Northern Cancer Alliance

Policies and Procedures

Standards for the Safe Use of Oral Anticancer Medicines

Contents

1 Introduction

1.1 Healthcare organisations are required to have local policies and procedures that describe the safe use of oral anticancer medicines following an alert from the National Patient Safety Agency (NPSA) in 2008. Whilst the NPSA no longer exists to issue new guidance the oral anticancer medicines standards are still relevant and must still be followed.

1.2 Standards for dealing with all adult systemic therapy chemotherapy are clearly defined in the NHS Cancer Standards. The overriding principle of this document is that oral anti-cancer medicines are managed to at least the same standards as IV anti-cancer medicines.

1.3 This document outlines the standards to be followed by all organisations and staff involved in the prescribing, dispensing, supply, administration and monitoring of the use of oral anticancer medicines in the Northern Cancer Alliance (NCA). This includes all secondary care, primary care and the independent sector.

1.4 This guidance should be available to all staff involved with receipt, storage, transport and disposal of oral anticancer medicines as well as those who prescribe, prepare, dispense or administer them.

1.5 Trusts within the Northern Cancer Alliance are expected to comply with these standards. Any deviations must be recorded via the Trust's Risk Management Process. Following the issuing of these standards Trusts will be peer reviewed to assess compliance by the Network Team.

1.6 **Definition**

For the purposes of this document the term "Oral Anticancer Medicine' is used to refer to all drugs with direct anti-tumour activity, orally administered to cancer patients, including traditional cytotoxic chemotherapy such as capecitabine, hydroxycarbamide, chlorambucil and small molecule/ antibody treatments such as imatinib, erlotinib, sunitinib and other agents such as thalidomide or lenalidomide. It does not include hormonal or anti-hormonal agents such as tamoxifen and anastrazole but does include Abiraterone and enzalutamide.

2 Scope of Document

2.1 This policy must be used in conjunction national chemotherapy standards as detailed in the Quality Surveillance Team (QST) website, see https://www.qst.england.nhs.uk/

2.2 This Alliance policy must be used in conjunction with local Trust Medicines Policies and Cytotoxic/ Anticancer medicines policies.

2.3 Acknowledgement must be given to the Scottish Executive 'Guidance For The Safe Use Of Cytotoxic Chemotherapy' HDL 2005(29)

2.4 It must be noted that some oral anticancer medicines are also used for non-cancer indications, e.g. methotrexate for rheumatoid arthritis, and pose similar risks to the patient. The NPSA recommends organisations to undertake a risk assessment and their guidance applied as appropriate. NCA advises the same approach for the application of these standards for non-cancer patients.

2.5 There are many non-cancer drugs designated as high risk for hospital use only, the so called 'red' drugs, which may also benefit from application of some of the standards in this document.

3 PRESCRIBING OF ORAL ANTICANCER MEDICINES

Standard Details and Demonstration of Compliance	
3.1	**Oral Same Standards as IV** The prescribing of oral anticancer medicines is carried out and monitored to the same standards as those for parenteral (IV) chemotherapy.
Compliance	Examine prescriptions, patient's records and peer review evidence.
3.2	**Clinical Lead** Each organisation to nominate a clinical lead for oral anticancer medicines. *Note*: This should be the same person who is responsible for IV chemotherapy to ensure consistency of standards. The clinical lead must work with Trust Management, Lead Clinician for Cancer, Chemotherapy Lead, Head of Pharmacy and Lead Cancer Nurse to ensure these standards are enforced.
Compliance	Lead to be identified.
3.3	**Prescribing Policy** Organisations have in place policies covering all aspects of prescribing oral anticancer medicines. The policies to include: • Who can prescribe • Use of electronically generated prescriptions • Reference to IV standards
Compliance	Examine Policy
3.4	**Who can prescribe** Prescribing of the first cycle of oral anticancer medicines is undertaken by either a haematologist or oncology specialist at Consultant/ SAS/SPR level or Non-Medical prescriber who has demonstrated competency
Compliance	Examine prescriptions and patients' records.
3.6	**Primary Care Prescribing** Prescribing oral anticancer medicines in primary care must only be undertaken within agreed cross boundary guideline (shared care) or an agreed framework of safe practice. The local clinical lead for oral anticancer medicines must be involved in the approval of guidelines. Good practice would be for any shared care guidelines to consider the following areas • assessment of patient's suitability to self-administer • assessment of patient's home environment for suitability • arrangements for pharmacist prescription verification • dispensing arrangements • Prescription authorisation, i.e. assessing if patient is fit to receive treatment and checking of blood counts (critical tests) before admin • delivery, storage and disposal arrangements, • managing side effects and/or adverse events • emergency contact(s) and follow up arrangements
Compliance	Copy of any guidelines examined.

3.7 Initiating treatment

All prescribers initiating treatment for oral anticancer medicines must:

- assess the patient's suitability for oral treatment including ability to swallow tablets or capsules
- assess patient's ability to comply with the proposed drug/ regimen
- Obtain consent from the patient following local Trust protocol
- provide verbal and written information about their oral anticancer therapy (this information should include contact details for specialist advice)
- ensure appropriate communication to patient's GP and referring consultant about the medicines, ensuring the GP is clear on the role they play in managing patient. *note*: caution must be taken if trusts issue a copy of 'prescriptions' to GPs as there is a risk of inappropriate continuation of medicine. It must be stated on any written communication that 'This medication is NOT for continuation by primary care'
- ensure patients are appropriately counselled on the use of their medicines. *note* this information may be provided/ reinforced by pharmacist /nurse according to local policy.

Note: Good practice would be to ensure all these checks have been undertaken on second and subsequent cycles.

Compliance Examine policy documents and patients records

3.8 Inpatient Prescribing (On Admission)

3.8.1 Patients admitted to hospital wards on oral anticancer medicines are at risk from uncontrolled prescribing. A detailed medication history must be taken on admission, including:

- indication for oral anticancer therapy
- drug(s) and dose(s), frequency of administration, e.g. daily, weekly, continuous or cyclical
- intended start date, duration of treatment, intended stop date for each cycle of treatment and date of next cycle
- any supportive medications, e.g. anti-emetics

Note where possible a copy of the original prescription for oral anti cancer medicine should be obtained.

3.8.2 The patient's original prescriber should countersign the drug Kardex (if they are available) or clinical staff must contact the prescriber to confirm medication history.

3.8.3 If the original prescriber is not available or cannot be contacted the oral anticancer medicine must be not be prescribed/ administered until it is confirmed that it is clinically appropriate and safe to do so.

3.8.4 If the original prescriber is not available, the oral anticancer medicine must be **only be** prescribed by an appropriately qualified and experienced member of the medical team. This must be defined locally in each Trust following appropriate governance procedures. It is suggested the clinical lead for oral anticancer medicines and the local chemotherapy group are involved in this decision.

3.8.5 The patient's current medical condition must be assessed to ensure suitability for continued treatment with the medicine.

	3.8.6 Where possible, the patients own medication should be utilised for the remainder of the cycle, thus minimising the risks associated with prescribing inappropriate / incorrect dose or duration of treatment. 3.8.7 All inpatient prescriptions for oral anticancer medicines must be checked by an oncology trained pharmacist. 3.8.8 On discharge the oral anticancer medicine must be prescribed as in 3.8.3 above and must be double checked to ensure the intended duration of treatment, including any stop dates is correct. Junior doctors (SHO/equivalent or lower) must **not** prescribe.
Compliance	Examine policy documents and patients records
3.9	**Inpatient Prescribing (New Patients)** Inpatient prescribing for new patients must be to same standards as prescribing for day case and out-patients and must only be initiated by those prescribers defined in section 3.4
Compliance	Examine prescribing policy
3.10	**Prescribing for External Healthcare Organisations** All prescribers who write prescriptions for oral anticancer medicines for patients who will have the medicines administered in organisations external to their Trust, e.g. nursing homes, prisons, children's homes must ensure that the external organisation has access to the specified regimens and protocols as detailed in standards 3.11 & 4.2. In the case of organisations such as prisons where medications are re-prescribed by the prison's medical officer in accordance with their own procedures it is recommended that the organisation ensures regimens and protocols are always obtained before re-prescribing. Note: Good Practice could be to ensure the external organisation has a copy of these standards.
Compliance	Use of documentation in external organisation checked
3.11	**Prescribed in context of a written protocol** Written regimen protocols must be available for all oral anticancer medicines. These can be paper-based or within an electronic prescribing system. The protocols must be consistent with the Network and Children's Cancer and Leukaemia Group (CCLG) agreed regimens. Good practice would be for a copy of the specific protocol to be filed in the patient's notes. Copies of protocols should be available on all wards where oral anticancer medicines are routinely administered or where patients receiving oral anticancer medicines may be admitted (e.g. emergency admissions wards). Protocols must contain: • definition of the clinical condition being treated • names (approved) of all medicines to be given • dosing schedule for each medicine • maximum individual dose where applicable • maximum cumulative doses where applicable • supportive therapy • any tests that need to be performed before chemotherapy starts and during treatment • special precautions, expected toxicities and contraindications

	• potential interactions and medications to be avoided • recommendations for dose modifications • review period • reference source(s)
Compliance	Examine protocols
3.12	**Availability of specified regimens /protocols** • Prescribers must have access to the agreed drug protocols for the regimens in use. The BNF is **not** recommended as a primary source of anticancer drug prescribing information. Links to chemotherapy regimen protocols can be found on the Northern Cancer Alliance webpages http://www.necn.nhs.uk/networks/cancer-network/expert-reference-groups/nccg-chemotherapy-group/chemotherapy-docs-protocols/
Compliance	Check availability in areas oral anticancer medicines prescribed.
3.13	**Treatment Review** The planned course of treatment and arrangements for review /follow up are recorded in the patient's notes and a review date set.
Compliance	Examine patient's notes
3.14	**Deviation from agreed protocols** All intended deviations from protocol, such as dose modifications, should be clearly identified as such and recorded in patient's notes, on the prescription form and communicated to the patient's GP and referring consultant. Pharmacy must be notified.
Compliance	Examine protocols, check patient notes
3.15	**Repeat prescription.** Oral anticancer medicines must not be prescribed by repeat prescriptions.
Compliance	Examine protocols, check prescription forms
3.16	**Prescription Forms** All prescriptions for oral anticancer medicines **MUST** be computer-generated using regimens from the Network agreed list. This must be via a chemotherapy electronic prescribing system. Any printed paper copies of the electronic prescription form must be clear and unambiguous and available to all prescribers.
Compliance	Check prescription forms

4 DISPENSING AND SUPPLY OF ORAL ANTICANCER MEDICINES

Standard Details and Demonstration of Compliance	
4.1	**Oral Same Standards as IV** Trust pharmacy departments dispensing oral anticancer medicines should operate to the same safety standards used when preparing and dispensing parenteral (IV) chemotherapy.
Compliance	Examine Policies and procedures,
4.2	**Availability of specified regimens /protocols** Pharmacy staff must have access to the agreed list of regimen protocols for the regimens in use. Note: the BNF is not recommended as a primary source of anticancer drug prescribing information. See 3.13 above. Check availability in areas oral chemotherapy prescribed.
Compliance	
4.3	**Prescription verification standards** All prescriptions for oral anticancer medicines must be checked and authorised by an appropriately experienced pharmacist, ideally a trained oncology pharmacist (see 4.6 below). NCA pharmacists have agreed to follow the National 'Standards for Pharmacy Clinical Verification of Cancer Medicines' produced by BOPA, British Oncology Pharmacy Association and the associated competencies for verification available at www.bopawebsite.org
Compliance	Examine dispensary procedures and check dispensed prescriptions
4.4	**Computer Generated Prescriptions** All prescriptions for oral anticancer medicines **MUST** be computer-generated (standard 3.16 above). Pharmacists must not accept paper prescriptions not generated by the electronic chemotherapy prescribing system or handwritten on out-patient prescription pads.
Compliance	Examine prescriptions
4.5	**Pharmaceutical Care Plans** Where practical pharmaceutical care plans should be put in place to identify the key issues that need to be monitored with the oral anticancer medicine/ regimen.
Compliance	Examine care plans
4.6	**Training Requirements for Pharmacy Staff** It is recognised that it may not be possible to ensure that all oral prescriptions are checked by a trained oncology pharmacist. Trusts must therefore ensure that appropriate training on the safety aspects of oral anticancer medicines is provided to pharmacy staff involved in dispensing and supply of these medicines. This must be undertaken as part of induction process for new staff and repeated every two years for all staff involved in dispensing and supply of oral anti-cancer medicines.
Compliance	Examine training records and dispensary procedures

4.7 **Access to Oncology Pharmacy Advice**

In order to support staff involved in the dispensing and supply of oral anticancer medicines, there must always be available in the organisation a trained oncology pharmacist who is able to provide oncology pharmacy advice to dispensary staff.

Note: Trained oncology pharmacists are those who are deemed competent to check and authorise IV chemotherapy prescriptions and are competent to provide pharmaceutical care to cancer patients and comply with local training standards based upon the BOPA verification standards associated guidance and competencies. www.bopawebsite.org

Examine training records and dispensary procedures

Compliance

4.8 **Dispensary Standards**

4.8.1 Pharmacists verifying oral anticancer medicine prescriptions should ensure the exact amount (number of tablets/capsules) to be supplied is clear from prescription.

4.8.2 The verifying pharmacist must ensure the directions on the prescription are clear and unambiguous and include, where relevant; the duration of treatment; start and stop dates for short term or intermittent treatment.

4.8.3 The exact quantity of tablets/capsules required must be supplied unless a risk assessment of a particular drug pack size/type identifies it as not suitable to be split. The quantity calculated by the pharmacist must be subject to a second independent check during the dispensing process. Wherever possible only packs that can be safely split will be purchased.

4.8.4 The quantity must be physically checked by counting the number of number of tablets/capsules supplied.

4.8.5 A different member of staff should final check the prescription from pharmacist who verified the prescription. Ideally the dispensed prescription should be subject to a second independent check

4.8.6 All patients must receive a manufacturer's Patient Information Leaflet, with their oral anticancer medicines.

4.8.7 Pharmacy staff must not break or crush tablets, capsules must not be opened. Queries about difficulties in taking the oral form should be directed to a specialist pharmacist. Use of a suspension or solution is preferred and a suitable preparation must be obtained from an NHS hospital pharmacy or commercial compounding/manufacturing facility with appropriate safe-handling facilities. It must be noted that in many cases there are no liquid alternatives, in these cases refer back to original prescriber.

4.8.8 Use of compliance aids is not routinely recommended. If there is thought to be a need a risk assessment must be undertaken and documented in the patient's notes.

4.8.9 Label directions must be clear and unambiguous and include where relevant; the intended period of treatment; start and stop dates or the number of days expressed as **'for X days ONLY'** to indicate that the medicine is not continuous (for short term or intermittent treatment); an appropriate indication of the need for safe handling. Any ambiguities must be referred back to the verifying pharmacist.

Compliance Examine pharmacy procedures

4.9	**Supply to inpatients** Where possible patient's own medicines must be used (see 3.8.5). Temporary stocks must **not** be used. All anticancer medicines must be dispensed and labelled to include the following information: • patient name • generic drug name • strength of tablets or capsules, or concentration of oral liquid • the number of tablets / capsules in the container, or volume of liquid • administration instructions • length of treatment, including stop date as appropriate • storage conditions • Caution: Cytotoxic Drug (as appropriate) • name and address of pharmacy department N.B. Patients should be advised to return any unused oral anticancer medication that they may have at home.
Compliance	Check supplied medicine on inpatient wards
4.10	**Supply to External Healthcare Organisations** Trusts supplying oral anticancer medicines to external organisations who will take responsibility for administering the medicines, e.g. nursing homes, prisons, children's homes must ensure that the medicines are labelled as in 4.8 above and the external organisation has access to the specified regimens protocols (3.10,4.2). Prescribers are responsible for ensuring pharmacies supplying the medicines know the medicines will be administered in an external organisation.
Compliance	Pharmacy to keep records of external organisations supplied.
4.11	**Primary Care Dispensing** Oral anticancer medicines MUST ONLY be dispensed by community pharmacies once an appropriate framework has been developed to ensure the principles and safety standards outlined in this document are met. Areas for consideration in the framework include: • suitability of drug/regimen, i.e. assessment of potential toxicity of the drug(s) and complexity of the regimen (more than one drug, pulsed schedule, variable dose) • availability of drugs (wholesaler or direct) • origin of prescription, primary or secondary care (the use of FP10 or FP10-HP prescriptions may be a barrier to the recommendation for regimen specific electronically generated prescriptions) • requirement for specialist clinical oncology pharmacy advice • training requirements for primary care pharmacists • remuneration issues • handling and disposal of cytotoxic drugs (COSHH) • out of hours support Trusts required to declare if dispensing for their cancer patients is undertake in primary care and provide evidence of their framework e.g. Service Level Agreements..
Compliance	

4.12 Medication Counselling/ Informational Care

4.12.1 When pharmacy staff and other healthcare professionals supply the oral anticancer medicine to the patient (or relative or carer) they must ensure that the person receiving the medicines fully understands how and when to take their medicines.

4.12.2 The member of pharmacy staff handing the drugs to the patient must also ensure the patient understands:

- what to do in the event of missing one or more doses
- what to do in case of vomiting after taking a dose
- likely adverse effects and what to do about them
- any need for and how to obtain further supplies
- the role their GP is expected to play in their treatment
- The need to inform their health care team if they are taking any over the counter medications/ supplements.
- principles of safe handling, storage and disposal
- that if used, medicine spoons or measures should be used once only and then disposed of safely
- any drug specific advice regarding safely crushing of tablets or opening of capsules.

4.12.3 Pharmacy departments must document which member of staff hands medicines to patients.

4.12.4 It is recognised that, in practice, most of the information may be provided by the consultant/ specialist nurse in clinic or by the pharmacist on the oncology ward. If the patient is not provided with this advice in clinic or on the ward pharmacy staff responsible for cancer services must ensure that systems are in place to provide the advice at the point of dispensing.

4.12.4 Oral anticancer patients must be able to access the same 24 hour telephone advice service provided for IV chemotherapy patients

4.12.5 Patients must be provided with the same patient held record document used for IV chemotherapy patients

4.12.6 The patient's 'key worker' must be identified to the patient.

4.12.7 Trusts must consider what action to be taken if after counselling the patient on their medication it becomes apparent that the patient does not understand how to take the medicines or will have difficulty in compliance.

Compliance Examine Pharmacy procedures.

5 ADMINISTRATION AND HANDLING OF ORAL ANTICANCER MEDICINES

Standard Details and Demonstration of Compliance	
5.1	**Oral Same Standards as IV** The administration of oral anticancer medicines on Trust premises is carried out and monitored to the same standards as those for parenteral (IV) chemotherapy.
Compliance	Examine prescriptions, patient's records and peer review evidence.
5.2	**Responsibility for Administration** 5.2.1 Administration of oral anticancer medicines on Trust premises on oncology/ haematology wards must be undertaken by appropriately qualified clinical staff who are competent to follow the same safeguards and checks as when administering IV anticancer medicines. 5.2.2 Clinical staff administrating oral anticancer medicines on non-oncology/ haematology wards to inpatients must contact members of the patient's specialist team for information and advice about the oral anticancer medicine (See Standard 3.8) 5.2.3 Two practitioners are required to check and administer oral anticancer medicines. Trusts' administration of medicines policies must be followed. 5.2.4 Trusts must keep a record of which members of staff are able administer oral anticancer medicines. 5.2.5 Staff administering oral anticancer medicines must have access to the specified regimens protocols (3.10 & 4.2). 5.2.6 When patients are self administering their oral anticancer medicines, the responsibility for administration lies with the patient and their carer. The health care professional's role is to support patients.
Compliance	Examine Policies and Procedure, check patient's records
5.3	**Pre-Treatment Review** Before oral anticancer medicines are administered on Trust premises the patient must be clinically reviewed by an appropriately qualified and competent clinical staff member who will: • ensure that the patient's is medically fit for ongoing treatment. • check results of all investigations, blood parameters and specific drug calculations specified within the treatment protocol / local guidelines. • document the administration of the medicine(s) in the patient's medical notes and patient held records (if used). • In the case of inpatients receiving their medications over a period of days the above checks must be done before the first dose is given in hospital and then regularly during treatment according to the parameters specified in the written protocol (standard 3.11)
Compliance	Check patient records
5.4	**Dealing with Waste / Unused Medication** 5.4.1 Clinical staff administering oral anticancer medicines to patients in Trust premises must be familiar with the Trust's procedures for safe handling of cytotoxic medicines and disposal of waste. 5.4.2 Patients must be given advice on how to safely store their oral anticancer medicines and told how to return unused medicines for disposal.
Compliance	Examine Policies and Procedures

6 Governance, Quality and Risk management

Standard Details and Demonstration of Compliance	
6.1	**Responsibility for Safe Use of Oral Anticancer Medicines** The responsibility for safe use of oral anticancer medicines and implementation of these standards must lie either with the Head of Cancer Services or Head of Medicines Management for each organisation.
Compliance	Responsible person identified
6.2	**Internal Audit** Organisations should consider auditing both the adherence and application of these standards to ensure the policy is still relevant to the service provided.
Compliance	Audit records examined
6.3	**Errors reporting** Organisations must ensure they have robust system for recording clinical incidents and near misses with oral anticancer medicines and must ensure they report all incidents to the Network. It is recommended that incidents be reported using the existing clinical governance framework to the relevant network clinical groups, cancer managers group and pharmacy groups and then subsequently discussed at Network board.
Compliance	Examine incident reporting for relevant examples

7 Document Control

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Author:	Steve Williamson	**Current Version:**	1.8
Approved by:	Chemotherapy Group	**Reviewed By**	Chris Beck
Due for Review:	January 2020	**Issue Date:**	January 2018
Summary of Changes			
1.21	Added in documentation control section prior to issuing		
1.3	Updated and re-numbered introduction section to reference final publication of NPSA alert on 22nd Jan 08. Updated sections: 3.4 added comment re competency and replaced staff grades with term SAS; 3.5 clarified types of NMPs; 3.8.2 'must' change to 'should'; 3.8.3 new point added suggesting not to prescribe until confirmed as appropriate:3.8.4 clarified how to make decision on appropriate prescribers; 3.8.8 clarified junior doctor grade; 3.10 expanded; 3.11 added reference to CCLG protocols; 3.12 added links to network protocols; 3.16 'long hand' changed to 'words and figures';4.6 & 4.8.4/5/6 & 4..8.7 wording amended to improve clarity;4.9 added comment on temp stocks; 4.12.2 added comment on crushing tablets; 4.12.7 wording amended to improve clarity.		
1.4	Updated after review date: minor changes 3.6 added 'an agreed framework of safe practice as an alternative to shared care 2.4, 3.12, 4.2 update web links, 4.3 and 4.7 changed pharmacy verification standards Updated pharmacy sections wording validate replaced with verity 6.2 & 6.3 updated audit section and added web link for audit form.		
1.5	Updated review date		
1.6	General updates too introduction, removal of standard 6.3 external audit by NECN, removal of reference section, appendix one pre-printed prescription examples and appendix two care plan		
1.7	Updated review date, Network website links and number		
1.8	Updated review date & version number. Rebranded to NCA, various changes to reflect use of electronic prescribing systems.		