Systemic Therapy Program

Standards of Practice

TITLE: **Oral Systemic Therapy for Cancer**	NUMBER: **STP-004**
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Applies To: Health care professionals practicing cancer care	
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PREAMBLE

1. Systemic therapy for cancer patients is a high-risk area of pharmacotherapy. Systemic therapy agents (drugs) used to treat cancer (including cytotoxic agents commonly called 'chemotherapy') may be given through oral or parenteral administration routes or other routes as specified in the treatment regimen. Some regimens may include both oral and parenteral systemic therapies in combination.
2. Types of systemic therapy include targeted agents, alkylating agents, antimetabolites, plant alkaloids and terpenoids, topoisomerase inhibitors, antitumour antibiotics, monoclonal antibodies, biologics, and related agents. Hormonal therapies are not included in the definition of systemic therapy for these standards.
3. Orally-administered systemic therapy drugs may be given in hospital inpatient units, hospital ambulatory clinics, continuing care facilities and other health care organizations. Most oral systemic therapy, however, is self-administered by patients in the home and dispensed by community pharmacies throughout the province.
4. Safety processes are established for parenteral systemic therapy administered in the hospital. Similar processes (e.g. order verification) must also be in place for oral systemic therapy agents delivered in community and hospital settings.
5. Handling cytotoxic chemotherapy agents is an area of occupational risk for all health care workers (including nurses, pharmacy staff, housekeepers, porters, etc.). Chemotherapy agents include cytotoxic (cell-killing) agents, which are known to be occupationally hazardous. Handling precautions may vary from one drug to another, based upon different biologic risks. People handling oral systemic therapy should make themselves aware of the specific precautions appropriate to each drug.
6. Many Nova Scotians must pay for some or all of the cancer treatment drugs prescribed for dispensing in their community pharmacy, therefore the issue of drug cost relative to the patient must be considered when these drugs are to be ordered and dispensed.
7. Some drugs are supplied through a pharmaceutical company-sponsored compassionate access program or CAP (e.g. drug supplies for patients with no prescription coverage or incomplete coverage, drugs newly released to the Canadian Market). These programs vary from one company to the next. Some programs are dispensed through community pharmacies, others through a central supplier (not always a pharmacy). Patients receiving drugs distributed through these programs must still be managed by their oncology health care team.

   7.1. Oral systemic therapy for cancer may be accessed by direct delivery to the patient's home (from a third party- not the community pharmacy). This is one option sometimes offered by CAP programs and it involves several different providers working in different locations.
8. Oral systemic therapy drugs which are dispensed from community pharmacy may require the use of prefilled compliance packaging (i.e. pill packs, dosettes) for

selected patients (such as those who need aids to enhance compliance with self-administration).

The community pharmacist is a member of the cancer patient care team when supplying oral systemic therapy drugs. The community pharmacist collaborates in the overall care, including:

- education reinforcement (medication counseling),
- ensuring optimal patient safety by following the specific dispensing procedures,
- advising the patient on supportive care products and measures during active systemic treatment
- follow up telephone calls and/or patient visits to screen for adverse effects and adherence issues.

Two-way communication between the community pharmacist and the cancer care team is crucial to make this collaboration efficient and effective.

9. These standards apply to activities in the ordering, verification, dispensing, administration, and patient care education and coordination that occur within organized health care facilities in the jurisdiction of a health authority. Activities outside the health authority may be assisted by guidance documents available from Cancer Care Nova Scotia.
10. These standards are one component of a set of provincial standards directing the provision of cancer systemic therapy to patients in Nova Scotia. (See Related Documents). Systemic therapy standards, common to the health districts and community providers in Nova Scotia, will enhance clarity and relationships between health care professionals providing systemic therapy, and thus further improve patient safety and quality care.

STANDARDS

1. All patients receiving cancer systemic therapy will be assessed by an *Oncologist* prior to initiation of a cancer systemic therapy protocol.
2. Each patient will be assessed prior to the start of each cycle.
3. Each patient receiving cancer systemic therapy treatment will have a plan for ongoing follow-up monitoring over the full duration of the treatment protocol.
4. Prior to administration of the first oral dose of a cancer systemic therapy protocol, informed consent will be obtained from the patient for the full planned course of systemic therapy.
5. All orders for cancer systemic therapy will be written and signed by an *Oncologist* or *Community Specialist* or an *Oncologist Delegate* (the 'prescriber').
6. An approved provincial *Pre-Printed Order for Oral Systemic Therapy* (PPO) *or equivalent order set,* will be used for each prescription. This includes prescriptions for inpatients, ambulatory care patients and take-home prescriptions.
7. Telephone or verbal orders/prescriptions for cancer systemic therapy are not acceptable, including telephone orders to a community pharmacy. Orders written by a prescriber may be clarified over the telephone by the nurse or pharmacist.
8. Each order for cancer systemic therapy will be verified by at least one oncology health professional (oncology pharmacist and/or oncology nurse) **BEFORE** the PPO is given to the patient, or transmitted to the community pharmacy, or sent to the hospital pharmacy for dispensing.
9. All oral systemic therapy doses for cancer to be dispensed and administered within the hospital will be prepared by pharmacy, including the crushing or splitting of tablets or capsules.
10. If the patient will use their own medications, dispensed from a community pharmacy, these agents will be verified by the hospital pharmacy before administration.
11. A nursing care plan *for oral systemic therapy* will be developed by an oncology nurse. The nursing care plan will be appropriate to the complexity of the patient and therapy. The nursing care plan will be used to direct the patient's care including determining the most appropriate nurse to administer the treatment (i.e. RNCC/RN/LPN).
12. If a patient currently receiving oral systemic therapy is admitted to the Emergency Department or to an inpatient bed in a health care facility, the oncologist will be notified and will determine if this systemic therapy will be continued. The order to continue this oral systemic therapy will be prescribed by or in direct consultation with an *Oncologist* (or *Community Specialist* or *Oncologist Delegate* in consultation with an *Oncologist*). The admitting or attending physician will not prescribe oral systemic therapy nor allow for the patient to continue use of their own medications without consultation.

DEFINITIONS

Biologic Agents (drugs):	Agents which work by suppressing malignant cell growth (cytostatic) and other mechanisms not directly targeted to cell death. These are more recent drug classes, including biochemical pathway targeted agents and monoclonal antibodies. Biologic agents are not currently known to be potentially teratogenic (fetal toxicity) or carcinogenic (cancer causing). Precautions while handling, preparing or administering these drugs by health care providers or other people than the patient are less stringent than those for cytotoxic agents.
Cancer Systemic Therapy:	All antineoplastic agents and other agents used to treat cancer, given *or self-administered* through oral or parenteral routes or other routes as specified in the *regimen*. Types include targeted agents, alkylating agents, antimetabolites, plant alkaloids and terpenoids, topoisomerase inhibitors, antitumour antibiotics, monoclonal antibodies, and biologics and related agents. Hormonal therapies are not included in the definition of systemic therapy for this *policy*[1].
Cancer Systemic Therapy Cycle:	A drug or combination of drugs, which is given to a patient over a fixed period of time or within a defined interval. Usually the cycle of cancer systemic therapy agent(s) will repeat at the start of the next time period. Most cancer systemic therapy regimens are given in repetitive cycles. Some cancer systemic therapy regimens include cycles with a different drug or combination of drugs planned for the next time period. The duration of a cycle is generally 2 to 8 weeks, and may be followed by the subsequent pre-determined cycle. For some oral systemic therapy, the drug(s) may be taken on a regular basis and the cycle may be the time period between planned visits or telephone calls for routine patient assessment.

[1] Jacobson JO, Polovich M, McNiff KK, et al. American Society of Clinical Oncology/Oncology Nursing Society chemotherapy administration safety standards. J Clin Oncol, 2009; 27: 5469-5475

Cancer Systemic Therapy Plan: *(also Cancer Chemotherapy Planned Course)*	The full number of cycles of cancer systemic therapy from beginning to end of the planned treatment. Alterations in the drugs (such as dose reductions or delays), to accommodate toxicities or events during the protocol, do not indicate the plan is ended, but a decision to change the cancer systemic therapy regimen indicates the end of one protocol planned course and the beginning of another.
Cancer Systemic Therapy Regimen:	The combination of systemic therapy drug(s), with predetermined relative or absolute doses, schedule of administration, and often with recommended supportive therapy (e.g. antiemetics, hydration).
Community Specialist:	A community specialist physician, with accredited prescribing privileges in the local treatment facility, designated to assess and diagnose cancer patients, and to initiate a cancer systemic therapy program within a defined scope of practice, as defined by the Nova Scotia Health Authority in consultation with *Cancer Care Nova Scotia.* For treatments given at the local treatment facility, this physician might be referred to as the 'most responsible physician'.
Compassionate Access Program (CAP)	*A pharmaceutical company-sponsored program offered to provide access to specific drugs, either through direct drug supply or partial reimbursement for patient copayment cost share. These programs vary from one company to the next. Some programs are dispensed through community pharmacies, others through a central supplier (not always a pharmacy).*
Continuing Care Prescription:	The continuation of a prescription by the community pharmacist beyond the number of refills ordered by the prescriber. This practice is allowed for certain medications used for chronic conditions and for which the patient has been on stable continuous therapy. Oral systemic therapy drugs for cancer DO NOT meet this definition and MAY NOT be continued on the authority of a community pharmacist beyond the order from an Oncologist (or other authorized prescriber)

Cytotoxic Agents (drugs)	Agents which work by killing malignant (and other) cells. These are the 'traditional' drug classes commonly referred to as 'chemotherapy'. Cytotoxic drugs are known or suspected to be potentially teratogenic (fetal toxicity) and likely carcinogenic (cancer causing), thus requiring precautions while handling, preparing or administering these drugs by health care providers or other people than the patient.
Independent Double Check:	A procedure in which two clinicians separately confirm (alone and apart from each other, then compare results) that the medication correctly reflects the original prescribed medication order, and the medication administration is in accordance with the drug monograph/reference and/or respective policy, before administering it to the patient.
Medical Record Number	A unique number for each patient, assigned by the health district. Often referred to as MRN or HUN (hospital unique number)
Nursing Care Plan	A written plan to direct nursing care of the patient receiving oral systemic therapy for cancer. The nursing care plan may be based upon a standardized care plan template and modified to meet the unique needs of each patient (when specific needs are not addressed in the standardized care plan). The nursing care plan will include *goals*, *specific nursing interventions*, and *evaluation of the expected outcomes*. The nursing care plan will act as a guide to delegating and assigning staff to specific patient care duties (e.g. medication administration, toxicity assessment, adherence management).
Oncologist:	A physician with specialized training in the management of cancer. Specialization may be formal or informal, and may be subcategorized within other specialty disciplines (e.g. gynecology, pediatrics, hematology, urology, thoracic surgery, etc.) or specific to cancer (e.g. medical oncology, radiation oncology). A physician designated as an *Oncologist* will be granted privileges for the full practice of cancer

	care within the scope of their specialty practice area and/or time limitation for cancer care. This definition includes Fellows in the appropriate subspecialty during the period of their fellowship (appropriate communication from the head of service will be available to managers, nurses and pharmacists to designate Oncologist privileges to Fellows, including start and stop dates).
Oncologist Delegate:	A physician designated as a Clinical Associate under the supervision of an oncologist; physician in training or, an Oncology Nurse Practitioner or Oncology Pharmacist under the supervision of an oncologist and practicing within the terms of a collaborative practice agreement with the relevant Oncologists and formally endorsed by the district health authority. All units will be informed of health care professionals granted Oncologist Delegate status, include start (and stop) dates. The Oncologist Delegate may perform the duties of an oncologist while under supervision, and may be included when Oncologist roles are mentioned in these policies and procedures.
Oncology Nurse:	A registered nurse who is experienced and skilled in the care of cancer patients and their families. Meets the practice standards and competencies for the Specialized Oncology Nurse, as determined by the Canadian Association of Nurses in Oncology (2006).
Oncology Pharmacist:	A pharmacist, trained and assigned to a clinical practice in the Cancer Care Program by the Pharmacy Department. An oncology pharmacist is certified through a training program offered in consultation with *Cancer Care Nova Scotia* or *an equivalent pediatric program*. The oncology pharmacist is designated by the district to have privileges to make changes to systemic therapy orders upon verbal instructions from the prescriber and within the stipulations of these policies.
Oral Systemic Therapy Dispensing Toolkit	An on-line document designed to provide detailed and operational information for community pharmacists

	who are dispensing oral systemic therapy for their cancer patient(s) and who are involved in providing advice to patients on treatment adherence and management of drug adverse effects
Oral Systemic Therapy Verification Checklist	A form for documentation of verification activities when oral systemic therapy is ordered. This form will be completed by the oncology nurse and/or oncology pharmacist in the location where oral systemic therapy prescriptions are ordered by oncologist(s) and, when complete, filed in the patient's health record
Order Clarification	Changes made to a written order by an oncology pharmacist or oncology nurse after the prescriber has signed an order are order clarifications. Clarifications may include dosage adjustment (due to patient factors or incorrect calculations), treatment date changes, addition/deletion of supportive medications or other clinical changes recommended during the order verification process, and verbally agreed to by the prescriber or delegate. Order clarifications may be written on the original order during the verification process. Clarifications are initialed by the person making the changes. Once the order is co-signed by the verifier(s), no further changes may be made to the original order
Personal Protective Equipment (PPE):	Equipment designated for personnel to wear during administration of cancer systemic therapy, and other activities where physical exposure to cytotoxic agents and/or waste is a risk. PPE may include a gown, gloves, goggles/face shield and/or a mask.
Registered Nurse with Chemotherapy Certification (RNCC):	The administration of cancer systemic therapy is a post entry-level competency and requires that a Registered Nurse complete a specified education program. The Registered Nurse with chemotherapy certification will hold a current certificate from the education program, and will be responsible for maintenance of certification, as defined by the Nova Scotia Health Authority (in collaboration with *Cancer*

	Care Nova Scotia).
Systemic Therapy Manual for Cancer Treatment:	A manual listing all drugs and treatment regimens typically used within Nova Scotia. The *Systemic Therapy Manual* is published by the Systemic Therapy Program of *Cancer Care Nova Scotia*.
Verification of Oral Systemic Therapy Calculations	A computer-generated form to document all dosing calculations have been verified by an oncology nurse and/or oncology pharmacist in the location where oral systemic therapy prescriptions are ordered by oncologist(s). When complete, the form is filed in the patient's health record.

RELATED DOCUMENTS:

Administration of Cancer Chemotherapy Policy (2011)*

Ordering Cancer Chemotherapy Policy (Draft)*

Education Standards for Adults Affected by Cancer (2011)

Systemic Therapy Manual for Cancer Treatment

Preparation of Cancer Chemotherapy Policy (2009)*

Provincial Cancer Drug Formulary (2011)*

A National Strategy for Chemotherapy Administration: Standards and Competencies for Cancer Chemotherapy Nursing Practices, Canadian Association of Nurses in Oncology, 2011 (www.cano-acio.ca/practice-standards)

* To be reformatted as standards

Appendix 1.

PRACTICE GUIDELINES FOR ORDERING ORAL SYSTEMIC THERAPY FOR CANCER

1. All patients will be fully assessed by an *Oncologist* before the first treatment with oral systemic therapy (alone or combined with parenteral systemic therapy).
2. The *Oncologist, Oncologist Delegate* or *Community Specialist* most responsible for cancer systemic therapy treatment (henceforth referred to as the prescriber) obtains an informed consent, as per institutional policy.
   - 2.1. The physician or delegate documents all informed consent discussions in the health record at each institution.
   - 2.2. If the patient is offered a new treatment protocol, obtain a new informed consent.
3. The prescriber will order oral systemic therapy using a *Pre-printed Order for Oral Systemic Therapy* (PPO) Form
   - 3.1. It is strongly recommended that the prescriber orders a **single cycle** of cancer systemic therapy on each PPO (i.e. NO REFILLS on the order).
     - 3.1.1. If the prescriber deems it necessary to order refills, the community pharmacist will place the order on HOLD until notified by the oncology team that the patient has been assessed and it is okay to go ahead with the refill.
   - 3.2. For drugs which are acquired through a compassionate access program (CAP), there may be additional approval forms required by the CAP sponsor. These approval forms may include multiple cycles as appropriate.
   - 3.3. The prescriber is to ensure that the correct PPO form is used for each patient, including correct regimen and correct diagnosis (where similar regimens exist for different diagnoses or stages)
   - 3.4. The prescriber is to ensure that the PPO is fully completed, appropriate to the specific regimen and cycle.
   - 3.5. If the prescriber intends to make a change to the pre-printed instructions on the PPO, the change is to be clearly documented on the PPO.
   - 3.6. For any PPO (or other prescription) to be given to the patient, a second complete copy is required for the institutional health record. The second copy may be a photocopy or a second printout from an electronic order set program.
4. The prescriber accepts or modifies the standard criteria on the PPO, selects appropriate optional criteria and completes the ordering information on each PPO:
   - 4.1. Patient Name and Medical Record Number (MRN); this may be done by a unit clerk or nurse, and may be the affixation of patient name labels and bar codes. The physician is responsible to ensure that the correct name label is affixed.
   - 4.2. Correct patient diagnosis and stage (where appropriate) are indicated. If there are optional diagnoses on the PPO, the correct diagnosis is checked off or handwritten on the PPO, as appropriate.

4.3. The number of cycles on a PPO is limited to one, and there is a stipulation for the dispensing pharmacist to not refill the order.

4.4. The patient weight and/or body surface area should be recorded on the PPO, as appropriate to the regimen

4.5. Actioning criteria may include bloodwork, lab & toxicity measurements. Actioning criteria must be met before treatment may begin.

4.6. Supportive care medication orders (e.g. antiemetics)

4.7. Instructions for patients on who to contact if there are adverse effects.

4.8. Intended starting date for self-administration

4.9. Specific instructions for dates when the oral drugs are to be taken and when the oral drugs are not to be taken (e.g. if drugs are taken for only the first 5 days in a 28 day cycle).

4.10. Signature of the prescriber, legible printed name, license registration number and date signed.

4.10.1. If the initial PPO (e.g. first cycle of treatment) was written by an *Oncologist Delegate* or any other physician or student training to be a physician or specialist, the PPO for filing on the health record or for filling and administration with the facility must be countersigned by the Oncologist (unless there is a collaborative practice agreement that allows for independent prescribing).

4.10.2. For subsequent cycles of treatment, the PPO may be signed by an *Oncologist Delegate* and may be given to the patient or actioned within the facility prior to countersignature of the *Oncologist* (as long as the order is consistent with the treatment plan and the actioning criteria are met)

4.11. If a patient is continuing treatment with an oral systemic therapy drug while in the hospital, the oncologist will be notified and will determine if this systemic therapy will be continued. If it is determined to continue treatment, the oncologist will reorder the drug and it will be verified. If any education is required, the oncology health professional will make appropriate arrangements.

5. Systemic therapy is to be ordered according to the stipulations of the PPO.

5.1. No systemic therapy drug may be added or substituted

5.2. A systemic therapy drug may be deleted from the PPO, with a clinical explanation written on the PPO. Strikethrough of the drug is not sufficient to indicate an omission- in addition, write the word “OMIT” next to the drug deleted.

5.3. The dose of any systemic therapy drug is not to be increased above the identified relative dose (e.g. mg/m^2 [Body Surface Area], AUC [Area Under the Curve]).

5.4. The dose of any systemic therapy drug may be decreased below the identified relative dose (e.g. mg/m^2) or the total dose may be decreased (e.g. removal of one or more days), with a clinical explanation written on the PPO.

5.4.1. The drug dose **may not be increased** on the PPO unless this is a clarification of a mathematic error or if the PPO has specific dose escalation criteria printed on the form.

5.5. Any decrease in dosing frequency (e.g. dose delay) is to be documented on the PPO with a clinical explanation.

5.6. Order clarifications to the original PPO may be made by the pharmacist and/or nurse performing the initial verification. Any changes must be documented clearly in the original PPO (with rationale for the change) and initialed by the verifying health professional, including notation of the verbal clarification from the prescriber.

5.6.1. Once the PPO has been signed by the authorized prescriber and the pharmacist and/or nurse(s) who initially verified the order, it may not be further altered.

Appendix 2.

PRACTICE GUIDELINES FOR PRE-TREATMENT ASSESSMENT AND PATIENT EDUCATION IN THE CANCER CLINIC

1. Prior to either providing the patient a prescription for oral systemic therapy (to be filled by their community pharmacy) or to the administration of oral systemic therapy within a health care facility, a **pre-treatment** assessment will be completed . Assessment is to be a shared responsibility among the *Oncologist*, *Oncologist Delegate*, *Community Specialist, Oncology Nurse*, *Registered Nurse with Chemotherapy Certification*, and *Oncology Pharmacist*.
   1.1. Each patient is to be assessed within 1 week prior to the start of each cycle.
   1.2. The timing of assessment may be longer in the case of combined oral systemic therapy and radiation therapy, where the delay for radiation may be longer than one week, or in other circumstances.
2. The **pre-treatment** assessment parameters will include but are not limited to:
   2.1. Height and current weight
   2.2. Vital signs
   2.3. History & Physical and toxicity assessment.
   2.4. History of allergies and other adverse drug reactions. Review procedure for hypersensitivity reactions (if appropriate)
   2.5. Performance status (ECOG)
   2.6. Lab values (CBC & differential, LFT's, creatinine, etc.)
   2.7. Best possible medication history
   2.8. Any potential drug-drug or drug-food interaction, factors which may increase likelihood of adverse drug reaction or factors which may affect patient adherence identified
   2.9. Assessment of the emotional, sexual, psychosocial and financial impact of the diagnosis and treatment on the patient and family. This will include the use of the Screening for Distress tool
      2.9.1. For financial and practical issues, the patient may be referred to a Cancer Patient Navigator, Medication Resources Specialist or social worker, as available.
      2.9.2. If necessary, referrals to other specialists may be given.
   2.10. Assessment of the understanding and learning needs of the patient/family, including potential difficulties with treatment adherence.
3. The **pre-treatment** assessment will be documented by the Oncology Health Professional
4. Patients will be re-assessed within cycles and between cycles, as needed to maintain patient safety, and as clinically indicated.

5. The Oncology Health Professional will inform/educate the patient/family in collaboration with other oncology health professionals, and provide the following materials, as needed:
    - ‘Oral Systemic Therapy: a Guide for Patients and Families’
    - “Cytotoxic Precautions at Home: a Guide for Patients and Families’
    - ‘Oral Systemic Therapy Patient Education: a Guide for Health Professionals’.

Educational interventions will be documented. The education plan must include (but not limited to):

5.1. Description of cancer systemic therapy, including drugs, specific protocol, scheduling and administration (see drug-specific Medication Info Sheet)

5.2. Review of potential side effects (immediate, early and delayed), management and self care practices to prevent/manage side effects, coping, psychosocial support.

5.3. Safe handling by health professionals relevant to each drug prescribed. (See drug-specific Oral Systemic Therapy Pharmacy Toolkit and/or the Systemic Therapy Manual for Cancer Treatment for more details)

Appendix 3.

PRACTICE GUIDELINES FOR VERIFICATION OF ORAL SYSTEMIC THERAPY ORDERS

1. Every PPO must be verified by one oncology health professional and is preferably verified by two oncology health professionals (excluding the prescriber).
   - 1.1. Whenever possible, the pharmacy verification and signature is to be performed by an *Oncology Pharmacist*.
   - 1.2. Nursing verification and signature is to be performed by an Oncology Nurse.
   - 1.3. If the PPO will be submitted to a central pharmacy designated by the sponsor of the compassionate access program, the order will be verified by BOTH an Oncology Nurse AND an Oncology Pharmacist within the facility before it is given to the patient.
     - 1.3.1. The Oncology Nurse and/or Oncology Pharmacist should arrange with the patient and/or family to be notified when the drug supply has been received from the central pharmacy and when the treatment began with the patient.
2. If the PPO will be administered within the health care facility, the order will be verified by both an Oncology Nurse (usually the RNCC) and the Oncology Pharmacist, similar to verification of other cancer therapy orders for administration within the facility.
3. Prior to giving the PPO to the patient, or transmitting the PPO to the community pharmacy, or administering the oral systemic treatment within the facility, the oncology health professional will:
   - 3.1. Check patient's name, patient identification number, and any allergy information included on the PPO.
   - 3.2. Verify that the consent has been obtained.
   - 3.3. Confirm the initial BSA (if used to calculate the dose) or recalculate the BSA (Standard BSA formula) if weight has changed by greater than10% from baseline.
   - 3.4. Recalculate or verify all doses, to confirm accuracy of calculations
   - 3.5. Verify that the correct drug(s) have been ordered consistent with the cycle and week(s) as defined by the regimen. Compare with last treatment order.
   - 3.6. Verify that the dose or dosage range is appropriate for the patient and treatment plan using an approved reference.
   - 3.7. Review lab results and other diagnostic test/procedures required by the regimen, and ensure these have also been reviewed by the physician.
     - 3.7.1. Sign or co-sign the verification section of the PPO when all criteria are satisfied.
   - 3.8. Verify supportive care medication(s) as ordered on the PPO or on a separate prescription.

3.9. Verify that any approval form or application for coverage has been submitted by the prescriber on behalf of this patient. If possible, determine when approval might be expected and plan the treatment start date accordingly.

3.9.1. If necessary, the verifying oncology health professional may contact or make a referral to a Cancer Patient Navigator, Medication Resource Specialist or social worker for assistance with coverage or funding assistance from insurance and/or compassionate drug access programs.

3.10. Check the drug name and dose, route, and dosing instructions.

3.11. Plan, in collaboration with the community pharmacist, a time with the patient and family for a follow up telephone call or visit within 48 to 72 hours of starting the cycle, to monitor adherence and any adverse effects experienced. The call may be made by either the oncology health professional or the community pharmacist.

3.12. If a second person is involved in an **independent verification** of the order, that person will co-sign the PPO once their own verification is completed.

3.13. Complete the 'Verification Checklist' for the patient's health record.

4. When completed, a copy of the PPO will be filed on the patient's health record.
5. If the prescriber has written for refills on the PPO, the oncology health professional will verify the order and perform any necessary follow up telephone call/toxicity checks with the patient prior to contacting the community pharmacist to authorize refill dispensing. This process will then be documented on the patient's health record.

Appendix 4.

PRACTICE GUIDELINES FOR DISPENSING ORAL SYSTEMIC THERAPY FOR CANCER IN THE COMMUNITY PHARMACY

1. If the PPO is filled at a community or hospital pharmacy, the pharmacist will follow the instructions printed on the PPO.
   - 1.1. The pharmacist will check for the signatures of both the prescriber and the oncology health professional who verified the order.
   - 1.2. If patient clinical data is available, the pharmacist will re-calculate the dose (where appropriate) and confirm that required clinical criteria (e.g. bloodwork or lab values) have been met before processing the prescription
     - 1.2.1. If there are any discrepancies noted, the pharmacist will contact the prescriber or contact oncology pharmacist to resolve the discrepancy(ies) prior to dispensing medications to the patient.
   - 1.3. The pharmacist should note in the pharmacy electronic record system that the order may NOT be refilled nor filled as a compassionate care prescription (i.e. on the authority of the dispensing pharmacist). A new PPO is required for each cycle of treatment (unless otherwise specified by the prescriber)
     - 1.3.1. If the prescriber has written for refills, the pharmacist will notify the oncology team contact member that the refill has been requested, then HOLD the refills for each cycle until notified by the oncology team member to proceed with dispensing the drug(s). This will be repeated for each cycle.
   - 1.4. Auxiliary labels are affixed to the prescription container as directed on the PPO. Each container will include an auxiliary label identifying the drug as “Chemotherapy” or “Cytotoxic”.
   - 1.5. Compliance packaging, such as prefilled blister packaging, may be indicated on the PPO, especially for more complicated oral systemic therapy regimens or drugs.
   - 1.6. If the tablets must be split or crushed, this must be done in a dedicated work space, away from other work spaces. Personal protective equipment (e.g. double gloves, mask, gown) must be worn, and the work space must be thoroughly cleaned immediately afterward.
     - 1.6.1. Tablets may be crushed using a crushing syringe (preferred) or inside double layers of sealed zip lock bags, to avoid powder in the work space air.
     - 1.6.2. Capsules may be opened inside a sealed zip lock bag
     - 1.6.3. Caution must be used when powder from the zip lock bags is poured into another container (e.g. oral syringe)
   - 1.7. To assist community pharmacists, drug-specific information is available in the “Oral Systemic Therapy Pharmacy Toolkit” for each drug on the CCNS website at: http://www.cancercare.ns.ca/en/home/healthprofessionals/stp/default.aspx.
2. The community pharmacist will conduct an initial assessment and patient counseling at each visit for prescription filling.

2.1. Assessment questions for community pharmacists to use when first dispensing the drug are outlined in the Pharmacy Practice Guide "Initial Assessment and Patient Counseling Visit", available on the CCNS website at: http://www.cancercare.ns.ca/en/home/healthprofessionals/SystemicTherapy/pharmacy.aspx.

2.2. Drug-specific questions are identified in the Pharmacy Toolkit for each drug at: http://www.cancercare.ns.ca/en/home/healthprofessionals/stp/default.aspx. Search for the drug monograph in the Systemic Therapy Manual and select the Pharmacy Toolkit button.

2.3. Drug-specific patient education materials are available in the Medication Info Sheets for each drug on the CCNS website at: http://www.cancercare.ns.ca/en/home/healthprofessionals/stp/default.aspx. Search for the drug monograph in the Systemic Therapy Manual and select the Med Info Sheet Toolkit button.

2.4. At each contact, the pharmacist should assess medication adherence, using the Morisky Medication Adherence Questionnaire to identify any real or potential problems. If an adherence problem is identified, consider the methods discussed in the Pharmacy Practice Guide "Medication Adherence Management", available on the CCNS website at: http://www.cancercare.ns.ca/en/home/healthprofessionals/SystemicTherapy/pharmacy.aspx

2.5. Patient monitoring and further counseling is outlined in the Practice Guidelines For Follow Up Monitoring Of Patients On Oral Systemic Therapy For Cancer **(**Appendix 6**)**.

3. The community pharmacist should plan for patient monitoring during treatment with oral systemic therapy drugs, including:

3.1. Reminder notes on the electronic patient profile for questions to ask at each return visit by the patient or family

3.2. Periodic telephone calls to the patient to monitor adherence and any adverse effects experienced (as guided by the Oral Systemic Therapy Pharmacy Toolkit(s) for the drug(s) dispensed. This should be coordinated with the primary oncology health professional(s).

4. Any potential or actual drug interaction, adverse drug reaction or problem with adherence identified by the community or hospital pharmacist will be reported back to the prescriber promptly and documented in the pharmacy electronic record system.

Appendix 5.

PRACTICE GUIDELINES FOR ADMINISTRATION OF ORAL SYSTEMIC THERAPY FOR CANCER IN HEALTH CARE FACILITIES

1. A nursing care plan for *oral systemic therapy* will be developed by an oncology nurse. The nursing care plan will be appropriate to the complexity of the patient and therapy. The nursing care plan will be used to direct the patient's care including determining the most appropriate nurse to administer the treatment (i.e. RNCC/RN/LPN).

   1.1. Registered Nurses will be responsible for the administration of oral systemic therapy in the instances of:

   - Administration of first cycles
   - Administration of doses if new toxicities are identified and/or doses require modification
   - Administration of clinical trials drugs
   - Administration of drugs to patients with unstable clinical status or unpredictable outcomes

2. Adjustments to care plans will be made by the registered nurse in accordance with the patient's tolerance, side effects/toxicities of treatment, as well as the environment and supports available. This includes changes to the most appropriate nurse to administer the treatment.
3. To administer oral systemic therapy, it is recommended that the nurse review the following resources: http://www.cancercare.ns.ca/en/home/healthprofessionals/SystemicTherapy/nursingtools/default.aspx
4. Oral systemic therapy drugs should not be self-administered in any health care facility

Appendix 6.

PRACTICE GUIDELINES FOR FOLLOW UP MONITORING OF PATIENTS ON ORAL SYSTEMIC THERAPY FOR CANCER

1. An oncology health professional and/or community pharmacist will contact the patient and family by telephone, as scheduled during the verification process, to monitor adherence and any adverse effects experienced. This contact may also be used to reinforce patient education on the drug(s) and the overall cancer therapy.
   - 1.1. Follow up monitoring may be a shared responsibility between the primary oncology health professional(s) and the community pharmacist.
   - 1.2. Members of the care team should negotiate in advance who will contact the patient at what times, to synchronize call backs and visits. The call back and visit schedule will be coordinated by the oral systemic therapy case manager (when available) or oncology nurse. Call backs may be performed by different team members at different times. Ongoing assessment, counseling, adherence management and adverse effect identification should also be included at each pharmacy visit for prescription fills.
   - 1.3. Call back questions for community pharmacists are outlined in the Pharmacy Practice Guides “First Follow-Up Call” and “Continuing Follow-Up Calls”, available on the CCNS website at: http://www.cancercare.ns.ca/en/home/healthprofessionals/SystemicTherapy/pharmacy.aspx.
   - 1.4. At each contact, the pharmacist or nurse should assess medication adherence, using the Morisky Medication Adherence Questionnaire to identify any real or potential problems. If an adherence problem is identified, consider the methods discussed in the Pharmacy Practice Guide “Medication Adherence Management”, available on the CCNS website at: http://www.cancercare.ns.ca/en/home/healthprofessionals/SystemicTherapy/pharmacy.aspx
   - 1.5. Drug-specific questions are identified in the Pharmacy Toolkit for each drug at: http://www.cancercare.ns.ca/en/home/healthprofessionals/stp/default.aspx. Search for the drug monograph in the Systemic Therapy Manual and select the Pharmacy Toolkit button.
   - 1.6. If an adverse drug reaction is identified during a call-back, the pharmacist or nurse may manage the problem according to the drug-specific Adverse Drug Reaction Management Guide, available on the CCNS website at: http://www.cancercare.ns.ca/en/home/healthprofessionals/stp/default.aspx. Search for the drug monograph in the Systemic Therapy Manual and select the ADR Guide Toolkit button.
   - 1.7. Any critical findings should be shared by the whole team to avoid miscommunication or duplication of efforts/services. These discussions should be documented by the community pharmacist, the home care provider(s) and the clinic-based cancer care team member, as appropriate.
   - 1.8. Any drug interaction, adverse drug reaction or problem with adherence identified in the follow up monitoring will be reported back to the prescriber promptly.

2. If there is any medication occurrence that involves oral systemic therapy, the health professional will report that occurrence in the local reporting system. This includes reporting occurrences from improper ordering, dispensing, or administration, regardless of where the incident occurred (e.g. in hospital or community setting).