Task: The ordering, Preparation and Administration of Systemic Therapy	**Version: 1.0**
Issue Date: June 2024	**Revision Dates:**

Purpose:

To detail the procedures to be followed for the prescribing, preparation, and administration of systemic therapy and outline the roles and responsibilities of all clinicians involved in the process.

Procedure:

Section 1: Ordering Systemic Therapy

Ordering Systemic Therapy at the Health Sciences Center

Ordering Process:

a) Medical oncologists (MO), gynecologic oncologists (GO), and hematologists (HO) oversee administration of both intravenous and oral systemic therapy for their patients. Systemic therapy may be ordered by them, or a designated most responsible practitioner (MRP) such as a general practitioner, medical internist, nurse practitioner (NPs), or oncology clinical pharmacist. MRP's with additional training in systemic therapy, can prescribe intravenous and oral systemic therapy under the direction of the primary oncologist (as per policy PHA-400).
   Note: As per policy, PRC-205, radiation oncologists are also authorized prescribers for oral chemotherapy.
b) The prescribing provider must obtain written patient consent prior to ordering systemic therapy. (Policy 340-ADM-040).
c) All orders for systemic therapy must be written or electronically documented. Verbal orders are *not* accepted for ordering systemic therapy. Verbal orders *are* acceptable for hold or discontinue/cancel Systemic Therapy (PHA-400; PRC-205).

The oncologist (s) will write a chemotherapy letter to the MRP(s) who will be assuming the care of the patient if treatment is to be administered outside the systemic therapy administration centers at the Health Sciences Center. (See Ordering Systemic Therapy at the Regional and Rural Centers)

d) Chemotherapy letters **are not to be used** as a systemic therapy order by the MRP.
e) Prescriptions for all systemic therapy drugs must be documented on pre-printed orders (PPOs) (see linkages section for link to PPO's) when available or the institution's approved medication order form. Any changes to these prescriptions or orders must also be documented on the PPO/ systemic therapy medication order.
f) If a prescription requires a change, the dose reduction in the PPO must be used or a new order must be documented, signed, and dated by the MRP before the treatment is dispensed or administered.
g) Prescriptions for oral systemic therapy agents must **NOT** indicate repeats or refills.

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h) The MRP must assess the patient for treatment related toxicity and fitness to proceed prior to ordering systemic therapy.
i) The MRP is responsible for:
   i. the drug dosage calculations, and route of administration specified in the systemic therapy order.
   ii. reviewing the patient's height and weight and ensuring accurate body surface area calculations
   iii. checking all relevant safety parameters such as complete blood counts or bio-chemical tests. A maximum of a 5% variance from the original prescription (according to protocol dosages) in dosage calculation is permitted. If the variance exceeds 5% the treating oncologist must be consulted.
   NOTE: Bloodwork is to be completed according to the acceptable timelines for bloodwork document (Appendix A)
j) Body surface area (BSA) calculations are based on actual body weight for all oncology protocols. If the patient's body weight changes by more than 10%, the BSA must be recalculated, and the dose adjusted accordingly.
k) Height and weight must be measured as per policy (340-NB-15).

Prescription Elements:

a. Prescriptions for systemic therapy drugs must be complete, clear, and simple to follow. When systemic therapy medication orders/PPOs are completed by the MRP and are forwarded to pharmacy, the prescription must contain the following elements:

- Allergies or sensitivities.
- Prescribing date and time of order
- Patient name and HCN (Health Care Number) on each page
- Patient's height and weight (Policy 340-NB-15)
- Body surface area (BSA)
- Relevant lab data to calculate dose (e.g., serum creatinine, bilirubin)
- Specific indication for the treatment (cancer type and site)
- Protocol name
- Name of drug – use approved generic drug names, no abbreviations.
- Protocol dosage of the drug (usually units/m^2, units/kg, or AUC)
- Calculated patient dose and number of days of treatment
- Calculated dose [if dosage reduction is required, the standard total dose is provided minus the amount of percentage reduction (e.g., 400 mg/m^2 minus 30% = 280 mg/m^2 dose)]
- Number of cycles and day number
- Route of administration and any administration instructions
- Starting dates (and times when appropriate).

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Verification of Systemic Therapy Medication Orders

a. All orders are compared against a standard reference or protocol by two pharmacists.
b. If the medication order is not consistent with the usual or standard therapy, the prescriber must follow one of the below options:
    i. If the drug is not on the formulary for the specific indication, the oncologist must seek approval from the tumor disease site group. The disease site lead can present the new indication to the Provincial Systemic Antineoplastic Therapy Advisory Committee (PSATAC) for funding consideration.
    ii. If the Oncologist is seeking a one-time approval for a single patient, and treatment cannot wait for the preceding processes to be adhered to, then approval must be requested from the Cancer Care Program Director through the Rapid Response Committee Application.

MRP Assessment:

a. All patients must be assessed by the MRP within seven (7) calendar days prior to ordering systemic therapy.
b. Bloodwork is to be checked by the MRP to confirm acceptable parameters that are indicated in the order to proceed with systemic therapy. (Bloodwork is to be completed according to the acceptable timelines for bloodwork document - Appendix A)
c. The MRP is required to reassess patients that are identified as having a change in condition prior to systemic therapy administration.
d. Patients may be assessed in the MRP's office, hospital, clinic setting, or virtually.
e. To assess side effects and toxicities of systemic therapy, the MRP must:
    a. complete a relevant assessment on all patients.
    b. compare the most recent height and weight documented and compare to baseline (first height and weight documented in preparation for systemic therapy).
    c. assess for evidence of disease response/progression.
f. If necessary, dosage adjustments are to be made following consultation with the primary oncologist.

Ordering Systemic Therapy at the Regional and Rural Centers

1. All patients receiving systemic cancer therapy **(IV or Oral)** at regional and rural health care facilities must have a **chemotherapy letter** provided by the primary oncologist. A copy of the chemotherapy letter must remain on the patient's chart. The chemotherapy therapy letter is to be personally addressed to the "MRP(s) (first and last names) or

Approved Delegate" overseeing the patient's care and systemic therapy administration in the regional/rural centers. Letters addressed to the **"Physician In-Charge" are unacceptable**.

2. When a patient is transferred to a new systemic therapy site or new MRP(s), (other than the MRP(s) named on the chemotherapy letter) the MRP overseeing the patient's treatment must contact the primary oncologist for approval, and to arrange transfer of the patient.
3. The oncologist must generate all chemotherapy letters on the Cancer Care Program approved ARIA letter template. Handwritten chemotherapy letters are not permitted and will not be accepted.
4. A clinical pharmacist must review the systemic therapy protocol outlined in the letter for accurate and correct prescription. The oncologist must sign off electronically on the approved chemotherapy letter before it is sent to the regional center or rural site.
5. All chemotherapy letters, including those for oral systemic therapy agents, must be:
    a. mailed to the responsible physician caring for the patient.
    b. faxed to the pharmacy department preparing the systemic therapy
    c. faxed to the nursing unit responsible for administering the systemic therapy.
6. All chemotherapy letters must contain the following:
    a. Patient name, date of birth and HCN (Health Care Number) on each page.
    b. Patient data pertinent to the medication being administered such as: age, height, weight, BSA, serum creatinine, and estimated creatinine clearance.
    c. Diagnosis and intent of treatment.
    d. Systemic therapy regimen including the name of the protocol.
    e. Dose and dosing information, including dose reductions. If dosage is based on BSA, the dose per meter squared and the calculated dose to be administered must be included. If based on AUC, the body weight used in the calculations must also be included.
    f. Laboratory parameters
    g. Anti-emetics and pre-medications to be administered.
    h. Cycle frequency.
    i. Duration of therapy.
    j. Allergies or sensitivities.
    k. Details of required follow-up or note that follow-up has been arranged.
7. All chemotherapy letters must be accompanied by the patient's first assessment summary and/or recent progress notes. If there is no patient first assessment summary available, the primary oncologist must be contacted.
8. Upon Receipt of the Chemotherapy Letter: The MRP in the regional/rural center overseeing the care of the patient must download and use an approved preprinted order

(PPO). If no PPO is available, they must transcribe the systemic therapy orders onto the institution's approved medication order form. Please Note: **Signing a chemotherapy letter is not considered a substitution for a systemic therapy prescription and cannot be sent to the pharmacy department for the ordering of systemic therapy. Registered nurses are not authorized to accept or administer systemic therapy unless it is ordered on a PPO or the institution approved medication order form.**

9. If a systemic therapy order or prescription is changed, the reason for the change(s) must be documented on the patients' health record. The change(s) must be written on a PPO / medication order form and be signed and dated by the MRP before the systemic therapy treatment is dispensed and administered.

10. MRP(s) in the regional/rural centers are responsible for:
    a. Calculating the drug dosage
    b. Specifying the route of administration in the order.
    c. Calculating body surface area.
    d. Ensuring accuracy of all relevant safety parameters such as complete blood counts or bio-chemical tests have been checked. See appendix A for bloodwork timelines.

    NOTE: A maximum of a 5% variance from the original prescription (according to protocol dosages) in dosage calculation is permitted. If the variance exceeds 5% the treating oncologist is to be consulted.

Section 2: Pharmacy

Parenteral systemic therapy is prepared following the policy and procedures of the pharmacy department at the treating facility as per the National Association of Pharmacy Regulatory Authority (NAPRA) standards for hazardous sterile compounding. (See Linkages for policies).

Oral and parenteral anti-cancer therapies are High-Alert medications which require an independent double check of dose and calculations. (EH Policy PHA-150)

Chemotherapy Letters

1. **Chemotherapy letters** received from the Health Science Center sites must be generated by the primary oncologist. The primary oncologist and the clinical oncology pharmacist must review the chemotherapy letter. The chemotherapy letter is signed by the oncologist.

2. The prescription for the systemic therapy must be written by the MRP overseeing the patient's systemic therapy treatment. The order must be written on a PPO. If no PPO is available, the

order will be written on an approved medication order form. Note: **A signed chemotherapy letter will not be accepted as the medication prescription.** Upon receipt of the prescription, the pharmacist verifies the order with the original chemotherapy letter to ensure that any necessary adjustments in dosage (e.g., due to weight change) are correctly calculated.

3. The chemotherapy letter from the oncologist is placed in the patient's specific file in the pharmacy department.

Pharmacy Verification of Systemic Therapy Orders

1. The prescription is reviewed, ensuring all prescription elements identified in Section 1 above are included. The prescription is entered into the pharmacy patient profile by a pharmacy technician or pharmacist and labels are generated. Labels are checked against the prescription by two registered pharmacy personnel.

2. A pharmacist reviews and verifies:
   a) Patient name and health care number, information on requisition (ARIA #, cycle #, date and time) or chemotherapy letter (cycle #, date and time) matches the prescription.
   b) Appropriateness of medication therapy as per indication/diagnosis, allergies or adverse drug reactions, drug interactions, contraindications, or therapeutic duplication.
   c) Laboratory data to calculate dose (e.g., serum creatinine) and to meet specific protocol monitoring specifications.
   d) Protocol, including cycle number, frequency, and sequencing of therapy.
   e) Weight, height and BSA, including comparison with previous cycle.
   f) Dosage calculations (mg/m2, dose/kg, AUC, or banded dose).
   g) Dosage, route, frequency and duration of administration and dosage form.
   h) Directions for intravenous administration include Verify dilution volume, rate and duration of administration, medication stability and potential incompatibilities.

3. Registered pharmacy personnel perform an independent verification of:
   a) Patient name and health care number, information on requisition (ARIA #, cycle #, date and time) or chemotherapy letter (cycle #, date and time) matches the prescription.

b) Appropriateness of medication therapy as per indication/diagnosis (pharmacist).
c) Protocol, including cycle number, frequency, and sequencing of therapy.
d) Weight, height and BSA.
e) Dosage calculations (mg/m2, dose/kg, AUC, or banded dose).
f) Dosage, route, frequency and duration of administration and dosage form.
g) Directions for intravenous administration include dilution volume, rate and duration of administration, medication stability and potential incompatibilities.

Section 3: Nursing

Administration of systemic therapy is defined by the College of Registered Nurses of Newfoundland and Labrador (CRNNL) as a Specialty Nursing Competency. Registered Nurses must be certified and competent in the administration of systemic therapy through the completion of an approved systemic therapy course recognized by the Provincial Cancer Care Program.

Pre-Systemic Therapy the Registered Nurse (RN) will:

1. Review the patient's health record and information concerning cancer diagnosis, staging, comorbidities, medications, previous toxicities and/or side effects.
2. Verify the systemic therapy order(s):
    i. For the Health Science Center, verify the systemic therapy order(s) is in ARIA
    ii. For regional and rural sites, verify that the copy of the original chemotherapy letter corresponding with the systemic therapy prescription is on the patient's health record. Copies of chemotherapy letters for oral systemic therapy agents must also be maintained on the patient's health record.
3. Verify that a copy of the informed consent for systemic therapy has been signed by the patient and MRP and is maintained in the patient's health record.
4. Verify that the patient has been assessed by the MRP prior to the delivery of each cycle of systemic therapy, oral or intravenous.
5. Verify that appropriate laboratory tests have been completed and are within acceptable limits. See Appendix A for acceptable timelines.

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6. The RN is responsible for performing an oncology nursing assessment during each systemic therapy treatment including;
    - a review of the patient's Screening for Distress
    - measurement and documentation of the patient's height and weight (as per Policy: 340-NB-15)
    - verifying with the patient if there are any changes or additions to current medication list
7. Provide appropriate patient education and teaching, including but not limited to specific systemic therapy information, blood counts, side effects and the management thereof. Instruct the patient regarding self-care and their role in safety, including the use of personal protective equipment when handling blood, vomitus, or excreta, and double flushing the toilet when receiving systemic therapy.

Prior to the Systemic therapy Administration, the RN will:

1. Perform Positive Patient Identification
2. Verify patient's allergy history.
3. Measure and record baseline vital signs.
4. Determine appropriate site for venous access and utilize appropriate sterile technique for access or assess and ensure patency, including blood return of central venous access device, per the institutional policy.
5. Initiate pre-treatment therapies (e.g., hydration, test dosing, anti-emetics, anti-hypersensitivity meds, etc.) as per authorized prescriber's orders.
6. Verify that appropriate personnel and emergency equipment, including an approved spill kit and extravasation kit is ready and easily accessible.

Drug Preparation:

1. Obtain prepared drug and verify that systemic therapy medications are received in clean, dry syringes or bags of IV fluids inside zipper-seal plastic bags and are appropriately labeled by pharmacy. Inspect bags before opening to ensure there is no spillage in the bag. If spillage has occurred, keep the container sealed and notify pharmacy.

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2. Prepare intravenous sets and prime IV lines with compatible IV solution. Alert: RNs do not prime IV sets with systemic therapy.
3. Inspect systemic therapy labels for clarity and accuracy against the MRP's prescription. At the time of systemic therapy administration, two clinicians (nurses, physicians, pharmacists) are to **independently** verify information on the systemic therapy label (including: patient name, HCN (Health Care Number), drug name, dosage, etc.). Two clinicians are to check the final product label against the MRP's medication order.

Drug Administration:

1. Wash hands and don appropriate Personal Protective Equipment (PPE) for the handling of cytotoxic agents
2. Complete positive patient identification (PPI) as per policy (PRC-130) and verify immediately prior to administering systemic therapy at point of care.
3. Prepare to administer systemic therapy as per protocol. When spiking a bag of systemic therapy medication, spike at waist level to decrease the risk of eye/face contamination.
4. Attach closed system equipment or specialized filter(s) to IV if applicable.
5. All infusions of systemic therapy are administered via an infusion pump. EXCEPTION: vesicant agents that are being administered through a peripheral venous access device. Refer to policy Administration of Vesicant Chemotherapy Drugs to Oncology Clients (Adult Only) 204 (NUR)-8-020
6. Long term outpatient systemic therapy infusions are administered using an elastomeric infusor.
7. Assess patient's tolerance of therapy. Monitor venous access site, infusion set and pump hourly during systemic therapy administration. EXCEPTION: Elastomeric pumps in the community setting.
8. Monitor administration sets and IV sites for leakage. If shows leakage, institute procedure for cleaning a systemic therapy spill.
9. Assess IV site before and after each drug.
10. Flush between each drug with normal saline (NS) or dextrose 5% in water (D5W) to avoid drug admixture and potential precipitation.
11. Flush IV line with NS or D5W after the last drug is administered. Do not disconnect tubing at any point in the system until the tubing has been thoroughly flushed.

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Post Systemic therapy Administration the RN will:

1. Discard all materials (needles, syringes, bags, tubing, chemotherapy gown, gloves, shoe coverings mask, face shield etc.) in designated cytotoxic waste containers and perform hand hygiene.

Note: Refer to the Eastern Health or health facility specific Policy on: *Management of Exposure to Hazardous Medications (HR-OH (O)-090).*

2. Assess client's status and provide follow-up supportive therapies.
3. Provide patient education regarding self-care and side effect management.
4. In the outpatient setting, ensure the client has transportation to return home, follow up appointment and prescriptions for anti-emetics and/or other supportive therapies. Ensure the client has the telephone number of an appropriate health care provider.
5. Document care and client's response to treatment on approved medication administration record, systemic therapy flow sheet and nursing notes as per the policy of the health facility where the systemic therapy is being administered.

Section 4: Administration of New Agents

To ensure patient and practitioner safety when a new agent is to be given, in addition to the procedure established by Provincial Cancer Care Program for the administration of systemic therapy, the following process will be followed.

A ***new agent*** is defined as any medication that is to be given as an antineoplastic or an adjunct to an antineoplastic that has not been administered previously in a particular health care facility.

Prior to the administration of any new agent, education for health care providers involved in the ordering, mixing, and administration of the agent must be completed. All physicians, pharmacy and nursing staff must be aware of:

a) approved indication(s), contraindications, therapeutic dose range, dosage adjustments (if necessary), monitoring parameters and special precautions of all new agents.
b) storage, stability, method of preparation, and recommended concentration of final product.
c) recommended method of administration, rate of administration, and infusion related reactions.

d) potential adverse reactions, and management thereof.
e) issues regarding waste disposal.

Reference materials and information relating to the new agent will be provided.

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Appendix A

Acceptable Timelines for Bloodwork:
Systemic Therapy for Cancer Care Program

These recommended timelines are to be used in the absence of protocol specific bloodwork requirements, as indicated on the Standard Order Set. *Any bloodwork that falls outside of recommended timelines but is deemed acceptable to use for treatment by the oncologist/hematologist/oncology delegate **must** be indicated in the physician's orders.*

Treatment Type	Treatment Interval	Acceptable window for pre-treatment blood work
Cytotoxic Chemotherapy (pre-cycle 1 for chemotherapy naïve patient)	All	1 month
Cytotoxic Chemotherapy (Solid Tumor) (subsequent treatment)	21 days or longer	96 hours
Cytotoxic Chemotherapy (Solid Tumor) (subsequent treatment) Also include: FOLFOX, FOLFIRI, FOLFIRONOX, Pembrolizumab, Panitumumab, Cetuzimab, Ramicirumab, weekly chemotherapy, Bevecizumab	Less than 21 days	72 hours
Immune Checkpoint Inhibitor (CPI)	All	7 days
Cytotoxic Chemotherapy (Hematology)	All	7 days
Clinical Trials	Consult protocol-specific requirements/Standard Order Set	
Pediatric, adolescent, or young adult under the care of the Janeway	Consult protocol-specific requirements as directed by the Janeway	

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LINKAGES

HR-OH(o)-090 Management of exposure to Hazardous Medications
204(NUR)-8-010 Administration of Parenteral Chemotherapy to Oncology Patients
204(NUR)-8-020 Administration of Vesicant Chemotherapy
340-ADM-040 Informed Consent in Ambulatory Oncology
340-NB-15 Height and Weight Measurement and Documentation for Oncology Patients (Adult Only)
440-PHA-CH-010 Accidental Contact with Hazardous Compounded Sterile and Non-Sterile Preparations
440-PHA-CH-030 Biological Safety Cabinet Malfunction or Planned Shutdown
440-PHA-CH-050 Disposal of Hazardous Waste Compounding Sterile Preparations
440-PHA-CH-060 Hazardous Medication Spills
440-PHA-CH-155 Preparation and dispensing of Intravenous Vinca Alkaloids – Adult
440-PHA-CH-160 Processing and Verification of Chemotherapy Compound Sterile Preparations (CSP Log Sheets)
440-PHA-CH-165 Processing Oral Chemotherapy for the Treatment of Cancer Policy
440-PHA-CH-170 Receiving-Unpacking and Storage of Hazardous Medications
440-PHA-CH-240 Processing and Pharmacy Keeper Verification of Chemotherapy CSPS
PHA-150 High Alert Medications
PHA-400 Ordering-Processing of Parenteral Chemotherapy Orders for the Treatment of Cancer (Acute Care) (Inpatients and Outpatients)
PRC-205 Writing Oral Chemotherapy Orders for the Treatment of Cancer (Adult Acute Care, Inpatients)

https://cancercare.easternhealth.ca/health-care-professionals/pre-printed-orders/

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