

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	filgrastim
Brand Name	Grastofil [®]
Dosage Form(s)	300 µg/0.5 ml and 480 µg/0.8 ml pre-filled syringes
Manufacturer	Apobiologix, a division of Apotex Inc.
Submission Type	New Submission & Line Extension
Use Reviewed	Prevention/treatment of neutropenia
Common Drug Review (CDR)	Yes, CDR recommended: to Reimburse with clinical criteria and/or conditions. Visit the CDR website for more details: https://www.cadth.ca/about-cadth/what-we-do/products-services/cdr/reports
Drug Benefit Council (DBC)	DBC met on April 4, 2016 to review filgrastim (Grastofil), a biosimilar of innovator product Neupogen and request for modification of filgrastim Limited Coverage criteria to include primary prophylaxis of febrile neutropenia in cancer patients. DBC considered various inputs including: the final review for Grastofil completed by the CDR on March 18, 2016, which included clinical and pharmacoeconomic evidence review material and the recommendation from the Canadian Drug Expert Committee (CDEC). The DBC also considered CDR Patient Group Input Submissions; Clinical Practice Reviews from two specialists; a Budget Impact Assessment; the 2015 BC Cancer Agency (BCCA) Guidelines for the treatment of febrile neutropenia; a 2010 update of the European Organization for Research and Treatment of Cancer (EORTC) guidelines for the use of granulocyte colony stimulating factor (G-CSF) to reduce the incidence of chemotherapy-induced febrile neutropenia; and a 2015 Guideline Update on the Recommendations for the Use of WBC Growth Factors from the American Society of Clinical Oncology Clinical Practice. No Patient Input Questionnaire responses were received from patients, caregivers or Patient Groups.
Drug Coverage Decision	Limited Coverage Benefit. Access the filgrastim criteria from www.gov.bc.ca/pharmacarespecialauthority
Date	January 31, 2017
Reason(s)	<ul style="list-style-type: none"> Based on the available evidence, efficacy and safety of Grastofil appears similar to Neupogen for the treatment of neutropenia. Grastofil is less expensive than Neupogen based on manufacturer's list prices. There is sufficient evidence to support use of filgrastim for primary prophylaxis of febrile neutropenia in cancer patients with regimens where the risk of febrile neutropenia is equal to or greater than 20%. However, due to budgetary constraints, Limited Coverage criteria for filgrastim will not be expanded to include this indication but may be considered in the future.
Other Information	<ul style="list-style-type: none"> As of January 31, 2017, PharmaCare covers Neupogen vials and Grastofil for patients who were granted a Special Authority for Neupogen before January 31, 2017. PharmaCare covers only the Grastofil brand of filgrastim for all new Special Authority

approvals granted on or after January 31, 2017.

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 [Common Drug Review \(CDR\)](#)
- 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 [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.