

# 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

<b>Drug</b>	<b>Filgrastim biosimilar</b>
Brand Name	Nypozi <sup>®</sup>
Dosage Form(s)	300 mcg/0.5 mL and 480 mcg/0.8 mL prefilled syringe
Manufacturer	Tanvex BioPharma USA, Inc.
<b>Submission Type</b>	<b>Biosimilars</b>
Use Reviewed	For the prevention and treatment of neutropenia.
Canada's Drug Agency (CDA-AMC) Reimbursement Reviews (CRR)	As of June 1, 2019, the Canada's Drug Agency (CDA-AMC) no longer conducts reviews of biosimilars as it became apparent that the CRR process may delay access to new biosimilar treatments, and because it allows CDA-AMC to deploy its limited resources to other drug reviews.
Provincial Review	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 Nypozi was reviewed internally by the Ministry of Health.
<b>Drug Coverage Decision</b>	<b>Limited Coverage Benefit</b> Access the filgrastim criteria from <a href="http://www.gov.bc.ca/pharmacarespecialauthority">www.gov.bc.ca/pharmacarespecialauthority</a>
Date	<b>May 14, 2024</b>
Reason(s)	<ul style="list-style-type: none"> <li>Based on Health Canada's reviews on comparative chemistry and manufacturing studies, comparative non-clinical studies, comparative pharmacokinetic (PK) / pharmacodynamics (PD) and clinical trials in patients that established the similarity between Nypozi and the</li> </ul>

	<p>reference biologic filgrastim, Neupogen® in efficacy, safety , pharmacokinetics and immunogenicity.</p> <ul style="list-style-type: none"> <li>• Based on Health Canada’s reviews on Study TX01-02, TXO1-03, Study TXO1-04, there were no clinically meaningful safety or immunological differences observed with Nypozi and Neupogen, further supporting the biosimilarity of Nypozi to Neupogen.</li> <li>• BC participated in the pan-Canadian Pharmaceutical Alliance (pCPA) negotiations with the manufacturer of Nypozi that concluded with an agreement.</li> <li>• Effective <b>May 14, 2024</b>, Nypozi will be listed as a Limited Coverage benefit with the same criteria as the other filgrastim biosimilars, Grastofil and Nivestym.</li> </ul>
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.