East Midlands Clinical Networks

Policy for Preventing Regular Deviation from Approved Network Chemotherapy Treatment Algorithms

1. Purpose of The Policy

- To ensure safe prescribing dispensing and administration of non-protocol chemotherapy
- To monitor the use of regimens not on the accepted network chemotherapy algorithm
- To outline the requirements for the occasional use of regimens not on the accepted algorithm

Until the advent of National Algorithms, East Midland Network Algorithms are agreed with the site specific oncologists / ECAG chair as appropriate, taking account of historic practice and commissioning policies. The CYPICS approved list is reviewed annually by the CYPICS Chemotherapy Group in consultation with all paediatric Haem/Onc consultants

2. Scope of Policy

2.1 This policy applies to all EM health professionals who prescribe dispense or administer anti cancer chemotherapy.

2.2 The policy covers cytotoxic medicines, monoclonal agents and small molecule drugs e.g. TKIs .Unlicensed medicines available on a compassionate use programme (as-opposed to off label use) are included in this policy. This policy does not cover the use of hormonal agents for cancer treatment.

2.3 The policy should be used in conjunction with local guidelines where available.

3. Non-Network Approved Regimen Request

3.1 Non-network approved regimens are regimens that have NOT been approved within a chemotherapy algorithm for a particular indication by the relevant ECAG and commissioners, or have a significant modification of the regimen detail agreed at trust level. e.g. omission substitution or addition of a drug

3.2 Dose reductions to an approved regimen due to renal or hepatic function, other co-morbidities or performance status do not require a “non-protocol” request form. However, the reason for dose reduction must be clearly documented in accordance with local procedures.

3.3 Occasional use of such regimens may occur in exceptional circumstances, for example for one-off patients for whom there is no suitable regimen currently agreed by the Network.

3.4 The “non-protocol” request form must be completed by the relevant consultant.

It must contain the following information:

- Details of the regimen with indication, drugs, doses and scheduling

- Detail of treatment intent must be provided
- The performance status of the patient
- Published literature should be provided (not just a reference) to support the use of the regimen
- Clear evidence that the patient should have been discussed at the relevant MDT.
- Confirmation that the case has been discussed in accordance with trust procedures involving the chemotherapy lead/clinical director/pharmacy/ chemotherapy nurse.
- Costs implications must be confirmed and the appropriate application made to secure funds
- Where access to a non-commissioned protocol is required involving drugs licensed since 1 January 2005 which are not routinely funded by the NHS as they have either been rejected by NICE, are yet to receive a Final Appraisal Determination or fall outside the scope of NICE e.g. unlicensed indication) an application must be made through the IFR process or by requesting a new regimen is considered for funding through the NHSE portal by an application here: https://specialisedservices.formstack.com/forms/untitled_form_3.
- Confirmation of funding approval should be received prior to treatment commencing unless the trust medical director agrees funding locally.

3.5 Pharmacy must be given a copy of the supporting evidence and funding approval, and as early as possible (preferably at least 2 weeks before anticipated treatment) to enable development of protocols, prescriptions and ordering of medicines, where necessary.

3.6 Clinical trial requests go through a separate approval process and are outside the scope of this document

4. Non-Network Approved Regimen Follow up

4.1 A 6 monthly report from each trust must be submitted to the Network Chemotherapy group via the chair of the group. This should include a nil return from those trusts with no non–protocol prescribing. This is to ensure regimens requested in a particular area are monitored and reviewed at regular intervals allowing algorithm review via the appropriate NSSGs.

4.2 Trusts will have in place a mechanism for developing regimens at a local level with sufficient detail to enable prescribing and details dosage adjustment.

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Before chemotherapy can be given this form MUST be completed and sent to the Pharmacy Department and agreed in line with EMCN Policy for Preventing Regular Deviation from Approved Network Chemotherapy Treatment Algorithms

Consultant:	
Diagnosis:	
Treatment Intent:	
Preferred start date:	
Performance Status	
Patient's : Height (cm)	
Weight (kg)	
Surface Area (m^2)	

Addressograph

Proposed protocol	**Dose**	**Actual Dose**	**Route**	**Schedule**

Interval between course state dates:	**Number of Chemotherapy cycles intended:**	**Treatment Review Frequency:**

Has this been discussed at a chemotherapy (Oncology or Haematology) Multi Disciplinary Team meeting/Peers:	**Yes**	**No**	**Date:**

REASONS FOR USE OF NON-PROTOCOL REGIMEN (Please indicate the appropriate reason)

Toxicity		No standard treatment	
Rare disorder		Non-malignant	
Refractory to standard Rx		Pregnancy	
Age		Clinical judgment	

Other (Please state) ……

Supporting Information & References **(Full details must be attached as supporting evidence i.e. not just an abstract)**

Are you going to propose adding this regimen to the network algorithm of approved regimens: Yes/No

Are there funding implications with the use of this regimen? If Yes: Cost per cycle ……	**Additional time:** Nursing - ……per cycle Pharmacy - …… per cycle **Additional equipment:** No Yes – Type…… **Other resources required:** imaging etc ……	**Pharmacy – Number of similar requests in last 12 months:** **Lead Pharmacist signature:** **Lead Chemo nurse signature:**
Consultant signature:	**Print Name:**	**Date:**

Head of Service signature:(Local Funding approval only)	**Funding via:** CDF IFR local mechanism	**Print Name:**

Pharmacy use Entered on spreadsheet by:	**Sent**	**Returned**	**Form Number**

Form /Trust	Date	Speciality	NSSG	Consultant	Hospital No	Patient Name	Diagnosis	Protocol/ Regimen	Performance Score PS
e.g. Number or received		State Onc/haem/ paed	Tumour site group-pick list	Initials	Identifier-not for submission	Local Identifier-not for submission	e.g Squamous NSCLC	e.g. Name with sufficient detail to clarify. Dose /m2 freqency etc	0-4

Treatment Intent	Reason	Discussed at MDT/or with Onc Peers	Chemo Admin Started	Comments/Follow-up
			Date of admin	