



**Duke**Medicine

Division of Cellular Therapy

**DOCUMENT NUMBER:** ABMT-GEN-032

**DOCUMENT TITLE:**

Alemtuzumab-Campath® Monoclonal Antibody Protocol

**DOCUMENT NOTES:**

**Document Information**

**Revision:** 02

**Vault:** ABMT-General-rel

**Status:** Release

**Document Type:** General

**Date Information**

**Creation Date:** 17 Mar 2014

**Release Date:** 18 Jun 2014

**Effective Date:** 18 Jun 2014

**Expiration Date:**

**Control Information**

**Author:** JL26

**Owner:** JL26

**Previous Number:** ABMT-GEN-032

**Change Number:** ABMT-CCR-070

## **ABMT-GEN-032 ALEMTUZUMAB (CAMPATH®) MONOCLONAL ANTIBODY PROTOCOL**

### **1 PURPOSE**

- 1.1 Care of the patient receiving Alemtuzumab Monoclonal Antibody (MoAb) therapy requires consistency in practice. The purpose of this protocol is to provide guidance for the safe administration of this MoAb.

### **2 INTRODUCTION**

- 2.1 Alemtuzumab is a humanized monoclonal antibody that is directed against the cell surface antigen CD-52, which is expressed on normal and malignant B and T lymphocytes, but not on hematopoietic stem cells.
- 2.2 This antibody is commonly given to the transplant patient to purge the immune system and prevent rejection and graft versus host disease.

### **3 SCOPE AND RESPONSIBILITIES**

- 3.1 Physicians and nurses responsible for the care of the blood and marrow transplant patient. Physicians write orders and nursing would verify and carry out those orders, administering the antibody and monitoring the patient.

### **4 DEFINITIONS/ACRONYMS**

- 4.1 Alemtuzumab- Campath®
- 4.2 MoAb- Monoclonal Antibody

### **5 MATERIALS**

- 5.1 Personal Protective Equipment

### **6 EQUIPMENT**

- 6.1 N/A

### **7 SAFETY**

- 7.1 Verify that informed consent has been obtained
- 7.2 Complete ABMT Clinic or 9200 Unit Chemotherapy Checklist.
- 7.3 Discuss possible side effects and symptom management strategies with the patient.
  - 7.3.1 Rigors
  - 7.3.2 Fevers
  - 7.3.3 Nausea and vomiting
  - 7.3.4 Rash

- 7.3.5 Hypotension (Map<60 mmHg)
- 7.3.6 Hypertension
- 7.3.7 Dyspnea
- 7.3.8 Anaphylaxis
- 7.3.9 Fatigue
- 7.3.10 Thrombocytopenia
- 7.3.11 Urticaria

## 8 PROCEDURE

- 8.1 Verify drug dose calculations and patient identity with second chemo competent RN prior to each dose as per DUH Chemotherapy Administration Protocol.
- 8.2 Verify patency of IV site.
  - 8.2.1 Central line access is recommended.
  - 8.2.2 Assess line for blood return.
  - 8.2.3 Use an IV infusion pump to regulate Alemtuzumab infusion rate.
- 8.3 Premedicate as ordered with:
  - 8.3.1 Acetaminophen 650 mg PO.
  - 8.3.2 Diphenhydramine 50 mg IV (order may be written for PO in the ambulatory clinic).
  - 8.3.3 Hydrocortisone 100 mg IV (optional) or other corticosteroid as ordered.
- 8.4 Chemo protective gloves and a chemo protective gown must be worn when administering this drug. For additional information, refer to DUH Chemotherapy Safe Handling and Spill Management Protocol via intranet.
- 8.5 Monitor vital signs prior to infusion, hourly during infusion and for 1 hour after completion of initial infusion and/or as indicated by patient status.
- 8.6 Verify that patient and caregiver have emergency contact numbers of 9200 and physician to call for after hours for any problems.
- 8.7 Anti-infective prophylaxis should be considered.
- 8.8 Document the following:
  - 8.8.1 Patency of IV site/blood return from catheter.
  - 8.8.2 Patient's tolerance of Alemtuzumab.
  - 8.8.3 Response to interventions to minimize side effects.
  - 8.8.4 Patient's understanding of expected side effects and symptom management strategies.
- 8.9 Reportable Conditions:
  - 8.9.1 Rigors

- 8.9.2 Fever
- 8.9.3 Dyspnea
- 8.9.4 Anaphylaxis
- 8.9.5 Rash
- 8.9.6 Urticaria

## 9 RELATED DOCUMENTS/FORMS

- 9.1 N/A

## 10 REFERENCES

- 10.1 Alemtuzumab. Advice for the Patient. Micromere Inc.  
[www.nlm.nih.gov/medlineplus/druginfo/uspdi/500303.html](http://www.nlm.nih.gov/medlineplus/druginfo/uspdi/500303.html)
- 10.2 Campath® (Alemtuzumab) Product Information. Berlex Laboratories.  
[www.campath.com/pi.html](http://www.campath.com/pi.html)
- 10.3 Clinical Pharmacology. Available via Clinical and Medical Reference Program.
- 10.4 Introducing Campath®: Information for Patients and Caregivers. Berlex Laboratories. [www.campath.com/ptindex.html](http://www.campath.com/ptindex.html)
- 10.5 Perez-Simon J et al. Nonmyeloablative transplantation with or without alemtuzumab: comparison between two prospective studies in patients with lymphoproliferative disorders. *Blood* 2002;100(9):3121-3167.
- 10.6 Polovich M, Whitford JM, Olsen M. Editors. Chemotherapy and Biotherapy Guidelines and Recommendations for Practice. 3rd ed © Oncology Nursing Society, Pittsburgh, PA 2009.

## 11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
02	J. Loftis	Clarify introduction and premedication recommendations.

**Signature Manifest****Document Number:** ABMT-GEN-032**Revision:** 02**Title:** Alemtuzumab-Campath® Monoclonal Antibody Protocol

All dates and times are in Eastern Time.

**ABMT-GEN-032 Alemtuzumab-Campath® Monoclonal Antibody Protocol****Author**

Name/Signature	Title	Date	Meaning/Reason
Jennifer Loftis (JL26)		02 Jun 2014, 03:27:23 PM	Approved

**Management**

Name/Signature	Title	Date	Meaning/Reason
Jennifer Loftis (JL26)		02 Jun 2014, 03:27:34 PM	Approved

**Medical Director**

Name/Signature	Title	Date	Meaning/Reason
Nelson Chao (CHAO0002)		03 Jun 2014, 11:14:58 AM	Approved

**Quality**

Name/Signature	Title	Date	Meaning/Reason
John Carpenter (JPC27)		10 Jun 2014, 10:49:48 AM	Approved

**Document Release**

Name/Signature	Title	Date	Meaning/Reason
Betsy Jordan (BJ42)		11 Jun 2014, 09:52:45 AM	Approved