Feidhmeannacht na Seirbhíse Sláinte, Seirbhís Aisíocaíochta Cúraim Phríomhúil
Bealach amach 5, M50, An Bóthar Thuaidh, Fionnghlas
Baile Átha Cliath 11, D11 XKF3
Fón: (01) 864 7100 Facs: (01) 834 3589

Health Service Executive, Primary Care Reimbursement Service
Exit 5, M50, North Road, Finglas, Dublin 11, D11 XKF3
Tel: (01) 864 7100 Fax: (01) 834 3589

Circular 004/24 26th March 2024

High Tech Ordering and Management System (High Tech Hub) Long-acting GCSFs

Dear Pharmacist

Following review of the medicinal products containing long-acting granulocyte-colony stimulating factors (G-CSFs) (i.e. lipegfilgrastim, pegfilgrastim) that are available on the High Tech Arrangement, a number of best-value biological medicines (BVBs) have been recommended. Please find enclosed a copy of a letter and supporting documentation issued to prescribing consultants, by the HSE Medicines Management Programme.

From 1st April 2024, the High Tech Hub will be extended to include medicinal products containing long acting G-CSFs, lipegfilgrastim and pegfilgrastim. The updated drug codes listed in Appendix 1 which are licensed for use across the therapeutic area of haematology and oncology will be added to those that are already available for ordering via the hub.

The following are the relevant suppliers for the next cohort of medications:

- Rx Source
- United Drug Dublin
- United Drug Limerick
- United Drug Ballina
- Uniphar
- PCO

The most efficient way to place orders is to use the Hub to set up your preferred high tech supplier(s) or alternatively you can select a preferred supplier(s) at drug level. It is vitally important that you set up your preferred supplier as soon as you access the Hub for the first time.

Please note reimbursement will only be facilitated for orders placed through the hub for the listed “hub only” High Tech medications. Any High Tech drug available for ordering through the Hub but ordered via a separate mechanism will be treated as a private transaction and will result in the pharmacy being liable for payment. The suppliers of listed ‘hub’ drugs will not be able to process an order that does not occur through the hub. We are continuously updating our User Guide and FAQ documents and these are

available under the ‘Help’ section on the High Tech Hub application. Please ensure you inform your staff and locums of this process.

The support team in the High Tech Co-Ordination Unit can be contacted by email, pcrs.hitech@hse.ie or by phone 01 864 7135.

It is expected that the remainder of medicines on the High Tech Arrangement will be added to the High Tech Hub over the coming year. Further update communications in relation to this will be issued in due course.

I would like to take this opportunity to thank you for your continued co-operation and support regarding the High Tech Hub.

Yours Sincerely

Shaun Flanagan
Primary Care Reimbursement Service

Appendix 1 – Products Extended to High Tech Hub on 1st April 2024

Drug Code	Drug Name	INN
88826	Pelgraz Soln For Inj In Pre Filled Injector 6 Mg/0.6ml	Pegfilgrastim
88961	Pelgraz Soln. For Inj. In Pre Filled Syringe 6 Mg/0.6 Ml	Pegfilgrastim
89301	Ziextenzo Soln. For Inj. In Pre Filled Syringe 6 Mg/0.6 Ml	Pegfilgrastim
88484	Neulasta Soln. For Inj. Ang Pre Filled Syr 6 Mg/0.6ml	Pegfilgrastim
88171	Lonquex Soln For Inj 6 Mg	Lipegfilgrastim
89056	Pelgraz (Originalis B.V.) Soln. For Inj. In Pre Filled Syringe 6 Mg/0.6ml	Pegfilgrastim
89271	Lonquex (Originalis B.V.) Soln For Inj In Pre Filled Syringe 6 Mg	Lipegfilgrastim
89202	Lonquex (P.C.O. Mfg.) Soln. For Inj. In Pre Filled Syringe 6 Mg	Lipegfilgrastim

Re: Best-Value Biological Medicines – Long-acting granulocyte-colony stimulating factors

22 March 2024

Dear Colleagues,

I am writing to inform you that the HSE-Medicines Management Programme (MMP) has completed a review of the medicinal products containing long-acting granulocyte-colony stimulating factors (G-CSFs) (i.e. lipegfilgrastim, pegfilgrastim) that are available on the High Tech Arrangement, and is now recommending a number of best-value biological medicines (BVBs) for this category of medicines.

Expenditure on medicinal products containing long-acting G-CSFs under the High Tech Arrangement was approximately €14.7 million in 2023. Biosimilar medicines containing pegfilgrastim are now available; the MMP recognises the potential savings arising from these. These savings, however, can only be realised by prescribing and utilisation of the BVB medicines recommended by the MMP.

The MMP recommends the following as BVB medicines for long-acting G-CSFs:

- **Lonquex®** solution for injection pre-filled syringe 6 mg/0.6 ml (Teva Pharmaceuticals Ireland)
- **Neulasta®** solution for injection pre-filled syringe 6 mg/0.6 ml (Amgen Ireland Limited)
- **Pelgraz®** solution for injection pre-filled injector/pre-filled syringe 6 mg/0.6 ml (Accord Healthcare Ireland Limited)
- **Ziextenzo®** solution for injection pre-filled syringe 6 mg/0.6 ml (Rowex Limited).

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

Prescribing of the recommended BVB medicines for long-acting G-CSFs reduces the financial burdens on the HSE arising out of the funding of reimbursed medicines, and can assist in facilitating access to new, innovative medicines for patients. At this point in time, in order to ensure that the potential savings arising from this recommendation are fully realised, additional measures are being put in place for adult patients who are being initiated on treatment with long-acting G-CSFs.

Accordingly, from 1 April 2024, reimbursement of long-acting G-CSFs on the High Tech Arrangement will only be supported for the identified BVB medicines in adult patients commencing such therapy. Clinicians will have the option to initiate a patient on any of the four recommended BVB medicines outlined above.

In addition, all medicinal products containing long-acting G-CSFs will be added to the High Tech Hub from 1 April 2024. From this date, there will be two possible options for prescribers:

1. Generate the prescription for a long-acting G-CSF 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 for the long-acting G-CSF via the Hub.

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*.

A process to review the recommended BVB medicines for long-acting G-CSFs will commence one year after the initial date of implementation.

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

My thanks for your ongoing support in promoting safe, effective and cost-effective prescribing.

With best wishes,

Michael Barry.

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

Reimbursement of Medicinal Products containing Long-acting granulocyte-colony stimulating factors: Questions and Answers for Healthcare Professionals
March 2024

Introduction

Reimbursement of medicinal products containing long-acting granulocyte-colony stimulating factors (G-CSFs) (i.e. lipegfilgrastim and pegfilgrastim) is supported on the High Tech Arrangement in line with their licensed indication, i.e. the reduction in the duration of neutropenia and the incidence of febrile neutropenia in patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndrome).

As of 1 March 2024, there are four medicinal products containing long-acting G-CSFs available on the High Tech Arrangement:

- Lonquex® solution for injection pre-filled syringe 6 mg/0.6 ml (Teva Pharmaceuticals Ireland)
- Neulasta® solution for injection pre-filled syringe 6 mg/0.6 ml (Amgen Ireland Limited)
- Pelgraz® solution for injection pre-filled injector/pre-filled syringe 6 mg/0.6 ml (Accord Healthcare Ireland Limited)
- Ziextenzo® solution for injection pre-filled syringe 6 mg/0.6 ml (Rowex Limited).

In addition, there are three medicinal products available on the High Tech Arrangement for which the European Medicines Agency has issued parallel distribution notices:

- Lonquex® solution for injection pre-filled syringe 6 mg/0.6 ml (Originalis B.V.)
- Lonquex® solution for injection pre-filled syringe 6 mg/0.6 ml (PCO Manufacturing Limited)
  - Pelgraz® solution for injection pre-filled syringe 6 mg/0.6 ml (Originalis B.V.).

Lonquex® contains lipegfilgrastim. In relation to pegfilgrastim, Neulasta® is the reference medicinal product. Pelgraz® and Ziextenzo® are licensed as biosimilar medicines of the reference medicinal product, Neulasta®.

In February 2024, following a review of medicinal products containing long-acting G-CSFs, the HSEMedicines Management Programme (MMP) has identified best-value biological medicines (BVBs) for long-acting G-CSFs on the High Tech Arrangement;

- **Lonquex®** solution for injection pre-filled syringe 6 mg/0.6 ml (Teva Pharmaceuticals Ireland)
- **Neulasta®** solution for injection pre-filled syringe 6 mg/0.6 ml (Amgen Ireland Limited)
- **Pelgraz®** solution for injection pre-filled injector/pre-filled syringe 6 mg/0.6 ml (Accord Healthcare Ireland Limited)
- **Ziextenzo®** solution for injection pre-filled syringe 6 mg/0.6 ml (Rowex Limited).

The MMP recommends that when initiating a patient on a medicinal product containing a longacting G-CSF, the clinician should prescribe one of the recommended BVB medicines outlined above.

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.

What changes are being introduced for long-acting G-CSFs on the High Tech Arrangement from 1 April 2024?

From 1 April 2024, it is HSE policy that all adult patients who are commencing treatment with a long-acting G-CSF on the High Tech Arrangement should be prescribed and receive one of the MMP BVB medicines.

Why have these changes been introduced?

The BVB medicines for long-acting G-CSFs are provided to the HSE at a much lower cost than the other medicinal products containing long-acting G-CSFs 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. Prescribing of the BVB medicines will lead to significant savings for the health service, which can assist in facilitating access to new, innovative medicines for patients.

What do these changes mean for new patients, i.e. those commencing treatment with a long-acting G-CSF?

From **1 April 2024**, all adult patients who are commencing treatment with a long-acting G-CSF on the High Tech Arrangement should be prescribed and receive one of the identified BVB medicines:

- **Lonquex®** solution for injection pre-filled syringe 6 mg/0.6 ml (Teva Pharmaceuticals Ireland)
- **Neulasta®** solution for injection pre-filled syringe 6 mg/0.6 ml (Amgen Ireland Limited)
- **Pelgraz®** solution for injection pre-filled injector/pre-filled syringe 6 mg/0.6 ml (Accord Healthcare Ireland Limited)
- **Ziextenzo®** solution for injection pre-filled syringe 6 mg/0.6 ml (Rowex Limited).

What is the definition of a new patient?

A new patient, is an adult, who has never been prescribed a long-acting G-CSF before, or has not received this medicine within the last six months.

What do these changes mean for existing patients prescribed a long-acting G-CSF prior to 1 April 2024?

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

Do these changes apply to all patients?

These changes **do not apply to paediatric patients,** i.e. patients who are less than 18 years of age.

Where can I get information on the best-value biological medicines for long-acting GCSFs?

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 Long-acting granulocyte-colony stimulating factors: Questions and Answers for Healthcare Professionals
- Information for Patients about Medicines containing Long-acting granulocyte-colony stimulating factors

- MMP product information sheets for Lonquex®, Neulasta®, Pelgraz® and Ziextenzo®
- Information on patient support services for Lonquex®, Neulasta®, Pelgraz® and Ziextenzo®

Will the MMP recommendations be reviewed?

A process to review the recommended BVB medicines for long-acting G-CSFs will commence one year after the initial date of implementation.

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 long-acting G-CSFs. 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.

Pelgraz® and Ziextenzo® are both biosimilar medicines containing pegfilgrastim; 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/specialtopics/biosimilar-medicines
European Medicines Agency: www.ema.europa.eu/en/human-regulatory/overview/biosimilarmedicines-overview#information-for-patients-and-healthcare-professionals-section

The HSE-National Cancer Control Programme (NCCP) guidance on the use of biosimilar medicines highlights that biosimilar medicines and generics represent some of the ways to obtain sustainability in relation to the cost of systemic anti-cancer therapy and maximise the funding for new medicines to be made available for treatment of patients.

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 long-acting G-CSFs be prescribed on the High Tech Hub?

Yes, from 1 April 2024, prescriptions for medicinal products containing long-acting G-CSFs 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.

Information for Patients about Medicines containing Lipegfilgrastim or Pegfilgrastim

March 2024

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.

G-CSF is made naturally in the body, but it can also be made as a drug. Lipegfilgrastim and pegfilgrastim are biological medicines containing G-CSF. They are long-acting versions of G-CSF.

Lipegfilgrastim and pegfilgrastim are biological medicines that are often given with 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.

The number of white blood cells usually goes back up naturally between the cycles of chemotherapy. Some people need lipegfilgrastim or pegfilgrastim 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.

Your doctor has given you lipegfilgrastim or pegfilgrastim to encourage the part of your bone that makes blood cells to produce more white blood cells quickly.

What are the best-value biological medicines for long-acting G-CSFs?

The best-value biological medicines identified by the HSE for long-acting G-CSFs are:

- Lipegfilgrastim: **Lonquex®**
- Pegfilgrastim: **Neulasta®**, **Pelgraz®** and **Ziextenzo®**.

Pelgraz® and Ziextenzo® 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.

Neulasta® was the original biological medicine for pegfilgrastim. When the patent for Neulasta® expired, biosimilar medicines containing pegfilgrastim became available. Pelgraz® and Ziextenzo® 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?

From **April 2024**, we are changing the way medicines containing long-acting G-CSFs (i.e. pegfilgrastim and lipegfilgrastim) are prescribed under the HSE's High Tech Arrangement.

I am a new patient, what do the changes mean for me?

From **1 April 2024**, if you are starting treatment on a long-acting G-CSF, you will be prescribed and receive one of the best-value biological medicines:

- Lipegfilgrastim: **Lonquex®**
- Pegfilgrastim: **Neulasta®**, **Pelgraz®** and **Ziextenzo®**.

What's the definition of a new patient?

A new patient, is an adult, who has not been prescribed or received pegfilgrastim or lipegfilgrastim within the last six months.

I am an existing patient prescribed pegfilgrastim or lipegfilgrastim, what does the change mean for me?

If you are an existing patient, you will continue to receive your medicine from your community pharmacy. The changes outlined above do not apply to you.

Does my consultant know about these changes?

Yes. Consultants who care for patients with cancer are aware of these changes.

Why have the changes been introduced?

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 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/specialtopics/biosimilar-medicines

European Medicines Agency:

www.ema.europa.eu/en/humanregulatory/overview/biosimilar-medicines-overview#information-for-patients-and-healthcareprofessionals-section