Cipla

Lenalidomide

Pregnancy Prevention Program

Information for Healthcare Professionals

Prescribing or Dispensing Lenalidomide

Australia

Approved by TGA: July 2023

This brochure contains information needed for the prescribing and dispensing of lenalidomide, including information about the Pregnancy Prevention Program (PPP).

It is a requirement of the PPP that all healthcare professionals ensure they have read and understood this pack before prescribing or dispensing lenalidomide for ANY patient.

Please also refer to the Product Information (PI), which can be found on the TGA website:
https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2019-PI-02101-1&d=20220418172310101 for further information.

Lenalidomide Pregnancy Prevention Program:

If lenalidomide is taken during pregnancy, it is expected to cause severe birth defects or death to an unborn baby. This program is designed to ensure that unborn babies are not exposed to lenalidomide. It will provide you with information about how to follow the program and explain your responsibilities.

Other side effects of lenalidomide:

A full list of all side effects, further information and recommended precautions can be found in the lenalidomide PI.

Important information about the safe disposal of unwanted capsules and restrictions on donating blood during treatment is also included in this brochure.

This brochure will help you understand these problems and make sure you know what to do before prescribing and dispensing lenalidomide.

To ensure your patients' safety, please read this brochure carefully. In addition, you must ensure that your patients fully understand what you have told them about lenalidomide and that they have provided written confirmation on the Treatment Initiation Form (TIF) before starting treatment.

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1. Introduction

lenalidomide is an immunomodulating medicinal product. lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic agent that causes severe life-threatening birth defects.

Two phase III clinical studies assessed lenalidomide maintenance in patients with newly diagnosed multiple myeloma who have undergone autologous stem cell transplantation (ASCT) in (CALGB 100104 and IFM 2005-02).

In study CALGB 100104, patients were randomised 1:1 within 90 to 100 days after ASCT to receive either lenalidomide or placebo maintenance. The maintenance dose was 10 mg once daily on days 1 to 28 of repeated 28-day cycles (increased up to 15 mg once daily after three months in the absence of dose-limiting toxicity). Treatment was continued until disease progression.

The progression-free survival (PFS) results at unblinding (cut-off of 17 December 2009) showed a 62% reduction in risk of disease progression or death, favouring lenalidomide over placebo. The Hazard Ratio was 0.38 (95% CI 0.27, 0.54; p <0.001). The median overall PFS was 33.9 months (95% CI not evaluable [NE], NE) in the lenalidomide arm versus 19.0 months (95% CI 16.2, 25.6) in the placebo arm. The updated PFS, using a cut-off of 01 February 2016, continued to show a PFS advantage for lenalidomide (Hazard Ratio = 0.61; p <0.001)

In Study IFM 2005-02, patients who had undergone ASCT and had achieved at least a stable disease response at the time of haematologic recovery were randomised 1:1 to receive either lenalidomide or placebo maintenance (10 mg once daily on Days 1 to 28 of repeated 28-day cycles increased up to 15 mg once daily after three months in the absence of dose-limiting toxicity) following two courses of lenalidomide consolidation (25 mg/day, Days 1 to 21 of a 28-day cycle). Treatment was to be continued until disease progression. The study was unblinded upon the recommendations of the data monitoring committee after surpassing the threshold for a preplanned interim analysis of PFS. After unblinding, patients receiving placebo were not crossed over to lenalidomide therapy prior to progressive disease. The lenalidomide arm was discontinued, as a proactive safety measure, after observing an imbalance of second primary malignancies (SPM). The results of PFS at unblinding, following a preplanned interim analysis, using a cut-off of 07 July 2010 (31.4 months follow up), showed a 48% reduction in risk of disease progression or death favouring lenalidomide over placebo. The Hazard Ratio was 0.52 (95% CI 0.41, 0.66; p <0.001). The median overall PFS was 40.1 months (95% CI 35.7, 42.4) in the lenalidomide arm versus 22.8 months (95% CI 20.7, 27.4) in the placebo arm. The updated PFS, using a cut-off of 01 February 2016 (96.7 months follow-up), continued to show a PFS advantage for lenalidomide (Hazard Ratio = 0.57; p <0.001).

A Phase III clinical study in newly diagnosed multiple myeloma (MM-020) compared lenalidomide and dexamethasone (Rd) given for two different durations of time (i.e. until progressive disease [Arm Rd] or for up to eighteen 28-day cycles [72 weeks, Arm Rd18]) to that of melphalan, prednisone and thalidomide (MPT) for

a maximum of twelve 42-day cycles (72 weeks). The study showed a statistically significant prolongation of PFS benefit in patients receiving Rd compared to MPT. The Hazard Ratio was 0.69 (p <0.001).

Another Phase III study in newly diagnosed multiple myeloma (MM-015) was conducted to evaluate the safety and efficacy of lenalidomide in combination with melphalan and prednisone (MPR) with or without lenalidomide maintenance therapy until disease progression, to that of melphalan and prednisone for a maximum of 9 cycles.

The study showed a statistically significant prolongation of PFS benefit in patients receiving MPR+R compared to MPp+p (melphalan, prednisone, placebo + placebo maintenance). The Hazard Ratio was 0.37 (p <0.001).

In Phase III clinical studies in multiple myeloma with at least one prior therapy, the median time to progression (TTP) was 60.1 weeks in patients treated with lenalidomide/dexamethasone versus 20.1 weeks in patients treated with placebo/dexamethasone. The median PFS was 48.1 weeks in patients treated with lenalidomide/dexamethasone versus 20.0 weeks in patients treated with placebo/-dexamethasone.

In a Phase III clinical study in myelodysplastic syndromes (MDS-004), a significantly larger proportion of patients achieved the primary endpoint of transfusion independence (>182 days) on lenalidomide 10 mg compared with placebo (55.1% vs. 6.0%). The median time to transfusion independence in the lenalidomide 10 mg arm was 4.6 weeks. The median duration of transfusion independence was not reached in any of the treatment arms, but should exceed two years for the lenalidomide-treated subjects. The median increase in haemoglobin (Hgb) from baseline in the 10 mg arm was 6.2 g/dL.

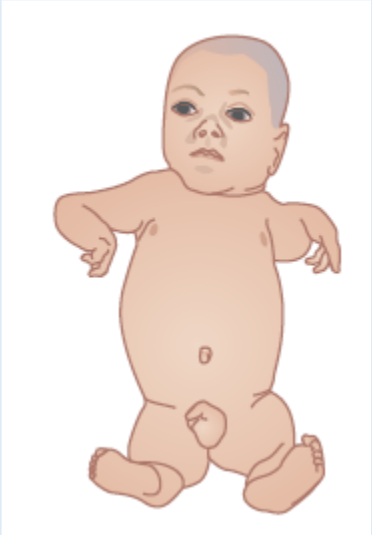
In a phase II study of lenalidomide (N=170) versus a single agent of investigator's choice of monotherapy with either chlorambucil, cytarabine, rituximab, fludarabine, or gemcitabine (N=84) in patients with mantle cell lymphoma (MCL) who were refractory to their last regimen or had relapsed one to three times (Study MCL-002), median PFS was significantly improved for lenalidomide versus investigator's choice (37.6 versus 22.7 weeks; Hazard Ratio = 0.61, p = 0.004).

2. Indication

Lenalidomide is an immunomodulating medicinal product.

- CIPLA LENALIDOMIDE is indicated for the treatment of multiple myeloma.
- CIPLA LENALIDOMIDE is indicated for the treatment of patients with transfusion-dependent anaemia due to low- or intermediate-1 risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.
- CIPLA LENALIDOMIDE as monotherapy is indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma.

3. lenalidomide Pregnancy Prevention Program

lenalidomide is structurally related to thalidomide. Thalidomide is a known human teratogenic substance that causes severe life-threatening birth defects. An embryofoetal development study has been conducted in monkeys administered lenalidomide at doses up to 4mg/kg/day. Findings from this study showed that lenalidomide produced external malformations (short limbs, bent digits, wrist and/or tail, supernumerary, or absent digits) in the offspring of female monkeys who received the drug during pregnancy. Thalidomide produced similar types of malformations in the same study. If lenalidomide is taken during pregnancy, a teratogenic effect is expected. Therefore, lenalidomide is contraindicated in pregnancy and in women of childbearing potential unless the conditions of the Pregnancy Prevention Program are met.	

Cipla has developed a web-based platform named 'Cipla lenalidomide aRMM Program' for prescribing or dispensing lenalidomide to any patient. The mandatory parts of this controlled access program is the following:

- Only prescribers enrolled in the 'Cipla lenalidomide aRMM Program' can prescribe lenalidomide.
- Only patients enrolled in the 'Cipla lenalidomide aRMM Program' can receive lenalidomide.
- Only pharmacies registered with 'Cipla lenalidomide aRMM Program' shall be able to order and dispense lenalidomide
- It is a requirement of the Pregnancy Prevention Program that all Healthcare Professionals ensure that they have read and understood this brochure before prescribing or dispensing lenalidomide to any patient.
- The description of the Pregnancy Prevention Program and the categorisation of patients based on sex and childbearing potential is set out in the attached algorithm.
- All men and all women of childbearing potential should undergo, at treatment initiation, counselling on the need to avoid pregnancy (this must be documented via a Treatment Initiation Form and checklists for counselling are provided with 'Cipla lenalidomide aRMM Program')
- Patients should be capable of complying with the requirements for the safe use of lenalidomide
- Patients must be provided with the appropriate Patient Brochure, Treatment Initiation Form and Patient Card.

All of the Cipla lenalidomide Pregnancy Prevention Program materials are contained within the Healthcare Professional's Information Pack and additional copies can be downloaded from https://lenalidomide.cipla.com/

Also, additional copies case be obtained by using the contact details displayed on the front of this brochure.

Before starting the treatment, you must ensure that your patient fully understands what you have told them about lenalidomide.

In order to obtain lenalidomide, it is a requirement of the Pregnancy Prevention Program that all healthcare professionals ensure that they have read and understood this pack before prescribing or dispensing lenalidomide to **any** patient.

- Prescribers must complete the appropriate Treatment Initiation Form with every patient before the first prescription is issued and sent to Lenalidomide.cipla@cipla.com
- Pharmacies must register with Cipla to be able to order and dispense lenalidomide. To do this, the pharmacist must enrol with the web-based platform called 'Cipla lenalidomide aRMM Program' or the Pharmacy Registration Form.
- Every prescription for lenalidomide must be accompanied by an electronic Prescription Authorisation Form (ePAF), which must be completed by the prescriber and the pharmacist. A copy of each ePAF must be sent to Cipla at Lenalidomide.cipla@cipla.com
- The Pharmacy Registration Form and Prescription Authorisation Form are in subsequent sections of this pack.

All patients should be given a Patient Brochure and a Patient Card to take home – these materials remind patients of the key educational information and risks of treatment and can be found in the Information for Patients section.

For women of childbearing potential, prescriptions of lenalidomide should be limited to a maximum duration of **4 weeks** according to the approved indications dosing regimens (posology). Continuation of treatment requires a new prescription. Ideally, a prescription should be issued and dispensed on the same day as pregnancy testing.

Dispensing of lenalidomide should occur within a maximum of 7 days of the prescription, and the date of the last negative pregnancy test must be within three days prior to the date of the prescription.

For all other patients, prescriptions of lenalidomide should be limited to **12 weeks** and continuation of treatment requires a new prescription.

This Healthcare Professional's Information Pack also contains Adverse Event and Pregnancy Reporting Forms, Treatment Checklists, algorithms and Treatment Initiation Forms for obtaining consent.

In order to ensure that the actions to minimise the risk of foetal exposure are carried out for all patients, dispensing of lenalidomide will only be allowed from pharmacies registered with Cipla. Cipla will not authorise the supply of lenalidomide to pharmacies that are **not registered.**

The following are core requirements of the Pregnancy Prevention Program:

- All healthcare professionals dispensing or prescribing lenalidomide must read the lenalidomide Healthcare Professional's Information Pack.
- All pharmacies that dispense lenalidomide must agree to implement risk minimisation by registering with Cipla's Pregnancy Prevention Program
- Every prescription for lenalidomide must be accompanied by an electronic Prescription Authorisation Form, completed by the prescriber and the pharmacist, and a copy sent to Cipla Lenalidomide.cipla@cipla.com.

4. Safety Advice Relevant to all Patients

In addition to information about the Pregnancy Prevention Program, this brochure contains important advice for healthcare professionals about how to minimise the risk of adverse events during treatment with lenalidomide.

For further information about the appropriate use and safety profile of lenalidomide, please refer to the PI, which can be found on the TGA website: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2019-PI-02101-1&d=20220418172310101

You must immediately send a copy of every completed electronic Prescription Authorisation Form to Cipla for ALL patients, regardless of indication. This is an absolute requirement so that Cipla can fulfil regulatory obligations to monitor PPP adherence and off-label usage.

Cipla is obliged to provide anonymous reports on this data to the regulatory agencies, to assess the effectiveness of risk minimisation activities and will not be able to comply if pharmacies do not provide ALL their electronic Prescription Authorisation Forms to CIPLA. Prescription Authorisation Forms can be sent via email or post (a photocopy of the form), using the following contact details:

Risk Management (PV) Team

Email: Lenalidomide.cipla@cipla.com

Please keep a copy of the electronic Prescription Authorisation Forms for your records.

5. Therapeutic Management Advice to Avoid Foetal Exposure

5.1 Women of Childbearing Potential

Women of childbearing potential must never take lenalidomide if they are:

- Pregnant
- A woman who is able to become pregnant, even if not planning to become pregnant, unless all of the conditions of the Pregnancy Prevention Program are met.

In view of the expected teratogenic risk of lenalidomide, foetal exposure should be avoided.

- Women of childbearing potential (even if they are amenorrheic) must:
  - Use at least one effective method of contraception for at least four weeks before therapy, during therapy and until four weeks after lenalidomide therapy and even in case of dose interruption, or
  - commits to absolute and continuous abstinence, confirmed on a monthly basis.
    AND
  - have a medically supervised negative pregnancy test (with a minimum sensitivity of 25 mIU/mL) once she has been established on contraception for at least four weeks, at least every four weeks during therapy (this includes dose interruptions) and at least four weeks after the end of therapy (unless confirmed tubal sterilisation). This includes those women of childbearing potential who confirmed absolute and continued sexual abstinence.

Patients should be advised to inform the prescriber prescribing her contraception about the lenalidomide treatment.

Patients should be advised to inform you if a change or stop of the method of contraception is needed.

There must be no more than **three days** between the dates of the last negative pregnancy test and the prescription. The best practice is for the pregnancy test, prescribing and dispensing on the same day.

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

Examples of suitable methods of contraception include:

- Implant
- Levonorgestrel-releasing intrauterine system (IUS)
- Medroxyprogesterone acetate depot injection
- Tubal sterilisation
- Sexual intercourse with a vasectomised male partner only; vasectomy must be confirmed by two negative semen analyses
- Ovulation inhibitory progesterone-only pills (i.e. desogestrel)

TREATMENT FOR A WOMAN OF CHILDBEARING POTENTIAL CANNOT START UNTIL PATIENT IS ESTABLISHED ON AT LEAST ONE EFFECTIVE METHOD OF CONTRACEPTION FOR AT LEAST 4 WEEKS OR COMMITS TO ABSOLUTE AND CONTINUOUS ABSTINENCE AND PREGNANCY TEST IS NEGATIVE.

Because of the increased risk of venous thromboembolism in patients with multiple myeloma taking lenalidomide monotherapy, and to a lesser extent in patients with multiple myeloma, myelodysplastic syndromes and mantle cell lymphoma taking lenalidomide monotherapy, combined oral contraceptive pills are not recommended. If a patient is currently using combined oral contraception, the patient should switch to one of the effective methods listed above. The risk of venous thromboembolism continues for 4 to 6 weeks after discontinuing combined oral contraception. The efficacy of contraceptive steroids may be reduced during co-treatment with dexamethasone.

Implants and the levonorgestrel-releasing intrauterine system are associated with an increased risk of infection at the time of insertion and irregular vaginal bleeding. Prophylactic antibiotics should be considered, particularly in patients who develop neutropenia.

Copper-releasing intrauterine devices are generally not recommended due to the potential risk of infection at the time of insertion and menstrual blood loss, which may compromise patients with neutropenia or thrombocytopenia.

Your patient should be advised that if a pregnancy occurs whilst she is receiving lenalidomide, she must stop treatment immediately and immediately report the pregnancy to her prescriber.

Requirements in the event of a suspected pregnancy while on treatment with lenalidomide:

- **Stop treatment immediately**
- **Refer the patient to a physician specialised or experienced in teratology for evaluation and advice.**
- **Notify Cipla immediately of all such occurrences by contacting Cipla (Tel: 1800 87 86 85 Email: Lenalidomide.cipla@cipla.com. Please also complete the Pregnancy Reporting Form included in this pack. Cipla will wish to follow up with you on the progress of all suspected pregnancies in female patients or partners of male patient cases.**
- **Report the event to the Therapeutic Goods Administration (TGA) via the Blue Card Scheme website: www.tga.gov.au/reporting-problems**
- **Alternatively, Blue Card for reporting are available:**
  - by mail to Pharmacovigilance and Special Access Branch, Reply Paid 100, Woden ACT 2606;
  - by emailing adr.reports@tga.gov.au;
  - by FAX to 02 6232 8392;

5.2 Women of non-childbearing Potential

Women in the following groups are considered not to have childbearing potential and do not need to undergo pregnancy testing or receive contraceptive advice:

- Age ≥ 50 years of age and naturally amenorrhoeaic for ≥ 1 year. Please note amenorrhoea following cancer therapy or during breastfeeding does not rule out childbearing potential
- Premature ovarian failure confirmed by a specialist gynecologist.
- Previous bilateral salpingo-oophorectomy or hysterectomy.
- XY genotype, Turner syndrome or uterine agenesis

A female patient is considered to have childbearing potential unless she meets at least one of the above criteria. Prescribers are advised to refer their patient for a gynaecological opinion if at all unsure as to whether a woman meets the criteria for being of non-childbearing potential.

If a patient does not meet at least one of the above criteria, but the prescriber considers the patient to be of non-childbearing potential, then prior approval of any deviation from these stipulated criteria should be sought from Cipla. This is a mandatory requirement.

Please contact Cipla (Tel: 1800 87 86 85 Email: Lenalidomide.cipla@cipla.com). The following information is required to assess whether a patient, who does not meet at least one of the above criteria, can be treated as a woman of non-childbearing potential:

- DOB and Initials of the Patient
- Details of why the prescriber considers the patient to be of non-childbearing potential
- Background to why a deviation has been requested.

5.3 Men

- In view of expected teratogenic risk of lenalidomide, foetal exposure should be avoided.
- Inform your patient of the effective contraceptive methods his female partner can use.
- lenalidomide is present in semen. Therefore, all male patients should use condoms throughout the treatment duration., during dose interruption and for at least seven days after cessation of treatment if their partner is pregnant or of childbearing potential who is not using effective contraception and even if the male patient has undergone vasectomy. Patients should be instructed that if their partner becomes pregnant whilst he is taking lenalidomide, or within seven days after he has stopped taking lenalidomide, he should inform his prescriber immediately. The partner should inform her physician immediately. It is recommended that she be referred to a physician specialising in teratology for evaluation and advice.
- Male patients should not donate semen or sperm during treatment, including during dose interruptions and for at least 7 days following discontinuation of lenalidomide.

If the partner of a male becomes pregnant, then he must inform his prescriber immediately, then:

Refer the female partner to a physician specialised or experienced in dealing with teratology for advice and evaluation.

Notify Cipla immediately by contacting Cipla (Tel: 1800878685, email: Lenalidomide.cipla@cipla.com). Please also complete the Pregnancy Reporting Form included in this pack.

Cipla will wish to follow up with you on the progress of all suspected pregnancies in female patients or partners of male patient cases.

Report the event to the TGA via the Blue Card Scheme website: www.tga.gov.au/reporting-problems

Alternatively, Blue Card for reporting are available:
- by mail to Pharmacovigilance and Special Access Branch, Reply Paid 100, Woden ACT 2606;
- by emailing adr.reports@tga.gov.au**;**
- by FAX to 02 6232 8392;-

5.4 The risk of neutropenia and thrombocytopenia and its management

Rates of Grade 3 or 4 adverse events decrease over time with appropriate monitoring, management and treatment.

Multiple Myeloma

Newly Diagnosed Multiple Myeloma (NDMM) in Patients Not Eligible for ASCT

Neutropenia: Management recommendations

- Neutropenia may be managed with lenalidomide dose adjustments and/or administration of growth factors
- Complete blood counts, including white blood cell count with differential count, platelet count and haemoglobin, should be performed as follows:*
  - Transplant-ineligible ndMM patients: weekly for the first cycle, prior to the start of each new cycle and every 4 weeks thereafter when continued with dexamethasone
  - Transplant-eligible ndMM patients: weekly for the first cycle, prior to the start of each new cycle and every 4 weeks thereafter when continued with dexamethasone

* Patients with neutropenia should be monitored for signs of infection and patients should be advised to promptly report febrile episodes

Dose adjustments, as summarised below, are recommended to manage Grade 3 or 4 neutropenia judged to be related to lenalidomide:

Neutropenia [a]	
When neutrophils:	**Recommended Lenalidomide Course**
First fall to < 0.5 x 10^9/L or < 1.0 x 10^9/L associated with fever (temperature ≥ 38.5°C)	Interrupt lenalidomide treatment
Return to 1.0 x 10^9/L when neutropenia is the only observed toxicity	Resume lenalidomide at Starting Dose
Return to ≥ 0.5 x 10^9/L when dose-dependent haematological toxicities other than neutropenia are observed	Resume lenalidomide at Dose Level 1 once daily
For each subsequent drop below 0.5 x 10^9/L	Interrupt lenalidomide treatment
Return to ≥ 0.5 x 10^9/L	Resume at next lower dose level once daily. Do not dose below 2.5 mg daily

[a]At the physician's discretion, if neutropenia is the only toxicity at any dose level, treat the patient with granulocyte colony stimulating factor (G-CSF) and maintain the dose level of lenalidomide.

Thrombocytopenia: Management recommendations

Thrombocytopenia may be managed by adjusting the dose of lenalidomide

- Complete blood counts, including white blood cell count with differential count, platelet count and haemoglobin, should be performed as follows:1
  - Transplant-ineligible ndMM patients: weekly for the first cycle, prior to the start of each new cycle and every 4 weeks thereafter when continued with dexamethasone
  - Transplant-eligible ndMM patients: weekly for the first cycle, prior to the start of each new cycle and every 4 weeks thereafter when continued with dexamethasone

Dose adjustments, as summarised below, are recommended to manage Grade 3 or 4 Thrombocytopenia judged to be related to lenalidomide:

Thrombocytopenia	
When platelets:	**Recommended Lenalidomide Course**
First fall to < 25 x 10^9/L	Stop lenalidomide dosing for remainder of cycle [b]
Return to ≥ 50 x 10^9/L	Decrease by one dose level when dosing is resumed at next cycle. Do not dose below 2.5 mg daily

[b]If dose-limiting toxicity occurs on > Day 15 of a cycle, lenalidomide dosing will be interrupted for at least the remainder of the current 28- day cycle.

<u>Newly Diagnosed Multiple Myeloma (NDMM) in Patients Post-ASCT</u>

Thrombocytopenia	
When platelets:	**Recommended Course**
First fall to < 30 x 10^9/L	Interrupt lenalidomide treatment
Return to ≥ 30 x 10^9/L	Resume lenalidomide at Dose Level 1 once daily
For each subsequent drop below 30 x 10^9/L	Interrupt lenalidomide treatment
Return to ≥ 30 x 10^9/L	Resume lenalidomide at next lower dose level once daily

Neutropenia [a]	
When neutrophils:	**Recommended Course**
First fall to < 0.5 x 10^9/L	Interrupt lenalidomide treatment
Return to ≥ 0.5 x 10^9/L	Resume lenalidomide at Dose Level 1 once daily
For each subsequent drop below 0.5 x 10^9/L	Interrupt lenalidomide treatment
Return to ≥ 0.5 x 10^9/L	Resume lenalidomide at next lower dose level once daily

a. At the physician's discretion, if neutropenia is the only toxicity at any dose level, add G-CSF and maintain the dose level of lenalidomide.

<u>Previously Treated Multiple Myeloma (MM)</u>

- *Dose Reduction Guidance*

Thrombocytopenia	
When platelets:	**Recommended Course**
First fall to < 30 x 10^9/L	Interrupt lenalidomide treatment
Return to ≥ 30 x 10^9/L	Resume lenalidomide at Dose Level 1
For each subsequent drop below 30 x 10^9/L	Interrupt lenalidomide treatment
Return to ≥ 30 x 10^9/L	Resume at next lower dose level once daily.
Neutropenia [a]	
When neutrophils:	**Recommended Course**
First fall to < 0.5 x 10^9/L	Interrupt lenalidomide treatment
Return to 0.5 x 10^9/L when neutropenia is the only observed toxicity	Resume lenalidomide at Starting Dose
Return to ≥ 0.5 x 10^9/l when dose-dependent haematological toxicities other than neutropenia are observed	Resume lenalidomide at Dose Level 1 once daily
For each subsequent drop below 0.5 x 10^9/L	Interrupt lenalidomide treatment
Return to ≥ 0.5 x 10^9/L	Resume at next lower dose level once daily. Do not dose below 5 mg once daily.

a. In case of neutropenia, the physician should consider the use of growth factors in patient management.

Myelodysplastic Syndromes (MDS)

For patients with MDS, dose reduction guidelines are divided into 2 sets - for within the first 4 weeks of treatment, and after the first 4 weeks of treatment.

i. For patients who experience thrombocytopenia or neutropenia within the first 4 weeks of treatment:

Thrombocytopenia		
When baseline:	**When platelets:**	**Recommended Course**
Platelet count ≥ 100 x 10^9/L	Fall to < 50 x 10^9/L	Interrupt lenalidomide treatment
	Return to ≥ 50 x 10^9/L	Resume lenalidomide at 5 mg/day
Platelet count ≥ 60 x 10^9 and < 100 x 10^9/L	Fall by 50% of the baseline value	Interrupt lenalidomide treatment
	Return to ≥ 50 x 10^9/L	Resume lenalidomide at 5 mg/day
Platelet count < 60 x 10^9/L	Fall by 50% of the baseline value	Interrupt lenalidomide treatment
	Return to ≥ 30 x 10^9/L	Resume lenalidomide at 5 mg/day

Neutropenia		
When baseline:	**When neutrophils:**	**Recommended Course**

ANC ≥ 1 x 10^9/L	Fall to < 0.75 x 10^9/L	Interrupt lenalidomide treatment
	Return to ≥ 1 x 10^9/L	Resume lenalidomide at 5 mg/day
ANC < 1 x 10^9/L	Fall to < 0.5 x 10^9/L	Interrupt lenalidomide treatment
	Return to ≥ 0.5 x 10^9/L	Resume lenalidomide at 5 mg/day

ii. For patients who experience thrombocytopenia or neutropenia after the first 4 weeks of treatment:

Thrombocytopenia	
During treatment at 10 mg/day:	
When platelets:	**Recommended Course**
Fall to < 30 x 10^9/L or < 50 x 10^9/L with platelet transfusions	Interrupt lenalidomide treatment
Return to ≥ 30 x 10^9/L (without haemostatic failure)	Resume lenalidomide at 5 mg/day
During treatment at 5 mg/day:	
Fall to < 30 x 10^9/L or < 50 x 10^9/L with platelet transfusions	Interrupt lenalidomide treatment
Return to ≥ 30 x 10^9/L (without haemostatic failure)	Resume lenalidomide at 5 mg/day every other day

Neutropenia	
During treatment at 10 mg/day:	
When neutrophils:	**Recommended Course**
Fall to < 0.5 x 10^9/L for ≥ 7 days or to < 0.5 x 10^9/L associated with fever (temperature ≥ 38.5°C)	Interrupt lenalidomide treatment
Return to ≥ 0.5 x 10^9/L	Resume lenalidomide at 5 mg/day
During treatment at 5 mg/day:	
Fall to < 0.5 x 10^9/L for ≥ 7 days or to < 0.5 x 10^9/L associated with fever (temperature ≥ 38.5°C)	Interrupt lenalidomide treatment
Return to ≥ 0.5 x 10^9/L	Resume lenalidomide at 5 mg every other day

5.5 The risk of venous and arterial thromboembolism and its management

In patients with multiple myeloma, the combination of lenalidomide/dexamethasone is associated with an increased risk of venous thromboembolism [VTE (predominantly DVT and PE)]. In patients with multiple myeloma or Myelodysplastic syndrome, treatment with lenalidomide monotherapy was associated with a lower risk of VTE (predominantly DVT and PE) than in MM patients treated with lenalidomide in combination therapy. In patients with multiple myeloma, the combination of lenalidomide/dexamethasone is associated with an increased risk of arterial thromboembolism [ATE (predominantly myocardial infarction and cerebrovascular event)]. The risk of ATE is lower in multiple myeloma patients treated with lenalidomide monotherapy than in multiple myeloma patients treated with lenalidomide in combination therapy

If a patient experiences any thromboembolic events, treatment must be discontinued and standard anticoagulation therapy started. Once the patient has been stabilised on the anticoagulation treatment and any complications of the thromboembolic event have been managed, the lenalidomide treatment may be restarted at the original dose dependent upon a benefit-risk assessment. The patient should continue anticoagulation therapy during the course of lenalidomide treatment.

Patients with known risk factors for thromboembolism (including prior thrombosis) should be closely monitored, and action should be taken to try to minimise all modifiable risk factors (e.g. smoking, hypertension, and hyperlipidaemia). Concomitant administration of erythropoietic agents or previous history of DVT may also increase thrombotic risk in these patients. Therefore, erythropoietic agents, or other agents that may increase the risk of thrombosis, such as hormone replacement therapy, should be used with caution in MM patients receiving lenalidomide/dexamethasone. A haemoglobin concentration above 120 g/L should lead to discontinuation of erythropoietic agents.

Patients and physicians are advised to be observant for the signs and symptoms of thromboembolism. Patients should be instructed to seek medical care if they develop symptoms such as shortness of breath, chest pain, arm or leg swelling. Prophylactic antithrombotic medicines, such as low molecular weight heparins or warfarin, should be recommended, especially in patients with additional thrombotic risk factors. The decision to take antithrombotic prophylactic measures should be made after careful assessment of an individual patient's underlying risk factors.

5.6 The risk of Ischaemic Heart Disease including Myocardial infarction

Myocardial infarction has been reported in patients receiving lenalidomide, particularly in those with known risk factors. Patients with known risk factors (including prior thrombosis) should be closely monitored, and action should be taken to try to minimise all modifiable risk factors (e.g. smoking, hypertension, and hyperlipidaemia).

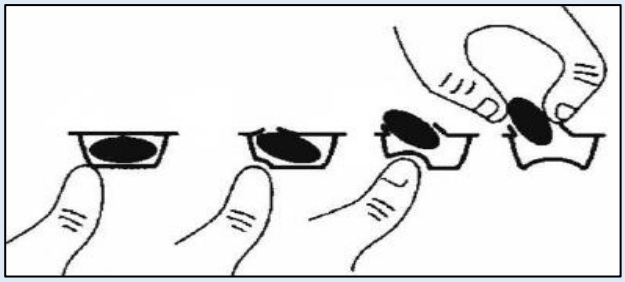
6. Advice to all patients

6.1 Points to consider for Handling the medicinal product: For Healthcare Professionals and Caregivers

Keep the capsules in the blister in the original package.

The capsules can occasionally become damaged when pressing them out of the blisters, especially when the pressure is put onto the middle of the capsule. The capsules should not be pressed out of the blisters by putting pressure on the middle nor by putting pressure on both ends, as this can result in deformation and breaking of the capsule.

It is recommended to press only on one site at the end of the capsule (see figure), as therefore the pressure is located to one site only, which reduces the risk of capsule deformation or breakage.



Healthcare professionals and caregivers should wear disposable gloves when handling the blister or capsule. Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic polyethylene bag and disposed of in accordance with local requirements. Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule.

Refer below for further guidance.

When handling the medicinal product, use the following precautions to prevent potential exposure if you are a healthcare professional or caregiver

- If you are a woman who is pregnant or suspect that you may be pregnant, you should not handle the blister or capsule
- Wear disposable gloves when handling the product and / or its packaging (e.g. blister or capsule).
- Use proper technique when removing gloves to prevent potential skin exposure (see below)
- Put gloves in a sealable plastic polyethylene bag and dispose of them according to local requirements.
- Wash hands thoroughly with soap and water after removing gloves.

If a drug product package appears visibly damaged, use the following extra precautions to prevent exposure.

- If the outer carton is visibly damaged - **Do Not Open.**
- If the blister strips are damaged or leaking or capsules are noted to be damaged or leaking,
- **Close the outer carton immediately.**
- Place the product in a sealed plastic polyethylene bag.
- Return unused packs to the pharmacist for safe disposal as soon as possible.

If the product is released or spills, take appropriate precautions to minimise exposure by using appropriate personal protection:

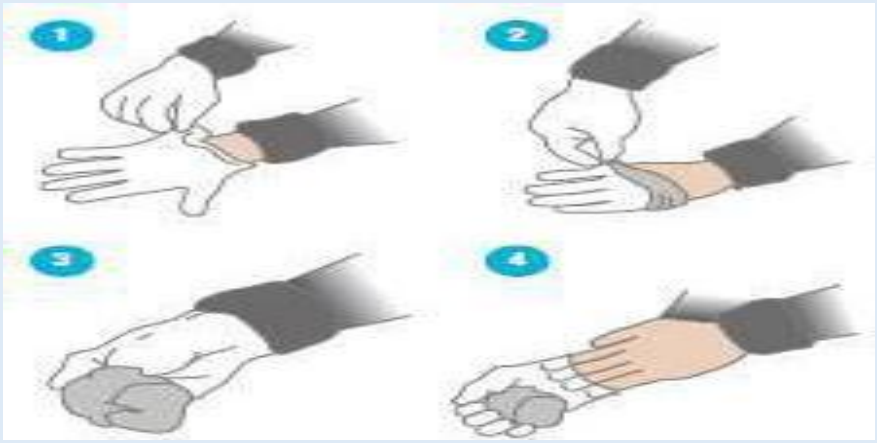
- If the capsules are crushed or broken, dust-containing drug substance may be released. Avoid dispersing the powder and avoid breathing the powder.
- Wear disposable gloves to clean up the powder.
- Place a damp cloth or towel over the powder area to minimise the entry of powder into the air. Add excess liquid to allow the material to enter the solution. After handling, clean the area thoroughly with soap and water and dry it.
- Place all contaminated materials, including damp cloths or towels and gloves, into a sealable polyethylene plastic bag and dispose of them in accordance with local requirements for the disposal of medicinal products.
- Wash your hands thoroughly with soap and water after removing the gloves.

Please report to Cipla immediately to Lenalidomide.cipla@cipla.com

If the contents of the capsules are attached to the skin or mucous membranes

- If you touch the powder, wash the exposed area thoroughly under running water and soap.
- If the powder gets in contact with your eye, if worn and easy to do, remove contact lenses and discard them. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs, please contact an ophthalmologist.

Proper technique for removing gloves:



- Grasp the outer edge near the wrist (1).
- Peel away from the hand, turning the glove inside out (2).
- Hold in opposite gloved hand (3).
- Slide ungloved fingers under the wrist of the remaining glove. Be careful not to touch the outside of this glove (4).
- Peel off from inside, creating a bag for both gloves.
- Discard in the appropriate container.
- Wash your hands with soap and water thoroughly.

6.2 Blood/Semen Donation

Patients should not donate blood/semen during treatment and for at least seven days after cessation of treatment with lenalidomide.

7. Prescribing lenalidomide

7.1 Maximum Prescription Lengths

Prescriptions for women of childbearing potential can be for a maximum duration of 4 weeks according to the approved indications dosing regimens (posology). For all other patients, prescriptions of lenalidomide should be limited to a maximum duration of 12 weeks and continuation of treatment requires a new prescription. Lenalidomide treatment must be initiated and monitored under the supervision of physicians with expertise in managing immunomodulatory or chemotherapeutic agents and a full understanding of the risks of lenalidomide therapy and monitoring requirements

7.2 Initial prescription

Before issuing the initial prescription, you must:

- Counsel the patient on the safe use of lenalidomide in accordance with the measures described in this brochure and the PI, which can be found on the TGA website: https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2019-PI-02101-1&d=20220418172310101
- Obtain their written confirmation (using the correct Treatment Initiation Form) that they have received and understood this information, and provide the patient with a copy
- Provide the patient with a Patient Brochure and a Patient Card. Provide an 'electronic Prescription Authorisation Form' to the patient with each lenalidomide prescription, and this will contain:
  - Patient initials, date of birth and diagnosis
  - Prescriber name, signature and date
  - Patient category (women of childbearing potential, women of non-childbearing potential or male)
  - Confirmation that they have received counselling about the teratogenic risk of lenalidomide and the required contraceptive measures for women of childbearing potential and male patients
  - For women of childbearing potential, the pregnancy test date and result.
  - That your patient is using effective contraception (if appropriate)

The patient must present their 'electronic Prescription Authorisation Form' to the pharmacy along with their prescription, and the pharmacy will check this form prior to dispensing lenalidomide.

7.3 Repeat of Subsequent Prescriptions

The patient must return to a prescriber for every repeat prescription of lenalidomide and a new ePAF must be completed and submitted.

8. Dispensing lenalidomide

It is a requirement of the Pregnancy Prevention Program that pharmacies wishing to purchase and dispense lenalidomide are registered with Cipla. Registration involves receiving a Healthcare Professional's Information Pack.

Dispensing of lenalidomide will only be allowed from pharmacies registered with Cipla. Cipla will not authorise the purchase and supply of lenalidomide to pharmacies not registered with Cipla.

Lenalidomide is supplied to pharmacies registered with Cipla's Risk Minimisation Program, known as the web-based platform named 'Cipla lenalidomide aRMM Program', only for the purpose of dispensing the product by the PPP registered pharmacy to the patient.

In order to be registered, the Chief Pharmacist or appointed deputy of the institution wishing to dispense must agree to implement the use of an electronic Prescription Authorisation Form.

When completing ePAF, it asks the prescriber to confirm:

- The patient's diagnosis
- Whether the patient is male or female
- If female, the patient's childbearing potential
- If of childbearing potential that adequate contraception is in place and the date of the last negative pregnancy test, which must be within the three days prior to the date of the prescription
- If male, counselling regarding the use of condoms has taken place

- That informed consent has been completed by the patient
- That the prescriber has read and understood the contents of this Healthcare Professional's Information Pack.

When completing ePAF, it asks the pharmacist to confirm:

- That the electronic Prescription Authorisation Form has been completed in full by the prescriber

- That dispensing for women of childbearing potential is taking place within **seven days** of the prescription date
- That the pharmacist has read and understood the contents of this Healthcare Professional's Information Pack.

For women of childbearing potential, prescriptions for lenalidomide should be limited to 4 weeks of treatment and continuation of treatment requires a new prescription. Ideally, pregnancy testing, issuing a prescription and dispensing should occur on the same day.
Dispensing of lenalidomide should occur within a maximum of 7 days of the prescription, and the date of the last negative pregnancy test must be within 3 days prior to the date of the prescription.

For males and women of non-childbearing potential, prescriptions of lenalidomide should be limited to 12 weeks and continuation of treatment requires a new prescription.

Pharmacists are required to send a copy of **every** electronic Prescription Authorisation Form to Cipla immediately after dispensing (Lenalidomide.cipla@cipla.com).

8.1 Dispensing Advice

- Please ensure that you dispense lenalidomide blisters intact; capsules must not be removed from blisters and packaged into bottles
- For each prescription, dispense a maximum of a 4-week supply for women of childbearing potential or a 12-week supply for all other patients
- Please educate all pharmacists within your pharmacy about the dispensing procedures for
- lenalidomide
- Instruct patients to return any unused lenalidomide to the pharmacy. Pharmacies must accept any unused lenalidomide returned by patients for destruction and follow Good Pharmacy Practice guidelines for the destruction of dangerous medicines.

8.2 Follow-up Assessment of the Effectiveness of the Program

The terms of the lenalidomide Marketing Authorisation require Cipla to assess the effectiveness of the Pregnancy Prevention Program in order to ensure that all reasonable steps are being taken to reduce the risk of foetal exposure to lenalidomide.

Cipla is therefore obliged to perform audits at regular intervals and to report appropriately anonymous and aggregated results to the TGA.

Cipla will conduct the audit from all of the completed electronic Prescription Authorisation Forms received.

Pharmacies must send a copy of every completed electronic Prescription Authorisation Form immediately after dispensing to Cipla, then Cipla will be able to conduct the pharmacy audit using these forms (a manual self-audit by pharmacies will not be required). It is critical, therefore, that electronic Prescription Authorisation Forms are completed accurately and that pharmacies thereby assist Cipla in auditing the effectiveness of the Pregnancy Prevention Program.

9. Posology

9.1 Multiple Myeloma (MM)

9.1.1 Lenalidomide Maintenance in Patients who have undergone autologous stem cell transplantation (ASCT)

The recommended starting dose is lenalidomide 10 mg orally once daily continuously (on Days 1 to 28 of repeated 28-day cycles) given until disease progression or intolerance. After 3 cycles of lenalidomide maintenance, the dose can be increased to 15 mg orally once daily if tolerated.

Dose reduction steps are provided in Section 4.2 of the PI.

9.1.2 Lenalidomide in Combination with Dexamethasone Until Disease Progression in Patients who are Not Eligible for Transplant.

The recommended starting dose of lenalidomide is 25 mg orally once daily on Days 1 to 21 of repeated 28-day cycles.

The recommended dose of dexamethasone is 40 mg orally once daily on Days 1, 8, 15 and 22 of repeated 28-day cycles. Patients may continue lenalidomide and dexamethasone therapy until disease progression or intolerance.

Dose reduction steps are provided in Section 4.2 of the PI.

9.1.3 Lenalidomide in Combination with Bortezomib and Dexamethasone Followed by Lenalidomide and Dexamethasone until Disease Progression in Patients who are Not Eligible for Transplant

The recommended starting dose of lenalidomide is 25 mg orally once daily on Days 1 to 14 of each 21-day cycle in combination with bortezomib and dexamethasone. The recommended dose of bortezomib is 1.3 mg/m2 body surface area subcutaneously twice weekly on Days 1, 4, 8 and 11 of each 21-day cycle. Up to eight 21-day treatment cycles (24 weeks of initial treatment) are recommended. Continue lenalidomide 25 mg orally once daily on Days 1 to 21 of repeated 28-day cycles in combination with dexamethasone. Treatment should be continued until disease progression or unacceptable toxicity.

Dose reduction steps are provided in Section 4.2 of the PI

9.1.4 Lenalidomide in Combination with Melphalan and Prednisone Followed by Lenalidomide Maintenance in Patients who are Not Eligible for Transplant

The recommended starting dose is lenalidomide 10 mg orally once daily on Days 1 to 21 of repeated 28-day cycles for up to 9 cycles, melphalan 0.18 mg/kg orally on Days 1 to 4 of repeated 28-day cycles, prednisone 2 mg/kg orally on Days 1 to 4 of repeated 28-day cycles. Patients who complete 9 cycles or who are unable to complete the combination therapy due to intolerance are treated with lenalidomide monotherapy as follows: 10 mg orally once daily on Days 1 to 21 of repeated 28-day cycles given until disease progression.

Dose reduction steps are provided in Section 4.2 of the PI.

9.1.5 Multiple Myeloma with at Least One Prior Therapy

The recommended starting dose of lenalidomide is 25 mg orally once daily on Days 1 to 21 of repeated 28-day cycles.

The recommended dose of dexamethasone is 40 mg orally once daily on Days 1 to 4, 9 to 12, and 17 to 20 of each 28-day cycle for the first 4 cycles of therapy and then 40 mg once daily on Days 1 to 4 every 28 days. Prescribers should carefully evaluate which dose of dexamethasone to use, taking into account the condition and disease status of the patient.

Dose reduction steps are provided in Section 4.2 of the PI.

9.2 Myelodysplastic Syndromes (MDS)

For patients on therapy for del 5q MDS, CBC should be monitored weekly for the first eight weeks of therapy and at least monthly thereafter.

The recommended starting dose of lenalidomide is 10 mg given orally once a day on Days 1 to 21 of repeating 28-day treatment cycles. Dosing is continued or modified based upon clinical and laboratory findings

Dose reduction steps are provided in Section 4.2 of the PI.

9.3 Mantle Cell Lymphoma

The recommended starting dose of lenalidomide is 25 mg once daily on Days 1 to 21 of repeated 28-day cycles. Dose reduction steps are provided in Section 4.2 of the PI.

10. Selected Risks of lenalidomide

The following section contains advice to Healthcare Professionals about how to minimise some of the main risks associated with the use of lenalidomide. Please also refer to PI (Section 4.2 Dose and Method of Administration, 4.3 Contraindications, 4.4 Special warnings and precautions for use and 4.8 Adverse Effects (Undesirable Effects).

10.1 Tumour flare reaction and tumour lysis syndrome

Tumour flare reaction (TFR) has commonly been observed in patients with mantle cell lymphoma who were treated with lenalidomide. The patients at risk of TFR are those with high tumour burden prior to treatment. Caution should be practiced when introducing these patients to lenalidomide. These patients should be monitored closely, especially during the first cycle or dose-escalation and appropriate precautions taken.

At the prescriber's discretion, lenalidomide may be continued in patients with Grade 1 or 2 TFR without interruption or modification. At the prescriber's discretion, therapy with non-steroidal anti-inflammatory drugs (NSAIDs), limited duration corticosteroids, and/or narcotic analgesics may be administered. In patients with Grade 3 or 4 TFR, withhold treatment with lenalidomide and initiate therapy with NSAIDs, corticosteroids and/or narcotic analgesics. When TFR resolves to ≤ Grade 1, restart lenalidomide treatment at the same dose level for the rest of the cycle. Patients may be treated for management of symptoms per the guidance for treatment of Grade 1 and 2 TFR.

There have been rare reports of tumour lysis syndrome (TLS) in patients with MM treated with lenalidomide and no reports in patients with MDS treated with lenalidomide (see section 4.4 of PI).

10.2 Second Primary Malignancies (SPM)

In clinical trials in NDMM patients not eligible for ASCT, a 4.9-fold increase in the incidence rate of haematologic second primary malignancies (SPM) (cases of AML and MDS) has been observed in patients receiving lenalidomide in combination with melphalan and prednisone (MPR+R) until progression (1.75 per 100 person-years) compared with melphalan in combination with prednisone (MPp+p) (0.36 per 100 person-years). A 2.12-fold increase in the incidence rate of solid tumour SPM has been observed in patients receiving MPR+R (9 cycles) (1.57 per 100 person-years) compared with MPp+p (0.74 per 100 person-years).

In NDMM patients receiving lenalidomide in combination with dexamethasone (len/dex) until progression or for 18 months, the haematologic SPM incidence rate (0.16 per 100 person-years) was not increased as compared to thalidomide in combination with melphalan and prednisone (MPT) (0.79 per 100 person-years). A 1.3-fold increase in the incidence rate of solid tumour SPM has been observed in patients receiving len/dex until progression or for 18 months (1.58 per 100 person-years) compared to MPT (1.19 per 100 person-years).

In clinical trials of NDMM patients eligible for ASCT, an increased incidence rate of haematologic SPM (most notably AML, MDS and B-cell malignancies [including Hodgkin's lymphoma] has been observed in patients receiving lenalidomide maintenance immediately following high-dose melphalan/ASCT (1.31 per 100 person-years) compared with patients who received placebo (0.58 per 100 person-years). The incidence rate of solid tumour SPMs was 1.36 per 100 person-years for the lenalidomide arms and 1.05 per 100 person-years for the placebo arms.

Based on a low number of cases, a numerical imbalance in SPM (comprising mainly of basal cell and squamous cell skin cancers) has been observed in clinical trials in previously treated MM patients with len/dex (3.98 per 100 patient-years) compared with placebo/dex (1.38 per 100 patient-years).

Subjects who received lenalidomide-containing therapy until disease progression did not show a higher incidence of invasive SPM than subjects treated in the fixed duration lenalidomide-containing arms. These results suggest that the duration of lenalidomide treatment is not associated with an increased risk for the occurrence of invasive SPM.

Both the benefit achieved with lenalidomide and the risk of SPMs should be considered and discussed with patients before initiating treatment with the product. Physicians should also carefully evaluate patients before and during treatment using standard cancer screening for the occurrence of SPMs and institute treatment as appropriate.

11. Disposal and other handling of unwanted medicine

Capsules should not be opened or crushed. If powder from lenalidomide makes contact with the skin, the skin should be washed immediately and thoroughly with soap and water. If lenalidomide makes contact with the mucous membranes, they should be thoroughly flushed with water.

Healthcare professionals and caregivers should wear disposable gloves when handling the blister or capsule.

Gloves should then be removed carefully to prevent skin exposure, placed in a sealable plastic polyethylene bag and disposed of in accordance with local requirements. Hands should then be washed thoroughly with soap and water. Women who are pregnant or suspect they may be pregnant should not handle the blister or capsule.

Patients should be instructed never to give lenalidomide to another person and to return any unused capsules to the pharmacist at the end of treatment for safe disposal in accordance with local requirements.

12. Reporting of adverse reactions, Suspected and Confirmed Pregnancies, and Foetal Exposures

The safe use of lenalidomide is of paramount importance. As part of the safety monitoring, Cipla wants to know about the side effects that have occurred with lenalidomide. Adverse event and pregnancy reporting forms are included in Healthcare Professional's Information Pack. Adverse event form should be forwarded to Cipla via drugsafety@Cipla.com, and the pregnancy reporting form should be forwarded to Cipla via Lenalidomide.cipla@cipla.com.

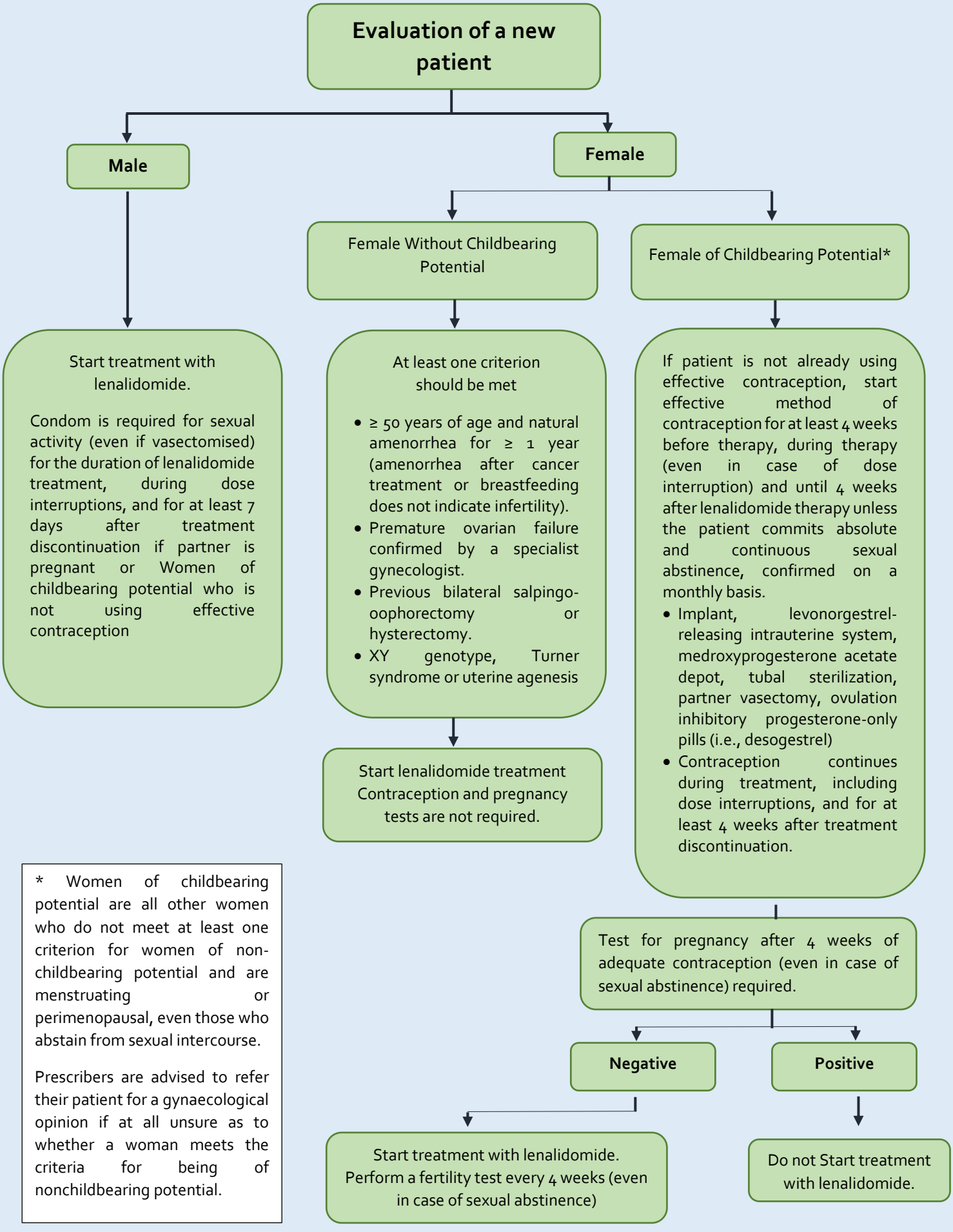
Report the suspected pregnancy to the TGA via the Blue Card Scheme website: www.tga.gov.au/reporting-problems

- You can report the suspected pregnancy online via the Blue Card website: www.tga.gov.au/reporting-problems
- Alternatively, Blue Cards for reporting are available:
    - by mail to Pharmacovigilance and Special Access Branch, Reply Paid 100, Woden ACT 2606;
    - by emailing adr.reports@tga.gov.au ;
    - by FAX to 02 6232 8392;

13. Patient Categorisation Algorithm

The description of the Pregnancy Prevention Program and the categorisation of patients based on sex and childbearing potential is presented in the below-given algorithm.

Patient Categorization Algorithm



* Women of childbearing potential are all other women who do not meet at least one criterion for women of non-childbearing potential and are menstruating or perimenopausal, even those who abstain from sexual intercourse.

Prescribers are advised to refer their patient for a gynaecological opinion if at all unsure as to whether a woman meets the criteria for being of nonchildbearing potential.

14. Contact Details

For information and questions on the Risk Management of Cipla products, the Pregnancy Prevention Program, pregnancy reporting form and pharmacy registrations, please contact Cipla:
Email: Lenalidomide.cipla@cipla.com

For adverse event form: drugsafety@Cipla.com

Phone no: 1800 87 86 85

Approved by TGA:Jul 2023