BRITISH COLUMBIA | Ministry of Health

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	**indacaterol – mometasone furoate**
Brand Name	Atectura® Breezhaler®
Dosage Form	150 mcg indacaterol – 80 mcg mometasone furoate 150 mcg indacaterol – 160 mcg mometasone furoate 150 mcg indacaterol – 320 mcg mometasone furoate
Manufacturer	Valeo Pharma Inc.
Submission Type	**New Submission**
Use Reviewed	For the maintenance treatment of asthma in adults and adolescents 12 years of age and older with reversible obstructive airways disease.
Common Drug Review (CDR)	Yes, CDR recommended: **to Reimburse with clinical criteria and/or conditions**. Visit the CDR website for more details: https://www.cadth.ca/sites/default/files/cdr/complete/SR0646%20Atectura%20Breezhaler%20-%20CDEC%20Final%20CDEC%20Recommendation%20November%2026%2C%202020_for%20posting.pdf
Drug Benefit Council (DBC)	The DBC met on January 4, 2021. DBC considered various inputs including: the final reviews completed by the CDR on November 24, 2020, which included clinical and pharmacoeconomic evidence review material and the recommendations from the Canadian Drug Expert Committee (CDEC); no Patient Input Questionnaire responses from patients, caregivers, or patient groups were received, as such, the DBC instead considered patient input provided to the CDR; Clinical Practice Reviews from two specialists; and a Budget Impact Assessment.
Drug Coverage Decision	**Limited Coverage Benefit. Access the indacaterol – mometasone furoate criteria from www.gov.bc.ca/pharmacarespecialauthority**
Date	June 14, 2022

Reasons	**Drug coverage decision is consistent with the CDEC and DBC recommendation.** • The drug demonstrated some advantage over mometasone furoate alone with respect to efficacy. • There is no evidence that the combination of indacaterol-mometasone furoate is clinically superior to other combinations of inhaled corticosteroid with a long-acting beta-agonist. • The Ministry of Health was able to address the concerns identified by the CDEC and DBC with respect to the cost effectiveness and value for money.
Other Information	None

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.

Appendix

Drug Benefit Council (DBC) Recommendation and Reasons for Recommendation

FINAL

Indacaterol-mometasone furoate (Atectura® Breezhaler®)
Manufacturer

Description:
Drug review of **indacaterol-mometasone furoate (Atectura® Breezhaler®)** for the following Health Canada approved indications:

For the once-daily maintenance treatment of asthma in adults and adolescents.

In their review, the DBC considered the following: the final reviews completed by the Common Drug Review (CDR) on November 24, 2020, which included clinical and pharmacoeconomic evidence review material and the recommendations from the Canadian Drug Expert Committee (CDEC). The DBC received no Patient Input Questionnaire responses from patients, caregivers, or Patient Groups. The DBC also considered patient input provided to the CDR, Clinical Practice Reviews from two specialists, and a Budget Impact Assessment.

Dosage Forms:
Atectura® Breezhaler® is available as indacaterol-mometasone furoate 150-80 mcg, 150-160 mcg, and 150-320 mcg hard capsules with inhalation powder.

Recommendations:
1. The Drug Benefit Council (DBC) recommends not to list indacaterol-mometasone furoate (Atectura® Breezhaler®) at the submitted price.

Of Note:
- If an acceptable price reduction is achieved, indacaterol-mometasone furoate (Atectura® Breezhaler®) may be listed in a similar manner to other inhaled corticosteroid (ICS)-long-acting beta-agonist (LABA) combination products.

Reasons for the Recommendation:
1. Summary
- In two randomized controlled trials (RCTs), indacaterol-mometasone furoate demonstrated improvement in asthma control and lung function at week 26 in one RCT and at week 12 in the other as compared with mometasone furoate alone.
- There is no evidence that the combination of indacaterol-mometasone furoate is clinically superior to other combinations of ICS/LABA.

- At the manufacturer submitted price, the 150 mcg-80 mcg and 150 mcg-160 mcg indacaterol-mometasone furoate dosages are not cost-effective for individuals requiring a low or medium-dose ICS-LABA combination.
- Only the 150 mcg-320 mcg dosage may be cost saving for patients who require a high-dose ICS/LABA combination.

2. Clinical Efficacy

- The DBC considered the CDR systematic review, which included two double-blind, parallel-group, double- or triple-dummy randomized controlled trials (RCTs) of patients with asthma: the QUARTZ and PALLADIUM trials.
- In QUARTZ, patients were randomized at a 1:1 ratio to indacaterol-mometasone furoate 150 mcg-80 mcg once daily or mometasone furoate 200 mcg once daily.
- In PALLADIUM, patients were randomized at a ratio of 1:1:1:1:1 to one of five treatment groups: indacaterol-mometasone furoate 150 mcg-160 mcg once daily, indacaterol-mometasone furoate 150 mcg-320 mcg once daily, mometasone furoate 400 mcg once daily, mometasone furoate 800 mcg once daily, or salmeterol xinafoate-fluticasone propionate (salmeterol-fluticasone propionate) 50 mcg-500 mcg twice daily.
- The primary outcome in both trials was the change from baseline in trough forced expiratory volume in one second (FEV1) at week 12 in QUARTZ and week 26 in PALLADIUM for indacaterol-mometasone furoate versus mometasone furoate.
- Indacaterol-mometasone furoate, as compared with mometasone furoate alone, demonstrated improvement in asthma control (measured by the change in Asthma Control Questionnaire [ACQ-7] score) and lung function (measured by the change in trough FEV1) at week 26 in PALLADIUM and at week 12 in the QUARTZ.
- QUARTZ and PALLADIUM demonstrated an improvement in the change from baseline in trough FEV1 with indacaterol-mometasone furoate that was statistically significant, with treatment group differences corresponding to low-, medium-, and high-dose indacaterol-mometasone furoate versus mometasone furoate comparisons, respectively, compared with mometasone furoate. The treatment group difference was maintained at week 52 for the medium and high dose strengths in PALLADIUM.
- The comparative evidence between indacaterol-mometasone furoate and other available ICS-LABA fixed-dose treatments comes from a secondary comparison (without multiplicity adjustment) in PALLADIUM, which indicated that indacaterol-mometasone furoate 150 mcg-320 mcg daily was noninferior to salmeterol-fluticasone propionate 50 mcg-500 mcg twice daily for improving pulmonary function (as measured by FEV1) at week 26.
- For detailed information on the systematic review of indacaterol-mometasone furoate please see the CDEC Final Recommendation at: https://www.cadth.ca/indacaterol-mometasone-furoate.

3. Safety

- Reported serious adverse events were infrequent in QUARTZ and ranged from 5.0% to 8.0% among treatment groups in PALLADIUM trial (approximately 5% in all treatment groups, except for mometasone furoate 400 mcg, which was 8.0%). The most common reason for a serious adverse event or withdrawal due to an adverse event in both studies was asthma, which occurred in less than 2% of patients in each treatment group.

- One death was reported between the two included studies, which occurred in an adolescent patient in the mometasone furoate 400 mcg treatment group of the PALLADIUM trial. The cause of death was determined by an independent adjudication committee to be due to asthma exacerbation.
- In general, the occurrence of specific adverse events was infrequent and did not suggest any imbalances between treatment groups.
- For detailed information on the safety and tolerability of indacaterol-mometasone furoate, please see the CDEC Final Recommendations at the link above.

4. Economic Considerations

- The CDR reanalysis of the manufacturer submission reported that indacaterol-mometasone furoate 150 mcg-80 mcg and 150 mcg-160 mcg are not cost-effective at a $50,000 willingness-to-pay threshold for individuals requiring low and medium-dose ICS-LABA. For those who require high-dose ICS/LABA, indacaterol-mometasone furoate 150 mcg-320 mcg may be cost saving, providing similar health outcomes at a lower cost than high-dose ICS/LABA.

5. Of Note

- Patient input provided to the CDR noted that once-daily dosing of a combination product may be more convenient for patients requiring treatment with an ICS-LABA.
- Because differences between inhaler devices can affect how patients are able to achieve optimal asthma control and to reduce the occurrence of asthma exacerbations, training and education may be required to most effectively use the Breezhaler® device.