


**Duke**Medicine


**Pediatric Blood and Marrow Transplant**  
**Adult Blood and Marrow Transplant**  
**Stem Cell Laboratory**

**DOCUMENT NUMBER:** COMM-PAS-018 FRM3

**DOCUMENT TITLE:**

APBMT Chemotherapy and Treatment Plan Audit Report

**DOCUMENT NOTES:**
**Document Information**
**Revision:** 01

**Vault:** COMM-PAS-rel

**Status:** Release

**Document Type:** COMM-PAS

**Date Information**
**Creation Date:** 20 Jun 2025

**Release Date:** 01 Jul 2025

**Effective Date:** 01 Jul 2025

**Expiration Date:**
**Control Information**
**Author:** MC363

**Owner:** MC363

**Previous Number:** None

**Change Number:** PAS-CCR-043

**COMM-PAS-018 FRM3**  
**APBMT Chemotherapy and Treatment Plan Audit Report**  
 (CONFIDENTIAL)

**Date(s) of Audit:**

**Program(s) Audited:**

**Audit Period:**

**SECTION I.**

The Adult and Pediatric Blood and Marrow Transplant Program (APBMT) Chemotherapy and Treatment Plan Audit should be conducted by a Subject Matter Expert (SME) in coordination with the APBMT Clinical Quality Program (CQP). A qualified representative from CQP will serve as the Lead Auditor and verify that the appropriate resolution to any discrepancies is remediated. The APBMT Chemotherapy and Treatment Plan Audit will be completed at least annually. The result of this audit will be reported to the APBMT and Cell Therapy Quality Assurance (QA) Committee and the Program's Medical Director(s). A selection of 20 patients from both the adult and pediatric transplant patient files for the timeframe described above will be reviewed using the following criteria listed in Section III and labeled Questions 1-3 for the initial review. If the program has fewer than 20 total patient files, review all files for the specified timeframe.

The lead CQP auditor will complete the fields located in the table below.

Medical Record Number (MRN) included in the Audit	

**SECTION II.**

For the initial review, the SME will complete each question's check boxes and complete the "Description" box, if applicable, for all the MRNs listed above. If a discrepancy is found, the SME will provide a detailed description. It is recommended to use a chemotherapy template in Excel or Word to track audited data. Once this review is completed, the review will be submitted to the Lead Auditor for review.

<i>The below section is completed by the SME.</i>			
<b>1. Correct dosing weight per hospital policy:</b> Was the chemotherapy dose prescribed within the chemotherapy treatment plan based on the correct weight and within the 10% rule per the age-specific <i>DUH Safe Prescribing of Chemotherapy</i> policy? If no, describe the discrepancy in the description box below.		<input type="checkbox"/> YES	<input type="checkbox"/> NO
<b>Description:</b>			
<i>The below section is completed by the APBMT audit representative</i>			
<b>Person Responsible:</b>		<b>Estimated Completion Date:</b>	
<b>Response:</b>			
<i>The below section is completed by the Lead Auditor</i>			
<b>Response Approved?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <b>Initials/Date:</b>			

<i>The below section is completed by the SME.</i>			
<b>2. Correct medication against the written order and physician plan:</b> Was the intended <u>prescribed chemotherapy medication</u> , dose, route, frequency, and infusion duration administered to the patient? <ul style="list-style-type: none"> <li>For pediatrics, check the medication administration record (administered dose) against the chemotherapy roadmap (intended dose) and the treatment plan order (actual order), including the presence of the appropriate number of authorizing signatures in accordance with <i>The DUH Safe Prescribing of Chemotherapy in Pediatrics</i> policy.</li> <li>For adults, check the medication administration record (administered dose) against the provider progress note (intended dose) and the treatment plan order (actual order).</li> </ul> If no, describe the discrepancy in the description box below.		<input type="checkbox"/> YES	<input type="checkbox"/> NO
<b>Description:</b>			
<i>The below section is completed by the APBMT audit representative</i>			
<b>Person Responsible:</b>		<b>Estimated Completion Date:</b>	
<b>Response:</b>			
<i>The below section is completed by the Lead Auditor</i>			
<b>Response Approved?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <b>Initials/Date:</b>			

<i>The below section is completed by the SME.</i>			
<b>3. Correct medication order (prescription) and protocol verification:</b> <input type="checkbox"/> N/A NOTE: Question #3 may or may not apply to your patient selection as not all chemotherapy medications carry guidelines for dosing adjustments. Check N/A above if this question is deemed not applicable to your entire patient sample.  For patients with treatment plans that contain recommendations and/or guidelines for <u>dosing adjustment</u> in the comment section of the chemotherapy order: Was the intended adjusted dose, route, frequency, and duration ordered and subsequently administered to the patient? <ul style="list-style-type: none"> <li>• For pediatrics, check the medication administration record (administered dose) against the chemotherapy roadmap (intended dose) and treatment plan order (actual order).</li> <li>• For adults, check the medication administration record (administer dose) against the provider progress note (intended dose) and the treatment plan order (actual order).</li> </ul> If no, describe the discrepancy in the description box below.		<input type="checkbox"/> YES	<input type="checkbox"/> NO
<b>Description:</b>			
<i>The below section is completed by the APBMT audit representative</i>			
<b>Person Responsible:</b>		<b>Estimated Completion Date:</b>	
<b>Response:</b>			
<i>The below section is completed by the Lead Auditor</i>			
<b>Response Approved?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <b>Initials/Date:</b>			

**SECTION III.**

Once the SME has completed the review using the established criteria listed in Section II. A review of the discrepancies, if any, will be discussed with the SME and the Lead Auditor. The SME and the Lead Auditor will sign, indicating that the discrepancies listed in the description in Section II are accurate. Once signed, the report will be distributed to the appropriate APBMT audit representative for completion of Section II, if applicable, by the Lead Auditor. The APBMT audit representative will complete the remaining portion of Section II, including the Person Responsible, Estimated Completion Date, and Response fields. Upon completion, the APBMT audit representative will return the completed document to the Lead Auditor.

<b>SME's Signature &amp; Date:</b>	
<b>Lead Auditor's Signature &amp; Date:</b>	

**SECTION IV.**

Once the APBMT audit representative completes the document, they will return it to the Lead Auditor for final review. Based on the response received, the Lead Auditor will then complete the Response Approved field, as appropriate. If the response was not approved, the Lead Auditor will discuss potential ways to correct the response for approval. This may be a simple language change or an initiation of a corrective action and preventive action (CAPA) report.

Documentation of the failed or marked "No" response approved question may be documented outside of this form.

**SECTION V.**

After the final review is completed and signed by the Lead Auditor, the document will be sent to the SME, APBMT audit representative, the Program Medical Director, and the CQP Director or designee for signature.

By signing below, all follow-up items have been resolved, verified, and the audit is now closed.

<b>Lead Auditor's Signature:</b>	
<b>SME's Signature:</b>	
<b>APBMT Audit Representative:</b>	
<b>APBMT Program Medical Director:</b>	
<b>CQP Director or designee:</b>	



**Signature Manifest****Document Number:** COMM-PAS-018 FRM3**Revision:** 01**Title:** APBMT Chemotherapy and Treatment Plan Audit Report**Effective Date:** 01 Jul 2025

All dates and times are in Eastern Time.

**COMM-PAS-018 FRM1 -- COMM-PAS-019 FRM4****Author**

Name/Signature	Title	Date	Meaning/Reason
Mary Beth Christen (MC363)		26 Jun 2025, 05:13:00 PM	Approved

**Management**

Name/Signature	Title	Date	Meaning/Reason
Stefanie Sarantopoulos (SS595)	Professor of Medicine	26 Jun 2025, 06:34:43 PM	Approved

**Medical Director**

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		26 Jun 2025, 07:29:32 PM	Approved

**Quality**

Name/Signature	Title	Date	Meaning/Reason
Mary Beth Christen (MC363)		27 Jun 2025, 12:35:34 AM	Approved

**Document Release**

Name/Signature	Title	Date	Meaning/Reason
Amy McKoy (ACM93)	Document Control Specialist	30 Jun 2025, 05:43:50 PM	Approved