

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.

Details of Drug Reviewed

Drug	insulin glargine
Brand Name	Semglee®
Dosage Form	Solution for subcutaneous injection
Manufacturer	Viartis Canada
Submission Type	Biosimilars
Use Reviewed	Type 1 or Type 2 diabetes mellitus
Canadian Agency for Drugs and Technologies in Health (CADTH) Reimbursement Reviews (CRR)	As of June 1, 2019, the Canadian Agency for Drugs and Technologies in Health (CADTH) no longer conducts reviews of biosimilars as it became apparent that CADTH Reimbursement Review (CRR) process may delay access to new biosimilar treatments, and because it allows CADTH to deploy its limited resources to other drug reviews. For similar reasons, PharmaCare no longer requires the Drug Benefit Council (DBC) to review biosimilars as we believe Health Canada's review of biosimilars is thorough and without compromise to efficacy and patient safety. Therefore Semglee was reviewed internally by PharmaCare.
Provincial Review	PharmaCare covers insulin glargine biosimilar product for the treatment of patients over 17 years of age with Type 1 or Type 2 diabetes mellitus and of pediatric patients (>6 years old) with Type 1 diabetes mellitus. As of May 25, 2023 patients with Type 1 or Type 2 diabetes mellitus will be eligible for reimbursement of Semglee, in addition to Basaglar.
Drug Coverage Decision	Limited Coverage Benefit and Regular Benefit for Plan W Access the insulin glargine criteria from www.gov.bc.ca/pharmacarespecialauthority
Date	May 25, 2023
Reason(s)	<ul style="list-style-type: none"> In 2019, PharmaCare changed coverage from the reference insulin glargine (Lantus) to the biosimilar insulin glargine (Basaglar). 97% of patients successfully switched from Lantus to Basaglar.

	<ul style="list-style-type: none"> • On April 8 2022, Semglee received a notice of compliance (NOC) from Health Canada. • The Ministry reviewed comparative chemistry and manufacturing studies, comparative non-clinical studies, comparative pharmacokinetic (PK) / pharmacodynamics (PD) and clinical trials in patients with Type 1 and Type 2 diabetes mellitus that established the similarity between Semglee and Lantus in product quality, mechanism of action, safety profile, and dosage regimen. • The ministry also reviewed a multicenter, open-label, randomized, parallel-group, phase 3 study (INSTRIDE 3), that switched participants between Semglee and Lantus. Switching participants between Semglee and Lantus demonstrated equivalent efficacy and similar safety and immunogenicity, showing that people taking reference insulin glargine can safely switch to Semglee. • The pan-Canadian Pharmaceutical Alliance (pCPA) and the Ministry were involved in negotiations with the manufacturer for Semglee which were successfully completed resulting in a Product Listing Agreement. • Semglee and Basaglar are eligible for PharmaCare coverage subject to meeting Limited Coverage Criteria and as regular benefits under Plan W.
Other Information	None

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 [Canadian Agency for Drugs and Technologies in Health \(CADTH\) Reimbursement Reviews\(CRR\)](#)
- 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 [The Drug Review Process in B.C. - Overview](#) and [Ministry of Health - PharmaCare](#) 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.