



ADULT AND PEDIATRIC BLOOD AND MARROW TRANSPLANT PROGRAM

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Administration of Preparative Regimens

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Author: MOORE171

Owner: MOORE171

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ADMINISTRATION OF PREPARATIVE REGIMENS

1 PURPOSE

- 1.1 To describe the types of preparative regimens utilized in Hematopoietic Stem Cell Transplantation (HSCT) patients.
- 1.2 To outline minimum categories of follow-up for recipients following administration of the preparative regimen.

2 INTRODUCTION

- 2.1 Patients undergoing HSCT are treated with chemotherapy, and/or radiation therapy, and/or serotherapy which can lead to immunosuppression and myelosuppression. The therapy administered in preparation for transplant is intended to facilitate engraftment and prevent host rejection as well as to eradicate tumor cells in patients undergoing HSCT for the treatment of malignant conditions. The specific therapy to be utilized for each patient is determined based on their age, diagnosis, disease state, type of donor, type of transplant and performance status by the attending physician caring for the patient.
- 2.2 The types of transplant are varied and include related versus unrelated; myeloablative, reduced intensity and/or non-myeloablative. Donor sources include Peripheral Blood Stem Cells (PBSC), Bone Marrow (BM) and Umbilical Cord Blood (UCB). Some graft sources are manipulated (e.g. T-cell depleted, ex-vivo expansion).
- 2.3 Pediatric patients are transplanted for either malignant or non-malignant conditions. In either case, they need immunosuppressive and myelosuppressive therapy to prevent graft rejection. Children with non-malignant conditions are generally not exposed to total body irradiation (TBI) because of the long term adverse effects. Children with malignancies are treated with combination high dose chemotherapy or high dose chemotherapy combined with TBI depending on their age and disease status. TBI is avoided in children less than 2 years of age if possible.
- 2.4 Adult patients undergo either non-ablative, myeloablative, or reduced-intensity (RIC) preparation for HSCT. The choice of regimen is dependent upon disease, disease status, organ function, performance status and age.

3 SCOPE AND RESPONSIBILITIES

- 3.1 Physicians, advanced practice providers, nurse clinicians, inpatient and outpatient nurses, search coordinators, transplant patient financial coordinator, radiation oncologists, and pharmacists are responsible for ensuring that this procedure is carried out.
- 3.2 Nursing staff is responsible for providing patient care and administering chemotherapy treatments as ordered by physicians.

- 3.3 The Radiation Oncologist is responsible for prescribing, administering and monitoring radiation therapy.

4 DEFINITIONS/ACRONYMS

- 4.1 BM Bone Marrow
- 4.2 BSA Body Surface Area
- 4.3 GVHD Graft Versus Host Disease
- 4.4 HCST Hematopoietic Stem Cell Transplantation
- 4.5 PBSC Peripheral Blood Stem Cells
- 4.6 TBI Total Body Irradiation
- 4.7 UCB Umbilical Cord Blood
- 4.8 RIC Reduced Intensity Conditioning

5 MATERIALS

- 5.1 N/A

6 EQUIPMENT

- 6.1 N/A

7 SAFETY

- 7.1 N/A

8 PROCEDURE STEPS

- 8.1 The physician is responsible for determining the type of preparative regimen prescribed for the patient.
- 8.2 During the workup phase and the pre-consenting educational period, the physician, advanced practice providers, and the nurse coordinator are responsible for providing the patient/family or legally authorized representative(s) with information regarding side effects and potential risks and benefits of drugs/radiation therapy they will be receiving.
- 8.3 The physician is responsible for confirming that the patient meets eligibility criteria for the therapy planned.
- 8.4 The physician is responsible for confirming that a donor has been selected and worked up for the patient.
- 8.5 The physician is responsible for confirming that the donor/donor cells are available before the patient starts the preparative regimen.
- 8.6 The physician is responsible for obtaining written informed consent for treatment.
- 8.7 The Transplant Patient Financial Coordinator is responsible for ensuring the reservation for admission to the hospital is completed, if indicated.

- 8.8 The physician is responsible for writing and signing orders for chemotherapy as per the hospital age appropriate chemotherapy policies. (See related Duke University Hospital Department of Pharmacy policies: *Safe Prescribing and Dispensing of Chemotherapy in Adults*. *Safe Prescribing and Dispensing of Chemotherapy in Pediatrics*.)
- 8.9 Orders will include documentation of patient height, weight, body surface area (BSA), specific dates of administration, time of administration (if applicable) and route of administration of each agent.
- 8.10 Standardized orders are used either electronically through the electronic medical health record or in the case of downtime, manually on hospital chemotherapy ordering forms as per hospital policy. These orders shall be verified and documented by the attending physician.
- 8.11 The pharmacist shall verify and document the chemotherapy and doses against the protocol or standardized regimen listed on the orders.
- 8.12 All patients receiving TBI will be seen in consult by a licensed Radiation Oncologist. All pertinent medical information, including but not limited to, diagnosis and proposed plan of care will be obtained. The Radiation Oncologist will prescribe, administer, and monitor radiation therapy.
- 8.13 Before administration of chemotherapy, 2 nurses sign off on the identity of the patient order, drug preparation and medication administration record comparing these to the original physician order.
- 8.14 The nurses are responsible for administering chemotherapy/immunosuppressive therapy per the specific recommendations for that agent (see appended job aides for each agent).
- 8.15 Blood levels may have to be obtained for certain chemotherapy agents, such as Busulfan. Separate physician orders for Busulfan pharmacokinetic levels are obtained.
- 8.16 Follow-up of recipients after the administration of the preparative regimens will be the responsibility of all nursing, advanced practice and physician staff (within their scope of care) caring for the patient and will include at a minimum the following elements:
 - 8.16.1 Assessment for and management of nausea and vomiting.
 - 8.16.2 Assessment for and management of pain and other discomforts.
 - 8.16.3 Monitoring of blood counts and evaluation for the need for transfusion of blood products, when required. See related SOPs: PBMT-GEN-039 *Continuous Platelet Infusion*; PBMT-GEN-041 *Infusion of Platelets*; DUH Policy: Administration of Blood Products Policy; ABMT-GEN-001 *Electrolyte Supplementation Protocol*
 - 8.16.4 Monitoring of infections and evaluation for the need for antimicrobials. See related SOPs: APBMT-COMM-016 *Cytomegalovirus (CMV) Prevention and Treatment*; APBMT-COMM-017 *Pneumocystis Jiroveci Pneumonia (PJP) Prophylaxis*; PBMT-GEN-025 *Evaluation and Therapy of Neutropenic Fever*; ABMT-GEN-013 *Evaluation and*

Therapy of Neutropenic Fever; PBMT-GEN-009 Infection Prevention and Control for the Pediatric Transplant Patient. ABMT-GEN-010 Infection Prevention and Control

- 8.16.5 Monitoring of organ function for detection of dysfunction or failure and institution of treatment when applicable.
- 8.16.6 Assessment of graft function including detection of graft failure and institution of treatment when applicable.
- 8.16.7 Monitoring for evidence of acute Graft versus Host Disease (GVHD) using an established staging and grading system. See related SOPs: APBMT-COMM-013 *Prophylaxis and Treatment of Acute GVHD*.
- 8.16.8 Monitoring for evidence of chronic Graft versus Host Disease (GVHD) using an established staging and grading system. See related SOPs: APBMT-COMM-038 *Prophylaxis and Treatment of Chronic GVHD*.

9 RELATED DOCUMENTS/FORMS

- 9.1 ABMT-GEN-001 Electrolyte Supplementation Protocol
- 9.2 ABMT-GEN-010 Infection Prevention and Control
- 9.3 ABMT-GEN-013 Evaluation and Therapy of Neutropenic Fever
- 9.4 APBMT-COMM-013 Prophylaxis and Treatment of Acute GVHD
- 9.5 APBMT-COMM-016 Cytomegalovirus (CMV) Prevention and Treatment
- 9.6 APBMT-COMM-017 Pneumocystis Jiroveci Pneumonia (PJP) Prophylaxis
- 9.7 APBMT-COMM-038 Prophylaxis and Treatment of Chronic GVHD.
- 9.8 DUH Policy: Administration of Blood Products Policy
- 9.9 DUH Department of Pharmacy policy: Safe Prescribing and Dispensing of Chemotherapy in Adults
- 9.10 DUH Department of Pharmacy policy: Safe Prescribing and Dispensing of Chemotherapy in Pediatrics
- 9.11 PBMT-GEN-025 Evaluation and Therapy of Neutropenic Fever
- 9.12 PBMT-GEN-009 Infection Prevention and Control for the Pediatric Transplant Patient
- 9.13 PBMT-GEN-039 Continuous Platelet Infusion
- 9.14 PBMT-GEN-041 Infusion of Platelets

10 REFERENCES

- 10.1 NA

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
10	<u>MC Author:</u> S. McCollum J. Frith <u>SMEs:</u> Tim Driscoll Elizabeth Rogers Jill Lawrence	<ul style="list-style-type: none"> • Section 2.1: removed “high-dose” from first sentence • APBMT-COMM-016 title updated throughout

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APBMT-COMM-026 Administration of Preparative Regimens**Author**

Name/Signature	Title	Date	Meaning/Reason
Sally McCollum (MOORE171)		25 Jan 2022, 03:50:47 PM	Approved

Management

Name/Signature	Title	Date	Meaning/Reason
Nelson Chao (CHAO0002)		25 Jan 2022, 04:03:34 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		25 Jan 2022, 05:44:14 PM	Approved

Quality

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Bing Shen (BS76)		28 Jan 2022, 09:19:49 AM	Approved

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