Pan Birmingham NHS
Cancer Network

PROCEDURE FOR THE AUTHORISATION OF A CHEMOTHERAPY REGIMEN NOT INCLUDED IN THE ACCEPTED LIST OF REGIMENS

Version History

Version	Date	Summary of Change/Process
1.0.1	June 2010	Ratified by Chemotherapy Lead Cancer Clinician for Birmingham Children's Hospital NHS Foundation Trust
1.0.2	June 2010	Approved by Birmingham Children's Hospital NHS Foundation Trust Chemotherapy Working Group

Date Approved by Birmingham Children's Hospital NHS Foundation Trust Chemotherapy Working Group	**June 2010**

Date for Review by Birmingham Children's Hospital NHS Foundation Trust Chemotherapy Working Group	**June 2012**

Date Adopted by Network	**October 2011**

This is a Birmingham Children's Hospital NHS Foundation Trust policy. POSCUs must never initiate treatment off the approved list without approval from a Birmingham Children's Hospital NHS Foundation Trust Consultant. Once approval has been sought the Birmingham Children's Hospital NHS Foundation Trust Consultant would follow this policy for approval.

This policy has been reviewed and approved by the Chair of the West Midlands Children's Cancer Network Co-ordinating Group

Gail Fortes-Mayer
Chair of the West Midlands Children's Cancer Network Co-ordinating Group
October 2011

Birmingham Children's Hospital NHS
NHS Foundation Trust

PROCEDURE FOR THE AUTHORISATION OF A CHEMOTHERAPY REGIMEN NOT INCLUDED IN THE ACCEPTED LIST OF REGIMENS

Contents

1 Introduction

This policy has been written and implemented in order to address Measure 09-7B-134 (DH Manual for Cancer Services 2008: Children's Cancer Measures 2009) which requires that *'the PTC chemotherapy group should agree a written policy with the CCNCG (CCNCG – Children's Cancer Network Coordinating Group) for preventing regular use of regimens not on the accepted list'.*

2 Purpose

- To ensure that consultant staff and/or clinical trial Chief or Principal Investigators are aware of the procedure for the inclusion into the 'accepted list' of a new chemotherapy regimen not previously used at BCH.

- To ensure that when chemotherapy is prescribed using a regimen not included in the 'accepted list' that an appropriate process is followed to ensure that the intended regime is clinically appropriate, that nursing and pharmacy staff have all the information they require in order to obtain and administer the regimen and that all funding issues have been addressed.

3 Duties

3.1 Duties within the Organisation

The lead officer for this document is identified on the title page.

3.2 Identification of Stakeholders

The following stakeholders have been identified within BCH: The Chemotherapy Working Group (CWG); the Cancer Locality Group; the Haematology Oncology Programme meeting; consultant staff and senior/specialist nursing staff within the Haematology Oncology specialty.
Outside BCH: The West Midlands Children's Cancer Network Group; Pan Birmingham Cancer Network Drug & Therapeutics Committee.

4 Method for development

4.1 Consultation and Communication with Stakeholders

The policy was drafted by Nigel Ballantine (Chair, CWG) and reviewed by the stakeholders previously identified. Comments and suggestions were incorporated until a final version was agreed by the CWG and ratified by the Head of Chemotherapy (HoC) and Lead Cancer Clinician (LCC).

5 Content

The following procedure should be followed whenever it is proposed to use a chemotherapy regimen that is not included in the current 'accepted list' of chemotherapy regimes:

- The Chair of the CWG should receive a request for use of the proposed regimen from the appropriate Diagnostic and Therapeutic Multidisciplinary Team (D+T MDT). The request should provide clear and explicit details of:
  - The patient, including BCH registration number, date of birth, a recent body weight and consultant.
  - The clinical reasons for considering a treatment regimen not on the current 'accepted list'.
  - The chemotherapy regimen, including but not limited to:
    - The doses of the individual drugs comprising the chemotherapy regimen
    - Dose reductions appropriate for young patients on the basis of age and/or body weight
    - The method of administration
    - The duration of any intravenous infusion(s)
    - Any regimen-specific timing of administration of chemotherapy drugs with respect to other chemotherapy drugs and/or supportive treatment
    - The frequency with which individual cycles will be given
  - An outline treatment plan with respect to number of cycles to be given and the criteria for dose modification and stopping treatment.
  - laboratory blood tests and other investigational parameters to be fulfilled prior to starting the chemotherapy course (intended number of cycles) and before individual cycles
  - The treatment and/or prevention of regimen-specific complications, including but not limited to
    - intravenous pre- and post-hydration
    - folinic acid rescue
    - the use of MESNA
    - the prevention of serious hypersensitivity reactions.
- The Chair will forward copies of the request to members of the Working Group and seek confirmation that the necessary information is available to permit the safe and effective delivery of the proposed treatment.
- If a scheduled meeting of the CWG is not imminent this should not preclude communication within the group via phone and email in order to provide a prompt response to the requesting clinician/D+T MDT.
- Should members of the group not have the necessary information available it is anticipated that that they will take responsibility, as appropriate to their professional duties and expertise, for finding the information required, communicating it to the group and making recommendations based upon it.
- Should it be necessary to seek further information or clarification from the patient's consultant this should be done through the Chair of the CWG.

- The Chair will also liaise with the Interface team in pharmacy to identify any funding issues related to the use of high cost drugs and, whenever necessary, assist the requesting consultant to complete a request for PCT funding.

- If any of the drugs in use in the regimen are not on the BCH hospital formulary the Chair or Head of chemotherapy will assist the requesting consultant to complete an application form for the BCH Drug and Therapeutics Committee

- Once the CWG is satisfied that all clinical issues relevant to the safe and effective preparation and administration of the regimen have been addressed, and funding secured, the Chair will inform the HoC and LCC of their recommendation that use of the regimen should be approved.

- The HoC and LCC, if satisfied with the recommendation, ratify the decision and inform both the Chair of the appropriate D+T MDT and the patient's consultant.

- In situations where a delay in agreeing the proposed regimen would have adverse clinical implications for the patient, provided all the information in the checklist in Appendix I is available treatment may be initiated with Chair's approval provided that the members of the CWG, the HoC and the LCC are informed the following day.

- The provisions in the paragraph immediately above do not remove the need to ensure before prescribing the regimen that funding is secured whenever the drug(s) to be administered will have a significant cost consequence to BCH.

  Nor should they be used to avoid informing the CWG of the intention to use a regimen not included in the 'accepted list' in a timely manner such that a decision can be made following proper consideration of all the issues and circumstances.

The procedure above should be followed for the first three patients it is intended to treat with the individual regimen. Following approval of the third use, or sooner if it is anticipated at the outset that three or more patients will be eligible to receive the regimen each year, it is expected that the appropriate D+T MDT will make a formal application to the CWG for the regimen to be included in the 'accepted list'.

6 References

Not applicable

7 Equality Impact Assessment

See Appendix F

8 Approval, Dissemination and Implementation

8.1 Approval of document

This document has been approved by the CWG and ratified by the HoC and LCC.

8.2 Dissemination

An electronic copy will be provided for all consultant staff within the Specialty and to pharmacy.

It will be available electronically via the Trust Intranet in the Oncology department and Trust policies folders.

8.3 Implementation

Compliance with the policy will be monitored by the Pharmacy department who will identify any prescription for a regimen that is not included on the 'accepted list' and ensure that the CWG is informed of any such situation.

9 Monitoring Compliance With and the Effectiveness of the policy

9.1 Process for Monitoring Compliance and Effectiveness

It is intended that the CWG will receive a report on the use of regimens not included in the 'accepted list' at six monthly intervals. Such reports will inform an assessment as to whether the procedure set out above is appropriate to the needs of patients, staff and the service and suggest regimens that should be considered for inclusion in the 'accepted list'.

9.2 Standards/Key Performance Indicators

- All proposed use of regimens not at the time included in the 'accepted list' to have been notified to the CWG in a timely manner.
- All issues regarding high-cost drugs to have been addressed to ensure financial risk and implications for the Trust are minimised.
- All required information to enable the regime to be safely and effectively prescribed, prepared and administered is available at the outset.
- The accepted list is maintained and updated to ensure it reflects current practice with respect to the delivery of chemotherapy to patients in the care of the Trust.

10 Associated Documentation

The 'accepted list' of chemotherapy regimens at BCH

Appendix I

Check list for use of a non-approved regimen

Has the request come from a Diagnostic & Therapeutic MDT?	
Is the patient appropriately identified?	
Is the clinical rationale clearly stated?	
Is the chemotherapy regimen explicit with respect to:	
Laboratory and other investigations required prior to each treatment course?	
Drugs required?	
Dose(s), and any dose reduction for young age / low body weight?	
Route(s) of administration?	
Method(s) of administration – dilution, infusion time etc?	
Supportive treatment(s) required e.g. rescue medication, supportive care?	
Number of intended cycles, and cycle frequency?	

Appendix D - Checklist for the Review and Approval of Procedural Document

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Is the method described in brief?	Yes	
	Are people involved in the development identified?	Yes	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	N/A	
	Are key references cited?	N/A	
	Are the references cited in full?	N/A	
	Are supporting documents referenced?	Yes	
6.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	N/A	

	Title of document being reviewed:	Yes/No/ Unsure	Comments
7.	**Dissemination and Implementation**		
	Is there an outline/plan to identify how this will be done?	Yes	
	Does the plan include the necessary training/support to ensure compliance?	N/A	
8.	**Document Control**		
	Does the document identify where it will be held?	Yes	
	Have archiving arrangements for superseded documents been addressed?	N/A	
9.	**Process to Monitor Compliance and Effectiveness**		
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Yes	Yes, use of regimens not included on the list
	Is there a plan to review or audit compliance with the document?	Yes	
10.	**Review Date**		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so is it acceptable?	Yes	
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for co-ordinating the dissemination, implementation and review of the document?	Yes	

Individual Approval			
If you are happy to approve this document, please sign and date.			
Name		Date	
Signature			
Committee Approval			
If the committee is happy to approve this document, please sign and date it and forward copies to the person with responsibility for disseminating and implementing the document and the person who is responsible for maintaining the organisation's database of approved documents.			
Name		Date	
Signature			

Appendix F - Equality Impact Assessment

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

EQUALITY IMPACT ASSESSMENT FORM

SECTION 1:

Department: Haematology Oncology	**Assessor: Nigel Ballantine**
Policy/ Service Title: Procedure for the authorisation of a chemotherapy regimen not included in the list of accepted regimens	**Date of Assessment:** 10-5-2010
1. Describe the purpose of this policy or function	The Children's Cancer Measures 2008 (7B-134) require that the *'PTC (principal treatment centre) chemotherapy group should agree a written policy with the CCNCG (Children's Cancer Network Co-ordinating Group) for preventing regular use of regimens not on the accepted list. The policy should state:* • *the exceptional circumstances under which such a regimen could be used;* • *the procedure which is then required to authorise it'.* This policy has been created to address this requirement.
2. Who is affected by this policy?	Medical, nursing and pharmacy staff at BCH.
3. What are the outcomes or intended outcomes of this policy/ function?	This policy will ensure that when unusual or previously unused regimens are used staff will have the information necessary to ensure that, if approved, the treatment can be prescribed, prepared and administered safely and effectively. Secondarily, compliance with Children's Cancer Measure 7B-134.
4. What consultation has been undertaken during the development of this policy/function?	Stakeholders identified in the policy
5. What information or evidence has been used to assess the potential impact across the equality strands?	This policy will have no implications with respect to Equality Impact

IMPACT		
1. What is the impact or likely impact, either positive or negative, of the initiative on individuals, staff, or the public at large? None		
2. Please complete the following list and identify if there is, or likely to be, an impact on a group		
a) Grounds of race, ethnicity, colour, nationality or national origins.	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
b) Grounds of sexuality or marital status	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
c) Grounds of gender	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
d) Grounds of religion or belief	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
e) Grounds of disability	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
f) Grounds of age	~~Yes~~ ☐ No ☐	Adverse? ☐ Provide further details:
If you have stated that there is an adverse impact a Full Impact Assessment is Required. Complete Section 2.		

SECTION 2:

Modifications
1. If you stated that the policy/ function has or could have an adverse impact on any group, how could you modify it to reduce or eliminate any identified negative impacts?
2. If you make these modifications, would there be an impact on other groups, or on the ability of the policy to achieve its purpose?
Consultation **Under the Race Relations (Amendment) Act 2000 you are required to consult on the impact of new policies, functions and service change.**
3. How do you plan to consult on these modifications? Specify who would be involved, timescales and methods.

Decision Making
1. Who will make the decision?
2. What is the decision? ☐ Reject the policy/ function ☐ Introduce the policy/ function ☐ Amend the policy/ function ☐ Other (Please explain)

Monitoring and Review
1. How will the implementation of the policy/ function and its impact be monitored?
2. What are the overall learning points from this assessment?
3. What actions are recommended from this assessment?
4. When is the review date?

For advice in respect of answering the above questions, please contact the Equality and Diversity Officer on Ext: 8611. A completed form must be returned with your procedural document.

Appendix G - Version Control Sheet

Version	Date	Author	Comment (Identify any significant changes to the procedural document)

Appendix H - Plan for Dissemination of Procedural Documents

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

Title of document:	Procedure for the authorisation of a chemotherapy regimen not included in the list of accepted regimens		
Date finalised:		**Dissemination lead: Print name and contact details:** Nigel Ballantine (NB)	BCH email Ext: 8673
Previous document already being used?	~~**Yes**~~ **/ No** (Please delete as appropriate)		
If yes, in what format and where?			
Proposed action to retrieve out-of-date copies of the document:			

To be disseminated to:	**How will it be disseminated, who will do it and when?**	**Paper or Electronic**	**Comments**
HaemOnc consultants	NB	E	
D+T MDT leads	NB	E	
Pharmacy	NB	E	
Trust policies	NB	E	

Dissemination Record – to be used once document is approved.

Date put on register / library of procedural documents		**Date due to be reviewed**	

Disseminated to: (either directly or via meetings, etc)	**Format (i.e. paper or electronic)**	**Date Disseminated**	**No. of Copies Sent**	**Contact Details / Comments**