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 – glycopyrronium - mometasone furoate**
Brand Name	Enerzair® Breezhaler®
Dosage Form	150 mcg indacaterol – 50 mcg glycopyrronium - 160 mcg mometasone furoate
Manufacturer	Valeo Pharma Inc.
Submission Type	**New Submission**
Use Reviewed	For the maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta2-agonist and a medium or high dose of an inhaled corticosteroid who experienced one or more asthma exacerbations in the previous 12 months.
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/SR0645%20Enerzair%20Breezhaler%20-%20CDEC%20Final%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 – glycopyrronium - 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 indacaterol – mometasone furoate with respect to efficacy. • The drug was similar to salmeterol – fluticasone propionate plus tiotropium with respect to health-related quality of life. • The Ministry of Health was able to address the concerns identified by the CDEC and DBC with respect to 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-glycopyrronium-mometasone furoate (Enerzair® Breezhaler®)
Novartis Pharmaceuticals Canada Inc.

Description:

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

> For the maintenance treatment of asthma in adult patients not adequately controlled with a maintenance combination of a long-acting beta2-agonist (LABA) and a medium or high dose of an inhaled corticosteroid (ICS) who experienced one or more asthma exacerbations in the previous 12 months.

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, and instead considered patient input provided to the CDR. The DBC also considered Clinical Practice Reviews from two specialists, and a Budget Impact Assessment.

Dosage Forms:

Enerzair® Breezhaler® is available as indacaterol-glycopyrronium-mometasone furoate inhalation powder hard capsules 150 mcg-50 mcg-160 mcg.

Recommendations:

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

Of Note:

- The drug plan cost of treatment with indacaterol-glycopyrronium-mometasone furoate should not exceed the drug plan cost of the least costly currently reimbursed medium- or high-dose ICS and a LABA and a long-acting muscarinic antagonist (LAMA) used singly or in combination

Reasons for the Recommendation:

1. Summary

- In two randomized controlled trials (RCTs), treatment with indacaterol-glycopyrronium-mometasone furoate was associated with improved pulmonary function compared with indacaterol-mometasone furoate and was noninferior to salmeterol-fluticasone propionate plus tiotropium for improving health-related quality of life.
- There is limited comparative evidence between the indacaterol-glycopyrronium-mometasone furoate Breezhaler device and other available asthma inhaler devices.
- Indacaterol-glycopyrronium-mometasone furoate is less costly and about as effective as salmeterol/fluticasone propionate plus tiotropium. The lack of comparative efficacy evidence to other ICS/LABA plus LAMA treatments means the cost-effectiveness of indacaterol-glycopyrronium-mometasone furoate compared to these treatments could not be assessed.

2. Clinical Efficacy

- The DBC considered the CDR clinical review report, which included two RCTs: IRIDIUM and ARGON. IRIDIUM was a phase III multicenter, randomized, double-blind, double-dummy, parallel-group study with a total 52-week treatment period. ARGON was a phase IIIb multicenter, randomized, partially-blinded, parallel-group, noninferiority, open-label active-controlled study with a 24-week treatment period.
- The primary outcome for IRIDIUM was the change from baseline in trough forced expiratory volume in one second (FEV1) after 26 weeks, which was defined as the average of the two FEV1 measurements taken 23 hours 15 minutes and 23 hours 45 minutes after the evening dose of treatment.
- The primary outcome in ARGON was the change from baseline in the asthma quality of life questionnaire (AQLQ) total score at Week 24.
- IRIDIUM demonstrated that indacaterol-glycopyrronium-mometasone furoate 150 mcg-50 mcg-160 mcg was associated with improved pulmonary function (as measured using trough FEV1) compared with indacaterol-mometasone furoate 150 mcg-320 mcg at 26 weeks.
- ARGON demonstrated that indacaterol-glycopyrronium-mometasone furoate 150 mcg-50 mcg-160 mcg was noninferior to salmeterol-fluticasone propionate 50-500 mcg plus tiotropium 50 mcg for improving health-related quality of life (as measured by the AQLQ) at 24 weeks.
- For detailed information on the systematic review of indacaterol-glycopyrronium-mometasone furoate please see the CDEC Final Recommendation at: https://www.cadth.ca/indacaterol-glycopyrronium-mometasone-furoate.

3. Safety

- Overall, the frequency of adverse events, serious adverse events, and withdrawals from treatment due to adverse events did not suggest any imbalances between treatment groups in IRIDIUM and in ARGON.
- Seven deaths were reported between the two trials. None were caused by asthma-related events or considered by the investigators to be related to study drug.
- Infections (systemic and local) were the most frequently reported notable harm, followed by local systemic effects and cardiovascular disorders.
- Specific adverse events were infrequent and did not suggest any imbalances between treatment groups.
- For detailed information on the safety and tolerability of indacaterol-glycopyrronium-mometasone furoate, please see the CDEC Final Recommendations at the links above.

4. Economic Considerations

- The DBC considered the CADTH reanalysis of the manufacturer's submission. At the manufacturer-submitted price, indacaterol-glycopyrronium-mometasone furoate was less costly and about as effective as salmeterol-fluticasone propionate plus tiotropium.
- There is uncertainty around the cost-effectiveness of indacaterol-glycopyrronium-mometasone furoate relative to other ICS/LABA/LAMA treatments due to the lack of comparative efficacy evidence.
- To be cost-effective, indacaterol-glycopyrronium-mometasone furoate would need to be priced at or below the lowest cost ICS plus LABA plus LAMA alternative.

5. Of Note

- The DBC received no patient input responses, and instead considered patient input provided to the CDR. Patient respondents reported that asthma limited their daily activities and ability to be physically active, as well as their social activities and their attendance and performance at work and school.
- Patient responses indicated that difficulty using a device is a possible cause of nonadherence to proper administration, which may contribute to poor control of their disease. None of the patients reported having tried the Enerzair® Breezhaler® device.