Northamptonshire Healthcare
NHS Foundation Trust

MMG019 PRESCRIBING GUIDELINE FOR ORAL SYSTEMIC ANTI-CANCER THERAPIES

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Why we need this Guideline

In 2008 the NPSA alerted all healthcare professionals involved in the use of oral anti-cancer medicines of potentially fatal outcomes if incorrect doses of these medicines are used. The Rapid Response Report recommended that the prescribing, dispensing and administration of oral anti-cancer medicines be carried out in the same way as injectable chemotherapy.

For the purposes of this guidance the recommendations which are relevant are;

- Treatment should be initiated by a cancer specialist.
- All oral anti-cancer medicines should be prescribed only in the context of a written protocol and treatment plan.
- Non-specialists who prescribe or administer on-going oral anti-cancer medication should have ready access to appropriate written protocols and treatment plans including guidance on monitoring and treatment of toxicity.

What the Guideline is trying to do

The purpose of this guidance is to provide a framework of the process to follow if a patient who is receiving a systemic oral anti-cancer drug is admitted to an inpatient area.

Which stakeholders have been involved in the creation of this Guideline

KGH/NGH oncology pharmacists
Specialist Palliative Care Consultants
NHFT Advanced Pharmacist, Palliative Medicine

Any required definitions/explanations

NPSA - The NPSA is an arm's length body of the Department of Health. It was established in 2001 with a mandate to identify patient safety issues and find appropriate solutions. The organisation works to identify and reduce risks to patients receiving NHS care, and also leads on national initiatives to improve patient safety.

Oral systemic anti-cancer therapy (SACT) - for the purposes of this document the terms "oral chemotherapy" and "oral cytotoxic medication" are 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. Please see Appendix 1 for a list of oral agents.

NHFT - Northamptonshire Healthcare NHS Foundation Trust
POD – Patient's Own Drugs
SACT – Systemic anti-cancer therapy

Key duties

The Medicines Management Committee

Will review and approve these guidelines

Medical Director

Responsible for dissemination of this guideline to their clinical directors and tutors

Doctors

Will be responsible for following the MMPr034 Medicines Reconciliation Protocol to ensure all relevant information is available on admission.

Nurses

Will be responsible for administering according to MMP001 Control of Medicines Policy.

Assessing for self-medication where appropriate.

Appropriate disposal of SACT if they are discontinued.

Pharmacists

Where a ward pharmacy service is available they will aid in information gathering.

Appropriate disposal of SACT if they are discontinued.

Guideline detail

When a patient is admitted to an in-patient area who is identified to be taking an oral systemic anti-cancer therapy (SACT) the medication **should be stopped.** An appropriate discussion with the patient/relative should occur to explain the safety reasons for not prescribing on admission.

The following steps must be undertaken before prescribing can be considered. (See Appendix 1 for list of SACT and summary flowchart, Appendix 2).

Confirmation of the regime

The patient's specialist oncology team must be contacted as part of the medicines reconciliation process to obtain details of the regime the patient has been prescribed, and whether it is appropriate for this treatment to continue (to ensure any symptoms the patient is suffering are not toxicity related).

Request all relevant clinical information e.g. clinic letters to be faxed to the inpatient unit. The patient's admission should be discussed with the specialist consultant/registrar and a clinical decision made about whether to continue the drug made. The decision should be clearly documented in the clinical record.

If the consultant/registrar is not available for a verbal discussion at the time of admission other possible sources of information are specialist oncology nurse, on-call oncology consultant or specialist oncology pharmacist. The consultant/registrar must be contacted back at the earliest opportunity to discuss. The drug **should not** be charted until the decision to continue the drug has been made. Again a conversation with the patient/relatives about why the drug is not being immediately prescribed should take place if appropriate.

Northampton General Hospital

Chemotherapy suite - 01604 545230

Talbot Butler ward - 01604 545534

Oncology Out of Hours (Talbot Butler Ward) 01604 545534

NGH Switchboard for on call team

Kettering General Hospital

Centenary Wing (Mon to Fri 9 - 5 excluding Bank Holidays) 01536 493638

Chemotherapy Services Supportive Treatment Unit – CSSTU

(Mon to Fri 9 - 5 excluding Bank Holidays) 01536 492788

Haematology Out of Hours (Lilford Ward) 01536 492834

KGH Switch for Haematology Consultant / Registrar

Obtain a copy of the prescription from the dispensing hospital pharmacy

Telephone the dispensing hospital pharmacy/ chemotherapy unit to request a fax copy of the prescription. Where this is unavailable obtain written confirmation from prescriber. Where this is unavailable obtain written confirmation from prescriber.

Kettering General Hospital

Pharmacy: 01536 493540 Pharmacy fax: 01536 492424

Lead Cancer Pharmacist: 01536 493734 / bleep: 01536 492000 – bleep 238

Northampton General Hospital

Pharmacy: 01604 545700 Pharmacy fax: 01604 545694

Cancer Pharmacists: 01604 545703 fax: 01604 544513

Transcribing the drug

Once all the relevant information has been gathered and a decision to continue treatment is made, the drug should be transcribed onto the drug chart.

The prescription must be signed to make it legal, and annotated with "prescribed on behalf of…." the specialist's name, including stop date.

If the patient subsequently has an outpatient appointment at the acute hospitals during their admission further medicines reconciliation will need to be completed on their return to ensure any changes have been incorporated on to the drug chart.

Administration

Self-administration is always be the preferred method (refer to MMPr0033 – Self Administration of Medication Protocol) if it is appropriate for the patient.

If the nursing staff are to administer, they would need to observe standard precautions for handling anti-cancer medications i.e. no-touch technique and wearing gloves and apron. Under no circumstances should any such medications be crushed or halved, or the contents of capsules opened. Contact pharmacy for advice if there is any doubt.

Disposal

If a decision is made to stop the chemotherapy, then the drug needs to be disposed of according to Waste Management Policy & Procedures Manual HSCp001in a purple lidded sharps bin. Estates need to be informed that there is cytotoxic waste to be collected.

Training requirements associated with this Guideline

Mandatory Training

There is no mandatory training associated with this Guideline.

Specific Training not covered by Mandatory Training

Ad hoc training sessions based on an individual's training needs as defined within their annual appraisal or job description.

How this Guideline will be monitored for compliance and effectiveness

There is no monitoring associated with this guideline.

Equality considerations

Refer to MMP001 Control of Medicines Policy

Reference Guide

MMP001 Control of Medicines Policy
MMPr034 Medicines Reconciliation Protocol

Document control details

Author:	Advanced Pharmacist Palliative Care
Approved by and date:	17.01.17
Responsible committee:	Medicines Management Committee
Any other linked Policies:	MMP001 - Control of Medicines Policy
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Version control:	2

Version No.	Date Ratified/ Amended	Date of Implementation	Next Review Date	Reason for Change (eg. full rewrite, amendment to reflect new legislation, updated flowchart, minor amendments, etc.)
1	17.01.17	17.01.17	31.01.19	Review
2	05.12.18	28.12.18	30.11.20	Review

APPENDIX 1 – ORAL SYSTEMIC ANTI-CANCER THERAPIES (SACT)

Drug	Commonly used for
Afatinib (Giotif®)	Advanced small cell lung cancer
Alectinib (Alecensa®)	ALK positive lung cancer
Axitinib (Inlyta®)	Advanced renal cell carcinoma
Bexarotene (Targretin®)	Advanced stage cutaneous T-cell lymphoma
Bosutinib (Bosulif®)	Philadelphia positive chronic myeloid leukaemia
Busulfan (Myleran®)	Leukemias
Cabozantinib (Cometriq® & Cabometyx®)	Medullary thyroid carcinoma
Capecitabine (Xeloda®)	Breast, colorectal & upper GI cancer
Ceritinib (Zykadia®)	ALK positive lung cancer
Chlorambucil (Leukeran®)	Leukaemia, lymphoma
Cobimetinib (Cotellic®)	BRAF V600 positive melanoma
Crizotinib (Xalkori®)	Advanced non-small cell lung cancer
Cyclophosphamide (Endoxana®)	Leukaemias, lymphomas and many solid tumours
Dabrafenib (Tafinlar®)	Metastaic melanoma with BRAF V600 mutation
Dasatanib (Sprycel®)	Chronic myeloid leukaemia
Erlotinib (Tarceva®)	Lung cancer
Estramustine phosphate	Prostate cancer
Etoposide (Vepesid®)	Leukamias and solid tumours
Everolimus (Votubia®, Afinitor®)	Various indications – check BNF for preparations
Fludarabine (Fludara®)	Leukaemia
Gefinitib (Iressa®)	Lung cancer
Hydroxycarbamide (Hydrea®)	Leukaemia
Idarubicin (Zavedos®)	Leukaemia
Ibrutinib (Imbruvica®)	Mantle cell lymphoma
Idelalisib (Zydelig®)	Chronic lymphocytic leukaemia
Imatinib (Glivenc®)	Chronic myeloid leukaemia
Ixazomib (Ninlaro®)	Multiple Myeloma
Lapatanib (Tykerb®)	Breast cancer
Lenalidomide (Revlimid®)	Myeloma
Lenvatinib (Kisplyx®)	Advanced renal cell cancer
Lenvatinib (Lenvima®)	Progressive, locally advanced or metastatic thyroid cancer
Lomustine (CCNU®)	Lymphoma
Melphalan (Alkeran®)	Myeloma
Mercaptopurine (Puri-Nethol®)	Leukaemia
Methotrexate (Maxtrex®)	Leukaemia & solid tumours
Midostaurin (Rydapt®)	Acute myeloid leukaemia, aggressive systemic mastocytosis
Mitotane (Lysodren®)	Adrenocorticoid carcinoma
Nilotinib (Tasigna®)	Chronic myeloid leukaemia
Nintedanib (Vargatef®)	Non-small cell lung cancer
Niraparib (Zejula®)	Ovarian, fallopian tube, peritoneal cancer
Olaparib (Lynparza®)	Ovarian, fallopian tube or primary peritoneal cancer
Osimertinib (Tagrisso®)	EGFR T790M mutation positive non small cell lung cancer
Palbociclib (Ibrance®)	HR +ve, HER2 -ve locally advanced/metastatic breast cancer
Panobinostat (Farydak®)	Relapsed/refractory myeloma
Pazopanib (Votrient®)	Renal cell carcinoma
Pomalidomide (Innovid®)	Relapsed/refractory myeloma

Drug	Commonly used for
Ponatinib (Iclusig®)	Chronic myeloid leukaemia / acute lymphoblastic leukaemia
Procarbazine	Lymphoma
Regorafenib (Stivarga®)	Metastatic colorectal cancer / GI stromal tumours
Regafun / gimeracil / oteracil (Teysuno®)	Gastric cancer
Ribociclib (Kisqali®)	HR +ve, HER2 -ve locally advanced/metastatic breast cancer
Ruxolitinib (Jakavi®)	Disease related splenomegaly / myelofibrosis
Sorafenib (Nexavar®)	Renal & liver cancers
Sunitinib (Sutent®)	Renal & GIST cancers
Temozolamide (Temodal®)	Glioma (brain tumours)
Temsirolimus (Torisel®)	Adanced renal cell cancer
Thalidomide	Myeloma
Tioguanine (Lanvis®)	Leukaemia
Tivozanib (Fotivida®)	Advanced renal cell cancer
Toptecan (Hycamtin®)	Lung cancer
Trametinib (Mekinist®)	Unresectable melanoma with BRAF600 mutation
Treosulfan	Ovarian cancer
Tretinoin (Vesanoid®)	Acute promyelocytic leukaemia
Trifluridine / tipiracil (Lonsurf®)	Metastatic colorectal cancer
Vandetanib (Caprelsa®)	Thyroid cancer
Vemurafenib (Zelboraf®)	Melanoma
Venetoclax (Venclyxto®)	Chronic lymphocytic leukaemia
Vinorelbine (Navelbine®)	Lung and breast cancer
Vismodegib (Erivedge®)	Basal cell carcinoma

Please note this list may not be exhaustive.

APPENDIX 2 - FLOWCHART FOR ORAL SACT

Patient admitted who is taking oral anti-cancer drug

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Perform medicines reconciliation as per protocol (MMPr034) using PODs, clinic letters if available

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Check regime on EMCN website
http://www.eastmidlandscanceralliance.nhs.uk/cancer/chemotherapy

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Discuss with initiating specialist consultant/registrar whether appropriate to continue cytotoxic drug. Document in notes treatment plan and stop date. If not available contact specialist nurse/pharmacist to collate information.

Contact relevant hospital pharmacy department for a copy of the supply prescription. (File in medical notes/ scan onto SystmOne

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Document decision to continue drug in clinical record.
Transcribe drug onto the drug chart detailing drug name, dose, frequency and stop date; regime and cycle number. Prescriber must indicate on the prescription that they are prescribing on behalf of the specialist.

Prescriber must SIGN and DATE prescription.
IF VERIFICATION CANNOT BE OBTAINED DRUG MUST STOP UNTIL SPECIALIST HAS CONFIRMED IT IS SAFE TO CONTINUE

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Make sure nursing staff aware that an anti-cancer drug is prescribed and that special handling precautions apply. This medication cannot be ordered from pharmacy in the usual way and can only be supplied at the specialist oncology appointment.

N.B. if the patient attends an oncology out-patient appointment during their admission, further medicines reconciliation must be performed on their return to ensure correct drug and dose prescribed