



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	berotralstat
Brand Name	Orladeyo®
Dosage Form(s)	150mg capsule
Manufacturer	BioCryst Pharmaceuticals, Inc.
Submission Type	New Submission
Use Reviewed	Hereditary angioedema (HAE)
Canada's Drug Agency's Reimbursement Reviews (CRR)	Yes, the CRR recommended to Reimburse with clinical criteria and/or conditions . Visit the CRR website for more details .
Drug Benefit Council (DBC)	The Drug Benefit Council (DBC) now screens drug submissions under review by Canada's Drug Agency to determine whether or not a full DBC review is necessary, based on past DBC reviews, recommendations, and existing PharmaCare coverage. If a full DBC review is determined to not be required, the Ministry's drug coverage decision will be based on the CRR recommendation and an internal review only. The DBC advised that because berotralstat is similar to some of the other drugs used for the routine prophylaxis of HAE, the Ministry of Health based their decision on the CRR decision and their own internal review.
Drug Coverage Decision	Expensive Drugs for Rare Diseases (EDRD) Process
Date	November 7, 2024

Reason(s)	<p>Drug coverage decision is consistent with the CRR recommendation.</p> <ul style="list-style-type: none"> • Evidence from two studies suggests that berotralstat may reduce the number of HAE attacks. • Based on economic considerations and the submitted product price, the drug was not cost effective and did not offer optimal value for money. • B.C. participated in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer and the pCPA was able to address the concerns identified by Canada’s Drug Agency with respect to the cost-effectiveness and value for money. The negotiations concluded with an agreement on September 12, 2024.
Other Information	See the Canada’s Drug Agency Reimbursement Recommendation

The Drug Review Process in B.C.

A manufacturer submits a request to the Ministry of Health (the 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 [Canada’s Drug Agency \(CDA-AMC\) Reimbursement Reviews \(CRR\)](#)
- 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, 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.