

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)	omaveloxolone
Brand name	TBC (to be confirmed)
Manufacturer	Biogen Canada Inc.
Indication	For the treatment of Friedreich’s ataxia (FA) in adults and adolescents aged 16 years 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 omaveloxolone (TBC), Search the CDA-AMC Reports .
Public input start date	Wednesday , January 29, 2025
Public input closing date	Tuesday , February 25, 2025, at 11:59 PM
How is the drug taken?	Omaveloxolone is taken orally (by the mouth).
How often is the drug taken?	Omaveloxolone is taken once a day.

Drug information	
General drug and/or drug study information	<p>Friedreich's ataxia (FA) is a rare, inherited condition that damages the nervous system, causing muscle weakness, balance issues and sensory deficits that worsen over time. The most common neurological symptom is gait instability (i.e., ataxia), which sometimes looks like clumsiness and/or falls, as well as problems with hand skills and fine motor tasks.</p> <p>FA is associated with the inhibition of nuclear factor erythroid 2-related factor 2 (Nrf2). When Nrf2 is suppressed, it leads to cell death and tissue degradation, causing the symptoms of FA. Omaveloxolone works by restoring Nrf2 levels and increasing their activity, allowing the body's cells to produce more energy and protecting them from damage.</p> <p>Studies looked at the following:</p> <ul style="list-style-type: none"> • Improvement in Friedreich's Ataxia Rating Scale (mFARS) scores compared to placebo • Changes in Friedreich's Ataxia-Activities of Daily Living (FA-ADL), upper limb function (9-Hole Peg Test [9-HPT]), mobility (25-foot timed walk test) and frequency of falls • Bad reactions • Serious bad reactions • Patients leaving the trial due to bad reactions • Bad reactions of special interest, including elevations in liver enzymes
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](#).

Cost of the drug compared to other drugs used to treat the same indication				
Generic Name (Brand Name) of Drug Comparator	PharmaCare Status (if and how the drug is already covered)	Dosage Form	Usual Dose	Cost of Therapy
omaveloxolone (TBC)	Under Review	Oral Capsule	Once daily	TBC

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 [Canada’s Drug Agency-L’Agence des médicaments du Canada \(CDA-AMC\)](#)
- 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 PharmaCare coverage decisions by taking into account:

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

For more information about the drug review process in B.C., visit: the [How PharmaCare decides which drugs to cover](#).

This document provides information only.

It does not take the place of advice from a physician or other qualified health care provider.