NHS
Kent and Medway
Cancer Collaborative

Policy for the Management of Algorithm deviations and the use of unfunded medicines which form part of treatment algorithms as defined in the Oncological Treatment Guidelines.

Network Guidance Document

Kent & Medway Cancer Collaborative

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TABLE OF CONTENTS

1.0 NOMENCLATURE

A chemotherapy **regimen** is defined by the therapeutic chemotherapy drugs used, often expressed as an acronym e.g. FEC. A change of one or more of these drugs themselves would normally be necessary for it to be classed as a change of regimen. In some cases, major changes in the dose or route of administration of one or more of the drugs effectively changes the regimen. A **treatment protocol** is defined as constituting all the parameters specified in the bullet points below:

- Cancer type
- Name of regimen and the therapeutic drugs used
- Therapeutic intent—palliative/adjuvant/neo-adjuvant/radical, as applicable
- Doses of therapeutic drugs
- Routes of administration
- Number of cycles or whether this is indeterminate
- Length of cycle and number and timing of administrations within a cycle
- Tests required before starting a course and prior to an individual cycle
- Supportive drugs with each cycle
- Therapeutic drug dose modifications and their indications.

A change in any of these parameters would change the treatment protocol but any change other than the therapeutic drugs themselves (apart from the exceptions specified above) would change only the protocol, not the regimen as well.

A chemotherapy **treatment algorithm** is defined as a guideline which specifies the acceptable **regimen or range of regimens** which may be used for named steps on the patient pathway (Treatment algorithms are cancer site-specific. They are not specific to individual patients, i.e. they are not individual treatment plans). Thus, a change of regimen or order of regimens may no longer comply with a previous treatment algorithm, but a change of one of the minor aspects of a treatment protocol would still comply.

For example:

If in the regimen FEC-T the Epirubicin is substituted for Liposomal Doxorubicin then this would constitute a **major** change. This regimen would no longer comply with the treatment algorithm and should therefore be assessed as set out in section 4.1 of this policy.

In contrast, if the anti-emetic Domperidone were to be prescribed as an alternative to Metoclopramide as part of the supportive medication in a regimen this would constitute a **minor** change and as such would still comply with the treatment algorithm.

Obviously, whilst the overall intent of the algorithm deviation policy is to ensure that chemotherapy prescribing outside of the agreed treatment algorithms is subject to clinical governance oversight, what constitutes a major or minor change will to some extent be open to individual interpretation. As such, decisions can be made at the individual pharmacists' professional discretion.

2.0 BACKGROUND

The Non-surgical Oncology Sub-groups (NOGs or HOG) in consultation with the Network Chemotherapy Group within Kent and Medway agree chemotherapy treatment algorithms to be used within their speciality. These are described within the Oncological Treatment Guidelines. The NOGs work with the Network Chemotherapy Group (in particular the e-prescribing sub-group) to maintain a set of Network Chemotherapy Prescribing Protocols on the e-prescribing system which acts as a "list of approved protocols". Some of these protocols may be unfunded where they are not subject to a positive NICE technology appraisal and have not been agreed as part of commissioning arrangements. Chemotherapy should normally only be prescribed in accordance with the treatment algorithms set out in the Oncological Treatment Guidelines and within the protocols on the e-prescribing system.

There may be exceptional circumstances where a consultant wishes to treat a patient with a protocol not described within the Oncological Treatment Guidelines or outside of the context of the e-prescribing protocol. These circumstances may relate to patient factors such as allergies, needle phobia, poor compliance to oral treatment or contraindications to a medication or procedure, or the circumstances may relate to the disease itself, for example a patient with a multi-drug resistant tumour. In these circumstances, the consultant must obtain approval through the process described in section 4.1 below. Application for regular use of a new protocol should be made through the NOG.

There is a separate process to request funding approval for a medicine which is not routinely commissioned by NHSE but which forms part of the treatment algorithm set out in the Oncological Treatment Guidelines. While discussions around treatment choice should be transparent, it should be made clear to the patient that the drug(s) will only be available if funding for the treatment is agreed. Patient expectations should not be raised if drugs are not NICE Technology Appraisal approved or routinely commissioned for that indication. The clinician has a duty to ascertain the NHS commissioned status before discussing the therapy option with the patient. Routine funding should not be assumed until 3 months after publication of guidance. In cases where the therapy is not routinely funded, the clinician must obtain explicit permission from the patient to share their individual details with the relevant commissioner as required under the Data Protection Act.

3.0 PROCEDURE

It is the responsibility of the clinician and pharmacist to ensure that chemotherapy is prescribed according to the treatment algorithms set out in the Oncological Treatment Guidelines.

When a chemotherapy prescription is received by the pharmacy, reference should be made to the relevant Oncological Treatment Guidelines, electronic action sheet and previous chemotherapy records to ensure the prescription is in line with the chemotherapy treatment algorithm.

3.1 Process for managing requests for a protocol which deviates from the treatment algorithm

In exceptional circumstances a consultant may wish to treat a patient with a protocol not described within the Oncological Treatment Guidelines or outside of the context of the e-prescribing protocol. In this case, the consultant in charge of the patients' care should complete a "treatment algorithm deviation request form". (A change of regimen or order of regimens would be classified as an algorithm deviation, but a change of one of the minor aspects of a treatment protocol would still comply). The treating consultant should indicate the rationale for use of the drug or regimen including supportive evidence from the literature, and any patient specific factors influencing choice of therapy. As this is an exceptional request, the consultant should draw attention to exceptional aspects of this case relative to similar cases. Additional supportive therapies and investigations over standard treatment should be specified. Advice should be sought from the authorised Lead pharmacist at each individual Trust on the cost of the proposed regimen (this may be the lead oncology, haemato-oncology, or formulary pharmacist as delegated by the Trust Chief pharmacist / Director of Pharmacy).

NB Drugs which form part of the CDF list will be incorporated into the Kent and Medway Oncological Treatment Guidelines.

3.1.1 For Oncology regimens

a) The form should be forwarded to another oncology consultant specialising in the particular tumour type within Kent and Medway, for peer review and completion of section B of the "Treatment algorithm deviation request form". Forms should be reviewed within 3 days of the date completed.

b) The form should then be sent to the Deputy Clinical Director Oncology (Chemotherapy) or in his absence the Clinical Director of Cancer services for Kent who, in conjunction with the Lead Oncology Pharmacist at the relevant Trust where the patient is being managed, will review the information on the form and assess the appropriateness of the choice of therapy. The authorised lead pharmacist will then decide if the request is to be approved or whether funding needs to be sought as outlined in the NHS England Individual Funding Request Standard Operating Procedure.

   Note: All Trusts have delegated clinical (not financial) decisions relating to algorithm deviations in oncology patients to the Deputy Clinical Director Oncology (Chemotherapy) at Maidstone & Tunbridge Wells (MTW). If funding has to be obtained for a therapy to be administered at a site other than MTW, the submission of the case for funding will be taken on by the authorised Pharmacist at the relevant Trust who will be responsible for advising the clinician of the progress of the application.

   Note: The authorised Lead Pharmacist at each Trust is responsible for maintaining a database of all requests in line with the agreed dataset outlined in appendix 1.

   i) If the decision is taken to approve the request (without external funding required) the Deputy Clinical Director Oncology (Chemotherapy) (or deputy) must sign section C and return a copy of the form to the requesting consultant. A decision should be made within one week of the initial request (date Section A completed). Very rarely, circumstances may arise which mean the 1 week turn around for this procedure is inappropriate. In this case, a decision for use of a drug must only be made by the Deputy Clinical Director

Oncology (Chemotherapy) or his deputy. If the treatment is for a new drug, the Lead Oncology Pharmacist at MTW is responsible for informing the authorised Lead Pharmacist at the relevant Trust to ensure that ordering can take place.

ii) If the request is referred to the NHS England IFR system, the requesting consultant should send the completed IFR form to the authorised Lead pharmacist at each individual Trust who will make a record of the request and forward the form to the relevant signatories within the Trust and then to the commissioner (e-mail address specified on form). Where there are exceptional circumstances, the consultant should draw attention to these aspects of the case relative to similar cases. The Requesting Clinician and the authorised pharmacist at each individual Trust will receive a decision on whether the request will be considered through the IFR process.

c) Following a positive decision, the drug may be ordered and the patient offered the proposed treatment. The Lead Oncology Pharmacist will liaise with the relevant consultant and the e-prescribing pharmacist to write a chemotherapy protocol on the e-prescribing system. Decisions for requests made via the IFR process should be logged on the database held by the Lead Pharmacist at each acute Trust.

4.1.2 For haemato-oncology regimens:

a) The request should be discussed within the context of an MDM. The "treatment algorithm deviation request form" should be completed with the details of the discussion in the MDM and name of two other Haemato-oncology consultants who are members of the MDM.
b) The reviewing consultants should carefully examine the information submitted and assess the appropriateness of the choice of therapy. This must include an assessment of patient specific factors. All comments must be included either supportive or otherwise in section B of the form. Forms should be completed electronically.
c) The consultant making the request should then liaise with the authorised Lead pharmacist at each individual Trust. This may be the lead oncology, haemato-oncology, or formulary pharmacist as delegated by the Trust Chief pharmacist / Director of Pharmacy in order to assess the need for commissioner approval.

If the decision is taken to approve the request: Section C must be signed by the authorising pharmacist and a log kept in line with the agreed dataset laid out in appendix 1.

Very rarely, circumstances may arise which mean there is insufficient time for the patient's treatment to be discussed at an MDM. In this case, the use of a drug must be endorsed by two other Consultants who treat haemato-oncology malignancies and who are members of the relevant Haemato-oncology Multidisciplinary Team. The individual Trusts pathway for authorising internal funding for urgent treatment, pending commissioner approval must be adhered to in all such cases where the treatment is not routinely funded.

If the treatment is for a new drug the oncology/ haematology pharmacist should liaise with the cytotoxic reconstitution unit to ensure that ordering takes place. Documentation must be completed accordingly.

If the request is referred to the NHS England IFR system proceed as set out in section 4.1.1 b) ii

d) Following a positive decision, the drug may be ordered and the patient offered the proposed treatment. Specific details of the chemotherapy regimen including supportive care and necessary investigations should be included in the chemotherapy action sheet. The designated Pharmacist will liaise with the relevant consultant and the electronic prescribing pharmacist to write a chemotherapy protocol on the e-prescribing system. Decisions for requests made via the CDF should be logged on the database held by the Lead Pharmacist at each acute Trust.

The authorised lead pharmacist (as specified in section 4.1) at each Trust is responsible for submitting a quarterly summary of all algorithm deviation requests for oncology and haematology (at their individual Trust) to the Kent and Medway Transition Network – Cancer for onward distribution to the Kent and Medway Chemotherapy Group and all Non-surgical Oncology Sub- groups.

4.2 Process to request funding approval for a medicine without a routine commissioning policy which forms part of the treatment algorithm as defined in the oncological treatment guidelines

a) Where a consultant wishes to treat a patient with a protocol described within the Oncological Treatment Guidelines but which is not routinely commissioned (i.e. not subject to a positive NICE technology appraisal or commissioning arrangement, but is listed on the CDF, or is listed as a drug which will receive interim funding via the CDF until final NICE technology appraisal is published) there is no requirement for the consultant in charge of the patients' care to complete a "treatment algorithm deviation request form". The request should be referred to the CDF.

b) Following a positive decision, the drug may be ordered and the patient offered the proposed treatment. The Lead Oncology Pharmacist will liaise with the KMCC system administrator and Trust electronic prescribing pharmacist to ensure a protocol is available on the e-prescribing system. (Regimens described in the oncological treatment guidelines should have a protocol **routinely** available on the e-prescribing system).

5.0 ADDITIONAL PRIVATE CARE

Where all routes of NHS funding have been exhausted, consider additional private care in line with Trust Additional Private Care Policy.

6.0 PROCESS FOR MANAGING REGIMENS WHICH DO NOT FORM PART OF THE KMCC ONCOLOGICAL TREATMENT GUIDELINES

Regimens described within the oncological treatment guidelines, regardless of whether subject to routine commissioning or not, will have a corresponding protocol built in the e-prescribing system. Please refer to the Organisational Structure and Governance Processes for Chemotherapy Protocols on Aria MedOnc document.

For protocols which are requested outside of the oncological treatment guidelines, following a successful application using the Treatment Algorithm Deviation Request form, the following process will be followed:

a) Upon receipt of the approved Treatment Algorithm Deviation Request form, the authorised Lead Pharmacist will liaise with the Trust electronic prescribing pharmacist/technician who will allocate a name for the protocol on the e-prescribing system and advise on whether any existing protocols could be adapted or copied and amended for use. If the protocol has already been built on the e-prescribing system, see point f below.

b) The authorised Lead Pharmacist liaises with the electronic prescribing pharmacist/technician (oncology/ haematology) within their own Trust to manage the build and validation of the protocol on the e-prescribing system. Where resource is not available within a Trust for separate individuals to build and validate a protocol, advice should be sought from the system administrator at KMCC. The lead electronic prescribing nurse for the Trust (or deputy) and the requesting consultant should validate the protocol on the e-prescribing system.

c) Once validation is complete, the paperwork should be sent to the Trust electronic prescribing pharmacist.

d) The Trust electronic prescribing pharmacist will follow the process to release the protocol (make 'live') for use on the e-prescribing system. Use will be restricted to the requesting consultant. This will be reviewed if a subsequent request is made.

e) Notification by the Trust electronic prescribing pharmacist that the protocol is available for use in the system, will only be given to the requesting consultant and the authorised Lead Pharmacist. Notification will be sent to the system administrator via the completion of validation form.

Where more than one request is made for a particular regimen within a 12 month period, this should be highlighted to the KMCC pharmacist who will bring this to the attention of the relevant NOG for discussion regarding possible inclusion within the Oncological Treatment Guidelines.

7.0 APPENDIX 1: AGREED DATASET FOR ALL TREATMENT ALGORITHM DEVIATION REQUESTS

- Date request received
- Patient's name
- Patients Initials
- DOB
- Gender
- NHS number
- Diagnosis / tumour type
- Previous SACT
- Proposed SACT
- Standard regimen within algorithm
- Reason for deviation
- Further action taken
- Names of requesting and approving consultants
- Date of approval
- Whether a referral has been made to commissioner for funding through IFR process & date of referral.
- Outcome of request to IFR and date of notification of outcome
- Where funding has been approved, but only for a initial period, date of expiry of funding

8.0 APPENDIX 2: TREATMENT ALGORITHM DEVIATION REQUEST FORMS

FORM A

TREATMENT ALGORITHM DEVIATION REQUEST FORM FOR ONCOLOGY

This form must be completed as fully as possible by the requesting consultant.
For guidance on completing the form please refer to the Algorithm Deviation policy.
A decision should be made within 1 week of the form being completed (unless funding is sought through the CDF).

Section A			
Hospital label:			
Consultant:		Diagnosis:	
Treating Hospital:		Date form completed:	
Prior treatment: **(Please indicate whether treatment was in adjuvant / neo-adjuvant or advanced/metastatic setting)**			
Proposed treatment (include doses and interval between cycles):			
☐ *Adjuvant*	☐ *Neo-adjuvant*	☐ *Metastatic:* ☐ *1st* ☐ *2nd* ☐ *≥3rd line*	
Estimated number of cycles:			
Is NICE appraisal imminent?		If yes, when?	
Is this product licensed for this indication?			
Cost of proposed course of treatment (seek advice from oncology pharmacist):			
Are there any special reconstitution or handling requirements above those required for cytotoxic chemotherapy? (seek advice from oncology pharmacist)			
Are any additional supportive therapies or investigations over standard treatment required?			
Rationale for prescribing (include supportive evidence from the literature including references and any patient specific factors):			

Requesting consultant:			
Name:			
Signature:		Date:	

Forward to another consultant oncologist specialising in the particular tumour type for review.

Section B			
Reviewing consultant:			
Comments:			
Do you support this request?			
Name:			
Signature:		Date:	

Forward to the deputy Clinical Director of Cancer Services for Chemotherapy or Clinical Director of Cancer Services for Kent

Section C			
Referred to IFR:			
Approved for use:		If no, state reason:	
Financial approval: *(Note: Medway & DVH to approve locally, sign below)*		If no, state reason:	
Name:			
Signature:		Date:	
Name:			
Signature:		Date:	

The form should be returned to the reviewing consultant, who may on approval of the request, offer the proposed treatment to the patient.

A copy of the form must be forwarded to the Senior Oncology Pharmacist EKH NHS Trust (Cathedral Day Unit, Kent and Canterbury Hospital) or Principal Pharmacist Oncology Services MTW NHS Trust (Oncology Pharmacy, Maidstone Hospital) or Principal Haematology-Oncology Pharmacist Medway Hospital or Lead Cancer Pharmacist Darent Valley Hospital and a copy filed in the patient's notes as soon as the form has been completed.

Under no circumstances should treatment begin before a decision has been made by the Clinical Director and where appropriate the CDF, and a completed form has been received by the persons named above.

FORM B

TREATMENT ALGORITHM DEVIATION REQUEST FORM FOR HAEMATO-ONCOLOGY

This form must be completed as fully as possible by the requesting consultant.
For guidance on completing the form please refer to the Algorithm Deviation policy.
A decision should be made within 1 week of the form being completed (unless funding is sought through the CDF).

Section A			
Hospital label:			
Consultant:		Treating Hospital:	
NHS Number:		Date form completed:	
☐ Multiple Myeloma	☐ Leukaemia (please specify below)	☐ Lymphoma (please specify below)	☐ Other (please specify below)
Prior treatment: **(Please indicate all previous lines of treatment, extent of response, dates of treatment and relapse)**			
Proposed treatment (include doses and interval between cycles, and drugs to be used in combination):			
Line of treatment:	☐ *1st* ☐ *2nd* ☐ *≥3rd line*		
Estimated number of cycles:			
Is NICE appraisal imminent?		If yes, when?	
Is this product licensed for this indication?			
Cost of proposed course of treatment (seek advice from haematology pharmacist):			
Are there any special reconstitution or handling requirements above those required for cytotoxic chemotherapy? (seek advice from haematology pharmacist)			
Are any additional supportive therapies or investigations over standard treatment required?			
Rationale for prescribing (include supportive evidence from the literature including references and any patient specific factors):			
Requesting consultant:			

Name:			
Signature:		Date:	

Complete section B with the names of 2 consultants that were present at the MDM where the proposed treatment was discussed and agreed.

Section B	
Supporting consultant 1:	
Comments:	
Do you support this request?	
Name:	
Signature:	Date:

Section B	
Supporting consultant 2:	
Comments:	
Do you support this request?	
Name:	
Signature:	Date:

Forward to the Authorised Trust oncology, haemato-oncology or formulary pharmacist, as delegated by the Chief pharmacist.

Section C (To be completed by the Authorised pharmacist)			
Referred to IFR:			
Approved for use:		If no, state reason:	
Name:			
Signature:		Date:	

Once approval has been granted the form should be returned to the reviewing consultant, who may offer the proposed treatment to the patient. If the treatment is a completely new drug, please inform pharmacy of the intended treatment start date, so that the ordering process can be initiated.

A copy of the form must be filed in the patient's notes as soon as the form has been completed.

Under no circumstances should treatment begin before a decision has been made by the Authorised pharmacist and where appropriate the CDF, and a completed form has been received by the persons named above.

9.0 GLOSSARY

Acronyms in common usage throughout KMCC documentation

BNF	British National Formulary
BOPA	British Oncology Pharmacist Association
CCG	Clinical Commissioning Group
CDF	Cancer Drugs Fund
CNB	Cancer Network Board
COSHH	Control of substances hazardous to health regulations.
CYP	Children & Young People (in relation to the IOG)
DCCAG	Diagnostic Cross Cutting Advisory Group
DOG	Disease Orientated Group (NSSG/TSSG/TWG)
DVH	Darent Valley Hospital
DGT	Dartford and Gravesham NHS Trust
EK	East Kent
EKHUFT	East Kent Hospitals University Foundation Trust
EPS	Electronic Prescribing System
FP10(HNC)	Prescriptions issued by hospital doctors for dispensing in the community
GP	General Practitioner
HoP	High Level Operational Policy
IFR	Individual Funding Request
IOSC	Improving Outcomes: A Strategy for Cancer
IV	Intravenous
K&C	Kent & Canterbury Hospital, Canterbury, (EKHUFT)
KMCC	Kent & Medway Cancer Collaborative
KMCRN	Kent & Medway Cancer Research Network
KOMS	Kent Oncology Management System
LSESN	London & South East Sarcoma Network
MDM	Multidisciplinary team Meeting
MFT	Medway Foundation Trust
MTW	Maidstone & Tunbridge Wells NHS Trust
NHS	National Health Service
NHSE	National Health Service England
NMP	Non-medical prescriber
NPSA	National Patient Safety agency
NOG	Non Surgical Oncology Group *(Permanent oncologist sub group of the DOGs with a specific responsibility for chemo/rad pathways and advice to the DOG, Network and GEOGRAPHICAL LOCATIONs on new drugs)*
PoC	Pathway of Care *(Network agreed disease site specific clinical guidelines)*
QEQM	Queen Elizabeth the Queen Mother Hospital, Margate (EKHUFT)
QoL	Quality of life

QSIS	Quality service information system
QST	Quality Surveillance Team
RAT	Research and Trial Group *(Permanent sub-group of the DOGs with a specific responsibility for taking forward the clinical trials agenda)*
RMH	Royal Marsden Hospital
RNOH	Royal National Orthopaedic Hospital
SACT	Systemic Anti-Cancer therapy
SACT regimen	Systemic Anti-cancer prescription on the electronic prescribing system
SACT protocol	Systemic Anti-cancer protocol on KMCC website
TTO	Treatment to take home
QVH	Queen Victoria Foundation Trust Hospital East Grinstead
UCLH	University College Hospital London
WHH	William Harvey Hospital, Ashford (EKHUFT)
WK	West Kent

10.0 DOCUMENT ADMINISTRATION

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