GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Caerdydd a'r Fro | Cardiff and Vale University Health Board	**Reference Number: UHB 283** **Version Number: 1** **Date of Next Review: 23/02/19** **Previous Trust/LHB Reference Number: N/A**

POLICY ON THE MANAGEMENT OF ORAL ANTICANCER THERAPY

Introduction and Aim

Cardiff and Vale University Health Board is committed to ensuring that oral anticancer therapy is administered safely and that the organisation is compliant with national guidance. The policy will clearly identify the key elements of oral anticancer therapy

Objectives

- To ensure that oral anticancer therapy is prescribed and administered safely

Scope

This policy applies to oral anticancer drugs when used to treat cancer.

Equality Impact Assessment	An Equality Impact Assessment has been completed.
Documents to read alongside this Procedure	Policy for the management of parenteral cytotoxic chemotherapy
Approved by	Medicines Management Group
Accountable Executive or Clinical Board Director	Medical Director
Author(s)	Lead Haematology Pharmacist

Summary of reviews/amendments			
Version Number	**Date of Review Approved**	**Date Published**	**Summary of Amendments**
1	23/02/2016	21/03/2016	New Document

Contents Page

1. Definitions

Management of oral anticancer therapy includes prescribing, preparation, storage, administration, safe handling and disposal.

Cancer Specialist Consultant or specialist registrar specialising in cancer treatment who prescribe to patients under their care.

Specialist independent prescriber Independent prescriber specialising in cancer treatment who prescribes to patients under their care.

Treatment Plan An individual patient plan documenting treatment i.e. documentation of protocol that will be followed, number of cycles intended to be given, any dose adjustments, any investigations required (a template for treatment plan for adult patients is included in appendix 1).

Written protocol Cytotoxic chemotherapy regimens are often complex, involving a number of drugs, given by a variety of routes, over a number of days. All oral drugs must have an information sheet for healthcare professionals or a copy of the protocol available to explain indication, drug regimen, cycle frequency, expected side effects, concurrent medications required. Paediatric ALL patients have a specific monitoring tool for variable dosing which is managed by the Leukaemia Nurse Specialist and is available in the medical notes.

My chemotherapy handbook a handbook written by the SE Wales Cancer Network that should be given to all adult patients as a hand held record of their treatment. Paediatric patients may use the LATCH diary for recording changes in their treatment.

2. Introduction and background

There has been a significant increase in the availability of oral anticancer therapy treatments in recent years. This has led to a shift in treatment from IV to oral therapy which offers many advantages but changes the risks associated with prescribing, dispensing and administration. The Department of Health Standards for Cancer Services 2004 states the importance of guidelines and protocols in management of patients on oral chemotherapy. The British Oncology Pharmacy Association (BOPA) published a position statement in January 2004 and in January 2008 the National Patient Safety Agency (NPSA) issued a Rapid Response Report (NPSA/2008/RRR001) about the “Risks of incorrect dosing of oral anti-cancer medicines”. The NPSA indicate there were at least three deaths and over four hundred patient safety incidents concerning oral anticancer therapy between November 2003 and July 2007.

This policy has been produced with reference to all of these documents and sets out how oral anticancer therapy will be prescribed, dispensed, labelled and issued to the patient. In addition it includes information to be provided to the patient and information to be held by the pharmacy and treatment areas in relation to the regimen.

3. Written protocols (Information Sheets for Health Professionals), Treatment Plans and Consent

All oral chemotherapy regimens must have an associated protocol (this includes oral agents given as a single agent as well as combination oral therapies). The protocol must include:

- Indication
- Pre treatment evaluations required
- Drug regimen (**Drug, Dose, Route, Frequency, duration** and **maximum dose** if applicable)
- Cycle frequency and duration / maximum number (where applicable)
- Dose modifications in renal/hepatic impairment or for other chemotherapy induced toxicities
- Investigations required prior to subsequent cycles
- Concurrent medications recommended or contraindicated
- Patient counselling points
- Key references for the regimen

Each patient will have a treatment plan in the front of their notes with a duplicate copy attached to their “My Chemotherapy handbook” booklet, and a third copy to take to pharmacy with their initial prescription. This plan will have patient’s name, address, date of birth, hospital number, consultant, diagnosis, PMH/Medication history, regimen, planned number of courses, cycle length, monitoring and if applicable plan for restaging.

Treatment plans for paediatric patients will be based on the treatment plans included in their clinical trial protocols. Those patients not included in clinical trials will have individualised treatment plans provided.

Written consent to treat, using the University Health Board approved consent form, should be obtained from the patient, responsible parent, court appointed deputy or attorney of a personal welfare LPA, prior to the administration of chemotherapy. In the case of a clinical trial, the specific clinical trial consent form may be used.

4. Prescribing

4.1 Initiation of treatment must be undertaken by consultant, specialist registrar or specialist independent prescriber.

4.2 All modifications to treatment must be recorded in the medical notes. The patient should be encouraged to record this in their "My chemotherapy handbook" booklet, or LATCH diary.

4.3 It is good practice to use pre-printed approved chemotherapy prescriptions or a validated electronic prescribing system to prescribe oral chemotherapy.

4.4 All prescriptions must clearly state for each cycle of treatment:

- Height, weight and body surface area (if appropriate for dosing)
- The Drug, Dose and Route
- Frequency of administration
- Intended start date
- Duration of treatment
- Intended stop date (where applicable)
- Dose adjustments from the standard are clearly identified.
- Prescriber's name and contact number

4.5 Follow up and monitoring must be undertaken as indicated in the information sheet for health professionals, and documented in the medical notes.

4.6 If a patient is admitted to hospital whilst on chemotherapy and is not under the care of the original prescribing team it is a multi-professional responsibility to review the continuing need for this treatment with the original prescribing team (including chemotherapy for non cancer indications). Prescribing should comply with the All Wales prescription writing standards.

5. Dispensing & Labelling Standards

5.1 All chemotherapy prescriptions must be clinically checked by a pharmacist.

5.2 Information sheets are available to staff involved in dispensing, this includes advice on dose reductions for hepatic and renal dysfunction.

5.3 Dispensing and labelling comply with pharmacy directorate dispensing standards

5.4 Labels must be clear and unambiguous and must include the start and stop dates for short term or intermittent treatment – this may be in the form of a start date and number of days to be continued.

5.5 All labels must include the “CYTOTOXIC DRUGS HANDLE WITH CARE” warning. This will generally be in the form of an additional label.

5.6 EXACT number of days of therapy (as specified on the prescription) will be dispensed.

5.7 All dispensed chemotherapy agents must be issued with a patient information leaflet (PIL) if possible.

5.8 Where swallowing difficulties are present alternative instructions or alternative drugs must be discussed with the prescriber and patient.

6. Patient Education & Information

6.1 Patients must be seen by a specialist nurse or pharmacist before every treatment cycle.

6.2 The specialist nurse or pharmacist will ensure that all patients understand:

- How and when to take their medication
- What to do in the event of missing one or more doses
- What to do in case of vomiting after taking a dose
- The likely adverse effects and what to do about them
- Principles of safe handling, storage and disposal

6.3 Only trained and competent staff must issue drugs to patients.

6.4 All patients are provided with:

- Contact details for any queries
- General advice booklet (My Chemotherapy Record) with treatment plan
- LATCH booklet and diary for paediatric patients

6.5 Patients should be assessed on an individual basis and consideration given to the use of e.g. compliance aids, colour coding, large print, translation and interpretation facilities as necessary.

Resources

It would be optimal to use an electronic prescribing system, but this would require substantial investment.

7. Equality Impact and Assessment

An equality impact assessment has been undertaken to assess the relevance of this policy to equality and potential impact on different groups, specifically in relation to the 2010 Equality Act.

8. Distribution

This Policy will be available for viewing via the UHB Intranet.
A copy will also be provided to all Clinical Directors, Clinical Board directors, Heads of Operational Delivery and Directorate Managers for onward distribution and circulation to staff as necessary.

9. References

1. Standards for Cancer Services (2004) Department of Health, London

2. Position Statement on safe practice and the pharmaceutical care of patients receiving oral anticancer therapy, British Oncology Pharmacy Association (BOPA) January 2004.

3. Rapid Response Report: Risks of incorrect dosing of oral anti-cancer medicines (NPSA/2008/001), National Patient Safety Agency (NPSA), January 2008

Cytotoxic Chemotherapy Group

This policy was prepared by the Lead Haematology Pharmacist and the Cardiff and Vale University Health Board Cytotoxic Chemotherapy Group

Dr Jonathan Kell, Consultant Haematologist
Paul Spark, Principal Pharmacist, Sterile Production Services
Mair Robinson, Macmillan Lung Cancer Pharmacist
Sarah Irwin, Haematology Pharmacist
Eurig Jenkins, Lead Pharmacist Paediatric Oncology
Dr Ata Maaz, Consultant Paediatric Oncologist
Noreen Lewis, Nurse Manager, Heamatology, UHW
Sarah Rowland, Chemotherapy Nurse Trainer
Julie Broughton, Paediatric Clinical Nurse Specialist
Caroline Bates, Urology Clinical Nurse Specialist
Elaine Hatton, Sister SKY ward