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PBMT-GEN-058 CRITERIA FOR RE-TRANSPLANTATION

1 PURPOSE

1.1 To describe the criteria for patient selection for second or subsequent Hematopoietic Stem Cell Transplant (HSCT).

2 INTRODUCTION

2.1 Some patients will fail to respond to HSCT because of primary or secondary graft failure, severe graft dysfunction, autologous reconstitution or relapse of their primary disease. In some of these cases, when the patient's situation is lifethreatening, a subsequent transplant is indicated.

3 SCOPE AND RESPONSIBILITIES

3.1 Physicians, advanced practice nurses, and nursing staff are responsible for adhering to the contents of this procedure.

4 DEFINITION/ACRONYMS

- 4.1 ALL Acute Lymphoblastic Leukemia
- 4.2 ANC Absolute Neutrophil Count
- 4.3 HSCT Hematopoietic Stem Cell Transplant
- 4.4 TBI Total Body Irradiation

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 N/A

7 SAFETY

7.1 N/A

8 PROCEDURE STEPS

- 8.1 The selection criteria for second or subsequent HSCT include:
 - 8.1.1 Documentation of graft failure or autologous recovery from prior transplant.
 - 8.1.1.1 Defining Primary Graft Failure: While the timing of engraftment, a sustained neutrophil count > 0.5 x 10e9/L, varies according to donor source, neutrophil engraftment for all donor sources is expected within the first 42 days post-transplant. Erythroid and megakaryocytic engraftment usually follows. Graft failure will be defined as the absence

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- of engraftment of ANC with donor cell chimerism prior to day +42 post-transplant for all transplant donor source types.
- 8.1.1.2 Defining Secondary Graft Failure: Secondary graft failure is characterized by a significant drop in donor chimerism at any point after donor engraftment has occurred. Secondary graft failure can be characterized by: a) normal or near normal counts without detection of significant numbers of donor cells or; b) by pancytopenia with marrow aplasia and absent or near absent donor or host hematopoiesis.
- 8.1.1.3 Defining Autologous Recovery: Autologous recovery is defined as recovery of blood counts but absence of donor chimerism.
- 8.1.2 Relapse of malignancy after prior transplant with a reasonable expectation that a subsequent transplant provides a chance of long-term relapse free survival.
 - *An example of this would be a patient relapsing after a chemotherapy-based or reduced intensity transplant who could be re-transplanted using a Total Body Irradiation (TBI)-based prep regimen.
 - *A second example would be a patient experiencing a late relapse (>1 year) after a matched sibling transplant who could be re-transplanted using an unrelated donor.
- 8.1.3 Adequate organ function to withstand planned cytoreduction. The patient would go through a complete transplant work-up including reevaluation of disease status, infectious disease status, organ function, "donor" screening, infectious disease screening and would need be deemed able to withstand the anticipated toxicity of planned therapy.
- 8.1.4 Control of active infections.
- 8.1.5 Availability of a suitable donor.
- 8.1.6 Availability of a fulltime care taker.
- 8.1.7 Parental/patient consent

9 RELATED FORMS/DOCUMENTS

9.1 Patient specific consents are composed for second transplants.

10 REFERENCES

10.1 See materials attached to specific drug information utilized in the preparative regimen selected for the patient.

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)	
06	MC Author: S. McCollum	 Section 4 updated with acronyms Section 5 updated to remove materials no longer 	
	Content Authors: PTCT attending Team h	in use • Minor formatting updates throughout	

Signature Manifest

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