Guideline for the management of G-CSF (Granulocyte-Colony Stimulating Factor) in children and young people with a cancer diagnosis

Trust Ref: E8/2024

Introduction and Who this Standard Operating Procedure applies to

This CYPICS network guideline has been developed by clinicians from Nottingham Children's Oncology Unit with consultation across the network including from the Leicester Royal Infirmary and has been ratified by the Leicester Children's Hospital guideline process.

This guideline applies to all children and young people under the age of 19 years who are receiving chemotherapy for malignant disease

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Guidelines for the use of Granulocyte Colony Stimulating Factor (G-CSF) in paediatric oncology and haematology

Introduction

Granulocyte Colony Stimulating Factor (G-CSF) is a recombinant human growth factor which acts on neutrophil precursor cells resulting in an increase in the neutrophil count.

It can be used to reduce the period of neutropenia in children and adults treated with established cytotoxic chemotherapy regimens associated with prolonged neutropenia, and to reduce the period of neutropenia in children with prolonged sepsis.

GCSF is also used to reduce the duration of neutropenia and the associated complications in patients following peripheral stem cell or bone marrow transplant.

Pegylated GCSF is a sustained duration form of GCSF. Due to its long half-life, pegylated GCSF is given as a single once only injection for each chemotherapy cycle rather than daily (which is often for up to 14 days).

Currently, daily injections of GCSF, for paediatric patients, are administered either in hospital or at the patients' home, with significant input from children's community nurses (CCN).

Pegylated GCSF is administered only ONCE after each course of chemotherapy in comparison to regular GCSF which is required daily. This offers the benefits of a single injection per course rather than once daily which is potentially more patient/carer friendly and/or releases nursing time for other activities.

In the UK, pegfilgrastim is licensed for use in adults but not for use in children.[1]

The originator pegfilgrastim (Neulasta®) has an FDA licence for use in children.[2]

Indications for G-CSF

- Reduction in the duration of neutropenia and incidence of febrile neutropenia in patients receiving cytotoxic chemotherapy for a cancer indication
- Stem cell mobilisation prior to stem cell harvest (following specialist centre guidelines)
- To reduce the duration of neutropenia in complicated neutropenic sepsis
- Support dose intense chemotherapy strategies

G-CSF should only be used as primary prophylaxis if specified in the chemotherapy protocol used or where clinically indicated (e.g. due to comorbidities).

Secondary prophylaxis (i.e. following the first incidence of prolonged neutropenia) should be initiated at the discretion of the treating consultant where the following conditions apply:

- Prolonged neutropenia with previous chemotherapy resulting in complications or potential complications such as febrile neutropenia
  OR
- Where prolonged neutropenia would otherwise result in a reduction in cytotoxic dose intensity when the intention for chemotherapy is curative

G-CSF should **NOT** be used to increase intensity of cytotoxic chemotherapy above doses specified in the chemotherapy protocol.

G-CSF should **NOT** be used in patients with haematological malignancies unless specifically recommended by a consultant in paediatric haematology/oncology.

Selection of GCSF Formulation

Biosimilar Pegfilgrastim can be considered first line for patients with:

- Intensive chemotherapy regimens for oncology indications where GCSF use is a pre-requisite in protocol with chemotherapy intervals of 3 weeks or more, including patients with metastases and bone marrow disease.
- Patients who have previously been delayed in count recovery post chemotherapy and are at risk of systemic infections including episodes of Febrile Neutropenia (FN)
- Needle phobic patients

Biosimilar Pegfilgrastim should NOT be considered in patients who are:

- Patients requiring GCSF for harvest prior to apheresis (See overleaf)
- Post bone marrow transplant
- For chemotherapy courses 14 days or less apart from IE chemotherapy in EuroEwing where there is an evidence base to use so.
- **Contraindicated** in Rapid COJEC for High risk Neuroblastoma.
- Patients with a history of severe hypersensitivity reactions.
- Patients with a history of hypersensitivity reactions to filgrastim or pegfilgrastim
- Patients with a history of severe hypersensitivity to latex
- Patients under 2 months old
- Patients with myeloid leukaemia and myelodysplastic syndromes

In these scenarios, daily lenograstim or filgastrim must be used

There may be other scenarios that require individual case by case assessment and MDT discussion. These guidance examples should be considered as a guide only and not exhaustive and should not replace individual patient assessment.

The decision to use biosimilar pegylated GCSF must be made by an oncology/haematology consultant only.

Stem cell mobilisation and after-care

Stem cell harvest and return is undertaken at Sheffield Children's Hospital (NHS) Foundation Trust. The patient's named consultant and liaison nurses will receive mobilization form from the transplant team in Sheffield.

The G-CSF should be prescribed and administered in accordance with the mobilisation and harvest checklist.

A baseline FBC should be taken prior to commencing G-CSF for mobilisation. A copy of this mobilisation and harvest checklist should be added to the patient's medical record or the following information should be clearly documented in the patient's medical notes:

- The specific agent required (**lenograstim**)
- Intended dose and calculation (e.g. units or microgram per kg)
- Frequency of administration
- Route of administration
- Start date
- Duration of treatment

The dose of **Lenograstim** for mobilisation for intended harvest will be calculated using BNFc.
Dose of 10 micrograms/kg daily by subcutaneous injection for 4 - 6 days when it is used alone or 150 micrograms/m^2 daily by subcutaneous injection following adjunctive myelosuppressive chemotherapy.
G-CSF administered for stem cell mobilisation pre-harvest must be given via the subcutaneous route.
An Insuflon® **must not be used** for this patient group.

Dose and duration

If a patient is on trial, the trial protocol must be followed for dose, frequency, route and duration.

G-CSF should be started at least 24 hours after the last dose of cytotoxic chemotherapy and should stop at least 24 hours before the next dose. This includes use in weekly chemotherapy regimens.

Biosimilar Pegfilgrastim

Biosimilar Pegfilgrastim 100 microgram/kg (maximum 6mg) by SUBCUTANEOUS bolus injection as a SINGLE DOSE post a chemotherapy cycle. Prescribe as per the dose banding below to facilitate measurable volumes for administration

Weight	Dose	mLs
<10kg	100 micrograms/kg	As calculated by dose
10kg to 20kg	1.5mg	0.15mL
21kg to 30kg	2.5mg	0.25mL
31kg to 45kg	4mg	0.4mL
>45kg	6mg	0.6mL

See Appendix 1 for guidance if administering a proportion of the pre-filled syringe (i.e. all doses less than 6mg):

Where possible the dose will be given as directed by Summary of Product Characteristics (SPC)[1] – at least 24 hours after cytotoxic chemotherapy and not less than 14 days prior to chemotherapy. The next dose will be given based on the chemotherapy schedule. At the consultant's discretion, this may be within 14 days of the next chemotherapy provided that the white cell count (WCC) is reviewed before each dose is administered and for the high WCC the consultant will consider if pegfilgrastim should continue.

Pegfilgrastim is available as different **brands.** Pegfilgrastim (Pelgraz®) 6mg in 0.6mL pre-filled syringe is approved within local formularies, for use within EM CYPICS.

The following biosimilars have a UK marketing authorization but are not approved for routine use within local formularies:

- Pegfilgrastim (Pelmeg®) 6mg in 0.6mL pre-filled syringe
- Pegfilgrastim (Ziextenzo®) 6mg in 0.6mL pre-filled syringe
- Pegfilgrastim (Neulasta®) 6mg in 0.6mL pre-filled syringe

Note - The needle cover of Neulasta® and Pelgraz® pre-filled syringe contains dry natural rubber (a derivative of latex) which may cause allergic reactions. For patients who are allergic to latex, Pelmeg® should be used, which contains a synthetic rubber, not from any latex derivatives.

Patients should be observed for signs of side effects in hospital for at least **2 hours after the first dose is administered** for signs of hypersensitivity reactions and other adverse drug reactions listed below. If there are no reactions, subsequent doses do not require observation in hospital.

Biosimilar Filgrastim/Lenograstim

Unless specified otherwise in the treatment / trial protocol G-CSF should be continued past the expected nadir of neutrophil counts, and until the neutrophils are back in normal range (ie above 1 x 10^9/L). For outpatients who are not having daily blood tests it is typical to advise that GCSF is continued until Neutrophils >5 x 10^9/L. The threshold should be set by the prescriber and noted with the discharge prescription.

Daily doses of G-CSF should be prescribed as follows

Drug	Prescribed As
Filgrastim	Filgrastim (Accofil®)
Lenograstim	Lenograstim

Dosing tables for measurable doses of filgrastim is shown in Appendix 2 and lenograstim in Appendix 3. Check locally which product is available for each centre.

The preferred route for administering daily G-CSF is subcutaneous, but it may also be given by intravenous infusion. One paper has shown that daily G-CSF given subcutaneously resulted in a shorter time of neutropenia than when given intravenously.[3]

Parents / carers may be trained to administer daily G-CSF subcutaneously.

An Insuflon® must not be used for patients having daily G-CSF.

If the daily dose is to be given by the INTRAVENOUS use, this may be done by attendance on Day Care / ward or by nursing teams in the community.

See Appendix 4 for information on preparing lenograstim for INTRAVENOUS use. Refer to local guidelines or Medusa for other preparations.

Treatment duration is variable and previous response for that patient should be taken into consideration when initiating a supply.

A plan must be in place for follow up blood results and when to stop treatment. A specific person or team should take responsibility for following up these results and informing the patient / carers of the treatment plan.

It is the responsibility of the prescriber to ensure these plans are in place and complete the treatment plan in Appendix 5. The treatment plan should be given to E39 Day Care (NUH), Ward 27 Day Care (ULH) or Disney ward (NGH) when the patient is discharged. A copy of the plan for the children's community nurses (CCN) should be sent home with the family or e-mailed to the relevant CCN team.

Adverse effects / potential risks

The most frequently occurring adverse drugs reactions (≥1/10) reported with pegfilgrastim were headache, nausea and bone pain.

Serious adverse drug reactions include:

- Capillary leak syndrome
- Splenomegaly
- Splenic rupture
- Hypersensitivity reactions including anaphylaxis
- Pulmonary adverse reactions including interstitial pneumonia, pulmonary oedema, pulmonary infiltrates and pulmonary fibrosis. Uncommonly cases have resulted in respiratory failure or acute respiratory distress syndrome.

MHRA drug safety advice: Capillary leak syndrome (CLS)[4]

CLS results from massive leakage of plasma from blood vessels and is characterized by hypotension, oedema, hypoalbuminaemia, and haemoconcentration – the condition may be fatal if not properly managed.

Healthcare professionals should closely monitor for CLS symptoms in patients and healthy donors receiving filgrastim or pegfilgrastim. Standard symptomatic treatment should be given immediately if symptoms occur (this may include intensive care).

Patients should be advised to contact their doctor immediately if they develop symptoms (often with rapid onset) such as generalised body swelling, puffiness (which may be associated with passing water less frequently), difficulty breathing, abdominal swelling and tiredness.

Refer to relevant SPC for all adverse effects.

Biosimilars (Pelgraz®, Pelmeg® and Ziextenzo®) are black triangle drugs and therefore clinicians are required to report any ADRs via the MHRA Yellow Card scheme.

Discharging a patient home on G-CSF in a shared care setting

If a patient requires G-CSF at home (either single dose biosimilar pegfilgrastim, or daily lenograstim/filgastrim) then the nurse discharging the patient should ensure that the patient's CCN team is aware that the patient is on or due to commence G-CSF, route of administration, the duration of treatment and the parameters for stopping G-CSF. A supply of disposable equipment should be sent home with the patient.

If a CCN is to administer or continue the process of teaching a parent / carer to administer G-CSF then a valid correctly completed, prescription chart must also be sent home with the patient.

A FBC should be obtained at least twice a week, or as specified in the treatment plan by the prescriber (see Appendix 5). On the day the blood tests are taken, the sample should be obtained prior to the dose being given.

Blood results should be checked and emailed by the CCN to the relevant email account as follows

Treatment provider	Contact E-mail address
Nottingham	NUHNT.paediatriconcology@nhs.net
Leicester	uhl-tr.oncologyliasonnurse@nhs.net or uhl-tr.leicshaemliasonnurses@nhs.net
Northampton	Paedonc.ngh@nhs.net

The CCN must inform and liaise with the Day Care nurses if the blood results are outside the normal parameters. Decisions to stop G-CSF should be made by the treatment centre based on the plan made by the prescriber. Parents should only be informed of the blood results once decisions about whether to stop or continue G-CSF have been made.

If the patient requires Intravenous (IV) G-CSF at home, the discharging nurse must liaise with the patient's CCN team at the earliest opportunity to ascertain if they have the capacity to undertake this procedure at home. On some occasions, including weekends and bank holidays it may be necessary for the patient to attend the local children's ward for the IV infusion. The CCN would be able to advise when this will be necessary and liaise as appropriate with the local children's ward.

If a child requires IV G-CSF at home the child must be discharged with a supply of G-CSF, including appropriate line flushes and a valid prescription chart detailing the reconstitution and dilution volumes to be administered and the duration of infusion. (Note this is a requirement for single checking by CCN's). The CCN team will supply the

IV pump. The discharging nurse should ensure that the correct equipment is available to home, either supplied by the CCN, or supplies from the discharging area.

Appendix 1 - GUIDANCE ON THE MANIPULATION AND ADMINISTRATION OF BIOSIMILAR PEGFILGRASTIM[v]

Nursing Instructions if administering a proportion of the pre-filled syringe (Pegfilgrastim doses less than 6mg):

Equipment:
Tray
Sharps bin
Clean Gloves
Pegfilgrastim (in pre-filled syringe with needle attached)
1ml syringe
Orange needle
Skin prep stick
Gauze
Plaster

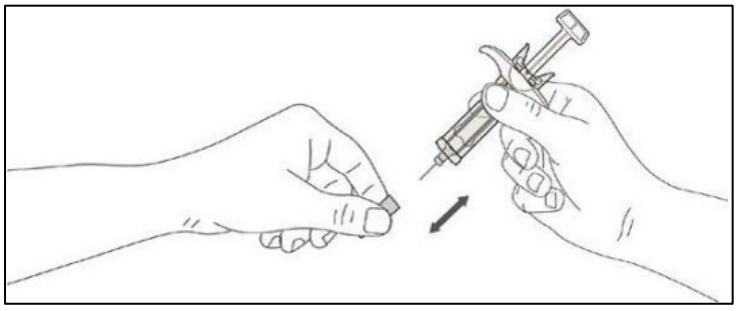
Preparation:
1. Gather all equipment
2. Remove Pegfilgrastim (PEG) from fridge and check that the syringe is in date
3. Clean Tray
4. Open all equipment and place in tray
5. Check the appearance of the syringe (it should be clear and colourless fluid)
6. Wash hands as per policy (NUHa, 2023)
7. Remove the protective cap from the needle on the end of the pre-filled syringe
8. Pull back plunger on 1ml syringe to just past the required amount
9. Put the needle of the PEG pre-filled syringe into the tip of the empty 1ml syringe and inject just over the required volume of PEG
10. Place the pre-filled syringe back in tray (there may be some medication left in this)
11. Attach the orange needle to the end of the 1ml syringe
12. Slowly press the plunger on the 1ml syringe to expel the excess drug until there is only the required volume left in the syringe
13. Check the syringe against the prescription as per policy (NUHb, 2023) and place in tray

Injection:
1. Wash hands as per policy
2. Apply clean gloves
3. Positively identify patient as per local policy
4. Clean the skin with the Chlorhexidine 2% and Alcohol 70% skin prep stick
5. Lightly pinch the skin with one hand (without squeezing it)
6. With the other hand insert the needle into the injection site at a 45 degree angle
7. Hold needle in position for the count of 3 after injecting the drug
8. Remove needle
9. Place used syringe and needle in tray
10. Press firmly over injected area with gauze
11. Put on plaster if required
12. Discard needles and syringes in sharp bin
13. Sign for drug on prescription chart

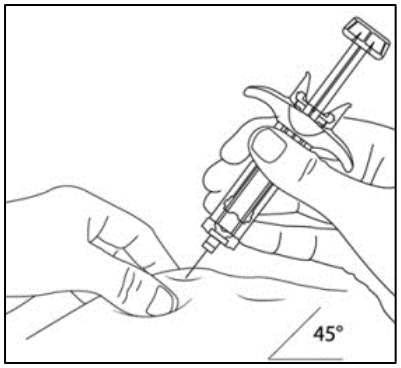
If administering the entire 6mg/0.6ml pre-filled syringe:
1. Remove Pegfilgrastim pre-filled syringe from the fridge
2. Gather all equipment required

3. Clean tray
4. Open all equipment and place in tray
5. Check the appearance of the syringe (it should be clear and colourless fluid)
6. Check the syringe against the prescription as per policy and place in tray
7. Wash hands as per policy
8. Apply clean gloves
9. Positively identify patient as per policy
10. Clean the skin with the Chlorhexidine 2% and Alcohol 70% skin prep stick
11. Remove the protective cap from the syringe (Picture 1)
12. Lightly pinch the skin with one hand (without squeezing it)
13. With the other hand insert the needle into the injection site at a 45 degree angle (Picture 2)
14. Inject the prescribed dose by pushing firmly on the plunger
15. The safety device will activate once the plunger is fully pressed and drug is administered, the plunger will retract the needle from the site once pressure is removed from the plunger (Picture 3)
16. Remove the syringe from the skin, press firmly over injected area with gauze
17. Apply plaster if required
18. Discard syringe into sharps bin
19. Sign for drug on prescription chart

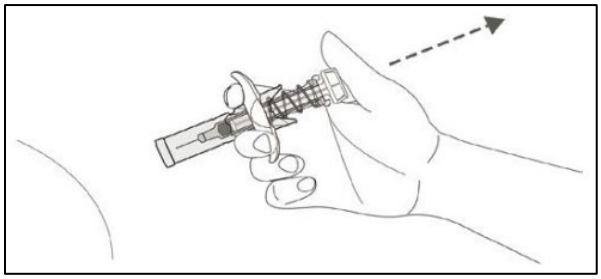
Picture 1



Picture 2



Picture 3



(Accord Healthcare, 2023)

Appendix 2 - Dosing table for filgrastim 300microgram in 0.5ml at 5 microgram/kg/day

Weight (kg)	Dose (microgram)	Volume (ml)
9 – 11	48	0.08
11 – 13.5	60	0.1
13.5 – 16	72	0.12
16 – 18	84	0.14
18 – 21	96	0.16
21 – 23	108	0.18
23 – 26	120	0.2
26 – 29	132	0.22
29 – 33	150	0.25
33 – 39	180	0.3
39 – 45	210	0.35
45 – 51	240	0.4
51 – 56	270	0.45
56 and above	300	0.5

Appendix 3 - Dosing table for Lenograstim 5 microgram/kg/day (equivalent to 0.64 million units/kg)

Syringe	Weight (Kg)	Dose (Micrograms)	Volume (ml)
105 microgram/ml (13.4 MU/ml) Syringe	1	10.5	0.1
	1.5	10.5	0.1
	2	10.5	0.1
	2.5	21	0.2
	3	21	0.2
	3.5	21	0.2
	4	21	0.2
	4.5	31.5	0.3
	5	31.5	0.3
	5.5	31.5	0.3
	6	31.5	0.3
	6.5	31.5	0.3
	7	42	0.4
	7.5	42	0.4
	8	42	0.4
	8.5	42	0.4
	9	52.5	0.5
	9.5	52.5	0.5
	10	52.5	0.5
	10.5	52.5	0.5
	11	52.5	0.5
	11.5	63	0.6
	12	63	0.6
	12.2	63	0.6
	13	63	0.6
	13.5	73.5	0.7
	14	73.5	0.7
	14.5	73.5	0.7
	15	73.5	0.7
	15.5	84	0.8
	16	84	0.8
	16.5	84	0.8
105 microgram/ml	17.5	94.5	0.9
	18	94.5	0.9
	18.5	94.5	0.9
	19	94.5	0.9
	19.5	105	1
	20	105	1
	20.6	105	1
	21	105	1
	21.5	105	1
263 microgram/ml (33.6 MU/ml) Syringe	22	131.5	0.5
	24.5	131.5	0.5
	25	131.5	0.5
	27.5	131.5	0.5
	28	157.8	0.6
	30	157.8	0.6
	30.5	157.8	0.6
	32.5	157.8	0.6
	33	184.1	0.7
	35	184.1	0.7
	35.5	184.1	0.7
	37.5	184.1	0.7
	38	210.4	0.8
	40.5	210.4	0.8
	41	210.4	0.8
	43	210.4	0.8
	43.5	236.7	0.9
	45.5	236.7	0.9
	46	236.7	0.9
	48	236.7	0.9
	48.5	263	1
	51	263	1
	51.5 and over	263	1

	17	84	0.8

Summary

Calculated Dose (Micrograms)	Prescribed Dose (Micrograms)
0 – 11.25	10.5
> 11.25 - 21.25	21
> 21.25 - 33.75	31.5
> 33.75 – 43.75	42
> 43.75 – 56.25	52.5
> 56.25 - 66.25	63
> 66.25 – 76.25	73.5
> 76.25 - 86.25	84
> 86.25 – 93.25	94.5
> 96.25 – 108.75	105
> 108.75 – 138.75	131.5
> 138.75 – 163.75	157.8
> 163.75 – 188.75	184.1
> 188.75 – 216.25	210.4
> 216.25 – 241.25	236.7
>241.25	263

Appendix 4 - GUIDANCE ON RECONSTITUION AND INTRAVENOUS ADMINISTRATION OF LENOGRASTIM (Granocyte®)

PRESENTATION(S) OF MEDICINE

Vial containing lenograstim 13.4million units (105micrograms) powder plus 1ml prefilled syringe containing water for injections for reconstitution.
Vial containing lenograstim 33.6million units (263micrograms) powder plus 1ml prefilled syringe containing water for injections for reconstitution.

METHOD OF ADMINISTRATION

Child 2 - 18 years
IV infusion [unlicensed]: over 30 minutes via an infusion pump.

INSTRUCTIONS FOR RECONSTITUTION

***Lenograstim 13.4million unit vial*.**
Reconstitute by adding the total contents of the disposable prefilled syringe to the vial to give a concentration of 13.4million units in 1ml (105micrograms in 1ml).

Lenograstim 33.6million unit vial.
Reconstitute by adding the total contents of the disposable prefilled syringe to the vial to give a concentration of 33.6million units in 1ml (263micrograms in 1ml).

Agitate the vial gently until completely dissolved. Do not shake vigorously.
Requires further dilution before Intravenous administration.

INSTRUCTIONS FOR DILUTION AND IV ADMINISTRATION

Lenograstim 13.4million unit vial.
Dilute the reconstituted solution (105micrograms in 1ml) to a concentration of not less than 0.26million units/ml (2micrograms in 1ml) with sodium chloride 0.9%.
Suggested dilution
Dilute the reconstituted solution containing 105 micrograms in 1ml to a **maximum** total volume of 50ml with sodium chloride 0.9%. Whilst a smaller total volume can be used if preferred, the total diluted volume must not exceed 50ml.

Lenograstim 33.6million unit vial.
Dilute the reconstituted solution (263micrograms in 1ml) to a concentration of not less than 0.32million units/ml (2.5micrograms in 1ml) with sodium chloride 0.9%.
Suggested dilution
Dilute the reconstituted solution containing 263 micrograms in 1ml to a **maximum** total volume of 100ml with sodium chloride 0.9%. Whilst a smaller total volume can be used if preferred, the total diluted volume must not exceed 100ml.

FLUSHING:

Flush with sodium chloride 0.9% or glucose 5%.

Reference

Medusa injectable medicines guide. [Accessed via NUH intranet 8.9.2023]

Appendix 5 - Treatment plan for GCSF managed as out-patient – Top section to be completed by the prescriber, second section to be completed by nursing team

Patient name:	
Patient date of birth	
Drug	☐ Pegfilgrastim ☐ Lenograstim
Dose:	
Route:	☐ Sub-cuteous injection ☐ Intravenous infusion
Frequency:	☐ SINGLE dose ☐ Once daily
Frequency of FBC:	
Minimum duration:	
Target neutrophil count (x 10^9/L) to stop at or stop date:	

Prescriber / consultant …… Date ……

Who is administering?	☐Parent ☐Community team ☐E39 Day Care ☐Other (specify below)
If community or other – which team? And has it been booked?	
Where is FBC being done?	

And has it been booked?	
Who is monitoring results / informing family?	

Nurse and ward …… Date ……

Table for monitoring results:

Date	Neutrophil count (x 10^9/L)	Patient / family contacted	Notes / comments	Signature

This must be filed in the patient's notes once complete.

References:

Neulasta® Summary of Product Characteristics – Last updated on emc: 01 Jul 2021

[1] Neulasta® Prescribing Information (US)

[1] Paul M et al. Subcutaneous versus intravenous granulocyte colony stimulating factor for the treatment of neutropenia in hospitalized hemato-oncological patients: Randomized controlled trial. American Journal of Hematology 2014: (89) 243-248.

[1] MHRA Drug Safety Update: Filgrastim and pegfilgrastim: risk of capillary leak syndrome. 20th August 2013

[1] Clinical Guidelines for the Use of Pegfilgrastim in Paediatric Oncology patients at Great Ormond Street Hospital (Version 3, June 2023)

Accord Healthcare (2023) Patient information leaflet. Available at: Pelgraz Solution | Accord-UK Products (accord-healthcare-products.co.uk) Accessed: 07/12/2023

NUH a (2023) Hand Hygiene Policy. Available at: Details for: Hand Hygiene Policy › NUHT Clinical Guidelines and Policies catalogue (koha-ptfs.co.uk) Accessed: 07/12/2023

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NUH c (2023) Positive Identification of Patients procedure. Available at: Details for: Positive Identification of Patients Procedure › NUHT Clinical Guidelines and Policies catalogue (koha-ptfs.co.uk). Accessed:07/12/2023

IV (Intravenous Therapy) UHL Policy Trust ref: B25/2010

Infection Prevention UHL Policy Trust ref: B4/2005

Leicestershire Medicines Code UHL Policy Trust ref: B60/2011

Patient ID Band UHL Policy.pdf Trust ref: B43/2007

UHL Education and Training

None

Key Words

Filgrastim, Lenograstim Neutropenia, Oncology, Pegfilgrastim

The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.
As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

	Title of Guideline	**Guideline for the management of G-CSF (Granulocyte-Colony Stimulating Factor) in children and young people with a cancer diagnosis**
	Contact Name and Job Title (author)	Colin Ward Lead Pharmacist, EM CYPICs
	Directorate & Specialty	Directorate: Family Health – Children Specialty: Oncology and Haematology
	Date of submission	January 2024
	Date when guideline reviewed	January 2029
	Guideline Number	
	Explicit definition of patient group to which it applies (e.g. inclusion and exclusion criteria, diagnosis)	Children and young people under the age of 19 (Nottingham & Northampton) or under the age of 25 (Leicester) with a cancer diagnosis who need treatment with Granulocyte Colony Stimulating Factor (G-CSF)
	Abstract	This guideline describes the assessment and management of children and young people with a cancer diagnosis who need treatment with Granulocyte-Colony Stimulating Factor (G-CSF)
	Key Words	
	Statement of the evidence base of the guideline – has the guideline been peer reviewed by colleagues?	
1a	meta analysis of randomised controlled trials	
2a	at least one well-designed controlled study without randomisation	

2b	at least one other type of well-designed quasi-experimental study	
3	well –designed non-experimental descriptive studies (ie comparative / correlation and case studies)	
4	expert committee reports or opinions and / or clinical experiences of respected authorities	
5	recommended best practice based on the clinical experience of the guideline developer	Yes
	Consultation Process	Medical, nursing and pharmacy staff across CYPICS
	Target audience	All clinical staff working in Paediatric Haematology and oncology to include doctors, nurses and pharmacists.
	This guideline has been registered with the trust. However, clinical guidelines are guidelines only. The interpretation and application of clinical guidelines will remain the responsibility of the individual clinician. If in doubt contact a senior colleague or expert. Caution is advised when using guidelines after the review date.	

CONTACT AND REVIEW DETAILS	
SOP Lead (Name and Title) Emma Ross; Consultant Paediatric Oncologist	**Executive Lead** **Chief Medical Officer**

Details of Changes made during review:

Document Amendment Record

Version	Issue Date	Author
V1		Jenni Hatton
V2	April 2023	Colin Ward
V3	January 2024	Colin Ward

General Notes:

Summary of changes for new version:
Incorporation of PEG-Filgrastim