Great Ormond Street Hospital for Children NHS Foundation Trust

Haematology Oncology Department

North Thames Children's Cancer Network Group Policy for the Prevention of the Use of Chemotherapy Regimens not on the Agreed Network List (Off Protocol Prescribing)

CODE		Version Number	2.0	Number of pages	07	Copy number	

REPLACES: V1.0 **REVISION DETAILS:** GENERAL REVIEW

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Approved by		**June 2014**

Date Effective	June 2014
Last revised	June 2010
Review Date	June 2016
Distribution List **1.**	Joint Cancer Centre Operational Policy – Appendix

North Thames Children's Cancer Network Group

Policy for the Prevention of the Use of Chemotherapy Regimens not on the Agreed Network List (Off protocol prescribing)

Introduction

The North Thames Children's Cancer Network Group (NTCCNG) has agreed a list of acceptable regimens for its services at Great Ormond Street Hospital as well as Paediatric Oncology Shared Care Units located within the network.

The list covers all agreed chemotherapy for solid tumour oncology and haemato-oncology in the NTCCNG, including those regimens which are agreed as deliverable in the community.

The intention of this list is to agree a consensus and standardise best practice, preventing individual practitioners having unorthodox obsolete and unpredictably varying practice, which is against the opinion of their peers within the NTCCNG.

This policy defines the process for preventing the regular use of regimens not on the agreed list, including the exceptional circumstances under which such a regimen could be used and the procedure which is then required to authorise and record it.

Exceptional circumstances

- No suitable regimen on approved list due to pre–existing organ toxicity
- Rare condition for which no authorised regimen is currently available
- New evidence for best treatment
- Expert advice

At Great Ormond Street hospital any clinician intending to use a chemotherapy regimen not on the agreed network list should follow these steps.

1. Discuss the use of the proposed regimen at either the relevant multi-disciplinary team meeting or ward round.
2. Inform one of the senior Haematology/oncology pharmacists of the proposed use of the regimen.
3. Complete an off protocol form and supply any supporting documentation and references. The original off protocol form must be kept in the patient's notes and a copy made for pharmacy
4. If the regimen involves a new drug the appropriate Drug & Therapeutic Committee requirements must be fulfilled.

If all these steps have been followed and use of the regimen has been signed off at each stage then the use of the regimen may take place.

Paediatric Oncology Shared Care Units - Levels 1, 2 and 3

There are no circumstances under which it is permitted for a POSCU to deviate from the approved network list of regimens unless expressly instructed to do by a consultant Paediatric oncologist from the PTC.

Annual Review of the Use of Regimens not on the Accepted List

The NTCCNG should review annually the use within the network of regimens not on the agreed list.

At the PTC any instances of use of regimens not on the agreed list should be collated by the Chemotherapy Group, and fed back to the NTCCNG at the annual review.

It is not anticipated that there will be any instances within the POSCUs of the use of regimens not on the agreed network list. However each POSCU will need to declare, through their local Cancer Network representative, that this is actually the case, or report any instances of deviation.

It is recommended that any instances of deviation within the group should be reported to the Network Clinical Advisory Group.

Request for new regimens

If the off protocol request has been made based on new evidence and no national guidelines are available the requesting consultant must write a GOSH treatment guideline for review by the Chemotherapy Group to be added to the list of approved regimens.

Review of this Policy

This policy is subject to review in line with changes to National Peer Review Guidance.

Great Ormond Street Hospital for Children NHS Foundation Trust

Chemotherapy Off Protocol Form

This form must be completed by the requesting consultant for all cancer chemotherapy protocols that are not on the Trust approved list. Once completed please contact the oncology pharmacist to verify the protocol and confirm availability. A copy of the completed form should be filed in the patient's medical notes and a copy sent to the Head of the Clinical Chemotherapy Service.

If the same off protocol regimen is used TWICE a GOSH treatment guideline must be written and submitted to the GOSH chemotherapy group for consideration and approval.

It is the responsibility of the requesting consultant to report any unexpected toxicity to the Lead Clinician for the MDT and the chair of the GOSH chemotherapy group.

Patient Name:	**Hospital Number:**
Date of Birth:	**Diagnosis:**

Indicate reason why regimen on approved list is not being used:

- Toxicity of authorised regimen
- Rare condition for which no authorised regimen currently available
- New Evidence for best treatment
- Expert advice

Details:

References:

Proposed Regimen:

Drug	**Dose** Intended dose of each drug in mg or units per sq. metre or per kg. For Carboplatin the desired AUC should be quoted	**Frequency** Days of treatment or number of doses	**Route**	**Schedule** Rate of infusion, infusion fluid and volume (may be completed by pharmacist)

Please state overall course length and interval between course start dates.		
How many cycles in total will be given?		
Is continued treatment conditional upon anything?		
How often will the patient be reviewed?		
Has this been discussed at a MDT meeting Y/N Date:		
Supportive care information: (may be completed by pharmacist)		
Critical tests:		
Has this OFF PROTOCOL regimen been used before : Y/N		
If Yes Treatment Guideline being written by:		
REQUESTING CONSULTANT:		
Name [print]	Signature	Date
VERIFIED BY SENIOR ONCOLOGY PHARMACIST		
Name [print]	Signature	Date

Guidance for Serious Adverse Event Reporting for Patients Receiving Off-Protocol Treatment

Definition:

Serious Adverse Event (SAE)

Any adverse event that:

- Results in death,
- Is life threatening
- Requires unexpected hospitalisation or unexpected prolongation of existing hospitalisation
- Results in persistent or significant disability or incapacity
- Results in any unexpected Grade IV toxicities

Except the following which should NOT be reported as SAEs:

- Hospitalisation due to febrile neutropenia
- Death following relapse

The following form must be completed by the requesting consultant or associate specialist within one week of knowlegde of the SAE.

Send to Judith Delaney and Dr N Goulden.

SAEs will be monitored by the Haematology/Oncology Chemotherapy Group and the outcome will be signed off by Dr N Goulden (Consultant Haematologist / PTC Lead Clinician) and J Delaney (Lead Pharmacist).

SERIOUS ADVERSE EVENT REPORT

Serious Adverse Event Report for Patients Receiving Off-Protocol Treatment

A Serious Adverse Event (SAE) is any adverse event that:

- results in death
- is life threatening
- requires unexpected hospitalisation or unexpected prolongation of existing hospitalisation
- results in persistent or significant disability or incapacity
- results in any unexpected grade IV toxicities

PATIENT NAME:……

DOB: [DD/MMM/YYYY].....

CONSULTANT:……

HOSPITAL……

DATE OF EVENT:……

TREATMENT RECEIVED:

BRIEF DESCRIPTION OF EVENT:

Form submitted by: ……

Date: [DD/MMM/YYYY].....