POLICY

Title: SYSTEMIC THERAPY TREATMENT DELIVERY PROCESS	**Number:** III-10
Effective Date: Feb 1999	**Approved By:** Provincial Systemic Program Committee
Revision Date: Nov 1, 2016; Nov 30, 2017	

DIRECTIVE:

In order to ensure the safe prescribing, preparation, dispensing and administration of all systemic cancer drug treatments to BC Cancer patients, health care providers will adhere to the process steps below. For the purpose of this policy, cancer drug treatments refer to drugs which inhibit or prevent the proliferation of cancers, including chemotherapy, hormonal therapy, immunotherapy, targeted therapy and others. (See Appendix A for further definitions)

Note: Policies referenced in this document that are located in H:\ Drive are accessible by BC Cancer staff members only.

Disclaimer: Systemic Therapy Treatment Delivery Process Policy III-10 is subject to change as per Clinical Systems Transformation Electronic Health Care System development.

PROCESS:

1. **Authorized prescribers:**

- Physicians
    - At BC Cancer, medical oncologists, hematologists, gynecological oncologists, associates in oncology, general practitioners in oncology and medical oncology or hematology residents and fellows in training may prescribe cancer treatments in accordance with the plan developed by the most responsible physician for systemic therapy.
    - At BC Cancer, radiation oncologists may prescribe cancer drug treatments within their defined scope of practice e.g. anti-cancer radio-pharmaceuticals and hormonal therapies in accordance with the systemic therapy treatment guidelines.
    - Within the Community Oncology Network, medical oncologists, hematologists, internal medicine consultants and general practitioners in oncology may prescribe cancer treatments in accordance with the plan developed by the most responsible physician for systemic therapy.
    - Surgeons and other physicians may prescribe and renew cancer drug treatments within their defined scope of practice, e.g. anti-cancer radio-pharmaceuticals, hormonal therapies and intravesicular cancer drug treatments in accordance with the systemic therapy treatment guidelines.
    - All other physicians, not listed above, must have their cancer drug treatment orders countersigned by one of the above listed practitioners authorized to order the prescribed treatment.

- Exceptions:
  - Leukemia/Bone Marrow Transplant (BMT) Protocols: (Refer to Leukemia/BMT Program for most up-to-date requirements)
    - Cancer drug treatment orders must be written and co-signed by two physicians. One of the signatories must be the most responsible physician /attending physician for that patient.
  - Other high dose cancer drug treatment protocols will only require two signatures if this is a requirement written in the protocol summary.

- Nurse practitioners:
  - At BC Cancer:
    - Nurse practitioners employed by BC Cancer and who have completed the General Practitioner in Oncology (GPO) course (didactic and practicum) may prescribe medications within the scope, limitations, restrictions and conditions for prescribing set by the College of Registered Nurses of British Columbia and federal or provincial regulations. Nurse practitioners prescribing practice will meet the same standards and adhere to the same policies expected of other BC Cancer prescribers.
    - For cancer drug treatments, nurse practitioners:
      - may prescribe cancer treatments for the second and subsequent cycles of a BC Cancer chemotherapy protocol, in accordance with the plan developed by the most responsible physician for systemic therapy, and may continue ongoing treatments with hormonal therapies
  - In the community, nurse practitioners may continue a prescription for tamoxifen and aromatase inhibitors for those patients who are being treated with a BC Cancer Protocol for adjuvant breast cancer.

2. Prescription Requirements:

- Prescriptions must be ordered in accordance with provincially legislated requirements, Accreditation Canada standards, approved BC Cancer policies, BC Cancer tumour group protocols, or medical oncology/radiation oncology clinical trial requirements.

- Prescriptions must be complete, clear, simple to follow and must not include any abbreviations, symbols, and dose designations identified on the BC Cancer Do Not Use List (also see BC Cancer Policy on of Use of Abbreviations/Acronyms in Clinical Documentation [PIM 060-IV-B-65] H:\EVERYONE\BCCA Policy Manual\Health Information Management); BC Cancer Medication Order Requirements Policy [BCCA MA PS04]) (Add link when published)

- Designated health care professionals must complete allergy assessment and document new treatment related hypersensitivity reactions as per BC Cancer Documentation of Allergy Status Policy (PC 020) (H:\EVERYONE\BCCA Policy Manual\Patient Care\Allergy and Alert forms).

- Prescriptions and modifications to prescriptions, for cancer drug treatments must be written (where electronic prescriber order entry is not in place). Verbal and telephone orders are not permitted. If a prescription is modified, the changes must be signed and dated by an authorized prescriber before the treatment is dispensed or administered. Emailed prescriptions are not acceptable. Changes to cancer drug treatments must be documented in patient's medical record and communicated clearly between health care professionals and to the patient.

  Exceptions: (See also BC Cancer Medication Order Requirements Policy [BCCA MA PS04]) (Add link when available)

  - Telephone orders are acceptable for hormonal therapies only.
  - Telephone orders to suspend (hold) chemotherapy for reasons of safety. Reasons must be documented in patient's medical record.
  - Telephone orders to discontinue current chemotherapy for reasons of safety. Reasons must be documented in patient's medical record. (Note: This does not necessarily imply permanently discontinuing cancer treatment. Ongoing treatment plan must be discussed with most responsible physician.)
  - Faxed prescriptions are only acceptable in limited circumstances. Clinic specific directives and procedures must be developed, with consideration to downstream operational supports, safety checks and cross health authority regulations e.g. prescribing privileges.

- Provincial Pre-printed Order or Prescription form or Doctors' Order form:

  - The following elements must be provided for each drug order:

    - Patient name and second unique patient identifier e.g. personal health number (PHN)
    - Prescribing date
    - When treatments are to be administered
    - Cycle and day number (if applicable)
    - The protocol code (or specific diagnosis if no protocol code assigned)
    - Generic drug name; no abbreviations.
      - Brand name, in addition to generic name, may be included for reasons of safety to distinguish between look-alike/sound-alike drugs.
    - Route of administration and any administration instructions
    - Height (in centimeters) and Weight (in kilograms).
      - Patient's weight is reviewed and documented in patient's medical record upon each cycle or as clinically indicated (e.g. per protocol requirement

and resulting clinic booking schedule). Any significant changes (greater than 10 %) are communicated to the prescriber (See dose recalculation point below).

- Dosing method: For example, body surface area (BSA), weight-based (mg/kg). Follow protocol requirements.
  - BSA calculation:
    - Use Mosteller equation.

$$BSA(m^2) = \sqrt{\frac{HEIGHT(cm) x WEIGHT(kg)}{3600}}$$

    - BSA must be calculated for the first treatment of each chemotherapy protocol that is dosed by surface area. Round to two decimal places.
  - Dose recalculation based on patient weight changes for subsequent cycles:
    - BSA recalculations/Dose recalculation (for weight-based dosing) should be done:
      - If a patient's weight change is greater than 10% from cycle 1 of the regimen or from the most recent BSA/dose recalculation. Review with prescriber to determine if dose change is required.
      - If patient clinical status warrants a dose adjustment.
    - The reasons prompting the recalculation must be documented on the preprinted order and patient's medical record.
  - Use actual body weight except for the designated high dose protocols described e.g. Leukemia/Bone Marrow Transplant protocols, where corrected body weight is used. (Refer to specific protocol for details).
- Calculated dose and number of days of treatment
  - Dose calculation check:
    - A maximum of 5% variance is permitted in dose calculation, unless otherwise specified by the treatment protocol. If the calculated dose variance is greater than 5%, review with the prescriber. Follow specific protocol parameters.
- Parameters that would require holding or modifying the dose, e.g. laboratory values, diagnostic test results and patient's clinical status.
- Supportive care treatments appropriate for the regimen (e.g. pre-medications, hydration, hypersensitivity management)
- Prescriber's name and signature
- For outpatient prescriptions, the following information is also required:
  - Quantity of the drug
  - Refill authorization if applicable, including number of refills and interval between refills

- College Registration Number of the Prescriber

- Laboratory/Diagnostic test requirements:
    - Every BC Cancer treatment protocol must specify the tests required and the frequency of those tests.
    - The protocol may indicate the appropriate time interval for tests required for dose modifications to be performed prior to each cycle of treatment. This information must be included in the corresponding Provincial Pre Printed Order. For tests with time interval specified, prescriber should have the option to specify the date of the laboratory results to be used. Refer to protocol for detail requirements.
    - Prescribers may request additional tests as clinically indicated.
    - For new patients or patients beginning a new course of cancer treatment, baseline laboratory tests must have been conducted within four weeks of the start of therapy or as clinically appropriate per protocol requirements.

- Follow-up requirements
    - Each patient is assessed for treatment efficacy and adverse effects.
    - Toxicity management is documented in patient's medical record.
    - Serious and unexpected adverse drug reactions are reported to Health Canada using the Patient Safety Learning System (PSLS) as per Provincial Health Services Authority (PHSA) policy. (See PHSA Unexpected and Serious Adverse Drug Reactions: Reporting to Health Canada Directive) (Add link when published)

3. Prescriber Process:

- To initiate a new course of cancer drug treatment, physicians should dictate for the medical record the diagnosis, proposed cancer drug treatment regimen, treatment intent (curative/adjuvant/palliative), alternatives to the proposed treatment, confirmation of discussion of the risks and benefits, and confirmation of consent. (See BC Cancer Dictation Guideline Oct 19 2017. Add link when available)
- Assess pregnancy status for all new female patients aged 11-56. If there is a possibility of pregnancy, the prescriber will order a pregnancy test. Follow protocol requirements.
- Submit online request for protocols requiring Compassionate Access Program review. Approval must be obtained prior to the commencement of treatment.
- Complete Doctor order form, Preprinted Orders/prescription form as per prescription requirements in sections above.
- Prescribers are responsible for ensuring that all relevant clinical parameters such as laboratory or imaging results, allergies, patient specific alerts have been checked.
- Document clinical assessment and reasons for modifications in doses/protocols in patient's medical record. (Consider the cumulative amount of drug previously administered for medications with established absolute cumulative dosage limits (e.g. anthracyclines, bleomycin) or constraints against repeated administration as a function of time.)

- If a cancer drug treatment order is modified or clarified by another health care professional, the changes must be signed and dated by the originating or covering prescriber before the treatment is dispensed or administered (Exception: hormonal therapy).

4. Pharmacy and Nursing Processes:

- The following outlines high level Pharmacy and Nursing processes. Refer to discipline specific policies for details. (See also Provincial Pharmacy Directive III-30-07– Medication Orders; BC Cancer Provincial Nursing Practice Reference C-252 Chemotherapeutic Drugs, Administration of (http://www.bccancer.bc.ca/health-professionals/clinical-resources/nursing/nursing-practice-references)

- Prior to dispensing (pharmacist) or administering (chemotherapy certified nurse) all dosage forms of cancer drug treatments, each clinician will review the medication orders, and independently verify them according to the tumour group protocol, referenced Compassionate Access Program approved treatment regimen or the Cancer Drug Manual monograph and determine appropriateness based on patient specific information, including allergies, alerts and protocol required laboratory values and tests. For new patients or patients beginning a new course of cancer treatment, baseline tests must have been conducted within four weeks of the start of therapy or as per protocol requirements. Prescriptions must comply with requirements outlined in previous sections.

- Clinical assessment includes reviewing:

    - Previous and current treatment as documented in the patient's medical record, pharmacy computerized medication profile (pharmacy), Pharmanet (pharmacy), medication administration record (nursing), documentation of treatment given in other jurisdictions.
    - Relevant clinical documentation.
    - Tumour group protocol or referenced treatment regimen, BC Cancer benefit status of the medication(s) and receipt of approval, if required.
    - Protocol code, cycle, and day number (if appropriate)
    - Treatment interval (since previous dose of cancer treatment)
    - Duration of therapy (cycle number is within protocol or Compassionate Access Program approved limits)
    - BSA calculation:
        - Use Mosteller equation.

$$BSA(m^2) = \sqrt{\frac{HEIGHT(cm) x WEIGHT(kg)}{3600}}$$

- BSA must be calculated for the first treatment of each chemotherapy protocol that is dosed by surface area. Round to two decimal places.
- Dose recalculation based on patient weight changes for subsequent cycles:
  - BSA recalculation/Dose recalculation (for weight-based dosing) should be done:
    - If a patient **weight** change is greater than 10% from cycle 1 of the regimen or from the most recent BSA/dose recalculation. Review with prescriber to determine if dose change is required. (NOTE: BSA/dose recalculation is not required if weight change is less than 10%, unless clinically indicated.)
    - If patient clinical status warrants a dose adjustment.
- Use actual body weight except for designated high dose protocols described in previous sections. Refer to the specific protocol for details.
- The reasons prompting the recalculation of BSA must be documented on the preprinted order and patient's medical record.

- Drug
- Dose:
  - A maximum of 5% variance is permitted in dose calculation, unless otherwise specified by the treatment protocol. If the calculated dose variance is greater than 5%, review with the prescriber. Follow specific protocol parameters.
  - Dose modifications are calculated according to applicable laboratory and diagnostic test results and patient toxicities as per protocol.
- Route
- Duration of administration for each medication ordered
- Drug interactions (pharmacist)

- Any discrepancies identified will be discussed with the prescriber or covering prescriber prior to dispensing and administering the medication(s). Documentation of the discrepancy and resolution will be completed by the clinician originating the review:
  - In the patient's record (nurse or pharmacist)
  - In the pharmacy medication profile (pharmacist)

- Other discipline specific processes:

  - Pharmacy
    - Clinical assessment:
      - The pharmacist performing the clinical review of medication orders will document on the appropriate form that the order is approved for preparation.
    - Computer order entry/medication label check:

- The pharmacist or pharmacy technician performing the check will verify correct computer entry as compared with the medication order and confirm required calculations e.g. infusion solution concentrations and rate. Permanent documentation of the check must be completed.

▪ Final product check:
- The pharmacist or pharmacy technician will verify accurate and appropriate drug preparation, as compared with medication order or verified manufacturing form/label. Permanent documentation of the check must be completed.
- Quantity Dispensed:
  - For cyclical therapies:
    - Dispense one cycle at a time or as defined by the protocol or dose adjustment requirements.
    - Follow drug specific regulatory or manufacturer requirement e.g. lenalidomide.
  - Exceptions may be made for travel if patients are stable on the medications as per discussion with prescriber.

▪ Counselling:
- For take-home medications, the pharmacist must perform and document patient counselling as per BC College of Pharmacists Bylaws and Accreditation Canada standards.

▪ Documentation:
- The pharmacist or pharmacy technician must:
  - Complete any mandatory documentation as per Health Canada, BC College of Pharmacists (e.g. PharmaNet), Accreditation Canada or clinical trial requirements.
  - Document in original prescription, department records and pharmacy computerized medication profile as per local departmental policy.

o Nursing:

▪ Documentation:
- The treating nurse's pre-chemotherapy nursing assessment of the patient and other relevant nursing care will be documented according to organizational policies.

(For BC Cancer: Nursing Practice Reference D-75: Documentation, Nursing (H:\EVERYONE\nursing\REFERENCES AND GUIDELINES\BCCA Nursing Practice Reference Manual)

- Medication administration will be documented on the Medication Administration Record (MAR), and when appropriate, on other relevant nursing documents as per organizational documentation guidelines.

5. Patient Education and Information Process:

- Education and information will be provided by physicians, nurse practitioners, pharmacists and nurses. Other health care professionals may also provide information as appropriate.
- Each new patient receiving cancer treatment will have a group and/or individualized teaching session. (See BC Cancer Website information: http://www.bccancer.bc.ca/health-professionals/education-development/nursing/chemotherapy-patient-education; patient teaching standard: systemic therapy: H:\EVERYONE\nursing\Education\Chemotherapy Patient Education)
- Information about medications is discussed with patients and documented prior to the initial dose and when the dose is adjusted.
- Education will include both verbal and written information for topics such as:
    - General cancer treatment information
    - Specific protocol or drug treatment information to meet individual patient needs:
        - For "take home" treatments, patients will be educated to be part of the checking process such that they know the name and dose of medication that they are being prescribed.
    - Follow-up counselling for repeat prescriptions.
    - Management and reporting of side effect and symptoms.
    - Guidelines for handling cancer drugs and body fluids in the home. http://www.bccancer.bc.ca/health-professionals/clinical-resources/cancer-drug-manual
- Resource information for patients can be found on BC Cancer Website: http://www.bccancer.bc.ca/our-services/patient-guide
- Documentation of counselling will be done in the appropriate section of the patient's medical record.

6. Related Documents:

- Provincial Systemic Program Policies: (http://www.bccancer.bc.ca/health-professionals/clinical-resources/systemic-therapy)
    - III-60 Physician Coverage for Medical Emergencies During Delivery of Selected Chemotherapy Drugs
    - V-10 Hazardous Drug Safe Handling Standards
    - V-20 Employee Health Risks Related to Hazardous Drugs
    - V-30 Hazardous Drug Spill Management
- Safe Handling Standards Manual: BC Cancer Pharmacy Practice Standards for Hazardous Drugs http://www.bccancer.bc.ca/health-professionals/clinical-resources/pharmacy

- BC Cancer Provincial Nursing Practice Reference: C-252 Chemotherapeutic Drugs, Administration of (http://www.bccancer.bc.ca/health-professionals/clinical-resources/nursing/nursing-practice-references).
- BC Cancer Medication Order Requirements Policy [BCCA MA PS04] (add link when published)
- Provincial Pharmacy Directive III-30-07– Medication Orders: H:\Pharm-prov\BCCA Pharmacy Directives\BCCA Pharmacy Directives\III_PatientCare\III-30 Distribution

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Appendix A: Definitions

Biological Response Modifier: treatment using substances made from living organisms to stimulate or suppress the immune system to help the body fight cancer, slow or stop the growth of specific cancer cells, or lessen certain side effects caused by some cancer treatments (e.g., immunotherapy, gene therapy, some targeted therapies); biological therapy

Cancer drug treatments: treatments using drugs which inhibit or prevent the proliferation of cancers, including chemotherapy, hormonal therapy, immunotherapy, targeted therapy and others.

Chemotherapy: treatment using drugs to destroy cancer cells by killing the cells or by stopping them from dividing

Hormonal Therapy: treatment that removes, blocks or adds hormones to slow or stop the growth of certain cancers; endocrine therapy

Immunotherapy: a type of biological therapy that uses substances to stimulate or suppress the immune system to help the body fight cancer (e.g., checkpoint inhibitors, cytokines, vaccines, bacillus Calmette-Guerin, some monoclonal antibodies)

Systemic Therapy: treatment using substances that travel through the bloodstream, reaching and affecting cells all over the body

Targeted Therapy: treatments using drugs or other substances that target the action of specific enzymes, proteins, or molecules involved in the growth of cancer cells, or help the immune system kill cancer cells, or help deliver drug or other substances directly to cancer cells; most are small molecule drugs and monoclonal antibodies