Mid Essex Hospital Services NHS
NHS Trust

Prescribing and dispensing of Lenalidomide (Revlimid®)	**Type: Policy** **Register No: 09131** **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, Dr S Elshazly, Dr W Nagi, Dr S Islam	Consultant Haematologists	January 2017
Professionally Approved By	SACT Quality Group	January 2017

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Author/Contact for Information	Sophie Wahlich, Principle Pharmacist – Oncology and Haematology
Policy to be followed by (target staff)	Clinicians, Nurses 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	Active Date
1.0	Rosemary Oakley	3rd December 2009
2.0	Netty Cracknell	October 2014
3.0	Sophie Wahlich	25 July 2017

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1. Purpose

1.1 To ensure safe prescribing and dispensing of Lenalidomide (Revlamid®) capsules.

2. Scope

2.1 All persons involved in the prescribing and 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. Responsibilities

5.1 It is the responsibility of any individual involved in any stage of the prescribing and dispensing process to ensure that the relevant steps are completed properly. This procedure includes the process to be used in the clinic as well as the dispensing process.

6. Prior to starting treatment with Lenalidomide

6.1 All patients should be fully educated about the teratogenic effects of Lenalidomide and advised that it should not be given to any other person.

6.2 All unused capsules should be returned to the pharmacist.

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

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

6.4 All patients must be counselled about lenalidomide and receive a patient information booklet. This is given out by the clinic.

6.5 Prior to cycle 1 a treatment initiation form should be completed; the original form needs to be filed in patient's notes, and copy given to patient.

6.6 A Prescription Authorisation Form (PAF) needs to accompany each cycle of treatment. These are completed online via the Celgene® ePAF website: https://ermp-ukire.celgene.com/_layouts/RMP.UKROI.FBA/LogIn.aspx?ReturnUrl=%2f_layouts%2fAuthenticate.aspx%3fSource%3d%252F&Source=%2F

6.7 All prescribing of lenalidomide should take place on ChemoCare®; the Trust's electronic prescribing system for Systemic Anti-Cancer Therapy.

7. Women of childbearing potential

7.1 Requirements for Contraception

7.1.1 All women of childbearing potential must use effective contraception for 4 weeks before therapy is commenced, during therapy and for 4 weeks after therapy has completed, unless the patient commits to absolute and continuous abstinence on a monthly basis.

7.1.2 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.

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

7.2 Pregnancy testing

7.2.1 Once the patient has been using effective contraception for at least 4 weeks, a medically supervised pregnancy test should be performed before treatment initiation, every 4 weeks during therapy and 4 weeks after therapy has completed.

7.2.2 The test should ensure that the patient is not pregnant when she starts treatment with Lenalidomide.

7.2.3 There must be no more than 3 days between the date of the pregnancy test and the date on the prescription

7.2.4 Best practice is for the pregnancy test, prescribing and dispensing to take place on the same day.

7.3 Prescription Restrictions

7.3.1 Lenalidomide prescription should be limited to **4 weeks of treatment**.

7.3.2 Continuation of treatment requires a new prescription and a new PAF.

7.4 Dispensing restrictions

7.4.1 Pharmacists may not dispense more than 4 weeks supply for women of childbearing potential.

7.4.2 Dispensing of Lenalidomide capsules should occur within a **maximum of 7 days** of the date of prescription (and see note above about timing of pregnancy test).

8. Women of non-childbearing potential

8.1 Prescription Restrictions

8.1.1 Lenalidomide should be limited to 4 weeks of treatment. Continuation requires a new prescription and a new PAF.

8.2 **Dispensing restrictions**

8.2.1 Pharmacists may not dispense more than 4 weeks supply.

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

9. Male patients

9.1 Contraception

9.1.1 Lenalidomide is found in semen, therefore if their partner is pregnant or of childbearing potential and not using effective contraception, male patients should use condoms throughout the duration of treatment, during dose interruption and for 1 week after cessation of treatment, even if the male patient has undergone a vasectomy.

9.2 Prescription Restrictions

9.2.1 Lenalidomide should be limited to 4 weeks of treatment. Continuation requires a new prescription and a new PAF.

9.3 **Dispensing restrictions**

9.3.1 Pharmacists may not dispense more than 4 weeks supply.

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

10. Continuing Treatment

10.1 A Prescription Authorisation Form (PAF) must accompany each prescription for Lenalidomide and each form must be checked for completeness by the dispensing pharmacist. These should be completed online via the Celgene® ePAF website.

10.2 The Prescription Authorisation Form (PAF) 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 Lenalidomide Celgene Healthcare Professional's Education Kit.

10.3 Any paper Prescription Authorisation Forms (PAF) received must be faxed by Pharmacy to Celgene®, **(Fax number 0808 156 3058).**

11. Incidents

Any breaches of this policy must be reported on a Risk Event Form.

12. Audit and Monitoring

12.1 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.

12.2 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.

12.3 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.

12.4 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".

13. Communication

13.1 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".

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

14. References

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

Celgene®, Revlimid® (lenalidomide), Healthcare Professional's Information Pack for the UK, version 4.0. Accessed online 06/01/2017 at 15:15 via: http://celgene.co.uk/content/uploads/sites/3/Revlimid_Healthcare_Professional_Information_Pack.pdf