PBMT-GEN-032
ADMINISTRATION OF RITUXIMAB

1 PURPOSE
1.1 To outline the procedure required for indications for and administration of Rituximab (anti-CD20).
1.2 Responsibilities of the nursing staff for administration and monitoring reactions to Rituximab are described.

2 INTRODUCTION
2.1 The RITUXAN® (Rituximab) antibody is a genetically engineered chimeric murine/human monoclonal antibody directed against the CD20 antigen found on the surface of normal and malignant B lymphocytes. Rituximab is used to treat patients with autoimmune diseases (ITP, autoimmune hemolytic anemia), Graft Versus host Disease (GVHD) and certain lymphoid malignancies.

3 SCOPE AND RESPONSIBILITIES
3.1 Interdisciplinary: Requires an order placed by a chemotherapy certified physician into the electronic medical record.
3.2 Registered Nurses (RNs) may administer Rituximab after successful completion of medication administration test, the chemotherapy certification test and demonstration of clinical competency with their preceptor.

4 DEFINITIONS/ACRONYMS
4.1 BSA Body Surface Area
4.2 GVHD Graft Versus Host Disease
4.3 PFO Patent foramen ovale
4.4 PPE Personal Protective Equipment
4.5 RN Registered Nurse

5 MATERIALS
5.1 See the materials section of related SOP titled PBMT-GEN-069 Administration of Chemotherapy Inpatient Unit-5200.

6 EQUIPMENT
6.1 Volumetric infusion pump
6.2 Cardiac Monitor
6.3 See the equipment section of related SOP titled PBMT-GEN-069 Administration of Chemotherapy Inpatient Unit-5200.
7 SAFETY

7.1 Use appropriate Personal Protective Equipment (PPE) when handling chemotherapy.

8 PROCEDURE

8.1 Patient Assessment

8.1.1 See related SOP titled PBMT-GEN-069 Administration of Chemotherapy Inpatient Unit-5200.

8.1.2 Assess the intravenous access device for leakage, patency, and blood return.

8.1.3 Assess the central venous access site for redness, swelling, drainage and pain.

8.1.4 Have emergency medications, as applicable, available at the bedside.

8.1.5 Assess vital signs every 15 minutes for the first hour, then with every rate increase until the maximum rate is reached, then every hour until infusion is complete.

8.2 Precautions:

8.2.1 Rituximab should not be mixed with other medications.

8.2.2 NOTE: DO NOT ADMINISTER AS AN INTRAVENOUS PUSH OR BOLUS.

8.2.3 Hypersensitivity reactions may occur. Premedication consisting of acetaminophen and diphenhydramine should be administered if ordered to attenuate infusion-related events.

8.2.4 Infusion rates are based on BSA (body Surface Area) – see below.

8.3 First Infusion

8.3.1 Adults and patients with a BSA greater than (>1 \ m2):

8.3.1.1 The infusion should be administered intravenously at an initial rate of 50 mg/hr.

8.3.1.2 If hypersensitivity or infusion-related events do not occur, escalate the infusion rate in 50 mg/hr increments every 30 minutes, to a maximum of 400 mg/hr.

8.3.1.3 If hypersensitivity or an infusion-related event develops, the infusion should be temporarily slowed or stopped (see WARNINGS) and the physician or designee notified. The infusion can continue at one-half the previous rate upon improvement of patient symptoms.

8.3.2 Pediatric patients with a BSA = 0.6-1 m2

8.3.2.1 The infusion should be administered intravenously at an initial rate of 25 mg/hr.
8.3.2.2 If hypersensitivity or infusion-related events do not occur, escalate the infusion rate in 25 mg/hr increments every 30 minutes, to a maximum of 100 mg/hr.

8.3.2.3 If hypersensitivity or an infusion-related event develops, the infusion should be temporarily slowed or stopped (see WARNINGS) and the physician or designee notified. The infusion can continue at one-half the previous rate upon improvement of patient symptoms.

8.3.3 Pediatric patients with a BSA less than (<) 0.6 m²

8.3.3.1 The infusion should be administered intravenously at an initial rate of 12.5 mg/hr.

8.3.3.2 If hypersensitivity or infusion-related events do not occur, escalate the infusion rate in 12.5 mg/hr increments every 30 minutes, to a maximum of 100 mg/hr.

8.3.3.3 If hypersensitivity or an infusion-related event develops, the infusion should be temporarily slowed or stopped (see WARNINGS) and the physician or designee notified. The infusion can continue at one-half the previous rate upon improvement of patient symptoms.

8.4 Subsequent Infusions (ADULT sized patients only)

8.4.1 Subsequent infusions can be administered at an initial rate of 100 mg/hr, and increased by 100 mg/hr increments at 30-minute intervals, to a maximum of 400 mg/hr as tolerated.

8.5 Adverse Reactions - Common:

8.5.1 Arthralgia
8.5.2 Cytopenia
8.5.3 Immunodeficiency
8.5.4 Infection
8.5.5 Infusion related reactions – chills, fever; hypertension, hypotension
8.5.6 Fatigue
8.5.7 Headache
8.5.8 Leukopenia
8.5.9 Lymphopenia
8.5.10 Myalgia
8.5.11 Nausea
8.5.12 Neutropenia
8.5.13 Night sweats
8.5.14 Peripheral neuropathy
8.5.15 Rash
8.5.16 Thrombocytopenia
8.5.17 Vomiting

8.6 Adverse Reactions- Infrequent/Incidence Unknown:
8.6.1 Anemia
8.6.2 Anxiety
8.6.3 Bronchospasm
8.6.4 Elevated hepatic enzymes
8.6.5 GI obstruction/perforation
8.6.6 Hepatitis
8.6.7 Flushing
8.6.8 Hyperglycemia
8.6.9 Leukopenia
8.6.10 Pancytopenia
8.6.11 Renal failure (unspecified)
8.6.12 Stevens-Johnson syndrome
8.6.13 Tachycardia
8.6.14 Throat irritation
8.6.15 Urticaria

9 RELATED DOCUMENTS
9.1 PBMT-GEN-069 Administration of Chemotherapy Inpatient Unit-5200.

10 REFERENCES
10.1 Clinical Pharmacology – current version.

11 REVISION HISTORY

<table>
<thead>
<tr>
<th>Revision No.</th>
<th>Author</th>
<th>Description of Change(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>09</td>
<td>S. McCollum</td>
<td>Thrombocytopenia added to the list of possible adverse reactions.</td>
</tr>
</tbody>
</table>
## Signature Manifest

<table>
<thead>
<tr>
<th>Document Number: PBMT-GEN-032</th>
<th>Revision: 09</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title:</strong> Administration of Rituximab</td>
<td></td>
</tr>
</tbody>
</table>

All dates and times are in Eastern Time.

### PBMT-GEN-032 Administration of Rituximab

### Author

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sally McCollum (MOORE171)</td>
<td></td>
<td>03 Dec 2018, 01:37:48 PM</td>
<td>Approved</td>
</tr>
</tbody>
</table>

### Medical Director

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joanne Kurtzberg (KURTZ001)</td>
<td></td>
<td>03 Dec 2018, 07:14:35 PM</td>
<td>Approved</td>
</tr>
</tbody>
</table>

### Quality

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bing Shen (BS76)</td>
<td></td>
<td>07 Dec 2018, 01:12:21 PM</td>
<td>Approved</td>
</tr>
</tbody>
</table>

### Document Release

<table>
<thead>
<tr>
<th>Name/Signature</th>
<th>Title</th>
<th>Date</th>
<th>Meaning/Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Betsy Jordan (BJ42)</td>
<td></td>
<td>07 Dec 2018, 01:31:37 PM</td>
<td>Approved</td>
</tr>
</tbody>
</table>