Mid Essex Hospital Services NHS
NHS Trust

Thalidomide: Prescribing and Supply Policy	**Policy** **Register No: 09130** **Status: Public**

Developed in response to:	Local Needs and National Patient Safety Agency alert for Oral Chemotherapy
Contributes to CQC Outcome number:	9

Consulted With	**Post/Committee/Group**	**Date**
Dr V Chowdhury	Consultant Haematologist	October 2014
Dr H. Eden	Consultant Haematologist	October 2014
Dr A Jackson	MMSG Chairman's action	October 2014
Professionally Approved By	Jane Giles	October 2014

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Author/Contact for Information	Netty Cracknell
Policy to be followed by (target staff)	All Clinicians and Pharmacy Staff
Distribution Method	Trust Intranet and Website
Related Trust Policies (to be read in conjunction with)	Trust policies for Management of Medicines and Guidelines for the Management of Medication Errors, Investigating & Learning from Incidents policy, Near Misses and Adverse Drug Reactions and Mandatory Training Policy (training needs analysis)

Document Review History

Version No	Authored/Reviewed by	Review Date
1.0	Rosemary Oakley	3rd December 2009
2.0	Netty Cracknell	September 2014

Index

1. Purpose

1.1 Following the introduction of the licensed Thalidomide product manufactured by Pharmion, there is a change in the procedure for prescribing and dispensing thalidomide.

1.2 This is to ensure safe prescribing and dispensing of Thalidomide tablets.

2. Scope

2.1 All persons involved in the supply process, including clinicians, nurses, and pharmacy staff.

3. Training

3.1 Training is delivered in accordance with the training needs analysis (Learning & Development strategy).

4. Equality and Diversity

4.1 Mid Essex Hospital Services NHS Trust (MEHT) is committed to the provision of a service that is fair, accessible and meets the need of all individuals.

5. Prior to starting treatment with Thalidomide

5.1 All patients should:

- be fully educated about the teratogenic effects of Thalidomide
- be advised that Thalidomide must not be given to any other person
- return all unused capsules to the pharmacist
- not donate blood during or up to 1 week after treatment

5.2 All patients should be assessed and categorised into the following categories:

- Women of child bearing potential,
- Women of non-child bearing potential
- Male patients

5.3 All patients must receive a patient information booklet – given out by the clinic.

6. Women of child bearing potential;

6.1 Contraception; All women of childbearing potential must use effective contraception for 4 weeks before therapy is commenced, unless the patient commits to absolute and continuous abstinence on a monthly basis.

6.1.2 If not established on effective contraception, the patient must be referred to an appropriately trained healthcare professional for contraceptive advice in order that contraception can be initiated.

6.1.3 Because of the increased risk of venous thromboembolism in patients with multiple myeloma, combined oral contraceptive pills are not recommended.

6.2 Pregnancy testing; Once the patient has been using effective contraception for at least 4 weeks, a medically supervised pregnancy test should be performed within 3

days prior to the visit to the prescriber. The test should ensure that the patient is not pregnant when she starts treatment with thalidomide.

6.3 Prescription Restrictions; Thalidomide prescription should be limited to **4 weeks of treatment**.

6.3.1 Continuation of treatment requires a new prescription.

6.4 Dispensing restrictions; Pharmacists may not dispense more than 4 weeks supply for women of childbearing potential.

6.4.1 Dispensing of thalidomide capsules should occur within a **maximum of 7 days** of the date of prescription.

7. Women of non childbearing potential

7.1 Prescription Restrictions; Thalidomide should be limited to 12 weeks of treatment.

7.1.1 Continuation requires a new prescription.

7.1.2 However, in order for the Trust to comply with NPSA oral chemotherapy guidance, prescriptions should usually only be for 4 weeks.

7.2 Dispensing restrictions; Pharmacists may not dispense more than 12 weeks supply.

7.2.1 However, in order for the Trust to comply with NPSA oral chemotherapy guidance, supply should usually only be for 4 weeks.

7.2.2 Dispensing of Thalidomide capsules should occur within a **maximum of 7 days** of the date prescription.

8. Male patients: as Thalidomide is found in semen, male patients must use condoms during treatment and for 1 week after dose interruption and /or cessation of treatment if their partner is pregnant or of childbearing potential and not using effective contraception.

9. Continued Treatment

9.1 A ‘Prescription Authorisation Form (PAF)’ must accompany each prescription for Thalidomide and each form must be checked for completeness by the dispensing pharmacist.

9.2 The prescription authorisation form documents that;

- the patient has been counselled,
- relevant pregnancy prevention measures are in place
- dispensing is taking place within 7 days of the prescription date.
- The prescribing physician and dispensing pharmacist have read and understood the Thalidomide Pharmion Healthcare Professional’s Education Kit.

9.3 For women of child bearing capacity:

- continued use of effective contraception during treatment and for 4 weeks after stopping therapy even in the case of a temporary dose interruption

- A medical supervised pregnancy test is performed every 4 weeks, including 4 weeks after end of treatment. The pregnancy test should be performed on the day of prescribing visit or in 3 days prior to visit to prescriber.

10. Summary:

- Appropriate initiation form completed (one copy in notes, two copies to patient, one to be handed to pharmacy with prescription. Pharmacy copy to be filed in Thalidomide folder in aseptics office.

- If 'woman of child bearing potential', regular pregnancy tests to be arranged by haematology consultant.

- New PAF to accompany every prescription presented at pharmacy. Pharmacy copy to be filed in Thalidomide folder in aseptics office.

11. Audit and Monitoring

11.1 The Pharmacy department has a responsibility for monitoring all prescribing and administration of medicines. This is done daily by the intervention reporting scheme (Intervention policy is being addressed by the department) and a full report is presented to the Medicines Management Safety Group (MMSG) bimonthly.

11.2 Significant prescribing errors identified will also be reported using the Risk Event Form following the Trust's Investigating & Learning from Incidents policy and fed back to the MMSG.

11.3 The MMSG is a group made up of wide representation of stakeholders who meet bimonthly within MEHT and any action plans will be allocated as appropriate.

11.4 Key learning points will be disseminated by a Drug Safety Bulletin every 2 months which shall be attached to the Trust's weekly newsletter "Focus".

12. Communication

12.1 Once professionally approved and ratified by DRAG this policy will be placed on the Trust's internet and highlighted via the Trust's weekly newsletter "Focus".

12.2 A copy of this policy will be placed in the Junior Doctor Handbook which is issued to all new doctors at induction, and referred to during the Medicines Management session delivered to Junior Doctors by the Pharmacy Department at their induction.

12.3 Areas of this policy relevant to Nursing Staff will be addressed at the mandatory Medicines Management training for nurses delivered by the Pharmacy Department.

13. References

National Patient Safety Agency, Rapid Response Report - Risks of incorrect dosing of oral anti-cancer medicines,reference: NPSA/2008/RRR001.