol Fumerate, powder for inhalation (capsule), 12ug/dose (Foradil-NVR); powder for inhalation (inhaler), 6ug/dose, 12ug/dose (Oxeze Turbuhaler-AZE)**
- Formoterol & Budesonide, powder for inhalation, 6ug & 100ug per dose, 6ug & 200ug per dose (Symbicort Turbuhaler-AZE)**
- Glycopyrroonium Bromide, capsule for inhalation, 50mcg (Seebri Breezhaler-NVR)**
- Indacaterol, capsule, inhalation powder, 75mcg (Onbrez-NVR)**
- Salmeterol Xinafoate, aerosol powder disk, 50µg/dose (Serevent Diskus-GSK)**
- Salmeterol & Fluticasone, aerosol inhalation, 25ug & 125ug per dose, 25ug & 250ug per dose (Advair-GSK); inhaled powder disk, 50ug & 100ug per dose, 50ug & 250ug per dose, 50ug & 500ug per dose (Advair Diskus- GSK)**
- Tiotropium, capsule for inhalation, 18ug/dose (Spiriva-BOE)**
- Tiotropium, mist inhaler, 2.5ug/dose (Spiriva Respimat-BOE)**
- Umeclidinium Bromide, blister with inhalation device, 62.5mcg (Incruse Ellipta-GSK)**

Table 1 (of 3)

LABA	LAAC
Formoterol fumarate dehydrate (Oxeze Turbuhaler)	Acclidinium (Tudorza Genuair)
Formoterol fumarate (Foradil)	Glycopyrroonium Bromide (Seebri)
Indacaterol maleate (Onbrez)	Tiotropium (Spiriva) 18mcg; (Spiriva Respimat) 2.5mcg
Salmeterol (Serevent)	Umeclidinium Bromide (Incruse Ellipta)

For any one agent listed in Table 1:

For the treatment of chronic obstructive pulmonary disease (COPD) as defined by spirometry¹ in patients

AND

- Experiencing persistent symptoms, as defined by Medical Research Council (MRC) score of at least 3² or a COPD Assessment test (CAT) score ≥ 10 ³ and a post-bronchodilator FEV₁ < 80% predicted

OR

- Experiencing 2 or more moderate exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids OR at least 1 acute severe exacerbation of COPD (AECOPD) requiring hospitalization..

NOTE: Coverage for both a LABA and a LAAC as separate inhalers will not be considered. See below for combination LABA/LAAC coverage criteria.

Table 2 (of 3)

LABA/LAAC
Acclidinium Bromide & Formoterol Fumarate Dihydrate (Duaklir Genuair)
Indacaterol/Glycopyrronium (Ultibro Breezhaler)
Tiotropium/Olodaterol (Inspiroto Respimat)
Umeclidinium Bromide & Vilanterol Trifenatate (Anoro Ellipta)

For any one agent listed in Table 2:

- For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry¹, in patients with inadequate control⁴ with either a long-acting beta-2 agonist (LABA) or long-acting anticholinergic (LAAC).

Coverage for both a LABA and a LAAC as separate inhalers will not be considered. LABA/LAAC inhalers are not intended to be used in combination with an inhaled corticosteroid (ICS) unless criteria for triple therapy⁵ is fulfilled.

Table 3 (of 3)

LABA/ICS
Budesonide/ formoterol (Symbicort)
Fluticasone/vilanterol (Breo Ellipta)
Salmeterol /fluticasone (Advair)

For any one agent listed in Table 3:

- For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry¹
AND
- When the LABA/ICS is part of triple therapy⁵ in patients with COPD
OR
- In patients with asthma/COPD (ACO) overlap, based on patient history and lung function studies indicating an ACO diagnosis

Clinical Notes:

- 1.COPD is defined by spirometry as a post bronchodilator FEV₁/FVC ratio of < 0.70. Spirometry reports from any point in time will be accepted.
- 2.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.
- 3.The COPD assessment test (CAT) is an 8-item tool for measuring health status impairment with scores from 0-40. It is available online at <http://www.catestonline.org/images/pdfs/CATest.pdf>
4. Inadequate control is defined as persistent symptoms after at least 1 month of long- acting beta-agonist (LABA) or long-acting anticholinergic therapy (LAAC); and an MRC² score of at least 3 or a CAT score $\geq 10^3$.
- 5.Triple therapy criteria:
Combination therapy with LABA/LAAC/ICS will be considered for patients who experience inadequate control (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 exacerbation requiring hospitalization) while being treated with a LABA/LAAC combination for at least two months.