

Drug Coverage Decision Update for BC PharmaCare

About PharmaCare

BC PharmaCare is a publicly funded drug plan that helps B.C. residents pay for most prescription drugs and pharmacy services, and some medical devices and supplies.

Details of Drug Reviewed

Drug	sodium phenylbutyrate and ursodoxicoltaurine (PB-TURSO)
Brand name	Albrioza
Dosage form(s)	Powder for oral suspension, 3g/1g sachet
Manufacturer	Amylyx Pharmaceuticals Inc.
Review type	Benefit Status Update
Indication reviewed	Amyotrophic lateral sclerosis (ALS)
Drug Coverage	Non-Benefit
Decision	
Date	July 19, 2024
Reason(s)	 Orug coverage decision is consistent with recent evidence from Phase 3 trial On July 19, 2023, the Ministry of Health (the Ministry) made a decision to reimburse Albrioza as a Limited Coverage Benefit. This decision was consistent with the recommendation of the CDA, based on available evidence at the time, but was pending results of a Phase 3 confirmatory trial to verify the clinical benefit of Albrioza. The confirmatory trial is a Phase 3, randomized, double-blind study that aimed to further evaluate the safety and efficacy of Albrioza versus placebo over a 48-week duration in 664 participants with ALS. In March 2024, the confirmatory trial concluded. The study did not meet its primary or secondary endpoints; Albrioza did not slow decline in physical and respiratory function compared to placebo.

	On June 7, 2024, Health Canada published a Health Professional Risk
	 On Julie 7, 2024, Realth Canada published a Realth Professional Risk Communication which outlines the decision to withdraw the drug from the Canadian market by December 31, 2024. Consistent with the updated clinical evidence and clinical experts' recommendation, the Ministry has made the decision to terminate funding of Albrioza through PharmaCare effective July 19, 2024.
Other Information	Health Canada's Safety and Efficacy Advisory on Albrioza can be found <u>here</u> .

The drug review process in B.C.

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

An independent group called the <u>Drug Benefit Council (DBC)</u> gives advice to the Ministry by considering:

- whether the drug is safe and effective
- advice from a national group called Canada's Drug Agency (CDA)
- what the drug costs and whether funding it provides good value to the province
- ethical considerations of covering and not covering the drug
- input from physicians, patients, caregivers, patient groups and drug submission sponsors

The Ministry makes a BC PharmaCare coverage decision by taking into account:

- existing BC PharmaCare policies, programs and resources
- the evidence-informed advice of the DBC
- drugs already covered by BC PharmaCare that treat similar medical conditions
- the overall cost of covering the drug

Visit <u>BC PharmaCare</u> and <u>Drug reviews</u> 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.