Celgene Pty Ltd
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Melbourne VIC 3004
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ABN 42 118 998 771

Dear Doctor,

Re: Celgene Revlimid® 4Plus Access Program

In response to your request for access to Revlimid® (lenalidomide) for use in relapsed refractory multiple myeloma (rrMM) treatment following failure of three prior lines of therapy, please see the below information.

As Revlimid® is not PHARMAC reimbursed post third-line myeloma therapy, Celgene will provide Revlimid® free of charge^ for these patients.

This program will be open for new applicants until 30 June 2015 (subject to review).

As part of this program:

- Revlimid® will be available in **25mg** and **10mg** strengths.
- All initial requests must be completed on the attached application form, and must be reviewed and approved by the Medical Director of Celgene Australia/New Zealand **prior** to the commencement of therapy.
- You and your patient agree to register on the Celgene Access Program.
- You and your patient agree to register on, and comply with the requirements of, the *i*-access® Program – **separate paperwork is required.**
- You and your patient agree to complete a declaration form, which will be supplied by Celgene, every 6 months to confirm the patient is still deriving benefit from treatment. This form must be completed to ensure continued supply of free-of-charge^ product.
- The patient is aware that Celgene will collect their personal information in order to manage and supply Celgene products.
- If the patient becomes eligible to receive product via PHARMAC while on the Celgene Access Program, every effort will be made to access PHARMAC-reimbursed product.
- Any unused stock *must* be destroyed by the pharmacy, according to their local protocols, and confirmation of destruction sent to Celgene.

Please report any adverse events experienced with our products to Celgene Drug Safety on 0800 526 529 (option 4) or drugsafety-australia@celgene.com

If you have any questions on the above, please do not hesitate to contact Celgene on 0800 526 529.

Yours sincerely,

Dirk Hoenemann
Medical Director
Haematology/Oncology, Australia & New Zealand

^Please be aware additional pharmacy costs may be incurred.

NZ Revlimid® 4Plus Application Form

(Note: approved patients must also be registered on the i-access® Program)

*ALL APPLICATIONS MUST BE APPROVED BY CELGENE **PRIOR** TO STARTING ANY TREATMENT, OTHERWISE FREE OF CHARGE PRODUCT CANNOT BE GUARANTEED*

PATIENT INFORMATION

Patient initials: Date of birth:

Sex: ☐ Male ☐ Female *i-access* UPIN (if known):

APPLICATION DETAILS

Product: Revlimid® (lenalidomide)

Indication: Relapsed Refractory Multiple Myeloma (≥ 3 prior therapies)

Dose: Dosage schedule:

Intended duration of treatment:

If the Celgene Access Program was not available, what other treatment would you have offered this patient?

MEDICAL HISTORY AND TREATMENT HISTORY

(Please also include any previous/current medical condition(s) that may significantly affect the safety of treatment)

PLEASE INCLUDE DESCRIPTION OF ALL PRIOR LINES (≥ 3) OF THERAPY FOR MULTIPLE MYELOMA

NZ Revlimid® 4Plus Application Form

(Note: approved patients must also be registered on the i-access® Program)

*ALL APPLICATIONS MUST BE APPROVED BY CELGENE **PRIOR** TO STARTING ANY TREATMENT, OTHERWISE FREE OF CHARGE PRODUCT CANNOT BE GUARANTEED*

PRESCRIBER INFORMATION

Name: Institution:

e-mail: Phone:

***i*-access® Registered PHARMACY INFORMATION**

Pharmacy Name: Contact person:

e-mail: Phone:

PATIENT SECTION

I, the patient described in this application, have been informed that:

1. *This application requires approval from Celgene BEFORE the proposed treatment commences, and approval is not guaranteed.*
2. *This is not a PHARMAC-reimbursed treatment.*
3. *I must be registered on, and comply with, the i-access® Risk Management Program (separate paperwork is required)*
4. *I need to sign a Declaration Form every 6 months to ensure ongoing access to free-of-charge product.*
5. *Celgene will collect my personal information in order to manage and supply Celgene products.*
6. *Celgene is required by law to provide data and safety updates to regulatory authorities. Celgene may also use data obtained from this application and access program for discussions with, and submissions to, regulatory and reimbursement authorities.*

Patient Signature: _____ **Date**: _____

PRESCRIBER SECTION

I, the prescriber described in this application, confirm and agree that:

- *I have counseled the patient on the conditions of the Celgene Access Program.*
- *I will abide by the requirements of the i-access® Risk Management Program (separate paperwork is required)*
- *I will complete a Declaration Form every 6 months to confirm the patient is continuing to benefit from treatment which will ensure ongoing access to free-of-charge product.*
- *If the patient becomes eligible for PHARMAC treatment while on the Celgene Access Program, I will make every effort to provide treatment via PHARMAC.*
- *Celgene will collect my personal information in order to manage and supply Celgene products.*

Prescriber Signature: _____ **Date**: _____

FOR CELGENE INTERNAL USE ONLY

☐ Approved CAP ID: _____

☐ Not Approved Reason: _____

Name/Position: _____

Signature:_____ Date:_____

Please return the completed form to Celgene via fax +61 3 9539 5566 or email to accessprogramsanz@celgene.com