1. Introduction

In June 2008, thalidomide was licensed by Celgene for first line treatment of multiple myeloma in combination with melphalan and prednisolone (M-PT). Thalidomide is also given as a single agent and combination with cyclophosphamide and dexamethasone. Formulary approval has also been granted for bowel angiodysplasia in patients with an inherited/ acquired bleeding disorder.

Due to the highly publicised teratogenic effects of thalidomide when taken in pregnancy, Celgene in conjunction with the Medicines and Healthcare Products Regulatory Agency (MHRA) developed the Thalidomide Pregnancy Prevention Programme. The license for this drug was granted due to the inclusion of this mandatory programme.

Lenalidomide and pomalidomide are also immunomodulating agents and are structurally similar to thalidomide. In June 2009, NICE recommended lenalidomide in combination with dexamethasone for the treatment of multiple myeloma for patients who have received two or more prior therapies. In September 2014 NICE also recommended lenalidomide for people with transfusion-dependent anaemia caused by low or intermediate -1 risk myelodysplastic syndromes associated with an isolated 5q deletion cytogenetic abnormality. Lenalidomide is also available via the Cancer Drugs Fund. Patients must be registered before treatment can commence. The supply of lenalidomide is also supported by a Pregnancy Prevention Programme.

Pomalidomide is only available for patients who were registered with the Cancer Drugs Fund prior to 4th November 2015. Patients registered prior to this date are eligible to continue treatment until relapse. Pomalidomide is currently undergoing NICE review. The guidance may change prior to the next document review. It is licensed for the treatment of refractory multiple myeloma, in patients previously treated with bortezomib, lenalidomide and an alkylating agent. As with thalidomide and lenalidomide, pomalidomide is supported by a Pregnancy Prevention Programme.

The Pregnancy Prevention Programmes for thalidomide, lenalidomide and pomalidomide have core requirements that include:

- All healthcare professionals dispensing or prescribing must read the Healthcare Professional Information Packs
• All pharmacies who dispense prescriptions must agree to implement risk minimisation by registering with Celgene using the Pharmacy Registration Form.
• A Treatment Initiation / Consent Form should be completed with the patient before the first prescription is issued.
• Every prescription must be accompanied by a Prescription Authorisation Form or an Electronic Prescription Authorisation Form (ePAF).

2. Scope

This policy applies to all staff involved in the prescribing and supply of thalidomide, lenalidomide and pomalidomide for all patients for all indications.

3. Aims

This policy is to ensure that all prescribing and supply of thalidomide, lenalidomide and pomalidomide for all patients and indications, follows the guidance in the Healthcare Professional's Information Packs and all requirements in the Pregnancy Prevention Programme.

4. Duties of Staff

4.1 All consultants must ensure that:

4.1.1 The patient is fully educated on the risks of these drugs and is supplied with appropriate information card and booklet.

4.1.2 The correct documentation is completed and available with the prescription.

4.1.3 If relevant, the patient is using the appropriate pregnancy prevention measures.

4.1.4 Female patients of child-bearing potential receive a pregnancy test, which must be negative, before every prescription issued.

4.1.5 All prescribing is in accordance with the Healthcare Professionals Information Packs available for thalidomide, lenalidomide and pomalidomide.

4.2 All Clinical Nurse Specialists and general nurses must ensure that:

4.2.1 They have read the Healthcare Professionals Information Packs available for thalidomide, lenalidomide and pomalidomide.

4.2.2 The patient is fully educated on the risks of these drugs and is supplied with appropriate information card and booklet.
4.3 All pharmacists must ensure that:

4.3.1 The pharmacy is registered with Celgene for the supply of thalidomide, lenalidomide and pomalidomide.

4.3.2 The drugs are only dispensed when accompanied by a Prescription Authorisation Form/ePAF.

4.3.3 The prescription is dispensed in accordance with measures given in the Healthcare Professionals Information Packs.

4.3.4 An audit of thalidomide is performed and submitted annually to Celgene.

4.3.5 The Prescription Authorisation Forms for lenalidomide and pomalidomide are sent to Celgene.

4.3.6 Where the prescription has an associated ePAF the dispensing pharmacy must tick ‘Dispensed’. This sends the information to Celgene.

4.3.7 Patients are reminded of the key education messages regarding the use of these drugs.

4.4 All pharmacy technicians must ensure that:

4.4.1 The drugs are only dispensed when accompanied by a Prescription Authorisation Form/ePAF.

4.4.2 The prescription is dispensed in accordance with measures given in the Healthcare Professionals Information Packs.

4.4.3 Patients are reminded of the key education messages regarding the use of these drugs.

5. Definitions

Teratogenic - Capable of producing foetal malformations.

6. Policy

6.1 Governance Information

6.1.1 Thalidomide, lenalidomide and pomalidomide treatment must be initiated and monitored under the supervision of a physician with expertise in managing immunodulatory or chemotherapeutic agents and has a full understanding of the risks of such therapy and the monitoring requirements.

6.1.2 It is a requirement of the PPPs that all healthcare professionals ensure that they have read and understood the Healthcare Professionals
Information Packs for all drugs before prescribing or dispensing thalidomide, lenalidomide and pomalidomide for all patients.

6.1.3 The pharmacy department must be registered with Celgene to be able to order and dispense thalidomide, lenalidomide and pomalidomide. The chief pharmacist or appointed deputy must complete the Pharmacy Registration Form and fax to Celgene to register the premises. This form confirms adherence to all procedures stipulated in the Healthcare Professionals Information packs and agreement that an annual audit of these procedures will be conducted by the pharmacy department.

6.1.4 Lloyds’ pharmacies based within Newcastle upon Tyne Hospitals NHS Foundation Trust will be responsible for dispensing thalidomide, lenalidomide and pomalidomide for both outpatients and inpatients.

6.1.5 The Pregnancy Prevention Programmes for thalidomide, lenalidomide and pomalidomide have core requirements that include:

- All healthcare professionals dispensing or prescribing must read the Healthcare Professional Information Packs
- All pharmacies who dispense prescriptions must agree to implement risk minimisation by registering with Celgene using the Pharmacy Registration Form.
- The prescriber must communicate the risks and benefits of thalidomide and lenalidomide therapy to the patient on all occasions and provide counselling and information.
- A Treatment Initiation Form should be completed with the patient before the first prescription is issued for thalidomide only. A Consent form should be completed by the prescriber and signed by the patient for lenalidomide and pomalidomide therapy.
- The prescriber must perform a pregnancy test (as appropriate) prior to every prescription.
- For thalidomide, lenalidomide and pomalidomide, ALL prescriptions must be accompanied by a completed Prescription Authorisation Form/ePAF.

6.1.6 All prescriptions will be clinically checked by a cancer services pharmacist or suitably trained dispensary pharmacist competent to check immunomodulating agents prior to dispensing. The pharmacist will discuss any errors on the prescription or required documentation with the prescriber before signing accordingly.
6.2 Prior to Starting Treatment with Thalidomide, Lenalidomide and Pomalidomide

6.2.1 All patients should be fully educated regarding the following:

- Teratogenic effects of the drugs,
- Advised that these drugs must not be given to any other person,
- That they should return unused capsules to the pharmacy
- They should not donate blood during or up to one week after treatment.

6.2.2 All patients should be assessed and categorised into one of the following categories:

- Women of childbearing potential,
- Women of non-childbearing potential
- Male patients

These categories define the education and risk minimisation measures that should be followed. Women of childbearing potential must be using an effective method of contraception for four weeks before therapy is commenced. Further information to define these categories and details concerning contraception can be found in the Healthcare Professionals Information packs.

6.2.3 In the case of thalidomide, 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.

6.2.4 For lenalidomide and pomalidomide patients, a consent form must be completed by the prescriber and signed by the patient. A copy should be made available for the patient if required. The Pharmacy department does not receive a copy of the consent form.

6.2.5 All patients should be given a copy of the Patient Booklet to take home. The booklet contains separate sections providing information for women of childbearing potential, women of non-child bearing potential and men, as well as a section describing safety information relevant to all patients. A Health Card or Wallet card should also be issued before initiating treatment which provides details of emergency contact numbers, side
effects, the teratogenic effects and information for other Healthcare professionals.

6.3 During Treatment with Thalidomide, Lenalidomide and Pomalidomide

6.3.1 A “Prescription Authorisation Form/ePAF” must accompany each prescription. 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 and will be retained for a minimum of two years.

6.3.2 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).

6.3.3 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.

6.3.4 For women of child bearing potential, the pharmacy will not dispense more than a four weeks supply. Continuation of treatment requires a new prescription and pregnancy test result.

6.3.5 With regards to thalidomide, lenalidomide and pomalidomide, 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.

6.4 Admission to Hospital during Thalidomide, Lenalidomide or Pomalidomide Treatment

6.4.1 On admission patients already prescribed these drugs must bring their medication into hospital with them or ask a relative to do so for them.

6.4.2 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 clinic appointment.

6.4.3 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. A “Prescription Authorisation Form/ePAF” must also be supplied.

6.4.4 If a new supply is required during admission to hospital Lloyds’ pharmacies will dispense this.
6.4.5 During the admission for haematology patients, the prescription can be confirmed with Chemocare and then prescribed on E-record.

6.4.6 Thalidomide for non-haematological indications can be prescribed on E-Record.

6.4.7 A message will alert the prescriber when the drug is being prescribed. This reads as follows: **Thalidomide must be prescribed and supplied in accordance with the Healthcare Professionals Information Pack. A Prescription Authorisation Form must accompany the prescription before the drug can be supplied. For haematological indications prescribe on Chemocare.**

6.4.8 Duration of treatment, pregnancy testing and validity of the prescription stipulated for out-patients also apply for in-patient supply.

6.4.9 The drugs will not be dispensed as a temporary stock, medication request or in the CD order book.

7. **Training**

7.1 It is a requirement of the PPPs that all healthcare professionals should ensure that they have read and understood the Healthcare Professionals Information Packs before prescribing or dispensing thalidomide, lenalidomide or pomalidomide for all patients.

- Thalidomide Healthcare Professionals Information Pack
- Revlimid® Healthcare Professionals Information Pack
- Imnovid® Healthcare Professionals Information Pack

7.2 This should ideally be completed in the induction period for new members of staff.

8. **Equality and Diversity**

The Trust is committed to ensuring that, as far as is reasonably practicable, the way we provide services to the public and the way we treat our staff reflects their individual needs and does not discriminate against individuals or groups on any grounds. This document has been appropriately assessed.
9. Monitoring Compliance

9.1 Thalidomide Audit

<table>
<thead>
<tr>
<th>Standard / process / issue</th>
<th>Monitoring and audit</th>
<th>By</th>
<th>Committee</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provide background information on the audit</td>
<td>Provide background information for the audit, by providing feedback on the use of the material supplied by Celgene</td>
<td>Lloyds’ Pharmacy</td>
<td>Medicines Management Committee</td>
<td>Annually</td>
</tr>
</tbody>
</table>
| Evaluate the extent of off-label prescribing and determine the patient populations receiving treatment | Evaluate the extent of off-label prescribing from diagnosis recorded on the Prescription Authorisation form  
Determine the patient populations receiving treatment from the DOB, sex and childbearing status on the Prescription Authorisation Form                                                                 | Lloyds’ Pharmacy          | Medicines Management Committee           | Annually  |
| Evaluate the coverage of the audit                                                         | Establish what proportion of the total prescription Authorisation Forms processed in the current audit period is represented by the 20 most recent forms audited for part 4                                                      | Lloyds’ Pharmacy          | Medicines Management Committee           | Annually  |
| Evaluate compliance with the Thalidomide Celgene Prescription Authorisation Form            | Establish whether the prescription authorisation forms are filed/ stored in registered pharmacies.  
Determine if every pharmacy dispensing thalidomide has access to a current copy of information pack.  
Ascertain if a Prescription Authorisation Form is completed with every prescription.  
Audit a sample of 20 Prescription Authorisation Forms with respect to: they are fully completed and signed by the prescriber. They are countersigned by a pharmacist. For women of childbearing | Lloyds’ Pharmacy          | Medicines Management Committee           | Annually  |
they show evidence of a negative pregnancy test. All patients dispensing is within 7 days of the prescription date.

9.2 Lenalidomide and Pomalidomide Audit

9.2.1 Lenalidomide and pomalidomide Prescription Authorisation Forms are recorded electronically using the ePAF system. Any data required for audit is collected directly from this system by Celgene.

10. Consultation and review

This policy has been reviewed and agreed by members of the Medicines Management Committee.

11. Implementation (including raising awareness)

Changes to the policy will be published on the intranet and in the Trust Policy Newsletter.

12. References

- Thalidomide Healthcare Professionals Information Pack
- Revlimid® Healthcare Professionals Information Pack
- Imnovid® Healthcare Professionals Information Pack
- Lenalidomide for the treatment of multiple myeloma in people who have received at least one prior therapy : Technology Appraisal Guidance No. 171 (NICE)
- Lenalidomide for treating myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality | Guidance and guidelines | NICE
- National Cancer Drugs Fund List Version 6.0

13. Associated Documentation

- SOP for the Supply of Thalidomide, Lenalidomide and Pomalidomide, Pharmacy, Newcastle upon Tyne Hospital NHS Foundation Trust
- Anti-cancer Medicines Policy and Guidance on the Management of Patients receiving Cytotoxic Chemotherapy
The Newcastle upon Tyne Hospitals NHS Foundation Trust

Equality Analysis Form A

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

PART 1

1. Assessment Date: 10/02/2016

2. Name of policy / strategy / service:
   Thalidomide, Lenalidomide and Pomalidomide Prescribing Policy

3. Name and designation of Author:
   Sumantha Gabriel Lead Clinical Pharmacist – Specialist Haematology

4. Names & designations of those involved in the impact analysis screening process:

5. Is this a: Policy X Strategy Service
   Is this: New Revised X
   Who is affected Employees X Service Users Wider Community

6. What are the main aims, objectives of the policy, strategy, or service and the intended outcomes? (These can be cut and pasted from your policy)
   To ensure the safe prescribing and dispensing of thalidomide, lenalidomide and pomalidomide.

7. Does this policy, strategy, or service have any equality implications? Yes No X
   If No, state reasons and the information used to make this decision, please refer to paragraph 2.3 of the Equality Analysis Guidance before providing reasons:
   The policy has no equality implications
8. **Summary of evidence related to protected characteristics**

<table>
<thead>
<tr>
<th>Protected Characteristic</th>
<th>Evidence, i.e. What evidence do you have that the Trust is meeting the needs of people in various protected Groups</th>
<th>Does evidence/engagement highlight areas of direct or indirect discrimination? If yes describe steps to be taken to address (by whom, completion date and review date)</th>
<th>Does the evidence highlight any areas to advance opportunities or foster good relations. If yes what steps will be taken? (by whom, completion date and review date)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Race / Ethnic origin (including gypsies and travellers)</td>
<td>No reference is made within the policy to any particular racial group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sex (male/ female)</td>
<td>No reference is made within the policy to any particular sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Religion and Belief</td>
<td>No reference is made within the policy to any particular religion or belief</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sexual orientation including lesbian, gay and bisexual people</td>
<td>No reference is made within the policy to any particular sexual orientation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>No reference is made within the policy to any particular age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Disability – learning difficulties, physical disability, sensory impairment and mental health. Consider the needs of carers in this section</td>
<td>No reference is made within the policy to any particular disability</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender Re-assignment</td>
<td>No reference is made within the policy to Gender Re-assignment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marriage and Civil Partnership</td>
<td>No reference is made within the policy to Marriage and Civil Partnership</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maternity / Pregnancy</td>
<td>The policy details specific guidance to avoid pregnancy whilst taking this medication. There is a compulsory pregnancy prevention programme (PPP) associated with prescribing these medications as they are all teratogenic.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. **Are there any gaps in the evidence outlined above? If ‘yes’ how will these be rectified?**

   No

10. **Engagement has taken place with people who have protected characteristics and will continue through the Equality Delivery System and the Equality Diversity and Human Rights Group. Please note you may require further engagement in respect of any significant changes to policies, new developments and or changes to service delivery. In such circumstances please contact the Equality and Diversity Lead or the Involvement and Equalities Officer.**
Do you require further engagement?  Yes  No  

11. Could the policy, strategy or service have a negative impact on human rights? (E.g. the right to respect for private and family life, the right to a fair hearing and the right to education?)  

No  

PART 2  

Name:  
Sumantha Gabriel  

Date of completion:  
10th February 2016  

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