Chemotherapy, Oral and Parenteral

Scope: Unless otherwise stated, these items pertain to cytotoxic, antineoplastic agents administered by any route (i.e., oral, IM, subcutaneous, IV, intrathecal, intraventricular, intraperitoneal, intra-arterial, intravesicular, intrapleural, implantable) and used to treat an oncologic diagnosis. Chemotherapy agents prescribed for a non-oncologic indication are **EXCLUDED** (although the same safety strategies described in these assessment items are fully applicable to all cytotoxic, antineoplastic agents regardless of the indication).

Demographic Questions

1) Is your facility a National Cancer Institute (NCI)-designated or Commission on Cancer (CoC)-accredited cancer center?

- ☐ Yes
- ☐ No

2) What is the average number of chemotherapy doses administered per month at your facility?

- ☐ Less than 50
- ☐ 50 to 100
- ☐ 101 to 250
- ☐ 251 to 1,000
- ☐ 1,001 to 3,000
- ☐ More than 3,000

3) Does your facility participate in CLINICAL TRIALS involving chemotherapy in which INVESTIGATIONAL DRUGS are used?

- ☐ Yes
- ☐ No

4) Who is permitted to prescribe chemotherapy for patients in your facility without final verification by another prescriber? (select all that apply)

- ☐ Board certified oncologists
- ☐ Board certified hematologists
- ☐ Oncology fellows
- ☐ Oncology residents
- ☐ Urologists (regional treatment of urinary tract cancers)
- ☐ Interventional radiologists (intra-arterial chemotherapy)
- ☐ Surgical oncologists
- ☐ Advanced practice oncology nurse(s)
- ☐ Oncology physician assistant(s)
- ☐ Other: (please specify) _____

5) Who prepares (i.e., compounds or mixes) chemotherapy for patients in your facility? (select all that apply)

- ☐ Pharmacists
- ☐ Pharmacy technicians
- ☐ Physicians
- ☐ Registered nurses
- ☐ Advanced practice nurses
- ☐ Outsourced through compounding pharmacy
- ☐ Other: (please specify) _____

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Self-Assessment Items

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C	This item has been partially implemented for some or all patients, orders, drugs, or staff.
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		A	B	C	D	E
General Items						
Protocols, Guidelines, and Order Sets						
1	Standard order sets have been established for at least 90% of all chemotherapy protocols that are used in the facility; **and** these standard order sets are used to prescribe the chemotherapy.					
2	The type of metric weight used for dosing chemotherapy (i.e., actual weight, ideal weight, or adjusted weight) is predefined in the order set or identified by the prescriber.					
3	A literature/compendia reference and patient-specific monitoring plan are provided when prescribing chemotherapy that is outside of generally established guidelines.					
Prescribing						
4	All chemotherapy (e.g., initial **CYCLE**, subsequent **CYCLES**, changes/modifications) used to treat an oncologic diagnosis is ordered (or verified prior to initiating the order) by an attending-level prescriber who has been granted privileges to order the specific chemotherapy.					
5	Prescribers enter inpatient and outpatient chemotherapy (non-**INVESTIGATIONAL DRUGS**) and other treatment-related medication orders into a **COMPUTERIZED PRESCRIBER ORDER ENTRY** system that is directly **INTERFACED** with an EHR, including the pharmacy computer. ***Scoring guideline:*** *Scoring should be based on all settings—inpatient, outpatient, or both—where chemotherapy (non-**INVESTIGATIONAL DRUGS**) is prescribed in your facility.*					
6	Verbal/telephone orders are never accepted for chemotherapy except to hold or discontinue chemotherapy.					
Expression of Drug Names						
7	If an acronym is used to identify the chemotherapy protocol, the acronym is defined in the order, and each medication is prescribed individually, with the dose and schedule designated for each. (For example: CMV for bladder cancer is defined as **CIS**platin 100 mg/m^2/day on Day 2, methotrexate 30 mg/m^2/day on Day 1 and Day 8, vin**BLAS**tine 4 mg/m^2/day on Day 1 and Day 8.)					
Expression of Drug Doses						
8	Chemotherapy drugs for specific days are written explicitly (e.g., orders are written as "Day 1, 2, 3," and never as "Days 1-3," which can be misunderstood as days 1 and 3; orders are written as "Daily for 21 consecutive days and stop for 7 consecutive days," and never as "Days 1-21, stop for Days 22-28").					
9	Prescribers include the patient-specific dose and the mg/kg, mg/m^2, units/m^2, **AUC**, or other dosing method used to calculate the patient-specific dose for all chemotherapy orders (e.g., for a 1.67 m^2 patient: 240 mg/m^2; dose = 400 mg).					

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10	Prescribing the total chemotherapy dose for the entire **CYCLE** of treatment is prohibited (e.g., order for 400 mg/m^2 on day 1, 2, 3, and 4, not 1,600 mg/m^2 over 4 days; or fluorouracil 750 mg/m^2 continuous infusion on day 1, 2, 3, 4, and 5, not 3,750 mg/m^2 continuous infusion over 5 days).					
11	A standardized rounding procedure exists and is followed for **PARENTERAL** chemotherapy doses, unless otherwise required by an **INVESTIGATIONAL DRUG** protocol (e.g., calculated chemotherapy doses with a decimal point that are less than 10 mg are rounded to the nearest tenth, and doses greater than or equal to 10 mg are rounded to the closest whole number).					
Technology Alerts						
12	The computer order entry system has been programmed to exclude inappropriate routes of administration from selection choices, or it alerts the practitioner if an inappropriate route has been selected and prevents (**HARD STOP**) the order from being processed (e.g., vin**CRIS**tine can only be ordered IV).					
13	The computer order entry system alerts prescribers and pharmacists to excessive or subtherapeutic chemotherapy doses using protocol-specific dosing ranges.					
Dispensing						
14	All chemotherapy is provided to patient care areas in a form that requires no further preparation or manipulation by the practitioner who will be administering it (e.g., the medication is in a syringe, or in an infusion bag with an attached administration set fully primed and a closed system transfer device).					
15	**GRAVIMETRICS** is used to confirm the expected weight and volume of a **COMPOUNDED STERILE PREPARATION** containing chemotherapy that is prepared in the facility.					
Drug Preparation and Administration						
16	Chemotherapy is prepared, dispensed, and administered only within facility-defined timeframes when adequate resources and trained staff are available to review the order, assess the patient, prepare and check the chemotherapy, and administer the chemotherapy without feeling rushed.					
Products Used						
17	Commercially available standard base solutions (e.g., sodium chloride 0.9%, dextrose 5% in water) are used for chemotherapy preparation and not compounded by the facility.					
Product Labeling						
FAQ 18	For **COMPOUNDED STERILE PREPARATIONS** of chemotherapy solutions, the total volume to be infused is expressed on the pharmacy label, which includes the volume of all additives, the base solution, and any overfill volume that exists in the container (including the manufacturer's overfill in a container of premixed base solution).					
19	For chemotherapy infusions in which the dose remaining in the tubing must also be infused to deliver the entire dose, the product label specifies that the tubing should be flushed with a particular diluent and volume.					
20	The prescribed rate of infusion is included on the product label of chemotherapy infusions.					

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Independent Double Checks						
21	The patient's **BSA** (unless **AUC** is used for dosing) and creatinine clearance are calculated before each **CYCLE** of chemotherapy, using a standard method defined by the facility.					
22	Before preparing and dispensing chemotherapy, a pharmacist conducts and documents (e.g., initials or electronically) an **INDEPENDENT DOUBLE CHECK** of the prescriber's dosing method (e.g., mg/kg, mg/m^2, units/m^2, or **AUC**) and calculated dose per the protocol or treatment plan, using the patient's **BSA**, weight, or **AUC**.					
23	Before preparing the chemotherapy, a pharmacist conducts and documents (e.g., with initials or electronically) an **INDEPENDENT DOUBLE CHECK** of the anticipated diluent, drug, and proper dilution volume for chemotherapy preparations; **and** the base solution and all additives (including the actual drug amount and volume in syringes) are verified prior to mixing. (The **SYRINGE PULLBACK METHOD** is not used as part of the verification process.)					
24	Before dispensing and administering each dose of chemotherapy, the dispensing pharmacist and nurse administering the chemotherapy independently verify and document the current **CYCLE** and the day within the **CYCLE** of chemotherapy (e.g., **CYCLE** 3 of 6, day 3 of 5) against an established protocol or treatment plan for the patient.					
25	Before administering chemotherapy, a nurse conducts and documents (e.g., with initials or electronically) an **INDEPENDENT DOUBLE CHECK** of the prescriber's dosing method (e.g., mg/kg, mg/m^2, units/m^2, or **AUC**) and calculated dose per the protocol or treatment plan, using the patient's **BSA**, weight, or **AUC**.					
Emergency Preparedness						
26	A protocol(s) exists and is used to direct the emergency treatment of hypersensitivity reactions, overdoses, or life-threatening toxicities related to certain types of chemotherapy (e.g., uridine triacetate for treating overdoses of fluorouracil or capecitabine).					
Patient Monitoring						
27	Current general and treatment- and drug-specific diagnostic and laboratory test results (e.g., Multi Gated Acquisition [MUGA] scan for anthracyclines; renal function tests for **CIS**platin-based treatments) are evaluated prior to preparation and administration of the first dose of chemotherapy, and before subsequent doses when indicated.					
28	A system is in place (electronic or manual) to document, track, and communicate the lifetime cumulative dose of chemotherapy as appropriate (e.g., anthracyclines, bleomycin).					
Staff Competency and Education						
29	Before granting or renewing privileges for prescribing chemotherapy, a thorough vetting of the prescriber's therapy-specific training, scope of practice, certification, experience, and familiarity and compliance with the facility's safety strategies is carried out by the medical staff to confirm and document initial and ongoing competency.					

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30	The facility requires mandatory internal and/or external staff training/certification in chemotherapy and assesses staff competency prior to prescribing, preparing, dispensing, or administering chemotherapy, or monitoring patients who have received chemotherapy.					
Patient Education (Includes Caregiver Education When Appropriate)						
31	Before the first dose of chemotherapy and prior to each subsequent **CYCLE**, the prescriber or other qualified practitioner provides patients with the treatment protocol (schedule); the brand and generic name of the drug(s); the general purpose of the drug(s); the dose(s) and duration of therapy; immediate and delayed side effects; and when to seek medical help.					
Oral Chemotherapy						
General						
32	The processes used to ensure the safety of orders for cytotoxic oral (e.g., temozolomide, lomustine) and other **NON-PARENTERAL** dosage forms of chemotherapy are the same as those in place for **PARENTERAL** dosage forms.					
Expression of Drug Doses						
33	In treatment plans, prescriptions or orders, and instructions for the patient, oral chemotherapy doses and schedules are described as the amount of medication to be taken per dose, not as a total daily dose that is to be taken in divided doses.					
34	Unless otherwise required by an **INVESTIGATIONAL DRUG** protocol, a standardized procedure exists and is followed throughout the facility for rounding oral chemotherapy doses to the nearest capsule or tablet strength, or otherwise providing the medication in a form that can be taken by the patient in the proper dose.					
Quantity Dispensed						
35	For intermittent treatment with oral chemotherapy, the quantity of drugs prescribed and dispensed for ambulatory patients (e.g., number of tablets/capsules) is the exact quantity required for a single **CYCLE** of treatment (e.g., capecitabine is available in 500 mg tablets; one **CYCLE** of treatment is ordered for capecitabine 1,250 mg/m^2 [**BSA** = 1.6 m^2] twice a day for 2 weeks = 2,000 mg twice a day for 2 weeks = 112 tablets). ***Scoring guideline:*** *If your facility does not dispense oral chemotherapy for patients to self-administer at home, score this item as it relates to prescribing chemotherapy for ambulatory patients only. If your facility dispenses oral chemotherapy for ambulatory patients, score this item as it relates to both prescribing and dispensing the chemotherapy. Choose Not Applicable only if your facility does not prescribe or dispense oral chemotherapy for patients to self-administer at home.*					NOT APPLICABLE
Patient Education (Includes Caregiver Education When Appropriate)						
36	When providing patients with a prescription for oral chemotherapy, the prescriber or another qualified practitioner reviews the brand and generic name of the drug; the general purpose; amount of each single dose; the duration of therapy; what to do if a dose is missed; safe handling, storage, and disposal of the drug; immediate and delayed side effects; and when and how to seek medical help.					

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Vinca Alkaloids (vinBLAStine, vinCRIStine, vindesine, vinorelbine) and bortezomib						
Dispensing						
37	Vin**CRIS**tine is dispensed in a minibag of a compatible solution (e.g., 25 mL for pediatric patients, 50 mL for adults); **and** vin**CRIS**tine doses are never dispensed and/or administered in a syringe.					
38	Vinca alkaloids and bortezomib are dispensed with a prominent warning label that reads: **FOR INTRAVENOUS USE ONLY—FATAL IF GIVEN BY OTHER ROUTES**.					
Administration						
39	The presence of vinca alkaloids and bortezomib is prohibited in areas where intrathecal medications are administered. ***Scoring guideline:*** *Choose Not Applicable only if you never administer intrathecal medications in your facility.*	NOT APPLICABLE				
40	Confirmation that the administration of any prescribed intrathecal medications has been completed is required before dispensing a vinca alkaloid or bortezomib. ***Scoring guideline:*** *Choose Not Applicable only if you never administer intrathecal medications in your facility.*	NOT APPLICABLE				
INVESTIGATIONAL Chemotherapy						
Scoring guideline for this section: *Choose Not Applicable for these items only if your facility never prescribes, dispenses, or administers* ***INVESTIGATIONAL*** *chemotherapy.*						
Prescribing						
41	Prescribers enter inpatient and outpatient **INVESTIGATIONAL** chemotherapy and other treatment-related medication orders into a **COMPUTERIZED PRESCRIBER ORDER ENTRY** system that is directly **INTERFACED** with an EHR, including the pharmacy computer. ***Additional scoring guideline:*** *Scoring should be based on all settings—inpatient, outpatient, or both—where* ***INVESTIGATIONAL*** *chemotherapy is prescribed in your facility.*	NOT APPLICABLE				
Protocols, Checklists, and Reference Sheets						
42	Practitioners involved in prescribing, preparing, dispensing, or administering **INVESTIGATIONAL** chemotherapy drugs have real-time access to current study protocols, investigator's brochures, safety data sheets, and protocol summary sheets.	NOT APPLICABLE				
43	Checklists or study-specific reference sheets applicable to required tasks have been created for pharmacy and nursing staff to ensure consistent processes.	NOT APPLICABLE				
Storage						
44	**INVESTIGATIONAL** chemotherapy drugs are stored in a designated, secure area in the pharmacy, and separated by different strengths and by protocol name, number, or other identifier (e.g., Protocol A, Placebo A; Protocol B, Placebo B; Drug A or B (blinded); Drug A + Drug B; Drug A x mg, Drug A 2x mg) in labeled bins or shelves.	NOT APPLICABLE				

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Product Labeling						
45	A pharmacy-prepared label is affixed to individual **INVESTIGATIONAL** chemotherapy drugs or a bag that holds a supply of vials/containers of the same drug/strength/concentration to provide any information that is poorly visible or missing on the product label (e.g., strength, concentration, lot numbers).					
		NOT APPLICABLE				
46	A pharmacy-prepared label is affixed to **INVESTIGATIONAL** chemotherapy drugs dispensed for a specific patient to provide dosing and other important information that is poorly visible or missing on the product label (e.g., strength, concentration).					
		NOT APPLICABLE				
Staff Competency and Education						
47	Pharmacists, pharmacy technicians, and nurses who handle, prepare, dispense, administer, or monitor the storage conditions of **INVESTIGATIONAL DRUGS** have received standardized training on relevant facility policies and procedures; **and** competency has been verified prior to participation in these processes.					
		NOT APPLICABLE				
Patient Education (Includes Caregiver Education When Appropriate)						
48	When dispensing **INVESTIGATIONAL** chemotherapy drugs to patients, contact information, including both a daytime telephone number and an emergency number for any questions or issues that arise, is provided in writing. ***Additional scoring guideline:*** *Choose Not Applicable only if your facility does not dispense oral **INVESTIGATIONAL** chemotherapy to patients to self-administer at home.*					
		NOT APPLICABLE				