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PBMT-GEN-066 ADMINISTRATION OF ALEMTUZUMAB (CAMPATH®)

1 PURPOSE

1.1 To outline the procedure required for administration of alemtuzumab (Campath). Responsibilities of the nursing staff for administering and monitoring adverse reactions to alemtuzumab are described.

2 INTRODUCTION

- 2.1 Alemtuzumab (Campath) indicated for the treatment of B-cell chronic lymphocytic leukemia (CLL) in patients who have been treated with alkylating agents and who have failed fludarabine therapy. Because the CD52 antigen is found on a variety of cells in the body, it is anticipated that the drug will be used in a variety of hematologic and lymphoid disorders—either alone or in combination with other cytotoxic agents.
- 2.2 Alemtuzumab is a humanized monoclonal antibody that targets the CD52 antigen. Alemtuzumab acts by binding to the CD52 antigen on a variety of cells, resulting in an immune-medicated cell lysis.
- 2.3 There are 3 major side effects associated with alemtuzumab:
 - 2.3.1 Hematologic Toxicity pancytopenia, bone marrow hypoplasia, autoimmune ITP, and autoimmune hemolytic anemia. The incidence of these complications increases with the dose
 - 2.3.2 Infusion reactions hypotension, rigors, fever, shortness of breath, bronchospasm, chills, and/or rash
 - 2.3.3 Infections due to severe lymphopenia, therefore it is important to ensure appropriate antiviral, antifungal, and antimicrobial (including PCP coverage) prophylaxis and/or treatment is in place for any patient receiving alemtuzumab therapy.
- 2.4 Alemtuzumab is also used for the treatment of graft versus host disease (GVHD) and to enhance pre-transplant immuno-suppression in allogeneic transplant patients and may be administered either intravenously (IV) or subcutaneously (SC) although SC administration is limited to the inpatient setting.

3 SCOPE AND RESPONSIBILITES

- 3.1 Interdisciplinary: Attending physicians, advanced practice providers (APPs), pharmacists and registered nurses (RNs) are all responsible for the contents of this procedure.
 - 3.1.1 The nurse is responsible for administration of chemotherapy, the management of side effects and assessment of response.
 - 3.1.2 The attending physician is responsible for placing chemotherapy orders in the medical records.

- 3.1.3 The physician and advanced practice providers are responsible for assessment and direction of management of patients receiving chemotherapy agents.
- 3.1.4 The pharmacist is responsible for review of the chemotherapy order and all downstream pharmacy processes in compliance with chemotherapeutic policies and procedures.
- 3.2 Registered Nurses (RNs) may administer alemtuzumab after successful completion of the medication administration test, the chemotherapy certification test and demonstration of clinical competency with their preceptors.
- 3.3 Nursing Certified Assistants (NCAs) are allowed to monitor vital signs during alemtuzumab administration.

4 DEFINITIONS /ACRONYMS

| 4.1 APP Advance Practice Provid |
|---------------------------------|
|---------------------------------|

- 4.2 GVHD Graft Versus Host Disease
- 4.3 IV Intravenous
- 4.4 NCA Nursing Certified Assistant
- 4.5 RN Registered Nurse
- 4.6 SC Subcutaneous

5 MATERIALS

5.1 See the health-system related policy: *Chemotherapy Administration Policy*.

6 EQUIPMENT

6.1 See the health-system related policy: *Chemotherapy Administration Policy*.

7 SAFETY

7.1 Use appropriate Personal Protective Equipment (PPE) when handling chemotherapy. See the health-system related policy: *Chemotherapy Administration Policy*.

8 PROCEDURE

- 8.1 See over-arching procedural steps, including steps for patient assessment and chemotherapy administration steps, in the health-system related policy: *Chemotherapy Administration Policy*.
- 8.2 Patient assessment will be performed as outlined in the health-system related policy *Chemotherapy Administration Policy*.
- 8.3 Additionally:
 - 8.3.1 Assess IV for patency; or in the case of SC administration determine and assess the location for injection.

- 8.3.2 Pre-medicate 30 minutes prior to infusion with required pre-medications as per provider orders which may include: acetaminophen, diphenhydramine, and/or hydrocortisone
- 8.3.3 Assess vital signs as follows:

8.3.3.1

| 8.3.3.1.1 | Pre infusion | |
|-----------|--------------|--|
| | | |

IV administration:

8.3.3.1.2 15 minutes into infusion

8.3.3.1.3 Then every 30 minutes until 30 minutes after completion of infusion

8.3.3.2 SC administration:

| SC ddfffffishation. | | | |
|---------------------|--------------------------------|--|--|
| 8.3.3.2.1 | Pre administration | | |
| 8.3.3.2.2 | 15 minutes post administration | | |
| 8.3.3.2.3 | 30 minutes post administration | | |

- 8.3.4 Additional Monitoring:
 - 8.3.4.1 Monitor all patients for fever, chills, and signs/symptoms of respiratory distress.
 - 8.3.4.2 Monitor patients for injection sight reactions following SC administration.

9 RELATED DOCUMENTS/FORMS

9.1 Duke Health System Policy: *Chemotherapy Administration Policy*.

10 REFERENCES

10.1 Experience with alemtuzumab plus rituximab in patients with relapsed and refractory lymphoid malignancies. S Faderl, DA Thomas, S O'Brien, G Garcia-Manero, HM Kantarjian, FJ Giles, C Koller, A Ferrajoli, S Verstovsek, B Pro, M Andreeff, M Beran, J Cortes, W Wierda, N Tran, and MJ Keating Blood, May 2003; 101: 3413-5.

11 REVISION HISTORY

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| 06 | Sally McCollum | Acronyms defined: APP Reference to PBMT-GEN-069 removed and updated to the Duke University Health System <i>Chemotherapy Administration Policy</i> Scope and Responsibilities section updated to |
| | | include all applicable roles. |

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