ASCO® Standards ONS®

Antineoplastic Therapy Administration Safety Standards for Adult and Pediatric Oncology: ASCO-ONS Standards			
Domain	**Standards**		
Domain 1: Creating a Safe Environment	**1.1.** The health care organization has a policy to document the qualifications of clinical staff who order, prepare, and administer antineoplastic therapy and documents:		
		1.1.1. Description of initial educational requirements and competencies.	
		1.1.2. Description of (at least) annual, ongoing continuing education requirements.	
		1.1.3. Description of credentialing processes (licensed practitioners) and how credentialing is documented.	
		1.1.4. Description of competency demonstration and how competency is documented and maintained.	
	1.2. The health care organization uses a comprehensive education program for initial and ongoing educational requirements for all staff who prepare and administer antineoplastic therapy.		
	1.3. At least one practitioner who maintains current certification in (age-appropriate) basic life support is present during antineoplastic therapy administration.		
	1.4. A licensed practitioner is on-site and immediately available to staff who administer antineoplastic therapy in the health care organization.		
	1.5. Before the first administration of a new antineoplastic therapy regimen, medical record documentation is available that includes at least the following nine elements:		
		1.5.1. Pathologic confirmation or verification of initial diagnosis.	
		1.5.2. Initial cancer stage or current cancer status.	
		1.5.3. Complete medical history and physical examination, including fertility status and pregnancy status, as applicable.	
			1.5.3.1. The health care organization has a policy for pregnancy testing prior to initiating antineoplastic therapies.
			1.5.3.2. The health care organization has a policy for assessing risk of pregnancy in patients while receiving antineoplastic therapies.
			1.5.3.3. The health care organization has a policy for determining a patient's desire for ongoing or future fertility preservation prior to initiating antineoplastic therapy and making appropriate referrals when feasible.
		1.5.4. Presence or absence of allergies and history of hypersensitivity and anaphylactoid reactions.	

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		1.5.5. Assessment of the patient's and/or caregiver's comprehension of information regarding the disease and treatment plan including an initial psychosocial assessment, with action taken when indicated and agreeable to the patient.
		1.5.6. The plan for antineoplastic therapy, including, at a minimum, the patient diagnosis, drugs, doses, route of administration, duration of treatment, and goals of therapy (e.g., palliative versus curative).
		1.5.7. Planned frequency of patient assessments and monitoring that is appropriate for the individual antineoplastic agent(s).
		1.5.8. Initial and ongoing assessments of social determinants of health and barriers to care including financial and logistical constraints and supports needed to provide access to required medications (if applicable).
		1.5.9. Informed consent and/or assent for the antineoplastic therapy.
	1.6. On each clinical encounter or day of treatment, staff performs and documents a patient assessment that includes at least the following six elements and takes appropriate action:	
		1.6.1. Functional status and/or performance status.
		1.6.2. Vital signs.
		1.6.3. Date of birth.
		1.6.4. Allergies and previous treatment-related reactions.
		1.6.5. Treatment toxicities.
		1.6.6. Pain assessment.
	1.7. Weight and height are measured and documented in the medical record in metric units (e.g., kg and cm). Both the measurement and documentation are verified by two individuals, one of whom is a licensed clinician, prior to preparation and administration of a newly prescribed antineoplastic treatment plan. The measurement is repeated when clinically appropriate as determined by the policy of the health care organization.	
	1.8. Staff screens for and documents the patient's psychosocial concerns and need for support with each cycle or more frequently as indicated, with action taken when indicated and agreeable to the patient.	
	1.9. The patient's medication list inclusive of prescribed and over-the-counter medications, herbal products, and supplements, is updated and documented in the medical record at every encounter and reviewed by a licensed practitioner when a change occurs.	
	1.10. The health care organization has a policy for documentation and follow-up for patients who miss or cancel scheduled visits and/or antineoplastic therapy.	
	1.11. The health care organization has a policy that addresses mandates and processes for pediatric patients that account for legal requirements.	

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	1.12. The health care organization has a policy that identifies a process to provide 24/7 triage to a licensed practitioner, for example, on-call practitioners or emergency department, to manage treatment-related toxicities and emergencies. If the patient's initial contact is not a practitioner from the treating health care organization, the person having initial patient contact must have continuous access to consultation from an experienced licensed oncology practitioner and the opportunity for transfer of the patient to a health care organization with dedicated oncology services.	
	1.13. The health care organization has a policy for standardized documentation in medical record and communication of toxicities, modifications in dose or schedule, or discontinuation of treatment for antineoplastics, regardless of the health care setting.	
	1.14. The health care organization has a policy for hand-off process between all sites of care, which includes patient's care plan, antineoplastic therapy treatment schedule, safety concerns including critical laboratory values, current condition, and any recent or anticipated changes.	
	1.15. The health care organization has a policy for reporting of adverse events (e.g., infusion reactions and toxicities), medication errors, and near misses and has a formal process for collecting, evaluating data at a defined frequency, and intervening as appropriate.	
	1.16. The health care organization uses an electronic medical record ordering format for antineoplastic therapy, when feasible.	
Domain 2: Patient Consent and Patient Education	**2.1.** The health care organization has a policy that documents a standardized process for obtaining and documenting informed consent and assent (if applicable) for antineoplastic therapy regardless of route of administration.	
	2.2. Informed consent and assent (if applicable) for antineoplastic therapy, as appropriate to the treatment population, is documented before initiation of the regimen.	
	2.3. Patients are provided with verbal and written or electronic information as part of an education process before the first administration of antineoplastic agents in each treatment plan. The content of this educational material will be documented and should be administered in the patient's preferred language. Educational information includes the following at a minimum:	
		2.3.1. Patient's diagnosis.
		2.3.2. Goals of treatment, that is, cure disease, prolong life, or reduce symptoms.
		2.3.3. Planned duration of treatment, schedule of treatment administration, plan for missed doses, drug names and supportive medications, and drug interactions with prescribed drugs, integrative therapies, over the counter drugs, and foods.
		2.3.4. Documentation of current medications to include herbal products and complementary medications.
		2.3.5. Potential long-term and short-term adverse effects of therapy, including infertility risks for appropriate patients.
		2.3.6. Pregnancy prevention including contraception.

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		2.3.7. Symptoms or adverse effects that require the patient to contact the health care organization or to seek immediate attention.
		2.3.8. Symptoms or events that require immediate discontinuation of oral or other self-administered treatments.
		2.3.9. Procedures for safe handling medications in the home, including disposal of waste, handling body secretions, storage, safe handling, and management of unused medication, and clean-up of drug spills.
		2.3.10. Follow-up plans, including laboratory and/or provider visits, and approximate timeline for follow-up radiographic tests.
		2.3.11. Contact information for the health care organization, with availability and instructions on when and whom to call.
		2.3.12. The missed appointment policy of the health care organization and expectations for rescheduling or canceling.
	2.4. Education includes family, caregivers, or others on the basis of the patient's ability to assume responsibility for managing therapy. Educational activities will be performed based on the patient's learning needs, abilities, preferences, and readiness to learn.	
Domain 3: Ordering, Preparing, Dispensing, and Administering Oral and Parenteral Antineoplastic Therapies in a Health Care Facility, Organization or in the Home	**3.1.** The health care organization defines standard antineoplastic therapy regimens by diagnosis with references.	
	3.2. The health care organization verifies institutional review board approval of research regimens.	
	3.3. Orders for antineoplastic therapy, regardless of route, are signed manually or by using the electronic health record by licensed practitioners who are determined to be qualified by the health care organization.	
	3.4. The health care organization has a policy for managing antineoplastic therapy orders that vary from standard regimens (exception orders) such as using an order set for a disease not assigned, adding a medication not included in the standard regimen, escalation of dose or schedule beyond that defined in the standard regimen.	
		3.4.1. The policy requires a supporting reference and/or authorization by a second licensed practitioner prior to ordering, signing or administration of an exception order.
		3.4.2. The rationale for an exception order is documented in the health record.
	3.5. The health care organization has a policy for antineoplastic therapy orders that ensure:	
		3.5.1. Verbal orders are not allowed except to hold or stop antineoplastic therapy administration.
		3.5.2. New orders or changes to orders for antineoplastics, regardless of route, including dose and schedule changes communicated directly to patients, are documented in the medical record.
	3.6. The health care organization uses standardized, regimen-level, preprinted or electronic orders for parenteral and oral antineoplastic therapies.	

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	3.7. If the health care organization administers parenteral antineoplastic therapies that are prepared or compounded offsite, the health care organization maintains a policy for quality control of that product including documentation of the offsite or third party's pharmacy or manufacturing facility that complies with all applicable regulatory requirements.
	3.8. If the health care organization maintains its own pharmacy, there is a policy regarding safe storage of the antineoplastic agents including separation of look-a-like products, sound-a-like products, and investigational agents available in multiple strengths.
	3.9. Ordering Antineoplastics (Both oral and parenteral): Antineoplastic orders must include the patient's name and date of birth. In addition, the following elements must be included in the patient's medical record:
	3.9.1. A second patient identifier.
	3.9.2. The date the order was signed.
	3.9.3. Prescriber name.
	3.9.4. Regimen name or protocol name and/or number.
	3.9.5. Cycle number and day number, when applicable.
	3.9.6. All medications within the order set are listed by using full generic names.
	3.9.7. Doses are written following health care organization policy for preventing the use of unapproved abbreviations, omitting trailing zeros, and including leading zeros.
	3.9.8. The dose calculation, including:
	3.9.8.1. The calculation methodology.
	3.9.8.2. The variables used to calculate the dose.
	3.9.8.3. The frequency at which variables are re-evaluated, such as weight or laboratory data.
	3.9.8.4. The changes in the values that prompt confirmation or recalculation of doses.
	3.9.9. The date of administration.
	3.9.10. The route of administration.
	3.9.11. Allergies, confirmed prior to administration of antineoplastics.
	3.9.12. Supportive care medications appropriate for the regimen including premedication, hydration, growth factors, and hypersensitivity and anaphylactoid medications are included in the preprinted or electronic order forms.

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		3.9.13. Parameters that would require holding or modifying a dose, for example, laboratory values, diagnostic test results, or change in patient's clinical status.
		3.9.14. Sequencing of oral and/or parenteral drug administration, when applicable.
		3.9.15. Rate of drug administration for parenteral medications, when applicable.
		3.9.16. Explanation of time limitation, such as number of cycles for which an order is valid.
	3.10. Ordering Oral Antineoplastics: All oral antineoplastics must be ordered in the electronic medical record or on pre-printed forms and documented in the patient's medical record whether dispensed by the ordering health care facility, an alternative facility, or a specialty pharmacy. Elements unique to oral antineoplastics should be included in addition to the patient's name and date of birth:	
		3.10.1. Drug quantity or volume to be dispensed.
		3.10.2. Number of refills, with zero being the preferred default value for oral antineoplastics.
		3.10.3. Schedule of administration.
	3.11. Preparation of Antineoplastics (Both oral and parenteral)	
		3.11.1. Oral or parenteral antineoplastics are prepared by a licensed pharmacist, pharmacy technician, or registered nurse with documented antineoplastic preparation education, training, and annual competency evaluation.
		3.11.2. Labels for oral or parenteral antineoplastics and supportive care medications are placed immediately upon preparation or compounding whether dispensed from the ordering health care organization, an alternative facility, or a specialty pharmacy, to be administered in the health care facility or in the home:
		3.11.2.1. Patient's name.
		3.11.2.2. Patient's date of birth.
		3.11.2.3. Prescriber's name.
		3.11.2.4. Date of preparation and expiration, day and/or time.
		3.11.2.5. Full generic name of the antineoplastic and supportive care medications.
		3.11.2.6. Drug dose.
		3.11.2.7. Route of administration.
		3.11.2.8. A label denoting HAZARDOUS DRUG, if applicable.
		3.11.3. Labels Specific for parenteral medications:

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			3.11.3.1. Total volume required to administer the drug.	
			3.11.3.2. Total number of products to be administered when the medication is dispensed in divided doses-each product should be labeled with the total number of products to be administered and the individual product sequence within the total grouping, for example: one of five, two of two, etc.	
			3.11.3.3. Date the medication is to be administered.	
			3.11.3.4. A warning or precautionary label or sticker, as applicable, for storage and handling.	
		3.11.4. Labels Specific for oral medications:		
			3.11.4.1. Dosage form of the medication.	
			3.11.4.2. Quantity to be dispensed within each container.	
			3.11.4.3. Number of pills per dose when the container holds more than one dose.	
			3.11.4.4. Administration schedule, including number of times per day to take medication and days on or off medication (cycle length) when applicable, and when follow up is scheduled.	
			3.11.4.5. Administration instructions related to food ingestion and other non-antineoplastic medications taken at home.	
			3.11.4.6. A warning or precaution label, as applicable, for specific storage and handling instructions.	
	3.12. Dispensing and administering parenteral antineoplastics whether administered in a health care organization or at home.			
		3.12.1. A licensed pharmacist verifies all orders before dispensing parenteral antineoplastics in the health care organization that treats pediatric patients under age 18.		
		3.12.2. Personnel approved by the health care organization to prepare or administer antineoplastic therapy perform four separate verifications in person, or by institutionally approved video-enabled technology.		
			3.12.2.1. First Verification. Before preparation of the antineoplastic therapy personnel approved by the health care organization to prepare or administer antineoplastic therapy verifies and documents in the patient's medical record:	
				3.12.2.1.1. Two patient identifiers.
				3.12.2.1.2. Drug name.
				3.12.2.1.3. Drug dose.
				3.12.2.1.4. Route of administration.
				3.12.2.1.5. Rate of administration.

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				3.12.2.1.6. The calculations for dosing, including the variables used in the calculation.
				3.12.2.1.7. Treatment day and cycle.
			3.12.2.2. Second Verification. Upon preparation of the antineoplastic medication, a second licensed clinician approved by the health care organization to prepare antineoplastic therapy verifies:	
				3.12.2.2.1. The drug vial(s).
				3.12.2.2.2. Concentration.
				3.12.2.2.3. Drug volume or weight.
				3.12.2.2.4. Diluent type and volume when applicable.
				3.12.2.2.5. Administration route, filters, and tubing if applicable.
			3.12.2.3. Third Verification. After preparation and before each antineoplastic therapy administration, at least two licensed clinicians approved by the health care organization to administer or prepare antineoplastic therapy independently verify and document the accuracy of the following elements in the patient's medical record:	
				3.12.2.3.1. Drug name.
				3.12.2.3.2. Drug dose.
				3.12.2.3.3. Infusion volume or drug volume when prepared in a syringe.
				3.12.2.3.4. Rate of administration.
				3.12.2.3.5. Route of administration.
				3.12.2.3.6. Expiration date/times.
				3.12.2.3.7. Appearance and integrity of the drugs.
			3.12.2.4. Fourth Verification. In the presence of the patient: at least two licensed clinicians approved by the health care organization to administer or prepare antineoplastic therapy in person or through appropriate institutionally approved video-enabled technology, with at least one person on site, verify the patient's identification using at least two identifiers and document accuracy in the patient's medical record. Document the accuracy of the following elements in the patient's medical record:	
				3.12.2.4.1. Drug name.
				3.12.2.4.2. Drug dose.

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				3.12.2.4.3. Rate and duration of infusion.
				3.12.2.4.4. Route of administration.
				3.12.2.4.5. Administration set (as applicable) e.g., filters, specialized tubing.
				3.12.2.4.6. Infusion pump (if applicable) settings, including rate.
		3.12.3. Before initiation of antineoplastic therapy, personnel approved by the health care organization who is administering the antineoplastic(s) confirms the therapy with the patient, including, at a minimum, the name of the drug, the infusion time, route of infusion, symptoms to report, for example: hypersensitivity symptoms or pain at infusion site.		
		3.12.4. Parenteral antineoplastic therapy is administered by a licensed clinician approved by the health care organization as defined in Standard 1.1.		
		3.12.5. Documentation in the patient's medical record confirms the four verifications prior to parenteral antineoplastic administration and the patient's clinical status during and upon completion of antineoplastic therapy.		
		3.12.6. Infiltration and extravasation management policy is present and aligns with current literature and guidelines. Antidote order sets and the antidotes are accessible within the appropriate time frame for treatment.		
		3.12.7. Hypersensitivity and anaphylactoid management policy is present and aligns with current literature and guidelines. Hypersensitivity order sets and medications are accessible within the appropriate timeframe for optimal treatment.		
		3.12.8. Cytokine release syndrome (CRS) management policy is present and aligns with current literature and guidelines when administering antineoplastics with this potential adverse effect. Antidote and CRS-directed therapy order sets and medications are accessible within the appropriate timeframe for optimal treatment.		
	3.13. Administering antineoplastics directly into the cerebrospinal fluid: The health care organization that administers intrathecally or intraventricularly maintains policy that specifies that these agents are:			
		3.13.1. Prepared separately from other antineoplastic therapies.		
		3.13.2. Labeled immediately after preparation with a uniquely identifiable label for intrathecal or intraventricular medication.		
		3.13.3. Stored in an isolated container or location after preparation from any other antineoplastic medications.		
		3.13.4. Delivered to the patient only with other medications intended for administration into the central nervous system.		
		3.13.5. Administered immediately after a time out, double check procedure that involves two licensed practitioners or other licensed clinicians approved by the health care organization to prepare or administer antineoplastic therapy.		
		3.13.6. The health care organization that administers antineoplastic therapy directly into the cerebral spinal fluid has policy that specifies that intravenous vinca alkaloids are administered only by infusion, for example, mini bags.		

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Domain 4: Monitoring During and After Antineoplastic Therapy Is Administered, Including Adherence, Toxicity, and Complications	**4.1.** The health care organization uses standard, disease-specific processes to monitor treatment response based on evidence and national guidelines when available.	
	4.2. The health care organization has a policy for emergent treatment of patients that aligns with current literature and guidelines and addresses:	
		4.2.1. Availability of appropriate emergency equipment and rescue agents and antidotes in the health care organization, whether in a health care facility or the patient's home.
		4.2.2. Procedures to follow and a plan for escalation of care, when required, for life-threatening emergencies.
	4.3. The health care organization has a policy that determines the appropriate time interval for regimen-specific laboratory and organ function tests that are based on evidence and national guidelines when available.	
	4.4. The health care organization policy outlines the procedure to monitor initial and subsequent assessment and documentation of patients' adherence to antineoplastic therapy.	
	4.5. The health care organization has a policy that strives to minimize treatment toxicity:	
		4.5.1. The health care organization has a policy that requires assessment and documentation of toxicity at each clinical encounter to address any issue.
		4.5.2. The health care organization has a policy that requires documentation of treatment-related toxicities, dose modification related to toxicities, and how these are communicated before subsequent administration.
		4.5.3. Cumulative doses of antineoplastic therapy are tracked for agents associated with cumulative toxicity.
	4.6. The health care organization has a policy that requires ongoing assessment of barriers to adherence, including social determinants of health and financial constraints.	

Note on terminology changes: 1. "chemotherapy" changed to "antineoplastic therapy." 2. "health care setting" changed to "health care organization."