• PREGNANCY PREVENTION PROGRAM •

PATIENT AGREEMENT FORM

FOR IMMUNOMODULATORY AGENTS

Revlimid® (Lenalidomide) and Pomalyst® (Pomalidomide)

INTRODUCTION

This form must be completed for each patient prior to the initiation of treatment with lenalidomide and pomalidomide. A separate copy should be filled out per product, specifying which immunomodulatory agent the patient is receiving. Both the healthcare professional and patient must fill out parts of this form.

This patient is receiving: ☐ Lenalidomide ☐ Pomalidomide

The aim of this form is to ensure patients are aware of the risks associated with product exposure to a developing fetus and understand the risk of teratogenicity associated with use of lenalidomide and pomalidomide. It is not a contract and does not absolve anyone from their responsibilities with regard to the safe use of the product and prevention of fetal exposure to lenalidomide and pomalidomide.

Warning: Thalidomide is a powerful human teratogen and, if taken during pregnancy, can cause severe birth defects or death to a developing fetus. In the 1950s and 1960s, thalidomide was prescribed to pregnant women as a sedative and to relieve morning sickness. Consequently, approximately 12,000 children were born with severe birth defects caused by thalidomide. Lenalidomide and pomalidomide are structurally related to thalidomide. Lenalidomide induced malformations in monkeys similar to those described with thalidomide, and pomalidomide was found to be teratogenic in both rats and rabbits when administered during the period of major organogenesis. If lenalidomide or pomalidomide are given during pregnancy, a teratogenic effect in humans cannot be ruled out. The conditions of the Pregnancy Prevention Program (PPP) must be fulfilled for female patients unless there is reliable evidence that the patient is not of childbearing potential. Lenalidomide and pomalidomide can pass into seminal fluid. Male patients must also follow the necessary requirements of the PPP to prevent product exposure to a female partner.

To aid healthcare professionals in counseling their patient on the risk of teratogenicity associated with lenalidomide and pomalidomide and the steps necessary to mitigate this risk, as well as ensuring patients fully understand such measures, it is important that the following points are discussed and checklists completed to document patient understanding. Healthcare professionals are advised that the following checklists are intended to be used alongside those in the Risk Awareness Form for Counseling Patients Receiving Immunomodulatory Agents to ensure patient understanding of the requirements of the PPP prior to initiation of treatment. Separate checklists are provided per patient risk categorization: female patients of childbearing potential, male patients, and female patients not of childbearing potential.

PATIENT DETAILS

• Please complete this form in BLOCK CAPITAL LETTERS.

Patient's First Name :

Patient's Last Name :

Date of Birth :

Patient's Risk Categorization
☐ Female Patient of Childbearing Potential
☐ Male Patient
☐ Female Patient Not of Childbearing Potential

Counseling Date :

PRESCRIBER CONFIRMATION

I confirm that I have fully explained to the patient named above the nature, purpose, and risks of the treatment associated with lenalidomide or pomalidomide and the need for compliance with the conditions of the PPP using the Risk Awareness Form for Counseling Patients Receiving Immunomodulatory Agents.

• Please complete this form in BLOCK CAPITAL LETTERS.

Prescriber's First Name :

Prescriber's Last Name :

Prescriber's Institution Name :

Prescriber's Signature :

Date :

Bristol Myers Squibb™

For Female Patients of Childbearing Potential: please read thoroughly.

If you agree, mark an X by the statement. It is important that you complete this checklist in order to receive treatment.

I agree that:	Add 'X' if agree
I have been fully informed by my healthcare professional about the nature, purpose, and risks of the treatment associated with lenalidomide or pomalidomide.	
I understand that severe birth defects may occur with lenalidomide or pomalidomide. I have been informed by my healthcare professional and understand that any fetus has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking such medicines.	
I understand that I must not receive lenalidomide or pomalidomide if I am pregnant or plan to become pregnant.	
I understand that I must use at least one effective method of contraception for at least 4 weeks before starting treatment, throughout the entire duration of treatment, even during dose interruptions, and for at least 4 weeks after stopping treatment, even if I have amenorrhea (lack of menstrual periods) or irregular menstrual periods. The following methods are examples of effective contraception: • implant, levonorgestrel-releasing intrauterine system, medroxyprogesterone acetate depot, tubal sterilization, sexual intercourse with a vasectomized male partner only (vasectomy must be confirmed by two negative semen analyses), and ovulation inhibitory progesterone-only pills (i.e. desogestrel) The need for contraception does not apply to patients who confirm monthly absolute and continuous abstinence from heterosexual intercourse.	
I understand that if I need to change or stop my method of contraception, I will discuss this first with: • the healthcare professional prescribing my lenalidomide or pomalidomide treatment; AND • the healthcare professional prescribing my contraception	
I understand that before starting treatment with lenalidomide or pomalidomide, I must have a pregnancy test. I will then have a pregnancy test at least every 4 weeks during treatment and a test at least 4 weeks after stopping treatment, even if I confirm monthly absolute and continuous abstinence.	

I agree that:	Add 'X' if agree
I understand that periodic abstinence (calendar, symptothermal, and post-ovulation methods), withdrawal (coitus interruptus), spermicides only, and the lactational amenorrhea (the absence of a menstrual period during breastfeeding) method are not acceptable methods of absolute and continuous abstinence.	
I understand that I must immediately stop taking lenalidomide or pomalidomide and inform my healthcare professional immediately if I become pregnant while taking such medicines; or if I miss my menstrual period or experience any unusual menstrual bleeding; or think FOR ANY REASON that I may be pregnant.	
I understand that lenalidomide or pomalidomide will be prescribed ONLY for me. I must not share them with ANYONE.	
I understand that I must store lenalidomide or pomalidomide safely so that no-one else can take the medicine by accident and that they must be kept out of reach of children.	
I understand that I must not open, crush, or overly handle the lenalidomide or pomalidomide.	
I know that I cannot donate blood while receiving lenalidomide or pomalidomide, even during dose interruptions, and for at least 7 days after stopping treatment.	
I have received the Patient Medication Guide for Immunomodulatory Agents.	
I understand that I must return of any unused medication to pharmacist for safe disposal at the end of my treatment.	

PATIENT CONFIRMATION

I confirm that I understand and will comply with the requirements of the PPP and I agree that my healthcare professional can initiate my treatment.

Patient/Legal Representative's Signature :

Date :

For Male Patients: please read thoroughly.

If you agree, mark an X by the statement. It is important that you complete this checklist in order to receive treatment.

I agree that:	Add 'X' if agree
I have been fully informed by my healthcare professional about the nature, purpose, and risks of the treatment associated with lenalidomide or pomalidomide.	
I understand that severe birth defects may occur with lenalidomide or pomalidomide. I have been informed by my healthcare professional and understand that any fetus has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking such medicines.	
I understand that lenalidomide or pomalidomide pass into seminal fluid. If my partner is pregnant or able to become pregnant, and she does not use effective contraception, I must use condoms throughout the duration of my treatment, even during dose interruptions, and for at least 7 days after stopping treatment, even if I have had a vasectomy.	
I have been informed which effective contraceptive methods may be appropriate for a female partner of a male patient. The following methods are examples of effective contraception: • implant, levonorgestrel-releasing intrauterine system, medroxyprogesterone acetate depot, tubal sterilization, sexual intercourse with a vasectomized male partner only (vasectomy must be confirmed by two negative semen analyses), and ovulation inhibitory progesterone-only pills (i.e. desogestrel)	
I understand that if my partner does become pregnant while I am receiving lenalidomide or pomalidomide, or within 7 days after I have stopped taking such medicines, I should inform my healthcare professional immediately, and my partner should also consult her healthcare professional immediately.	

I agree that:	Add 'X' if agree
I understand that lenalidomide or pomalidomide will be prescribed ONLY for me. I must not share them with ANYONE.	
I understand that I must store lenalidomide or pomalidomide safely so that no-one else can take the medicine by accident and that they must be kept out of reach of children.	
I understand that I must not open, crush, or overly handle the lenalidomide or pomalidomide.	
I know that I cannot donate blood while receiving lenalidomide or pomalidomide, even during dose interruptions, or for at least 7 days after stopping treatment.	
I know that I cannot donate semen or sperm while receiving lenalidomide or pomalidomide, even during dose interruptions, and for at least 7 days after stopping treatment as lenalidomide and pomalidomide can pass into seminal fluid.	
I have received the Patient Medication Guide for Immunomodulatory Agents.	
I understand that I must return of any unused medication to pharmacist for safe disposal at the end of my treatment.	

PATIENT CONFIRMATION

I confirm that I understand and will comply with the requirements of the PPP and I agree that my healthcare professional can initiate my treatment.

Patient/Legal Representative's Signature :

Date :

For Female Patients Not of Childbearing Potential: please read thoroughly.

If you agree, mark an X by the statement. It is important that you complete this checklist in order to receive treatment.

I agree that:	Add 'X' if agree
I have been fully informed by my healthcare professional about the nature, purpose, and risks of the treatment associated with lenalidomide or pomalidomide.	
I understand that severe birth defects may occur with lenalidomide or pomalidomide. I have been informed by my healthcare professional and understand that any fetus has a high risk of birth defects and could even die if a woman is pregnant or becomes pregnant while taking such medicines.	
I understand that lenalidomide or pomalidomide will be prescribed ONLY for me. I must not share them with ANYONE.	
I understand that I must store lenalidomide or pomalidomide safely so that no-one else can take the medicine by accident and that they must be kept out of reach of children.	
I understand that I must not open, crush, or overly handle the lenalidomide or pomalidomide.	

I agree that:	Add 'X' if agree
I know that I cannot donate blood while receiving lenalidomide or pomalidomide, even during dose interruptions, and for at least 7 days after stopping treatment.	
I have received the Patient Medication Guide for Immunomodulatory Agents.	
I understand that I must return of any unused medication to pharmacist for safe disposal at the end of my treatment.	

PATIENT CONFIRMATION

I confirm that I understand and will comply with the requirements of the PPP and I agree that my healthcare professional can initiate my treatment.

Patient/Legal Representative's Signature :

Date :

- I consent to the collecting and processing of my personal information by Bristol -Myers Squibb Pte Ltd ("BMS") for the purposes of this Pregnancy Prevention Program including Adverse Event reporting and program compliance. BMS may disclose my personal information as required by the Personal Data Protection Act 2012.
- I consent to the transfer of my personal information to BMS Affiliates and other third parties for the exclusive use of this Program. I understand BMS will take all steps reasonably necessary to ensure that my personal information is adequately protected according to the requirements of the data protection laws of Singapore.
- I understand that BMS will keep my personal information as long as it is necessary in accordance with the Program objectives and that I have the right to withdraw from the Program at any time by informing my prescribing physician or BMS in writing. Moreover, I have the right to request for change or removal of my personal data.