ORAL ANTI-CANCER THERAPY POLICY

Policy Type	Clinical
Directorate	Acute
Policy Owner	Chief Operating Officer Acute and Ambulance
Policy Author	Lead Oncology Pharmacist
Next Author Review Date	1st August 2021
Approving Body	Corporate Governance & Risk Sub-Committee 11th April 2017
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Policy Valid from date	1st April 2017
Policy Valid to date:	31st January 2022

'During the COVID19 crisis, please read the policies in conjunction with any updates provided by National Guidance, which we are actively seeking to incorporate into policies through the Clinical Ethics Advisory Group and where necessary other relevant Oversight Groups'

DOCUMENT HISTORY

(Procedural document version numbering convention will follow the following format. Whole numbers for approved versions, e.g. 1.0, 2.0, 3.0 etc. With decimals being used to represent the current working draft version, e.g. 1.1, 1.2, 1.3, 1.4 etc. For example, when writing a procedural document for the first time – the initial draft will be version 0.1)

Date of Issue	Version No.	Date Approved	Director Responsible for Change	Nature of Change	Ratification / Approval
March 2012	1.1	July 2011	Executive Medical Director	Logo and wording updated for new organisation	
Sept 2013	1.2		Executive Medical Director	Put into trust format due to demise of CSCCN and updated	
Dec 2013	1.3		Executive Medical Director	Ratified at	Clinical Chemotherapy Group
Jan 2014	2.0	21 Jan 2014	Executive Medical Director	Approved at	Policy Management Group
Nov 2016	2.1				Updated to include new terminology and remove sections applicable only to Primary Care
27 Jan 2016	2.1		Executive Medical Director	For ratification	Clinical Standards Group
11 April 2017	3.0	11 Apr 17	Executive Medical Director	Approved at	Corporate Governance & Risk Sub-Committee
26th March 2020	3.0	11 Apr 2017	Executive Medical Director	Extension to review date approved via chairs action at	Policy Management Sub-Committee
1st Dec 2020	3.0	11 Apr 2017	Executive Medical Director	Extension to review date approved by	Policy Lead Director – Medical Director
29 Jan 2021	3.0	11 Apr 2017	Chief Operating Officer Acute and Ambulance	12 month blanket policy extension due to covid 19 applied with author review date set 6 months prior to Valid to Date.	Quality & Performance Committee
19 May 2021	3.0	11 Apr 2017	Chief Operating Officer Acute and Ambulance	Extended policy uploaded and linked back with new cover sheet	Corporate Governance

NB This policy relates to the Isle of Wight NHS Trust hereafter referred to as the Trust

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1 Executive Summary

This policy describes the Trust's approach to the safe prescription of oral anti-cancer treatments, in accordance with the National Patient Safety Agency (NPSA) Rapid Response Report NPSA/2008/RRR001. 'Risks of Incorrect Dosing of Oral Anti-cancer Medicines (2008)'.

The policy applies to all prescriptions for oral anti-cancer medicines prescribed, administered or dispensed by trust staff.

2 Introduction

2.1 The treatment of cancer involves the administration of systemic cytotoxic and cytostatic agents (known as systemic anti-cancer therapy or SACT). Many of these therapies are associated with specific requirements safe handling by staff and for the safe monitoring of patients

2.2 Traditionally most agents have been administered parenterally. The prescribing, dispensing and administration of such agents has, therefore, largely taken place in specialised facilities by specialised staff well versed in the complexity of delivering a safe service for patients and healthcare workers.

2.3 Orally administered–anti-cancer agents are now in routine use in clinical practice. Their use is increasing and horizon scanning indicates that this increase is likely to continue. For the purposes of this document oral anti-cancer therapy is defined as all drugs with direct anti-tumour activity that are administered by mouth for the treatment of cancer. It encompasses targeted therapies such as the tyrosine kinase inhibitors, newer hormonal treatments such as Abiraterone, but excludes older hormonal treatments such as Tamoxifen for breast cancer.

2.4 Oral anti-cancer therapy is associated with a similar spectrum and severity of adverse effects as those associated with intravenous treatment.

2.5 Orally administered agents do not require specialised facilities for the dispensing or administration of treatment. There is the potential for oral anti-cancer therapy to be prescribed and dispensed by non-specialised staff, without reference to the safeguards developed for intravenous anti-cancer treatment.

2.6 For the period between November 2003 and July 2007 The National Patient Safety Agency (NPSA) received three reports of death and a further four hundred patient safety incidents in relation to oral cytotoxic therapy. This led to the publication of the NPSA Rapid Response Report on the "*Risks of Incorrect Dosing of Oral Anti-cancer Medicines"*.

2.7 This policy was developed to comply with the NPSA directive.

3 Definitions

3.1 Oral Anti-Cancer Therapy

All drugs with direct anti-tumour activity that are administered by mouth for the treatment of cancer (oral anti-cancer agents).

It encompasses targeted therapies such as the tyrosine kinase inhibitors, and newer targeted hormonal agents such as Abiraterone, but not traditional hormonal or anti-hormonal agents.

3.2 SACT

Systemically administered anti-cancer treatment - includes all injected and oral anti-cancer therapy.

4 Scope

4.1 It is expected that all staff will comply with this policy.

4.2 This policy must be available to all staff involved with the receipt, storage, transport and disposal of oral anti-cancer therapy as well as those who prescribe, prepare, dispense and administer and advise on such treatments. This refers to healthcare staff in the community and acute setting.

4.3 This policy is applicable to all situations where oral anti-cancer therapy may be used in the cancer setting.

4.4 This policy must be used in conjunction with the following trust policies:

- Medicines policy
- Chemotherapy services operational policy

4.5 It should be noted that some oral anti-cancer therapies are prescribed in non-cancer indications. An example is methotrexate for rheumatoid arthritis. These pose similar risks to patients. Staff are encouraged to apply the standards outlined in this policy to these disease areas where appropriate.

5 Purpose

The purpose of this document is to ensure that oral anti –cancer therapy is safely prescribed, dispensed and administered in accordance with current best practice, described in the NPSA Rapid Response Report NPSA/2008/RRR001. “Risks of Incorrect Dosing of Oral Anti-cancer Medicines (2008).

6 Roles and Responsibilities

6.1 The Chief Pharmacist responsible for ensuring that all doctors, nurses and Pharmacy staff are aware of the risks associated with prescribing oral anti–cancer therapy.

6.2 The Clinical Chemotherapy Group is responsible for keeping a register of approved SACT prescribers.

6.3 All Doctors and Non-Medical Prescribers are responsible for complying with this policy and refraining from prescribing oral anti-cancer therapy for outpatients, unless their name is included in the list of SACT prescribers held by the Clinical Chemotherapy Group.

6.4 All Pharmacists are responsible for identifying prescriptions for oral anti-cancer therapy and ensuring they are prescribed and screened safely, according to this policy.

6.5 All Nurses are responsible for ensuring that oral anti-cancer therapy is correctly identified and safely administered according to this policy.

7 Policy Detail/Course of Action

7.1 Prescribing

All oral anti-cancer therapy should be prescribed according to a written protocol.

The protocol should contain as a minimum;

- indication(s)
- drug
- dose (including a maximum cumulative dose if required)
- route
- cycle length and frequency
- duration of treatment
- monitoring requirements
- requirements for dose adjustments

All protocols should be readily available to all healthcare staff, irrespective of their occupation, place of work or the time of day. Protocols developed by the group of hospitals which previously made up the Central South Coast Cancer Network should be used. These are available via a link from the trust electronic prescribing system for oncology, or directly from the Southampton hospitals extranet site:
http://www.uhs.nhs.uk/HealthProfessionals/Extranet/Services/Cancer-care/Chemotherapy-protocols/Chemotherapy-protocols.aspx

All deviations from the protocol must be clearly recorded in the patient's notes and on the electronic prescribing system if appropriate.

If a suitable protocol is not available, the decision to initiate treatment must be undertaken by a consultant oncologist / haematologist, following discussion at the relevant multi-disciplinary team (MDT), and the Trust Oncology Pharmacist. . The decision and regimen must be recorded in the medical notes. Written consent should be obtained before treatment commences.

7.2 Outpatient Prescribing

Oral anti-cancer therapy may be prescribed by an oncology / haematology consultant, associate specialist, registrar or suitably qualified oncology / haematology non-medical prescriber, included in a list of approved SACT prescribers held by the Clinical Chemotherapy Group, once the decision to treat has been made and documented as in point 7.1.

All oral anti-cancer therapy must be prescribed within the context of a written protocol and treatment plan. Protocols developed by the group of hospitals which previously made up the Central South Coast Cancer Network should be used, as in section 7.1

All clinicians prescribing oral anti-cancer therapy must;

- assess the individual's suitability for systemic anti-cancer therapy
- assess the individual's ability to concord with treatment assess the patients home environment for suitability
- ensure consent is obtained before therapy is taken
- ensure suitable information is provided as detailed in section 7.9
- ensure communication to the general practitioner and / or referring doctor concerning the treatment plan. This should detail the role they play in providing therapy and a clear direction should be given as to whether the treatment is to be continued by the GP or remain the responsibility of the specialist centre.

7.3 Inpatient Prescribing

Inpatient prescribing for those starting a new treatment schedule should adhere to the same standards as described in 6.2

Individuals admitted to hospital wards already taking oral anti-cancer therapy are at risk from non-specialist prescribing. To reduce this risk, all prescriptions for oral anti-cancer therapy should be confirmed by an oncology / haematology consultant, associate specialist or, registrar within 48 hours of admission. It is safer to suspend treatment on admission until it can be confirmed as safe to continue.

The admitting doctor must ensure a detailed medication history is taken on admission including;

- indication for the oral anti-cancer therapy
- drug, dose, frequency of administration
- start and stop date for that cycle and duration between cycles
- supportive medications

Where possible a copy of the original prescription or protocol should be referred to.

The patient's own supply of medication should be used where possible. This minimises the risk of administration of an inappropriate dose or duration of treatment.

On discharge, the dose and duration of treatment (including a stop or review date) must be stated on the prescription. New courses must be prescribed as in 7.2 above. For completion of existing prescribed courses, the discharge prescription should be countersigned by an oncology / haematology consultant, associate specialist, registrar, non-medical prescriber or pharmacist.

No additional medication will be supplied on discharge for patients undergoing ongoing treatment, unless specifically requested by the oncology /haematology consultant.

7.4 External Organisation Prescribing

Prescribing for those receiving treatment in external organisations such as nursing homes or prisons should adhere to the same standards as described in 7.2

7.5 Primary Care Prescribing

Community prescribing for those starting a new treatment schedule should adhere to the same standards as described in 7.2

Prescribing of oral anti-cancer therapies remains the responsibility of the haematology or oncology consultant and should not be devolved to General Practitioners except under a specific and explicit shared care guideline. At the time of writing, no such guidelines are in place.

7.6 Prescription Forms

Wherever possible, oral anti-cancer therapy should be prescribed using the Trust's electronic prescribing system for oncology. In situations where this is not possible, the prescription should comply with an approved written protocol and contain the information listed below:

- patient details including name, date of birth, NHS / hospital number
- regimen name and indication
- height, weight and surface area (where appropriate)
- relevant treatment parameters e.g. neutrophil count, renal function
- drug name (generic and in full)
- dose (both as mg/m^2 and the calculated dose)
- number of days or doses to be dispensed
- intended start date and duration of treatment

7.7 Dispensing

It is recognised that not all prescriptions for oral anti-cancer therapy will be checked by an oncology trained pharmacist. However, all those involved in the supply of such medicines must have access to such an individual. The pharmacy department of the hospital where the treatment of the cancer is being undertaken should be contacted for advice.

Pharmacy staff must ensure the dose and duration of therapy is correct for the indication. This can be achieved by reference to the appropriate protocol or through discussion with a pharmacist with expertise in the treatment of cancer.

Pharmacy staff must ensure the patient is aware of the required monitoring arrangements as described in the protocol.

The exact number of dose units must be supplied to fulfil the course stated unless a risk assessment of a particular formulation states that it is not suitable to split, or if treatment is continuous and ongoing.

The prescription and dispensed item must be double-checked by a second individual. This must include a physical count of the amount of dose units dispensed.

A copy of the manufacturer's patient information leaflet must be supplied with all dispensed items.

Tablets must not be broken or crushed or capsules opened. Use of a liquid formulation is preferred. In children this may not always be possible. Administration difficulties should be directed to a specialist oncology pharmacist.

Use of compliance aids is not recommended. If there is a need for such aids a risk assessment must be undertaken.

Pharmacy staff must ensure patients or their carers are aware of the correct procedures for the supply and disposal of unused oral anti-cancer therapy.

Individuals admitted to hospital whilst taking a course of oral anti-cancer therapy should be encouraged to bring their supply with them for use. If not immediately available then a new supply may be made for the remainder of the course. The label must state this is a re-supply and the patient or carer should be counselled to return the medication at home to the hospital.

7.8 Administration

The administration of oral anti-cancer therapy on Trust premises must be conducted as described in the appropriate protocol. It must be undertaken by appropriately qualified clinical staff who must contact members of the specialist team for information and advice

Clinical staff administering oral anti-cancer therapy must be familiar with the local policy for the safe handling of anti-cancer medicines and if relevant, the disposal of cytotoxic waste.

7.9 Patient Information

Patients must provide informed, written consent prior to starting oral anti-cancer therapy.

Up to date written and verbal information must be provided. This information must contain the following details as a minimum;

- contact details for specialist advice
- regimen (drug(s) / dose / duration)
- monitoring requirements
- treatment plan

Information may also be included on adverse effects, actions to be taken where a dose is missed or vomiting occurs, supply routes and safe handling and disposal where appropriate.

8 Consultation

This policy was originally developed by the Pharmacists Group of the group of hospitals then known as the Central South Coast Cancer Network and approved by the Network Board.

The revised policy which simplifies the policy to exclude primary care, and updates the title, advice and wording to meet current standards and terminology, has been approved locally by the Clinical Chemotherapy Group.

9 Training

This Oral Anti-cancer Therapy Policy does not have a mandatory training requirement or any other training needs

10 Monitoring Compliance and Effectiveness

The policy will be monitored by the Clinical Chemotherapy Group, using Datix incident reports, which are considered by the group at monthly meetings, and pharmacy interventions, reported to the group by the Lead Oncology Pharmacist. If considered necessary, an audit of prescribing will be undertaken.

11 Links to other Organisational Documents

- Medicines Policy
- Chemotherapy Unit Operational Policy

12 References

British Oncology Pharmacy Association (2004). Position Statement on the Care of Patients Receiving Oral Chemotherapy. Pharm J 272, 422-423.

National Patient Safety Association (2008). Rapid Response Report. Risks of Incorrect Dosing of Oral Anti-cancer Medicines. NPSA/2008/RRR001.

13 Appendices

Appendix A

Financial and Resourcing Impact Assessment on Policy Implementation

NB this form must be completed where the introduction of this policy will have either a positive or negative impact on resources. Therefore this form should not be completed where the resources are already deployed and the introduction of this policy will have no further resourcing impact.

Document title	**Oral Anti-Cancer Therapy Policy**

Totals	**WTE**	**Recurring £**	**Non-Recurring £**
Manpower Costs	**0**		
Training Staff	**0**		
Equipment & Provision of resources	**0**		

Summary of Impact:

Risk Management Issues:

Benefits / Savings to the organisation:

Equality Impact Assessment

- Has this been appropriately carried out? YES
- Are there any reported equality issues? ~~NO~~

If "YES" please specify:

Please include all associated costs where an impact on implementing this policy has been considered. A checklist is included for guidance but is not comprehensive so please ensure you have thought through the impact on staffing, training and equipment carefully and that ALL aspects are covered.

Manpower	**WTE**	**Recurring £**	**Non-Recurring £**
Operational running costs	0		
Totals:	0		

Staff Training Impact	**Recurring £**	**Non-Recurring £**
	0	
Totals:	0	

Equipment and Provision of Resources	Recurring £ *	Non-Recurring £ *
Accommodation / facilities needed	0	
Building alterations (extensions/new)	0	
IT Hardware / software / licences	0	
Medical equipment	0	
Stationery / publicity	0	
Travel costs	0	
Utilities e.g. telephones	0	
Process change	0	
Rolling replacement of equipment	0	
Equipment maintenance	0	
Marketing – booklets/posters/handouts, etc.	0	
	0	
Totals:	0	

- Capital implications £5,000 with life expectancy of more than one year.

Funding /costs checked & agreed by finance:	
Signature & date of financial accountant:	
Funding / costs have been agreed and are in place:	
Signature of appropriate Executive or Associate Director:	

Appendix B

Equality Impact Assessment (EIA) Screening Tool

Document Title:	Oral Anti-Cancer Therapy Policy
Purpose of document	*To ensure that oral anti –cancer therapy is safely prescribed, dispensed and administered in accordance with current best practice*
Target Audience	*Nursing, medical and pharmacy staff.*
Person or Committee undertaken the Equality Impact Assessment	*Lead Oncology Pharmacist*

1. To be completed and attached to all procedural/policy documents created within individual services.

2. Does the document have, or have the potential to deliver differential outcomes or affect in an adverse way any of the groups listed below?

If no confirm underneath in relevant section the data and/or research which provides evidence e.g. JSNA, Workforce Profile, Quality Improvement Framework, Commissioning Intentions, etc.

If yes please detail underneath in relevant section and provide priority rating and determine if full EIA is required.

		Positive Impact	**Negative Impact**	**Reasons**
Gender	Men	*No*	*No*	
	Women	*No*	*No*	
Race	Asian or Asian British People	*No*	*No*	
	Black or Black British People	*No*	*No*	
	Chinese people	*No*	*No*	
	People of Mixed Race	*No*	*No*	
	White people (including Irish people)	*No*	*No*	

	People with Physical Disabilities, Learning Disabilities or Mental Health Issues	*No*	*No*	
Sexual Orientation	Transgender	*No*	*No*	
	Lesbian, Gay men and bisexual	*No*	*No*	
Age	Children	*No*	*No*	
	Older People (60+)	*No*	*No*	
	Younger People (17 to 25 yrs.)	*No*	*No*	
Faith Group		*No*	*No*	
Pregnancy & Maternity		*No*	*No*	
Equal Opportunities and/or improved relations		*No*	*No*	

Notes:
Faith groups cover a wide range of groupings, the most common of which are Buddhist, Christian, Hindus, Jews, Muslims and Sikhs. Consider faith categories individually and collectively when considering positive and negative impacts.

The categories used in the race section refer to those used in the 2001 Census. Consideration should be given to the specific communities within the broad categories such as Bangladeshi people and the needs of other communities that do not appear as separate categories in the Census, for example, Polish.

3. Level of Impact

If you have indicated that there is a negative impact, is that impact:			
		YES	**NO**
Legal (it is not discriminatory under anti-discriminatory law)			
Intended			

If the negative impact is possibly discriminatory and not intended and/or of high impact then please complete a thorough assessment after completing the rest of this form.

3.1 Could you minimise or remove any negative impact that is of low significance? Explain how below:	
3.2 Could you improve the strategy, function or policy positive impact? Explain how below:	
3.3 If there is no evidence that this strategy, function or policy promotes equality of opportunity or improves relations – could it be adapted so it does? How? If not why not?	
Scheduled for Full Impact Assessment	Date:

Name of persons/group completing the full assessment.	
Date Initial Screening completed	