I. Description

Explains the requirements for prescribing, dispensing, and administering chemotherapy and immunotherapy medications

II. Rationale

Prescribing, dispensing, and administering chemotherapy are high-risk procedures requiring the expertise of multiple disciplines. Each step of this process must be implemented safely due to the inherent narrow margin of error when utilizing these agents. The purpose of this policy is to enhance patient and provider safety by standardizing the ordering, dispensing, and administering of chemotherapy. This policy applies to all chemotherapy ordering, dispensing, and administration for both oncology and non-oncology settings, inpatient and outpatient. Additionally, all personnel who prescribe, dispense, prepare, and administer hazardous drugs must comply with the UNC Hospitals Environmental Health and Safety policy titled Handling and Disposal of Hazardous Agents (EHS 0024).

III. Policy

A. Definitions

1. Attending Role as Authorized Prescriber

An authorized prescriber of chemotherapy is an Attending who has met the established competency criteria for ordering chemotherapy (see High Alert Medications policy list for chemotherapy agents that must be ordered by an authorized prescriber). All Attending physicians within the hematology/oncology, stem cell transplantation (SCT), gynecology oncology and pediatric oncology departments can prescribe chemotherapy for a malignant indication. All attending physicians practicing at the University of North Carolina Hospitals and Clinics (UNC) can prescribe chemotherapy for a non-malignant indication. The chemotherapy order must legibly include the authorized prescriber’s name, MD number, and pager number. It is the responsibility of the Pharmacist to ensure that the chemotherapy order, malignant or non-malignant, is written by an authorized prescriber. The order must be cosigned by an authorized prescriber of chemotherapy if the order is written and signed by a scribe.

2. Biotherapy

Selected agents derived from biologic sources or agents that affect biologic responses; examples of categories of biotherapeutic agents include monoclonal antibodies, cytokines, conjugated antibodies, and cellular therapies; see High Alert Medication List for complete list of agents.

3. Chemotherapy

Agents with antineoplastic properties; see High Alert Medication List for complete list of agents considered chemotherapy.
4. **Competency and Training Criteria**
   Standards, behaviors, and/or training determined by each discipline (MD, Pharmacy, Nursing) that staff must meet in order to prescribe, dispense, and/or administer chemotherapy.

5. **Hazardous Drugs**
   Any agent listed on the UNC Hospitals Hazardous Drug list (see appendix to EH&S policy #24, Handling & Disposal of Hazardous Agents). Personal protective equipment must be used for preparation and administration of hazardous drugs.

6. **High Alert Medications**
   Medications that carry a high risk of adverse patient outcomes if ordered, dispensed, and/or administered improperly (see High Alert Medication List for complete list of agents considered chemotherapy). The High Alert Medication List details strategies for risk reduction, which stipulate what agents must be ordered by an authorized prescriber and must be ordered on an approved Chemotherapy Order Form or template and administered by staff deemed competent in preparing and administering chemotherapy.

7. **Immunotherapy**
   For the purposes of this policy, chemotherapy and select biotherapy agents

8. **Outpatient Pharmacies**
   Pharmacies of UNC that dispense medications for consumption at home to outpatients who are seen by UNC providers (including Central Outpatient Pharmacy and Ambulatory Care Clinic Pharmacy)

9. **Research Protocol**
   A research protocol or clinical trial is a controlled experiment having a clinical event as an outcome measure, is done in a clinical setting, and involves persons having a specific disease or health condition. It is approved by the Office of Human Research Ethics (OHRE), which is responsible for ethical and regulatory oversight of research at UNC involving human studies. The OHRE also supports and oversees the work of the Institutional Review Board (IRB). All patients participating in research protocols will have a signed OHRE approved informed consent in their medical record and all health care providers will follow the guidelines described in the OHRE approved research protocol.

10. **Study Drug**
    For the purposes of this policy, a study drug is a medication used as part of a research protocol that is intended for use as antineoplastic or immune therapies.

11. **Supportive Care Prescriber**
    The Fellow, Physician Assistant, Nurse Practitioner, or Clinical Pharmacist Practitioner may all serve as supportive care prescribers to amend orders for supportive care on the chemotherapy order.

B. **Procedure**

1. **Ordering**
   a. General Ordering Guidelines
      i. Only authorized prescribers may order agents defined as chemotherapy or immunotherapy (see High Alert Medication List for complete list of agents considered
chemotherapy/immunotherapy). Authorized prescribers must be an attending level physician and have reviewed this policy.

ii. Supportive care prescribers may prescribe adjunctive medications (e.g., intravenous fluids, antiemetics) to a chemotherapy or immunotherapy regimen and may write orders to initiate orders that have already been written by an authorized prescriber.

iii. All chemotherapy/immunotherapy orders must be signed by a UNC authorized prescriber of chemotherapy prior to execution of the order. Authorized prescribers must also write their provider & pager numbers on the order.

iv. Orders that require a Standard Physician’s Order Form and should be scanned to pharmacy include verbal orders for chemotherapy and are ONLY accepted for:

1. Changes in administration time
2. Infusion rate
3. Admixture (e.g., fluid and/or volume)
4. Shifting of day/date of dose

v. Orders that require a new Chemotherapy Form and should be scanned to pharmacy include changes to the original chemotherapy/immunotherapy orders that affect the:

1. Drug
2. Dose
3. Frequency
4. Number of days of treatment
5. Route

vi. The weight listed on the order form should represent the patient’s current weight unless otherwise specified.

vii. For all patients: a variation of ±10% for the final dose is acceptable if the recalculated dose differs from the ordered dose. The prescriber must specify if they intend to use original dosing weight instead of the patient’s current weight for dosing calculations.

viii. Doses may be rounded as long as the final dose falls within the ±10% variation.

b. Ordering Guidelines for Administration within UNC Hospitals (excludes outpatient pharmacies)

Orders for chemotherapy or immunotherapy administered within UNC must be typed on an approved UNC chemotherapy/immunotherapy order form, MIM #245 (see High Alert Medication policy for chemotherapy/immunotherapy agents that must be written on a chemotherapy order form or template). Non-modifiable regimen-specific order templates are preferred. Blank and regimen specific forms are located online. Typed chemotherapy/immunotherapy orders sent via fax are acceptable as long as all portions of the faxed order are visible and legible. Handwritten orders will not be accepted.

i. The following information must be indicated on chemotherapy and immunotherapy orders prior to execution (refer to the Medication Management: Prescribing Practices policy, ADMIN 0114, for other ordering practices):

1. Patient name and medical record number
2. Diagnosis or indication
(3) Allergies

(4) Height (in centimeters), weight (in kilograms), and body surface area (BSA) if used in dose calculations. If targeted area under the curve (AUC) is used to calculate a chemotherapy or immunotherapy dose, the following must be indicated on the order:

(a) The area under the curve value
(b) Patient’s estimated or actual creatinine clearance with designation of any cap, if applicable
(c) The name of the formula used to determine the estimated creatinine clearance
(d) The serum creatinine and/or urine creatinine value used to determine the creatinine clearance
(e) See carboplatin dosing Appendix A

(5) Dosing

(a) All chemotherapy or immunotherapy doses are ordered as:
   - metric unit per BSA per dose
   - metric unit per body weight per dose
   - metric unit per AUC per dose, when applicable
   - Flat dosing may be used when these criteria for dosing cannot be used
     
The calculated dose must be included in the order. Chemotherapy or immunotherapy ordered per “day” rather than per “dose” will not be accepted.

(b) Modifications of a protocol or standard dose must be indicated on the order with an explanation of the reason.

(6) The name and number of active research protocols (e.g., “POG protocol ####”), or the name of the standard regimen (e.g., “CHOP”), must be indicated on the chemotherapy/immunotherapy order form.

(7) If an active research protocol or UNC standard regimen is not used, the Authorized Prescriber will provide a reference from the literature supporting the use of the prescribed protocol on the order for nursing and pharmacy staff placing a copy of the supporting literature in the patient’s permanent medical record along with the chemotherapy order.

(a) Rationale for use of regimens for which supporting literature is not available must be documented on the chemotherapy/immunotherapy order form by the ordering Authorized Prescriber. In the absence of available literature, regimens will be discussed with the pharmacist covering/dispensing and the nurses administering the treatment. Provided that the drug doses ordered are consistent with or lower than those in standard or referenced protocols/regimens, dispensation can proceed after this discussion and documentation in WebCis by the Authorized Prescriber.

(b) For protocols/regimens without any drug dose support that is consistent with or lower than those in standard or referenced protocols/regimens,
dispensation will only occur when an attending level, peer-practitioner (Authorized Prescriber) has cosigned these orders.

(8) Generic name. Abbreviations, trade name or variations of the generic name will not be accepted. Scientific name can be used when generic name is not available.

(9) Actual start date, frequency, day(s) the drug is to be administered and proper sequence of administration where appropriate.

(10) Route

(11) Duration of infusion for intravenous administration

(12) Total number of doses

ii. Supportive medications, such as antiemetics and hydration.

All pertinent laboratory data for the regimen will be reviewed by the authorized prescriber, pharmacy, and nursing prior to order execution. Lab values used for dose calculations and/or to determine whether treatment can be initiated should be current. For inpatients, clarification with the ordering prescriber about whether a more recent sample is needed should occur if lab values are greater than 72 hours old. For patients receiving chemotherapy or immunotherapy in UNC, clarification with the prescriber about the date of lab samples will be done if the lab values are greater than 30 days old (for agents dosed by targeted AUC please refer to appendix A, attached to this policy, for time frame).

iii. Compatible chemotherapy agents may be admixed together if the administration rate and date of administration are the same. The physician may request an admixture or the pharmacist may at his/her discretion admix agents with documented physical and chemical compatibility. If a dilution is not specified on an order, a standard dilution based on known compatibility data will be used by the pharmacy.

iv. Chemotherapy/immunotherapy order forms must be received by the N.C. Cancer Hospital Infusion/Inpatient Pharmacy (CHIP) prior to 1900 hours Monday-Friday and prior to 1200/noon Saturday-Sunday/Holidays for same day dispensation.

v. Orders for chemotherapy or immunotherapy received after hours for conditions classified as emergent/life-threatening within the next 12-24 hours can be coordinated for dispensation via the CHIP and Pharmacy Administrator-On-Call and the Clinical-On-Call.

vi. Once the chemotherapy has started, any subsequent hold orders for chemotherapy will be treated as a discontinuation order (see ADMIN 0114 Medication Management: Prescribing Practices). Policy exceptions listed in ADMIN 0114 do not apply to chemotherapy. If any of the chemotherapeutic agents are held, all of the chemotherapy drugs in the regimen will be regarded as discontinued and removed from the MAR. If no changes to the drugs, doses, frequencies, total number of days of treatment, or route are warranted, the entire regimen may be resumed without new orders being written. A clarification order must be written to resume the previous regimen and signed by an attending physician. A change in the date of therapy does not require new orders to be rewritten, only a clarification order signed by an attending physician. The clarification order must contain, at a minimum, the patient’s name, medical record number (MRN), name of the regimen, calendar date regimen was originally written, calendar date regimen was started, calendar date regimen is being resumed, and the day of therapy in the regimen (Please see example below of how the hand-written order should be clearly written). If there are
any ambiguities within the hand-written clarification order, the attending physician who signed the resumed order will be contacted directly by pharmacy or nursing. If a change to the drugs, doses, frequencies, total number of days of treatment, or route occurs, a new chemotherapy order will be required to resume therapy. Any supportive medications on the chemotherapy order may remain effective. The stop date of supportive care medications should be extended as appropriate if the chemotherapy administration dates are modified.

Sample order for chemotherapy being resumed (change in date only):

Patient’s Name: James Doe
Patient’s MRN: 99999999

Name of the chemotherapy regimen: (Name of the protocol, cycle number) AALL0232 Intensification II

Calendar date chemotherapy orders originally written: 10/23/11
Calendar date chemotherapy orders started: 10/24/11
Calendar date resuming chemotherapy orders: 10/27/11

Day of chemotherapy to resume: (ie, day 8 of 11 or day -8): day +4

vii. All questions or concerns related to any component of the chemotherapy or immunotherapy order form will be clarified with the ordering physician or the immediate supervising authorized prescriber prior to dispensing or administering the agents.

viii. Hardcopy records of chemotherapy and immunotherapy ordered and dispensed will be maintained for a period of 3 years either onsite or at a designated offsite facility.

2. Dispensing and Preparation

a. Dispensing and Preparation Guidelines for Administration within UNC

i. A pharmacist will review all chemotherapy and immunotherapy orders for accuracy, completeness, and appropriateness and resolve any questions or concerns with the prescriber prior to product preparation. The review is conducted as follows:

   (1) The order form contains all required information.

   (2) Chemotherapy and non-chemotherapy doses are correct, given the patient’s weight, BSA, and laboratory/test results.

   (3) Doses correspond to those indicated by active research protocol, standard regimen, or supportive literature provided.

   (4) All calculations are verified.

   The pharmacist documents this review by signing the order form within 24 hours of inpatient admission where applicable.

ii. A pharmacist enters the order into the pharmacy computer system and generates preparation labels.

iii. A trained pharmacy technician or pharmacist prepares the chemotherapy/immunotherapy agents and affixes the medication label to the final product. Chemotherapy/immunotherapy training for pharmacy technicians includes all competencies established by the Department of Pharmacy’s Clinical Manager overseeing the day-to-day operations of the CHIP.
iv. The final product is checked by a different pharmacist. The pharmacist will review the chemotherapy and immunotherapy orders for accuracy, completeness, and appropriateness and resolve any questions or concerns with the prescriber prior to dispensing the medications as follows:

1. The order form contains all required information.
2. Chemotherapy and non-chemotherapy doses are correct, given the patient’s weight, BSA, and laboratory/test results.
3. Doses correspond to those indicated by active research protocol, standard regimen, or supportive literature provided.
4. All calculations are verified.
5. Accuracy of the order entry into the pharmacy computer system is verified. This check is documented manually by the pharmacist initialing the medication label and compounding sheet.

v. All personnel who dispense and prepare hazardous agents must comply with the UNC Hospitals Environmental Health & Safety policy titled Handling and Disposal of Hazardous Agents.

b. Chemotherapy or immunotherapy dispensed from the Investigational Drug Service (IDS) will follow precautions outlined by the investigational study protocol and IDS policy.

3. Ordering, Dispensing, and Preparation Guidelines for Outpatient Prescriptions

a. Chemotherapy or immunotherapy ordered and dispensed by UNC Ambulatory Pharmacy Care Network pharmacies will follow all state and federal regulations in addition to the following:

i. All completed prescriptions for chemotherapy or immunotherapy (new and refilled) must undergo an independent double-check by another pharmacist or a certified or trained pharmacy technician. For refills, the final product must only be checked against an image of the label generated from the original prescription. For new prescriptions, the independent double-check should include matching the final product with the original prescription for:

1. Patient name and medical record number
2. Generic drug name and dosage form
3. Patient instructions, including dose, route, frequency
4. Quantity to dispense
5. Number of refills

ii. Chemotherapy or immunotherapy handling and disposal will follow UNC Health Care Environmental Health and Safety 0024 (Handling and Disposal of Hazardous Drugs)

1. All doses will be stored in a separate area and counted on separate dispensing trays.

2. Trays will be cleaned with alcohol after each use

iii. Prescription for chemotherapy or immunotherapy may only be received by the patient or patient’s agent upon presentation of 2 patient identifiers per Patient Identification Policy (ADMIN 0145).
4. Administration

a. Physicians and licensed independent practitioners (LIP) who meet the competency criteria for chemotherapy and immunotherapy administration may administer chemotherapy/immunotherapy. Competency criteria will be set by that physician’s division or department. Additionally:
   i. All physicians/licensed independent practitioners (LIP) who administer chemotherapy or immunotherapy must review this policy.

b. Adult and pediatric inpatient and outpatient nurses who administer chemotherapeutic agents for the treatment of cancer via any route must meet the following competency criteria prior to administering these agents independently:
   i. Must be a Registered Nurse (RN) with a minimum of 6 months nursing experience; and
   ii. Must obtain and maintain Provider status from the nationally-recognized Chemotherapy & Biotherapy Provider Course most appropriate to the patient population served:
      (1) Oncology Nursing Society’s Chemotherapy (ONS) & Biotherapy Provider Course
      (2) Association of Pediatric Hematology/Oncology Nursing’s (APHON) Pediatric Chemotherapy and Biotherapy Provider Program; and
   iii. Demonstration and documentation of hands-on chemotherapy administration under the observation of a registered nurse who has met these competency criteria; and
   iv. Completion of annual competency assessment related to chemotherapy administration.

c. Inpatient and outpatient nurses who administer immunotherapeutic agents (as specified in the High Alert Medications policy) to patients with non-malignant diseases outside of oncology nursing units must meet the following competency criteria prior to administering these agents independently:
   i. Must be a Registered Nurse (RN) with a minimum of 6 months nursing experience; and
   ii. Must complete a didactic course designed to meet specific objectives for immunotherapeutic agents typically administered on their unit; and

NOTE: This specific course is designed and offered through the Nursing Practice, Education, & Research Department at UNC or the Children’s Hospital. Staff nurses may attend the APHON Chemotherapy & Biotherapy Provider Course or ONS Chemotherapy & Biotherapy Provider Course as requested.
   iii. Completion of a hands-on practicum in immunotherapy administration; and
   iv. Completion of annual competency assessment related to immunotherapy administration.

NOTE: Nurses do not have to attend a chemotherapy or immunotherapy course in order to administer those agents delineated in the High Alert Medication policy list as “independent double check only”.

d. For patients with malignant or non-malignant diseases requiring chemotherapy or immunotherapy who are temporarily boarded on a nursing unit where RNs are not competent in chemotherapy or immunotherapy administration and do not administer chemotherapy or immunotherapy, the following procedure must be followed:
   i. Charge Nurse on the boarding unit will notify the House Supervisor;
   ii. House Supervisor will prioritize transfer of the patient to the appropriate oncology or non-oncology unit based on the patient’s disease;
   iii. Staff nurse(s) on the boarding unit will begin pre-medications, lab work, and hydration per order while waiting for the patient’s transfer. Staff nurses on the boarding unit will NOT administer the chemotherapy or immunotherapy;
   iv. Information and resource contact information will be provided to staff nurses on these units.

e. If chemotherapy must be started while the patient is pending transfer and/or if the patient cannot be moved due to the patient’s acuity and nursing care needs, the following procedure must be followed:
   i. Charge Nurse on the boarding unit will notify the House Supervisor;
   ii. House Supervisor will identify an RN competent in chemotherapy/immunotherapy administration from within the service most associated with the patient’s disease (e.g., an Oncology RN for patients with cancer; a Medicine Service RN for patients with non-oncologic disease);
   iii. The identified chemotherapy/immunotherapy competent RN will initiate the chemotherapy on the boarding unit;
   iv. The RN initiating the chemotherapy/immunotherapy will provide information on necessary patient monitoring (e.g., vital signs, IV site assessment, lab work) and care considerations (e.g., side effect management) to the boarding nurse.

f. LPNs may NOT administer chemotherapy but can assist in monitoring patients for side effects, adverse reactions & IV site assessment.

g. Nurses must maintain competency by completing an annual competency assessment related to chemotherapy and immunotherapy administration. Any nurse who has not completed an annual competency assessment and/or has not administered chemotherapy or immunotherapy in the last 9 months must be observed by a chemotherapy and immunotherapy competent nurse during one real-time administration prior to administering independently.

h. Prior to the administration of chemotherapy or immunotherapy, a chemotherapy competent nurse must:
   i. Perform appropriate patient assessment based on specific drug regimen side effects and considerations;
   ii. Verify completion of pertinent baseline diagnostic tests;
   iii. Verify and monitor required lab test results;
   iv. Verify orders are written using the pre-printed template or chemotherapy/immunotherapy order form (no handwritten orders accepted);
   v. Administer intravenous hydration, pre-medication, and cytoprotective agents as ordered. NOTE: Some cytoprotective agents must be double-checked with a
second health care professional (see High Alert Medications policy for select cytoprotective agents);

vi. Verify compatibility of agents (e.g., Micromedex, Trissels, Kings);

vii. Notify provider with any discrepancies, abnormal values, or patient concerns.

i. Prior to administering the first dose of chemotherapy or immunotherapy agent, two chemotherapy and/or immunotherapy competent nurses must independently double-check the original order in order to:

   i. Verify order against the protocol, study, or regimen for its completeness;

   ii. Recalculate the body surface area (if used) and all dosing calculations (including AUC, ideal body weight, adjusted body weight);

   iii. Recalculate the final dose; and

   iv. Countersign on the original order.

j. Per the Medication Management High Alert Medication policy, prior to administering the initial and each subsequent dose(s) of chemotherapy or immunotherapy, two licensed professionals must simultaneously double-check the original order against the drug label and the Medication Administration Record (MAR) (for areas that utilize a MAR) for:

   i. patient name

   ii. medical record number

   iii. drug

   iv. dose

   v. route

   vi. time of administration

   vii. expiration and

   viii. document in the patient medical record that the double check was completed.

   **Key Point:** Physicians administering the agent must perform this double check with another licensed professional & document as above.

k. Patient identification must be verified at the bedside or chairside using two patient identifiers at the time of administration as specified in the UNC Patient Identification – Medication Administration, Administering Blood Products, Taking Blood Samples or Specimens, or Providing Treatment or Procedures policy, Admin 0145.

l. Special non-PVC tubing, vented tubing, filters, and/or other equipment should be utilized as necessitated by the agent and is available to be provided by pharmacy when the drug is delivered or available as dictated by the defined clinical area.

m. All intravenous (IV) infusions of chemotherapy or immunotherapy must be delivered via a dedicated infusion pump (EXCEPT agents ordered IV push). The following infusion guidelines must be followed:

   i. Administer continuous infusions of chemotherapy, immunotherapy, or agents that require special tubing via the primary line.

   ii. Infusions less than four hours in duration may be administered on the secondary line.

n. A closed system device (such as PhaSeal) approved for administration of hazardous drugs must be used when administering any hazardous drugs intravenously.
For IV push chemotherapies or immunotherapies, administer agents using the following procedures:

i. For Adults:
   (1) Assess vascular access site as stated below
   (2) Push agent through side arm of free-flowing line of normal saline or compatible fluid
   (3) Push agent at a rate of 2 mLs/min unless otherwise specified
   (4) Verify blood return every 2-5 mLs

ii. For Pediatrics:
   (1) Assess vascular access site as stated below
   (2) Push agent via direct push method
   (3) Push agent at a rate of 2 mLs/min unless otherwise specified
   (4) Verify blood return every 2-3 mLs

p. For peripheral and/or central venous access, assess and document IV access device patency, tubing connections, blood return, and site appearance during parenteral administration:

i. Pre & post administration

ii. During administration as follows:

   (1) For Pediatric Patients:

<table>
<thead>
<tr>
<th></th>
<th>Non-Vesicant IV Piggyback</th>
<th>Non-Vesicant Continuous Infusion</th>
<th>Vesicant IV Piggyback</th>
<th>Vesicant Continuous Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Return &amp; Patency Verification</td>
<td>Every 4 hours</td>
<td>Every 4 hours</td>
<td>Every 4 hours</td>
<td>Every 4 hours</td>
</tr>
<tr>
<td>IV Site Assessment</td>
<td>Every 1 hour</td>
<td>Every 1 hour</td>
<td>Every 1 hour</td>
<td>Every 1 hour</td>
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</tbody>
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   (2) For Adult Patients:

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<thead>
<tr>
<th></th>
<th>Non-Vesicant IV Piggyback</th>
<th>Non-Vesicant Continuous Infusion</th>
<th>Vesicant IV Piggyback</th>
<th>Vesicant Continuous Infusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Return &amp; Patency Verification</td>
<td>Every 4 hours</td>
<td>Every 4 hours</td>
<td>Every 20 minutes</td>
<td>Every 4 hours</td>
</tr>
<tr>
<td>IV Site Assessment</td>
<td>Every 4 hours</td>
<td>Every 4 hours</td>
<td>Every 20 minutes</td>
<td>Every 4 hours</td>
</tr>
</tbody>
</table>

**Note:** It is recommended to perform blood return and site assessment checks on a 10, 2, and 6 schedule, when applicable

q. Obtain vital signs (VS) before, during, and after administration, as necessitated by specific agent. Any RN, LPN, or NA may monitor VS during infusion.
r. Documentation in patient medical record or Echart where applicable. The documentation of chemotherapy/immunotherapy drug administration includes:

i. Date & time of therapy

ii. Drug name, dose, route and rate of administration, and infusion duration

iii. Volume & type of fluids administered

iv. Assessment of the site before, during, & after infusion

v. Information about the infusion device (e.g., site, needle size, type of device, infusion pump)

vi. Verification of blood return before, during & after IV therapy.

s. Administer supportive medications as scheduled and as needed for control of side effects and/or complications.

t. Patients with high alert medications infusing must remain within hearing distance of staff members and may not leave the unit/clinic for non-medical purposes as per the UNC policy titled Patients Off Unit with IV Pumps, Admin # 0140.

5. Venous Access

a. Administer all continuous infusions (agents infusing over 24 hours or more) of vesicant agents via a central venous access device. Document rationale for not infusing a continuous infusion of a vesicant agent via a central venous access device based on patient specific circumstances in the medical record. Refer to the UNC Nursing policy titled Prevention and Treatment of Extravasation/Infiltration of Caustic Agents for list of vesicants.

b. Every effort should be made to avoid peripheral infusion or intravenous push (IVP) of vesicants. In cases in which peripheral infusion or IVP of vesicants is unavoidable, every effort should be made to avoid peripheral infusion or IVP into a bony prominence or joint (e.g., the hand, the antecubital area).

c. Patent, functional venous access is necessary when administering parenteral chemotherapy. Both peripheral and central venous access used for chemotherapy administration must flush easily with normal saline and have a positive blood return prior to, during, and after administration. Document in the medical record the rationale for using any venous access that is not easily flushed and does not have a blood return.

d. Central venous catheter malfunctions, such as withdrawal or complete occlusion, fluid leakage, or migration, must be resolved prior to administering chemotherapy via that venous access device. If patency cannot be restored, obtain a chest x-ray and/or Doppler study to assess tip placement and potential thrombus formation. A venogram or dye study may also be necessary to confirm catheter placement prior to utilizing the venous access device if other means are insufficient in determining the reason for malfunction. Refer to the UNC nursing procedure titled Central Venous Access Device: Restoring Patency to Withdrawal Occlusions and Central Venous Access Device: Restoring Patency to an Occluded Catheter (Restricted) for resolving venous device occlusions.

6. Extravasation Management

a. Immediately stop infusions of chemotherapy or immunotherapy for actual or suspected infiltration or extravasation and notify the provider.
b. Initiate the UNC nursing protocol titled *Prevention and Treatment of Extravasation/Infiltration of Caustic Agents* for immediate and ongoing management of suspected or actual extravasations of chemotherapeutic or immunotherapeutic agents.

7. **Patient Education**

   a. Information must be provided to the patient prior to administration of chemotherapy related to the following (as applicable to the patient):
      
      i. Diagnosis
      
      ii. Goals of Therapy
      
      iii. Planned duration of chemotherapy, drugs, and schedule
      
      iv. Information on possible short and long term side effects
      
      v. Regimen or drug specific risks or symptoms that require notification to the healthcare provider or emergency assistance plan for monitoring and follow up

   b. Document education provided in patient medical record.

8. **Adverse Drug Reporting**

   a. An adverse drug reaction is a noxious response to a drug, which is unexpected, unintended, uncommon, or previously unreported, and occurs when the medication is prescribed and administered properly. Any health care professional can report a suspected adverse drug reaction by using the online patient occurrence reporting system: [http://patcomp.unch.unc.edu/PORS/riskweb3.dll/FrmLogin](http://patcomp.unch.unc.edu/PORS/riskweb3.dll/FrmLogin).

   b. If access to the online reporting system is unavailable, call the ADR Hotline at 966-2377 (ADRS).

   c. Notify provider of any adverse drug reactions.

9. **Safe Handling and Disposal of Hazardous Agents**

   a. All personnel who deliver, prepare, and administer chemotherapy or immunotherapy must abide by the Environmental Health & Safety policy # 24 titled *Handling & Disposal of Hazardous Drugs*. This policy contains information and required practices related to:
      
      i. General information
      
      ii. Agent identification
      
      iii. Use of personal protective equipment (PPE)
      
      iv. Preparing chemotherapy agents
      
      v. Administering chemotherapy agents
      
      vi. Personnel caring for patients receiving chemotherapy agents
      
      vii. Material Safety Data Sheets (MSDS)
      
      viii. Medical surveillance
      
      ix. Spill clean-up and response
      
      x. Chemotherapy drug waste management plan
      
      xi. Training of personnel
      
      xii. Identification of Hazardous Drugs
b. Notify provider of any spills and/or patient exposure.

10. Training
a. All persons required to handle hazardous drugs must be provided with initial orientation and annual competency as outlined in the Hazardous Drugs policy (see Environmental Health & Safety policy # 24, titled Handling & Disposal of Hazardous Drugs)

IV. References


V. Related Policies
- Refusal to Perform Assigned Duties
- Legibility of Entries in the Medical Record
- Medication Administration
- Resolution of Interdisciplinary Conflicts

Appendix A. Adult Carboplatin Dosing Guidelines

Description
Defines and outlines the process for carboplatin dosing for adult cancer patients treated at UNC.

Rationale
Due to concerns over changes in laboratory measures of serum creatinine, which affect estimates of renal function and may lead to doses of carboplatin exceeding those recommended by the National Cancer Institute (NCI), which could result in increased toxicities.

General information
I. Purpose
a. The purpose of the carboplatin dosing guideline is to:
   i. Ensure that a standardized method of determining the dose of carboplatin is used and
   ii. Prevent unnecessary toxicities with carboplatin in adult cancer patients.

II. Organization
a. All approved physicians writing chemotherapy orders containing carboplatin will comply with the carboplatin dosing guidelines.
   i. Gynecology oncology reserves the option to dose carboplatin according to national standards set forth by the Gynecologic Oncology Group (GOG) if the UNC protocol is not utilized.

b. Nursing and Pharmacy have the responsibility of checking all chemotherapy orders containing carboplatin for compliance with the carboplatin dosing guidelines.

c. For any orders not in compliance with the carboplatin dosing guidelines, the ordering physician will be contacted to rewrite the chemotherapy orders.

Procedure
I. Guidelines For Use
A. The initial dose of carboplatin may be calculated using an estimated glomerular filtration rate (GFR) or a measured GFR
B. Cockcroft Gault Equation is the preferred method for calculating an estimated GFR
   i. GFR = ((140-age)*weight/72*SrCr)) [note *0.85 for women]
      1. Actual body weight should be used when calculating GFR for carboplatin dosing.
   ii. Serum creatinine values obtained within 72 hours of chemotherapy administration are acceptable.
   iii. Correction factors to convert IDMS creatinine values to non-IDMS creatinine values should not be used.
C. If the initial dose is based on measured GFR, the following formula should be used to determine GFR:
   i. GFR = [Urine Creatinine X Urine Volume] / [Plasma Creatinine X Time (minutes)]
D. If the initial carboplatin dose is based on an estimated GFR, the dose should not exceed the maximum dose for carboplatin based on the target AUC as referenced below.
E. The Calvert formula should be used for all carboplatin doses which are based on renal function
   i. Calvert Formula: Total Dose (mg) = (Target AUC) X (GFR + 25)
F. Note: The GFR used in the Calvert formula to calculate AUC-based dosing should not exceed 125mL/min.
G. For specific patients, e.g. those with low muscle mass, direct measurement of GFR may be preferable to an estimation of GFR. In patients with an abnormally low serum creatinine, estimate GFR using a minimum creatinine level of 0.6mg/dL, or cap the estimated GFR at 125mL/min.

<table>
<thead>
<tr>
<th>Maximum AUC-based Carboplatin Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>AUC</td>
</tr>
<tr>
<td>7</td>
</tr>
</tbody>
</table>
6

5

4

3

2

900 mg

750 mg*

600 mg

450 mg

300 mg

* Exception when dosing carboplatin as part of ICE chemotherapy regimen (Cap = 800mg)

II. Documentation

a. When prescribing for carboplatin where dosing is based on renal function, the following information must be documented on the chemotherapy order form:
   i. Method used for determining renal function
   ii. GFR used for the Calvert formula
   iii. Creatinine or GFR caps where applicable

b. Documentation must be completed by both Nursing and Pharmacy for verification of carboplatin calculations

REFERENCES

National Institutes of Health/National Cancer Institute. Follow up for information letter regarding AUC-based dosing of carboplatin. (October 22, 2010).

Appendix B. UNC Standing Orders for Adult Chemotherapy Infusion Hypersensitivity and Anaphylaxis Reactions

<table>
<thead>
<tr>
<th>INCLUSION CRITERIA</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Adult patients receiving chemotherapy/biotherapy/intravenous iron replacement.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ALLERGY ASSESSMENT</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diphenhydramine</strong></td>
<td><strong>Meperidine</strong></td>
</tr>
<tr>
<td>☐Yes ☐No</td>
<td>☐Yes ☐No</td>
</tr>
<tr>
<td><strong>Methylprednisolone</strong></td>
<td><strong>Dexamethasone</strong></td>
</tr>
<tr>
<td>☐Yes ☐No</td>
<td>☐Yes ☐No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TREATMENT PROTOCOL</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Grade 1 - Mild Symptoms:</strong> (e.g., new onset itching, flushing, rash, runny nose, fevers, or rigors)</td>
<td></td>
</tr>
</tbody>
</table>
| • Stop infusion and notify covering provider.  
  • Normal Saline at KVO (Use a new bag and new IV tubing)  
  • Diphenhydramine 25mg IV once  
  • Meperidine 25mg IV once PRN for rigors  
  • Continuous pulse oximetry until resolution of symptoms  
  • Vital signs every 15 minutes until resolution of symptoms |

If ordered by Attending or Supportive Care Prescriber, resume infusion when symptoms have resolved.

| **Grade 2 - Moderate Symptoms:** (e.g., new onset shortness of breath, chest tightness, or back pain) |
| • Stop infusion and notify covering provider  
  • Administer oxygen at 2 liters via nasal cannula, titrate to O2 saturation ≥92%  
  • Normal Saline at KVO (Use a new bag and new IV tubing)  
  • Diphenhydramine 25mg IV once  
  • Famotidine 20mg IV once  
  • Methylprednisolone 125mg IV once  
  • Meperidine 25mg IV once PRN for rigors  
  • Continuous pulse oximetry until resolution of symptoms  
  • Vital signs every 5 minutes until return to baseline, then every 15 minutes until resolution of symptoms |

If ordered by Attending or Supportive Care Prescriber, resume infusion when symptoms have resolved.
Grade 3 - Severe/Anaphylaxis Symptoms: (e.g., new onset bronchospasm, stridor, wheezing, respiratory distress, generalized urticaria, angioedema, systolic BP ≤ 80mm Hg, or loss of consciousness)

- Stop infusion and notify covering provider.
- Call a RAPID RESPONSE, CODE BLUE, or 911 as appropriate given the patient’s location.
- Administer oxygen at 2 liters via nasal cannula, titrate to O2 saturation ≥92%.
- Normal Saline 1000ml IV bolus once (Use a new bag and new IV tubing)
- Diphenhydramine 25mg IV once
- Famotidine 20mg IV once
- Methylprednisolone 125mg IV once
  - If allergy, give dexamethasone 20mg IV once
- Epinephrine 0.3mg IM once
- Continuous pulse oximetry until resolution of symptoms
- Vital signs every 5 minutes until return to baseline, then every 15 minutes until resolution of symptoms

REFERENCES


Morris Cancer Center at Duke University Hospital Chemotherapy Hypersensitivity and Anaphylaxis Orders. Updated 9/2006.