

Drug Coverage Decision for B.C. PharmaCare

About PharmaCare

B.C. PharmaCare is a government-funded drug plan. It helps British Columbians with the cost of eligible prescription drugs and specific medical supplies.

Drug	Enoxaparin biosimilars		
Brand Name	Inclunox [®] , Inclunox [®] HP	Noromby [®] , Noromby [®] HP	Redesca [®] , Redesca [®] HP
Dosage Form(s)	30 mg/0.3 mL pre-filled	20 mg/0.2 mL PFS,	30 mg/0.3 mL PFS,
	syringe (PFS),	30 mg/0.3 mL PFS,	40 mg/0.4 mL PFS,
	40 mg/0.4 mL PFS,	40 mg/0.4 mL PFS,	60 mg/0.6 mL PFS,
	60 mg/0.6 mL PFS,	60 mg/0.6 mL PFS,	80 mg/0.8 mL PFS,
	80 mg/0.8 mg PFS,	80 mg/0.8 mL PFS,	100 mg/mL PFS,
	100 mg/mL PFS,	100 mg/mL PFS,	300 mg/3 mL vial,
	120 mg/0.8 mL PFS,	120 mg/0.8 mL PFS,	120 mg/0.8 mL PFS,
	150 mg/mL PFS.	150 mg/mL PFS.	150 mg/mL PFS.
Manufacturer	Sandoz Canada Inc.	Juno Pharmaceuticals Corp.	Valeo Pharma Inc.
Submission Type	Biosimilars		
Use Reviewed	The treatment and prophylaxis of venous thromboembolism (VTE)		
Common Drug	No, CDR did not review		
Review (CDR)			
Provincial	In June 2019, the Canadian Agency for Drugs and Technologies in Health (CADTH) provided		
Review	confirmation that a CDR submission for enoxaparin biosimilars for the same indications as the		
	biologic reference, Lovenox [®] ; as such, a full Drug Benefit Council (DBC) review is not required		
	-	rage decision will be based on ar	
Drug Coverage	Limited Coverage Benefit. Access the enoxaparin criteria from		
Decision	www.gov.bc.ca/pharmacarespecialauthority		
Date	March 22, 2022		

Details of Drug Reviewed

Ministry of Health

Therapeutic Assessment and Access Branch Pharmaceutical, Laboratory & Blood Services Division

Reason(s)	• Health Canada's review concluded that the enoxaparin biosimilars were similar to and had no clinically meaningful differences from the biologic reference drug, Lovenox [®] , with respect to efficacy, safety, pharmacokinetics and immunogenicity.
	• Based on the submitted product price, the enoxaparin biosimilars cost significantly less than the biologic reference, Lovenox.
	• BC participated in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations that concluded agreements with the three drug manufacturers for the biosimilars.
	• The Ministry also reviewed the limited coverage criteria of Low Molecular Weight Heparins (LMWHs) and Direct Oral Anticoagulants (DOACs) for the treatment of Cancer Associated Thrombosis (CAT).
	• On August 9, 2021, the DBC recommended that the Ministry modify the coverage criteria for LMWHs to make them a first-line therapy for the treatment of CAT (i.e., no requirement for a trial with a warfarin).
	• The DBC also recommended that other available LMWHs including enoxaparin may be used as treatment options for CAT in certain clinical scenarios.
Other	• On March 22, 2022, all new Special Authority (SA) requests for enoxaparin will only be
Information	approved for Inclunox, Noromby or Redesca. Patients with SA approval for Lovenox will not
	have to switch to a biosimilar unless their coverage ends.
	• On March 22, 2022, list enoxaparin biosimilars as Limited Coverage benefits for the
	treatment of CAT.
	CADTH Rapid Response Biosimilar Enoxaparin for the Prevention or Treatment of Thrombosis
	and Cardiovascular Conditions web LINK

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 the <u>Common Drug Review (CDR)</u>
- what the drug costs and whether it is a good value for the people of B.C.
- ethical considerations involved with 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:

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

Visit <u>The Drug Review Process in B.C. - Overview</u> and <u>Ministry of Health - PharmaCare</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.