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 HSE-Medicines 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 long-acting 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 G-CSFs?

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/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-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.