BC PharmaCare Drug Information

The drug below is being considered for coverage under the BC PharmaCare program. PharmaCare is a government-funded drug plan that helps B.C. residents with the cost of eligible prescription drugs and medical supplies. For more information about PharmaCare, visit the PharmaCare website.

PharmaCare reviews each drug for treating a specific illness or medical condition (also called an "indication"). If PharmaCare decides to cover a drug, that coverage applies only to the indication(s) specified. In some cases, PharmaCare covers a drug only for people who have not responded to other drugs that treat the same indication.

More information about the PharmaCare drug review process is provided on the last page of this document.

Drug information	
Generic name (scientific name)	**berotralstat**
Brand name	**Orladeyo®**
Manufacturer	BioCryst Pharmaceuticals Inc.
Indication	For the routine prevention of attacks of hereditary angioedema (HAE) in adults and pediatric patients 2 years of age and older. Note: Indication under review includes pediatric patients 2 to less than 12 years of age.
Has the drug been reviewed by CDA-AMC, or will CDA-AMC be reviewing it? (See note below.)	Yes For more information about the CDA-AMC Reimbursement Review (CRR) of berotralstat (Orladeyo®), Search the CDA-AMC Reports.
Public input start date	Wednesday, **November 18**, 2026
Public input closing date	Tuesday, **December 15**, 2026, **at 11:59 pm**
How is the drug taken?	Berotralstat is taken orally (through the mouth).
How often is the drug taken?	Berotralstat is taken once per day.

Drug information	
General drug and/or drug study information	The Ministry of Health is reviewing berotralstat for the routine prevention of attacks of HAE in adults and pediatric patients 2 years of age and older. HAE is a rare condition caused by a deficiency or dysfunction of the C1 esterase inhibitor (C1-INH) protein. Without enough working C1-INH, the body produces excessive amounts of bradykinin. High levels of bradykinin make blood vessels leak fluid into surrounding tissues, causing the swelling and pain associated with HAE attacks. The swelling can affect the face, limbs, genitals, gastrointestinal tract, or throat which can be life-threatening. Berotralstat helps prevent HAE attacks by blocking plasma kallikrein. This reduces the production of bradykinin, helping prevent HAE attacks. Berotralstat is unique among HAE prophylactic treatments because it is taken orally once daily, while other preventative therapies require an injection. Berotralstat is also the first HAE treatment reviewed by the Ministry for those aged 2 to 11.
Other considerations	None

Note:
CDA-AMC (Canada's Drug Agency-L'Agence des Médicaments du Canada) is a national organization that reviews drugs on behalf of Canadian public sector plans when drug manufacturers want those plans to provide coverage for the drug. For detailed information about the PharmaCare drug review process, including the role of the CDA-AMC Reimbursement Review (CRR) in that process, visit How PharmaCare Decides Which Drugs to Cover.

Table of Comparators Used to Treat the Same Indication		
Generic Name (Brand Name) of Drug Comparator	**Dosage Form**	**PharmaCare Status (if and how the drug is already covered)**
berotralstat (Orladeyo)	Oral sachet	Under Review
Other long-term prophylactic therapies		

Table of Comparators Used to Treat the Same Indication		
Generic Name (Brand Name) of Drug Comparator	**Dosage Form**	**PharmaCare Status (if and how the drug is already covered)**
lanadelumab (Takhzyro)	Solution in syringe/pen/vial for subcutaneous injection	Exceptional, case-by-case coverage provided through the BC PharmaCare EDRD process for hereditary angioedema
C1 esterase inhibitor (Haegarda, Berinert)	Powder and diluent for solution for subcutaneous injection	Available through Canadian Blood Services
garadacimab (Andembry)	Solution in syringe/pen for subcutaneous injection	Non-benefit

The Drug Review Process in B.C.

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

An independent national organization called Canada's Drug Agency (CDA-AMC) provides evidence-based recommendations to public drug plans across Canada through its reimbursement review process.

As part of the CDA-AMC's Clinical Reimbursement Review process, the Canadian Drug Expert Committee (CDEC) makes reimbursement recommendations for non-oncology pharmaceuticals to the participating federal, provincial, and territorial publicly funded drug plans. In developing its recommendations, the CDEC considers:

- whether the drug is safe and effective
- what the drug costs and whether it is a good value to the citizens of B.C.
- ethical considerations related to covering or not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes a BC PharmaCare coverage decision by considering:

- existing BC PharmaCare policies, programs and resources
- the evidence-informed advice of the CDA-AMC
- the recommendations and reimbursement conditions of the CDEC
- if a Ministry Initiated review, the advice of an independent expert group called the Drug Benefit Council (DBC)
- BC-specific patient input collected through the Your Voice website
- drugs already covered by BC PharmaCare that treat similar medical conditions
- the overall cost of covering the drug

Visit BC PharmaCare and Drug reviews for more information.

This document provides information only.
It does not take the place of advice from a physician or other qualified health care provider.