Guideline 12-10 Version 2

A Quality Initiative of the Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Regional Models of Care for Systemic Treatment: Standards for the Organization and Delivery of Systemic Treatment

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An assessment conducted in December 2023 deferred review of Guideline 12-10 Version 2. This means that the document remains current until it is assessed again next year. The PEBC has a formal and standardized process to ensure the currency of each document (PEBC Assessment & Review Protocol)

Guideline 12-10 Version 2 is comprised of 3 sections. You can access the summary and full report here: https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/60086

Section 1: Model and Standards
Section 2: Systematic Review
Section 3: Internal and External Review

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Regional Models of Care for Systemic Treatment: Standards for the Organization and Delivery of Systemic Treatment

Section 1: Model and Standards

This is a quick reference guide and provides the guideline's model and standards. For the systematic review and the guideline development process, see the Full Report.

OBJECTIVES

This document presents a practical framework and standards to guide the delivery of systemic treatment Ontario-wide, that is, within cancer-centres, and in facilities beyond the confines of regional cancer centres. The primary goal is to provide safe, evidence-based systemic cancer treatment, maximizing the efficient use of resources and employing the principle of person-centered care with an emphasis on providing care as close to home as possible. Service provision, complexity of care, safety, accessibility, and quality care across all levels defined by the patient, organization, and system perspective, as well as appropriateness, transparency, and accountability have been considered. Both education and research are integral due to their important roles in safety and quality improvement.

DEVELOPMENT OF THIS DOCUMENT

This document was developed by Cancer Care Ontario's (CCO) Systemic Treatment Program (STP) in collaboration with the Program in Evidence-Based Care (PEBC). It builds on the original 2007 version of this document and introduces revised standards (presented herein as statements) for the delivery of services. The guidance presented here represents the consensus of the members of the Regional Models of Care for Systemic Treatment Guideline Development Group (RMCSTP GDG), informed by the available evidence and information. The content is derived from three sources as outlined below:

- The Regional Model of Care structure and levels of service provision for the Regional Model for Quality Systemic Treatment is retained from 2007 (see Figure 1-1 below). Although there have been many advancements in the safety and quality of systemic treatment, the model-of-care is still relevant and applicable in 2019.
- Some standards have been retained from the 2007 version of this document. Some modifications and additions have been made to reflect technology changes and linkages to the wider community of care providers. In addition, a key set of priority statements has been developed by CCO's STP using a modified Delphi consensus process. The standards provide guidance on policies and procedures, training and education for providers, patient education and patient care, computerized prescriber order entry (CPOE), pumps and equipment and labelling of drug products. A summary checklist has been developed that can be used to assess a program for concordance with this standards document and also guide centres that need to prioritize as they further develop their systemic therapy services (Appendix 1). For more information on the modified Delphi consensus methodology used by the STP, please see full guideline report.
- For additional elements related to 1) Safe delivery of systemic treatment, 2) Skills and maintaining competency for health care providers and 3) Roles of health care providers that were not addressed in the original guideline or in the new STP Standards, an updated evidence search was conducted by the PEBC. Additional sources of information relevant to these areas for the purpose of providing guidance are presented in the full guideline report.

TARGET POPULATION

All adult patients with cancer who are receiving systemic treatment.

INTENDED USERS

The standards in this guideline apply to the organization and structure of systemic treatment programs in Ontario. They apply to all institutions and programs delivering ambulatory systemic treatment within the province of Ontario.

REGIONAL MODEL OF CARE FOR SYSTEMIC TREATMENT

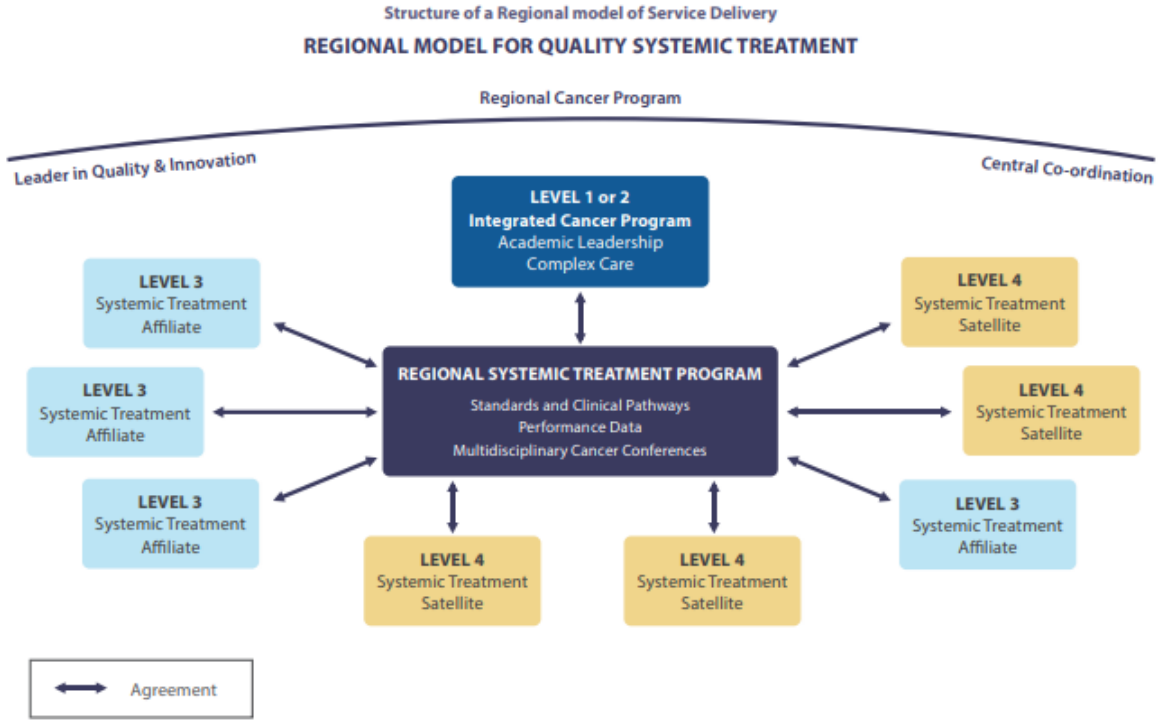
The planning and performance monitoring of cancer services is the responsibility of the Regional Cancer Programs (RCPs) that have been established by CCO. The RCP includes the Integrated Cancer Program (ICP), which is located at one host hospital, other hospitals and healthcare agencies, and health care providers involved in the delivery of cancer services. The RCP includes clinical and prevention programs associated with the various phases of care, each linked to a CCO provincial program. Through the Regional Vice President, the RCP advises CCO as to the appropriate distribution of services and is the primary mechanism through which existing and new CCO quality and access standards for cancer services are implemented and monitored

One component of each RCP is a Regional Systemic Treatment Program (RSTP), which is linked to the CCO provincial program for systemic treatment. The RSTP is comprised of physicians, pharmacists, nurses and administrative leads from the hospitals that organize the delivery of systemic treatment in the region. Their responsibility is to plan for and facilitate the implementation of the CCO standards outlined in this document. The medical oncologist identified as the lead for the region is a member of the RSTP and is expected to lead or participate in quality improvement initiatives with the RSTP.

The Regional Model for Quality Systemic Treatment (Figure 1-1) consists of a key set of fundamental elements and regional programs designed to implement, monitor, and evaluate quality indicators related to the delivery of safe, evidence-based, and person-centred care. The Model is an organizational framework for the delivery of systemic treatment within a RSTP. The main goal of the Model is to facilitate the provision of the appropriate care in the appropriate setting within the appropriate timeframe for all patients, regardless of where a patient receives systemic treatment. The Model is comprised of three integrated institutional structures each with a defined score of practice. The structures are ICPs, affiliate institutions, and satellite institutions. The ICPs are multidisciplinary organizations that provide complex cancer care. Affiliate institutions have their own systemic treatment programs, although they are linked through formal agreements with the RSTP. Satellite institutions have fewer oncology-related resources and have a formal linkage to the RSTP for support in delivering systemic treatment.

All regional partner institutions participate in the development of their RSTPs and collaboratively determine the appropriate configuration of their model, including the formal linkages that are required among institutions. The complexity of care delivered in each type of institution may vary; standards encompassing four levels of care (1-4) are recommended for the delivery of systemic treatment in Ontario. It is the level of complexity and the availability of services that differentiate one level from another. The RSTP determines the appropriate level of care for each institution. Levels are hierarchical, with the satellite responsibilities encompassed within the affiliate and ICP levels. As individual institutions expand or focus their services, the configuration of the model and designation of institutional levels may change over time, following consultation between the RSTP and the institution.

Figure 1-1. Regional Model for Quality Systemic Treatment



LEVELS OF FACILITIES

Each facility will have common expectations for the delivery of quality care. Some facilities may rely on regional networks to achieve access to services.

Level 4 (Satellite)
• Provides ambulatory facilities, and nursing, pharmacy, and physician support for the administration of intravenous and/or oral systemic treatment under the direction of an oncologist from an ICP or affiliate level 3 institution. • Access to onsite physician who could provide support for any urgent medical issues • Ideally, patients are stable without significant co-morbidities or organ dysfunction and have a low risk for hypersensitivity. First doses may be administered at the RCP to minimize risk. • Requires access to specialized services and providers with a formalized linkage to the RSTP.
Level 3 (Affiliate)
• Systemic treatments given under direct supervision of an on-site staff medical oncologist, hematologist, or gynecologic oncologist. • May participate in teaching, research and clinical trials • Must be part of a partnership for regionalized cancer services including but not limited to hepatobiliary, thoracic, gynecological oncology, and sarcoma • Must be part of a network for complex malignant hematology. May participate in shared care for leukemia and day 1 transfer programs for stem cell transplant.

Level 2 (ICP)

- Systemic treatments are given at an ICP with radiation treatment services and capable of providing most complex systemic treatments, including concurrent systemic treatment and radiation and/or radiolabelled conjugates.
- May participate in teaching, research, and clinical trials.
- Pathology consultation on site.
- On-site specialized diagnostic imaging including nuclear medicine, magnetic resonance imaging (MRI), and computerized tomography (CT).
- Must be part of a partnership for regionalized cancer services including but not limited to hepatobiliary, thoracic, gynecological oncology, and sarcoma and may host these services.
- Must be part of a network for complex malignant hematology. May be a full-service leukemia site or participate in shared care for leukemia and day 1 transfer programs for stem cell transplants

Level 1 (ICP)

- Systemic treatments are given at an ICP with radiation treatment services and capable of providing complex systemic treatments including concurrent systemic treatment and radiation and/or radiolabeled conjugates.
- Responsible for training future health professionals including medical students and residents in medical oncology/hematology.
- Research and clinical trial programs.
- Experimental Investigational New Drug (IND) Program (IND phase 1 and or 2 trials with highly developed clinical trials infrastructure, e.g., participate in the National Cancer Institute of Canada Clinical Trials Group [CCTG] IND program and Princess Margaret Hospital/National Institute of Health [PMH/NIH] new drug consortium)
- On site specialized diagnostic imaging including nuclear medicine, MRI, and CT.
- Host regionalized services including but not limited to hepatobiliary, thoracic, gynecological oncology, and sarcoma. Establish a partnership with other hospitals in the region to provide services.
- A full-service leukemia site and offer stem cell transplant services. Must participate in a network and offer shared care for leukemia and day 1 transfer programs for stem cell transplant with other sites in the region.

Responsibilities of the ICP

- Monitor wait times and other performance metrics
- Investigate and report incidents. Share learnings with the RSTP and CCO through the Incident Learning Committee at CCO.
- Ensure a mechanism to manage and report drug shortages in collaboration with other hospitals in the region.
- Establish or participate in RSTP/communities of practice for the region.

STANDARDS FOR SYSTEMIC TREATMENT

The goal of the RSTP is to ensure safe, standardized, evidence-based care across the regions. To ensure equitable access to systemic treatment, the standards described below delineate facility and program supports required to deliver systemic treatment, standards for health care providers and their roles, and standards for quality assurance and safety. Definitions for key terms are provided at the end of this section.

The standards are derived from three sources:

1. Some standards were retained from the original 2007 version guideline. Some modifications and additions have been made by the STP to reflect technology changes and linkages to the wider community of care providers. (indicated as *)
2. Some standards were developed by the STP modified Delphi consensus process (indicated as +). For more information on the STP modified Delphi consensus process methods, please see the full guideline report
3. Some standards were developed by the consensus of the RMCSTP GDG with the PEBC, informed by the available evidence and information summarized in section 2 in the full guideline report (indicated as **).

I. Facility and program supports required to deliver systemic treatment

The facilities should meet minimum requirements for space, service, and administrative supports in order to provide systemic treatment. There are many services that are necessary on site but also several that can be shared within a region to ensure sustainable care close to home.

Data Collection and Submission
• Collect data and monitor provincial indicators (including but not limited to wait times, volumes, unfunded systemic treatment regimens, patient reported outcomes) and other regional indicators as defined by the RCP.* • CCO Activity Level Reporting data book compliant.*
Systemic Treatment Suite Facilities
• Dedicated systemic treatment area adequate for volume of treatment visits with a quiet area for staff to perform checks.* For additional information, please see Appendix 1 #31. • Oxygen available to each systemic treatment infusion chair/stretcher.* • Appropriate equipment for delivery of systemic treatment including tubing, luer-lock syringes and, if needed, elastomeric devices. Consider the use of closed system transfer devices.* For additional information, please see Appendix 1 #14, #33, and #35. • Programmable pumps and the appropriate training/recertification for staff.+ For additional information, please see Appendix 1 #32. • Emergency resuscitation equipment (e.g. crash cart, other emergency supplies, drugs, oxygen and suction) in case of cardiorespiratory arrest or anaphylaxis.* • Supportive drugs and supplies for treatment of hypersensitivity/infusion reactions and extravasation. For additional information, please see Appendix 1 #24. • Additional Policies and Procedures are outlined in Appendix 1 #23-31.
Clinical Services and Clinic Facilities
• A process for patient identification using two patient identifiers such that patients are identified at entry into the system, and then at each step of the treatment process, by the different members of the healthcare team involved in their care+ . For additional information, please see Appendix 1 #23.

- Information system hardware and support to maintain a secure electronic systemic treatment order entry program and other electronic systems as indicated (e.g., electronic patient record).* For additional information, please see Appendix 1 #1.
- Process to review and check the new regimens in CPOE systems to ensure accuracy and a process for regular review of previously programmed regimens +. For additional information, please see Best Practice Recommendations for Regimen Development and Maintenance and Appendix 1 #1-2.
- Adherence to guidelines for CPOE and labelling.* For additional information, please see Computerized Prescriber Order Entry (CPOE) in the Outpatient Oncology Setting, Patient Safety Issues: Key Components of Chemotherapy Labelling, Systemic Treatment Computerized Prescriber Order Entry (ST CPOE: Best Practice Guideline for Intravenous and Oral Chemotherapy and Appendix 1 #3-5 .
- Ability to submit e-claims eligibility forms.*
- Potential for videoconference, remote web-based teaching as part of multidisciplinary cancer conference (MCC) or morbidity and mortality rounds.*For additional information, please see Appendix 1 #22 .
- Collection of near misses and incidents with reporting to National System for Incident Report (NSIR), a component of the Canadian Medication Incident Reporting and Prevention System, as required. For additional information, please see Appendix 1 #21 and #27 and Canadian Medication incident Reporting and Prevention System.
- Collect adverse events with reporting to Health Canada (or other mechanism) as required.

Patient Care

- All aspects of patient care should be clearly documented.+ For additional information, please see Appendix 1 #13.
- All treatment plans are recommended by an oncologist or hematologist and should be distributed to all providers involved in the patient's care. + For additional information, please see Appendix 1 #6 and #17.
- Contact information provided to patients so they may review symptoms between appointments with staff trained in triage and systemic treatment side effect management (e.g., Canadian Oncology Symptom Triage and Remote Support [COSTaRS])+. For additional information, please see Appendix 1 #40.
- Patients should be monitored for signs and symptoms of device-related issues and other serious adverse effects.+ For additional information, please see Appendix 1 #16 and #21.
- Patient assessments performed by the clinical team prior to systemic treatment including a Best Possible Medication History (BPMH) and document in the chart.+ For additional information, please see Appendix 1 #8.
- Collect patient-reported outcomes and have them available for the patient and clinician to review and plan interventions.

Patient Education

- Access to multidisciplinary teaching for patients on systemic treatment provided by nurses, physicians, and pharmacists. For additional information, please see Appendix 1 #11.
- Education should include diagnosis, intent of treatment, treatment plan, side effects, and how to manage intravenous and oral treatments in the home including recognizing pump malfunction, disposal, and safe handling. Approach to education should be standardized using validated teaching tools (e.g., Multinational Association for Supportive Care in Cancer (MASCC) Oral Agent Teaching Tool [MOATT]) and developed with patient and family advisors.** For additional information, please see Appendix 1 #9-10,#20, #33,#36,and #39.

Health Human Resources

- Adequate staff numbers to support independent double checks (correct dose, pump programming and other checks as required) for systemic treatment administration. This can occur virtually if required. ** For additional information please see Appendix 1 #12.*
- Assigning workload to nurses in the systemic treatment suite is best done with the Nursing Resource Intensity Weight (RIW) tool. **For Nursing RIW for specific regimens, refer to the "Administrative Information" section (section J) of the corresponding regimen monograph.
- The number of pharmacy technicians should be based on the Pharmacy RIW of the treatments prepared. **For Pharmacy RIW for specific regimens, refer to the "Administrative Information" section (section J) of the corresponding regimen monograph.
- Ideally there should be access to a minimum of two oncology pharmacists (can be remote or virtual). The number of pharmacists should be based on resource intensity weighting.

Administrative Support

- Physician and administrative leads identified with defined roles to manage strategic and operational issues through regional forums.*
- Incorporate patient and family advisors into leadership discussions and project management*.
- Nursing and pharmacy administrative leads identified with defined roles to manage strategic and operational issues through the RSTP.*
- Inventory management for systemic treatment drugs and a defined escalation procedure for drug shortages*.
- Clerical staff and clinic facilities to support patient scheduling, health record management, and clinic management including clinic and administrative supplies for systemic treatment suites and ambulatory clinic visits.*

Pharmacy

- Pharmacy must meet National Association of Pharmacy Regulatory Authorities (NAPRA) Model Standards for Pharmacy Compounding of Hazardous Sterile and Non-Sterile Preparations and Storage as mandated by the Ontario College of Pharmacists (OCP).+ For additional information, please see Appendix 1 #3 and #44
- Biological Safety Cabinet (class II) and external venting, with a preference for type B2. See CCO Safe Handing of Cytotoxics.*
- Adherence to the guidelines for ordering, mixing, and handling systemic treatment including but not limited to the following: Safe Handling of Cytotoxics; Safe Administration of Systemic Cancer Therapy: Introduction and General Methods; Safe Administration of Systemic Cancer Therapy Part 1: Safety During Chemotherapy Ordering, Transcribing, Dispensing, and Patient Identification; Safe Administration of Systemic Cancer Therapy Part 2: Administration of Chemotherapy and Management of Preventable Adverse Events

Clinical Trials

- Ensure patients have access to clinical trials on site or with a partner organization
- If trials are offered on site, the following should be available:
  - Specific clinical trial education for patients and health care providers.
  - Adequate space and designated clinical trial data storage.
  - Trials performed under direction of an oncologist with internists or general practitioners able to participate as co-investigators.

Medical Support Services
• Protocols to monitor and manage hypersensitivity/infusion reactions with onsite physician support while systemic treatment is being administered.* For additional information, please see Appendix 1 #15. • Emergency department onsite.* • Access to inpatient beds for oncology patients.* • Access to specialized diagnostic imaging (CT, ultrasound, nuclear medicine), laboratory tests, and pathology.* • Access to an intensive care unit.* • Ability to insert central venous catheters.* • Establish a network with the other systemic treatment delivery centres within the region and form a RSTP. Regular meetings including the pharmacy leads, nursing, administrative leadership, and the physicians/Regional Quality Lead. Advance the ICP agreement quality improvement projects, incident/near miss discussions through the Systemic Incident Learning (STIL) committee, and participation in the Regional Quality and Safety Network (ReQSN)*. • Establish connections with community pharmacies to enhance safe dispensing of take-home cancer drugs.* • Access to psychosocial oncology care (i.e., social worker, registered dietitian, physiotherapy, occupational therapy, speech language pathologist, and psychology and/or psychiatry).+ For additional information, please see Appendix 1 #19
Drug Access
• Provide a drug access navigator/facilitator to help patients navigate funding for drugs.+

II. Standards for health care providers and their roles

All health care providers within the systemic treatment program should be working collaboratively to care for patients and also contributing to the quality and development of the program within each centre and across the region. Although the oncologist/hematologist may have the primary role in discussing the treatment plan, several disciplines may have the role of prescribing and supervising systemic treatment. All health professionals should have a role in discussing a patient's goals of care and preferences for palliative care services.

Oncologist/Hematologist
• Determine and recommend the treatment plan, prescribe systemic treatment, manage disease status, and discuss patient management issues with the health care team. ** • May participate in on-site systemic treatment suite supervision and when supervising, must be available within 15 minutes during drug administration. * • May participate in academic responsibilities including teaching and research.* • Participate in administrative work as required by the centre*. • Mentor family physicians / internists*. • Undertake Continuing Medical Education (CME) as per Royal College of Physicians and Surgeons of Canada.* • Participate in multidisciplinary cancer conferences for their specialized disease sites* • Attend and discuss cases at regular mortality and morbidity rounds (MMRs) including all deaths on systemic treatment within 30 days of treatment.* • Participate as a representative on the RSTP committee, if requested or nominated. +

General Practitioners in Oncology

- Prescribe and supervise systemic treatment administration as defined by the oncologist/hematologist. ** For additional information, see Appendix 1 #7
- May participate in onsite systemic treatment suite supervision and when supervising, must be available within 15 minutes during drug administration.*
- Consult oncologist regarding patient management issues.*
- Assess and manage toxicity.*
- Complete initial orientation and annual CME.* For additional information, please see Appendix 1 #49.
- Mentoring should be available by a medical oncologist/hematologist. *
- Have knowledge of CCO regional systemic treatment guidelines and standards and regional policies and procedures.*
- Participate in MCCs. *
- Attend and discuss cases at regular MMRs including all deaths on systemic treatment within 30 days of treatment*.

Nurse Practitioners

- Prescribe and supervise patients on treatment as defined by the oncologist/ hematologist.* For additional information, see Appendix 1 #7.
- Manage well follow-up visits.*
- Participate in MCCs for their specialized disease sites.+
- Attend and discuss cases at regular MMRs including all deaths on systemic treatment within 30 days of treatment*.

Nurses

- All registered nurses (RNs), clinical nurse specialists (CNSs) and nurse practitioners (NPs) working primarily with patients with cancer and their families in the RCPs (Level 1-4 facilities) should obtain and maintain Canadian Nursing Association (CNA) certification as the nationally recognized nursing specialty credential by their 5th year of practice. All registered practical nurses (RPNs) should complete a relevant foundations course.+
    - RNs, CNSs and NPs should obtain CNA certification reflective of their main role and practice setting focus (e.g., Certified in Oncology Nursing [CON(C)], and/or Hospice Palliative Care [CHPCN(C)]).
    - RPNs should complete a foundations course reflective of their main role and practice setting in oncology or palliative care by an accredited Provincial College, Pallium Canada, Palliative Pain & Symptom Management Consultation Program of Southwestern Ontario, or relevant de Souza course.

  For additional information please see Appendix 1 #42 and #52
- Provide patient education related to planned systemic treatment, in collaboration with pharmacist and physicians*.
- Encouraged to participate in MCCs and MMRs *+.
- Provide symptom management education.+ For additional information please see Appendix 1 #9 and #20.
- Participate as a representative on the RSTP committee, if requested or nominated.

a) Clinical Nurse Specialist

• May manage selected patient populations independently or inter-dependently with oncologists*

b) Nurses involved in the management of outpatients within and between clinic visits

• Monitor and intervene for side effects and reactions, and provide supportive care. Receive standardized training for symptom assessment (e.g., COSTaRS).+ For additional information, please see Appendix 1 #40.

• Oriented to and practicing according to: CCO Telephone Practice Guidelines (expected date of publication – Summer 2019) and CCO Safe Handling of Cytotoxic Agents Standards*

c) Nurses involved in the administration of systemic treatment

• All RNs administering systemic parenteral therapy to patients affected by cancer, regardless of setting, should be certified which includes completion of standardized education through the recognized de Souza Provincially Standardized Chemotherapy and Biotherapy course or Oncology Nursing Society (ONS) Chemotherapy/Biotherapy Certificate equivalent course.+

• Receive central venous access device management education and selection, certification with annual updates.*

• Receive training and recertification on the use of infusion pumps.+ For additional information, please see Appendix 1 #18 and #32.

• Receive orientation to and practice according to: CCO Safe Handling of Cytotoxic Agents Standards, Safe Administration of Systemic Cancer Therapy Part 2: Administration of Chemotherapy and Management of Preventable Adverse Events

Pharmacists

- Review and verify systemic treatment orders and supervise the preparation and dispensing of systemic treatment.*
- ICP pharmacists provide support to allow consultation from other systemic treatment delivery centres in the region.*
- Manage or delegate the new drug funding program reimbursement process.*
- Provide patient education related to planned systemic treatment using a multi-disciplinary approach with nurses and physicians.
- Manage or delegate dispensing and documentation of clinical trials.
- Participate as a representative on the RSTP committee, if requested or nominated.+ All pharmacists working primarily with patients and families with cancer in the RCPs (level 1–3) should obtain certification from a recognized program such as the Board of Pharmacy Specialties (e.g., Board Certified Oncology Pharmacist [BCOP]) or the University of Toronto's Oncology Program for Pharmacists (Advanced Oncology program) by their 5th year of practice.
- All pharmacists working in satellite sites (level 4) should complete the University of Toronto's Oncology Program for pharmacists (Essentials of Oncology and Advanced Oncology Programs) by their 5th year of practice or have access to a pharmacist who has oncology certification. For additional information, please see Appendix 1 #43 and #46.
- Dedicated oncology pharmacists provide clinical services at levels 1-3 centres with access to a dedicated oncology pharmacist available at level 4 centres.*

Pharmacy Technician

- Prepare systemic treatment under supervision of a pharmacist or compounding supervisor.*
- Receive specialized training in the preparation of systemic treatment doses.* For additional information, please see Appendix 1 #43, #44 and #48.
- Dispense and document for clinical trials.*
- Receive training or certification program for staff involved in the handing of cytotoxic agents with policy on re-training. This may be done at or in collaboration with an ICP or affiliate institution and in compliance with NAPRA Model Standards for Sterile Preparation of Hazardous Drugs. *

III. **Standards for Quality Assurance and Safety**

- Ensure that there is sufficient patient volume at the location to maintain competency and skills of professional healthcare providers to address the acuity and complexity of the treatment modalities and/or to provide cost-effective use of resources and drugs (e.g., shared care program or collaboration with another program).*
- Facilities that have staff that see a lower volume of cancer patients should have an education and training plan to ensure competency of nurses, pharmacists and pharmacy technicians.**
- The number of patients that can be treated will be determined by the complexity of treatment regimens.*
- Staffing resources must be sufficient to provide safe quality care at all times, including during vacation, illness, etc.*
- Cancer care includes the management of symptoms and complications of therapy and oncological emergencies.*
- Follow regulatory guidelines and standards for the safe handling and disposal of hazardous drugs including personal protective equipment and training for staff who are handling systemic treatment or waste.* For additional information, please see Appendix 1 #25.
- Centres have policies and educational programs available for all staff involved in systemic treatment including storage, transport, spill management, preparation, administration, and waste disposal.* For additional information, please see Appendix 1 #26,#28-30, #34-39, #41, and #45.
- Track of incidents and near misses with a review and system improvement process. Share learnings within the RSTP and at provincial forums (e.g., ReQSN, STIL Committee). Consider reporting to provincial and national databases (e.g., NSIR). For additional information, please see Appendix 1 #27.
- Participate in MCCs as per CCO standards.* For additional information, please see Appendix 1 #22.
- Track and actively manage quality indicators including volume of patients treated, wait times, MCC attendance, proportion of non-evidence-informed regimens, patient experience measures, and adherence to guidelines.*

DEFINITIONS

Advanced Practice Nurse – The Advanced Practice Nurse has a Master's level education (MN, MSc or equivalent) education. Ideally, the graduate program would be focused in oncology nursing, likely with a particular emphasis on a subpopulation or area within cancer control such as prevention, screening, and counselling or a theme within cancer care such as coping, psychosocial care, and counselling. Theoretical knowledge in nursing and other sciences grounds the nurse in the advanced provision of care to patients, their families, and the communities within which cancer care is given. Additional certification as a Registered Nurse (Extended Class), or other levels, may be acquired either within the Graduate Program or through a post-graduate course and certification. The domains of the Advanced Practice Nurse include the following:

- advanced clinical practice
- education
- research
- scholarly/professional leadership
- organizational leadership [1]

Certification in Systemic Treatment Administration (*Certified in Systemic treatment*) – No registered nurse in Ontario should administer intravenous systemic treatment until and unless she/he has received additional education and has demonstrated competency in the delivery of these systemic treatment agents. This requirement is specific to the delivery of systemic treatment and is not to be confused with the national examination process for Certification as an Oncology Nurse through the Canadian Nurses Association.

Complexity – Determined by the preparation and administration requirements for systemic treatment, risk of immediate grade 3/4 toxicities, medical condition of the patient, or use of investigational agents or new agents just approved for which there are little long-term toxicity data.

ICP: Integrated Cancer Program – A multidisciplinary in and out-patient cancer program including medical, radiation, and surgical oncology. The ICP also provides research, education and organizational leadership for the RCP.

Institutional Facilities – Hospitals, clinics, or offices as outlined in the facility requirements element.

Local Health Integration Networks (LHINs) – The purpose of these regional health districts is to build a system that is focused on the needs of the local community and provides integrated, safe, and high-quality services to meet those needs.

Regional Cancer Program (RCP) – Links together cancer providers and organizations across the spectrum of cancer care.

Regional Systemic Treatment Program (RSTP) - An agreed-upon relationship among satellites, affiliates, and ICPs.

Medical Oncologist – A physician with subspecialty training in the administration of systemic treatment recognized by the Royal College of Physicians and Surgeons of Canada, including medical oncologists, hematologists and gynecologic oncologists.

Psychosocial Oncology (PSO) - A specialty in cancer care concerned with understanding and treating the social, psychological, emotional, spiritual, quality-of-life, and functional aspects of cancer, from prevention through bereavement. It is a whole-person approach to cancer care that addresses a range of human needs that can improve quality of life for people affected by cancer. Specialized PSO disciplines include social work, psychiatry, psychology, registered dietitians, physical therapy, occupational therapy, and spiritual care.

Quality Indicator – A specific, measurable, attainable, relevant, time-framed outcome from the patient, organizational, or system perspective to assess performance.

Specialized Oncology Nurse – A nurse who has a combination of expanded education focused on cancer care and experience such as two years in a setting where the primary focus is cancer care delivery. The Specialized Oncology Nurse might acquire specialty education through a variety of ways, such as enrolment in an undergraduate nursing program, completion of an Oncology Certificate Program, distance specialty education (e.g., Adult and Pediatric Oncology Nursing), or registration in and completion of the certification exam offered by the Canadian Nurses Association and attainment of the distinction Certified in Oncology Nursing Canada CON(C).

The Specialized Oncology Nurse works in a specialized inpatient setting such as an oncology unit or bone marrow transplant unit, an ambulatory setting focused on the delivery of cancer care; a screening program, or a supportive care setting or community setting offering palliative care. There are many environments where the enhanced specialty knowledge and skill of the nurse can be utilized to manage symptoms and side effects of treatment, counsel patients in coping strategies, teach self-care behaviours, and monitor the responses to treatment and interventions. [1]

Systemic Treatment – Any oral or parenteral anticancer agent including but not limited to hormonal, biological, immunotherapeutic, or chemotherapeutic, agents.

Appendix 1: STP Standards *(See the full report for the methods used by the STP to develop these standards)*

The standards have been prioritized into the following categories through a modified Delphi process as described in the methodology:

Very high priority: must be in place immediately at time of evaluation. Systemic treatment should be halted until criteria are met, or interim strategy must be developed in partnership with facility and CCO.

- For immediate evaluation
- All standards in this category have the potential to significantly impact patient and provider safety
- Facilities must re-confirm that these standards are met on an ongoing basis and new facilities must confirm that these are in place prior to starting a new program

High priority: must be in place within 6 months of evaluation.

- For immediate evaluation
- Standards in this category have potential to impact patient safety/quality of care
- Facilities must re-confirm that these standards are met on an ongoing basis and new facilities must confirm that these are in place within 6 months of starting a new program

Medium priority: strongly recommended that standards/guideline statements be implemented as soon as possible. Timelines for evaluation are to be determined. However, facilities must have an action plan in place to state when implementation will be complete.

Please note that in circumstances where individuals with appropriate training are not available, controlled acts can be delegated. There must be an individual willing to accept the delegation and they must receive appropriate training and evaluation of their skills. There must also be an individual willing and able to supervise the delegate who has competence in performing the delegated task. Please click on the following links for more information - The OCP Policy and the FHRCO Policy.

Computerized Physician Order Entry (CPOE) Very High 1.Computerized Physician Order Entry (CPOE) systems should be used in the inpatient and outpatient systemic treatment delivery setting to decrease systemic treatment-related medication errors. Where CPOE is not available, standardized, regimen-level pre-printed forms should be used to improve consistency and readability and to avoid prescription error. Handwritten orders are not acceptable. [2] High 2.Implementation, oversight, monitoring and sustainability of CPOE systems should be done through multi-disciplinary teams. These teams should conduct regimen review, quality evaluation, and risk assessment. [3,4]
Labelling of Drug Products Very High 3.In addition to regulatory requirements, including the National Association of Pharmacy Regulatory Authorities (NAPRA) Standards, labels affixed to final drug products should contain the following information (EBS #12-11) [5]:

a) Two unique identifiers consistent with the patient record
b) Drug name
c) Amount of drug per container
d) In those circumstances in which overfill is required, the overfill volume (in mL) should be printed on the label separately from the dose information
e) If a product contains two or more active ingredients, they should all appear in the generic name field
f) The route of administration
g) The volume of fluid to be administered
h) Duration of infusion
i) Rate of administration expressed in mL/hour or as a duration in minutes in the case of medications given by intravenous (IV) push
j) Number of medication containers, when the drug is to be administered sequentially (e.g., bag 1 of 3)
k) Relevant auxiliary information should be included on auxiliary labels. Examples of auxiliary labels include "AVOID EXTRAVASATION" and "FOR INTRAVENOUS USE ONLY – FATAL IF GIVEN BY OTHER ROUTES"
l) Use the complete generic drug name rather than an abbreviated version
m) Use lower case or mixed case lettering for generic drug names as appropriate. Use current TALL man lettering to differentiate between look-alike/sound-alike drug names [6].

4.When drug name, strength, dosage form, and dosage units appear together, provide a space between them [5].

Very High
5.Follow Institute for Safe Medication Practices (ISMP) guidelines for abbreviations and dose expressions and the United States Pharmacopeia (USP) standards for dosage units and standard units for weight and measures. Alternative abbreviations and dose expressions should be avoided [5,7]

Patient Care
Very High
6.All treatment plans are recommended by an oncologist or hematologist [8].

7. Satellite sites (Level 4) have access to oncologists and hematologists from level 1, 2 or 3 hospitals in addition to other healthcare professionals such as General Practitioners in Oncology (GPOs) and nurse practitioners who are required to manage disease status, and to discuss patient management issues with the healthcare team. [8]

8.A patient assessment prior to systemic treatment administration is the responsibility of the clinical team [2]. The assessment for systemic treatment administration should include, but may not be limited to, the following:
a) Baseline observations, specific to the protocol
b) Patient history (e.g., comorbidities)
c) Best Possible Medication History (BPMH) including alternative therapies
d) Presence of allergies or other hypersensitivity reactions
e) Patient performance status and physical findings that may impact on the treatment process
f) Patient weight, height, and body surface area
g) Laboratory results
h) Response to previous treatment and previous toxicities that may impact on treatment
i) Compliance with home pre-medication treatment
j) Assessment for and maintenance of access devices required for administration

k) Presence of psycho-social concerns

9.Patients who are going to receive or who are already receiving systemic treatment should be provided with information (ideally oral and written) that enables them to comprehend the intended aims, plans, effects, and outcomes of the proposed or ongoing treatment [2]. Information should cover the following, at a minimum:
a) Diagnosis
b) Intent of Treatment
c) Treatment plan (e.g., drugs, schedule, follow-up)
d) Short and long-term effects, management of side effects

10.Patients should be educated about the risk of vesicant extravasation that can occur during administration and actions that they can take in managing their care after administration, or after extravasation has been identified. [9]

11.Provide patient education related to planned systemic treatment using a multi-disciplinary approach which may include nurses, physicians and pharmacists [8].

12.Systemic treatment preparation and delivery should include the following [2]:
a) Verification of the systemic treatment order and preparation.
b) Verifying a systemic treatment order should include a systematic check of all the components of the systemic treatment order and its preparation and dispensing.
c) Verification and independent double checking processes should be regulated by oncology-specific policies and procedures and training and certification programs to maintain accuracy and quality.
d) Independent double checking at various points of the systemic treatment preparation process including the order and preparation of product.
e) Independent double checking during the systemic treatment preparation process is completed by a second pharmacist, by a pharmacy technician (Verification procedure where one technician checks the order-filling accuracy of another), or by another healthcare professional with appropriate knowledge, skills and training to perform this function.

13.Clearly document:
•Systemic treatment administration and verification including independent double checks to maintain accuracy and quality and relevant safety issues (e.g., allergies, reactions) as per oncology-specific policies, procedures, training and certification programs [e.g., Provincial Standardized Chemotherapy and Biotherapy Course (PSCB) by the de Souza Institute, Canadian Association of Pharmacy in Oncology (CAPhO) Standards of Practice for Oncology Pharmacy in Canada]. Independent double checking may still be required when CPOE is in place because of the possibility of major variations or deviations in protocol, protocols that are new or not yet built into the CPOE program, or complex calculations involved in systemic treatment preparation (EBS #12-12-1).
•A systemic treatment plan that is readily available (in the patient's medical record). The plan should reference all treatment modalities (e.g., surgery, radiation therapy) as well as involvement with other healthcare professionals such as nursing and allied healthcare staff. The plan should be available to everyone in the circle of care.
•Any change in treatment (i.e., a new protocol is initiated or a medication dose is changed)
•All patient education
•Assessment of toxicities and adverse reactions [2].

14.Luer-Lock connectors and needleless administration systems should be employed in the administration of intravenous medications[10].

15.Drugs with a high risk of hypersensitivity/infusion reaction require a physician to be available during administration. [9]

16.Healthcare professionals and where applicable patients and/or caregivers should monitor for early signs and symptoms of:
•Access device-related partial or total occlusion
•Local and systemic catheter-related infections on insertion, during infusion and maintenance of the access device
•Venous thrombosis[9]

High
17.A copy of the treatment plan should be distributed to all facilities involved in the patient's care as well as to the patient's primary healthcare provider [2].

18.Treatment factors are the primary consideration in the selection of an access device, as they may dictate the need for a particular device or class of devices. Clinical factors, patient informed decision-making, resource concerns and catheter-related complications may further direct or guide selection. [9]

19.Patients should have access to supportive care services to address specific patient needs (e.g., psycho-social support) [8].

Medium
20.Education on self-management should be encouraged for persons receiving systemic treatment (e.g., on prevention, management and reporting of side effects and adverse events). [9]

21.Surveillance programs should be in place to monitor for device-related complications and conduct systematic error analyses on incident events. [9]

22.There should be the potential for video conferencing, remote web-based teaching, as part of multi-disciplinary case conferences (MCC) at each site [8].

Policies and Procedures
Very High
23.There should be a process for patient identification (using two patient identifiers) such that patients are identified at entry in the system, and then at each step of the treatment process, by the different members of the healthcare team involved in their care [2].

24.There should be a complete description of precautions that need to be taken when starting and when monitoring intravenous treatment including standardized procedures for managing hypersensitivity/infusion reactions, allergic reactions, and extravasation [9].

25.Follow regulatory standards for the safe handling of hazardous drugs (E.g., EBS #16-3), including drug receiving, storage, preparation, packaging, transportation administration and disposal as well as personal protection equipment, spill management, waste disposal (used equipment and unused medication) and hand decontamination. [10]

26.There should be policies and procedures in place to address accidental worker exposure to hazardous drugs [10].

27.There should be a policy to track incidents electronically and to review all critical medication events in a multidisciplinary approach [8].

High
28.There should be policies for all major processes involved in prescribing, dispensing, handling, and administering systemic treatment (i.e., how systemic treatment is prescribed, the use of standardized protocols, a process for order verification and independent double-checking; preparation and dispensing; pre-treatment assessment, catheter selection, maintenance and removal; monitoring; patient education and discharge documentation). [9]

29.There should be policies to address prevention, early detection, and the management of complications related to the catheter/device use and to the drug administered. [9]

30.All sites should have a procedure to continue delivery of systemic treatment during downtime. [11]

Medium
31.The systemic treatment area should accommodate the volume of treatment visits, which includes:
•Adequate space to accommodate patients and equipment in an appropriate environment which meets infection control standards.
•Adequate slots to minimize day of treatment wait times.
•Adequate bookings to ensure access within wait times. [8]

Pumps and Equipment
Very High
32.For elastomeric or volumetric pumps, ensure the following are in place:
a) User-specific education materials for pharmacy staff, nurses and patients
b) Instructions on how to identify a pump failure, and appropriate interventions in case of failure
c) Collaboration with the vendors to improve educational materials.
d) Administration of systemic treatment via volumetric or elastomeric pumps should only be performed by registered nurses trained and certified in their use
e) The number of different brands or models of pumps in one institution should be minimized to reduce the risk for incorrect use or programming
f) Pumps in a hospital should all be programmed using the same units that are included in the labeling of systemic treatment. Standardize pump technology within an institution or at least use pumps with a common format. The use of pumps programmed in mL/hour is strongly recommended over the use of pumps programmed in mL/24 hour. Refer to Cancer Care Ontario (CCO) guidelines (EBS #12-11) for appropriate labeling of systemic treatment products[5]
g) Pump programming should be independently double checked by two registered nurses with the appropriate training for the particular brand and model of volumetric pump
h) Prior to systemic treatment administration, a final check of patient and drug information should be performed independently by two registered nurses with appropriate training and skills i) Administer continuous systemic treatment via a central venous access device
j) Only Luer-Lock fittings should be used with administration sets
k) Devices should be checked for leakage or contamination prior to use and throughout the infusion period. If the infusion is occurring at home, the patient should be educated on periodically performing this check
l) Where patients are receiving the infusion at home, they must be supplied with a spill kit and be educated on how to recognize and manage a spill
m) Unused or remaining systemic treatment drug and its devices should be returned to the systemic treatment suite or community/home care provider for disposal

n) Hazardous precautions (i.e., prevention of contact with systemic treatment drugs or bodily fluids of patients who received such drugs) should be taken according to the recommendations in EBS #16-3[10]

33.Patients who are going to be sent home with an ambulatory pump (e.g., volumetric or elastomeric) should understand who to contact for issues/concerns and before leaving the site, should be observed to ensure:
•Volumetric: The pump is functioning correctly
•Elastomeric: The site is intact and the patient has information about how to recognize when the pump is not functioning properly.
•There are no allergic or hypersensitivity/infusion reactions after the pump is connected. [9]

Safe Handling

Very High

34.Hazardous drugs should be handled in a manner that avoids skin contact or contact with mucous membranes, the liberation of aerosols or powdered medicine into the air, and cross-contamination with other medicines[10].

35.Spiking of bags and priming of tubing should occur before the addition of the hazardous drug if a closed system cannot be established or unless the clinical protocol requires otherwise. The use of a closed system transfer device may reduce contamination. Attaching the tubing to the spike port is acceptable after the hazardous drug has been added. If priming occurs outside of a closed system environment, prime IV tubing with a fluid that is compatible to but does not contain the systemic treatment medication or by using the backflow method.[10].

36.Patients/caregivers involved in administering hazardous drugs in the home should be provided with a process for the appropriate disposal of hazardous waste, including left-over drugs. A spill kit should be readily available in the home in case of accidental spills. There should be a clear process in place to address the disposal of hazardous waste from patients in their homes, in compliance with municipal or local hazardous waste rules. [10]

37.All staff should be fully informed of the potential reproductive risks of hazardous drugs. [10]

38.A list of hazardous drugs should be maintained at the site and updated on a regular basis. [10]

Very High

39.Patients should be informed of, and be provided with, written instructions for the safe handling of hazardous drugs in the home as well as contact information should they require any assistance. [10]

Training and Education for Providers

Very High

40.Educational programs and skills development should be available to establish competence in caring for persons receiving systemic treatment and in operating any equipment required to provide this care. Elements could include but are not limited to the following:
•Preventing, managing and reporting of side effects and adverse events using standardized tools, where available
•Healthcare professionals working in systemic treatment administration settings should receive training related to care of, and identification of complications including extravasation, phlebitis, infiltration, flare reaction, hypersensitivity/infusion and allergic reactions which are monitored in collaboration with the patient. [9]

41.Training and/or certification programs should be available for staff involved in the handling of hazardous agents and have a policy on re-training. This may be done at or in collaboration with an Integrated Cancer Program (ICP), Affiliate or satellite institution. [8]

42.All registered nurses administering systemic parenteral therapy to patients with cancer, regardless of setting, should maintain certification which includes the completion of standardized education through the recognized de Souza Cancer Chemotherapy Maintenance Course (CCMC) or ONS Chemotherapy/Biotherapy Renewal Course. [8]

43.Only pharmacists or pharmacy technicians with appropriate training and assessment will compound chemotherapy, immunotherapy and targeted therapy. [8]

44.All pharmacy technicians preparing systemic parenteral therapy, regardless of setting, should receive specialized training and maintain certification in the preparation of systemic treatment doses. This may be done at or in collaboration with an ICP, Affiliate or satellite institution. Training programs should incorporate the NAPRA Model Standards for Pharmacy Compounding of Hazardous Sterile Preparations. [8]

45.Educational programs and skills development should be available for all staff involved in systemic treatment including receiving, storage, transport, spill management, environmental cleaning, preparation, administration, and waste disposal. [8]

High
46.Dedicated oncology pharmacists should provide clinical services at level 1, 2, and 3 hospitals. Pharmacists who rotate through oncology should have a minimum exposure to maintain competence. [8]

47.There should be sufficient patient volume or a process at the site to maintain competency and skills of professional providers to address the acuity and complexity of the treatment modalities and/or to provide cost-effective use of resources and drugs (e.g., shared care program or collaboration with another program). [8]

Medium
48.All pharmacy technicians handling hazardous agents should complete training that may include continuing education programs or courses (CAPhO Fundamentals Day for Pharmacy Technician), oncology pharmacy review courses (e.g., American Society of Health-System Pharmacists (ASHP) Oncology Review) or preceptorship programs. [8]

49.Family physicians/internists/physician assistants participating in supervising oncology care in partnership with an oncologist should participate in education programs related to the management of patients receiving systemic treatment. [8]

50.All registered nurses (RNs), clinical nurse specialists (CNSs) and nurse practitioners (NPs) working primarily with patients and families with cancer in the Regional Cancer Programs (RCPs) (Level 1-4 facilities) should obtain and maintain Canadian Nursing Association (CNA) certification as the nationally recognized nursing specialty credential by their 5th year of practice. All registered practical nurses (RPNs) should complete a relevant foundations course.
a.RN's, CNSs and NPs should obtain CNA certification reflective of their main role and practice setting focus (E.g., Certified in Oncology Nursing (CON(C)), and/or Hospice Palliative Care (CHPCN(C)))

b.RPN’s should complete a foundations course reflective of their main role and practice setting in Oncology or Palliative Care by an accredited Provincial College, Pallium Canada, Palliative Pain & Symptom Management Consultation Program of Southwestern Ontario or de Souza Institute course

51.All registered nurses administering systemic parenteral therapy to patients affected by cancer, regardless of setting, should be certified which includes completion of standardized education through the recognized de Souza Provincially Standardized Chemotherapy and Biotherapy course or Oncology Nursing Society (ONS) Chemotherapy/Biotherapy Certificate equivalent course.

52.Nurses working in practice settings that less frequently encounter patients and families affected by cancer should have access to CNA certified nurses to support their care OR complete a foundations course in Oncology/Palliative care, OR obtain and maintain CNA certification CON(C) or CHPCN(C).

53.All pharmacists working primarily with patients and families with cancer in the Regional Cancer Programs (Level 1 – 3) should obtain certification from a recognized program such as the Board of Pharmacy Specialties (e.g., Board Certified Oncology Pharmacist (BCOP)) or the University of Toronto’s Oncology Program for Pharmacists (Advanced Oncology program) by their 5th year of practice.

54.All pharmacists working in satellite sites (Level 4) should complete the University of Toronto’s Oncology Program for Pharmacists (Essentials of Oncology and Advanced Oncology programs by their 5th year of practice) OR have access to a pharmacist who has oncology certification.

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