

# Drug Coverage Decision for B.C. PharmaCare

## About PharmaCare

B.C. PharmaCare is a government-funded drug plan. It helps British Columbians with the cost of eligible prescription drugs and specific medical supplies.

## Details of Drug Reviewed

Drug and Brand Name	Dosage Form	Manufacturer
<b>Long Acting Muscarinic Antagonists (LAMAs)</b>		
Acidinium (Tudorza® Genuair®)	400 mcg dry powder for oral inhalation	AstraZeneca Canada
glycopyrronium (Seebri® Breezhaler®)	50 mcg dry powder for oral inhalation	Novartis Pharmaceuticals Canada Inc.
tiotropium (Spiriva® Handihaler®)	18 mcg dry powder for oral inhalation	Boehringer-Ingelheim (Canada) Ltd.
tiotropium (Spiriva® Respimat®)	2.5 mcg solution for oral inhalation	Boehringer-Ingelheim (Canada) Ltd.
umeclidinium (Incruse® Ellipta®)	62.5 mcg dry powder for oral inhalation	GlaxoSmithKline Inc.
<b>Long Acting Beta2 Agonists (LABAs)</b>		
indacaterol (Onbrez® Breezhaler®)	75 mcg dry powder for oral inhalation	Novartis Pharmaceuticals Canada Inc.
salmeterol (Serevent® Diskus®)	50 mcg dry powder for oral inhalation	GlaxoSmithKline Inc.
<b>Combination Therapies (LAMA-LABA)</b>		
aclidinium-formoterol (Duaklir® Genuair®)	400 mcg/12 mcg dry powder for oral inhalation	AstraZeneca Canada
glycopyrronium-indacaterol (Ultibro® Breezhaler®)	50 mcg/110 mcg dry powder for oral inhalation	Novartis Pharmaceuticals Canada Inc.
tiotropium-olodaterol (Inspiolto® Respimat®)	2.5 mcg/2.5 mcg solution for oral inhalation	Boehringer-Ingelheim (Canada) Ltd.

umeclidinium-vilanterol (Anoro Ellipta)	62.5 mcg/25 mcg dry powder for oral inhalation	GlaxoSmithKline Inc.
<b>Inhaled Corticosteroid (ICS) Containing Combination Therapies (ICS-LABA)</b>		
fluticasone furoate-vilanterol (Breo Ellipta)	100 mcg/25 mcg dry powder for oral inhalation	GlaxoSmithKline Inc.
fluticasone propionate-salmeterol (Advair Diskus)	250 mcg/50 mcg and 500 mcg/50 mcg dry powder for oral inhalation	GlaxoSmithKline Inc.
<b>Triple Therapy (ICS-LAMA-LABA)</b>		
fluticasone furoate-umeclidinium-vilanterol (Trelegy Ellipta)	100 mcg/62.5 mcg/25 mcg dry powder for oral inhalation	GlaxoSmithKline Inc.
<b>Submission Type</b>	<b>Therapeutic Review</b>	
Use Reviewed	Chronic obstructive pulmonary disease (COPD)	
Common Drug Review (CDR)	<b>The CDR has reviewed several of the inhalers as individual submissions.</b> Visit the CDR website for more details: <a href="https://www.cadth.ca/about-cadth/what-we-do/products-services/cdr/reports">https://www.cadth.ca/about-cadth/what-we-do/products-services/cdr/reports</a> .	
Drug Benefit Council (DBC)	The DBC met on July 8, 2019. The DBC considered various inputs including: clinical evidence documents (e.g. Common Drug Review clinical and pharmacoeconomic review reports, and the Therapeutics Initiative); guideline documents; reports from other health technology assessment agencies (e.g. the Ontario Drug Policy Research Network and the Singapore Ministry of Health); Clinical Practice Reviews from two specialists and a general physician; manufacturer inputs; and Patient Input from 19 patients, 14 caregivers and 3 patient groups; and a budget impact assessment.	
<b>Drug Coverage Decision</b>	<p>The Ministry decided to make the following changes to coverage of COPD inhalers:</p> <ul style="list-style-type: none"> <li>improve access to LAMAs by making Spiriva Respimat and Incruse Ellipta Regular Benefits;</li> <li>modify Limited Coverage criteria for other LAMAs, LABAs, LAMA-LABAs and ICS-LABAs</li> <li>list Trelegy Ellipta as a Limited Coverage benefit.</li> </ul> <p>Access the Limited Coverage criteria from <a href="http://www.gov.bc.ca/pharmacarespecialauthority">www.gov.bc.ca/pharmacarespecialauthority</a></p>	
Date	July 7, 2020	
Reason(s)	<p><b>Drug coverage is consistent with the DBC recommendation.</b></p> <ul style="list-style-type: none"> <li>There is evidence to use single long-acting bronchodilators as preferred initial therapy for patients with COPD.</li> <li>There is some evidence favouring LAMAs over LABAs in reducing the risk of exacerbations and hospitalizations in patients with COPD.</li> <li>There is no published evidence that one LAMA is superior to another LAMA.</li> <li>Regular treatment with ICS increases the risk of pneumonia especially in those with severe disease.</li> </ul>	

	<ul style="list-style-type: none"> <li>• There is an absence of high quality evidence regarding the effect of intensifying inhaled therapy (e.g. progressing to a LAMA+LABA or an ICS+LAMA+LABA combination) on health-related quality of life and on the risk of exacerbations and death. The true effects of intensifying therapy cannot be firmly estimated.</li> <li>• There is evidence that LAMA-LABA results in fewer exacerbations, a lower risk of pneumonia, and improvement in quality of life when compared to ICS-LABA.</li> <li>• Based on the Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2020 guideline and evidences that ICS-containing regimens should be reserved only for patients at high risk of exacerbations (e.g. GOLD D patients) who do not show a reduction in exacerbations while on LAMAs or LAMA-LABAs.</li> <li>• The budget impact to list LAMAs as a regular benefit is significant, and to mitigate the cost impact of the LAMAs, the Ministry addressed the cost concerns through a competitive value process (CVP). The Ministry and the manufacturers were able to address the DBC concerns regarding the budget impact to list the successful LAMA inhalers as regular benefits.</li> </ul> <p>Listing Spiriva Respimat and Incruse Ellipta as regular benefits will allow patients to choose between a soft mist inhaler (SMI) and a dry powder inhaler (DPI). The budget impact to list LAMAs as a regular benefit is significant, and to mitigate the cost impact of the LAMAs, the Ministry addressed the cost concerns through a competitive value process (CVP).</p>
<p>Other Information</p>	<p>COPD inhalers webpage: <a href="https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/prescribers/copd-inhaler-criteria">https://www2.gov.bc.ca/gov/content/health/practitioner-professional-resources/pharmacare/prescribers/copd-inhaler-criteria</a></p> <p>The DBC recommendations and the evidence reviewed by the DBC are shared on the website at <a href="https://www2.gov.bc.ca/assets/gov/health/health-drug-coverage/pharmacare/2019-07-08_copd_dbc_recommendation.pdf">https://www2.gov.bc.ca/assets/gov/health/health-drug-coverage/pharmacare/2019-07-08_copd_dbc_recommendation.pdf</a></p> <p>BC Provincial Academic Detailing Services COPD update on February 2017—focus on intensifying LABA, LAMA and ICS therapy: <a href="https://www2.gov.bc.ca/assets/gov/health/practitioner-pro/provincial-academic-detailing-service/copd_update.pdf">https://www2.gov.bc.ca/assets/gov/health/practitioner-pro/provincial-academic-detailing-service/copd_update.pdf</a></p> <p>February 2019 Therapeutics Initiative update #2: <a href="https://www2.gov.bc.ca/assets/gov/health/health-drug-coverage/pharmacare/2019-02-28_abc_ti_report_copd.pdf">https://www2.gov.bc.ca/assets/gov/health/health-drug-coverage/pharmacare/2019-02-28_abc_ti_report_copd.pdf</a></p> <p>Canadian Thoracic Society (CTS) 2019 guidelines: <a href="https://cts-sct.ca/guideline-library/">https://cts-sct.ca/guideline-library/</a></p> <p>Global Initiative for Chronic Obstructive Lung Disease 2020 guidelines: <a href="https://goldcopd.org/gold-reports/">https://goldcopd.org/gold-reports/</a></p>

### The Drug Review Process in B.C.

A manufacturer submits a request to the Ministry of Health (Ministry).

An independent group called the [Drug Benefit Council \(DBC\)](#) gives advice to the Ministry. The DBC looks at:

- whether the drug is safe and effective
- advice from a national group called the [Common Drug Review \(CDR\)](#)
- what the drug costs and whether it is a good value for the people of B.C.
- ethical considerations involved with covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes PharmaCare coverage decisions by taking into account:

- the existing PharmaCare policies, programs and resources
- the evidence-informed advice of the DBC
- the drugs already covered by PharmaCare that are used to treat similar medical conditions
- the overall cost of covering the drug

Visit [The Drug Review Process in B.C. - Overview](#) and [Ministry of Health - PharmaCare](#) for more information.

**This document is intended for information only.**

It does not take the place of advice from a physician or other qualified health care provider.