Ontario Public Drug Programs

Grastofil (filgrastim) Frequently Asked Questions

1. What is the funding status of Grastofil (filgrastim)? Is it safe and effective?

Effective December 22, 2016, Grastofil (filgrastim) will be funded under the Ontario Drug Benefit (ODB) Program for eligible ODB recipients to prevent and treat neutropenia associated with chemotherapy.

Prescribers are encouraged to consider Grastofil (filgrastim) for new starts of a filgrastim regimen and a decision to begin treatment with Grastofil (filgrastim) should continue to be aligned with recognized clinical guidance, including but not limited to that released by Cancer Care Ontario at:

https://www.cancercare.on.ca/common/pages/UserFile.aspx?fileId=352101

Health Canada has reviewed the safety and efficacy of Grastofil (filgrastim) and approved the drug for use in the following indications:

- To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-neoplastic drugs.
- For the reduction in the duration of neutropenia, fever, antibiotic use and hospitalization, following induction and consolidation treatment for acute myeloid leukemia;
- To reduce the duration of neutropenia and neutropenia-related clinical sequelae, e.g. febrile neutropenia, in patients undergoing myeloablative therapy followed by bone marrow transplantation.
- For the mobilization of autologous peripheral blood progenitor cells in order to accelerate haematopoietic recovery by infusion of such cells, supported by filgrastim after myelosuppressive or myeloablative chemotherapy.
- For chronic administration to increase neutrophil counts and to reduce the incidence and duration of infection in patients with a diagnosis of congenital, cyclic or idiopathic neutropenia.
- In patients with HIV infection for the prevention and treatment of neutropenia, to maintain a normal absolute neutrophil count.

Please refer to Health Canada's website for further details on the market approval of Grastofil (filgrastim) at: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/sbd-smd/drug-med/sbd-smd-2016-grastofil-156897-eng.php#sbd

Ontario

2. Will there be any changes to the funding status of Neupogen (filgrastim) effective with the December 2016 ODB Formulary update?

Neupogen (filgrastim) is currently funded for under specific circumstances as a Limited Use (LU) benefit on the ODB Formulary, and through the ministry's Exceptional Access Program (EAP) according to clinical criteria.

There will be no changes to the funding status or criteria for Neupogen (filgrastim) effective with the December 2016 ODB Formulary update.

Claims for Neupogen (filgrastim) will continue to be reimbursed under the ODB program when prescribed in accordance with the LU criteria and accompanied by a valid, fully completed prescription with the appropriate LU documentation (Reason For Use, RFU code).

Additionally, patients who have an existing Exceptional Access Program (EAP) approval for Neupogen (filgrastim) can continue to receive Neupogen (filgrastim) for the duration of the EAP approval period. The ministry will also consider EAP renewal requests for Neupogen (filgrastim) for patients with existing EAP approvals.

3. What is difference between Grastofil (filgrastim) and Neupogen (filgrastim)?

Grastofil and Neupogen are both filgrastim products. Filgrastim is a hematopoietic agent medicine that helps to prevent or treat neutropenia (low white blood cell count) during cancer treatment. Grastofil (filgrastim) is approved by Health Canada as a subsequent entry biologic (SEB) to Neupogen. Grastofil (filgrastim) and Neupogen (filgrastim) are manufactured and marketed by different companies.

Grastofil (filgrastim) is currently available as pre-filled syringes.

4. What is the rationale behind funding Grastofil (filgrastim) as a General Benefit on the ODB Formulary?

Health Canada is responsible for assessing the safety and efficacy of drug products, including SEBs such as Grastofil (filgrastim) before they can be approved for sale in Canada. SEBs are subject to the same regulatory requirements as biologics.

Additionally, the clinical, economic and patient group evidence was reviewed through the national Common Drug Review (CDR), as with other drug products, including biologics, and a positive funding recommendation was rendered in support of funding for Grastofil's (filgrastim) approved indications.

SEBs present an important opportunity to achieve better value for money for biologic drugs and will help to support long-term sustainability and accessibility of Ontario's public drug programs. Listing Grastofil (filgrastim) as a General Benefit (GB) will support timely access to this product.

5. Are there other jurisdictions currently funding Grastofil (filgrastim)?

Yes. Grastofil (filgrastim) and other SEB filgrastim products have been prescribed and dispensed through European public drug plans for many years. Additionally, the Saskatchewan Cancer Agency has been funding Grastofil (filgrastim) for approved indications since May 2016.

6. How will this change impact patients?

Patients will see little to no impact to their care as a result of these changes. Patients currently receiving Neupogen (filgrastim) for a course of therapy to treat or prevent neutropenia will continue to be covered for this product. Prescribers are encouraged to consider Grastofil (filgrastim) for new starts of a filgrastim regimen. For those patients prescribed Grastofil (filgrastim), they may wish to be trained, or have a caregiver trained, to self-administer this product as it is available in a pre-filled syringe for ease of use. However, there may be instances such as use in pediatric patients where a vial format is preferable for dosing purposes.

7. How will this change impact prescribers writing prescriptions for filgrastim?

Prescribers should ensure all prescriptions for filgrastim going forward indicate the brand name of the product requested, either Grastofil (filgrastim) or Neupogen (filgrastim). Preprinted orders, where applicable, should also be updated to reflect this distinction.

8. How should pharmacies submit claims for Grastofil (filgrastim)?

When a prescription for filgrastim is received, pharmacists should verify whether the prescription is for Grastofil (filgrastim) or Neupogen (filgrastim). Pharmacies should submit claims using the drug identification number (DIN) for Grastofil (filgrastim) 300 mcg/0.5mL or 480 mcg/0.8mL when indicated on the prescription, and should continue to submit claims for Neupogen (filgrastim), where applicable, with the appropriate RFU code and/or EAP confirmation.

9. What are Subsequent Entry Biologics?

Subsequent entry biologics (SEBs), also referred to as biosimilars or follow-on biologics, are biologics that are similar to, and would enter the market after the patent for an innovator biologic has expired. They are similar to generic drugs. However, unlike generic drugs, biosimilars are not deemed bioequivalent to, nor interchangeable with, their reference drugs. SEBs are subject to the same regulatory requirements as biologics.