Filgrastim Frequently Asked Questions

1. What is the difference between Grastofil and Neupogen?

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.

2. What is the funding status of Grastofil (filgrastim)?

Grastofil (filgrastim) is listed on the Ontario Drug Benefit Formulary/Comparative Drug Index (Formulary) as a General Benefit as of December 22, 2016. There will be no changes to the funding status of Grastofil.

3. What is the funding status of Neupogen (filgrastim)?

Effective with August 2017 formulary update, changes to the funding status of Neupogen will be as follows:

- Neupogen will be listed under on the Formulary as a Limited Use (LU) benefit ONLY for the following indications:
    I. LU Code 447 (change in criteria): Pre-Stem Cell Transplant Mobilization - For peripheral blood progenitor cell collection for peripheral stem cell transplant as treatment for malignant disease. Approval for Neupogen 300 mcg and 480 mcg vial format only.
    II. LU Code 500: For pediatric patients (less than 18 years of age) who are unable to achieve the appropriate dose of granulocyte colony-stimulating factor with formulary listed formats of pre-filled syringes. Approval for Neupogen 300 mcg vial format only.

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III. LU Code 501: For patients who are unable to use available formats of Grastofil due to a documented latex allergy. Approval for Neupogen 300 mcg and 480 mcg vial format only.

- Please note the LU code 446 and associated clinical criteria will be deactivated.
- New requests for Neupogen under the Exceptional Access Program (EAP) for any indication will not be accepted. However, patients who have an existing EAP approval for Neupogen can continue to receive Neupogen for the duration of the EAP approval period.

4. What is the rationale behind changing the funding status for filgrastim?

Grastofil (filgrastim) was approved by Health Canada as a subsequent entry biologic (SEB) to Neupogen (filgrastim). SEBs have similar efficacy and safety as originator biologics and present an opportunity to achieve better value for money for biologic drugs that will help to support long-term sustainability and accessibility of Ontario's public drug programs.

5. How will these changes impact patients?

As of the August 2017 formulary update, ODB eligible patients will receive Grastofil when a new prescription for filgrastim is written, unless it specifies Neupogen with the appropriate LU code. Patients may wish to be trained, or have a caregiver trained, to administer Grastofil as it is available in a pre-filled syringe for ease of use.

Patients with an existing EAP approval for Neupogen can continue to receive Neupogen for the duration of the EAP approval. However, when the approval period expires, patients will be switched from Neupogen to Grastofil, unless they meet the new LU criteria outlined above.

6. How will these changes impact prescribers?

Neupogen and Grastofil are not interchangeable products. As of the August 2017 formulary update, new prescriptions for filgrastim for ODB eligible patients will be dispensed Grastofil, unless it specifies Neupogen with the appropriate LU code. Prescribers should notify their patients of the switch. Prescribers should also note the new LU criteria and reason for use code for Neupogen.

Prescribers should no longer submit new EAP requests for Neupogen. Pre-printed orders should also be updated to reflect the changes.

7. How will these changes impact pharmacies/pharmacists?

Neupogen and Grastofil are not interchangeable products. As of the August 2017 formulary update, new prescriptions for filgrastim for ODB eligible patients will be dispensed Grastofil, unless it specifies Neupogen with the appropriate LU code. Pharmacies/pharmacists should note the LU criteria and reason for use (RFU) code for Neupogen. Pharmacies/pharmacists should continue to submit claims for Neupogen (filgrastim), where applicable, with the appropriate RFU code and/or EAP confirmation.

8. 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. Health Canada evaluates all the information provided to confirm that the SEB and the reference biologic drug are similar and that there are no clinically meaningful differences in safety and efficacy between them.

Please refer to Health Canada's fact sheet on SEBs for more information:
https://www.canada.ca/en/health-canada/services/drugs-health-products/biologics-radiopharmaceuticals-genetic-therapies/applications-submissions/guidance-documents/fact-sheet-biosimilars.html

Additional information:
For pharmacies:
Please call ODB Pharmacy Help Desk at: 1-800-668-6641

For all other health care providers and the public:
Please call ServiceOntario, Infoline at 1-866-532-3161 TTY 1-800-387-5559. In Toronto, TTY 416-327-4282