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)	**crovalimab**
Brand name	**TBC (to be confirmed)**
Manufacturer	Hoffmann-La Roche Limited
Indication	Crovalimab is indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH).
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 crovalimab (Piasky®), 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?	Crovalimab is taken as an intravenous (IV) infusion (directly into the bloodstream through the vein, using a needle) and subcutaneous (SC) injection (under the skin, in the lower right or lower left part of the abdomen below the navel).
How often is the drug taken?	Crovalimab is taken as one loading dose by IV infusion on Day 1, followed by four additional weekly loading doses by SC injection on Days 2, 8, 15, and 22, then a maintenance dose by SC injection on Day 29 and every 4 weeks thereafter.

Drug information	
General drug and/or drug study information	Crovalimab is used to treat paroxysmal nocturnal hemoglobinuria (PNH). PNH is a rare blood disease caused by a genetic mutation in bone marrow stem cells. Bone marrow is responsible for making red blood cells (RBCs), which carry oxygen to tissues in the body, platelets, which help blood to clot, and white blood cells, which fight infections. PHN causes impaired bone marrow function, the destruction of RBCs, and blood clots. When RBCs break apart, the hemoglobin inside is released. Hemoglobin is the part of RBCs that carries oxygen around the body. The release of hemoglobin causes many of the PNH symptoms. These symptoms can include blood in the urine, anemia, abdominal pain, fatigue, difficulty swallowing, and erectile dysfunction. More serious complications of this disease can include dangerous blood clots, chronic kidney disease, and pulmonary hypertension, which is a type of high blood pressure that affects the arteries in the lungs and the right side of the heart. Crovalimab is a monoclonal antibody, which is a type of protein made in the laboratory that can bind to substances in the body. Crovalimab binds to the C5 complement protein, which is a part of the immune system involved in cell death. By binding to the C5 complement protein, Crovalimab stops the RBCs from prematurely breaking up. Studies looked at the following: • Hemolysis control, as measured by central lactate dehydrogenase (LDH). • The number of patients who stopped needing blood transfusions (transfusion avoidance) • Occurrences of breakthrough hemolysis (BTH) • Change from baseline in health-related quality of life (HRQoL) as measured by the European Organisation for Research and Treatment of Cancer Questionnaire (EORTC QLQ-C30). • Change from baseline in symptoms of PNH as measured by the Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) questionnaire. • Bad reactions • Serious bad reactions • Patients leaving the trial due to bad reactions. • Bad reactions of special interest, including type III hypersensitivity reactions related to drug-target-drug complexes, abnormal liver function tests, and suspected transmission of infection agents
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**	**Annual Cost of Therapy[a]**
crovalimab (TBC)	Under Review	Single-use vial for IV infusion or SC use	Loading: Once, on Day 1, followed by doses on Days 2, 8, 15 & 22. Maintenance: Once on Day 29 and every 4 weeks thereafter	TBC
Current Comparators				
eculizumab (Soliris)	Non-Benefit Exceptional funding on a case-by-case basis through the EDRD Process	Single-use vial for IV infusion	Loading dose once per week for four weeks. Maintenance dose one week later, then every two weeks thereafter.	Year 1: $559,586 Subsequent years: 525,876

[a] All prices as per PharmaCare formulary, unless otherwise specified. Weight-based dosing assumes a weight of 65 kg; dosing based on body surface area assumes an area of 1.8 m^2.

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 considering:

- 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.