

The Newcastle upon Tyne Hospitals NHS Foundation Trust

Thalidomide Prescribing Policy

Effective: July 2010

Review: July 2012

1. Introduction

Until recently thalidomide was only available as an unlicensed medicine. In June 2008 Thalidomide was licensed (by Celgene) for first-line treatment of multiple myeloma in combination with melphalan and prednisone - the MP-T regimen. Thalidomide is also used as a single agent and in combination with chlorambucil and dexamethasone.

Celgene in conjunction with the Medicines and Healthcare products Regulatory Agency (MHRA) developed the 'Thalidomide Pharmion™ Pregnancy Prevention Programme' (TPPPP). This was a condition of getting a product license because of risks associated with prescribing thalidomide. All documentation required for TTPPP and referred to in this policy is available under the BNF/ Medicines Info section on the intranet. Click on "Prescribers Forms" http://intranet/Pharm_Forms/forms.htm

This policy should be used in conjunction with the "Management of Anti-cancer Medicines within the Newcastle- upon Tyne NHS Foundation Trust – Interim Guidance for all oncology and Haemato-oncology patients receiving Thalidomide.

2. Governance Information

- 2.1 Thalidomide treatment must be initiated and monitored under the supervision of a physician with expertise in managing immunodulatory or chemotherapeutic agents and a full understanding of the risks of thalidomide therapy and monitoring requirements.
- 2.2 Patients must not become or attempt to become pregnant during thalidomide treatment. For women of child bearing potential a negative pregnancy test during the 24 hours prior to each cycle of thalidomide will be required.
- 2.3 In the Pregnancy Prevention Programme a prescriber must:
 - Communicate the risks and benefits of Thalidomide Pharmion™ therapy to their patients.
 - Complete a 'Treatment Initiation Form' with the patient before the first prescription is issued. This is only done at the first cycle. There are three versions of this form. Provide the patient with a 'Health Card'.

- Provide pregnancy prevention measures and counselling.
- Perform a pregnancy test (as appropriate) prior to every prescription
- Complete a 'Prescription Authorisation Form' with each prescription to show confirmation that the patient has received counselling and pregnancy test date and result (if appropriate) Remind the patient of the safe use of Thalidomide Pharmion™

3. Prior to Starting Treatment with Thalidomide

- 3.1 All patients should be fully educated regarding the teratogenic effects of thalidomide, advised that thalidomide must not be given to any other person, that they should return unused capsules to the pharmacy and that they should not donate blood during or up to one week after treatment.
- 3.2 All patients should be assessed and categorised into one of the following categories: women of childbearing potential, women of non-childbearing potential and male patients. These categories define the education and risk minimisation measures that should be followed. Further information can be found in the TPPPP Information for Healthcare Professionals.
- 3.3 The prescriber and patient should complete and sign a "Treatment Initiation Form" corresponding to their risk category. It is the responsibility of the prescriber to ensure that the form is completed correctly and signed. The prescriber should retain the completed form; provide one copy to the patient and a copy to the pharmacy department (together with the "Prescription Authorisation Form"). This form documents that the patient has received all necessary information and has understood the key education points.
- 3.4 All women of childbearing potential must be using an effective method of contraception for four weeks before therapy is commenced. Further information can be found in the TPPPP Information for Healthcare Professionals.
- 3.5 All patients should receive a "Health Card" which provides details of emergency contact numbers, side effects, the teratogenic effects and information for Healthcare professionals.

4. During Treatment with Thalidomide

- 4.1 A copy of the Treatment Initiation Form must be received by the pharmacy department for all new patients. If the form is missing or incomplete the prescription will not be dispensed and the prescriber contacted to complete the form.
- 4.2 A "Prescription Authorisation Form" must accompany each prescription of Thalidomide. The form must contain the correct patient details, patient category, details of the pregnancy test if applicable and details of appropriate counselling. This must be presented to the pharmacy for checking.

- 4.3 For women of childbearing potential, ideally the pregnancy testing, issuing of the prescription and dispensing should occur on the same day (the pregnancy test must not be more than three days old).
- 4.4 For women of non-childbearing potential and male patients dispensing should only occur within seven days of the prescription date. If more than seven days has elapsed, the prescription will not be dispensed and the prescriber will be contacted.
- 4.5 For women of child bearing potential, the pharmacy will not dispense longer than 4 weeks supply. Continuation of treatment requires a new prescription and pregnancy test result.
- 4.6 For women of non-child bearing potential and male patients, the pharmacy may dispense a maximum of twelve weeks, but further supplies will require a new prescription.

5. Admission to Hospital during Thalidomide Treatment

- 5.1 On admission patients already prescribed thalidomide must bring their medication into hospital with them or ask a relative to do so for them.
- 5.2 If deemed suitable for use by local Patient Own Drug assessment procedure, the patient's own supply must be used during admission and used as discharge supply until next "Thalidomide-clinic" appointment.
- 5.3 During the admission Thalidomide must be prescribed on an in-patient kardex.
- 5.4 The kardex must be annotated as per local policy to prompt the use of the patient's own medication.
- 5.5 If it is not possible to use the patients' own supply or if patients' own supply runs out, the original prescriber must be contacted in order to arrange a new prescription. This should be written on a pink discharge prescription. A "Prescription Authorisation Form" must also be supplied,
- 5.6 Thalidomide cannot be dispensed as a temporary stock or in the CD order book.

6. Monitoring

Compliance with the policy will be monitored through an annual audit by the Lead Clinical Pharmacist Adult Cancer Services. The audit will examine the completion of documentation. The results of the audit will be presented to the Chemotherapy Committee and in addition discussed with the Lead Clinical Pharmacist Team to identify any requirements for improving patient care.

This policy will be reviewed every two years. Comments on the content and implementation must be directed to E. Reay, Lead Clinical Pharmacist Adult Cancer Services or S. Brice, Assistant Director of Pharmacy

Author Lead Clinical Pharmacist Adult Cancer Services

7. References

Thalidomide Pharmion[™] Pregnancy Prevention Programme Educational Kit

Trustwide Procedure for Handling Prescriptions for Thalidomide, Northumbria Healthcare NHS Foundation Trust.

**The Newcastle upon Tyne Hospitals NHS Foundation Trust
Impact Assessment - Screening
Form A**

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

	Policy Title: THALIDOMIDE TRUST POLICY.....	Policy Author	ELIZABETH REAY
		Yes/No	What evidence can you provide to support your response
1.	Does the policy/guidance affect one group less or more favourably than another on the basis of:		
	• Race	NO	
	• Ethnic origins (including gypsies and travelers)	NO	
	• Nationality	NO	
	• Gender	NO	
	• Culture	NO	
	• Religion or belief	NO	
	• Sexual orientation including lesbian, gay and bisexual people	NO	
	• Age	NO	
	• Disability – learning difficulties, physical disability, sensory impairment and mental health problems.	NO	
2.	Is there any evidence that some groups are affected differently?	NO	
3.	If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?	N/A	
4.	Is the impact of the policy/guidance likely to be negative?	NO	
5.	If so can the impact be avoided?	N/A	
6.	What alternatives are there to achieving the policy/guidance without the impact?	N/A	
7.	Can we reduce the impact by taking different action?	N/A	

For advice on answering the above questions please contact Helen Lamont, Deputy Director Nursing & Patient Services, or, Christine Holland, Senior HR Manager. On completion this form must be forwarded electronically to Steven Stoker, Clinical Effectiveness Manager, (Ext. 24963) steven.stoker@nuth.nhs.uk together with the procedural document. If you have identified a potential discriminatory impact of this procedural

document, please ensure that you arrange for a full consultation with relevant stakeholders to complete a Full Impact Assessment (Form B) and to develop an Action Plan to avoid/reduce this impact; both Form B and the Action Plan should also be sent electronically to Steven Stoker.

Name of Person responsible for completion of this form:.....Elizabeth Reay.....
.....

Date of Completion:13 October 2008..... Action Plan due (or Not Applicable):.....N/A.....

(If any reader of this procedural document identifies a potential discriminatory impact that has not been identified on this form, please refer to the Policy Author identified above, together with any suggestions for the actions required to avoid/reduce this impact.)