Department of Clinical Haematology
Oxford BMT Programme

Plerixafor Use for Peripheral Blood Stem Cell Mobilisation in adult patients

1. PURPOSE

The purpose of this protocol is to ensure standardised practice for the use of Plerixafor in peripheral blood stem cell (PBSC) mobilisation. Plerixafor mobilises haematopoietic stem cells from the bone marrow increasing their number in peripheral blood. Unlike the standard treatment of granulocyte colony stimulating factor (G-CSF), Plerixafor is not a growth factor but works alongside G-CSF to release cells more efficiently.

2. ELIGIBLE PATIENTS

Patients with any type of blood cancer and specific solid tumours, who are scheduled for autologous HSCT in accordance with national guidance (British Society of Blood and Marrow Transplantation (BSBMT), Adult BSBMT Indications Table 2012, Paediatric BSBMT Indications Table 2015) and:

Option 1. Unplanned Plerixafor (Pre-emptive): Patients who are undergoing mobilisation with a standard chemotherapy + G-CSF or G-CSF based regimen, have a low peripheral blood CD34+ cell count on the day of expected harvest and are not considered by the transplant consultant to have a reasonable chance of collecting enough cells.

Option 2. Planned Plerixafor (Rescue): Patients who have failed one previous attempt at PBSC mobilisation using a standard mobilisation regimen combining chemotherapy + G-CSF or G-CSF alone.

The need for patients to receive **Unplanned treatment** with Plerixafor (option 1) is not predictable such that resources cannot be allocated in advance. The **ability to proceed is not guaranteed** and will be assessed on an individual case basis depending on availability of apheresis slots, stem cell processing and ward care on the day. At least 2 further days of apheresis/processing slots should be available before the patient receives Plerixafor. Where possible, patients with risk factors known to adversely affect PBSC mobilisation (see appendix 1) will be identified in advance and resource issues discussed at the weekly stem cell planning meeting.

3. PRE-ASSESSMENT

See PBSCH protocol.
Consider whether the patient needs accommodation in Oxford. Options include the Churchill flat for unplanned Plerixafor usage and bed and breakfast accommodation for planned Plerixafor.

4. INDICATED SCHEDULING PROTOCOLS

4.1 Option 1. Unplanned Treatment [4]

Day	Time	Treatment
Day 0		Expected day of apheresis after G-CSF with or without chemotherapy and WCC ≥ 1 x 10^9/L.
	08:30	Patient attends NHSBT apheresis unit: If PB $CD34^+$ ≥ 15 per µl (or HPC >0.045), proceed to harvest as standard. If PB $CD34^+$ 8-14 per µl proceed to harvest but consider plerixafor if yield suboptimal. If $CD34^+$ count is insufficient to harvest cells (< 8 per µl) or yield is insufficient patient should receive a dose of plerixafor at 17:00 or later*, see below
	17:00 or later	If **weight ≤ 83Kg:** Plerixafor 20mg fixed dose OD by SC injection If **weight > 83Kg:** Plerixafor 0.24mg/kg OD by SC injection (see section 7 for further details on dose)
	Afternoon/ evening	G-CSF to continue (to be administered at same time as before Plerixafor was started - usually evening). Check dose patient is receiving. **If patient is only on 0.5 MU/Kg for PBSC mobilisation (e.g. myeloma patient), the dose should be increased to 1 MU/Kg for use with Plerixafor.**
Day 1	**08:30**	Patient attends NHSBT apheresis unit: If PB $CD34^+$ ≥ 8 per µl, proceed to harvest. If PB $CD34^+$ 8-14 per µl proceed to harvest but consider plerixafor if yield suboptimal*. If PB $CD34^+$ < 8 per µl, discuss with consultant.**

*If harvest yield is less than target repeat Plerixafor + G-CSF doses after ensuring there is apheresis and stem cell lab availability (for at least 2 days after the first plerixafor dose) and after discussion with consultant.
**Consider apheresis if $CD34^+$ is 7 per µl -see appendix 2 for background.

4.2 Option 2 – Planned Treatment[2]

Day	Time	Treatment:
Day 1	**07:00**	G-CSF at 1 MU/Kg OD by SC injection
Day 2	**07:00**	G-CSF at 1 MU /Kg OD by SC injection
Day 3	**07:00**	G-CSF at 1 MU /Kg OD by SC injection
Day 4	**07:00**	G-CSF at 1 MU /Kg OD by SC injection

	17:00 or later	If **weight ≤ 83Kg:** Plerixafor 20mg fixed dose OD by SC injection If **weight > 83Kg:** Plerixafor 0.24mg/kg OD by SC injection (see section 7 for further details on dose)
Day 5	**07:00**	G-CSF at 1 MU/Kg OD by SC injection
	08:30	Patient attends NHSBT apheresis unit: If PB $CD34^+ \geq 8$ per µl (or HPC >0.045), proceed to harvest. If PB $CD34^+ < 8$ per µl, discuss with consultant.*
	17:00 or later**	If **weight ≤ 83Kg:** Plerixafor 20mg fixed dose OD by SC injection If **weight > 83Kg:** Plerixafor 0.24mg/kg OD by SC injection (see section 7 for further details on dose)

* Consider apheresis if CD34 is 7 per µl - see appendix 2 for background.
**If harvest yield is less than the target, repeat Plerixafor + G-CSF doses after ensuring there is apheresis and stem cell lab availability and after discussion with consultant.

Please note that NHSE funds a **maximum of 3 plerixafor doses.**

5. ACTIONS TO BE TAKEN BY TRANSFUSION SPR:

- If WCC > 70 x 10^9/L, discuss with consultant prior to proceeding with Plerixafor or G-CSF administration.
- Patients should not be informed they are having plerixafor until the capacity to accommodate this is confirmed with the referring team.
- If patient is being considered for plerixafor, liaise with the referring consultant or CNS:
    - If $CD34^+$ count < 8 per µl, consider if the referring team has capacity to administer plerixafor?
    - If $CD34^+$ 8-14 per µl, consider if the referring team has capacity to give plerixafor if the yield is low when this is known at about 4pm?
- For OUH adult patients inform patient's CNS and DTU co-ordinating nurse (bleep 5126).
- For OUH adult patients prescribe 3 doses of Plerixafor. Blueteq form required. If it is not clear whether patient has consented to Plerixafor, re-take consent and give patient a copy to take to DTU to be scanned onto the patient's record on EPR.
- For patients at other hospitals, discuss with their consultant or CNS
- For OUH patients ask CNS to review whether patient needs help with accommodation or transport.

6. ACTIONS TO BE TAKEN BY BMT CNS FOR OUH PATIENTS ONLY:

- Inform Pharmacy that **unplanned** Plerixafor is required for a patient by contacting the Day Treatment Unit Pharmacist via email (haemtechs@ouh.nhs.uk and screeningcancerpharmacists@ouh.nhs.uk). Complete the table template on **Appendix 3** and copy it to the patient's records on EPR before contacting Pharmacy to screen Plerixafor.

7. DOSE

Creatinine clearance (ml/min)	**Plerixafor dose (based on body weight)[1]**
>50	**Weight ≤ 83Kg:** 20mg fixed dose **Weight > 83Kg:** 0.24mg/Kg (maximum 40mg/day) Once daily given as subcutaneous injection
20-50	0.16 mg/kg (maximum 27mg/day) once daily given as subcutaneous injection
<20	Insufficient clinical evidence to recommend dose alterations. See section 9 for use of Plerixafor in dialysis-dependent patients

The patient's weight should be obtained within 1 week of the first dose. If the patient's weight is over 175% ideal body weight (IBW) the Plerixafor dose should be capped at the dose for 175% IBW.

IBW can be determined using the following equations:
Male (kg): 50 + 2.3 x ((height (cm) x 0.394) – 60)
Female (kg): 45.5 + 2.3 x ((height (cm) x 0.394) – 60)

8. ADMINISTRATION[1]

Plerixafor should be administered as a subcutaneous injection over the abdominal area. If the volume to be given exceeds 1.2ml the dose may be split and given in 2 injections.

Patients should be monitored for one hour after drug administration

*Timings are crucial to the success of Plerixafor treatment; any variations to the administration must be reported to the NHSBT apheresis unit.[3]

Contra-indications:

- Hypersensitivity to active substance or any of the excipients.

9. RECOMMENDED USE OF PLERIXAFOR IN DIALYSIS PATIENTS – Planned treatment (option 2)[5]

	Day 1 (Plan for Friday start)	Day 2	Day 3	Day 4	Day 5	Day 6
Morning **07:00**	G-CSF 1 MU/Kg	G-CSF 1 MU /Kg	G-CSF 1 MU /Kg	G-CSF 1 MU /Kg	G-CSF 1 MU /Kg	G-CSF 1 MU /Kg *
Morning after G-CSF					Apheresis*	Apheresis*
Day	HD anytime			HD prior to Plerixafor		HD prior to Plerixafor
17:00 or later				Plerixafor	?Plerixafor*	?Plerixafor*

HD=Haemodialysis;
*dependent on CD34+ count or yield
For dialysis patients that are having unplanned Plerixafor (option 1), it should be ensured that Plerixafor is given after dialysis.

10. ADVERSE EFFECTS

Commonly occurring side effects:
• Vasovagal reactions (can occur up to 1 hour after admin. hence monitoring need)
• Gastrointestinal effects including diarrhoea (more than 1 in 10 patients), nausea, vomiting, flatulence, dyspepsia, constipation.
• Reaction at injection site and allergic reactions
• Headache
• Arthralgia
• Dizziness
• Fatigue and insomnia

Potentially serious side effects:
- Hyperleucocytosis
- Thrombocytopenia,
- Splenic enlargement with potential for rupture (Rare)
- Allergic reactions

APPENDIX 1

Factors that may predict poor PBSC mobilisation include:
1. Heavy pre-treatment with any chemotherapy agents;
2. Previous treatment with any of fludarabine, alkylating agents, lenalidomide and possibly thalidomide;
3. Previous radiotherapy to large bone marrow-containing areas;
4. History of low grade lymphoma;
5. Bone marrow involvement.

APPENDIX 2

Audit of Correlation between Pre-CD34⁺ Counts and Stem Cell Yield

47 patients received plerixafor May 2012-Nov 2015, 45 in planned fashion.
In 64 of their apheresis episodes, pre-$CD34^+$ counts were available.
In 19 cases the pre-count was less than 8/µl. Only 3 of these episodes resulted in a yield that may have been useful (0.85, 1 and 1.12 x 10^6 $CD34^+$/kg). In all 3 of these cases the pre-$CD34^+$ count was 7. A pre-$CD34^+$ count of 6 or below was never associated with a useful yield (defined as ≥ 0.7 x 10^6 $CD34^+$/kg). **R Pawson, unpublished data Feb 2016**

APPENDIX 3

For OUH patients only: the BMT CNS will complete the below table or equivalent information and add it to the patient's record on EPR, prior to contacting Pharmacy to screen **unplanned** Plerixafor.

Pre-count	$CD34^+$ count:	
	Haematopoietic progenitor cells (HPC) count:	
	White cell count (WCC):	
Latest bloods	On EPR or ARIA:	
	Date:	
	Creatinine:	CrCl: ml/min (ARIA)
Plerixafor	Is it prescribed? Yes/No	
	Is Blueteq done? Yes/No	
	Has DTU been booked? Yes/No	
	Is patient aware? Yes/No	
Rationale for Plerixafor administration		
Plerixafor discussed with consultant?	Yes/No	
Has consent for Plerixafor been organised?	Yes/No	

11. REFERENCES

1. Mozobil: Summary of Product Characteristics last updated on the eMC: 30/05/2024. Available on Mozobil 20 mg/ml solution for injection - Summary of Product Characteristics (SmPC) - (emc)
2. Clinical Commissioning Policy: Plerixafor for stem cell mobilisation in adults and children (Publication reference no: 200601P). NHS England. https://www.england.nhs.uk/wp-content/uploads/2020/09/1902_Plerixafor_Clinical_Commissioning_Policy.pdf
3. Cooper et al Late afternoon dosing of plerixafor for stem cell mobilisation: Practical solution. Clinical Lymphoma, Myeloma & Leukemia, Vol. 11, No. 3, 267-72, 2011.

4. Nottingham University Hospitals Trust Bone Marrow Transplant Programme Standard Operating Procedure: Protocol for Plerixafor PBSC Mobilisation, Prof NH Russell July 2010.
5. Douglas K W et al Plerixafor for PBSC mobilisation in myeloma patients with advanced renal failure: safety and efficacy data in a series of 21 patients from Europe and the USA. Bone Marrow Transplantation advance online publication 28 February 2011; doi: 10.1038/bmt.2011.9
6. Baker J et al. Plerixafor: how can we achieve the best outcome for patients? The role of the apheresis nurse. Oral presentation EBMT April 2015.
7. The Nurses Group Oral Sessions. Bone Marrow Transplant. 2015;50.
8. Cooper DL et al. Late afternoon dosing of plerixafor for stem cell mobilisation: a practical solution. Clin Lymp Myeloma Leuk 2011 **11**: 267-272.

Audit: These processes are subject to the OxBMT audit programme

Original Author: Dr Rachel Pawson, Consultant Haematologist, updated

Circulation: NSSG website

Review

Name	Revision	Date	Version	Review date
Dr Rachel Pawson	Change to include rescue and pre-emptive use; G-CSF dosing in MIU/kg; change in layout.	April 2012	1.1	May 2014
Julia Wong, Pharmacist	Changed GCSF units from MIU to MU Changed Pre-Emptive Day 0 GCSF doses. Stock management.	15/08/14	1.2	August 2016
Sandy Hayes, Quality manager	Removal of pre-assessment information. Formatting. Change of location to DTU.	October 2014	2.0	October 2016
Dr Rachel Pawson	Change of earliest time for administration of plerixafor to 1700 in view of data on 147 patients in new references.	April 2015	2.1	October 2016
Dr Rachel Pawson	Re-formatting to simplify tables. Inclusion of HPC to assess mobilisation. Expansion of criteria for pre-emptive use to include patients with CD34 <15 per ul as per NHSE policy, Change to waiting for PB CD34 counts before harvest.	Feb 2016	3.1	Feb 2018

Dr Rachel Pawson	Addition of children and young people with paediatric-type solid malignant tumours into eligibility criteria as per updated NHSE policy August 2016.	October 2020	4.0	October 2022
Dr Asif Khan	No significant changes.	Oct 2023	4.1	Oct 2025
Ana Rita Gomes, Advanced Cancer Pharmacist, Dr Joseph Browning, Haematology Consultant	Reformatting. Clarification of Plerixafor indications. Addition of section 6. Action to be taken by BMT CNS nurses and Appendix 3 (relevant for OUH only).	Nov 2024	4.5	Nov 2026