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)	**leniolisib**
Brand name	**Joenja®**
Manufacturer	Pharming Technologies
Indication	For the treatment of activated phosphoinositide 3 kinase delta syndrome (APDS) in adults and adolescents 12 years of age and older.
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 leniolisib (TBC), Search the CDA-AMC Reports.
Public input start date	Wednesday, **July 29**, 2026
Public input closing date	Tuesday, **August 25**, 2026, **at 11:59 pm**
How is the drug taken?	Leniolisib is taken orally (through the mouth).
How often is the drug taken?	Leniolisib is taken twice a day.

Drug information	

General drug and/or drug study information	APDS is a genetic disease where someone is born with part of their immune system not working properly. APDS is caused by harmful genetic variations in genes that prevent the proper development and function of immune cells in the body. Most people with APDS end up experiencing frequent infections, swollen lymph nodes, enlarged livers or spleens, fatigue and digestive issues. Over time, some people develop autoimmune problems or even an increased risk of lymphoma (a type of blood cancer).
	
	There are currently no Health Canada approved-therapies or disease-modifying treatments for APDS. Leniolisib is an immunostimulant, which corrects the immune system so it can fight infections, disease, or cancer more effectively.
	
	Studies looked at the following:
	• Infections
	• Hospitalizations
	• Immune dysregulation, measured by:
	  ○ Average change from baseline in percentage of naïve B cells out of total B cells (immune cells)
	  ○ Average change from baseline in serum immunoglobulin M (IgM) concentration
	  ○ Annualized immunoglobulin replacement therapy (IRT) use
	• Lymphadenopathy, as measured by:
	  ○ Average change from baseline in the log10-transformed sum of product diameters (SPD) in the index lesions selected as per the Cheson methodology from CT or MRI scan
	• Health-related quality of life, as measured by:
	  ○ Short Form (36) Health Survey Physical Component Summary (SF-36 PCS) and Mental Component Summary (MCS)
	  ○ Patient's Global Assessment visual analogue scale (PtGA VAS)
	• Serious adverse events
	• Bad reactions
	• Serious bad reactions
	• Patients leaving the trial due to bad reactions

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)**
leniolisib (TBC)	Tablet	Under Review

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.