LENALIDOMIDE Prescription Authorisation Form
Australia

A newly completed copy of this form MUST accompany EVERY CIPLA lenalidomide prescription.

Completion of this information is mandatory for ALL patients.

Instructions for prescribers and pharmacists

Instructions for prescribers

1. Please enter the full hospital name where the patient is treated.
2. Please enter the patient's first name, middle name, last name, address, mobile number and Date of Birth.
3. Please write the name clearly of supervising physician, i.e. physician experienced in managing immunomodulatory drugs and supervising treatment.
4. Tick the diagnosis box or state other usage -this will allow an assessment of the clinical usage of lenalidomide, which is important for ongoing monitoring of the appropriateness of the Pregnancy Prevention Program.
5. Enter the capsule strength and quantity of each strength prescribed.
6. Complete this section to indicate counselling and appropriate use of contraception has occurred. This is a requirement of the Pregnancy Prevention Program.
7. For women of childbearing potential, you must provide a valid negative pregnancy test (within three days prior to prescribing). If this is not the case, lenalidomide must not be dispensed.
8. You must electronically sign, date, and add your name to declare that all steps have been observed and that you authorise the electronic Prescription Authorisation Form.

Instructions for pharmacists

A. Check that all relevant sections of the form have been fully completed by the prescriber
   a) Counselling and contraception measures must be in place
   b) Prescription must be accompanied by an electronic Prescription Authorisation Form
   c) For women of childbearing potential lenalidomide can only be dispensed within seven days of the prescription date.
   d) Only a maximum of 4 weeks supply for women of childbearing potential, or a maximum of 12 weeks supply for all other patients, of lenalidomide can be dispensed at any one time

B. Check the form is complete and legible -Cipla will request that ALL incomplete or illegible forms are resent. If you obtained information from the prescriber or patient to complete the form, please follow the instructions in the Pharmacist Confirmation box.

C. You must electronically sign, date, and add your name to declare that the form has been completed fully and dispensing for women of childbearing potential is taking place within seven days of the date of prescription.

D. Complete the Home delivery information if applicable.

Approved by TGA: November 2022

Completion of this information is mandatory for ALL patients.

Name of treating Hospital:	
Patient Details	
Patient ID/Initials:	Patient Type:
Risk Category:	Date of Birth:
Care Type:	
Prescriber Information	
Name:	Email Address:
Registration Number:	Mobile Number:
Institution:	Country:
Pregnancy Update	
Test date:	Result:
Prescription Authorisation Form General Information	
Prescription Creation date:	Valid to:
Prescription authoristion Form Creation Date:	
Treatment Information	
Product Name:	Patient Informed Consent (Yes/No):
Indication: Multiple Myeloma ☐ Myelodysplastic Syndromes (MDS) ☐ Other ☐ If other please specify: _____	
Treatment Stage: 1st ☐ 2nd ☐ 3rd ☐ 4th ☐	

Cycle and Prescription Authorisation Form					
Capsule strength prescribed: (tick)	5 mg☐	10 mg☐	15 mg☐	20 mg☐	25 mg☐
Quantity of Capsules per cycle prescribed:					

Current Cycle No:	Product Pack:
Frequency:	Duration:

For ALL risk categories both signatures must be present before dispensing lenalidomide

WARNING: PRESCRIPTIONS FOR WOMEN OF CHILDBEARING POTENTIAL CATEGORY PATIENT CAN BE FOR A MAXIMUM DURATION OF TREATMENT OF 4 WEEKS, ACCORDING TO THE APPROVED INDICATIONS AND DOSING REGIMENS	
Woman of non-childbearing potential (maximum 12-weeks supply)	☐
Male (maximum 12-week supply)	☐
The patient has been counselled about the teratogenic risk of treatment with lenalidomide and understands the need to use a condom if involved in sexual activity with a woman of childbearing potential who is not using effective contraception or if their partner is pregnant (even if the patient has had a vasectomy).	Yes ☐ No ☐
Note to pharmacist - **do not dispense unless ticked**	
Woman of childbearing potential (maximum 4-week supply)	☐
The patient has been counselled about the teratogenic risk of treatment, the need to avoid pregnancy, and has been effective contraception for at 4 weeks or committed to absolute and continuous abstinence confirmed on a monthly basis.	Yes ☐ No ☐
Date of last negative pregnancy test:	
Note to pharmacist - **do not dispense unless ticked yes and a negative test has been conducted within 3 days prior of the prescription date, and dispensing is taking place within 7 days of the prescription date. A copy of every completed ePAF should be sent to CIPLA immediately after dispensing at XYZ.**	
Date of email / ePAF sent to CIPLA: Email sent by:	
Both signatures must be present prior to dispensing lenalidomide CIPLA	

DECLARATION BY THE PRESCRIBER	
As a prescriber, I have read and understood the Lenalidomide Healthcare Professional Information and confirm that information provided on this ePAF is accurate, complete and in accordance with the pregnancy prevention measures for lenalidomide. I confirm treatment has been initiated and is monitored under the supervision of a physician experienced in managing immunomodulatory drugs. Also, the patient has signed an informed consent for lenalidomide treatment.	
Sign:	**Date:**
Name in capital letters:	
Print:	

Pharmacist Confirmation	
Information which was not completed by the prescriber and is needed to confirm the required pregnancy prevention measures has been obtained by the Pharmacist (e.g., from the prescriber and/or patient) and documented on this form. Note to pharmacist: To indicate any changes/corrections made in the ePAF, please add your initials and date against the changes.	Yes ☐ No ☐

DECLARATION BY THE PHARMACIST	
I am satisfied that this CIPLA Lenalidomide Authorisation form has been completed fully and that I have read and understood the CIPLA Lenalidomide healthcare professional information. I understand that no more than a 4-week supply to women of childbearing potential and a 12-week supply for males and women of non-childbearing potential should be dispensed.	
Sign:	**Date:**
Name in capital letters:	
Print:	
Pharmacy Name and post code	**AHPRA Number**
Home delivery information:	
Name and postcode of home delivery company used, If applicable	
Prescription Authorisation Form Status	
Status	**Pharmacist Name**
Date of Approval	**Dispense Date**

Further information for adverse event form and materials are available from CIPLA:

Email: Lenalidomide.cipla@cipla.com

Phone number: 1800 87 86 85

Approved by TGA: November 2022