

MEDICINES STANDARD A6: PRESCRIBING ORAL CHEMOTHERAPY

INTRODUCTION

The treatment of malignant disease involves the administration of cytotoxic agents that are associated with specific requirements for the safe monitoring of patients and handling procedures by healthcare staff.

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

The increase in the range of oral chemotherapy available means that there is the potential for oral cytotoxic treatment to be prescribed and dispensed, by non-specialised staff, without reference to the safeguards developed for intravenous cytotoxic treatment.

Oral cytotoxic treatments are associated with a similar spectrum and severity of adverse effects as those associated with intravenous treatment.

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](#)".

This guidance aims to comply with the NPSA Rapid Response Report and covers all general practitioners (GPs) when acting under direct contract or SLA with the commissioners of chemotherapy, currently NHS England, and covers the prescribing of systemic, including oral, cytotoxic chemotherapy, or intracavitary cytotoxic chemotherapy for the treatment of malignant disease.

It does not apply to:

- GPs who are acting for that part of their practice under contract to a hospital Trust
- The prescription of oral hydroxycarbamide, for cases under the overall care of a hospital consultant haemato-oncologist

- The prescription of topical cytotoxic agents used for the treatment of some skin malignancies or premalignant conditions.
- This guidance must be used in conjunction with other locally approved policies and guidelines on medicines management and cytotoxic / anticancer medicines.

This guidance does not cover the use of oral cytotoxic 'anti-cancer' drugs in non-malignant disease; some oral cytotoxic 'anti-cancer' drugs are prescribed, under shared care guidelines in non-cancer /malignant disease indications, for example, methotrexate for rheumatoid arthritis.

Please refer to the relevant Medicines Code chapters and the respective shared care guidelines for the use of oral cytotoxic 'anti-cancer' drugs for non-malignant disease indications.

ROLES AND RESPONSIBILITIES

All practitioners should ensure that they are familiar with the [NPSA alert](#) document related to oral anti-cancer medicines, and local policies, [COSHH guidance](#) and assessments and local standard operating procedures (SOPs).

Prescribers are responsible for ensuring that appropriate checking mechanisms are in place for prescribing and monitoring of patients.

Community pharmacists and GP dispensary staff are responsible for ensuring that this guidance is communicated to all staff and locums and that the dispensing SOPs reflect CCG guidance.

PRESCRIBING

The decision to initiate treatment with cytotoxic chemotherapy must be undertaken by a consultant oncologist / haematologist or associate specialist, following discussion at the relevant multi-disciplinary team (MDT), where appropriate. The decision and regimen must be recorded in the medical notes. All cytotoxic chemotherapy must be prescribed within the context of a written protocol and treatment plan.

General practitioners (GPs) **should not** prescribe systemic cytotoxic chemotherapy (including oral chemotherapy), or intracavitary cytotoxic chemotherapy for the treatment of malignant disease.

The only exception is the prescribing of oral hydroxycarbamide, for cases under the overall care of a hospital consultant haemato-oncologist. Prescribing, in this instance, should only be undertaken by general practitioners according to the approved shared care guideline, available to download from the [Dorset formulary](#). The shared care guideline sets out basic responsibilities of each member of the shared care team. Supplementary information, such

as the treatment plan, should be available to the GP to enable the safe prescribing of hydroxycarbamide. Prescriptions issued in primary care should include the dose and duration of treatment, and any other relevant information.

Prescribing for those receiving treatment in external organisations such as nursing homes or prisons should adhere to the same standards as any other patient.

DISPENSING

All dispensing staff (including those in dispensing practices) should be aware of and adhere to this guidance.

Community pharmacists and dispensing practices should not be requested to dispense cytotoxic chemotherapy, or the targeted therapies such as the tyrosine kinase inhibitors (such as dasatinib, erlotinib, imatinib, sorafenib, and sunitinib) for the treatment of malignant disease. Such items have a 'red' traffic light status on the [Dorset prescribing formulary](#), and should be supplied by secondary care.

Requests of community pharmacies or dispensing practices to dispense cytotoxic chemotherapy for malignant disease should be discussed with the prescriber in regard to this guidance and the medicines management team contacted for advice (medicine.question@dorsetccg.nhs.uk).

As above, the only exception to community pharmacies and dispensing practices dispensing oral chemotherapy is oral hydroxycarbamide for cases under the overall care of a hospital consultant haemato-oncologist. The [shared care guideline](#) for hydroxycarbamide is available to download from the Dorset formulary.

Community pharmacists involved in the supply of hydroxycarbamide should ensure they have access to the [shared care guideline](#) and make supplies in accordance with the advice contained in the NPSA Rapid Response Report on the "Risks of Incorrect Dosing of Oral Anti-cancer Medicines".

Community pharmacists dispensing cytotoxic 'anti-cancer' drugs for non-malignant disease, for example, methotrexate for rheumatoid arthritis should ensure that, they have access to the most update version of the relevant shared care guideline and supply is in line with local/national guidance.

Pharmacy/dispensary staff must ensure the patient is aware of the required monitoring arrangements as described in the shared care guideline.

Unless exceptional circumstances occur the prescription and dispensed item should be double checked by a second individual. This must include a physical count of the amount of dose units dispensed.

A copy of the manufacturers patient information leaflet must be supplied with all dispensed items.

Use of compliance aids is not routinely recommended for cytotoxic drugs. If there is a need for such aids a risk assessment must be undertaken and documented.

Pharmacy staff must ensure patients or their carers are aware of the correct procedures for the supply and disposal of unused oral cytotoxic agents.

PATIENT COMMUNICATION AND SUPPORT

Patients should receive adequate information (verbal and written) to enable them to make an informed decision about therapy.

Patients should be adequately counselled and educated to ensure understanding of the dose to be taken, potential common side effects and contra-indications. In addition they should be advised of the requirement for regular monitoring.

Patients should be advised to consult their doctor/pharmacist prior to taking over the counter medicines.

REFERENCES

[Patient safety risks of incorrect dosing of oral anti-cancer medicines](#) (NPSA, January 2008)

[Safe handling of cytotoxic drugs in the workplace](#) (Health and Safety Executive)

APPENDIX 1 - ORAL CHEMOTHERAPY DRUGS

The number of orally active agents available, particularly the targeted therapies, continues to increase. The following drug is amber under the Dorset prescribing formulary and may be prescribed in primary care on a shared care basis after initiation and stabilisation of dose by secondary care:

- **Hydroxycarbamide; in myeloproliferative disorders (essential thrombocythaemia, primary proliferative polycythaemia, myelofibrosis) see shared care guideline**

Methotrexate is categorised amber for specific indications (refer to [Dorset formulary](#)) but is categorised **RED** when used as a cytotoxic chemotherapy agent to treat malignant disease.

There are a number of other oral chemotherapy agents, for example:

- Chlorambucil
- Busulfan
- Cyclophosphamide
- Melphalan

This list is not exhaustive. Please contact the Medicines team for advice on medicine.question@dorsetccg.nhs.uk if you are asked to prescribe **any** oral chemotherapy agent.

The use of hormonal or anti-hormonal therapy used to treat cancer is not included within the remit of this guidance.