Re: Best-Value Biological Medicines – Filgrastim

24 March 2025

Dear Colleagues,

I am writing to inform you that the HSE-Medicines Management Programme (MMP) has completed a review of the medicinal products containing filgrastim that are available on the High Tech Arrangement, and is now recommending a number of best-value biological medicines (BVBs).

Expenditure on medicinal products containing filgrastim under the High Tech Arrangement was approximately €2.3 million in 2023. Biosimilar medicines containing filgrastim are on the HSE Reimbursement List, for prescribing and supply under the High Tech Arrangement; the MMP recognises the potential savings arising from these. These savings, however, can only be realised by prescribing and utilisation of the recommended BVB medicines.

The MMP recommends the following as BVB medicines for filgrastim:

- **Accofil®** solution for injection pre-filled syringe (Accord Healthcare Ireland Limited)
- **Tevagrastim®** solution for injection pre-filled syringe (Teva Pharmaceuticals Ireland).

Both Accofil® and Tevagrastim® are available in pre-filled syringe presentations containing 30 million international units (MU/MIU) or 48 MU of filgrastim.

An evaluation report entitled **Best-value biological medicine: Filgrastim on the High Tech Arrangement** is available at www.hse.ie/mmp in the section entitled *Best-value medicines.*

The MMP recommends that all new patients being initiated on treatment with filgrastim under the High Tech Arrangement should be prescribed one of the recommended BVB medicines.

Accord Healthcare Ireland have confirmed that sufficient stock of Accofil® is available from 1 April 2025 to support an uplift in demand arising from the MMP BVB medicine recommendations. Teva Pharmaceuticals Ireland have advised that additional stock of Tevagrastim® to support an uplift in demand arising from the MMP BVB medicine recommendations should be available in June 2025.

From 1 April 2025, where a clinician chooses to prescribe a BVB medicine for filgrastim for a patient, a prescription for Accofil® should be provided to the patient. A further communication will issue when there is sufficient stock to support prescribing of both Accofil® and Tevagrastim®.

In addition, all medicinal products on the HSE Reimbursement List containing filgrastim will be added to the High Tech Hub from 1 April 2025. From this date, there will be two possible options for prescribers:

1. Generate the prescription on the High Tech Hub. The Hub has been designated a national electronic prescription transfer system; therefore once the prescriber confirms the prescription on the Hub, it will be available in real time for the community pharmacy to access and order from via the Hub.
2. Write and issue a paper-based High Tech Prescription, which the patient then brings to their community pharmacy. The pharmacy then enters the prescription into the Hub and places the order via the Hub.

Prescribing of medicines via the High Tech Hub ensures that both the international non-proprietary name (i.e. filgrastim) and the medicinal product (e.g. Accofil®, Neupogen®, Nivestim®, Tevagrastim®) are included on the prescription. Where a patient is provided with a paper-based High Tech Prescription, the clinician should clearly indicate both the international non-proprietary name (i.e. filgrastim) and the medicinal product (e.g. Accofil®, Neupogen®, Nivestim®, Tevagrastim®) that they are prescribing on the prescription.

The MMP are available to engage with consultants and clinical teams to support prescribing of the BVB medicines via the High Tech Hub. This includes the provision of information sessions, in conjunction with the High Tech Co-ordination Unit, on the BVB medicines and the High Tech Hub. Please contact the MMP (mmp@hse.ie) if you wish to avail of this support.

Please find enclosed Questions and Answers document for Healthcare Professionals, and information for patients. Further information on this initiative, including information for healthcare professionals and resources to support initiating patients on the recommended BVB medicines are available on the MMP website (www.hse.ie/mmp) in the section entitled *Best-value medicines*.

The MMP will monitor uptake of the recommended BVB medicines; the introduction of additional measures to support prescribing of the BVB medicines may be considered to ensure uptake is optimised.

Funding to facilitate access to new medicines for patients in 2025 is dependent on the delivery of savings from within the medicines budget. Prescribing of the BVB medicines reduces the financial burden on the HSE arising out of the funding of reimbursed medicines, and therefore can assist in securing ongoing access for patients to new, innovative medicines.

I would ask that you support this important initiative, which helps to secure ongoing access for patients to new and innovative medicines.

With best wishes,

Michael Barry.

Professor Michael Barry,
National Clinical Lead,
HSE-Medicines Management Programme.

Reimbursement of Medicinal Products containing Filgrastim: Questions and Answers for Healthcare Professionals
April 2025

Introduction

Reimbursement of medicinal products containing filgrastim is supported on the High Tech Arrangement in line with their licensed indications, as outlined in the relevant Summary of Product Characteristics.

As of 1 March 2025, there are four medicinal products containing filgrastim on the HSE Reimbursement List, for prescribing and supply under the High Tech Arrangement:

- Accofil® solution for injection (Accord Healthcare Ireland Limited)
- Neupogen® solution for injection (Amgen Ireland Limited)
- Nivestim® solution for injection (Pfizer Healthcare Ireland)
- Tevagrastim® solution for injection (Teva Pharmaceuticals Ireland)

All four medicinal products are available in pre-filled syringe presentations, containing 30 million international units (30 MIU/MU) or 48 MU of filgrastim. Neupogen® is also available in a 1 millilitre (mL) vial presentation, containing 30 MU of filgrastim.

In March 2025, following a review of medicinal products containing filgrastim, the HSE-Medicines Management Programme (MMP) has identified best-value biological medicines (BVBs) for filgrastim on the High Tech Arrangement:

- **Accofil®** solution for injection pre-filled syringe 30 MU/0.5 mL and 48 MU/0.5 mL (Accord Healthcare Ireland Limited)
- **Tevagrastim®** solution for injection pre-filled syringe 30 MU/0.5 mL and 48 MU/0.8 mL (Teva Pharmaceuticals Ireland).

An evaluation report, which includes information on the process followed to identify the BVB medicines, is available on the website of the MMP under *Best-value medicines*: www.hse.ie/mmp.

I am initiating a patient on filgrastim for supply under the High Tech Arrangement; what should I do in light of the BVB medicine recommendations?

The MMP recommends that clinicians should prescribe one of the BVB medicines (Accofil®, Tevagrastim®) when initiating a patient on a medicinal product containing filgrastim for supply under the High Tech Arrangement.

Accord Healthcare Ireland have confirmed that sufficient stock of Accofil® is available from 1 April 2025 to support an uplift in demand arising from the MMP BVB medicine recommendations.

Teva Pharmaceuticals Ireland have advised that additional stock of Tevagrastim® to support an uplift in demand arising from the MMP BVB medicine recommendations should be available in June 2025.

From 1 April 2025, where a clinician chooses to prescribe a BVB medicine for filgrastim for a patient, a prescription for Accofil® should be provided to the patient. A further communication will issue from the MMP when there is sufficient stock to support prescribing of both Accofil® and Tevagrastim®.

Are changes being introduced in relation to the reimbursement of filgrastim on the High Tech Arrangement from 1 April 2025?

At present, no changes are being introduced in relation to the reimbursement of filgrastim on the High Tech Arrangement.

The HSE-MMP has identified BVB medicines for filgrastim on the High Tech Arrangement, **Accofil®** and **Tevagrastim®**. The MMP recommends that all new patients being initiated on treatment with filgrastim under the High Tech Arrangement should be prescribed one of the recommended BVB medicines.

The MMP will monitor uptake of the recommended BVB medicines; the introduction of additional measures to support prescribing of the BVB medicines may be considered to ensure uptake is optimised.

What are the benefits of prescribing the BVB medicines for filgrastim?

The BVB medicines for filgrastim are provided to the HSE at a much lower cost than the other medicinal products containing filgrastim that are available for prescribing under the High Tech Arrangement. This provides an opportunity to reduce the cost to the HSE of providing these medicines to patients.

Funding to facilitate access to new medicines for patients in 2025 is dependent on the delivery of savings from within the medicines budget. Prescribing of the BVB medicines reduces the financial burden on the HSE arising out of the funding of reimbursed medicines, and therefore can assist in securing ongoing access for patients to new, innovative medicines.

What is the situation for patients currently in receipt of a medicinal product containing filgrastim under the High Tech Arrangement

There is currently no change for existing patients. They will continue to receive their medicine under the High Tech Arrangement from their community pharmacy.

At this point in time, all valid High Tech prescriptions for medicinal products containing filgrastim on the HSE Reimbursement List remain eligible for reimbursement under the High Tech Arrangement. The MMP recommends that all new patients being initiated on treatment with filgrastim under the High Tech Arrangement should be prescribed one of the recommended BVB medicines.

Where can I get information on the best-value biological medicines for filgrastim?

Information on the BVB medicines is available on the website of the MMP under *Best-value medicines*: www.hse.ie/mmp.

This includes support materials for clinical teams who are initiating patients on the BVB medicines:

- Reimbursement of Medicinal Products containing Filgrastim: Questions and Answers for Healthcare Professionals
- Information for Patients about Medicines containing Filgrastim
- MMP product information sheets for Accofil® and Tevagrastim®
- Information on patient support services for Accofil®.

Who should I contact if I have any questions?

MMP pharmacists are available to engage with consultants and clinical teams in relation to any queries on the BVB medicines for filgrastim. This includes the provision of information sessions, in conjunction with the High Tech Co-ordination Unit, on the BVB medicines and the High Tech Hub.

Please contact the MMP (mmp@hse.ie) if you wish to avail of this support.

Accofil® and Tevagrastim® are both biosimilar medicines containing filgrastim; where can I get more information on biosimilar medicines?

Further information for both healthcare professionals and patients on biosimilar medicines is available on the following websites:

Health Products Regulatory Authority: www.hpra.ie/homepage/medicines/special-topics/biosimilar-medicines
European Medicines Agency: www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview#information-for-patients-and-healthcare-professionals-section

The HSE-Access & Integration Drug Management Programme (AIDMP) has published guidance for biological and biosimilar medicine use in acute hospitals (version 2, May 2024). The guidance states that for a biological medicine with a biosimilar available for the same licensed indication, the medicine offering the better value should be prescribed. It also recommends that all treatment-naïve patients should be initiated on the better-value medicine (whether biosimilar or reference medicine).

The European Medicines Agency issued a joint statement with the Heads of Medicines Agencies on interchangeability of biosimilar medicines in September 2022. What did this say?

This statement confirmed that biosimilar medicines approved in the EU are interchangeable with their reference medicine or with an equivalent biosimilar medicine.

Interchangeability in this context means that a prescriber can replace the reference medicine with a biosimilar medicine without a patient experiencing any changes in the clinical effect.

The EMA highlighted that the experience obtained from clinical practice has shown that in terms of efficacy, safety and immunogenicity, biosimilar medicines are comparable to their reference medicine and therefore can be prescribed interchangeably.

Can medicinal products containing filgrastim be prescribed on the High Tech Hub?

Yes, from 1 April 2025, prescriptions for medicinal products containing filgrastim can be generated on the High Tech Hub.

Since August 2020, the High Tech Hub has been approved as a national electronic prescription transfer system.

Queries in relation to registration for the High Tech Hub should be directed to the HSE-Primary Care Reimbursement Service High Tech Co-ordination Unit at PCRS.HiTech@hse.ie.

Can I continue to issue paper-based High Tech prescriptions when prescribing medicinal products containing filgrastim?

Yes, paper-based High Tech prescriptions for medicinal products containing filgrastim remain valid and eligible for reimbursement under the High Tech Arrangement. The patient will bring this prescription to their community pharmacy, who then enter it into the High Tech Hub and places the order via the Hub.

Where a patient is provided with a paper-based High Tech Prescription, the clinician should clearly indicate the medicinal product containing filgrastim (e.g. Accofil®, Neupogen®, Nivestim®, Tevagrastim®) that they are prescribing on the prescription.

Information for Patients about Medicines containing Filgrastim

April 2025

G-CSF (granulocyte-colony stimulating factor) is a type of protein called a growth factor. It helps the bone marrow to make more blood cells, and increases the number of some types of white blood cells in the body. It can be used with, or after, chemotherapy.

Chemotherapy can reduce the number of white blood cells in your blood. These cells fight infection. If the number of white blood cells is low, you are more likely to get an infection. A low white blood cell count is sometimes called neutropenia.

G-CSF is made naturally in the body, but it can also be made as a drug. Filgrastim is a biological medicine containing G-CSF. They are also long-acting biological medicines containing G-CSF (lipegfilgrastim, pegfilgrastim).

The number of white blood cells usually goes back up naturally between the cycles of chemotherapy. Some people need a biological medicine containing G-CSF (e.g. filgrastim) to help increase their white blood cell count. This can reduce their risk of infection and mean that chemotherapy can be given on time and at the planned dose.

Filgrastim is also used in preparation for a stem cell transplant. It causes blood stem cells to be released from bone marrow into the bloodstream. These stem cells are then collected from the bloodstream.

What are the best-value biological medicines for filgrastim?

The best-value biological medicines identified by the HSE for filgrastim are:

- **Accofil®**
- **Tevagrastim®.**

Accofil® and Tevagrastim® are biosimilar medicines; what is a biosimilar medicine?

A biosimilar medicine is very similar to the original biological medicine. It works in the same way.

Neupogen® was the original biological medicine for filgrastim. When the patent for Neupogen® expired, biosimilar medicines containing filgrastim became available. Accofil® and Tevagrastim® are biosimilar medicines of Neulasta®.

Are biosimilar medicines safe?

Biosimilar medicines are tested to show they are just as safe and effective as the original biological medicine.

What's changing?

At present, no changes are being introduced in relation to the reimbursement of filgrastim on the High Tech Arrangement.

The HSE has identified best-value biological medicines for filgrastim on the High Tech Arrangement, Accofil® and Tevagrastim®.

The HSE recommends that all new patients being initiated on treatment with filgrastim under the High Tech Arrangement should be prescribed one of the recommended BVB medicines.

I am an existing patient prescribed filgrastim, what does this mean for me?

If you are an existing patient, you will continue to receive your medicine from your community pharmacy.

Has my consultant being informed about the best-value biological medicines?

Yes. Consultants who care for patients with cancer are aware of the best-value biological medicines.

Biosimilar medicines are widely used in hospitals for the treatment of cancer.

Why is the HSE recommending best-value biological medicines for filgrastim?

The best-value biological medicines are provided to the HSE at a lower cost. Prescribing the best-value biological medicines will save the HSE money. This means we can give new innovative medicines to even more patients, including for the treatment of cancer.

What supports are available?

Supports for patients prescribed this medicine can include:

- nurse home visit to provide training on administering the injection
- supply of sharps bins and waste collection service
- provision of product information.

Your consultant or a member of their team will register you for these services.

Where can I get more information on biosimilar medicines?

Further information on biosimilar medicines and the best-value biological medicines is available on the following websites:

HSE-Medicines Management Programme: www.hse.ie/mmp under Best-value medicines

Health Products Regulatory Authority: www.hpra.ie/homepage/medicines/special-topics/biosimilar-medicines

European Medicines Agency: www.ema.europa.eu/en/human-regulatory/overview/biosimilar-medicines-overview#information-for-patients-and-healthcare-professionals-section