

# High-Risk Medicine Standard: Anticancer medicines

## PRINTABLE STANDARD

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Anticancer medicines (sometimes referred to as chemotherapy) are a broad range of medicines used in the treatment of cancer and certain non-malignant conditions. Traditional cytotoxic anticancer medicines aim to disrupt the replication process of rapidly dividing cells. Newer classes of anticancer medicines usually target specific proteins or pathways important in the growth of cancers, with varying mechanisms of action, adverse effect profiles and occupational exposure considerations. New anticancer medicines are constantly emerging and like traditional agents, can often cause serious harm if prescribed, dispensed, or administered incorrectly.

For the purpose of this standard, the term anticancer medicines will encompass cytotoxic agents, monoclonal antibodies, and targeted therapies (excluding hormonal therapies).

Adherence to this standard is **mandatory** for:

- all anticancer medicines used for cancer care (malignant) indications
- cytotoxic medicines used in non-malignant indications.

Adherence to this standard is at the discretion of the Drug and Therapeutics Committee (or delegated governance committee) for monoclonal antibodies or targeted anticancer medicines used for non-malignant indications.

Anticancer medicines are high-risk due to their complex treatment regimens, narrow therapeutic range, and risk of acute or delayed toxicities. Errors involving anticancer medicines include:

- dose calculation errors related to use of incorrect weight or height or insufficient staff training
- omission errors, for example, omission of supportive care when prescribing or administering resulting in increased toxicity
- administration rate errors, particularly where medicines have differing infusion rates specific to a protocol
- programming errors for ambulatory infusion devices (for example, CADD® pumps) due to insufficient staff training or patient education resulting in incorrect administration
- insufficient or ineffective patient education about management and urgency of potential side effects resulting in delayed presentation and management, for example, auto-immune colitis from immunotherapy
- route of administration errors, for example, unintentional administration of vinca alkaloids intrathecally resulting in death (addressed by Clinical Excellence Commission [High-Risk Medicine Standard: Vinca alkaloids](#)).

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This standard outlines the minimum actions required to mitigate risks associated with anticancer medicine use. This standard does not contain clinical guidance on anticancer medicine use. This standard is to be read in conjunction with:

- Clinical Excellence Commission [High-Risk Medicine Standard: Vinca alkaloids](#)
- Clinical Excellence Commission [High-Risk Medicine Standard: Methotrexate \(Oral\)](#)
- Safe Work NSW [Cytotoxic Drugs and Related Waste – Risk Management](#)
- evIQ webpage [Safe handling and waste management of hazardous drugs](#)
- Clinical Oncology Society of Australia webpage [COSA guidelines for the safe prescribing, dispensing and administration of systemic cancer therapy](#)
- Pharmacy Board of Australia webpage [Codes, Guidelines and Policies](#)
- NSW Health Policy Directive *Preparation of Pharmaceutical and Advanced Therapeutic Products* ([PD2023\\_021](#))
- Australian Commission on Safety and Quality in Health Care [NSQHS Standards User Guide for Medication Management in Cancer Care](#)

### Minimum requirements for clinical protocols

The Drug and Therapeutics Committee (or delegated governance committee) must approve any clinical protocols relating to anticancer medicines and ensure the inclusion of the following, at a minimum:

- a statement that only staff specifically trained and who have been assessed as competent may prescribe, verify, prepare, dispense, or administer anticancer medicines
- instructions (or reference to local guidelines) on appropriate health monitoring, safe handling and waste management of cytotoxic and hazardous medicines for staff involved in storage, preparation, administration and the handling of waste
- a statement that all staff who are involved in the storage, preparation, or administration of cytotoxic or hazardous drugs, and the handling of waste, are to be informed of the reproductive risks and possible effects on foetal development
- requirements for the approval and review of treatment protocols or variations that are not available from accepted standard sources (for example, [eviQ Cancer Treatments](#)) by the Drug and Therapeutics Committee (or delegated governance committee)
- requirements for patient and/or carer consent
- requirements for patient and/or carer education (see *Patient information/education* section)

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- a requirement for a measured accurate patient height and weight to be documented for all patients prior to receiving treatment where appropriate
- requirement that all anticancer medication prescriptions are clearly documented within the appropriate electronic Medication Management (eMM) system or approved paper-based medication chart as per local policy
- a requirement for the specialist prescribing team to be contacted regarding the management of treatment-related adverse effects
- a requirement that monitoring of treatment-related toxicities are to occur at every hospital visit.

### Governance requirements

Adherence to the requirements specified in this standard is to be monitored by governance committees (for example, Drug and Therapeutics Committee) and service managers (including, but not limited to, Directors of Pharmacy and Nurse Unit Managers). An implementation checklist is available and can be used by facilities and individual units to determine compliance with these requirements.

### Prescribing

- Facilities are to establish policies outlining which clinicians can prescribe anticancer medicines depending on the local context. Best practice includes the consultant authorising the first cycle of anticancer medicines.
- Where Advanced Trainees, Nurse Practitioners or Career Medical Officers are given anticancer medication prescribing rights, supervision and support are to be established (for example, but not limited to, co-signing of medication orders).
- Advice is to be sought from the specialist anticancer medication prescribing team before continuing treatment on admission and/or discharge including any supportive care requirements.
- When prescribing anticancer medicines, the prescriber is to clearly document the patient's diagnosis (for example, tumour group and stage), treatment intent and relevant past medical history (if not already documented).
- Before prescribing anticancer medicines, written consent for the treatment is to be obtained in accordance with the NSW Health [Consent to Medical and Healthcare Treatment Manual \(Section 4.5\)](#). This is to include consent for the use of non-standard dose variations or protocols.
- Anticancer medicines are to be prescribed from an evidence-based source and validated standard reference (for example, eviQ, clinical trial protocol, or other locally approved standard reference). For protocols that do not meet this requirement; a governance procedure is to be in place for approval which include a documented multidisciplinary approach and local endorsement.

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- The patient's regular medications are to be reviewed prior to prescribing anticancer medicines to determine potential drug interactions. Dose adjustments or additional monitoring may be required. Any adjustments to the patient's medications are to be clearly documented in the patient's health record.
- Dose adjustments are to be considered when prescribing anticancer medicines for patients with existing clinical conditions (such as renal or hepatic impairment), medication interactions, or patients with poor tolerance to previous treatments.
- Clinicians are to clearly document the rationale for dose adjustments and the adjustment amount (for example, reduce by 50% due to renal impairment) in a locally determined and standardised manner. This will enable regular audits and encourage quality improvement.
- Facilities are to establish a formal auditing process to identify and review all protocol and dose variations including dose overrides and ensure they are reviewed by a multi-disciplinary team. This review process is to be documented and feedback provided to prescribers where appropriate.
- Where capability exists, anticancer medicines are to be prescribed in an Oncology Information System using standardised, pre-built electronic protocols that include all supportive medicines. Exceptions to this may occur:
  - for non-cancer specialty prescribers who are unable to access the Oncology Information System
  - when prescribing oral anticancer medicines or supportive medications for inpatients. Clinicians may choose to prescribe oral treatments outside an Oncology Information System where local guidelines state this is appropriate.
- Where anticancer medicines are prescribed outside an Oncology Information System, the electronic Medication Management (eMM) system is to be configured to flag that the medicine is cytotoxic or hazardous and special handling precautions are required.
- In addition to the requirements set out in NSW Health [Policy Directive Medication Handling \(PD2022\\_032\)](#) for a medication order, prescribers must ensure treatment orders are accompanied by the following information at a minimum:
  - chosen protocol name (avoiding abbreviation where possible)
  - cycle number and cycle frequency
  - day(s) and frequency that each medicine is to be administered
  - the dose basis (for example, mg/m<sup>2</sup>, area under the curve dose or mg/kg dose) and the actual dose to be administered
  - height, weight and body surface area (BSA) (where relevant) used in dose calculations
  - duration of administration for infusions.

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- Where possible, all orders necessary for an entire treatment cycle including anticancer medicines, hydration, and supportive care are to be prescribed concurrently.
- Inappropriate abbreviations used for medication names, units of measure, and dosing instructions are to be avoided in all orders. Refer to Australian Commission on Safety and Quality in Healthcare webpage [Recommendations for terminology, abbreviations and symbols used in medicine documentation](#) for more information.
- Where applicable, accurate height and weight are to be available to all clinicians and used to calculate medication doses.
- The re-weighing of the patient during therapy to recalculate the BSA and subsequent doses will depend on local policy, treatment intent and the extent of weight change. For paediatric patients, height and weight are to be current for that cycle and/or day of treatment or as per specifications in the treatment protocol.
- Treatment planned to commence after-hours is to be prescribed and clinically verified during standard working hours. Rarely, unplanned, and urgent treatment may need to commence after hours. Processes are to be in place for accredited, experienced clinicians to undertake prescribing, clinical verification, dispensing, preparation (if needed) and administration after-hours.
- Methods for calculating BSA and eGFR are to be standardised, and the same method used by all clinicians locally.
- Medication reconciliation is to occur at each clinical review to ensure dose adjustments and modifications to supportive care are reviewed and carried forward if appropriate.
- Verbal medication orders must not be used for the prescription of anticancer medicines, except to stop or hold administration. All verbal orders to stop or hold anticancer medicines are to be followed up with clear documentation by the prescriber including the rationale.

### **Clinical verification**

- All prescribed anticancer medicines that are to be dispensed or administered by an NSW Health facility are to undergo clinical verification.
- All clinicians involved in the clinical verification of anticancer medicines are to be adequately trained.
- Facilities are to establish a clear procedure outlining the roles and responsibilities of each healthcare professional in the clinical verification of anticancer medicines and supportive medication orders. Refer to the Clinical Oncology Society of Australia webpage [COSA guidelines for the safe prescribing, dispensing and administration of systemic cancer therapy](#) which outlines the clinical verification steps.

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- Verification is to be performed according to the protocol and individual patient parameters. Verification is to include checking:
  - the order matches the locally endorsed protocol. If not, the rationale for protocol modification is to be confirmed
  - all required supportive medicines are prescribed and appropriate
  - height, weight, BSA and dose calculations (if applicable), laboratory tests, and interactions with medications and/or diseases
  - specific medication requirements (for example, maximum lifetime cumulative doses)
  - the order(s) comply with the institutions authorised format and the prescriber is locally authorised to prescribe this protocol.
- All significant interventions made during clinical verification are to be documented in the patient's health care record.
- Medication reconciliation between treatment cycles is to occur to ensure that dose reductions and modifications to supportive care (if any) are considered and carried over if appropriate.

### Storage and packaging

- Cytotoxic medicines are to be stored as per the Safe Work NSW [Cytotoxic Drugs and Related Waste – Risk Management](#).
- Spill kits are to be available in all areas where cytotoxic medicines are prepared, stored, and administered, and must accompany parenteral cytotoxic medicines in transit.
- A dedicated and clearly marked area, is to be available for unpacking parenteral cytotoxic medication orders. Appropriate personal protective equipment is to be readily available in these areas and staff trained in appropriate use.
- Oral anticancer medicines are to be packaged in a sealed, leak-proof container with child-proof lids (if not supplied in blister packs by the manufacturer).
- For parenteral anticancer medicines:
  - products are to be packaged in a sealed, leak-proof container and where possible, to be lined with an absorbent pad (or similar) to absorb spills. The primary packaging is to be heat-sealed and translucent to enable staff to identify any leakage before opening
  - products that require protection from light are to be additionally packed in opaque outer wraps
  - containers used for transportation of parenteral hazardous or cytotoxic anticancer medicines are to be hard-walled (rigid) and securely closed to protect drugs from breakage and contain leakages if needed. Where appropriate, the container is to clearly identify the contents as cytotoxic or hazardous.

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### Preparation and dispensing

- All dispensing of anticancer medicines is to occur in accordance with national and state legislative and practice standards.
- It is recommended the dispensing and clinical verification of anticancer medicines is performed by two separate individuals to allow for an independent check of each medication order. Local processes are to be in place around the documentation of checks.
- To prevent wastage and delays to treatment, clinical verification is to occur prior to the preparation and dispensing of anticancer medicines wherever possible.
- Preparation of all compounded anticancer medicines are to be in accordance with the NSW Health Policy Directive *Preparation of Pharmaceutical and Advanced Therapeutic Products* ([PD2023\\_021](#)).
- Where preparation is carried out by a third party or external compounder/manufacturer they are to be provided with adequate information to ensure evidence-based care and safe medicine checks are completed. In cases where the external manufacturer has unresolved clinical concerns, there is to be a clearly documented pathway for escalating those concerns locally.
- Anticancer medicines are to be dispensed to individual patients.
- Clear labelling with the below is to occur:
  - all hazardous medication containers are to indicate that the medicines require safe handling precautions (for example, cytotoxic labelling)
  - storage conditions (for example, refrigeration where appropriate)
  - oral cytotoxic medicines – ‘Swallow whole – Do not crush’
  - bortezomib – ‘For intravenous or subcutaneous use only – Fatal if given by other routes’
  - vinca alkaloids – ‘For intravenous use only – Fatal if given by other routes’
  - [vesicants](#) – an ‘Avoid extravasation’ warning label
  - intrathecal medicines – ‘For intrathecal use only’
  - all compounded anticancer medicines – expiry date and time
  - the administration route where the injection/infusion is given by different routes (for example, trastuzumab may be given intravenously and subcutaneously)
  - where possible, multiple-day treatments are to be labelled with bag/syringe numbers and date of administration.
- Facilities are to establish local policies and procedures outlining the process for the supply of supportive medicines to patients (for example, supplying all supportive medicines on Day 1 of the treatment cycle).

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- For oral anticancer medicines:
  - separate, clearly labelled oral cytotoxic medication counting devices are to be available to all staff dispensing these medicines
  - all oral anticancer medicines dispensed on discharge or to outpatients, are to be labelled with clear instructions for use and include the duration of therapy and the total dose required. The exact quantity required for the duration of therapy (for example, one cycle or until next review) is to be provided to the patient to minimise the risk of incorrect administration.
  - Consideration is to be given to preparing and supplying all parenteral cytotoxic medicines with a closed system drug transfer device (unless the preparation process does not allow it) that minimises aerosol generation, reduces surface contamination and staff exposure.

### Administration

- Facilities are to establish guidelines on who is competent to administer anticancer medicines. For example, only those who are undergoing direct supervision or have been assessed as competent can administer intravenous or intrathecal treatment.
- Anticancer medicines are not to be administered from an unclear order that does not meet the criteria for an order described in the *Prescribing* section.
- Access to the intended and approved treatment protocol and any modifications is to be available to administering clinicians at the time of administration.
- All anticancer and supporting medication orders are to be verified against the protocol before administration. Refer to Clinical Oncology Society of Australia webpage [COSA guidelines for the safe prescribing, dispensing and administration of systemic cancer therapy](#) which outlines the order verification steps for administration.
- An independent second person check is to be employed when administering anticancer medicines. The second person check processes are outlined in the NSW Health Policy Directive *Medication Handling* ([PD2022\\_032](#)) including circumstances where a second person check is not mandated (for example, when a medicine is administered by an authorised prescriber).
- A review that the patient has received appropriate pre-medications (for example, those for nausea and to prevent hypersensitivity reactions) and supportive medicines based on the protocol and previous reactions is to occur.
- The supply of supportive medicines required on discharge is to be documented in the patient's health care record.
- Spill kits are to be available in clinical areas where hazardous or cytotoxic medicines are administered.



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- For parenteral anticancer medicines:
  - facilities are to use 'smart pumps' with drug error reduction software where possible that defaults to the safest setting for administration unless infusion via gravity is required
  - extravasation and anaphylaxis kits are to be available in clinical areas where parenteral anticancer treatment is administered where appropriate
  - the following assessments are to occur and documented prior to the administration of parenteral anticancer medicines:
    - a clinical assessment before each treatment. For example, [eviQ Anti-cancer drug patient assessment tool](#) or [eviQ Day of treatment \(DOT\) assessment tool](#) or [eviQ Immunotherapy patient assessment tool](#) are available for this purpose
    - a final check of the protocol, scheduling, and medicines. For example, [eviQ Anti-cancer drug administration time out checklist](#) is available for this purpose.
- For oral anticancer medicines:
  - for oral anticancer medicines administered as an inpatient, anticancer drug patient assessment tool and time-out checklist is to be completed on Day 1 of each cycle. Facilities are to establish guidelines on administration requirements for subsequent days of treatment
  - oral cytotoxic medicines must not be broken, cut, or crushed by administering clinicians. If the patient is unable to swallow, contact the prescriber and Pharmacy Department for advice.

### **Patient information/education**

- Facilities are to clearly define who is responsible for the provision of patient education.
- Patients and/or their carers are to be provided with the below information during education (for example, [eviQ Anti-cancer drug patient education checklist](#) or [Children's Oncology Group Medical Information](#) is available to facilitate education):
  - verbal and written education ahead of their first treatment. For example, a copy of the NSW Cancer Institute's eviQ treatment protocol or if using a non-eviQ protocol, the proposed protocol including the clinical rationale for its use. This includes:
    - their treatment plan outlining all medicines
    - instructions on how to take any medicines they are self-administering. For example, oral anticancer medicines and anti-nausea medicines
    - expected adverse effects (short and long term)
    - side effect management

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- whom to contact in the event of an emergency or severe adverse event.
- information regarding recognition of treatment-related emergencies and provision of immunotherapy or febrile neutropenia alert cards where appropriate
- education on the importance of follow-up medical appointments and tests
- education on the safe handling, storage and disposal of hazardous medicines and waste management at home
- information regarding their responsibilities and actions with their central venous access device where appropriate
- education on fertility, fertility preservation and contraception where appropriate.
- Patient and/or their carers comprehension of education is to be checked by the clinician providing education. Methods for achieving this may include the [Teach Back method](#).
- Documentation that patient education is to occur.
- Patients and/or their carer are to be informed and re-educated when their treatment plan changes. For example, protocol or dose modifications.
- Patients and/or their carer's knowledge regarding, and adherence to, their oral anticancer medicines are to be checked at each visit.
- Professional Health Care Interpreters are to be utilised for patient and/or carers who are not fluent in English or who are Deaf.

### Staff education

- All clinicians involved in the prescribing, clinical verification, dispensing, and administration of anticancer medicines are to receive adequate education and be deemed competent to ensure they can perform the functions within their scope of practice. It is recommended:
  - all pharmacy staff verifying anticancer medication orders are to have successfully completed the Pharmacy Antineoplastic Drug Administration Course developed by the Cancer Institute NSW (available via [eviQ Education](#)) or completed specific sections relevant to their scope of practice
  - all staff administering anticancer medicines are to have successfully completed the Antineoplastic Drug Administration Course (ADAC) developed by the Cancer Institute NSW (available via HETI or [eviQ Education](#)) or completed specific sections relevant to their scope of practice (for example, modules 1 and 6 for oral anticancer medication administration)
  - all staff involved in compounding anticancer medicines are to undergo training as outlined in the NSW Health Policy Directive *Preparation of Pharmaceutical and Advanced Therapeutic Products* ([PD2023\\_021](#)).

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- Reassessment of competency is to be completed periodically (at a frequency determined by local governance models).
- All staff are to have access to up-to-date information and resources to support the safe prescribing, dispensing, and administration of anticancer medicines.
- All staff involved in prescribing, dispensing, and administration of oral anticancer medicines are to be trained to assist patients and/or carers with issues on adherence, toxicity management and safety issues in the home setting.
- Medical and nursing staff are to be trained in identifying appropriate vascular access options for anticancer medication protocols.
- All staff administering parenteral anticancer medicines are to be assessed as competent to identify and manage extravasation and hypersensitivity reactions.
- It is recommended all staff (clinical and non-clinical) involved in the handling, storage, transport, dispensing and administration of anticancer medicines or related waste are to receive education on personal protective equipment, waste management, cytotoxic spills and clean-up procedures. My Health Learning modules are available on [HETI](#) and [eviQ Education](#) for this purpose.
- All staff using Oncology Information Systems are to receive appropriate orientation and training. Local policies are to inform the need for a formal competency assessment.

### Health monitoring

- Facilities are to ensure appropriate health monitoring for staff involved in the handling of cytotoxic medicines and related waste. This is to be in accordance with Safe Work NSW [Cytotoxic Drugs and Related Waste – Risk Management](#).

### Use of Oncology Information Systems

- A multidisciplinary committee is to oversee the local electronic Oncology Information System to ensure all stages of implementation and maintenance are safely managed.
- The roles and responsibilities of all staff involved in the use and management of electronic systems are to be well defined.
- All Oncology Information Systems must meet the criteria outlined in the NSW Health Policy Directive *Electronic Medication Management System Governance and Standards* ([PD2019\\_050](#)).
- Clear processes are to be in place surrounding the approval of new protocols and the ongoing maintenance of existing protocols (with a regular review process established).
- Where multiple Medication Management systems are in use (for example, paper based with electronic), facilities are to have:

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- clearly documented guidelines that ensure consistent charting practices between practitioners to reduce the risk of duplicate orders or omission of medications for inpatients, outpatients and at transfers of care
  - a prompt placed within the primary electronic Medication Management (eMM) system alerting clinicians that the patient has active medication orders in a separate system (for example, Oncology Information System or paper chart) where possible
  - all staff are to be educated on the need for medication reconciliation between the Medication Management systems.
- Clear procedures about the rescheduling of treatment cycles within Oncology Information Systems when anticancer treatment is delayed, omitted or ceased are to be in place.

### ***Intrathecal anticancer medicines including intraventricular administration via Ommaya reservoir***

- A local protocol is to be in place which outlines roles and responsibilities for prescribing, dispensing and administration of intrathecal medicines within each facility. This protocol is to include specific training and competency assessments for each step.
- A register of staff accredited to prescribe, dispense and administer intrathecal anticancer medicines are to be kept by each facility or group of facilities.
- All staff responsible for prescribing, dispensing, and administering intrathecal medicines are to be aware of the catastrophic outcomes associated with the incorrect administration of certain anticancer medication agents via the intrathecal route.
- All intrathecal medicines are to be isotonic and free from preservatives.
- Intrathecal medicines are to follow all other safety procedures outlined in this standard including the completion of a drug administration time out checklist.
- Procedures are to be in place to segregate medicines administered by the intrathecal route from all other anticancer medicines given by other routes during dispensing, transport, storage, and administration. For example, the pharmacy requires confirmation from the clinician that intrathecal administration has been completed prior to releasing intravenous anticancer medicines for the same patient due on the same day (or vice versa).
- Administration of intrathecal medicines via lumbar puncture are only to be performed by a medical officer or other clinician deemed appropriate as per local policy.

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